Chemical, Biological, Radiological Technology Survey

Peter Emanuel Ph.D.
Matthew Caples Ph.D.

Public Release – Unclassified

Disclaimer

The findings in this report are not to be construed as an official Department of Defense position unless so designated by other authorizing documents.

Dear Reader:

This *Chemical, Biological, Radiological Technology Survey* was funded by The Joint Program Executive Office for Chemical & Biological Defense and the Defense Threat Reduction Agency/Joint Science and Technology Office to compile a technology survey on biosurveillance hardware systems which have applicability in detecting and/or assessing human exposure to chemical, biological, and radiological agents. This survey encompasses a variety of systems from manual systems to fully automated technologies. Unlike previous market surveys this effort includes all forms of **CHEMICAL, BIOLOGICAL** and **RADIOLOGICAL** analysis platforms. The focus of this technology horizon scan is on the hardware systems that support biosurveillance; software biosurveillance efforts will be collected under a separate effort.

The information in this book was gathered using a detailed online survey that was completed by the vendor. The intent was to ensure that the information was accurate and was not derived from a 3rd party source or internet search that could result in incorrect or outdated information. The information was analyzed using a weighted system designed to determine the device's usefulness in four different scenarios: Field use, Transportable Laboratory use, Diagnostic Laboratory use, Analytical Laboratory use.
We would like to suggest the following methodology for using this guide.

1. Review the four different scenarios and note how the devices or systems ranked for a scenario of interest.
2. Remember that scores have a subjective component and that all the technologies are included in the ranking so don't go by the raw score only.
3. Go to Detailed Product Sheets Section and look up the product name for detailed information on the product.
4. Finally, contact the manufacturer for more information or visit their website.

The "Summary Section" is a quick reference guide to identify if a device detects chemical, biological, or radiologicals. The Summary Section includes a maturity gauge to quickly tell if the product is commercially available. The bulk of the survey is contained in the Detailed Product Sheets Section which includes product specifications in a standardized format for easy comparison. The devices are ***alphabetized*** to make it easier to find a product of interest. We hope that you find this survey both helpful and interesting.

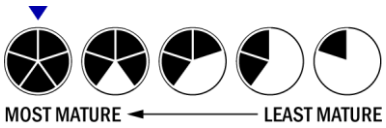
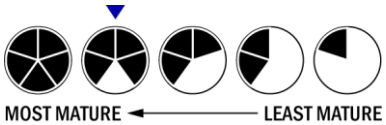
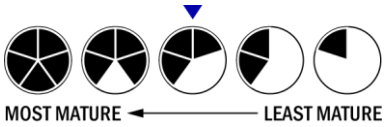
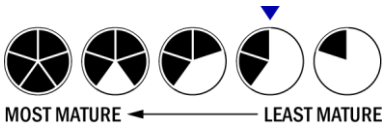
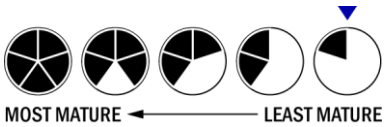
Sincerely,

Peter Emanuel Ph.D.
U.S. Army ECBC
BioScience Division Chief
Peter.emanuel@us.army.mil

Matthew Caples Ph.D.
Booz Allen Hamilton
Lead Associate
caples_matthew@bah.com

Lists of Symbols for Product Sheets

Symbols	Definition
	Biological Agent Idenfitication
	Chemical Agent Identification
	Radiological Identification

Symbol	Definition
	Commercially Available and Meets Military Specifications
	Commercially Available
	Brass Board
	Bread Board
	White Board

Contents

Contents 1
Introduction 3
Four Scenarios of Use 3
Man portable and field use 3
Mobile laboratory/ field laboratory 3
Diagnostic laboratory or point of care use 3
High sensitivity, high throughput analytical laboratory 4
Evaluation Process 4
Evaluation of Detection Devices or Systems 5
Field use 6
Results 6
Mobile laboratory/ field laboratory 10
Results 10
Diagnostic laboratory or point of care use 14
Results 14
High sensitivity, high throughput analytical laboratory 18
Results 18
Summary 22
Summary Section 23
Detailed Product Sheets 41
Appendix I I-1
Appendix II II-1

Figure 1: Hierarchy of Criteria 4
Figure 2: Description of Scoring Bar 5
Figure 3: Field Use Weights 6
Figure 4: NIDS Medical Reader System 6
Figure 5: ChemPro PD 6
Figure 6: RADIR 7
Figure 7: T2Dx 7

Figure 8: Biological Specific Systems – Field Use 8
Figure 9: Chemical Specific Systems – Field Use 8
Figure 10: Radiological Specific Systems – Field Use 9
Figure 11: Biological/Chemical Systems – Field Use 9
Figure 12: Chemical/Radiological Systems – Field Use 9
Figure 13: Biological/Chemical/Radiological – Field Use 9
Figure 14: Mobile Laboratory/ Field Laboratory Weights 10
Figure 15: uScope 10
Figure 16: CDS-100 (Compact Diagnostic System) 10
Figure 17: Radiation Pager 11
Figure 18: MICT 11
Figure 19: Biological Specific Systems – Mobile Laboratory 12
Figure 20: Chemical Specific Systems – Mobile Laboratory 12
Figure 21: Radiological Specific Systems – Mobile Laboratory 13
Figure 22: Biological/Chemical Systems – Mobile Laboratory 13
Figure 23: Chemical/Radiological Systems – Mobile Laboratory 13
Figure 24: Biological/Chemical/Radiological Systems – Mobile Laboratory 13
Figure 25: Diagnostic Laboratory or Point of Care Use Weights 14
Figure 26: Luminex 100/200 14
Figure 27: TIRF Sense Portable Sensor TIFR-EC 14
Figure 28: Radiation Control Monitor 15
Figure 29: REBS - Laboratory Variant 15
Figure 30: Biological Specific Systems – Diagnostic Laboratory 16
Figure 31: Chemical Specific Systems – Diagnostic Laboratory 16
Figure 32: Radiological Specific Systems – Diagnostic Laboratory 17
Figure 33: Biological/Chemical Systems – Diagnostic Laboratory 17
Figure 34: Chemical/Radiological Systems – Diagnostic Laboratory 17
Figure 35: Biological/Chemical/Radiological Systems – Diagnostic Laboratory 17
Figure 36: High Sensitivity, High Throughput Analytical Laboratory Weights 18
Figure 37: LightCycler 480 18
Figure 38: Chemical Biological Detection System 18
Figure 39: DCI-I 19
Figure 40: SAFESITE MTX 19
Figure 41: Biological Specific Systems – Analytical Laboratory 20
Figure 42: Chemical Specific Systems – Analytical Laboratory 20
Figure 43: Radiological Specific Systems – Analytical Laboratory 21
Figure 44: Biological/Chemical Systems – Analytical Laboratory 21
Figure 45: Chemical/Radiological Systems – Analytical Laboratory 21
Figure 46: Biological/Chemical/Radiological Systems – Analytical Laboratory 21

Table 1: Distribution of Scenario Weights 4

Introduction

This *Chemical, Biological, Radiological Technology Survey* was sponsored by Dr. Jason Roos of the Joint Program Executive Office, Chemical Biological Medical Systems, Biosurveillance (provisional) (JPM-BSV [provisional]) and Dr. William Huff of the Defense Threat Reduction Agency (DTRA). It provides a snapshot of available detection and diagnostic systems and devices that can detect and/or identify the presence of biological, chemical, and radiological agents. This report reviews and scores vendor-supplied information about detection devices or systems. The survey was publically available to all companies and widely publicized by Edgewood Chemical Biological Center (ECBC) and the Johns Hopkins University – Applied Physics Laboratory (JHU-APL) to promote a wide range of submissions. The devices or systems were scored using 74 specific questions that were weighted, based on four scenarios of use: field use; mobile or field laboratory; diagnostic laboratory or point of care use; and high sensitivity, high throughput analytical laboratory. The unique features of each scenario are detailed in the following section; each unique feature was considered in determining the weights of the survey evaluation criteria.

Four Scenarios of Use

The range of detection devices and systems is continually evolving and includes improvement on gold standard detection systems as well as development of new technologies. However, in different operational environments, one device or system may be preferred over others based on situational circumstances. In the following scenarios, four distinct environments demonstrate how different situations can require different devices or systems for biological agent detection.

Man portable and field use

Field use detection devices or systems are typically used by CBRN defense and force health protection Warfighters or scientists conducting analyses. These devices or systems would be used outdoors in a variety of environments (e.g., desert, forest, plains, urban) and be subjected to various environmental conditions (e.g., heat, cold, humidity). They need to be small, lightweight, and easy to carry. They should be simple to operate and should not require other machinery such as centrifuges or heat blocks. Kits or devices with limited electrical requirements are preferred. These devices can be disposable with a single use only or they can be reusable with minimal cleaning required for reuse. Signature is important in the operation of these devices or systems, as large ventilation systems or protective gear could jeopardize covert operations. Field use devices can have a narrow range of detectable agents, (e.g., can be specific for one particular target) because several different devices may be deployed on a mission.

Mobile laboratory/ field laboratory

Mobile and field laboratory detection devices or systems are located in mobile laboratories. They would likely be semi-automated or integrated into a system that is capable of a higher throughput of samples (i.e., 20-30 samples at a time). Some additional equipment such as centrifuges and vortexes can be used during operation, although smaller systems are preferred. Size is a concern with mobile laboratory components because space is limited and the detection device or system is likely only one component of the laboratory. A mobile laboratory would ideally be able to operate for a longer period of time than a field use item, therefore consumables and manpower are a concern. Signature is somewhat important for the mobile laboratory, as extensive safety precautions could hinder the mobility and camouflage of the mobile laboratory. The mobile laboratory detection device or system should ideally be able to detect a wide range of agents.

Diagnostic laboratory or point of care use

The diagnostic laboratory or point of care use scenario includes both brick and mortar laboratories, as well as non laboratory spaces such as a physician office or clinic. The ability to obtain FDA approval and 510k clearance were weighted heavily to emphasize diagnostic capability. The device or system must be able to detect agents from blood, tissue, cultured cells, and other typical samples. Logistical or operational concerns, such as size, weight, signature, transportation, additional equipment, and consumables were not considered essential for this scenario; however, logistics would be important in moving point of care use forward in the Combat Health Support system. Ideally, the diagnostic laboratory or point of care detection device or system must be able to detect biological agents from all encountered samples with a consistently high level of specificity and sensitivity.

High sensitivity, high throughput analytical laboratory

Analytical laboratory detection devices or systems are typically located in a brick and mortar building, such as a hospital or laboratory. They would be fully automated devices capable of high throughput of samples. An ideal detection device would detect a variety of agents quickly, have a high level of sensitivity, and be easy to operate. Because of the location of the system, device characteristics such as signature, additional equipment, and electrical requirements are of less concern. The device should be easily maintained with regularly scheduled maintenance and be relatively easy for a medical staff to operate.

Evaluation Process

The four scenarios detailed above represent distinctly different uses of detection technologies; in essence, each scenario involves different objectives and requirements for the devices or systems. Once the objectives and requirements for the four scenarios were clearly defined, the authors generated an evaluation model. The foundation of the model is the evaluation criteria, which represent the important attributes for detection and are intended to differentiate the various types of products. The criteria were structured in the form of a hierarchy, as shown in Figure 1.

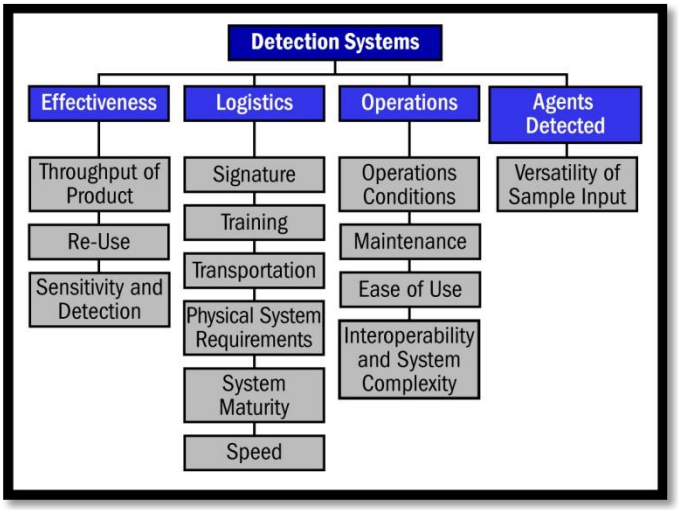


Figure 1: Hierarchy of Criteria

Each evaluation criterion was defined and then further described with a performance scale. The scales provide a means of measuring how well each product "performs" relative to each criterion. The performance scales can be quantitative (e.g., speed, measured in minutes) or qualitative (e.g., utility, measured by assessing the best fit).

Each level on the scale was assigned a utility value, ranging from zero for the lowest expected performance to 100 for the highest level of expected performance. Intermediate levels of performance were assigned values between zero and 100. The final step in developing the evaluation model was to weight the criteria. The weights indicate the relative value of a criterion, as defined by its performance scale, compared to the other criteria. The criteria were weighted by distributing 100 points amongst the individual criteria under the four headings of effectiveness, logistics, operations, and agents detected.. Because each scenario is concerned with different objectives and requirements, the criteria weights varied depending on the scenario. Table 1 shows how the weights were distributed relative to the different scenarios.

	FIELD USE	MOBILE LABORATORY/ FIELD LABORATORY	DIAGNOSTIC AND POINT OF CARE USE LABORATORY	HIGH SENSITIVITY, HIGH THROUGHPUT ANALYTICAL LABORATORY
Throughput of Product	3	5	11	20
Re-Use	6	3	2	2
Sensitivity and Detection	3	12	24	27
Signature	6	4	3	1
Training	1	1	1	1
Speed	6	6	6	6
Mobile Laboratory/ Field Laboratory	24	12	1	1
Physical System Requirements	16	12	8	3
System Maturity	1	1	1	1
Operational Conditions	14	10	5	1
Maintenance	6	6	5	3
Ease of Use	7	6	6	5
Interoperability and System Complexity	6	5	4	3
Versatility of Sample Input	1	17	23	26

Table 1: Distribution of Scenario Weights

The evaluation criteria were then used to formulate a questionnaire, which was sent to the various manufacturers of detection products. The information provided by the manufacturers was used as the basis for assessing the different products against the evaluation model. The authors evaluated every product that submitted a completed questionnaire.

Each device or system was scored relative to each criterion for each scenario. Overall scores and rankings were generated using IBM® Statistical Packages for Social Sciences (SPSS) Version 19 and Microsoft® Excel. In evaluations where risk is assessed with mixtures of quantitative and qualitative data, the most useful summary metrics are measures of total effectiveness. Measures of

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

total effectiveness are vastly superior to qualitative summaries and categorical means because they eliminate biases created by categorical limits and preserve variances in raw data throughout aggregate calculations. Furthermore, compared to less rigorous approaches, measures of total effectiveness are verifiable; effective at normalizing multiple inputs of unique scales; allow for visibility of influential data points; and improve overall reporting accuracy. For these reasons, measures of total effectiveness are the appropriate summary metrics to use in the analysis.

Evaluation of Detection Devices or Systems

The evaluation section is split into the four different scenarios: field use; mobile or field laboratory; diagnostic laboratory or point of care use; and high sensitivity, high throughput analytical laboratory. Within each section the results of the analyses are additionally split into four areas of focus: biological agent specific systems; chemical agent specific systems; radiological agent specific systems; and multi-functional systems. Multi-functional systems encompass systems that can detect or identify more than one of the three previous categories. In this survey, we identified systems that can address: biological and chemical agents; chemical and radiological agents; and biological, chemical, and radiological agents. Systems or devices that can detect or identify more than one type of agent are ranked both in the individual agent rankings as well as highlighted in multi-functional specific rankings. For example, the T2Dx system can identify both chemical and biological agents, therefore, it will be found in the biological specific rankings, the chemical specific rankings, and the multi-functional biological/chemical rankings.

This report ranks 282 different system or devices; however, due to space constraints in this section only the top 60 biological specific systems and top 60 chemical specific systems are listed. The full rankings of both the biological specific systems and chemical specific systems can be found in Appendix II. In comparison to biological and chemical specific systems there were fewer radiological specific systems and multi-functional systems, therefore these rankings can be presented in their entirety.

Each system or device is given an overall score for each of the four scenarios. The overall score is comprised of 4 scores that represent the criteria used for evaluation: effectiveness, logistics, operations and agents detected. In the rankings presented in this section each system or device score is represented by a bar (Figure 2).

Figure 2: Description of Scoring Bar

Field use

In the evaluation of detection equipment for field use, factors pertaining to mobility, physical system requirements (e.g., battery power, water use), and operational conditions were considered as the most important criteria (Figure 3). An ideal field use device would be small and easily transportable, easy to maintain, able to operate in a variety of environmental conditions, and require few manual steps to operate.

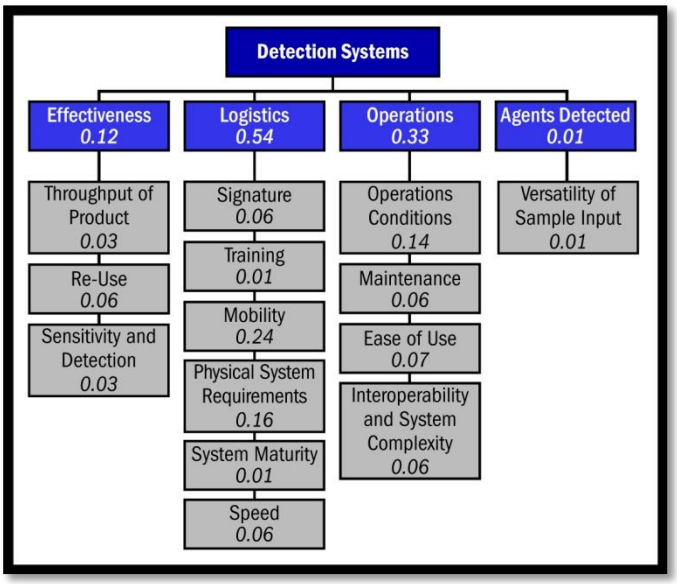


Figure 3: Field Use Weights

Results

The top biological specific systems are the Home Healthcare Diagnostics system and the NIDS Medical Reader System. Both systems are compact and easy-to-use. They both scored strongly in this scenario because of their light weight and relatively few components while maintaining the ability to detect agents in a variety of matrices.

Figure 4: NIDS Medical Reader System

The ChemPro products from Environics USA top the rankings for the best chemical agent systems or devices in the field. The ChemPro PD and the ChemPro 100i both provide handheld chemical agent detection capability. With a strong battery and limited components and consumables, these devices are ideal for field use.

Figure 5: ChemPro PD

RADIR and Radionuclide Isotope Identifier – SAM 940 are the two top radiological specific systems identified in this survey for field use. Both of these systems continue the common theme of small and portable systems. Neither device requires consumables limiting the logistics needed for field operation.

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

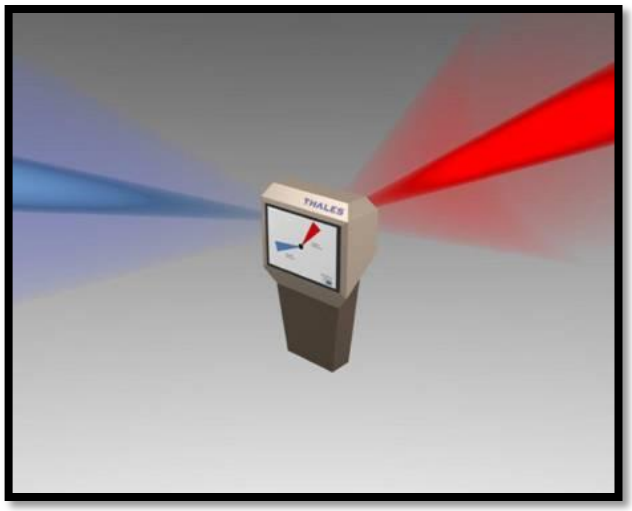


Figure 6: RADIR

The top three multi-functional systems are: T2Dx (Biological/ Chemical); SAFESITE MTX (Chemical/ Radiological); and Resource Effective BioIdentification System (REBS) (Chemical/ Biological/ Radiological). Each system also scored in the top third of their respective individual category rankings, in addition to having the added capability of multi-agent detection.

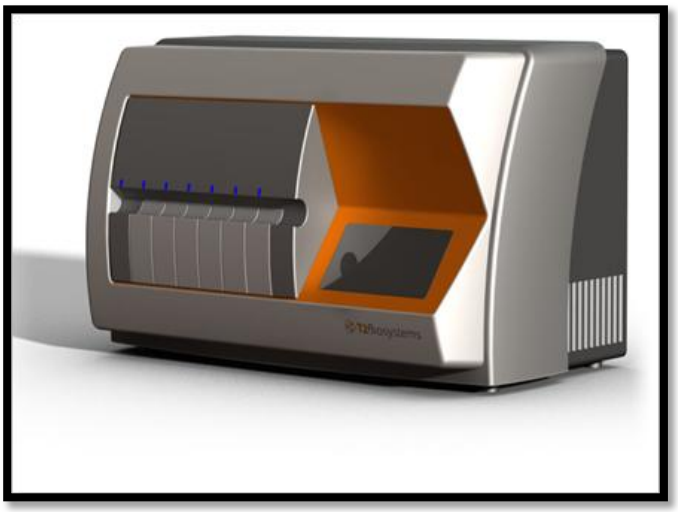


Figure 7: T2Dx

FIELD USE RANKINGS

Biological Specific Systems

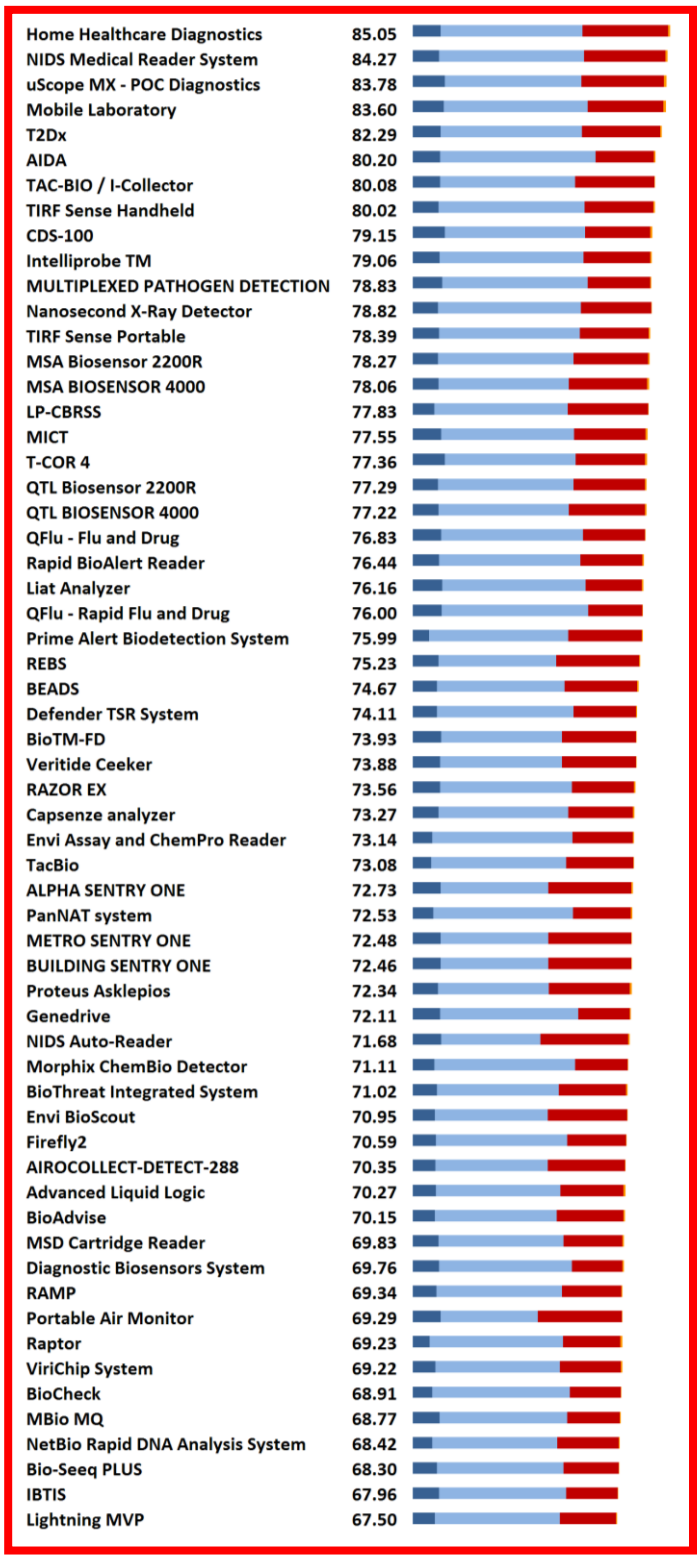


Figure 8: Biological Specific Systems – Field Use

Chemical Specific Systems

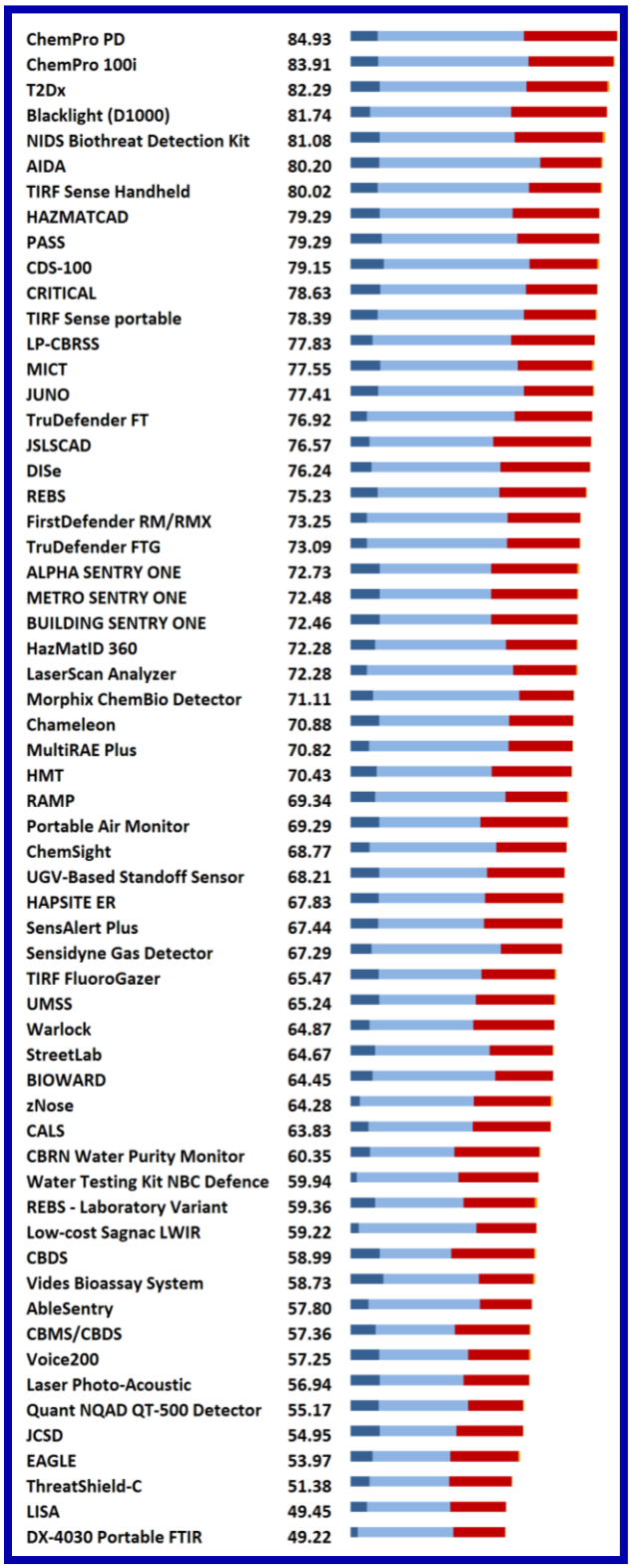


Figure 9: Chemical Specific Systems – Field Use

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Radiological Specific Systems

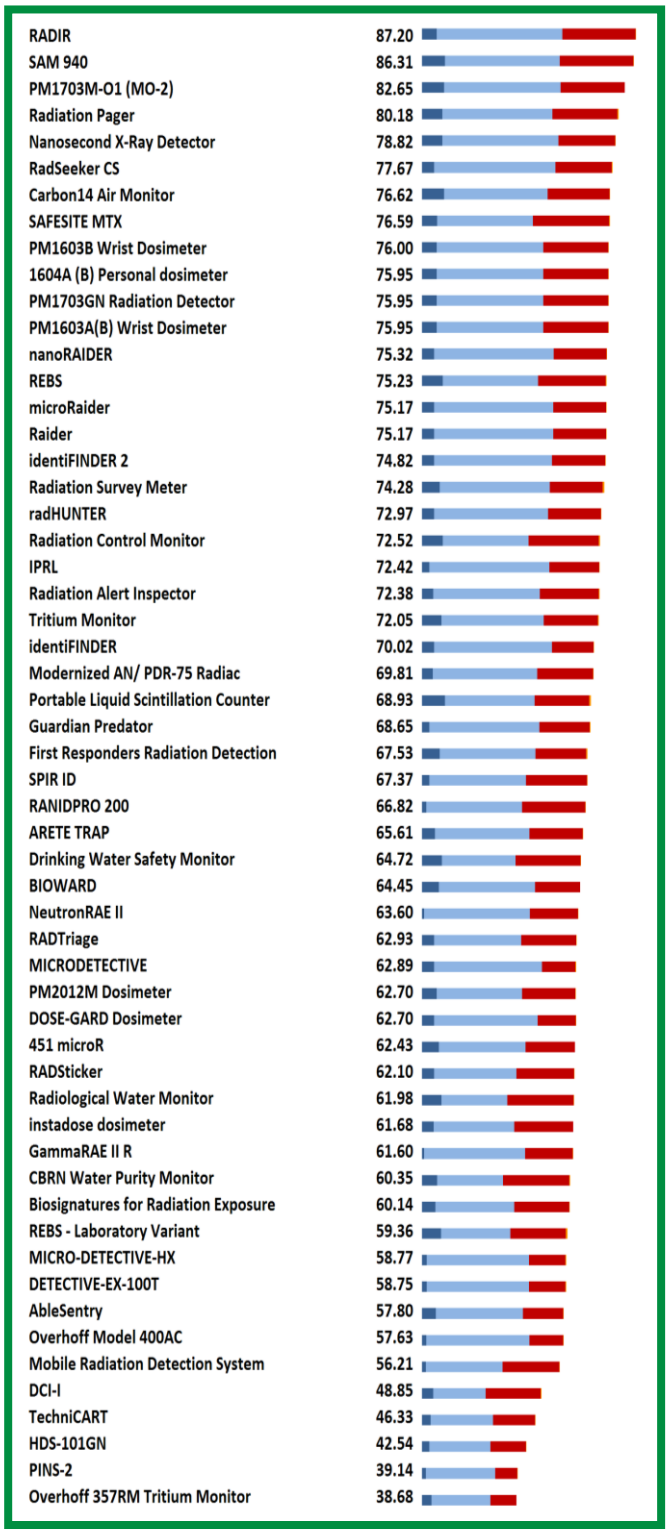


Figure 10: Radiological Specific Systems – Field Use

Multi-Functional Systems (Biological/Chemical)

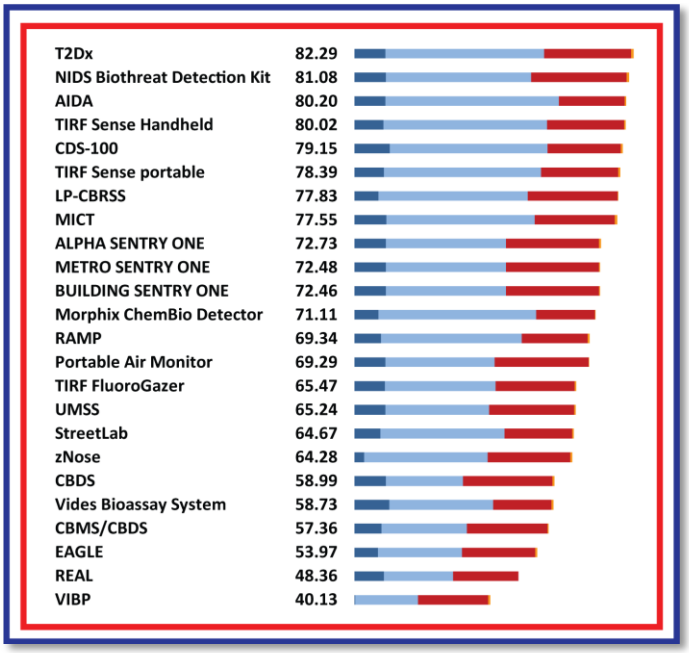


Figure 11: Biological/Chemical Systems – Field Use

Multi-Functional Systems (Chemical/Radiological)

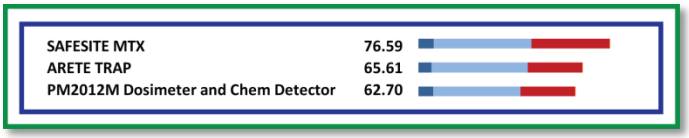


Figure 12: Chemical/Radiological Systems – Field Use

Multi-Functional Systems (Biological/Chemical/Radiological)

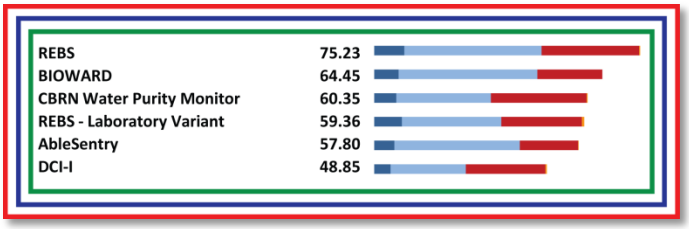


Figure 13: Biological/Chemical/Radiological – Field Use

Mobile laboratory/ field laboratory

In the evaluation of detection equipment for mobile laboratories, sensitivity; mobility; physical system requirements; operational conditions; and versatility of sample input were considered as the most important criteria (Figure 14). An ideal mobile laboratory device would require few manual steps to operate; require no or little additional equipment; and would have increased throughput, speed, and potential for automation.

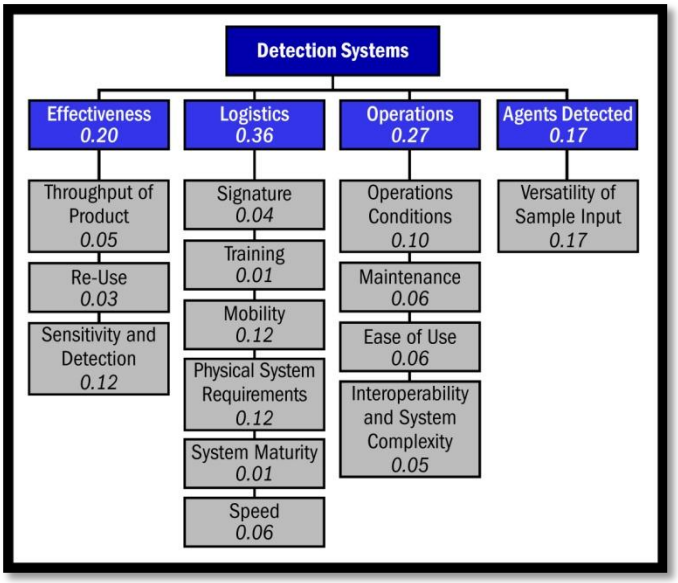


Figure 14: Mobile Laboratory/ Field Laboratory Weights

Results

The top biological agent specific system is the uScope from Microscopes International. This system utilizes bright-field and fluorescent microscopy to produce sensitive results, in a wide range of matrices. In addition, the system is small and lightweight, with limited logistics needed for sample analysis. The second system is the T2Dx, which uses magnetic resonance technology to provide sensitive results while maintaining a mobile footprint. Both of these technologies are excellent examples of cutting edge technologies outside the confines of traditional identification systems.

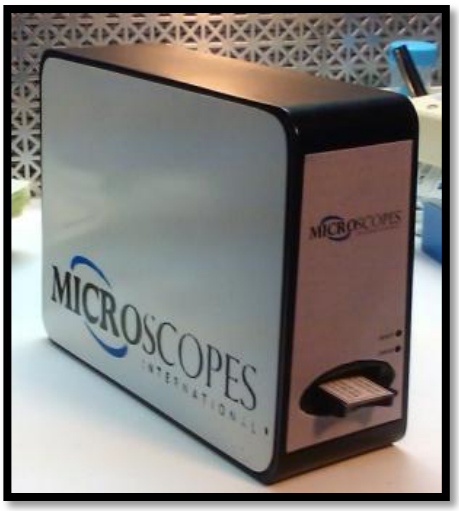


Figure 15: uScope

In addition to being highly ranked in the biological agent specific rankings, T2Dx tops the chemical agent specific rankings. Another highly rated chemical agent detector is the CDS-100 (Compact Diagnostic System), which uses guided-mode resonance (GMR) sensor technology that occurs in sub-wavelength waveguide-gratings. The angle of the light emitted from the sensors changes with the interaction of the analyte.

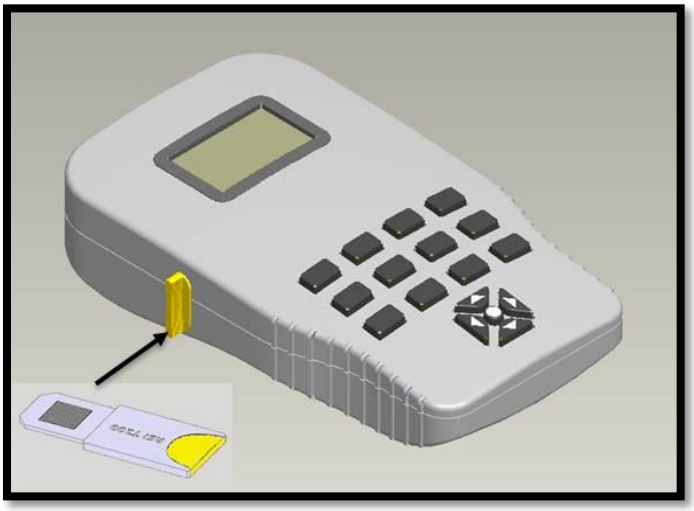


Figure 16: CDS-100 (Compact Diagnostic System)

The top radiological agent specific system is the Radiation Pager from Sensor Technology Engineering, Inc. This system can discriminate between radiation types while maintaining a compact footprint in a mobile laboratory. Also high in the rankings is the Portable Liquid Scintillation Counter, an all-in-one unit that also happens to be a multi-functional system.

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Figure 17: Radiation Pager

T2Dx is the top chemical/biological multi-functional system for mobile laboratories; also, on the list is the Magnetic ImmunoChromatographic Test (MICT) System. The MICT uses a magnetic detection array that binds analytes using magnetic nanoparticles. The top chemical/radiological multi-functional system is the SAFESITE MTX, and the top chemical/ biological/ radiological multi-functional system is the REBS-Laboratory variant. The REBS-Laboratory Variant works using the same Raman microspectroscopy technology as the REBS.

Figure 18: MICT

MOBILE RANKINGS

Biological Specific Systems

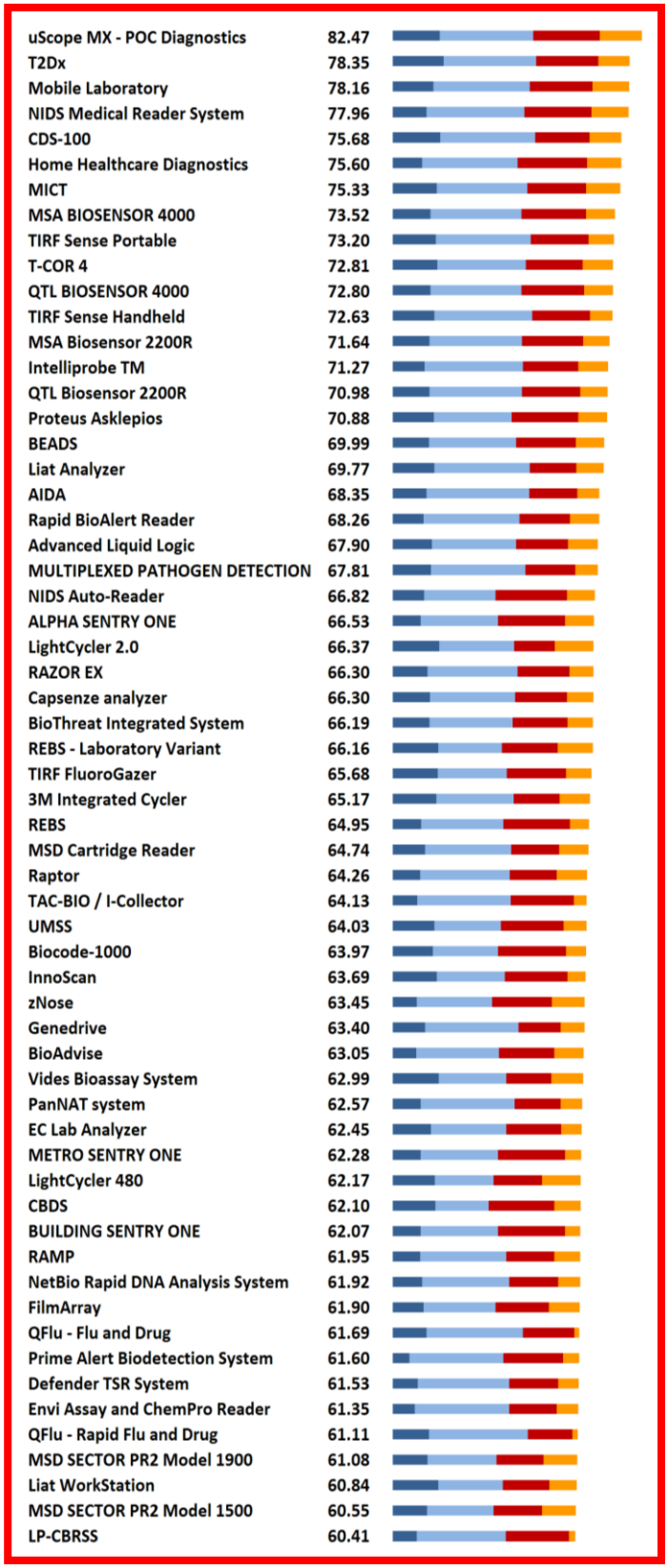


Figure 19: Biological Specific Systems – Mobile Laboratory

Chemical Specific Systems

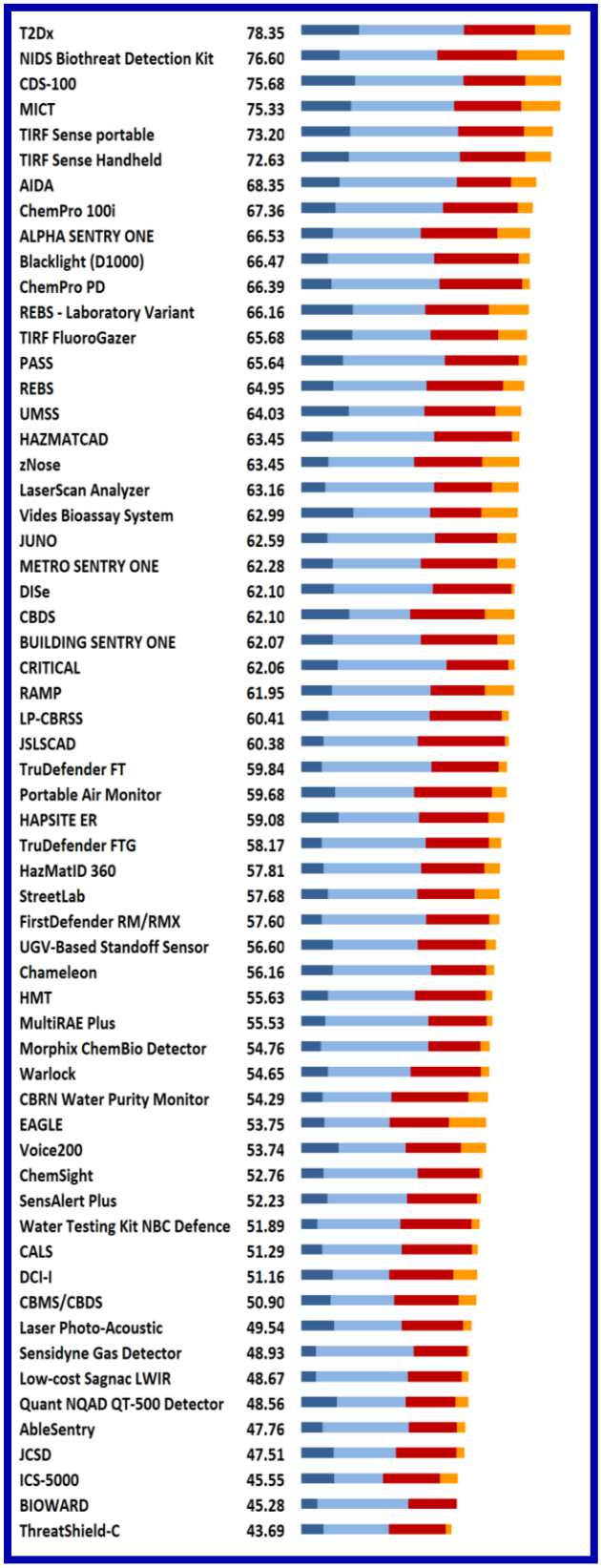


Figure 20: Chemical Specific Systems – Mobile Laboratory

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Radiological Specific Systems

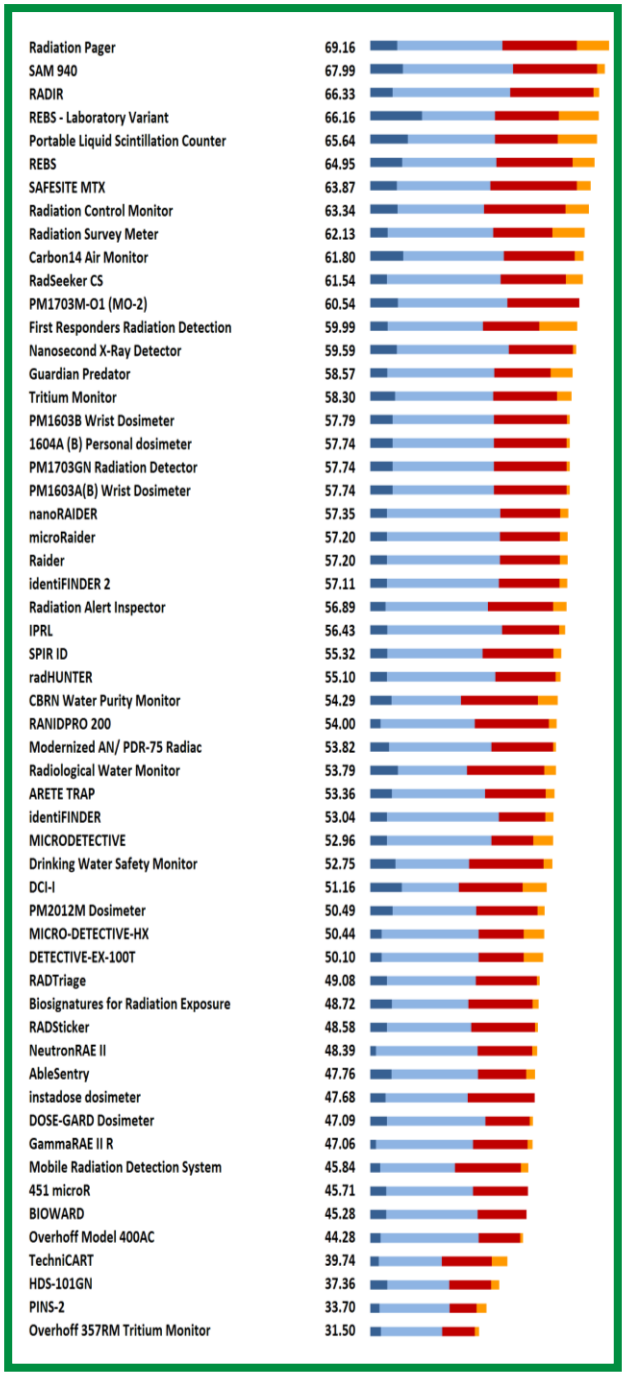


Figure 21: Radiological Specific Systems – Mobile Laboratory

Multi-Functional Systems (Biological/Chemical)

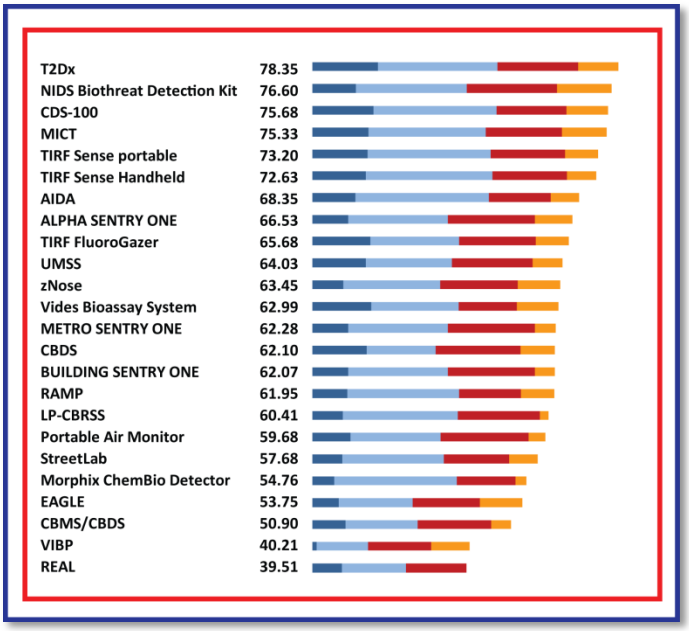


Figure 22: Biological/Chemical Systems – Mobile Laboratory

Mutli-Functional Systems (Chemical/Radiological)

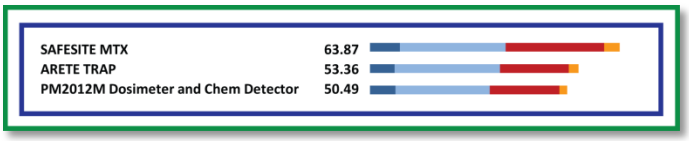


Figure 23: Chemical/Radiological Systems – Mobile Laboratory

Multi-Functional Systems (Biological/Chemical/Radiological)

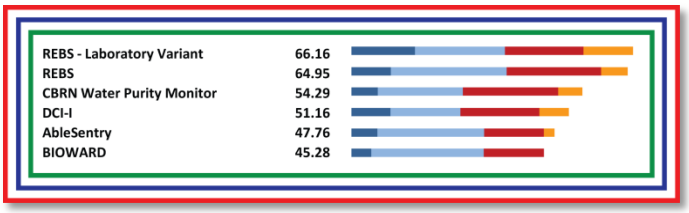


Figure 24: Biological/Chemical/Radiological Systems – Mobile Laboratory

Diagnostic laboratory or point of care use

In the evaluation of detection equipment for diagnostic laboratories, sensitivity and detection; versatility of sample input; and throughput of product were considered as the most important criteria (Figure 25). An ideal diagnostic laboratory device would require relatively quick performance and high sensitivity.

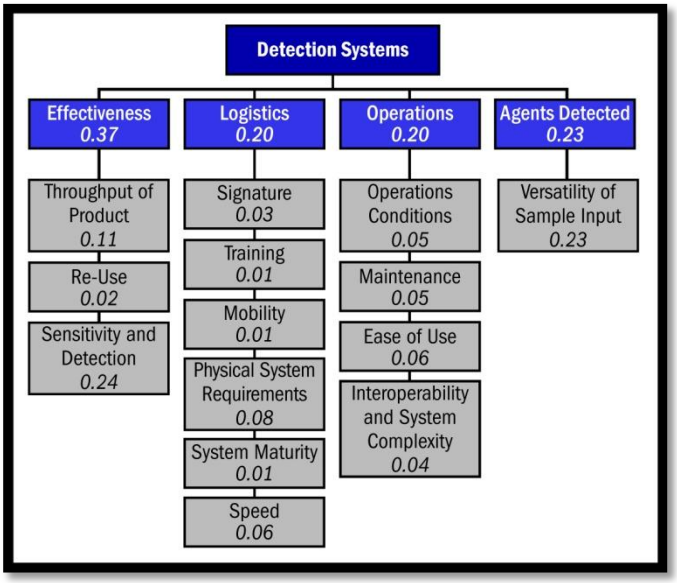


Figure 25: Diagnostic Laboratory or Point of Care Use Weights

Results

A number of the top scorers in this scenario have been highlighted in the field use and mobile laboratory scenarios, as the systems score well in sensitivity and speed, despite being mobile enough to perform well in the field.

One of the major drivers in this scenario for the top biological agent specific systems is the FDA approval and 510k clearance status. The top four systems have been highlighted in previous sections because of their speed, sensitivity and mobility, but these systems (uScope, Mobile Laboratory, T2Dx, MICT) are at least capable of FDA approval and 510k clearance and some are already approved (uScope) or pending (MICT). The other top performers in this scenario, LightCycler 2.0 and Luminex 100/200, have FDA approval and 510k clearance, as well as other positive attributes such as speed and sensitivity.

Figure 26: Luminex 100/200

The top chemical agent specific systems have been discussed previously (T2DX, MICT, REBS-Laboratory variant, Compact Diagnostic System). The next group of highly ranking chemical agent specific systems is: NIDS Biothreat Detection Kit; TIRF Sense portable sensor TIRF-EC; and the Vides Bioassay System. All these systems provide the capability to become FDA approved or 510k cleared and provide relatively good sensitivity in a wide range of detection matrices.

Figure 27: TIRF Sense Portable Sensor TIFR-EC

The top five radiation specific systems are: REBS-laboratory; Portable Liquid Scintillation Counter; Radiation Pager; REBS; and Radiation Control Monitor. With the exception of the Radiation Pager, all of these systems are capable of receiving FDA approval and 510k clearance. The Radiation Control Monitor is a multi-channel system that has 50 different configurations for detection radiation and has the capability of identifying in blood..

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Figure 28: Radiation Control Monitor

The top three multi-functional systems have all been identified in previous sections: T2Dx (chemical/ biological); SAFESITE MTX (chemical/ radiological); and REBS-Laboratory Variant (chemical/ biological/ radiological).

Figure 29: REBS - Laboratory Variant

DIAGNOSTIC RANKINGS

Biological Specific Systems

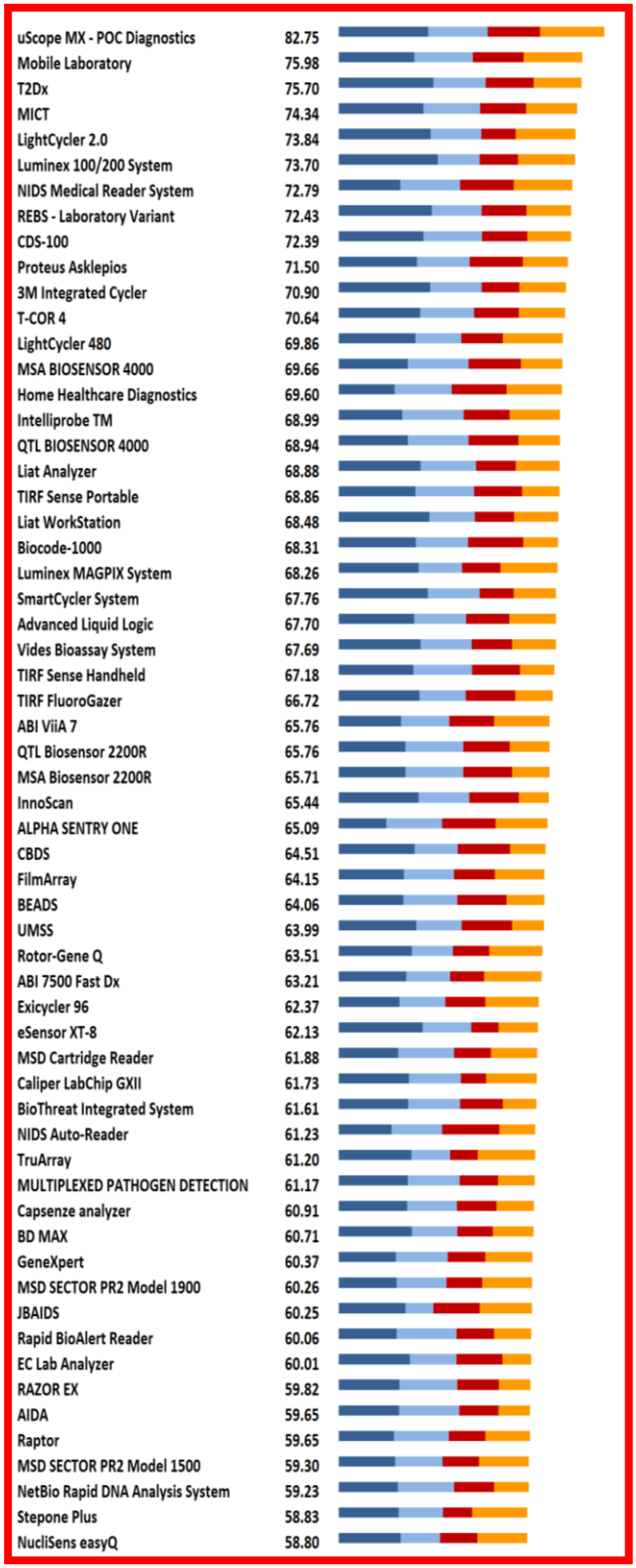


Figure 30: Biological Specific Systems – Diagnostic Laboratory

Chemical Specific Systems

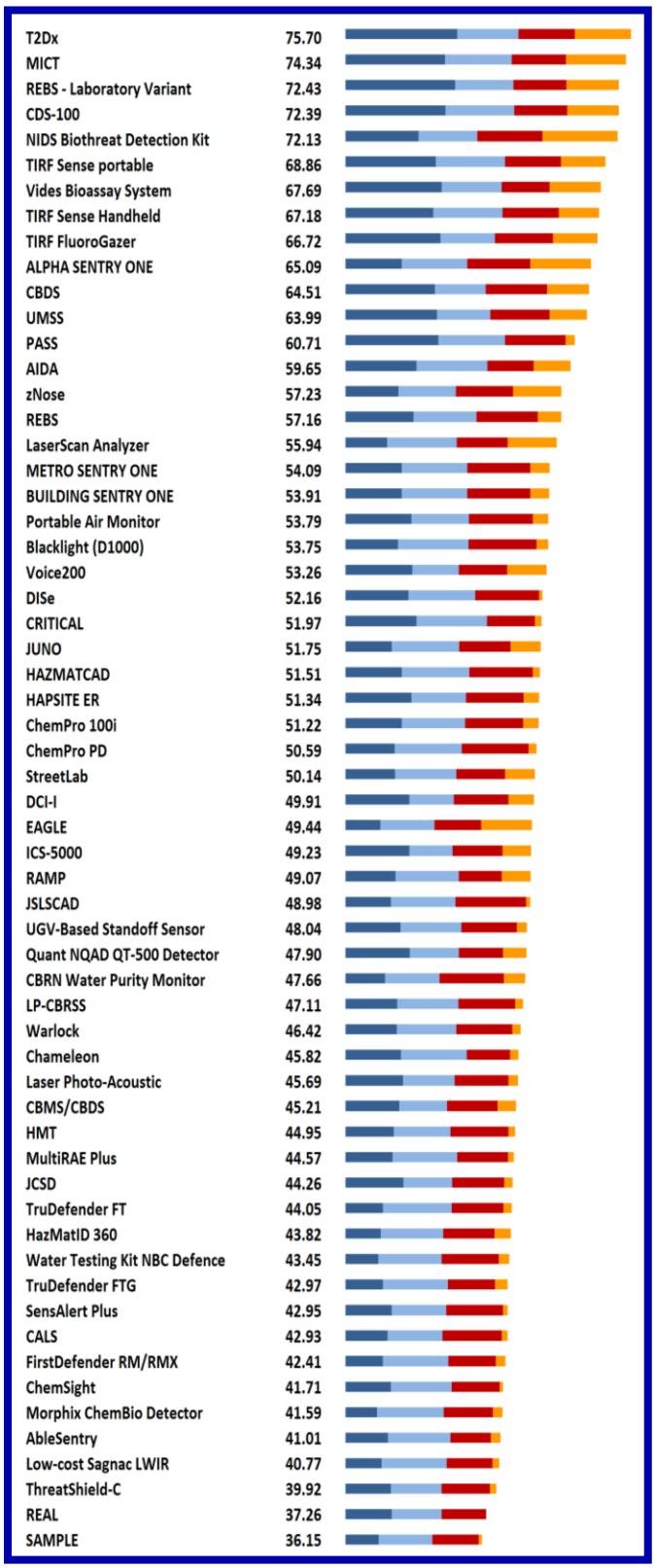


Figure 31: Chemical Specific Systems – Diagnostic Laboratory

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Radiological Specific Systems

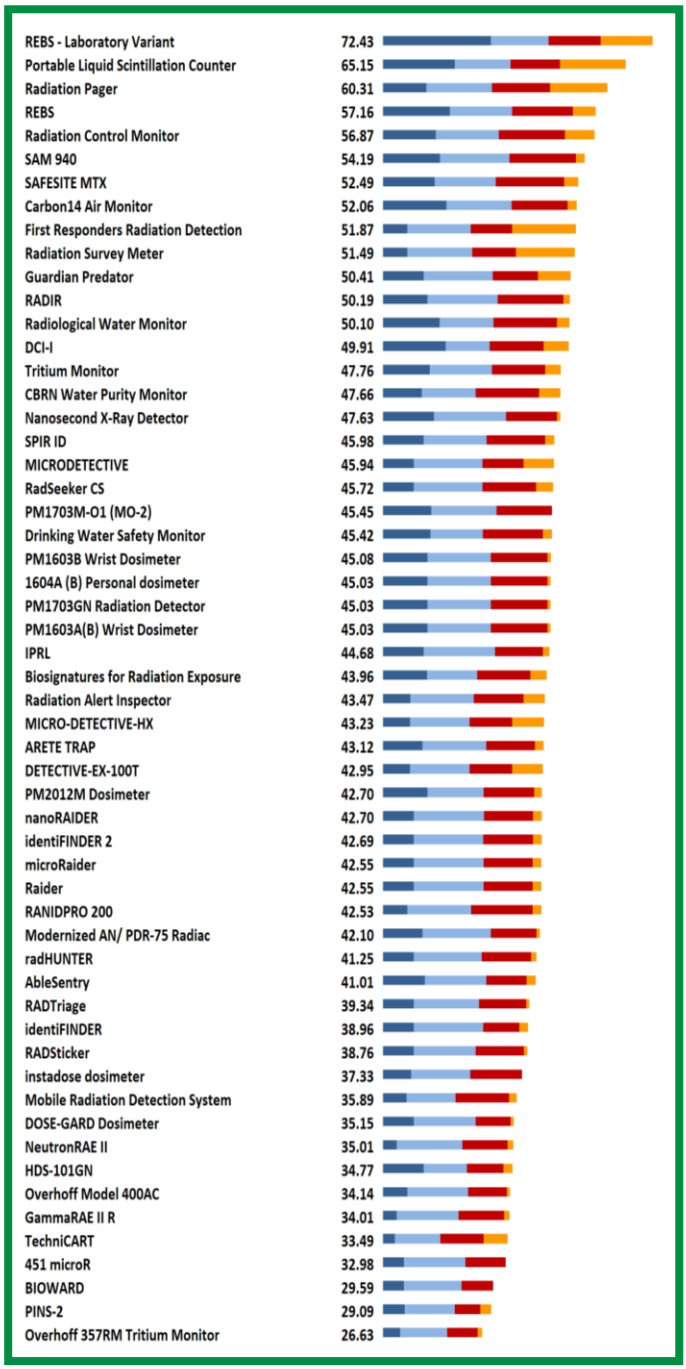


Figure 32: Radiological Specific Systems – Diagnostic Laboratory

Multi-Functional Systems (Biological/Chemical)

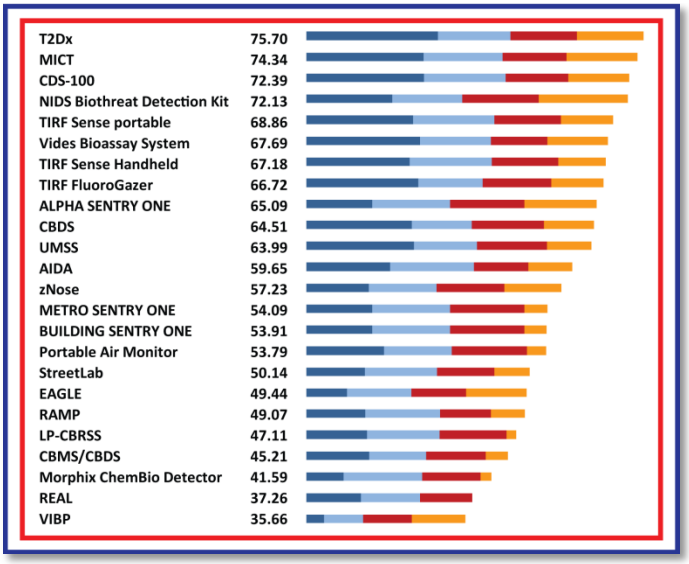


Figure 33: Biological/Chemical Systems – Diagnostic Laboratory

Multi-Functional Systems (Chemical/Radiological)

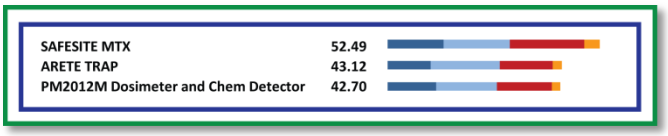


Figure 34: Chemical/Radiological Systems – Diagnostic Laboratory

Multi-Functional Systems (Biological/Chemical/Radiological)

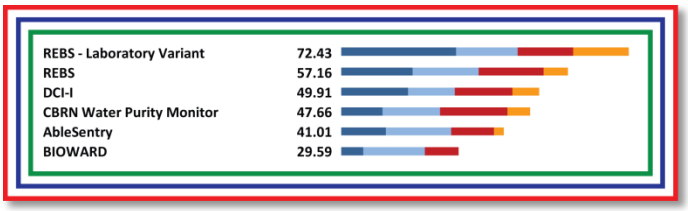


Figure 35: Biological/Chemical/Radiological Systems – Diagnostic Laboratory

High sensitivity, high throughput analytical laboratory

In the evaluation of detection equipment for analytical laboratories, sensitivity and detection; versatility of sample input; and throughput of product were considered to be the most important criteria (Figure 36). While these top criteria are the same as for the diagnostic laboratory scenario, they were even more highly rated for the analytical laboratory as essential components of a successful technology. An ideal analytical laboratory device would process samples at a high speed with optimal sensitivity.

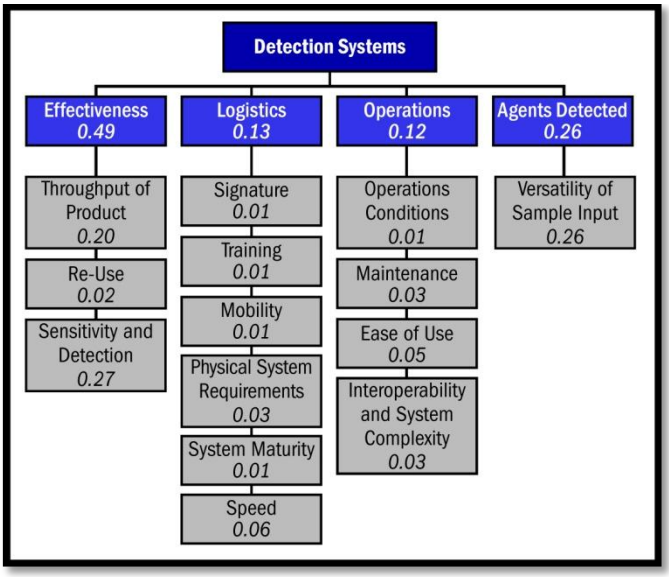


Figure 36: High Sensitivity, High Throughput Analytical Laboratory Weights

Results

The top biological agent specific systems for analytical laboratory use perform at a high rate of speed and have excellent sensitivity, yet have already been detailed in other sections because of their small size and mobility. (T2Dx, Compact Diagnostic System, REBS-Laboratory). The LightCycler 480 joins these systems at the top of the analytical laboratory list based on outstanding sensitivity and multi-well plate configuration for high sample throughput.

Figure 37: LightCycler 480

One of the top chemical agent systems is the Chemical-Biological Detection System (CBDS) that utilizes an integral mass spectrometer to detect, with good sensitivity, both chemical and biological agents. The CBDS is a large system but delivers quick analysis time (i.e., 2-15 minutes) and the ability to address multiple samples, with multiple tests in one run.

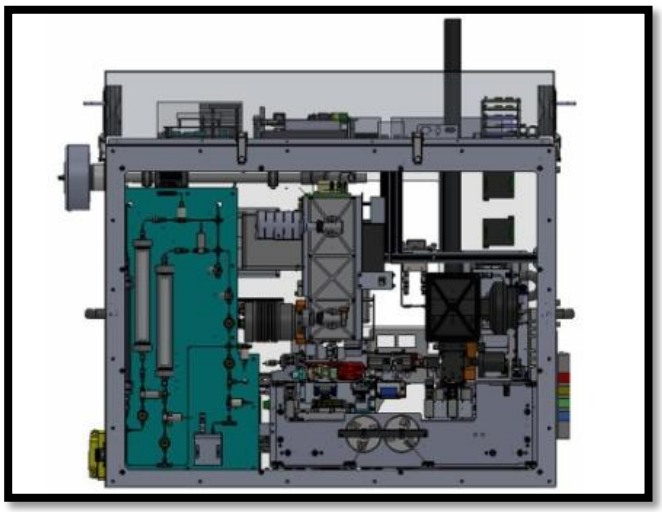


Figure 38: Chemical Biological Detection System

One of the top radiological systems is the DCI-I, which provides radiological, as well as biological and chemical identification using a system of different identifiers. It is at the top of the radiological agent system list with REBS-Laboratory, Portable Liquid Scintillation Counter, Radiation Pager, and SAFESITE MTX.

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Figure 39: DCI-I

The top three multi-functional systems have all been identified in previous sections: T2Dx (chemical/ biological); SAFESITE MTX (chemical/radiological); and REBS-Laboratory (chemical/biological/radiological).

Figure 40: SAFESITE MTX

ANALYTICAL RANKINGS

Biological Specific Systems

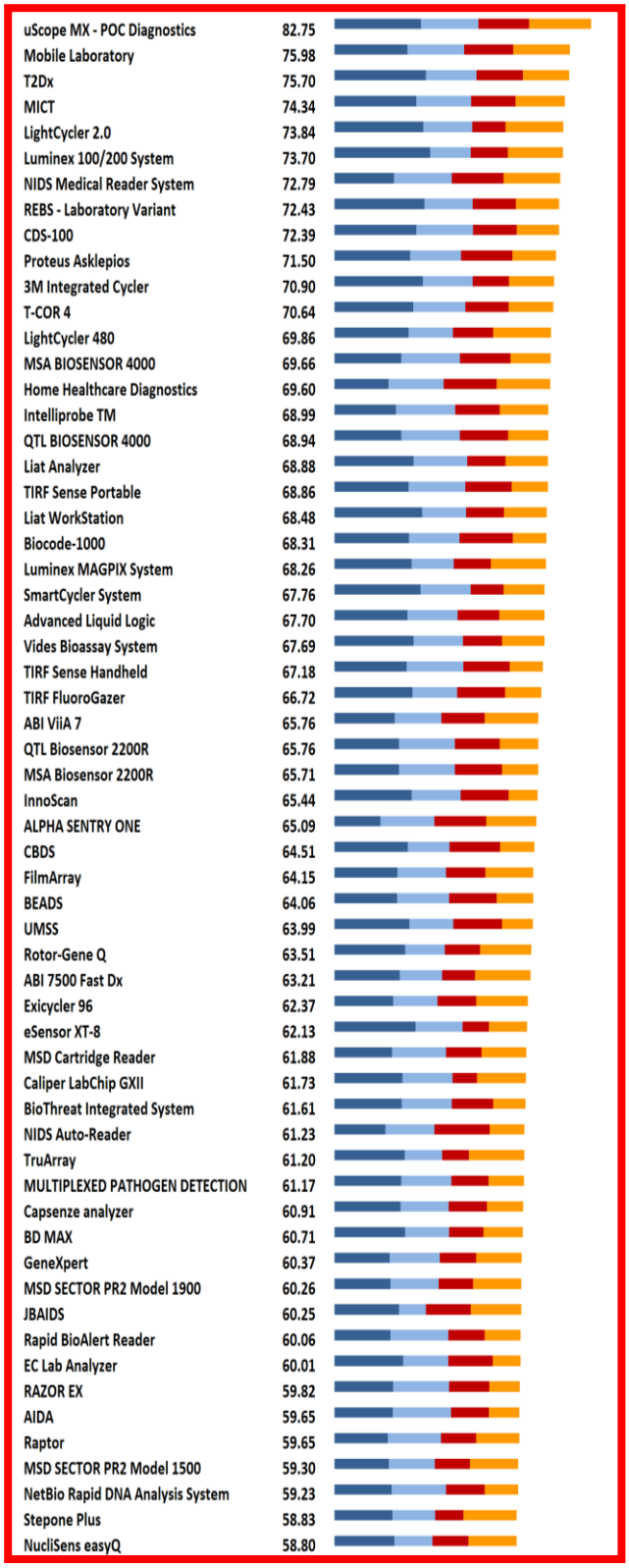


Figure 41: Biological Specific Systems – Analytical Laboratory

Chemical Specific Systems

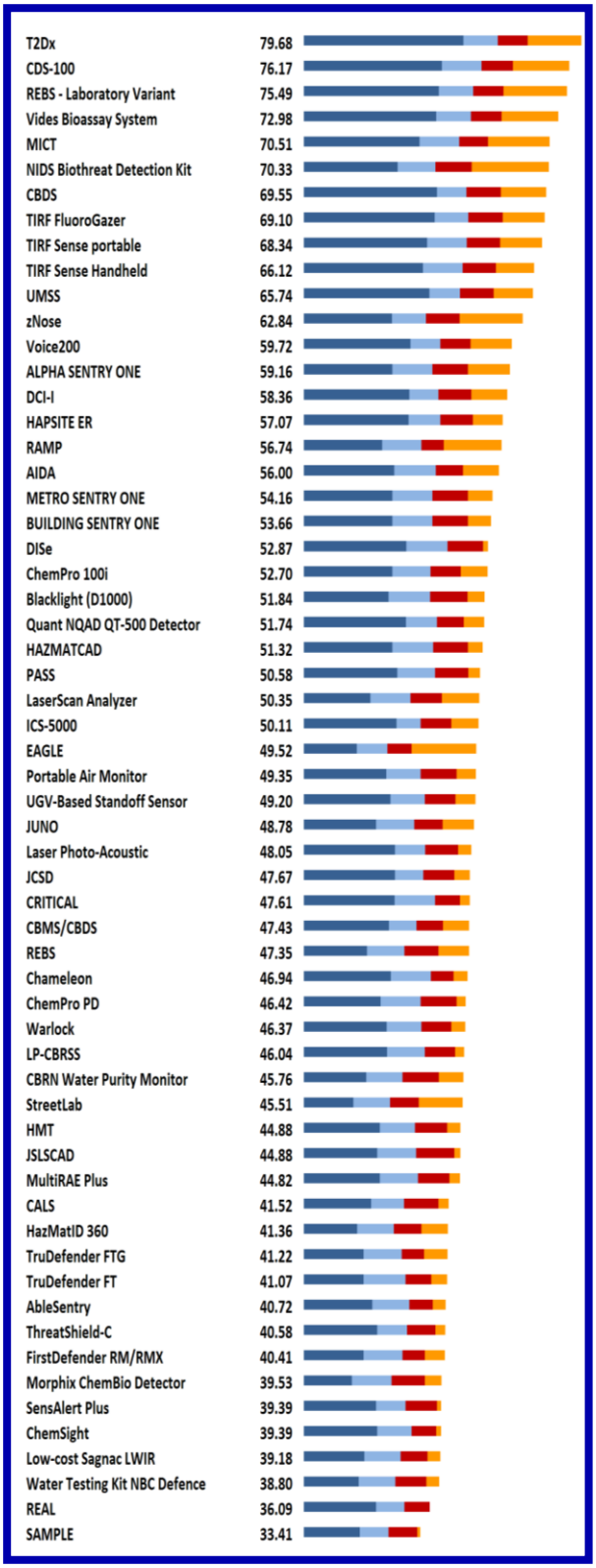


Figure 42: Chemical Specific Systems – Analytical Laboratory

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Radiological Specific Systems

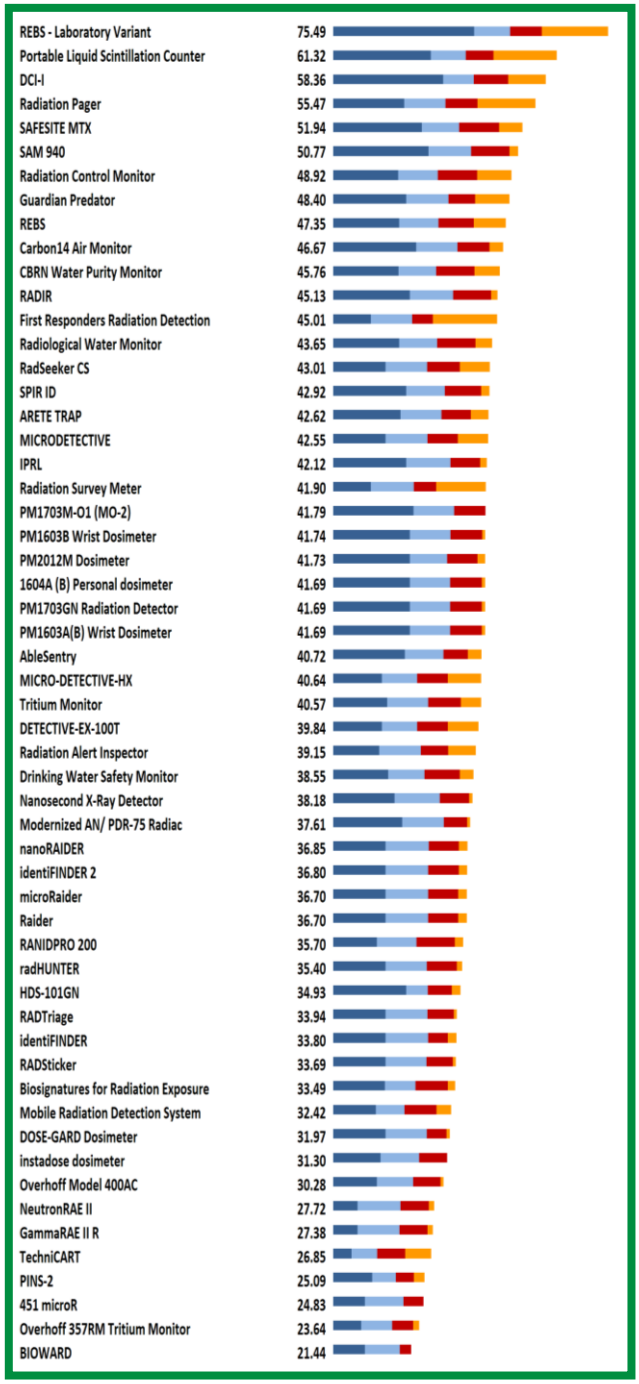


Figure 43: Radiological Specific Systems – Analytical Laboratory

Multi-Functional Systems (Biological/Chemical)

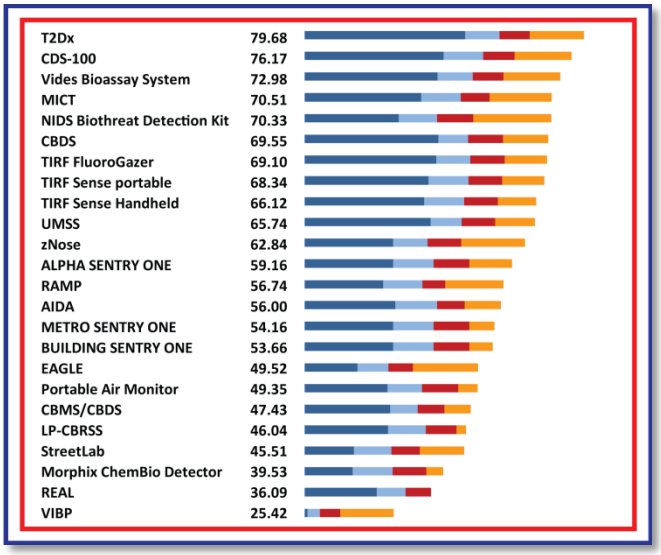


Figure 44: Biological/Chemical Systems – Analytical Laboratory

Multi-Functional Systems (Chemical/Radiological)

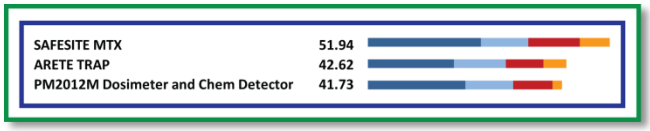


Figure 45: Chemical/Radiological Systems – Analytical Laboratory

Mutli-Functional Systems (Biological/Chemical/Radiological)

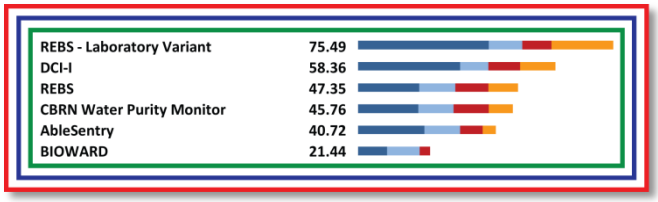


Figure 46: Biological/Chemical/Radiological Systems – Analytical Laboratory

Summary

In this survey, product information was collected using an extensive questionnaire that examined 14 different categories covering the capabilities and requirements of systems and devices for agent detection and identification. Completed surveys submitted by interested vendors were entered into a weighted model. A set of important and discriminating criteria were established to differentiate between competing technologies and used to generate overall rankings for four different usage scenarios. The scenario and question weights were developed by subject matter experts, and while these rankings would likely vary slightly from person to person, they were developed to approximate the general opinions of the detection and identification community at large. Appendix I lists the specific questions asked and the weights provided for each answer.

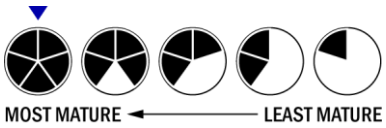
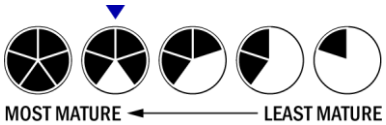
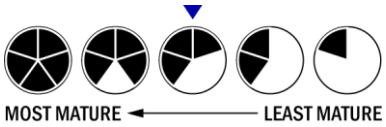
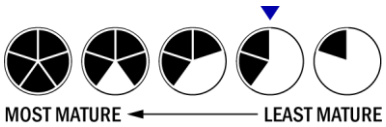
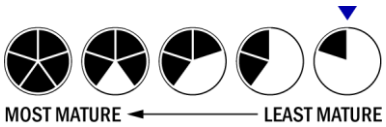
A potentially valuable way to use this guide would be to review the operational scenario that most relates to a specific area of interest, identify which products scored well in the evaluation for each technology, and then closely examine these products using the information contained within the Detailed Product Sheets section. When looking at the product score, do not judge the product based solely on the raw score. Examine how the system or device scored in relation to the other systems; the products are grouped into the top, middle and bottom third. Contact information for product representatives is included so that additional information can be obtained.

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary Section

Lists of Symbols for Product Sheets

Symbols	Definition
	Biological Agent Idenfitication
	Chemical Agent Identification
	Radiological Identification

Symbol	Definition
	Commercially Available and Meets Military Specifications
	Commercially Available
	Brass Board
	Bread Board
	White Board

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

System or Device	Biological Detection	Chemical Detection	Radiological Detection	Maturity
3M Integrated Cycler				
451P microR Ion Chamber survey meter				
ABI 2720				
ABI 7500 Fast Dx Real-Time PCR System				
ABI 7500 Real Time PCR System				
ABI 7900HT Fast Real-Time PCR System				
ABI 9700				
ABI Vii 7 Real-Time PCR System				
AbleSentry				
ABSS – ATHINA Biological Security System				
Advanced Liquid Logic				
AIDA: Autonomous Identification Diagnostics and Alert				
AIR (Arrayed Imaging Reflectometry) Bioassay System				
AIROCOLLECT-DETECT-288				
ALPHA SENTRY ONE				
Apollo 200 RapidHIT(tm) DNA Profiling system				
AreaRAE GAMMA Steel				
ARETE TRAP (Threat Reduction Advancement Processor)				
ASAP II				

System or Device	Biological Detection	Chemical Detection	Radiological Detection	Maturity
BADD Anth-Kit-10 Single Agent Threat Detection Test				
BADD Bot-Kit-10 Single Agent Detection Test				
BADD Pla-Kit-10 Single Agent Threat Detection Test				
BADD Ric-kit-10 Single Agent Threat Detection Test				
BADD SEB-Kit-10 Single Agent Threat Detection Test				
BADD Tul-Kit-10 Single Agent Threat Detection Test				
BD MAX Molecular Diagnostics Platform				
BEADS - Biodetection Enabling Analyte Delivery System				
BeadXpress Reader				
BioAdvise Portable Detection Device				
BioCheck				
Biocode-1000				
BioFlash - Dx				Not Available
BioHawk				
Biological alarm monitor (MAB)				
BioMark System for Real-Time PCR				
Bio-Plex 200 Suspension ArraySystem				
BioPlex 2200				
Bio-Seeq PLUS Biological Agent Identifier				

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

System or Device	Biological Detection	Chemical Detection	Radiological Detection	Maturity
BioSentryPlus	☣			◔
Biosignatures for Non – Invasive Detection of Exposure to Radiation			☢	◕
Biosignatures for Non – lnvasive Detection of Exposure Pesticides	☣			◕
BioThreat Alert ELISA Kit(s)	☣			◔
BioThreat Integrated Detection System	☣			◔
BioTM-FD	☣			◕
BIOWARD	☣	⚛	☢	◕
Blacklight (D1000)		⚛		◕
BoTest Botulinum Neurotoxin Detection Assays	☣			◔
BUILDING SENTRY ONE	☣	⚛		◔
C1000TM Thermal Cycler	☣			◔
Caliper LabChip GXII	☣			◔
CALS (Chemical Agent Line Sensor)		⚛		◕
Capsenze analyzer	☣			◕
Carbon14 Air Monitor			☢	◔
CARD Device	☣			◕
CBDS – Chemical-Biological Detection System	☣	⚛		◕
CBMS/CBDS – CB Mass Spectrometer/CB Detection System	☣	⚛		◔
CBRN Water Purity Monitor	☣	⚛	☢	◔

System or Device	Biological Detection	Chemical Detection	Radiological Detection	Maturity
CDS-100 - Compact Diagnostic System	☣	⚗		◔
C-FLAPS Biological Detection System	☣			◕
CFX Real-Time PCR Detection Systems	☣			◑
Chameleon		⚗		◕
ChemPro 100i		⚗		◕
ChemPro PD		⚗		◕
ChemSight		⚗		◑
Clinical Bio-Seeq System	☣			◔
CRITICAL Monitoring Badges and Taggants		⚗		◔
DCI-I	☣	⚗	☢	◔
Defender TSR System	☣			◑
DETECTIVE-EX-100T			☢	◑
Diagnostic Biosensors Field System	☣			◔
DISe		⚗		◔
DNA PROfiler	☣			◑
DOSE-GARD Microelectronic Alarming Dosimeter			☢	◕
Drinking Water Safety Monitor			☢	◕
DX-4030 Portable FTIR multi-component gas analyzer		⚗		◕
EAGLE	☣	⚗		◔

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

System or Device	Biological Detection	Chemical Detection	Radiological Detection	Maturity
EC BAND				
EC Lab Analyzer				
Eco Real-Time PCR System				
Enigma-FL				Not Available
Enigma-ML				
Envi Assay System and ChemPro reader Module				
Envi BioScout				
EpiSENSE				
eSensor XT-8				
Exicycler 96				
ExiStation Molecular Diagnostic Platform				
Experion Automated Electrophoresis System				
FABS – Fast Aerosol Bioclassification System				
Falcon II Wide-Field Raman Chemical Imaging System				
FilmArray Pathogen Detection System				
Firefly2				
First Responder's Radiation Detection Emergency Kit				
FirstDefender RM/RMX				
FLAPS III – TSI Fluorescence Aerosol Particle Sensor Model 3317				

System or Device	Biological Detection	Chemical Detection	Radiological Detection	Maturity
Food Safety Security Module	☣			◔
GammaRAE II R			☢	◕
Genedrive	☣			◕
GeneXpert System	☣			◕
Genome Analyzer IIx	☣			◕
Guardian Predator			☢	◕
Guardian Reader System	☣			◕
HAPSITE ER		⚛		◕
HAZMATCAD and HAZMATCAD Plus		⚛		◕
HazMatID 360		⚛		◕
HDS-101GN Search and Identification			☢	◕
High-Speed Resonant FTIR Spectrometer Liquids on Surfaces		⚛		◔
HiScanSQ Systems	☣			◕
HiSeq 1000 Sequencing System	☣			◕
HiSeq 2000 Sequencing System	☣			◕
HMT – Hardened MobileTrace		⚛		◕
Home Healthcare Diagnostics	☣			◕
IBTIS – Instantaneous Bio Threat Identification System	☣			◔
ICS-5000 Ion Chromatography system		⚛		◕

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

System or Device	Biological Detection	Chemical Detection	Radiological Detection	Maturity
ID-24	☣			◔
identiFINDER			☢	◕
identiFINDER 2			☢	◕
IMMULITE 2000 Immunoassay System	☣			◕
Informant 15-Minute Black Mold Detection Test	☣			◕
InnoScan	☣			◕
instadose dosimeter			☢	◕
InSyte	☣			◕
Intelliprobe TM	☣			◕
Ion Torrent Personal Genome Machine	☣			◕
IPRL – Morpho Detection Inc. Intelligent Personal Radiation Locator			☢	◔
iScan System	☣			◕
IVDS – Integrated Virus Detection System	☣			◕
JBAIDS – Joint Biological Agent Identification and Diagnostic System	☣			◕
JBPDS – Joint Biological Point Detection System	☣			◕
JBSDS, Increment 1 – Joint Biological Standoff Detection System	☣			◕
JBSDS, Increment 2 – Joint Biological Standoff Detection System	☣			◔
JCSD – Joint Contaminated Surface Detector		⚛		◕
JSLSCAD		⚛		◕

System or Device	Biological Detection	Chemical Detection	Radiological Detection	Maturity
JUNO				
KIM				
Laser Photo-Acoustic Spectrometer				
LaserScan Analyzer				
Liat Analyzer				
Liat WorkStation				
LightCycler 2.0				
LightCycler 480				
Lightning MVP				
LISA Manportable Standoff Chemical Detection System				
LLMDA (Lawrence Livermore Microbial Detection Array)				
Low-Cost Biological Standoff Detection System				
Low-cost Sagnac LWIR Interferometric HSI System				
LP-CBRSS – Longreach-Project Chem/Bio/Rad surveillance system				
LuBEA				
Luminex 100/200 System				
Luminex MAGPIX System				
M3IB				
Mass Spectrometry-Based Detection of Host Protein Response				

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

System or Device	Biological Detection	Chemical Detection	Radiological Detection	Maturity
M-BAND – Microfluidic Bioagent Autonomous Detector				
MBio MQ				
MENTOR-100				
METRO SENTRY ONE				
MICRODETECTIVE				
MICRO-DETECTIVE-HX				
microRaider				
MICT Platform (Magnetic ImmunoChromatographic Test System				
MiSeq System				
Mobile Laboratory				
Mobile Radiation Detection & Monitoring System				
Modernized AN/ PDR-75 Radiac				
Morphix ChemBio Detector				
MS-200 Microarray Scanner				
MSA Biosensor 2200R				
MSA BIOSENSOR 4000				
MSD Cartridge Reader				
MSD SECTOR PR2 Model 1500				
MSD SECTOR PR2 Model 1800				

System or Device	Biological Detection	Chemical Detection	Radiological Detection	Maturity
MSD SECTOR PR2 Model 1900				
Multiplexed Pathogen Detection at Point-Of-Use				
MultiRAE Plus				
MX300				
Mx3000P Mx3005P				
nanoRAIDER				
Nanosecond X-Ray Detector				
NetBio Rapid DNA Analysis System				
NeutronRAE II				
NIDS Auto-Reader				
NIDS Biothreat Detection Kit				
NIDS Medical Reader System				
NucliSens easyQ				
Octet				
Overhoff Model 357RM Tritium Monitor				
Overhoff Model 400AC				
Palladium Diagnostic System				
PanNAT system				
PASS (Product Acoustic Signature System)				

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

System or Device	Biological Detection	Chemical Detection	Radiological Detection	Maturity
Pathsenors BioFlash-E	☣			◕
PINS-2			☢	◔
PLEX-ID System	☣			◕
PM1603A(B) – Wrist gamma dosimeter			☢	◕
PM1603B – Wrist Gamma Dosimeter			☢	◕
PM1604A (B) Personal compact dosimeter			☢	◕
PM1703GN – Personal Radiation Detector			☢	◕
PM1703M-O1 (MO-2) – Personal Radiation Detector/ Dosimeter			☢	◕
PM2012M Combined Gamma Dosimeter and Chemical Detector		⚗	☢	◕
Portable Air Monitor	☣	⚗		◔
Portable Liquid Scintillation Counter	☣	⚗	☢	◔
Prime Alert Biodetection System	☣			◔
Pro-Strips Multi-Agent Detection Test	☣			◔
ProteOn(TM) XPR36 Interaction Array System	☣			◕
Proteus (robotic molecular analysis system) Asklepios (portable system)	☣			◕
pTD	☣			◕
QFlu Combo Test for POC Flu and Drug Resistance Detection	☣			◕
QFlu Combo Test for Rapid Flu and Drug Resistance Detection	☣			◕
qNano	☣			◕

System or Device	Biological Detection	Chemical Detection	Radiological Detection	Maturity
QTL Biosensor 2200R	☣			◔
QTL BIOSENSOR 4000	☣			◔
Quant NQAD QT-500 Detector		⚗		◕
R.A.P.I.D. BioThreat Detection System	☣			◔
radHUNTER			☢	◕
Radiation Alert Inspector	☣			◔
Radiation Control Monitor	☣	⚗	☢	◔
Radiation Pager			☢	◕
Radiation Survey Meter and Surface Monitor			☢	◕
Radio Frequency Phase Shift Sensor Platform	☣			Not Available
Radiological Contaminant Water Monitor			☢	◔
RADIR			☢	◕
RadSeeker CS			☢	◕
RADSticker			☢	◕
RADTriage			☢	◕
Raider			☢	◕
RAMP	☣	⚗		◔
RANIDPRO 200 - Portable Radiological and Nuclear Identification			☢	◔
Rapid BioAlert Reader and BioThreat Alert assays	☣			◕

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

System or Device	Biological Detection	Chemical Detection	Radiological Detection	Maturity
Rapid Detection of Ultra-Trace Levels of Pathogens (Listeria monocytogenes)	☣			◔
Rapid Portable Biosensor	☣			◔
RapidPlex	☣			◔
Raptor	☣			◕
RAZOR EX BioThreat Detection System	☣			◕
REAL – Raman Shifted Eyesafe Aerosol Lidar	☣	⚛		◕
REBS – Resource Effective BioIdentification System	☣	⚛	☢	◑
REBS – Resource Effective BioIdentification System - Laboratory	☣	⚛	☢	◑
Rotor-Gene Q Real-time PCR System	☣			◑
RuggID System	☣			◔
SABT	☣			◕
SAFESITE MTX (Multi Threat Monitor)		⚛	☢	◑
SAM 940 – Radionuclide Isotope Identifier			☢	◕
SAMPLE – Scanning Aerosol Micropulse LIDAR -Eyesafe		⚛		◔
SCIAB	☣			◔
SensAlert Plus Gas Detection Equipment		⚛		◑
Sensidyne/Kitagawa Gas Detector Tube System		⚛		◕
SilverQuant Pathogen Detection System	☣			◑
SmartBio Sensor (SBS)	☣			◕

System or Device	Biological Detection	Chemical Detection	Radiological Detection	Maturity
SmartCycler System				
SPIR ID Handheld Detection & Identification				
StepOne				
StepOne Plus real-time PCR system				
StreetLab Mobile Chemical/Biological Identification Instrument				
T2Dx				
TacBio				
TAC-BIO / I-Collector				
T-COR 4 Handheld Real-Time PCR Thermocycler				
TechniCART				
TessArray RPM-Flu Respiratory Pathogen Assay				
TessArray RPM-TEI Tropical and Emerging Infections Assay				
ThreatShield-C				
TIRF FluoroGazer analytical grade TIRF-EC microarray chem-bio sensor				
TIRF Sense handheld sensor TIRF-EC microarray chem-bio handheld sensor				
TIRF Sense portable sensor TIRF-EC microarray chem-bio portable sensor				
Tritium Monitor				
TruArray				
TruDefender FT				

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

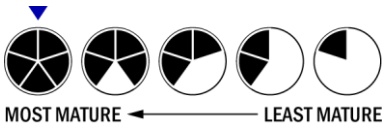
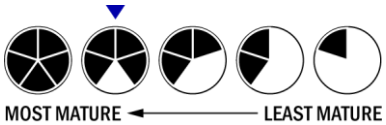
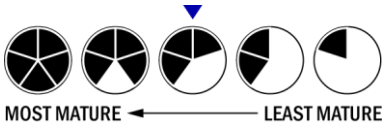
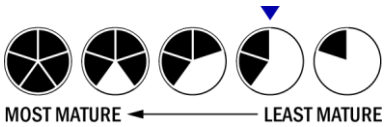
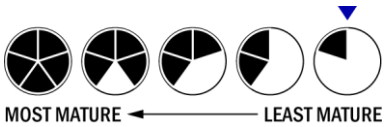
System or Device	Biological Detection	Chemical Detection	Radiological Detection	Maturity
TruDefender FTG		✓		●
UGV-Based Mountable and Dismountable Standoff Chemical Sensor		✓		●
UMSS – Universal Mass Spectrometer Sensor	✓	✓		◕
uScope MX - POC Diagnostics	✓			◕
VDSC-2M	✓			◕
VereID Biosystem and VereChip	✓			◕
Verigene System	✓			◕
Veriti Thermal Cycler	✓			◕
Veritide Ceeker	✓			◕
VIBP	✓	✓		●
Vides Bioassay System	✓	✓		◕
ViriChip System	✓			◔
Voice200		✓		◕
Warlock		✓		◕
Water Testing Kit NBC Defense		✓		●
zNose	✓	✓		●

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Detailed Product Sheets

Lists of Symbols for Product Sheets

Symbols	Definition
	Biological Agent Idenfitication
	Chemical Agent Identification
	Radiological Identification

Symbol	Definition
	Commercially Available and Meets Military Specifications
	Commercially Available
	Brass Board
	Bread Board
	White Board

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

3M Integrated Cycler

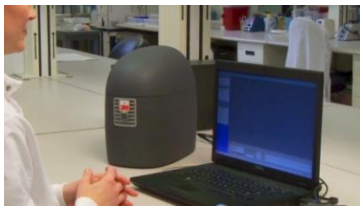
by 3M

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Environmental water, Food



DESCRIPTION:

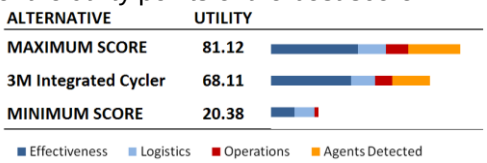
Disc-based molecular diagnostic test system for clinical labs. Current assays use clinical samples. We expect that it could be adapted for a wide variety of liquid matrices.

TECHNOLOGY:

Thermocycler with four-channel fluorescent detection for use with real time PCR assays.

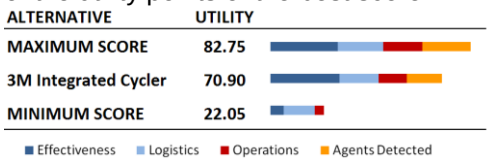
ANALYTICAL Laboratory Ranking

3M Integrated Cycler ranked in the top third of all evaluated products for analytical laboratories and earned 84% of the utility points of the best score.



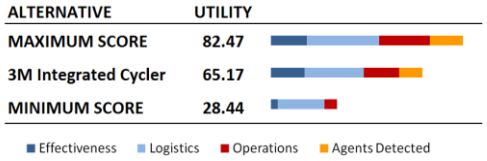
DIAGNOSTIC Laboratory Ranking

3M Integrated Cycler ranked in the top third of all evaluated products for diagnostic laboratories and earned 86% of the utility points of the best score.



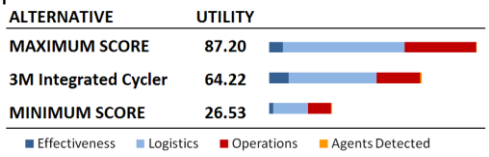
MOBILE Laboratory Ranking

3M Integrated Cycler ranked in the top third of all evaluated products for mobile laboratories and earned 79% of the utility points of the best score.



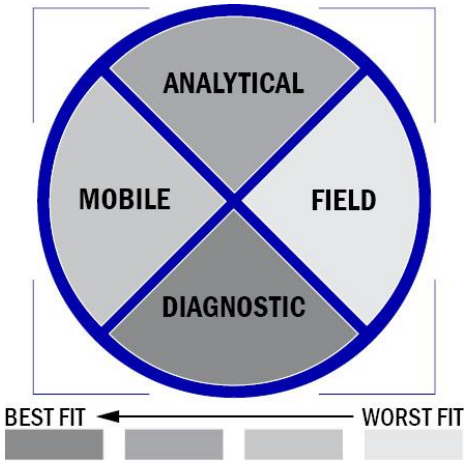
FIELD USE Ranking

3M Integrated Cycler ranked in the middle third of all evaluated products for field use and earned 74% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

3M Center
Bldg 270-2N-03
St. Paul, MN 55144-1000

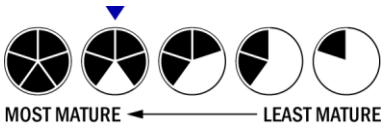
Point of Contact:
David Whitman
phone: 651-736-5378
email: david.whitman@mmm.com

COST

- $60,000.00/system or device
- Not Available

SPECIFICITY

- False Positives: <1%
- False Negatives: 0-4%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30-60 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- No sounds or alarms
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes for set up
- Almost no down time
- 3-5 steps are required
- Customer site training/ Hard copy manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components must be frozen
- Performance is not influenced by relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a toaster
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 4 components

Maintenance:
- Service less than once a year
- Preventive maintenance N/A
- Maintenance not included
- Expected life 3-5 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time available
- Data cannot be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance shown
- FDA approval shown
- Less than 100 ul for a test

System Maturity:
- Commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Satellite, wireless and wired connections
- Fully autonomous system with significant effort
- Laptop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

451P microR Ion Chamber Survey Meter

by Fluke Biomedical

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

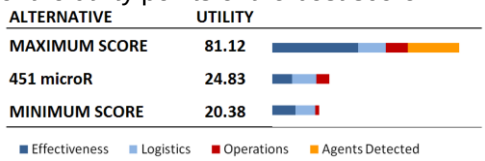
The 451P state-of-the-art ion chamber survey meter is a handheld battery operated unit designed for use in both rugged and normal environments. The 451P is a pressurized ion chamber for µR resolution. The 451P has auto-ranging and measure radiation rate and accumulated dose from various radiation sources (x-ray and gamma). The ion chamber detector allows for a fast response time to radiation from leakage, scatter beams, and pinholes. Additionally, the low-noise chamber bias supply provides for fast background-settling time.

TECHNOLOGY:

Pressurized ion chamber technology.

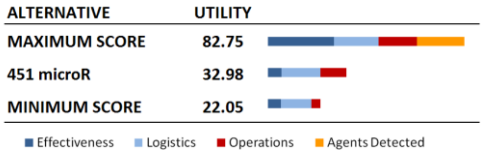
ANALYTICAL Laboratory Ranking

451P microR Ion Chamber ranked in the bottom third of all evaluated products for analytical laboratories and earned 31% of the utility points of the best score.



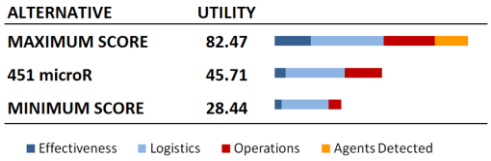
DIAGNOSTIC Laboratory Ranking

451P microR Ion Chamber ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 40% of the utility points of the best score.



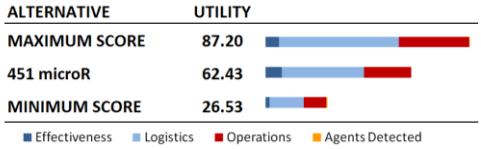
MOBILE Laboratory Ranking

451P microR Ion Chamber ranked in the bottom third of all evaluated products for mobile laboratories and earned 55% of the utility points of the best score.



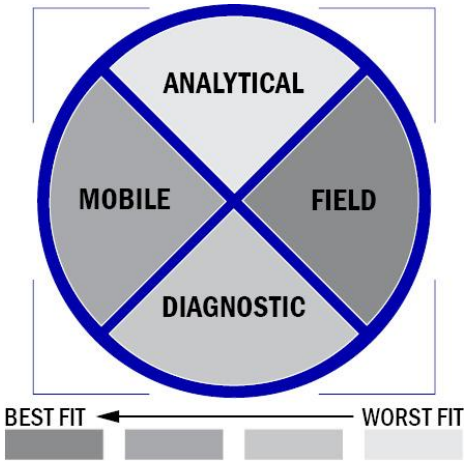
FIELD USE Ranking

451P microR Ion Chamber ranked in the middle third of all evaluated products for field use and earned 72% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

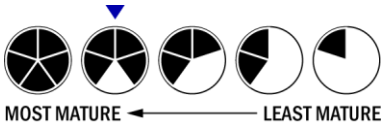
Fluke Biomedical
6920 Seaway Blvd
Everett, Wa. 98203

COST

- $2,700.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- Information not available

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Thermal output information not available

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- Down time information not available
- Steps required information not available
- Web-based video

Operational conditions:
- Can be used from < -21°C to > 42°C
- Components should be stored at room temp but can stand temps > 45°C for periods of < 24 hours
- Performance is not influenced by relative humidity
- Shelf life information not available

Transportation:
- Approximately the size of a toaster
- Commercial carrier
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- Solutions, buffer, reagents information not available
- Component information not available

Maintenance:
- Service once a year
- Preventive maintenance not applicable
- Maintenance not included
- Expected life 5-10 years
- <5 minutes daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- No electrical requirement
- >100 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- Centrifugation information not available
- Shaking, vortexing, mixing, degassing or filtering steps information not available
- Final result information not available

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Liquid test information not available

System Maturity:
- Is commercially available
- Peer reviewed publication or independent evaluation information not available
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- Raw data information not available
- Network capability information not available
- Wired connections
- Autonomy information not available
- Laptop computer
- Does not stores or archive data outputs or create an electronic record
- System software information not available
- System hardware not applicable

ABI 2720

by Applied Biosystems, part of Life Technologies

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Demonstrated:
Wound, Soil

DESCRIPTION:

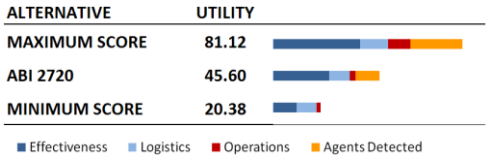
The Applied Biosystems 2720 Thermal Cycler is an automated instrument, specifically designed for the amplification of nucleic acids using the GeneAmp Polymerase Chain Reaction (PCR) process. The instrument has an integrated 96-well sample block, which houses an internal Peltier heating/cooling unit. The sample block is made of aluminum to provide optimal thermal transfer rate. Platinum sensors provide a wide temperature range (4°C to 99.9°C), accurate measurements (±0.25°C from 35°C to 100°C) and long term stability and high reliability. The sample block accommodates several different types of MicroAmp® disposable tubes and plates, which must be used in order to create a sealed chamber.

TECHNOLOGY:

The Applied Biosystems 2720 Thermal Cycler allows for fast and easy detection of genetic signatures using Polymerase Chain Reaction (PCR). PCR uses naturally occurring biological components to amplify genetic material (RNA or DNA) from a variety of biological and environmental sources by making billions of copies from a single copy. This amplification process requires repetitive and precise cycling of temperatures provided by peltier-based thermal cycling elements in the 2720 combined with specialized liquid reagents and plastic disposable reaction vessels. PCR amplifies specific genetic signatures (pathogens, human genetic signatures) only if they are present in the starting material.

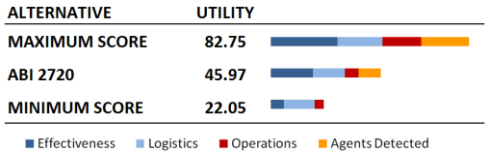
ANALYTICAL Laboratory Ranking

ABI 2720 ranked in the middle third of all evaluated products for analytical laboratories and earned 56% of the utility points of the best score.



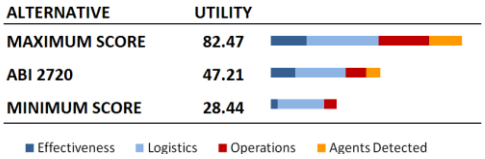
DIAGNOSTIC Laboratory Ranking

ABI 2720 ranked in the middle third of all evaluated products for diagnostic laboratories and earned 55% of the utility points of the best score.



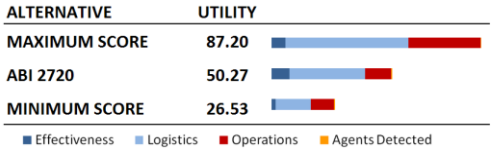
MOBILE Laboratory Ranking

ABI 2720 ranked in the bottom third of all evaluated products for mobile laboratories and earned 57% of the utility points of the best score.



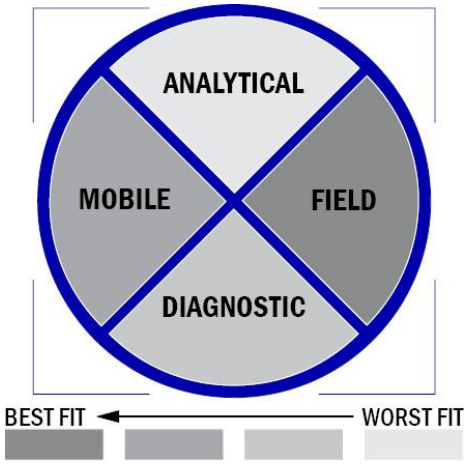
FIELD USE Ranking

ABI 2720 ranked in the bottom third of all evaluated products for field use and earned 58% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Applied Biosystems, part of Life Technologies
5791 Van Allen Way
Carlsbad, CA 92008

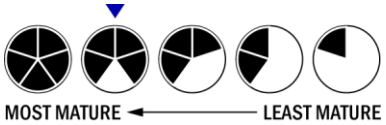
Point of Contact:
Cain Murphy
P (760) 603-7200
F (760) 602-6500
cain.murphy@lifetech.com

COST

- $4,580.00/system or device
- ~$1.50/analysis

SPECIFICITY

- False Positives: Not Available
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Semi-automated with some effort

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- 10-20 minutes set up
- <1 minute down time
- 3-5 steps are required
- Customer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components must be frozen
- Performance is not influenced by relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a toaster
- Commercial carrier
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance is no included
- Expected life 3-5 years
- No QA required
- Exposure to hazardous agent would require up to 1 day to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results not available
- Multiple centrifugation steps required
- Multiple shaking or vortexing, mixing, degassing or filtering step required
- Software will not call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 10 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Not network capable
- No data transmission
- Not capable of autonomy
- No computational power needed
- The system does not contain internal memory for data storage or electronic record keeping
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

ABI 7500 Fast Dx Real-Time PCR System

by Life Technologies

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Environmental air, Environmental water, Soil, Food, Powder, Insect vector

DESCRIPTION:

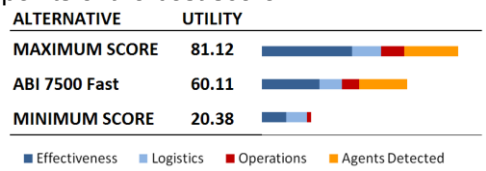
The Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument, with SDS v1.4 Software, is a 96-well, 5-color real-time PCR instrument available for in vitro diagnostic use.The 7500 Fast Dx Real-Time PCR Instrument delivers the performance required for high-quality results in a 96- well format. The 7500 Fast Dx Instrument's Sequence Detection Software v1.4 Security, Auditing, and E-Signature module offers the flexibility to develop assays and also run pre-optimized protocols for users operating in a secure environment.

TECHNOLOGY:

The 7500 Fast utilizes a tungsten-halogen lamp, a cooled charge coupled device (CCD) camera, and emission filters to enable multiple wavelength detection. Instrument software utilizes a multicomponenting algorithm to provide precise deconvolution of multiple dye signals to enable the simultaneous detection of multiple fluorophores with little crosstalk. The 7500 Fast supports a variety of available chemistries and is fully validated with Applied Biosystems' portfolio of assays and reagents.

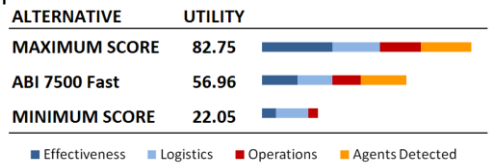
ANALYTICAL Laboratory Ranking

ABI 7500 Fast Dx ranked in the top third of all evaluated products for analytical laboratories and earned 75% of the utility points of the best score.



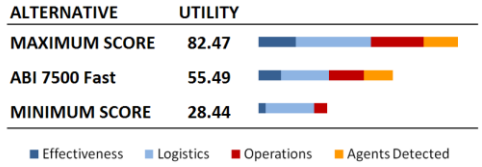
DIAGNOSTIC Laboratory Ranking

ABI 7500 Fast Dx ranked in the top third of all evaluated products for diagnostic laboratories and earned 76% of the utility points of the best score.



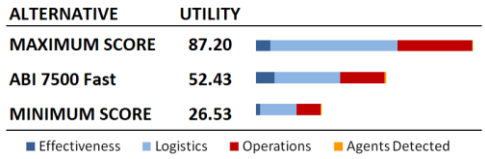
MOBILE Laboratory Ranking

ABI 7500 Fast Dx ranked in the middle third of all evaluated products for mobile laboratories and earned 69% of the utility points of the best score.



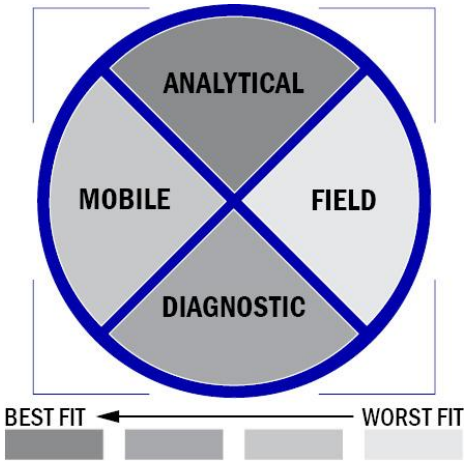
FIELD USE Ranking

ABI 7500 Fast Dx ranked in the bottom third of all evaluated products for field use and earned 60% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

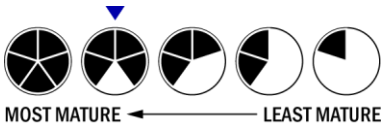
Life Technologies
5791 Van Allen Way
Carlsbad, California 92008 USA
(760) 603-7200
ww.lifetechnologies.com

COST

- $65,900.00/system or device
- $0.50/analysis

SPECIFICITY

- False Positives: Not Available
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30-60 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Semi-automated with some effort

Signature:
- Sounds or alarms not present
- No screen present
- Greater than 500 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- No set up required
- Less than 1 minute down time
- 3-5 steps are required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components must be stored at room temperature (27°C)/ Components must be stored at 4°C/ Components must be frozen
- Performance is not influenced by relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a carry-0n luggage suitcase
- Commercial carrier
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 3 components

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by technician
- Maintenance is not included
- Expected life 5-10 years
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can not be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance shown
- FDA approval capable
- Less than 50 ul for a test

System Maturity:
- Is commercially available
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Not capable of autonomy
- Laptop computer
- The system could be adapted to store and archive data outputs and create an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

ABI 7500 Real Time PCR System

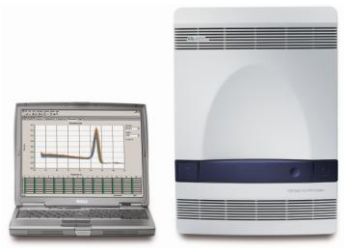
by Life Technologies Corporation

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Environmental air, Environmental water, Soil, Food, Powder, Insect vectors



DESCRIPTION:

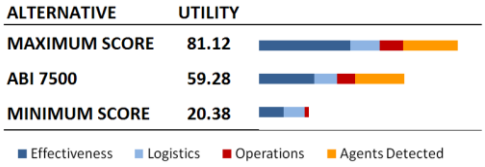
The instrument is an integrated system designed to perform both real-time PCR and post-PCR analysis. The instrument is capable of analyzing 96 samples simultaneously in a 96-well plate format. The instrument provides specialized application specific software that collects and analyzes the fluorescence data for the application of absolute quantitation and allelic discrimination/SNP (Single Nucleotide Polymorphism) detection.

TECHNOLOGY:

The instrument support two homogeneous reaction chemistries, the fluorogenic 5' nuclease assay using TaqMan® probes and the SYBR® Green I double stranded DNA binding dye chemistry. The instrument utilizes a tungsten-halogen lamp, a cooled charge coupled device (CCD) camera, and multiple emission filters, to enable multiple wavelength detection. Instrument software utilizes a multicomponenting algorithm to provide precise deconvolution of multiple dye signals, to enable the simultaneous detection of multiple fluorophores with little crosstalk.

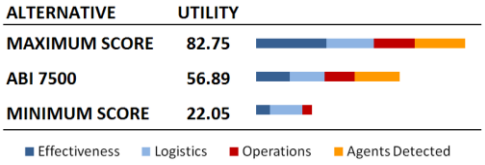
ANALYTICAL Laboratory Ranking

ABI 7500 Real Time PCR System ranked in the top third of all evaluated products for analytical laboratories and earned 73% of the utility points of the best score.



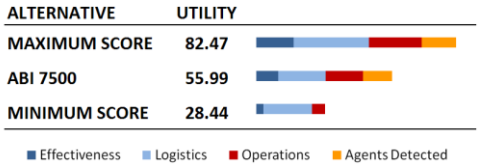
DIAGNOSTIC Laboratory Ranking

ABI 7500 Real Time PCR System ranked in the top third of all evaluated products for diagnostic laboratories and earned 69% of the utility points of the best score.



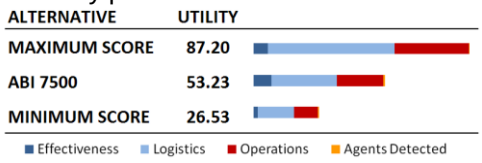
MOBILE Laboratory Ranking

ABI 7500 Real Time PCR System ranked in the middle third of all evaluated products for mobile laboratories and earned 68% of the utility points of the best score.



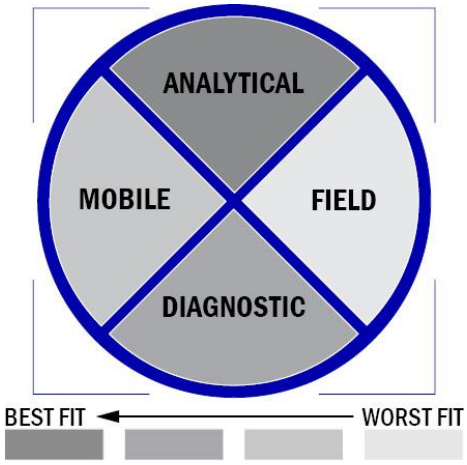
FIELD USE Ranking

ABI 7500 Real Time PCR System ranked in the bottom third of all evaluated products for field use and earned 61% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

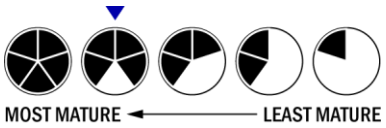
Life Technologies Corporation (Headquarters)
5791 Van Allen Way PO Box 6482
Carlsbad, California 92008
Call: 760.603.7200
Fax: 760.602.6500

COST

- $42,500.00/system or device
- $0.50/analysis + cost of Taq polymerase

SPECIFICITY

- False Positives: Not Available
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Semi-automated with some effort

Signature:
- Sounds or alarms not present
- No screen present
- Greater than 500 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- No set up required
- Less than 1 minute down time
- 3-5 steps are required
- Customer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components must be stored at 4°C
- Performance is not influenced by relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Commercial carrier
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 3 components

Maintenance:
- Serviced required once a year
- Preventive maintenance serviceable by technician
- Maintenance is not included
- Expected life 5-10 years
- No QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can not be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Less than 50 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Not capable of autonomy
- Laptop computer
- Could be adapted to store and archive data outputs and create an electronic record
- The system software is open but modification requires licensing
- The system hardware is open but modification requires licensing

ABI 7900HT Fast Real-Time PCR System

by Life Technologies

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Environmental air, Environmental water, Soil, Food, Powder, Insect vectors

DESCRIPTION:

The Applied Biosystems 7900HT Fast Real-Time PCR System is the only real-time quantitative PCR system that combines 96- and 384-well plate compatibility and the TaqMan® Low Density Array with fully automated robotic loading-and now also offers optional Fast real-time PCR capability. The system is intended for laboratory analysis and is versatile and adaptable for many matrices.

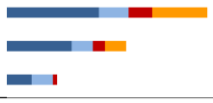
TECHNOLOGY:

Real-time TaqMan ® and other probe/dye polymerase chain reaction amplification of genes on a peltier-based thermocycling apparatus.

ANALYTICAL Laboratory Ranking

ABI 7900HT ranked in the middle third of all evaluated products for analytical laboratories and earned 60% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
ABI 7900HT	48.37
MINIMUM SCORE	20.38

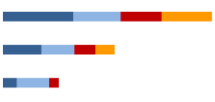


Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

ABI 7900HT ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 53% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
ABI 7900HT	44.14
MINIMUM SCORE	22.05

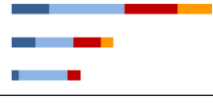


Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

ABI 7900HT ranked in the bottom third of all evaluated products for mobile laboratories and earned 51% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
ABI 7900HT	41.88
MINIMUM SCORE	28.44



Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

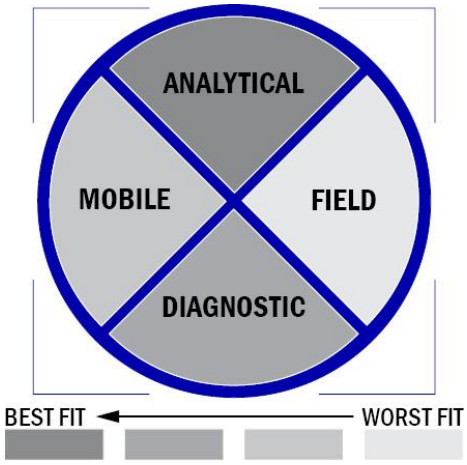
ABI 7900HT ranked in the bottom third of all evaluated products for field use and earned 46% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
ABI 7900HT	40.52
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Life Technologies
850 Lincoln Centre Dr
MS 407
Foster City, CA 94404

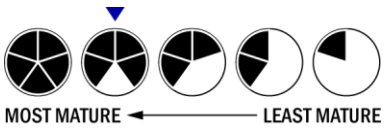
Point of Contact:
Levente Egry
levente.egry@lifetech.com
Phone: 650-554-3447

COST

- Cost is variable depending on block and automation options.
- Cost is variable depending on reagents used.

SPECIFICITY

- False positive and negative rates are assay dependent



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1- 8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Currently semi-automated

Signature:
- Sounds or alarms cannot be deactivated
- No screen
- Greater than 500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- < 5 minutes set up
- 1-3 minutes down time
- 3-5 steps are required
- Customer and manufacturer site training/ Hard-copy and web-based manual manuscript

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be stored frozen but can withstand temps < 4°C for < 24 hours/ Must be stored at room temp/ Must be stored at 4°C/ Must be frozen/ Must be frozen at ≤ -20°C
- Peak performance at normal relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a home dishwasher
- Transport via commercial carrier
- Weighs >50 kg

Re-use:
- Multiple detection assays
- 3 solutions and/or reagents
- 2 components

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by technician only
- Maintenance is not included
- Expected life 5-10 years
- No daily QA required
- Exposure to hazardous agent requires 4 hours to decon

Physical System Requirements:
- 220V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- Multiple centrifugation steps are required
- Multiple shaking or vortexing, mixing, degassing or filtering steps are required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Less than 50 ul for a test

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology is a combination of IP ownership and licensing

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Wired connections
- Not capable of autonomy
- Basic desktop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

ABI 9700

by Applied Biosystems, part of Life Technologies

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Demonstrated:
Stool

DESCRIPTION:

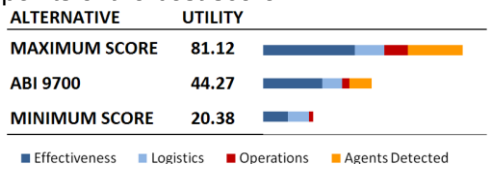
The GeneAmp PCR System 9700 is an automated instrument, specifically designed for the amplification of nucleic acids using the Polymerase Chain Reaction (PCR) process. The user interface consists of a control panel with a full numeric keypad, soft keys, and a graphical display screen that shows the time and temperature profile for each run. The sample compartment holds up to 96 MicroAmp Reaction Tubes (0.2 mL). The internal Peltier heating/cooling unit is housed in the sample block module. Platinum sensors provide a wide temperature range (4°C to 99.9°C), accurate measurements (±0.25°C from 35°C to 100°C) and long term stability and high reliability.

TECHNOLOGY:

The Applied Biosystems 9700 Thermal Cycler allows for fast and easy detection of genetic signatures using Polymerase Chain Reaction (PCR). PCR uses naturally occurring biological components to amplify genetic material (RNA or DNA) from a variety of biological and environmental sources by making billions of copies from a single copy. This amplification process requires repetitive and precise cycling of temperatures provided by peltier-based thermal cycling elements in the 9700 combined with specialized liquid reagents and plastic disposable reaction vessels. PCR amplifies specific genetic signatures (pathogens, human genetic signatures) only if they are present in the starting material.

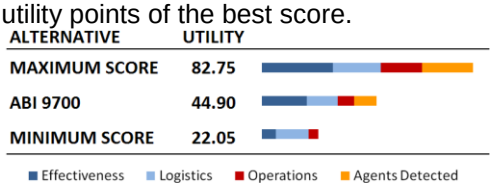
ANALYTICAL Laboratory Ranking

ABI 9700 ranked in the middle third of all evaluated products for analytical laboratories and earned 55% of the utility points of the best score.



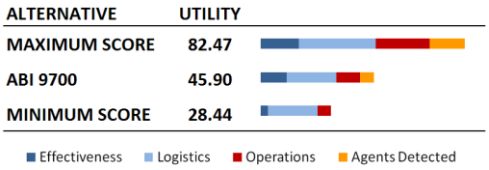
DIAGNOSTIC Laboratory Ranking

ABI 9700 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 544% of the utility points of the best score.



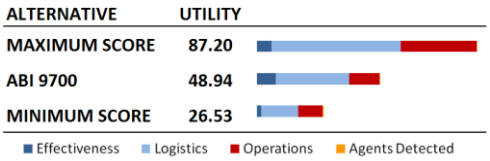
MOBILE Laboratory Ranking

ABI 9700 ranked in the bottom third of all evaluated products for mobile laboratories and earned 56% of the utility points of the best score.



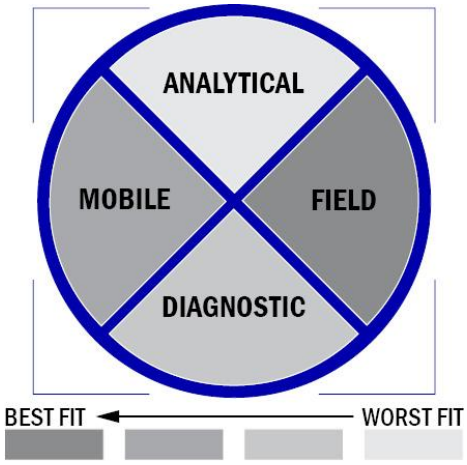
FIELD USE Ranking

ABI 9700 ranked in the bottom third of all evaluated products for field use and earned 56% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Applied Biosystems part of Life Technologies
5791 Van Allen Way
Carlsbad, CA 92008

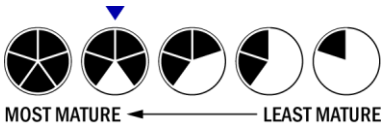
Point of Contact:
Cain Murphy
P (760) 603-7200
F (760) 602-6500
cain.murphy@lifetech.com

COST

- $8,010.00-15,820.00/system or device
- ~$1.50/analysis

SPECIFICITY

- False Positives: Not Available
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Semi-automated with some effort

Signature:
- Sounds or alarms present
- Screen cannot be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- 10-20 minutes set up
- 1-3 minutes down time
- 3-5 steps are required
- Customer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components must be frozen
- Performance is not influenced by relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a toaster
- Commercial carrier
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 3-5 years
- No QA required
- Exposure to hazardous agent would require up to 1 day to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results not available
- Data can not be processed while in progress
- Multiple centrifugation steps required
- Multiple shaking or vortexing, mixing, degassing or filtering steps required
- Software will not call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 10 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- No data transmission
- Not capable of autonomy
- No computational power
- The system does not contain internal memory for data storage or electronic record keeping
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

ABI® ViiA™ 7 Real-Time PCR System

by Applied Biosystems

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/ml of original sample)
Toxins

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Patient wound, Environmental air, Environmental water, Soil, Food, Powder

DESCRIPTION:

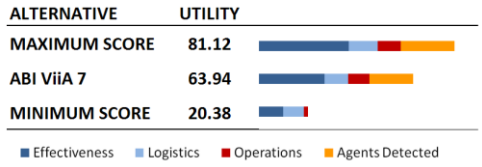
The Applied Biosystems ViiA™ 7 Real-Time PCR System is optimized for DNA/RNA from any sample type (industrial or environmental) that would serve the following applications: Gene Expression, Genotyping, Copy Number Variation, Pathogen Detection, Strain Typing, Viral Load, Mutation Scanning (High Resolution Melting), Methylation and other Epigenetic Applications, miRNA profiling, Protein analysis with proximity ligation assays, Quality control for detection of environmental contaminants, and Biofuel Development.

TECHNOLOGY:

The Applied Biosystems ViiA™ 7 Real-Time PCR System utilizes Real-Time PCR technology. Polymerase Chain Reaction (PCR) is a powerful technology that amplifies DNA or cDNA targets up to a million fold. Real-Time PCR amplifies the target in the presence of fluorescent dyes and the instrument captures the fluorescent signal in “real-time” to determine how many copies of DNA are present at each cycle. The ability of the real-time PCR instrument to monitor the amount of target that amplifies over the course of the run enables very precise, sensitive and accurate quantitative measurements to determine the number of starting copies in the reaction. Real-Time PCR amplifies DNA exponentially, doubling the number of molecules present with each amplification cycle. The increase of fluorescent signal is directly proportional to the amount of PCR product generated in the exponential phase of the reaction. The number of cycles and the amount of PCR end-product can be used to calculate the initial quantity of genetic material by comparing the final quantity with a known standard. Fluorescent reporters used include double-stranded DNA (dsDNA)-binding dyes, or dye molecules attached to PCR primers or probes that are incorporated into the product during amplification. By plotting fluorescence against the cycle number, the real-time PCR instrument generates an amplification plot that represents the accumulation of product over the duration of the entire PCR reaction.

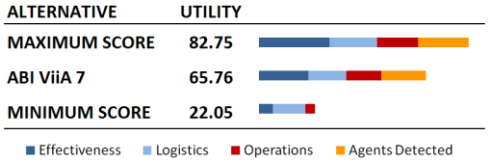
ANALYTICAL Laboratory Ranking

ViiA™ 7 Real-Time PCR System ranked in the top third of all evaluated products for analytical laboratories and earned 79% of the utility points of the best score.



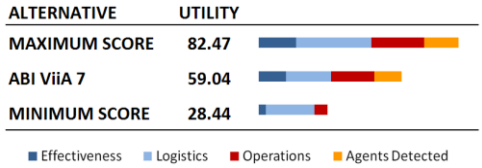
DIAGNOSTIC Laboratory Ranking

ViiA™ 7 Real-Time PCR System ranked in the top third of all evaluated products for diagnostic laboratories and earned 79% of the utility points of the best score.



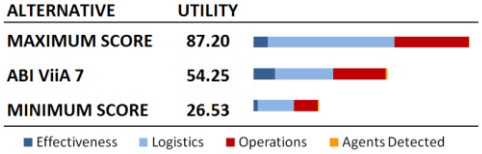
MOBILE Laboratory Ranking

ViiA™ 7 Real-Time PCR System ranked in the middle third of all evaluated products for mobile laboratories and earned 72% of the utility points of the best score.



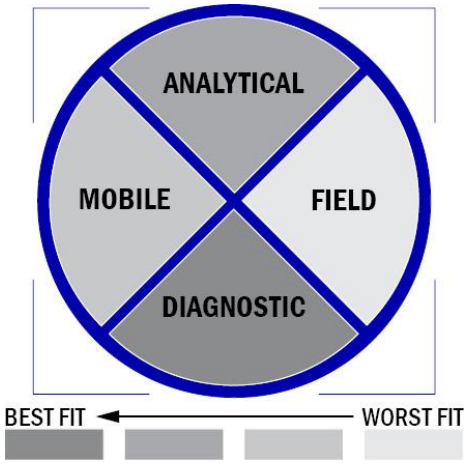
FIELD USE Ranking

ViiA™ 7 Real-Time PCR System ranked in the bottom third of all evaluated products for field use and earned 62% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Applied Biosystems
Lincoln Centre Dr
MS 407
Foster City, CA 94404

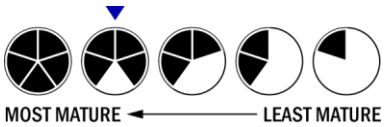
Point of Contact:
Damien Luk

COST

- $86,000.00 – 95,000.00/system or device

SPECIFICITY

- False Positives: Not Available
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1 - 8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- <5 minutes set-up
- <1 minute down time
- 0-2 steps required
- DVD/ Web-based video/ Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components must be stored at room temp (27°C)/ Must be stored at 4°C
- Performance is not influenced by relative humidity
- 6 months and 1 year shelf life

Transportation:
- Approximately the size of a home dishwasher
- Commercial / Fixed wing or rotary wing aircraft/ Ship
- Weighs more than 50 kg

Re-use:
- Single use
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service not required
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life not applicable
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 50 ul to test liquids

System Maturity:
- Is commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connections
- Could be adapted to a fully autonomous system with some effort
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software is open but modification requires licensing
- System hardware is open but modification requires licensing

AbleSentry®

by Lockheed Martin

DETECTS THE FOLLOWING:

Demonstrated:
Aerosolized chemical agent

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

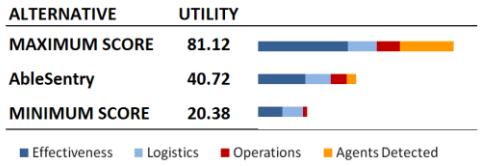
AbleSentry® is a flexible, functional, integrated system designed to provide tactical early warning of a possible attack with chemical, biological, or radiological agents. Fusing data from multiple sensor nodes over a wide area, AbleSentry® provides the capability to detect invisible threat clouds in sufficient time tp permit units to take protective action and thus significantly mitigate potential effects. By utilizing a true network of integrated sensor nodes, AbleSentry® provides high detection probability with low false alarm rates while utilizing straight-forward, easy-to-maintain technologies.

TECHNOLOGY:

Chemical: IMS Biological: Particle count, sizing, and fluorescence
Radiological: Gamma and Neutron.

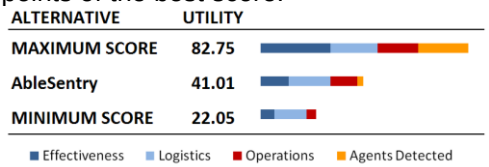
ANALYTICAL Laboratory Ranking

AbleSentry® ranked in the bottom third of all evaluated products for analytical laboratories and earned 50% of the utility points of the best score.



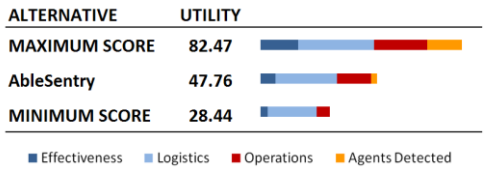
DIAGNOSTIC Laboratory Ranking

AbleSentry® ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 50% of the utility points of the best score.



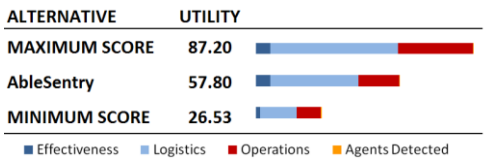
MOBILE Laboratory Ranking

AbleSentry® ranked in the bottom third of all evaluated products for mobile laboratories and earned 58% of the utility points of the best score.



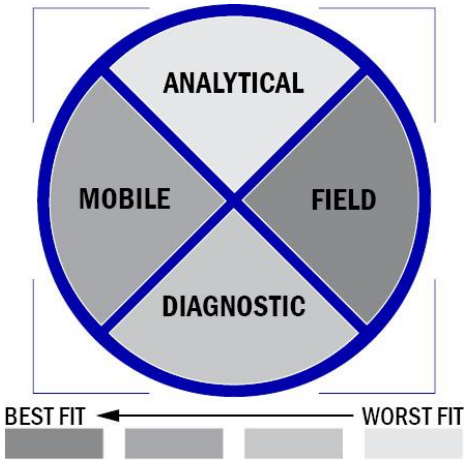
FIELD USE Ranking

AbleSentry® ranked in the middle third of all evaluated products for field use and earned 66% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

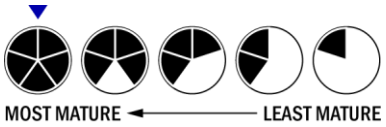
Biomatrica
5627 Oberlin Dr.
Suite 120
San Diego, CA 92121

COST

- ≥$750,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- <5 minutes set-up
- Almost instantaneous down time
- 3-5 steps required
- Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from -21°C to 41°C
- Does not require consumables
- Peak performance at normal relative humidity conditions
- Shelf life not applicable

Transportation:
- Approximately the size of a carry-on luggage
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- No additional consumables

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- 24 hours continuous operation on single set of batteries; fully rechargeable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- Centrifugation not applicable
- Shaking or vortexing, mixing, degassing or filtering not applicable
- System call of final result not applicable

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Liquid testing not applicable

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property owned

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Satellite, wireless and wired connections
- Fully autonomous
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software closed, not available for modification
- System hardware open and available for modification

ABSS (ATHINA Biological Security System)

by General Dynamics Armament and Technical Products

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria
Viruses
Toxins

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

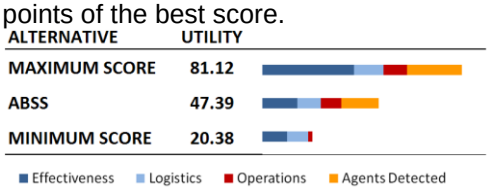
ABSS is an integrated solution for biological security missions requiring detection, collection, sample preparation, and identification of potential biological threats. ABSS utilizes GDATP's All Threats and Hazards Identification and Notification Architecture (ATHINA) to integrate sensing and support components based on the Common CBRN Sensor Interface (CCSI) Standard. The system is ruggedized and suitable for on scene and site monitoring by first responders, commercial security providers, and the military. With minimal training, ABSS allows the operator to rapidly detect and identify biological materials. The sensing components have been partitioned into three packages: an intelligent collector module, a manual identification module, and an electronics module. The intelligent collector continuously samples air, searching for biological compounds. Upon detection of a biological event, the collector warns, notifies and performs an automatic sample collection. Modules can utilize advanced detection algorithms and be networked for enhanced performance. The manual identification module provides sample preparation and identification capabilities needed to identify potential threat material. Identification is achieved by utilizing industry leading PCR and immunoassay technologies with options for automated and guided manual sample preparation. The electronics module utilizes ATHINA to provide power management, operator interface, and networking infrastructure to operate the system. This module enables the system to be configured for task-specific requirements by changing the sensing modules. No changes to the operator interface or software are needed.

TECHNOLOGY:

The intelligent collector is triggered by a deep-UV LED Laser Induced Fluorescence detector which runs continuously. Sample collection is accomplished with a high efficiency dry sampler developed for the collection of airborne particulates, especially pathogenic bacteria and spores. Liquid samples are extracted from the collector's electrets filter using a manual particle extractor. ID is accomplished by utilizing PCR and immunoassay technologies with options for automated and guided manual sample preparation. System can be tailored or configured for mission-specific requirement by changing individual sensor modules.

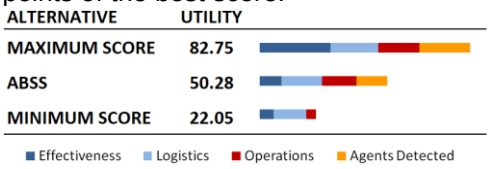
ANALYTICAL Laboratory Ranking

ABSS ranked in the middle third of all evaluated products for analytical laboratories and earned 58% of the utility points of the best score.



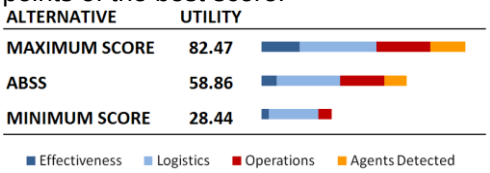
DIAGNOSTIC Laboratory Ranking

ABSS ranked in the middle third of all evaluated products for diagnostic laboratories and earned 61% of the utility points of the best score.



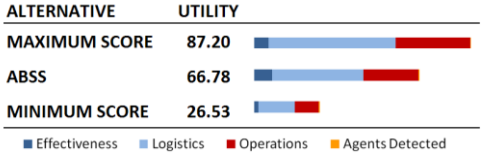
MOBILE Laboratory Ranking

ABSS ranked in the middle third of all evaluated products for mobile laboratories and earned 71% of the utility points of the best score.



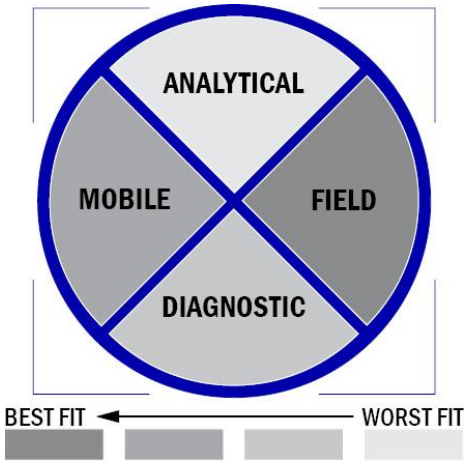
FIELD USE Ranking

ABSS ranked in the middle third of all evaluated products for field use and earned 77% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

General Dynamics Armament and Technical Products
4205 Westinghouse Commons Drive
Charlotte, NC 28273

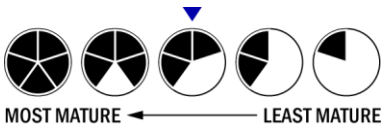
Point of Contact:
Doug Woody
980.235.2402
dwoody@gdatp.com

COST

- Information not available

SPECIFICITY

- False Positives: LIF Detector 1 per 1000 hours, CANARY <.05% @ 50 ACPLA, HyBeacons PCR not known
- False Negatives: LIF Detector 1 per 1000 possible detections, CANARY <.05% @ 50 ACPLA, HyBeacons PCR not known



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30 - 60 minutes for detection
- 1 sample, >10 tests/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Thermal output information not available

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- 5-10 minutes set-up
- <1 minute down time
- 6-8 steps required
- Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours/ Must be stored at room temp
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage
- All modes of transportation
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life not applicable
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 250 ul to test liquids

System Maturity:
- Brass board
- Expected to be ready for commercialization within one calendar year
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property owned

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Wireless, wired connections
- Could be fully autonomous with some effort
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- Software open, modification requires licensing
- Hardware open, modification requires licensing

Advanced Liquid Logic

by Advanced Liquid Logic, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (100-1,000 PFU/mL)
Toxins (<1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Environmental air

DESCRIPTION:

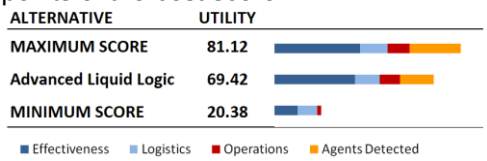
Advanced Liquid Logic, Inc. (ALL) has developed a patented liquid handling technology called "digital microfluidics' that reduces the cost, complexity and time required for automated sample-to-answer diagnostic testing. The instrument and cartridge-based platform developed by ALL eliminates the need for cumbersome pumps, valves and tubes by manipulating liquid droplets on an array of electrodes. The key factors that differentiate the ALL system are: 1. Assay flexibility – adding and optimizing assay types is rapidly accomplished by editing software 2. Low cost – component manufacturing processes are cost-effective and well-established 3. Broadly deployable – suited to any setting, from research lab to zero-resource field environment An exhaustive range of assay formats, relevant to clinical diagnostics and general life sciences research, have been translated to ALL's digital microfluidics technology. Some of the assays that have been implemented on our system include: Sample extraction & purification (from crude samples to pure: DNA, RNA or protein), Full sample-in-answer-out, hands-free integration, Newborn screening (enzymatic activity assays), Next-gen sequencing template prep, Real-time and Endpoint qPCR, DNA sequencing (pyrosequencing), Cell-based assays, Clinical chemistry, Coagulation monitoring, Immunoassays

TECHNOLOGY:

The instrument and cartridge-based platform developed by ALL eliminates the need for cumbersome pumps, valves and tubes by manipulating liquid droplets on an array of electrodes. The so-called "electrowetting" effect provides a motive force that can be flexibly controlled through software. In conventional microfluidics, liquid handling is directed by networks of tubes or channels that must be redesigned for every unique application. Within the ALL cartridge, electrode arrays are arranged on printed circuit boards (PCBs). An injection molded plastic plate above the PCB creates a chamber where droplets are manipulated.

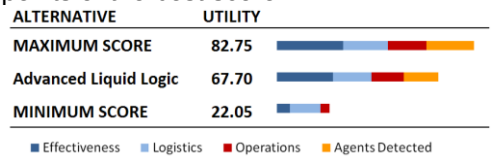
ANALYTICAL Laboratory Ranking

ALL ranked in the top third of all evaluated products for analytical laboratories and earned 86% of the utility points of the best score.



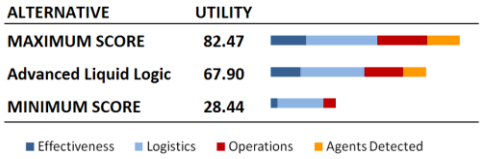
DIAGNOSTIC Laboratory Ranking

ALL ranked in the top third of all evaluated products for diagnostic laboratories and earned 82% of the utility points of the best score.



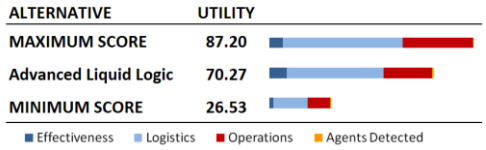
MOBILE Laboratory Ranking

ALL ranked in the top third of all evaluated products for mobile laboratories and earned 82% of the utility points of the best score.



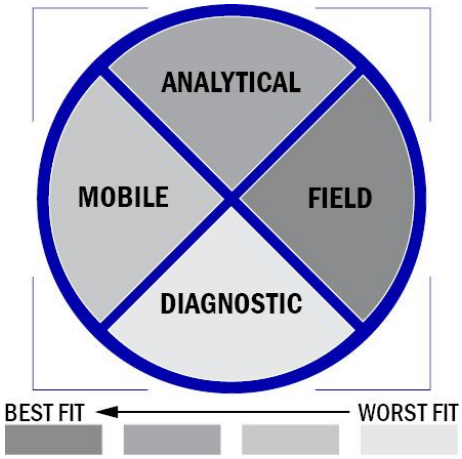
FIELD USE Ranking

ALL ranked in the top third of all evaluated products for field use and earned 81% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Advanced Liquid Logic, Inc.
615 Davis Drive, Suite 800
Research Triangle Park, NC 27709

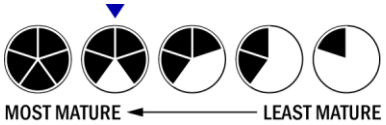
Point of Contact:
David Cohen
dcohen@liquid-logic.com
919-287-9010

COST

- $10,000.00-50.000.00/system or device
- $12.00-20.00/analysis

SPECIFICITY

- False Positives: Not Available
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15-30 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- No sounds or alarms
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- No set up required
- Less than 1 minute down time
- 0-2 steps are required
- DVD/ Customer and Manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temperature but can withstand temperatures > 45°C for periods of less than 24 hours
- Performance is not influenced by relative humidity
- Shelf life unknown

Transportation:
- Approximately the size of a toaster
- Commercial carrier/ Fixed wing and rotary aircraft/ Ship
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 4 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Unknown maintenance schedule
- Expected life 1-3 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- 2-4 hours battery use
- Requires water aliquots
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 10 ul for a test

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Fully autonomous system with some effort
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

AIDA: Autonomous Identification Diagnostics and Alert

by Prognosys

DETECTS THE FOLLOWING:

Demonstrated:

Bacteria (10e4-10e5 CFU/ml)
Toxins (10e4-10e5 ng/ml)
Liquid chemical agent
(1 ppb – 1 ppm)

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

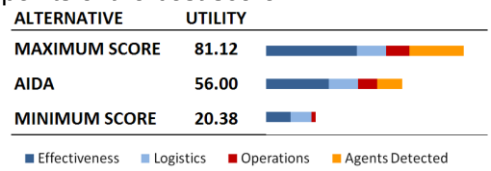
The AIDA™ system is comprised of a multiple pathogens and toxins diagnostic strip, a smart telephone for reading, analyzing and telemetry of the results indicated on the diagnostic strip, and a secure (encrypted) web portal for capturing test data, tracking results, prognosis, decision support, and mapping of identified pathogens and toxins anywhere on the globe. AIDA™ can be used to detect as many as ten pathogens, toxins, chemical threats, and physical conditions (such as temperature, time, vibration) simultaneously. AIDA™ devices can be configured as qualitative devices or fully quantitative systems with a limit of detection of about 50 ng/ml or 104 CFU, specificity of 95% or better, coefficient of variation of 5% or less, and detection time of less than 10 minutes for all indications on the strip. Prognosys has recently developed multiple pathogen cassettes for B. anthracis spores and PA, C. botulinum toxin, Yersenia pestis, SEB and Ricin, and a number of other diagnostics such as enteric diseases (V. colerae O1, O139, E-coli O157, Salmonella), cardiovascular disease markers (CRP, cTnI, TpP), and a number of kidney disease markers. Developed by Prognosys LLC as point-of-care diagnostic system, AIDA™ can be used by un-trained individuals at home, in the field, and points of care, without the need for instruments, reagents, and processing. AIDA™ is highly configurable not only for biological threats and medical applications, but also for supply chain tracking and security, tamper detection, and organizational planning and decision support.

TECHNOLOGY:

Commercially available lateral flow immuno-assays using colloidal gold labeled antibodies, incorporated into barcode diagnostic devices.

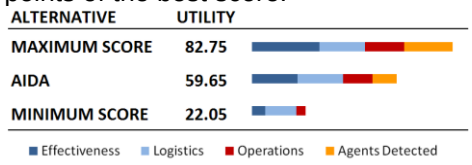
ANALYTICAL Laboratory Ranking

AIDA ranked in the top third of all evaluated products for analytical laboratories and earned 69% of the utility points of the best score.



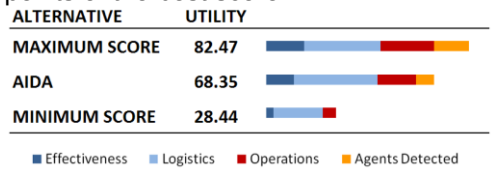
DIAGNOSTIC Laboratory Ranking

AIDA ranked in the top third of all evaluated products for diagnostic laboratories and earned 72% of the utility points of the best score.



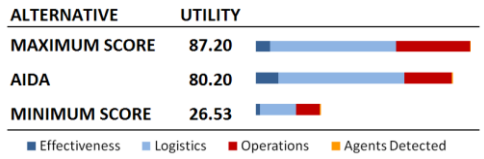
MOBILE Laboratory Ranking

AIDA ranked in the top third of all evaluated products for mobile laboratories and earned 83% of the utility points of the best score.



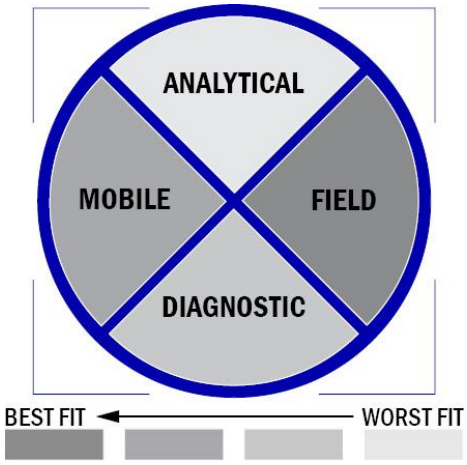
FIELD USE Ranking

AIDA ranked in the top third of all evaluated products for field use and earned 92% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Prognosys
108 Quay Street
Alexandria, VA 22314

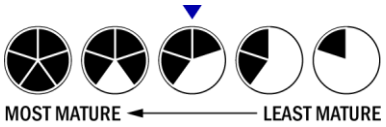
Point of Contact:
(832) 736-7677

COST

- Approximately $20 - $40/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, >10 tests/ sample per run
- Could easily be adapted into a fully automated system

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- No set-up required
- <1 minute down time
- 0-2 steps required
- Customer and manufacturer site training

Operational conditions:
- Can be used from 4°C to 41°C
- Components must be stored at 4°C
- Peak performance at normal relative humidity conditions
- Between 1 -3 years shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service not required
- Preventive maintenance not applicable
- Maintenance not included
- Expected life 1-3 years
- No daily QA required
- No decontamination required

Physical System Requirements:
- No electrical requirement
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 50 ul to test liquids

System Maturity:
- Brass board
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Satellite, wireless, wired
- Could easily be adapted to fully autonomous
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- Software open, modification requires licensing
- Hardware open, modification requires licensing

AIR (Arrayed Imaging Reflectometry) Bioassay System

by Research International, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria
Viruses
Toxins (<1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood

DESCRIPTION:

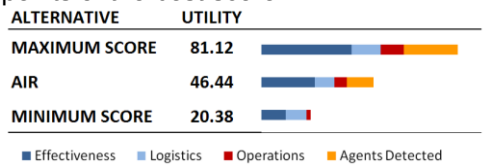
The AIR System performs extremely sensitive label-free, multi-analyte immunoassays (64 to several hundred array elements) on a silicon chip mounted in an injection-molded disposable cartridge. Protein assays typically have 1 pg/ml sensitivity, and a 5 to 6 log detection range. Assay protocols are completely automated and fluidic operations are controlled by an on-board microprocessor. These protocols primarily consist of incubation, wash and optical read-out steps that may be conveniently modified for specific applications or conditions using Windows software. All sample and wash fluids are stored onboard the cartridge after an assay is completed- there is no possibility of post-analysis sample contact. The hardware is currently in its fourth generation. The AIR platform is highly amendable to multiplexing, allowing for rapid, simultaneous quantification of potentially 100's of analytes with no increase in assay complexity. This robust detection platform is novel in its combination of rapid testing, highly multiplexed capacity and low assay cost. AIR has also been adapted for use in the field and at the point of need.

TECHNOLOGY:

AIR is a silicon chip-based label-free biosensor platform, which enables the detection and quantification of virtually any probe-target analyte pair with a high degree of sensitivity. Detection occurs via optical sensing of the binding of sub-Angstrom layers to the functionalized substrate surface. As AIR is an essentially reagentless assay, typical target analysis takes under 30 minutes of processing time (limited only by binding kinetics of the probe-target), in contrast to labeled techniques, which require further processing (usually 2-3 additional chemistries after target hybridization) and result in longer test times (>2 hrs) and substantially increased reagent costs.

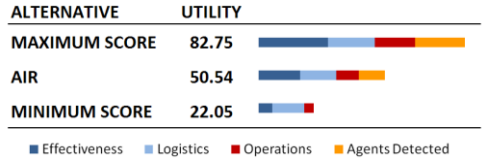
ANALYTICAL Laboratory Ranking

AIR ranked in the middle third of all evaluated products for analytical laboratories and earned 57% of the utility points of the best score.



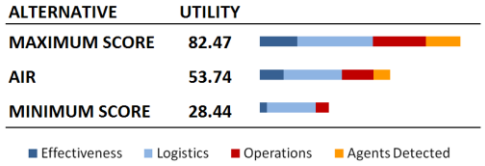
DIAGNOSTIC Laboratory Ranking

AIR ranked in the middle third of all evaluated products for diagnostic laboratories and earned 61% of the utility points of the best score.



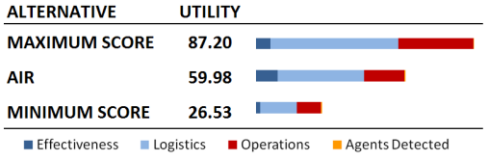
MOBILE Laboratory Ranking

AIR ranked in the middle third of all evaluated products for mobile laboratories and earned 65% of the utility points of the best score.



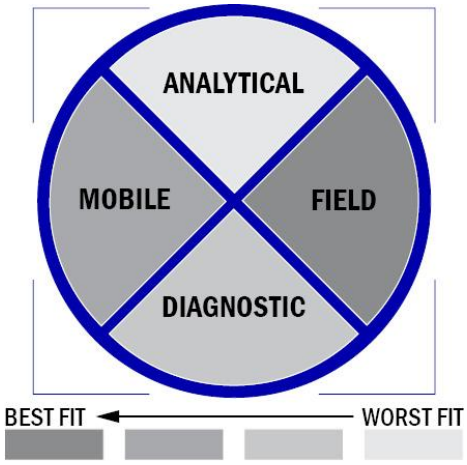
FIELD USE Ranking

AIR ranked in the middle third of all evaluated products for field use and earned 67% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Research International, Inc.
17161 Beaton Road SE
Monroe, WA 98272

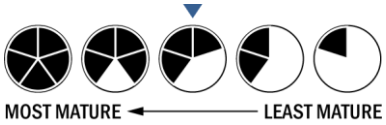
Point of Contact:
Jonathon Tobelmann
co. phone: 360-805-4930
direct phone: 703-625-8381

COST

- $30,000.00/system or device
- ~$20.00/analysis

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30-60 minutes for detection
- 1 sample, >10 tests/ sample per run
- Currently fully automated

Signature:
- No sounds or alarms
- Screen not present
- Less than 200 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- Greater than 20 minutes for set up
- 3-5 minutes down time
- 0-2 steps are required
- Customer and Manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components must be stored at 4°C
- Performance is not influenced by relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a toaster
- Commercial carrier
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician
- Maintenance not included
- Expected life 5-10 years
- 10-20 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Batteries
- 4-8 hours battery use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time not available
- Data cannot be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software could call final results in future

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 100 ul for a test

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Fully autonomous system with easy adaptation
- High end desktop computer
- No data storage or electronic record keeping
- The system software is closed with no modification
- The system hardware is closed and not available for modification

AIROCOLLECT-DETECT-288

by Airogistic, LLC

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

The AiroCollector-Detect is a combined laser induced florescence (LIF) detector and wetted-wall plastic cyclone (WWPC) bio-aerosol sample collection device that runs on AC power or batteries. This product was developed to be power efficient, light weight, and portable with the option to configure the product into a man portable backpack. The LIF detector continuously analyzes air samples for airborne pathogens. It statistically correlates particle size and florescence comparing samples to statistically known signatures of dangerous pathogens. If it finds a match, it triggers real-time collection of the airborne particulates into a saline solution. The AiroCollect-Detect is easy to operate and designed in modular fashion, so it can be easily packaged into larger systems. Alternatively, it can be environmentally enclosed and temperature regulated to operate standalone.

TECHNOLOGY:

The WWPC Collector uses inertial aerodynamic separation of bio-aerosols particulates in the human aspiration size range. Particles larger than 10 microns are removed using a pre-separator and inlet. Particles smaller than ½ micron escape the cyclonic force. The walls of the cyclone are wetted to achieve high collection efficiencies and concentration factors. The LIF Detector operates on the principle of Mie scattering, concurrently examining each particle for the presence of the metabolites NADH and riboflavin. The detector simultaneously measures particle size and florescence with a single illumination. It processes the two signals and compares results to known biological signatures.

ANALYTICAL Laboratory Ranking

AIROCOLLECT-DETECT-288 ranked in the middle third of all evaluated products for analytical laboratories and earned 52% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
AIROCOLLECT-DETECT-288	52.12
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

AIROCOLLECT-DETECT-288 ranked in the middle third of all evaluated products for diagnostic laboratories and earned 49% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
AIROCOLLECT-DETECT-288	48.75
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

AIROCOLLECT-DETECT-288 ranked in the middle third of all evaluated products for mobile laboratories and earned 59% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
AIROCOLLECT-DETECT-288	58.62
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

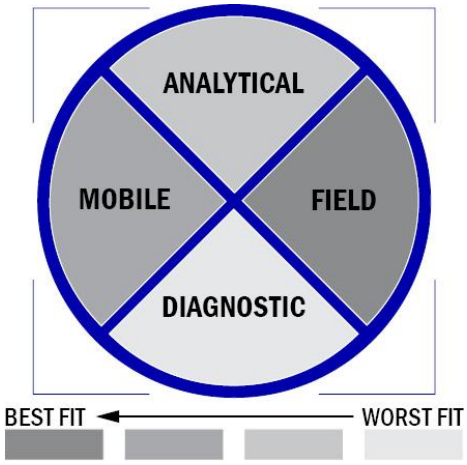
AIROCOLLECT-DETECT-288 ranked in the top third of all evaluated products for field use and earned 70% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
AIROCOLLECT-DETECT-288	70.35
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Airogistic, LLC
211 East 17 Street Suite 111L
Austin, TX 78701 512-743-3271

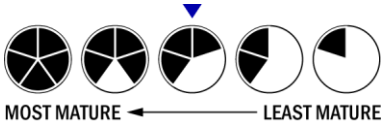
Point of Contact:
Jeff Michalski
michalski@airogistic.com

COST

- $25,000.00 – 50,000.00/system or device

SPECIFICITY

- False Positives: 1 for 1000 hours of operation
- False Negatives: 1 for 1000 detections



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- 5-10 minutes set-up
- 1-3 minutes down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 3 components

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 5-10 years
- <5 minutes daily QA
- Exposure to hazardous agent would require up to 4 hours to decon

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Requires water aliquots
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 100 ul to test liquids

System Maturity:
- Brass board
- Expected to be ready for commercialization within one calendar year
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property pending

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Wireless and wired connections
- Fully autonomous
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- Software open, modification requires licensing
- Hardware open, modification requires licensing

ALPHA SENTRY ONE (ASO)

by BPSI

DETECTS THE FOLLOWING:

Demonstrated:
Toxins
Aerosolized chemical agent (0.000001-0.00003 mg/m3)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swab, Stool, Urine, Wound, Environmental air

DESCRIPTION:

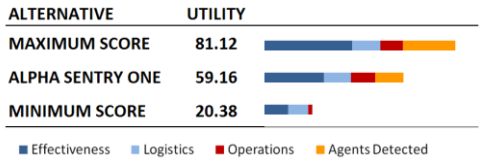
The Alpha Sentry One (ASO) is a U.S. Department of Homeland Security SAFETY Act Designated technology installed to monitor terrorist concerns of smaller venues such as a Commercial Office Building lobbies, perimeter protection and schools. Using the same sensory technology as the larger Building Sentry One, the ASO is limited to (2) or (4) sensors. If a toxin is detected, the ASO enacts a sequence of predetermined alerts and mechanical protocols to isolate toxins thus preventing continued distribution to prevent loss of life, preserve assets, and to provide an early warning system for first responders in the event of a targeted terrorist attack using chemical or radiological materials or an accidental release. The ASO is installed as an all-in-one full backbone system and can integrate directly into an existing Building Management System (BMS) or security command center. The ASO detects a defined spectrum of chemical contaminants and a wide library of radiological isotopes with sensitivity levels customized for each specific toxin. The ASO has been designed in modular fashion for a quick deployment with easy installation. No known similar systems exist. The Alpha Sentry One is a fully functioning "Next Generation" detection system that can integrate sensory technology into just about any market ready project. With embedded controls, logic, software, mechanical protocols and remote monitoring coupled with multiple security means, this system is designed to operate 24/7/365 in the absence of false positive readings.

TECHNOLOGY:

BPSI's Alpha Sentry One (ASO) is a COTS based system that detects a defined spectrum of toxic compounds and a 120+ library of radiological isotopes for smaller applications such as: perimeter protection, schools or building lobbies on a continuous 24/7/365 basis with virtually zero false positive alarms. Through the integration of programmable logic controllers and sensor arrays, linked to a PC infrastructure with multi-layer communications protocols, the Alpha Sentry One solution offers a dynamic set of customized security measures. The ASO's architecture mesh simply and easily with existing systems, in a seamless process that gives the end user superior detection protection.

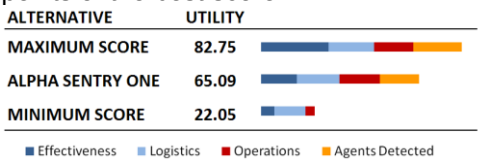
ANALYTICAL Laboratory Ranking

ASO ranked in the top third of all evaluated products for analytical laboratories and earned 73% of the utility points of the best score.



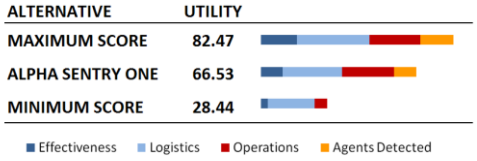
DIAGNOSTIC Laboratory Ranking

ASO ranked in the top third of all evaluated products for diagnostic laboratories and earned 79% of the utility points of the best score.



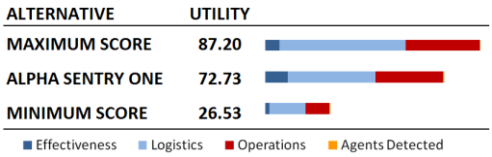
MOBILE Laboratory Ranking

ASO ranked in the top third of all evaluated products for mobile laboratories and earned 81% of the utility points of the best score.



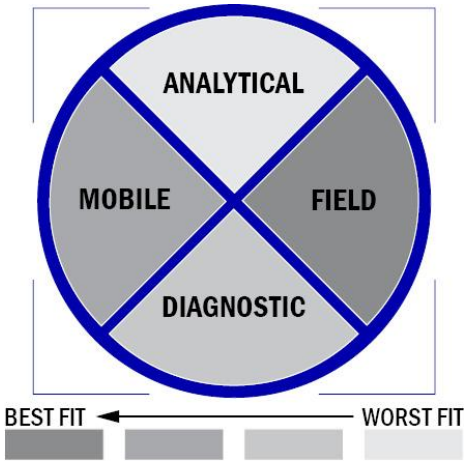
FIELD USE Ranking

ASO ranked in the top third of all evaluated products for field use and earned 83% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

BPSI
150 Post Street, Suite 750
San Francisco, CA 94108

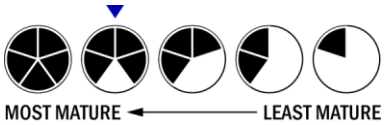
Point of Contact:
Greg Eiler
925-933-8600
geiler@bpsiglobal.com

COST

- $85,000.00 – 135,000.00/system or device depending on number of sensors

SPECIFICITY

- False Positives: .00005
- False Negatives: .000025



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- DVD/ Web video/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life >10 years
- No daily QA required
- Decontamination not applicable

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- Raw data information not available
- Network capable
- Wired connections
- Fully autonomous
- Basic desktop computer
- Stores and archives data outputs and creates an electronic record
- System software is open and available for modification
- System hardware is open and available for modification

Apollo 200 RapidHIT(tm) DNA Profiling system

by IntegenX Inc.

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

The Apollo 200 is a fully integrated sample-to-answer system that can process raw input samples providing automatic sample-to-DNA profile processing for field-forward testing and evaluation of up to eight samples simultaneously. The Apollo 200 project builds upon work at IntegenX that has successfully produced full sample-to-answer processing of buccal swabs, blood, sweat and other samples using push-button operation. The system will be available in a transportable configuration for field forward usage as well as a desktop/office based system for fixed location usage. Typical turnaround time from buccal swab to STR data ready for CODIS database entry requires numerous instruments, hands-on technical expertise, and at least 12 hours. The multistep workflow is laborious and tedious at times, is fragmented, and in the optimum case requires access to a laboratory setting including up to $2 Million of instrumentation and licensed software. Nevertheless, the use of DNA typing for criminal identification and crime scene evaluation have positively impacted the ability of law enforcement, intelligence, and DoD agencies to apprehend and convict criminals, or conduct operations in Theatre.

TECHNOLOGY:

IntegenX possesses strong capabilities, core technologies, and Intellectual Property (IP) in sample capture and purification; micro-valves, -pumps, and –routers; micro/nanofluidic control; nano-scale biochemistry; and micro-separations and software control systems. A core capability is the development and fabrication of low-cost, microfluidic devices for the life sciences using microvalves. The company's technology and patent family encompasses capillary and microchip implementations for sample preparation and analysis, including 11+ patent families covering capillary array electrophoresis for genotyping. Two key technologies continue to enable rapid progress: novel low-cost, manufacturable micro-valves, -pumps, and -routers; and the adaptation of bead-based processing to microfluidics.

ANALYTICAL Laboratory Ranking

Apollo 200 system ranked in the bottom third of all evaluated products for analytical laboratories and earned 44% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
Apollo 200	35.91
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

Apollo 200 system ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 44% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
Apollo 200	36.63
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

Apollo 200 system ranked in the bottom third of all evaluated products for mobile laboratories and earned 50% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
Apollo 200	41.41
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

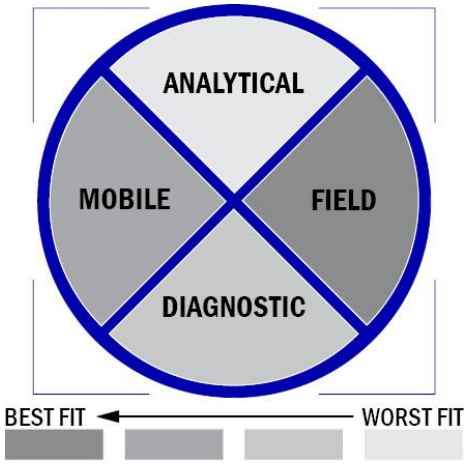
Apollo 200 system ranked in the bottom third of all evaluated products for field use and earned 60% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
Apollo 200	52.13
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

IntegenX Inc.
5720 Stoneridge Drive, suite 300
Pleasanton, CA 94588

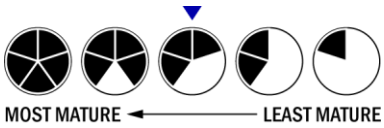
Point of Contact:
Howard Goldstein
email: howardg@integenx.com
phone: 925-701-3481

COST

- $245,000.00/system or device
- $500.00/analysis

SPECIFICITY

- False Positives: Not Applicable
- False Negatives: Not Applicable



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- >20 minutes set up
- <1 minute down time
- 0-2 steps are required
- Manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored frozen but can with stand temps in excess of 4°C for periods of less than 24 hours
- Device must be used in a temperature stable, dry environment for optimum performance
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means of transportation
- Weighs between 25 and 50 kg

Re-use:
- Single detection assay
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 3-5 years
- < 5 minutes QA required
- The device is single use and disposable so no decontamination is needed

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Less than 50 ul for a test

System Maturity:
- Brass board
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Not capable of autonomy
- Laptop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

AreaRAE GAMMA Steel

by RAE Systems Inc.

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

The AreaRAE Gamma is a combination multi-gas and radiation detector equipped with a wireless, RF (radio-frequency) modem that allows the unit to communicate and transmit sensor and other information on a real-time basis with a remotely located base controller. In the stand alone operation, the AreaRAE Gamma is a rugged, weather-resistant, one-to-five sensor portable monitor that can run up to 18 hours on either rechargeable Lithium-ion or optional alkaline batteries. It is also the first "lunchbox"- type multi-sensor instrument able to include a gamma sensor for measurement of gamma radiation, a photoionization detector (PID) for parts-per-million measurement of volatile organic compounds (VOCs), as well as an LEL combustible gas sensor, oxygen sensor, and a selectable electrochemical toxic sensor. Key Features • Up to four gas sensors (PID, LEL, O2 and selectable toxic gas) • One radiation sensor (Gamma) • Loud buzzer and large, extra-bright warning light • Large LCD display and keypad • Rugged, weather-resistant housing • Built-in sampling pump • Interchangeable Lithium-ion or alkaline battery pack • Continuous operation via AC source Additional Advantages • Real-time wireless data transmission with built-in RF modem • View real-time sensor data and alarm status at headquarters or command center • Optional GPS provides ability to track and display readings from remote detectors • License-free, ISM-band RF transmission with communication range up to 2 miles.

TECHNOLOGY:

In addition to the Scintillation Crystal Detector, the AreaRAE GAMMA has a photoionization detector (PID) which uses an ultraviolet lamp and sensor to detect volatile organic compounds (VOCs) and halocarbons.

ANALYTICAL Laboratory Ranking

AreaRAE GAMMA Steel ranked in the middle third of all evaluated products for analytical laboratories and earned 57% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
AreaRAE GAMMA Steel	45.98
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

AreaRAE GAMMA Steel ranked in the middle third of all evaluated products for diagnostic laboratories and earned 55% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
AreaRAE GAMMA Steel	45.82
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

AreaRAE GAMMA Steel ranked in the top third of all evaluated products for mobile laboratories and earned 68% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
AreaRAE GAMMA Steel	55.99
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

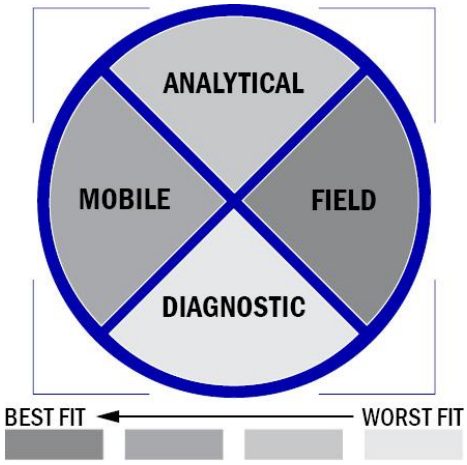
AreaRAE GAMMA Steel ranked in the middle third of all evaluated products for field use and earned 79% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
AreaRAE GAMMA Steel	69.11
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

RAE Systems Inc.
3775 N. First Street
San Jose, CA 95134

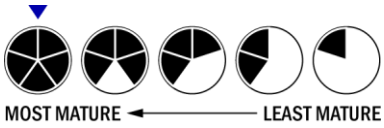
Point of Contact:
Jim Kane
757-746-5554
jkane@raesystems.com

COST

- $9,594.00/system or device

SPECIFICITY

- False Positives: Less than 5%
- False Negatives: Less than 5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, single tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 5-10 minutes set-up required
- <1 minute down time
- 0-2 steps required
- DVD/ Customer and manufacturer site training

Operational conditions:
- Can be used from -21°C to 41°C
- Components must be stored at 4°C
- Peak performance at normal relative humidity conditions
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service more often than every 6 months
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 5-10 years
- <5 minutes daily QA
- Likely that exposure to hazardous agent cannot be decontaminated

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- > 250 GB raw data generated
- Network capable
- Satellite, wireless and wired connections
- Fully autonomous
- Desktop or laptop computer
- Stores and archives data outputs and creates an electronic record
- System software open but modification requires licensing
- System hardware open but modification requires licensing

ARETE TRAP (Threat Reduction Advancement Processor)

by Arete

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

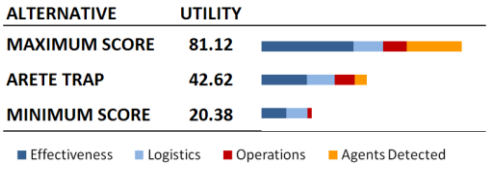
Based on Arete's 30+ year history of delivering advanced algorithm and electro-optical solutions, TRAP provides a highly configurable, bio-detection solution for a variety of environmental monitoring scenarios. The TRAP detector provides 24/7 real-time triggering & classification monitoring, and is well suited for both indoor and outdoor operation. TRAP may be used as a stand-alone detector or embedded into a variety of systems including unmanned platforms. The TRAP is man portable and may be configured with an integrated air sample collector for post analysis and identification. With its advanced networking capabilities, the TRAP bio-detector is ideally suited for wide area surveillance and integration into large sensor networks. User defined settings allow control of key parameters such as time to detect, based on mission requirements and operating conditions. TRAP uniquely adapts to changing background environment to provide high sensitivity processing while maintaining optimized FAR levels regardless of operating conditions.

TECHNOLOGY:

TRAP is a multi-channel ,LIF based optical detector consisting of an integrated LED source and flow module. Patented flow processing technology provides operation in the harshest of environments while maintaining high sensitivity and response. Built upon Arete's broad expertise in advanced signal processing and algorithm development, the TRAP system employs Arete's unique TRIAD algorithm tool set. TRIAD provides real-time, multi-level trigger and classification outputs to the end-user, while adaptively correcting for changing background conditions. When coupled with Arete's TRAN predictive networking capabilities, a distributed collection of TRAP sensors optimize spatial and temporal data to provide further bio-detection optimization.

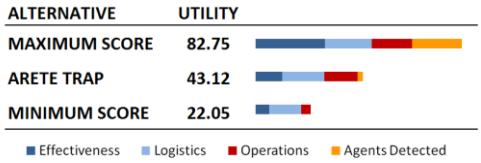
ANALYTICAL Laboratory Ranking

ARETE TRAP ranked in the middle third of all evaluated products for analytical laboratories and earned 53% of the utility points of the best score.



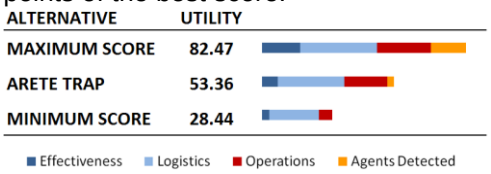
DIAGNOSTIC Laboratory Ranking

ARETE TRAP ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 52% of the utility points of the best score.



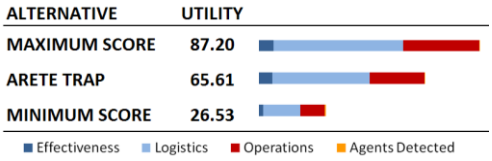
MOBILE Laboratory Ranking

ARETE TRAP ranked in the middle third of all evaluated products for mobile laboratories and earned 65% of the utility points of the best score.



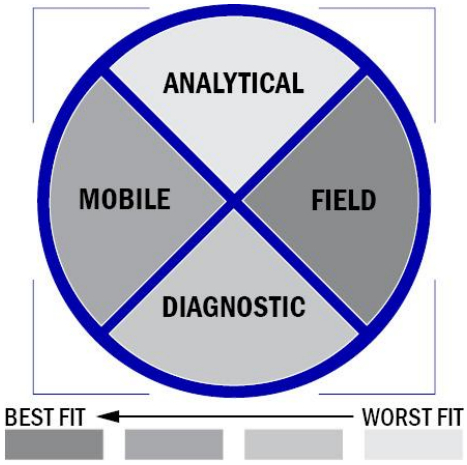
FIELD USE Ranking

ARETE TRAP ranked in the middle third of all evaluated products for field use and earned 75% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Arete
9301 Corbin Avenue
Northridge, CA 91324

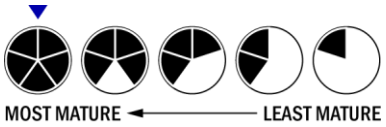
Point of Contact:
Scott D. McGill
smcgill@arete.com
(512) 565-8508

COST

- $12,000.00 - $25,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less
- 1 sample, single test/sample per run
- Fully automated

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Does not require consumables
- Performance not influenced by relative humidity
- Shelf life not applicable

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Continuous operating device
- 0-1 solutions, buffer, and/or reagents
- No additional consumables

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life information not available
- No daily QA required
- Decon not applicable

Physical System Requirements:
- 18+ hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Processing data while in progress information not available
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- Raw data size dependent on length of monitoring run
- Network capable
- Wireless and wired connections
- Fully autonomous
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software is open but modification requires licensing
- System hardware is open but modification requires licensing

ASAP II

by Research International, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e4-10e5 CFU/mL)
Viruses (> 10e5 PFU/mL)
Toxins (<1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Environmental air, Environmental water, Food

DESCRIPTION:

The ASAP II collection/detection system continuously monitors for the presence of aerosol biohazards, identifying threat agents ranging from protein toxins to whole cells and spores as frequently as every 20 to 30 minutes. It is an integration of Research International's proven SASS 2300 air sampler technology and RAPTOR four-channel bioassay system. ASAP II may be provided with a small fixed-installation environmental enclosure (the ASAP IIa, as seen on this page) that maximizes reagent life and unattended monitoring time, or in component form for minimum weight and volume (ASAP IIb). Both may operated minimally trained personnel. In operation, the SASS 2300 samples air continuously and transfers particulates into a secondary water phase of about 4 to 5 ml volume. Water samples of 4 to 5 mL are periodically transferred from the SASS 2300 to the RAPTOR. One mL is used for analysis and the remainder is saved as a confirmatory sample. The RAPTOR then automatically performs a multi-step bioassay for up to four agents on the liquid sample using a disposable assay coupon. Each of these 4-channel assay coupons may be reused up to 30 times over a 48-hour unattended operating period before replacement of the coupon and related reagents is necessary providing extremely competitive per-assay costs. The fixed-installation system includes 5-day fluid reservoirs, yet weighs only 80 pounds and consumes an average power of 30 watts. A remote PC allows operating personnel to monitor the system, while an optional green/amber safety light immediately communicates system status to nearby workers.

TECHNOLOGY:

The ASAP II uses a wetted-wall cyclone to concentrate particulates from the air into a water sample. Patented technology measures the volume of water in the cyclone and continuously replenishes evaporative losses, allowing unlimited collection periods. Fully automated analyses are based on 'sandwich format' fluoroimmunoassays taking place on the surface of injection molded polystyrene waveguides. The waveguide has a monolayer of capture antibody immobilized on its surface. It is incubated with sample, washed, then incubated with fluorophore-labeled antibody to form an antibody/antigen/labeled-antibody sandwich. Excitation light is injected into and fluorescence emission is collected from the waveguide.

ANALYTICAL Laboratory Ranking

ASAP II ranked in the middle third of all evaluated products for analytical laboratories and earned 63% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
ASAP II	51.33
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

ASAP II ranked in the middle third of all evaluated products for diagnostic laboratories and earned 59% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
ASAP II	49.17
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

ASAP II ranked in the bottom third of all evaluated products for mobile laboratories and earned 61% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
ASAP II	50.32
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

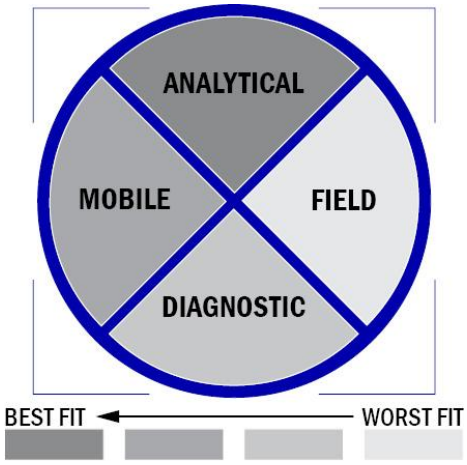
ASAP II ranked in the bottom third of all evaluated products for field use and earned 56% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
ASAP II	48.40
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Research International, Inc.
17161 Beaton Road SE
Monroe, WA 98272
360-805-4930

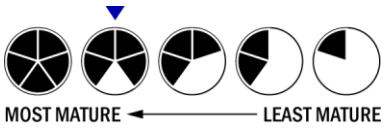
Point of Contact:
Jonathon Tobelmann
703-625-8381

COST

- $83,000.00/system or device
- $8.00-210.00/analysis

SPECIFICITY

- False Positives: ~1%
- False Negatives: ~1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15-30 minutes for detection
- 1 sample, <10 tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- 10-20 minutes set up
- Almost instantaneous down time
- 0-2 steps are required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components must be stored at 4°C
- Performance is not influenced by relative humidity
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of a home dishwasher
- Commercial carrier
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician
- Maintenance is not included
- Expected life 5-10 years
- No QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Requires water aliquots
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results not available
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance N/A
- FDA approval N/A
- Greater than 250 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Autonomous system
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

BADD Anth-Kit-10 Single Agent Threat Detection Test

by ADVNT Biotechnologies

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e4-10e5 CFU/mL)

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

A Single - threat detection device for anthrax designed for environmental use to test surface and liquid.

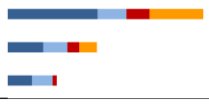
TECHNOLOGY:

A single-agent detection system that employs hand held immunochromatographic assay that uses colloidal gold antibodies for rapid detection.

ANALYTICAL Laboratory Ranking

BADD Anth-Kit-10 ranked in the bottom third of all evaluated products for analytical laboratories and earned 37% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
BADD Anth-Kit-10	37.06
MINIMUM SCORE	20.38

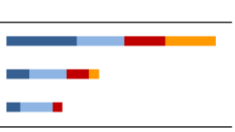


Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

BADD Anth-Kit-10 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 37% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
BADD Anth-Kit-10	36.53
MINIMUM SCORE	22.05

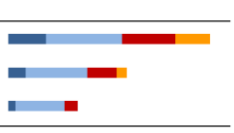


Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

BADD Anth-Kit-10 ranked in the bottom third of all evaluated products for mobile laboratories and earned 52% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
BADD Anth-Kit-10	48.46
MINIMUM SCORE	28.44

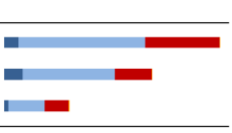


Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

BADD Anth-Kit-10 ranked in the middle third of all evaluated products for field use and earned 65% of the utility points of the best score.

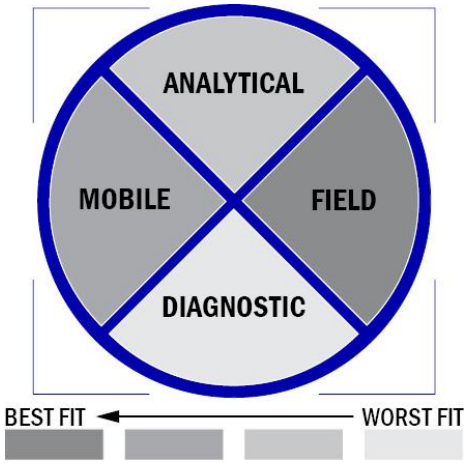
ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
BADD Anth-Kit-10	60.05
MINIMUM SCORE	26.53



Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ADVNT Biotechnologies
22510 N. 18th Dr.
Phoenix, AZ. 85027

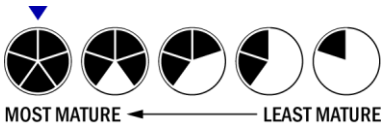
Point of Contact:
Kevin Borah
(888) 223 - 3269

COST

- $24.50/test

SPECIFICITY

- False Positives: Less than 1%
- False Negatives: Less than 1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, single test/sample per run
- Not amenable to full or semi-automation

Signature:
- Sounds or alarms not present
- No screen
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 6-8 steps required
- CD or DVD training

Operational conditions:
- Can be used from 25°C - 37°C
- Components should be stored at room temp but can stand temps >45°C for < 24 hours/ Must be stored at room temp (27°C);/ Must be stored at 4°C
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a soda can
- Transport via commercial carrier
- Weighs less than 1 kg

Re-use:
- Single use
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service not required
- Preventive maintenance not applicable
- Warranty does not apply
- Expected life does not apply
- No daily QA required
- No decon required

Physical System Requirements:
- No electrical equipment
- Does not use batteries
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering step
- System does not call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 250 ul required for test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property licensing not possible

Interoperability and System Complexity:
- Raw data size not applicable
- Network capability not applicable
- Not Autonomous
- No computer required
- Does not store or archive data outputs or create electronic records
- System does not employ software
- System is single use

BADD Bot-Kit-10 Single Agent Threat Detection Test

by ADVNT Biotechnologies

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e4-10e5 CFU/mL)

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

A Single - threat detection device for Botulinum designed for environmental use to test surface and liquid.

TECHNOLOGY:

A single-agent detection system that employs hand held immunochromatographic assay that uses colloidal gold antibodies for rapid detection of botulinum toxin.

ANALYTICAL Laboratory Ranking

BADD Bot-Kit-10 ranked in the bottom third of all evaluated products for analytical laboratories and earned 46% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
BADD Bot-Kit-10	37.06
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

BADD Bot-Kit-10 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 44% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
BADD Bot-Kit-10	36.53
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

BADD Bot-Kit-10 ranked in the bottom third of all evaluated products for mobile laboratories and earned 59% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
BADD Bot-Kit-10	48.46
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

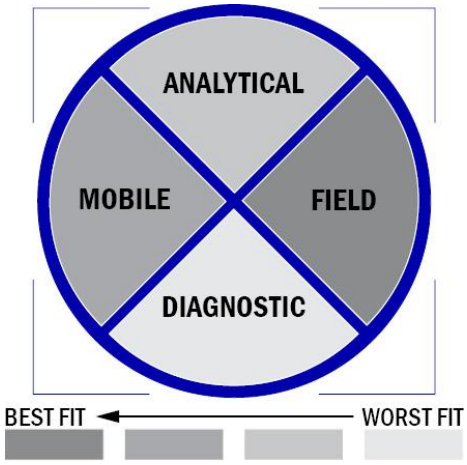
BADD Bot-Kit-10 ranked in the middle third of all evaluated products for field use and earned 69% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
BADD Bot-Kit-10	60.05
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ADVNT Biotechnologies
22510 N. 18th Dr.
Phoenix, AZ. 85027

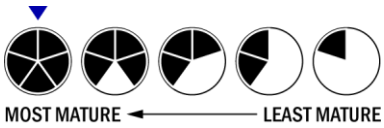
Point of Contact:
YP@advnt.org

COST

- $24.50/test

SPECIFICITY

- False Positives: Less than 1%
- False Negatives: Less than 1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, single test/sample per run
- Not amenable to full or semi-automation

Signature:
- Sounds or alarms not present
- No screen
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 6-8 steps required
- CD or DVD training

Operational conditions:
- Can be used from 25°C - 37°C
- Components should be stored at room temp but can stand temps >45°C for < 24 hours/ Must be stored at room temp (27°C)/ Must be stored at 4°C
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a soda can
- Transport via commercial carrier
- Weighs less than 1 kg

Re-use:
- Single use
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service not required
- Preventive maintenance not applicable
- Warranty does not apply
- Expected life does not apply
- No daily QA required
- No decon required

Physical System Requirements:
- No electrical equipment
- Does not use batteries
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering step
- System does not call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 250 ul required for test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property licensing not possible

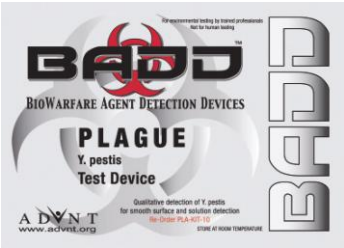
Interoperability and System Complexity:
- Raw data size not applicable
- Network capability not applicable
- Not autonomous
- No computer required
- Does not store or archive data outputs or create electronic records
- System does not employ software
- System is single use

BADD Pla-Kit-10 Single Agent Threat Detection Test

by ADVNT Biotechnologies

DETECTS THE FOLLOWING:
Nothing demonstrated.

DETECTION MATRICES:
Nothing demonstrated.



DESCRIPTION:
A Single - threat detection device for Plague (Y. Pestis) designed for environmental use to test surface and liquid.

TECHNOLOGY:
A single-agent detection system that employs hand held immunochromatographic assay that uses colloidal gold antibodies for rapid detection of Y.Pestis.

ANALYTICAL Laboratory Ranking
BADD Pla-Kit-10 ranked in the bottom third of all evaluated products for analytical laboratories and earned 37% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
BADD Pla-Kit-10	29.85
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking
BADD Pla-Kit-10 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 37% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
BADD Pla-Kit-10	30.37
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking
BADD Pla-Kit-10 ranked in the bottom third of all evaluated products for mobile laboratories and earned 52% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
BADD Pla-Kit-10	42.82
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

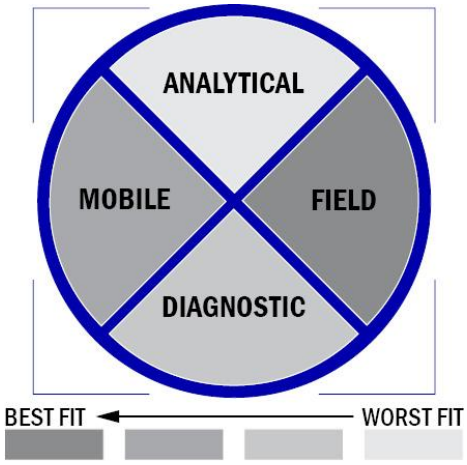
FIELD USE Ranking
BADD Pla-Kit-10 ranked in the middle third of all evaluated products for field use and earned 65% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
BADD Pla-Kit-10	56.52
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ADVNT Biotechnologies
22510 N. 18th Dr.
Phoenix, AZ. 85027

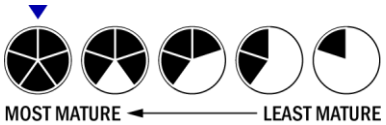
Point of Contact:
Kevin Borah
(888) 223 - 3269

COST

- $24.50/test

SPECIFICITY

- False Positives: Less than 1%
- False Negatives: Less than 1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, single test/sample per run
- Not amenable to full or semi-automation

Signature:
- Sounds or alarms not present
- No screen
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 6-8 steps required
- CD or DVD training

Operational conditions:
- Can be used from 25°C - 37°C
- Components should be stored at room temp but can stand temps >45°C for < 24 hours/ Must be stored at room temp (27°C)/ Must be stored at 4°C
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a soda can
- Transport via commercial carrier, rotary wing aircraft
- Weighs less than 1 kg

Re-use:
- Single use
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service not required
- Preventive maintenance not applicable
- Warranty does not apply
- Expected life does not apply
- No daily QA required
- No decon required

Physical System Requirements:
- No electrical equipment
- Does not use batteries
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering step
- System does not call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 250 ul required for test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property licensing not possible

Interoperability and System Complexity:
- Raw data size not applicable
- Network capability not applicable
- Not Autonomous
- No computer required
- Does not store or archive data outputs or create electronic records
- System does not employ software
- System is single use

BADD Ric-Kit-10 Single Agent Threat Detection Test

by ADVNT Biotechnologies

DETECTS THE FOLLOWING:
Nothing demonstrated.

DETECTION MATRICES:
Nothing demonstrated.

DESCRIPTION:
A Single - threat detection device for Ricin designed for environmental use to test surface and liquid.

TECHNOLOGY:
A single-agent detection system that employs hand held immunochromatographic assay that uses colloidal gold antibodies for rapid detection of Ricin toixin.

ANALYTICAL Laboratory Ranking

BADD Ric-Kit-10 ranked in the bottom third of all evaluated products for analytical laboratories and earned 38% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
BADD Ric-Kit-10	30.85
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

BADD Ric -Kit-10 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 37% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
BADD Ric-Kit-10	30.82
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

BADD Ric -Kit-10 ranked in the bottom third of all evaluated products for mobile laboratories and earned 49% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
BADD Ric-Kit-10	40.27
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

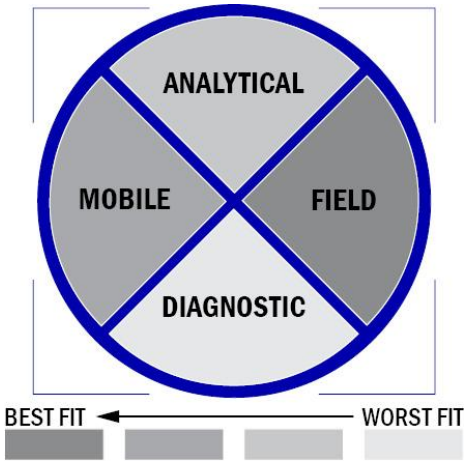
FIELD USE Ranking

BADD Ric -Kit-10 ranked in the bottom third of all evaluated products for field use and earned 58% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
BADD Ric-Kit-10	50.63
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

Summary of Analysis



CONTACT INFORMATION

ADVNT Biotechnologies
22510 N. 18th Dr.
Phoenix, AZ. 85027

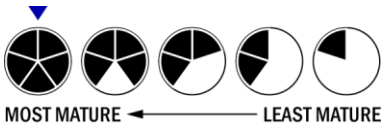
Point of Contact:
Kevin Borah
(888) 223 - 3269

COST

- $24.50/test

SPECIFICITY

- False Positives: Less than 1%
- False Negatives: Less than 1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, single test/sample per run
- Not amenable to full or semi-automation

Signature:
- Sounds or alarms not present
- No screen
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 6-8 steps required
- CD or DVD training

Operational conditions:
- Can be used from 25°C - 37°C
- Components should be stored at room temp but can stand temps >45°C for < 24 hours/ Must be stored at room temp (27°C)/ Must be stored at 4°C
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a soda can
- Transport via commercial carrier
- Weighs less than 1 kg

Re-use:
- Single use
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service not required
- Preventive maintenance not applicable
- Warranty does not apply
- Expected life does not apply
- No daily QA required
- No decon required

Physical System Requirements:
- No electrical equipment
- Does not use batteries
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering step
- System does not call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 250 ul required for test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property licensing not possible

Interoperability and System Complexity:
- Raw data size not applicable
- Network capability not applicable
- Not autonomous
- No computer required
- Does not store or archive data outputs or create electronic records
- System does not employ software
- System is single use

BADD SEB-Kit-10 Single Agent Threat Detection Test

by ADVNT Biotechnologies

DETECTS THE FOLLOWING:
Nothing demonstrated.

DETECTION MATRICES:
Nothing demonstrated.

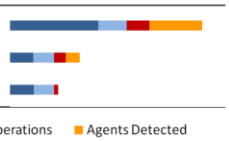
DESCRIPTION:
A Single - threat detection device for S.E.B designed for environmental use to test surface and liquid.

TECHNOLOGY:
A single-agent detection system that employs hand held immunochromatographic assay that uses colloidal gold antibodies for rapid detection for S.E.B. toxin.

ANALYTICAL Laboratory Ranking

BADD SEB-Kit-10 Test ranked in the bottom third of all evaluated products for analytical laboratories and earned 36% of the utility points of the best score.

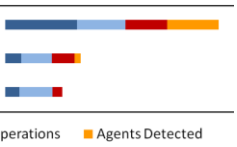
ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
BADD SEB-Kit-10	29.51
MINIMUM SCORE	20.38



DIAGNOSTIC Laboratory Ranking

BADD SEB-Kit-10 Test ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 35% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
BADD SEB-Kit-10	29.37
MINIMUM SCORE	22.05



MOBILE Laboratory Ranking

BADD SEB-Kit-10 Test ranked in the bottom third of all evaluated products for mobile laboratories and earned 50% of the utility points of the best score.

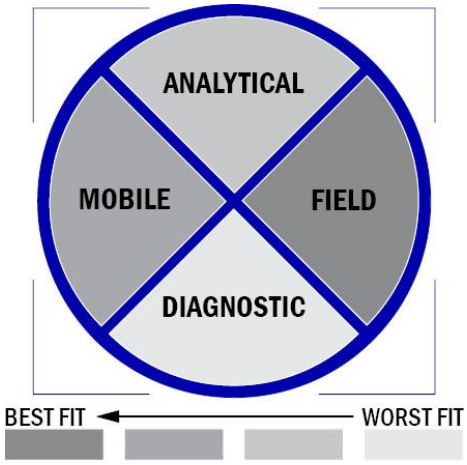
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
BADD SEB-Kit-10	41.49
MINIMUM SCORE	28.44

FIELD USE Ranking

BADD SEB-Kit-10 Detection Test ranked in the bottom third of all evaluated products for field use and earned 63% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
BADD SEB-Kit-10	54.52
MINIMUM SCORE	26.53

Summary of Analysis



CONTACT INFORMATION

ADVNT Biotechnologies
22510 N. 18th Dr.
Phoenix, AZ. 85027

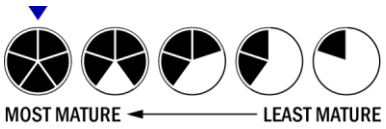
Point of Contact:
Kevin Borah
(888) 223 - 3269

COST

- $24.50/test

SPECIFICITY

- False Positives: Less than 1%
- False Negatives: Less than 1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 -15 minutes for detection
- 1 sample, single test/sample per run
- Not amenable to full or semi-automation

Signature:
- Sounds or alarms not present
- No screen
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 6-8 steps required
- CD or DVD training

Operational conditions:
- Can be used from 25°C - 37°C
- Components should be stored at room temp but can stand temps >45°C for < 24 hours/ Must be stored at room temp (27°C)/ Must be stored at 4°C
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a soda can
- Transport via commercial carrier
- Weighs less than 1 kg

Re-use:
- Single use
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service not required
- Preventive maintenance not applicable
- Warranty does not apply
- Expected life does not apply
- No daily QA required
- No decon required

Physical System Requirements:
- No electrical equipment
- Does not use batteries
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering step
- System does not call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 250 ul required for test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property licensing not possible

Interoperability and System Complexity:
- Raw data size not applicable
- Network capability not applicable
- Not autonomous
- No computer required
- Does not store or archive data outputs or create electronic records
- System does not employ software
- System is single use

BADD Tul-Kit-10 Single Agent Threat Detection Test

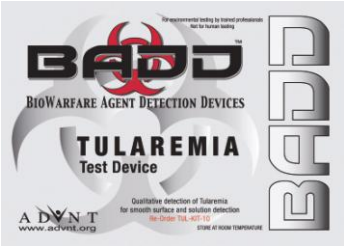
by ADVNT Biotechnologies

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10,000-100,000 CFU/ml of original sample)

DETECTION MATRICES:

Demonstrated:



DESCRIPTION:

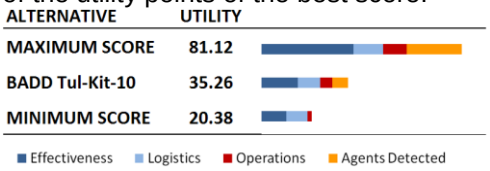
A Single - threat detection device for anthrax designed for environmental use to test surface and liquid.

TECHNOLOGY:

A single-agent detection system that employs hand held immunochromatographic assay that uses colloidal gold antibodies for rapid detection.

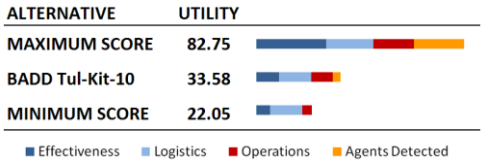
ANALYTICAL Laboratory Ranking

BADD Tul-Kit-10 ranked in the bottom third of all evaluated products for analytical laboratories and earned 43% of the utility points of the best score.



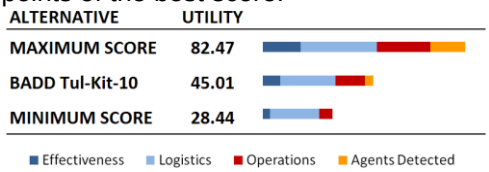
DIAGNOSTIC Laboratory Ranking

BADD Tul -Kit-10 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 41% of the utility points of the best score.



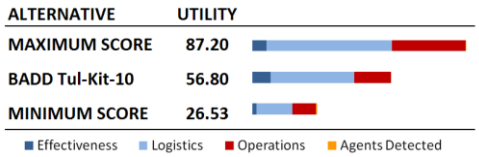
MOBILE Laboratory Ranking

BADD Tul -Kit-10 ranked in the bottom third of all evaluated products for mobile laboratories and earned 55% of the utility points of the best score.



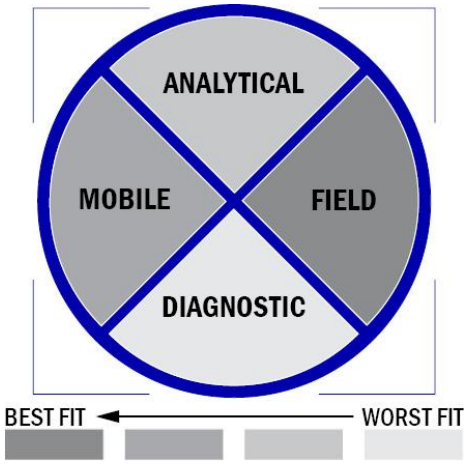
FIELD USE Ranking

BADD Tul -Kit-10 ranked in the middle third of all evaluated products for field use and earned 65% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ADVNT Biotechnologies
22510 N. 18th Dr.
Phoenix, AZ. 85027

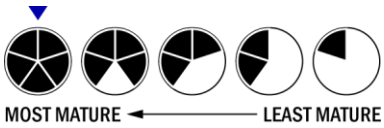
Point of Contact:
YP@advnt.org

COST

- $24.50/test

SPECIFICITY

- False Positives: Less than 1%
- False Negatives: Less than 1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, single test/sample per run
- Not amenable to full or semi-automation

Signature:
- Sounds or alarms not present
- No screen
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 6-8 steps required
- CD or DVD training

Operational conditions:
- Can be used from 25°C - 37°C
- Components should be stored at room temp but can stand temps >45°C for < 24 hours/ Must be stored at room temp (27°C)/ Must be stored at 4°C
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a soda can
- Transport via commercial carrier
- Weighs less than 1 kg

Re-use:
- Single use
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service not required
- Preventive maintenance not applicable
- Warranty does not apply
- Expected life does not apply
- No daily QA required
- No decon required

Physical System Requirements:
- No electrical equipment
- Does not use batteries
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering step
- System does not call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 250 ul required for test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property licensing not possible

Interoperability and System Complexity:
- Raw data size not applicable
- Network capability not applicable
- Not Autonomous
- No computer required
- Does not store or archive data outputs or create electronic records
- System does not employ software
- System is single use

BD MAX Molecular Diagnostics Platform

by Becton Dickinson Diagnostic Systems

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Nasal and Throat swabs, Stool, Urine,

DESCRIPTION:

BD MAX: Molecular Diagnostics Platform Instrument to be used to detect infectious diseases via DNA extraction/amplification from a variety of specimen types. Provides "sample in, result out" capability or wide variety of samples and diseases.

TECHNOLOGY:

System is based upon nucleic acid extracton via proprietary magnetic technology with Taqman-based PCR DNA amplification and detection. All reagents are provided dried and room temperature.

ANALYTICAL Laboratory Ranking

BD MAX ranked in the middle third of all evaluated products for analytical laboratories and earned 63% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
BD MAX	50.97
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

BD MAX ranked in the top third of all evaluated products for diagnostic laboratories and earned 73% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
BD MAX	60.71
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

BD MAX ranked in the middle third of all evaluated products for mobile laboratories and earned 63% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
BD MAX	51.73
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

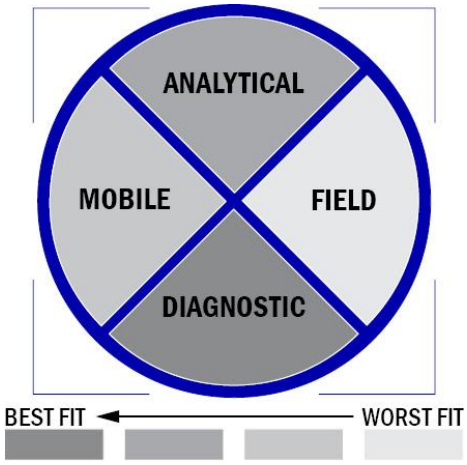
BD MAX ranked in the bottom third of all evaluated products for field use and earned 57% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
BD MAX	49.76
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

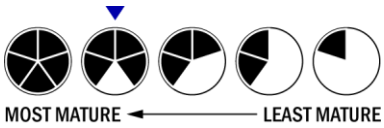
Becton Dickinson Diagnostic Systems
7 Loveton Circle
Sparks, MD 21152 USA
Attn: Business Development MC# 650

COST

- $95,000.00/system or device
- $25.00/analysis

SPECIFICITY

- False Positives: Not Available
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, single tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Thermal output unknown

Training and Speed:
- A day of training and technical skills are required
- < 5 minutes set up
- Almost no down time
- 3-5 steps are required
- Customer site training/ Hard-copy manual

Operational conditions:
- Can be used from 18°C to 30°C
- Components should be stored at room temp but can withstand temps > 45°C for periods of less than 24 hours
- Performance is not influenced by relative humidity
- 6 months to 1 year shelf life

Transportation:
- Larger than a home dishwasher
- Commercial carrier/ Fixed wing aircraft
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by technician
- Maintenance is included
- Expected life 5-10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1 hr

Physical System Requirements:
- 220V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can not be processed while in progress
- No centrifugation steps required
- A single shaking or vortexing, mixing, degassing or filtering step required
- Software will call final result

Sensitivity and Detection:
- 510K clearance shown
- FDA approval shown

System Maturity:
- Is commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Not capable of autonomy
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

BEADS (Biodetection Enabling Analyte Delivery System)

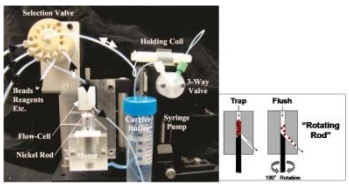
by Battelle - Pacific Northwest National Laboratory

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)
Toxins

DETECTION MATRICES:

Demonstrated:
Soil, Food, Powder



DESCRIPTION:

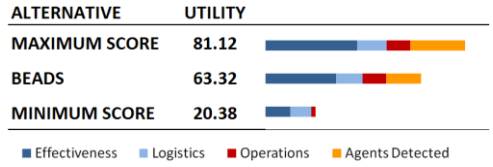
BEADS is a universal fluidics platform that enables automated processing of surface functionalized magnetic and non-magnetic beads. BEADS enables faster more sensitive assays for a wide range of biothreat targets including DNA/RNA, bacteria, viruses, spores, oocytes, proteins, etc. BEADS enables a high degree of sample purification and concentration and is applicable for a broad range of matrices. BEADS serves as a front-end to a variety of detectors (e.g., PCR, Flow Cytometry, Electrochemical detectors, Fluorescence or Absorbance Detectors, etc.)or can be integrated with robotic systems . BEADS can serve as a sample purification and concentration front-end, or detectors can be integrated within BEADS.

TECHNOLOGY:

The key enabling technology is a bead trap/flow-cell. The flow cell isolates surface functionalized magnetic or non-magnetic beads in a mini-column, which allows sample, reagents, and wash solutions to be passed over the bead column, resulting in significantly improved mass transport and faster, more sensitive assays. The microbeads can be functionalized with a wide range of target analyte capture ligands including oligonucleotides, antibodies and lectins. Semi-selective beads (e.g., silica, hydroxyapatite) can also be used to capture a wide range of pathogens or nucleic acids utilizing electrostatic capture.

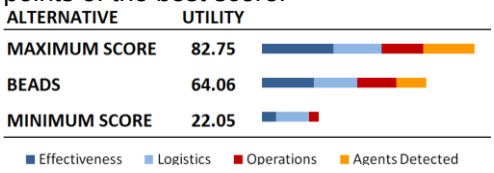
ANALYTICAL Laboratory Ranking

BEADS ranked in the top third of all evaluated products for analytical laboratories and earned 78% of the utility points of the best score.



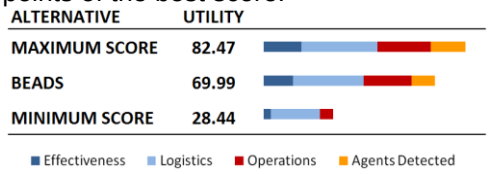
DIAGNOSTIC Laboratory Ranking

BEADS ranked in the top third of all evaluated products for diagnostic laboratories and earned 77% of the utility points of the best score.



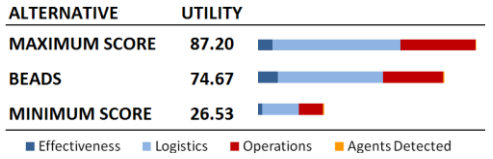
MOBILE Laboratory Ranking

BEADS ranked in the top third of all evaluated products for mobile laboratories and earned 85% of the utility points of the best score.



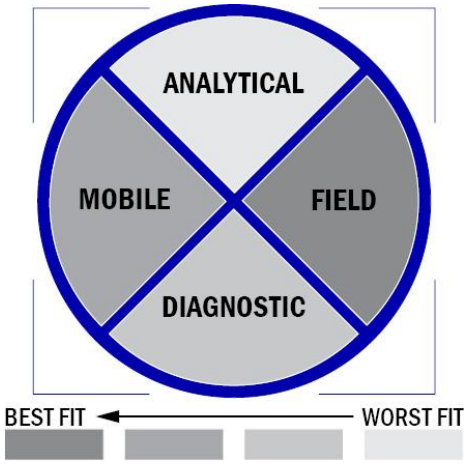
FIELD USE Ranking

BEADS ranked in the top third of all evaluated products for field use and earned 86% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Battelle - Pacific Northwest National Laboratory
P.O. Box 999
Battelle Blvd.
Mail Stop P7-50
Richland, WA 99354

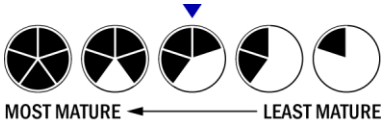
Point of Contact:
Dr. Richard M. Ozanich
richard.ozanich@pnl.gov

COST

- Projected to be $1,000.00 - $4,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, >10 tests/ sample per run
- Could be adapted to fully automated with some effort

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- 1-3 minutes down time
- 0-2 steps required
- Customer site training

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours/ Must be stored at 4°C
- Performance is not influenced by relative humidity
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of carry-on luggage
- All modes of transport
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 3 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life 3-5 years
- 10-20 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- 4-8 hours battery life
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System could call final result in the future

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 10 ul to test liquids

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Satellite, wireless and wired connections
- Fully autonomous
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software open and available for modification
- System hardware open and available for modification

BeadXpress Reader

by Illumina Inc.

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

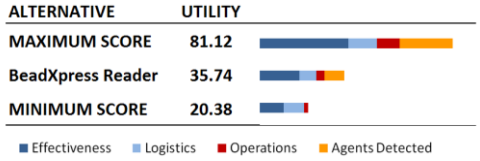
The BeadXpress Reader is the optimal solution for both small and high-throughput laboratories conducting molecular testing that benefit from robust, multiplexed-based assays. It employs a dual-color laser detection system that identifies the unique holographic codes embedded in VeraCode microbeads, and detects the signal intensity associated with each bead. This system supports the development of both single- and two-color assays, across genotyping, methylation, and protein-based assays. The BeadXpress System comes with VeraScan software, which provides a user-friendly graphical interface to control the BeadXpress Reader, enabling users to load assays, perform real-time scans, and view scan data for up to 96 samples per run. The software features administrator control of setting user specific accounts and rights, configuration of default file locations, and security options, including alerts via email. It also offers customization of scanning protocols, enables acquisition and viewing of intensity data, and report generation.

TECHNOLOGY:

VeraCode glass microbeads provide an ideal surface for numerous bioassays including genotyping, gene expression, and protein-based assays. Illumina's proprietary technology precisely embeds digital holographic elements within glass microbeads to create unique bead types. Each microbead can easily carry high-density codes (24-bit), for virtually unlimited development of bead types. When excited by a laser, each VeraCode bead emits a unique code image, allowing for quick and specific detection by Illumina's BeadXpress Reader System.

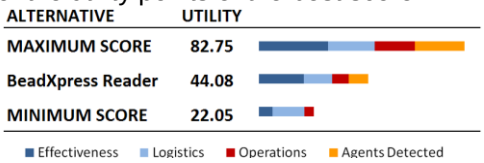
ANALYTICAL Laboratory Ranking

BeadXpress Reader ranked in the bottom third of all evaluated products for analytical laboratories and earned 44% of the utility points of the best score.



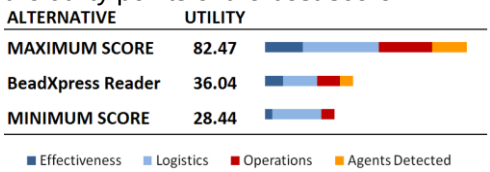
DIAGNOSTIC Laboratory Ranking

BeadXpress Reader ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 53% of the utility points of the best score.



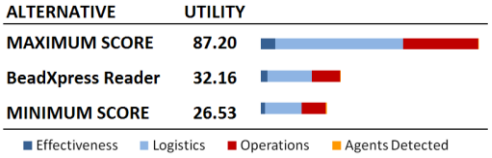
MOBILE Laboratory Ranking

BeadXpress Reader ranked in the bottom third of all evaluated products for mobile laboratories and earned 44% of the utility points of the best score.



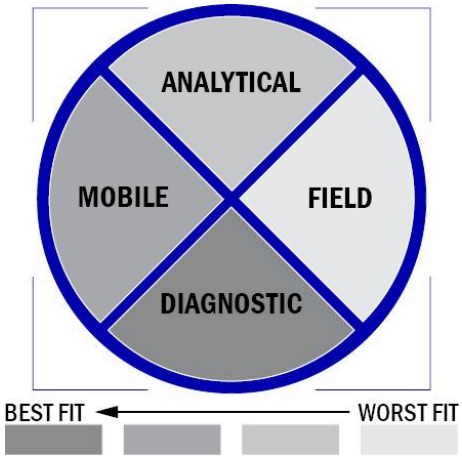
FIELD USE Ranking

BeadXpress Reader ranked in the bottom third of all evaluated products for field use and earned 37% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Illumina Inc.
9885 Towne Centre Drive
San Diego, CA 92121

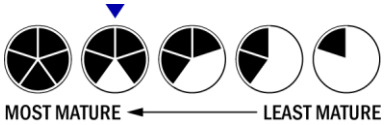
Point of Contact:
Dawn Barry
dbarry@illumina.com
1-800-809-4566

COST

- $98,500.00/system or device
- $10.50/sample analysis

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Adapted to full automation with some effort

Signature:
- No sounds or alarms present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- Less than 5 minutes for set up
- Less than 1 minute down time
- > 12 steps are required
- Customer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at room temp (27°C)/ Components must be stored at 4°C/ Components must be frozen
- Performance not influenced by relative humidity
- 1 to 6 months shelf life

Transportation:
- Approximately the size of a home dishwasher
- All means on transportation
- Weighs more than 50kg

Re-use:
- Multiple detection assays
- 5 or more solutions
- 5 or more components

Maintenance:
- Service once a year
- Maintenance is not included
- Expected life greater than 10 years
- Less than 5 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1 hr

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Requires water aliquots
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results not available
- Data can be processed while in progress
- Multiple centrifugation steps required
- Multiple shaking, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance shown
- FDA approval shown
- Greater than 250 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Not network capable
- Wired connections
- Fully autonomous system with significant effort
- Basic desktop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

BioAdvise Portable Detection Device

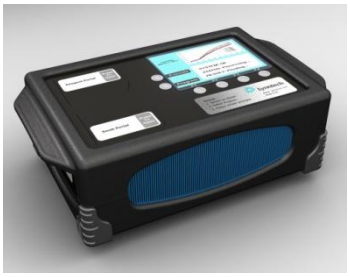
by Lynntech, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e3-10e4 CFU/mL)

DETECTION MATRICES:

Demonstrated:
Environmental water, Powder



DESCRIPTION:

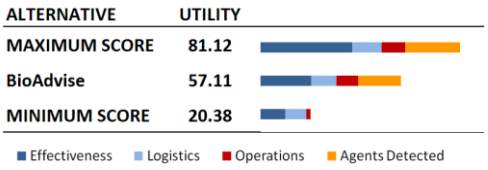
The product is a deployable, low-power system for the screening of unknown powders and liquids for the presence of biological threat agents. The unit will be designed to interface with the laptops available in first responder vehicles; all system control and analysis functions will be carried out on the laptop. Minimal user training and experience will be required. After the user introduces a swab of unknown material into the system, the unit will automatically perform the steps of sample recovery, lysing, purification, real-time PCR amplification, and fluorescence detection in order to determine if the material contains genetic material with a sequence matching an on-board library of known threats.

TECHNOLOGY:

The unit will be capable of sample recovery, cell lysis, DNA purification, 19-plex real-time target amplification and subsequent fluorescence detection in a convective PCR cell. Hardware development will enable controlled generation of the thermal environment necessary for sample preparation, convective PCR and real-time detection and analysis of the fluorescence signals during the amplification process. Reagent stabilization will enable the PCR reagents to be stored on-cartridge for extended periods with minimal degradation.

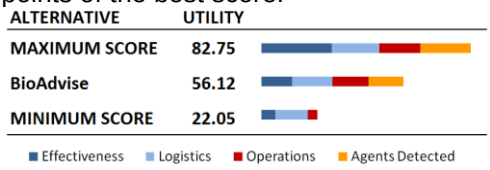
ANALYTICAL Laboratory Ranking

BioAdvise ranked in the top third of all evaluated products for analytical laboratories and earned 70% of the utility points of the best score.



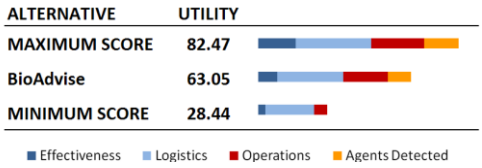
DIAGNOSTIC Laboratory Ranking

BioAdvise ranked in the top third of all evaluated products for diagnostic laboratories and earned 68% of the utility points of the best score.



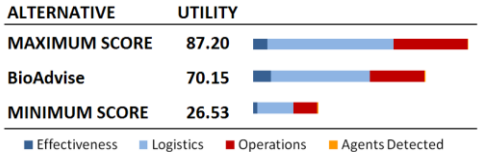
MOBILE Laboratory Ranking

BioAdvise ranked in the top third of all evaluated products for mobile laboratories and earned 76% of the utility points of the best score.



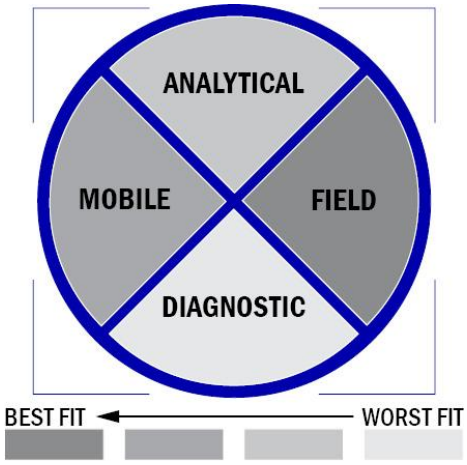
FIELD USE Ranking

BioAdvise ranked in the top third of all evaluated products for field use and earned 80% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Lynntech, Inc.
2501 Earl Rudder Freeway
South College Station, TX 77845

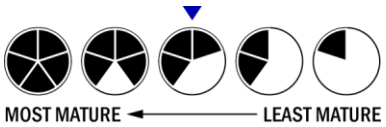
Point of Contact:
Wayne Evans
wayne.evans@lynntech.com
979-764-2309

COST

- $50,000.00

SPECIFICITY

- False Positives: <0.1%
- False Negatives: <2%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15 - 30 minutes for detection
- 1 sample, >10 tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- <1 minute down time
- 0-2 steps required
- DVD/ Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 4°C to 41°C
- Should be stored at room temp (27°C)/ Must be stored at 4°C
- Performance is not influenced by relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 3solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 5-10 years
- No QA required
- Hazardous agent isolated to discrete elements and/or decon requires up to 1 hour

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Greater than 250 ul to test liquids

System Maturity:
- Brass board
- Expected to be ready for commercialization within three or more years
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property pending

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Satellite, wireless and wired connections
- Not autonomous
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software closed, not available for modification
- Hardware closed, not available for modification

BioCheck

by 20/20 BioResponse

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (>100,000 CFU/mL)
Toxins (1,000-10,000 ng/mL)

DETECTION MATRICES:

Demonstrated:
Powder

DESCRIPTION:

BioCheck ® is a field deployable test to screen unknown powders for the presense of biological material. Designed for ease of use, high sensitivity and fast result delivery, BioCheck functions as presumtive test for an initial biological screen and can deliver a result in under five minutes. Normally, the BioCheck test will be performed prior to any pathogen specific tests are undertaken to determine whether there is justification for the time and cost for other tests to be preformed. As a highly sensitive field test for positive protein identification, BioCheck was designed specifically to quickly rule out the presense of any biological pathagen and quickly allow decisions to be made confidentely regarding the next steps for additional testing in a white powder / suspicious powder decision matrix or SOP. BioCheck test kits do not require any instrumentation, have no power requirements, and are rugged. Each kit is individually packaged with a very small form factor and are completely disposable after use. Extensively tested and validated, BioCheck has been shown to detect minute amounts of biological materal when testing unknown powders. Recent US Army ECBC testing showed sensitivity to as little as 100 µg of Ricin and 1 x 107 cfu of B. anthracis spores.

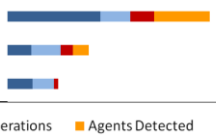
TECHNOLOGY:

BioCheck is a patented field test that functions as a colormetric assay that detects protein in solid materials and gives a color change when even minute amounts of protein are present. Specifically optimized in sensitivity and specificity its LOD is calibrated to give a high positive predictive value.

ANALYTICAL Laboratory Ranking

BioCheck ranked in the bottom third of all evaluated products for analytical laboratories and earned 40% of the utility points of the best score.

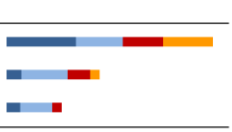
ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
BioCheck	32.66
MINIMUM SCORE	20.38



DIAGNOSTIC Laboratory Ranking

BioCheck ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 45% of the utility points of the best score.

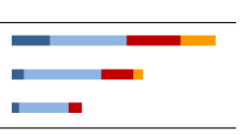
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
BioCheck	37.24
MINIMUM SCORE	22.05



MOBILE Laboratory Ranking

BioCheck ranked in the middle third of all evaluated products for mobile laboratories and earned 65% of the utility points of the best score.

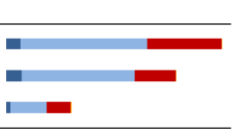
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
BioCheck	53.25
MINIMUM SCORE	28.44



FIELD USE Ranking

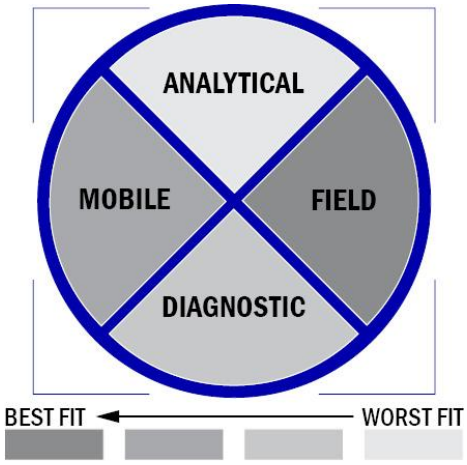
BioCheck ranked in the middle third of all evaluated products for field use and earned 79% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
BioCheck	68.91
MINIMUM SCORE	26.53



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

20/20 BioResponse
9430 Key West Avenue, Suite 100
Rockville, MD 20850

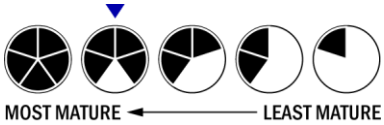
Point of Contact:
Barry Cohen
(240) 453-6339 ext 103
sales@2020gene.com

COST

- $26.20/system or device

SPECIFICITY

- False Positives: <1%
- False Negatives: <1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, single test/ sample per run
- Not amenable to full or semi-automation

Signature:
- Sounds or alarms not present
- No screen
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- DVD/ Web video/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 41°C
- Does not require consumables
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weigh less than 1 kg

Re-use:
- Single use
- 2 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- No service required
- Preventive maintenance not applicable
- Maintenance not included
- Expected life not applicable
- No daily QA required
- No decon required

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System does not call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Not network capable
- Not autonomous
- No computer required
- Does not store or archive data outputs or create electronic records
- System does not employ software
- System hardware not applicable

Biocode-1000

by Applied BioCode, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)

DETECTION MATRICES:

Demonstrated: Blood, Nasal and throat swabs

DESCRIPTION:

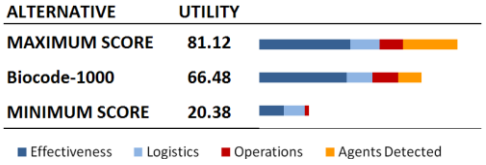
Applied BioCode, Inc. (ABC) has combined digital barcodes with immuno- and molecular chemistry to create a new, patented Barcoded Magnetic Bead (BMB) technology. The BMBs' barcode patterns give a high-contrast transmitted signal and no fluorescence background, allowing the barcode to be identified easily and accurately, with near 100% decoding accuracy. Barcoded Magnetic Beads, are functionalized with nucleic acids, proteins or other probe molecules, offer the highest multiplex capacities available (up to 128 targets or tests) in one sample in homogeneous media. Optically bar-coded polymer beads are mass produced at low cost by well established semiconductor processes. Biocode-1000 analyzer offers 128 tests per microwell in less than one minute. BMBs have 128 digital codes. Analyzer is a BMB imaging system for a 96-well microplate format. System reads and displays the barcode and fluorescence intensity for each BMB once they settle to the bottom of the well. The Analyzer has an XY translational stage and a 12-bit CCD camera. Typically uses PE (phycoerythrin), but other fluorophores can be used by switching the optical filter sets. Sources: LED for bright field decoding and Lamp for fluorescence detection. Sensitivity: 0.5 fmole of DNA, 1.0 pg/mL protein. Dynamic range: 3-4 orders of magnitude. Beads are 70 x25 x 6 µm. File export to Excel, CSV, and other formats.

TECHNOLOGY:

Barcoded Magnetic Beads (BMB): From 1 to 128 tests per microwell in 40 seconds! The BMB have 128 digital codes, and a diverse range of bioassay applications can be explored using BMB with the BioCode-1000A Analyzer. BioCode-1000A Analyzer: The BioCode-1000A Analyzer is a rapid BMB imaging system with auto loader for optional robotic loading for a 96-well microplate format. The system rapidly displays the barcode and fluorescence intensity for each BMB. BioCode-1000A Software: The BioCode-1000A software is a powerful, but easy to use control program and user interface for operating the BioCode-1000A Analyzer.

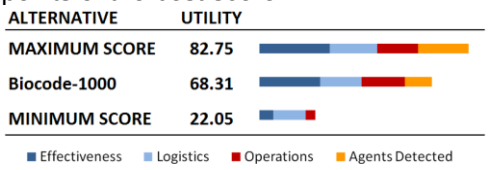
ANALYTICAL Laboratory Ranking

Biocode-1000 ranked in the top third of all evaluated products for analytical laboratories and earned 74% of the utility points of the best score.



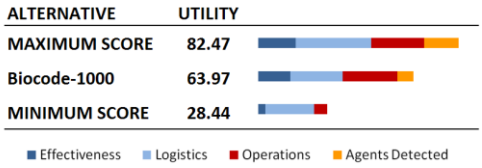
DIAGNOSTIC Laboratory Ranking

Biocode-1000 ranked in the top third of all evaluated products for diagnostic laboratories and earned 78% of the utility points of the best score.



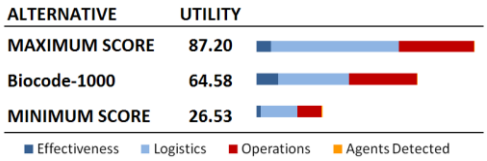
MOBILE Laboratory Ranking

Biocode-1000 ranked in the top third of all evaluated products for mobile laboratories and earned 83% of the utility points of the best score.



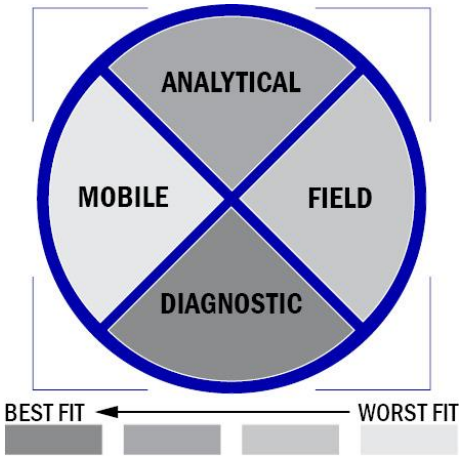
FIELD USE Ranking

Biocode-1000 ranked in the middle third of all evaluated products for field use and earned 82% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Applied BioCode, Inc.
10020 Pioneer Blvd.#102
Santa Springs,CA90670

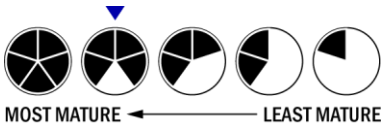
Point of Contact:
Winston Ho, PhD.
562-801-2088 ext 228
who@apbiocode.com

COST

- $45,000.00/system or device
- $0.50-$1.00/128 tests per sample

SPECIFICITY

- False Positives: near 0%
- False Negatives: near 0%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- No sounds or alarms
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes for set up
- Almost instantaneous down time
- 3-5 steps are required
- Customer site training

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can withstand temperatures in excess of 45°C for periods of less than 24 hours
- Performance is not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Commercial carrier
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 3 solutions, buffer, and/or reagents
- 2 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance is included
- Expected life 5-10 years
- No QA required
- Hazardous agent isolated and/or decontamination requires up to 1 hour

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 250 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Adapted with significant effort to a fully autonomous system
- Basic desktop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

BioFlash - Dx

by Innovative Biosensors, Inc.

DETECTS THE FOLLOWING:
Nothing demonstrated.

DETECTION MATRICES:
Demonstrated:
Nasal and throat swab, Wound, Powder

DESCRIPTION:
The BioFlash-Dx system is a semi-automated diagnostic device designed to detect pathogens (bacteria, viruses or toxins) from a variety of biological matrix materials. In its most mature form, the device is primarily designed for use in a hospital or clinical laboratory, however, the system has also been successfully used in a mobile laboratory setting.

TECHNOLOGY:
Information not available.

ANALYTICAL Laboratory Ranking
BioFlash - Dx ranked in the bottom third of all evaluated products for analytical laboratories and earned 40% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
BioFlash - Dx	38.87
MINIMUM SCORE	20.38

DIAGNOSTIC Laboratory Ranking
BioFlash - Dx ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 45% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
BioFlash - Dx	43.67
MINIMUM SCORE	22.05

MOBILE Laboratory Ranking
BioFlash - Dx ranked in the middle third of all evaluated products for mobile laboratories and earned 65% of the utility points of the best score.

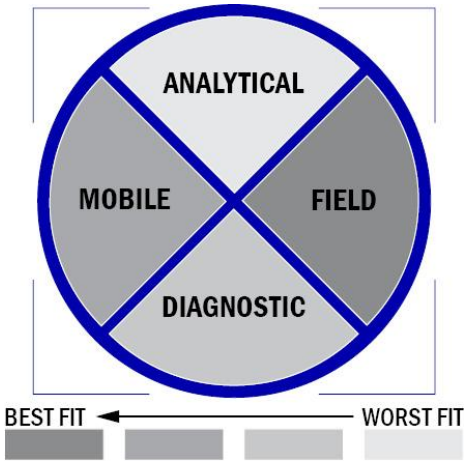
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
BioFlash - Dx	45.26
MINIMUM SCORE	28.44

FIELD USE Ranking
BioFlash - Dx ranked in the middle third of all evaluated products for field use and earned 79% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
BioFlash - Dx	52.12
MINIMUM SCORE	26.53

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Innovative Biosensors, Inc
15601 Crabbs Branch Way
Rockville, MD 20855

Point of Contact:
Dr. David Yost
Dr. P. J. Simpson

COST

- Information not available

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available

Maturity Not Available

Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- Multiple samples, single tests/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- >5 minutes set-up
- Almost instantaneous down time
- 3-5 steps required
- DVD/ Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components must be stored at room temp (27°C)/ Must be stored at 4°C/ Must be frozen
- Performance is not influenced by relative humidity
- Between 1 - 6 months shelf life

Transportation:
- Approximately the size of carry-on luggage
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Single use
- 3 solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life >10 years
- 10-20 minutes daily QA
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- Multiple centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- Information not available

System Maturity:
- Information not available

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Not network capable
- Wireless and wired connections
- Could be adapted to a fully autonomous system with significant effort
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software is closed and not available for modification
- System hardware is closed and not available for modification

BioHawk

by Research International, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e4-10e5 CFU/mL)
Viruses (>10e5 PFU/mL)
Toxins (1-100 ng/mL)

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

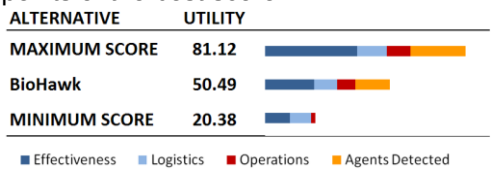
Developed for the military, but also laboratory friendly, the BioHawk is a portable 8-channel bioassay system with automated sample collection capability that is suitable for high-sensitivity monitoring of biological agents. Biohawk can be programmed to monitor surrounding air for aerosol threats with its built-in air sampler, and to periodically transfer a wet concentrate from the air sampler to the built-in biodetector. Assay results are typically available in 15 minutes. The biodetector portion of the instrument will also accept fluids for analysis from other sample collection systems, or will process liquid samples loaded into the instrument manually. Bioassays are performed within a small disposable credit card-sized plastic assay coupon that may be used for up to 10 assay procedures before being discarded. This capability can substantially reduce life cycle cost. Assay results may be transmitted to users through the touch panel LCD display, an audible alarm, a pulsating light, or by wireless or RS-232 link to personnel at a remote location. System operation may also be remotely controlled in real time- virtually every fluid or air handling function is capable of being operated remotely. Most global functions such as air sampling and biodetection are performed using multi-step recipes developed by Research International and stored in the system's computer memory. The unsophisticated user needs only the most fundamental level of training since the internal processes and steps are preset through the built-in computerized recipes.

TECHNOLOGY:

Research International's biosensor systems are based on 'sandwich format' fluoroimmunoassay reactions taking place on the surface of injection molded polystyrene waveguides. All fluidic and optoelectronic steps associated with the assay are performed automatically. In a typical waveguide-based sandwich immunoassay, the waveguide has a monolayer of capture antibody immobilized on its surface. The waveguide is first incubated with sample, washed, then incubated with fluorophore-labeled antibody to form an antibody/antigen/labeled-antibody sandwich. Excitation light is injected into the waveguide and fluorescence emission is collected by a sensitive photodetector that looks down the waveguide axis.

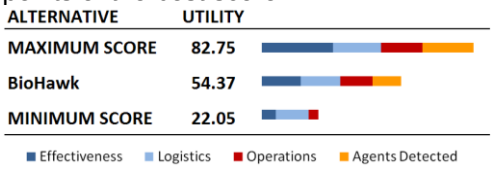
ANALYTICAL Laboratory Ranking

BioHawk ranked in the middle third of all evaluated products for analytical laboratories and earned 62% of the utility points of the best score.



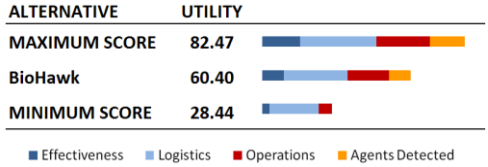
DIAGNOSTIC Laboratory Ranking

BioHawk ranked in the middle third of all evaluated products for diagnostic laboratories and earned 66% of the utility points of the best score.



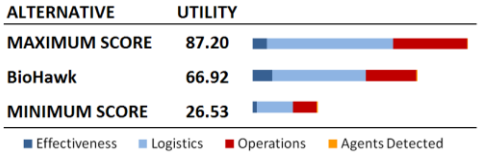
MOBILE Laboratory Ranking

BioHawk ranked in the top third of all evaluated products for mobile laboratories and earned 73% of the utility points of the best score.



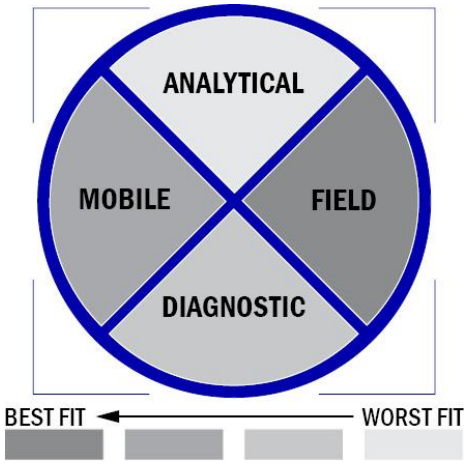
FIELD USE Ranking

BioHawk ranked in the middle third of all evaluated products for field use and earned 78% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Research International, Inc.
17161 Beaton Road SE
Monroe, WA 98272

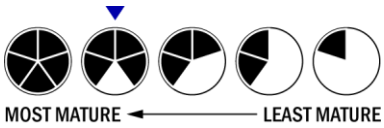
Point of Contact:
Jonathon Tobelmann
co. phone 360- 805-4930
direct phone 703-625-8381

COST

- $50,000.00/system or device
- $260/10 assay coupon

SPECIFICITY

- False Positives: ~1% per channel
- False Negatives: ~1% per channel



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15-30 minutes for detection
- 1 sample, <10 tests/ sample per run
- Currently fully automated

Signature:
- No sounds or alarms
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- > 20 minutes for set up
- Almost no down time
- 0-2 steps are required
- Customer and Manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components must be stored at 4°C
- Performance is not influenced by relative humidity
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means on transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 5-10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Batteries
- 4-8 hours battery use
- Requires water aliquots
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time not available
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Greater than 250 ul for a test

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Fully autonomous system
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

Biological alarm monitor (MAB)

by PROENGIN Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (down to 10 ACPLA)
Viruses (down to 10 ACPLA)
Toxins (down to 10 ACPLA)

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

MAB is an biological alarm monitor. This early warning system continuously analyses particles in the atmosphere, and searches for specific chemical signatures of bacteria or toxins such as anthrax, plague, Botox, legionella etc., and gives alarm when the concentration in the air of those suspect particles increases. It allows to trigger a bio sampler to determine the pathogenic characteristics of the detected particles. MAB works on a continuous basis and in real time (response time is some seconds) in the toughest environments. MAB immediately detects any evolution regarding to the atmospheric background and gives an alarm as soon as the measured biological characteristics exceed an adjustable threshold. MAB can be used by untrained people and is especially adapted to the harshness of a military use (fast start-up, reliability, environmental resistance, continuous running for several days). It has already been selected by several military forces and equips several NBC reconnaissance vehicles, as it is not sensitive to diesel vapors and smokes.

TECHNOLOGY:

The MAB use the Flame Spectrophotometry technology. It consists in analyzing the light spectrum of a flame in which burns the gas or the particles to be detected. Atomic elements or chemical liaisons have a specific light spectrum. Phosphorus, Sulphur, HN= O chemical liaison, Potassium, Sodium, Calcium and many other elements thus can be detected without mistake into any gas, aerosol, dust or particle. Proengin Detectors use that principle to detect those elements that are present in Biological Agents.

ANALYTICAL Laboratory Ranking

Biological alarm monitor (MAB) ranked in the middle third of all evaluated products for analytical laboratories and earned 60% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
Biological alarm monitor (MAB)	48.45
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

Biological alarm monitor (MAB) ranked in the middle third of all evaluated products for diagnostic laboratories and earned 56% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
Biological alarm monitor (MAB)	46.49
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

Biological alarm monitor (MAB) ranked in the middle third of all evaluated products for mobile laboratories and earned 62% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
Biological alarm monitor (MAB)	51.37
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

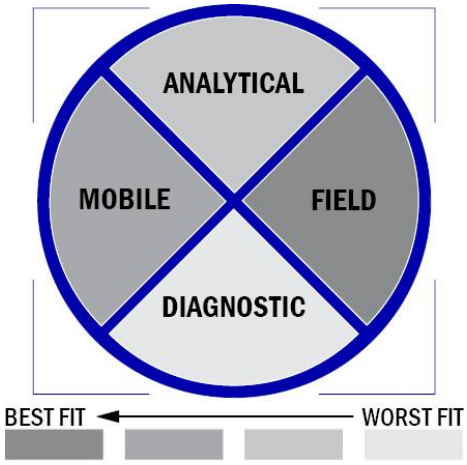
Biological alarm monitor (MAB) ranked in the middle third of all evaluated products for field use and earned 67% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
Biological alarm monitor (MAB)	58.56
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

PROENGIN Inc.
40 South University Drive Suite F
Plantation, FL 33324

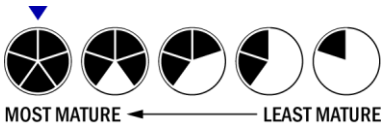
Point of Contact:
Mark Reuther
954-760-9990
mreuther@proenginusa.com

COST

- $108,000.00/system or device

SPECIFICITY

- False positives: 5%
- False negatives: 1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- System is fully automated

Signature:
- Sounds or alarms can be deactivated
- Screen is not present
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 10-20 minutes set up
- Minimal down time
- 0-2 steps are required
- Customer and manufacturer site training/hard-copy manual

Operational conditions:
- Can be used from -10°C to 50°C
- Components can be stored form -39°C to 71°C
- Performance is not influenced by relative humidity
- Shelf life greater than 3 years

Transportation:
- Approximately the size of carry on suitcase
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service more than every 6 months
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Battery life dependent on optional battery supply
- Does not require water
- External air or gas source is required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps are required
- No shaking or vortexing, mixing, degassing or filtering steps are required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Does not test liquids

System Maturity:
- Commercially available and meets military specifications
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB
- Network capable
- Wired connections
- Fully autonomous
- Laptop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open but modification requires licensing
- The system hardware is open but modification requires licensing

The BioMark System for Real-Time PCR

by BioMark

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swab, Stool, Insect vectors

DESCRIPTION:

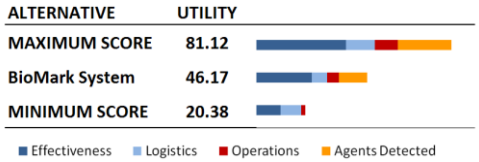
The BioMark Family of systems are designed for high throughput real-time PCR. The system is designed for research use only.

TECHNOLOGY:

The BioMark Family of Real-Time PCR systems enables high throughput real time PCR with nanoliter sized reaction volumes through the use of microfluidics. The microfluidic architecture does the work of combining samples and assays into 9,216 simultaneous PCR reactions, which is 24-fold more data than that produced by a 384-well plate.

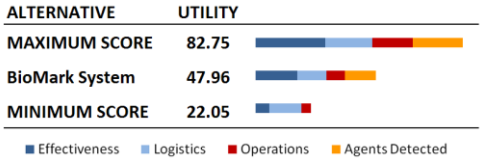
ANALYTICAL Laboratory Ranking

The BioMark System for Real-Time PCR ranked in the middle third of all evaluated products for analytical laboratories and earned 57% of the utility points of the best score.



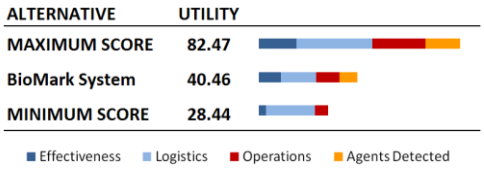
DIAGNOSTIC Laboratory Ranking

The BioMark System for Real-Time PCR ranked in the middle third of all evaluated products for diagnostic laboratories and earned 58% of the utility points of the best score.



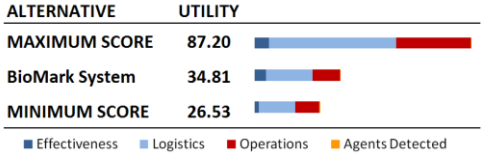
MOBILE Laboratory Ranking

The BioMark System for Real-Time PCR ranked in the bottom third of all evaluated products for mobile laboratories and earned 49% of the utility points of the best score.



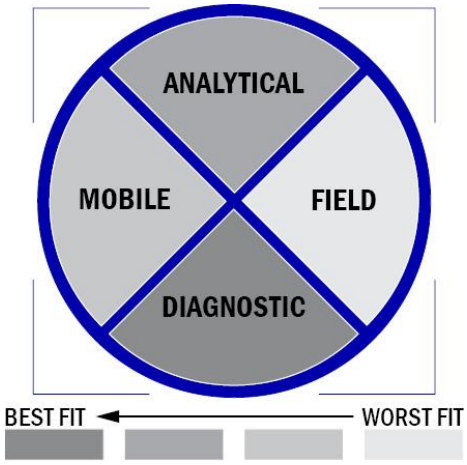
FIELD USE Ranking

The BioMark System for Real-Time PCR ranked in the bottom third of all evaluated products for field use and earned 40% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

BioMark Corporate Headquarters
7000 Shoreline Court, Suite 100
South San Francisco, CA 94080

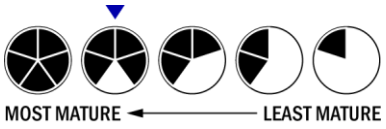
Point of Contact:
1-866-358-4354
650-266-6000

COST

- $250,000.00/system or device

SPECIFICITY

- False Positives: Highly dependent on the sample type and assay
- False Negatives: Highly dependent on the sample type and assay



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1 - 8 hours for detection
- Multiple samples, multiple tests/sample per run
- Could be adapted to semi-automated with some effort

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- >20 minutes set-up required
- <1 minute down time
- Greater than 12 steps required
- Customer and manufacturer site training

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at room temperature (27°C)
- Peak performance at normal relative humidity conditions
- 6 months - 1 year for detection

Transportation:
- Larger than home dishwasher
- Commercial carrier/ Tactical military wheeled and tracked vehicle/ Fixed wing military aircraft/ Ship
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 3 components

Maintenance:
- Once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- Multiple centrifugation steps
- Multiple shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Wired connections
- Not autonomous
- Basic desktop computer
- Stores and archives data outputs and creates an electronic record
- System software is closed and not available for modification
- System hardware is closed and not available for modification

Bio-Plex 200 Suspension ArraySystem

by Bio-Rad Laboratories

DETECTS THE FOLLOWING:
Nothing demonstrated.

DETECTION MATRICES:
Nothing demonstrated.

DESCRIPTION:
The Bio-Plex 200 System is a laboratory analysis tool designed for protein detection and analysis using immunoassay xMAP technology.

TECHNOLOGY:
The Bio-Plex 200 system is based on xMAP technology, a proprietary technology that color codes beads which are then used in sandwich immunoassay analysis. These assays are multiplexable.

ANALYTICAL Laboratory Ranking

Bio-Plex 200 Suspension ArraySystem ranked in the bottom third of all evaluated products for analytical laboratories and earned 41% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
Bio-Plex 200	33.03
MINIMUM SCORE	20.38

DIAGNOSTIC Laboratory Ranking

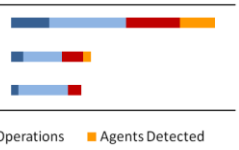
Bio-Plex 200 Suspension ArraySystem ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 40% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
Bio-Plex 200	33.07
MINIMUM SCORE	22.05

MOBILE Laboratory Ranking

Bio-Plex 200 Suspension ArraySystem ranked in the bottom third of all evaluated products for mobile laboratories and earned 39% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
Bio-Plex 200	32.27
MINIMUM SCORE	28.44



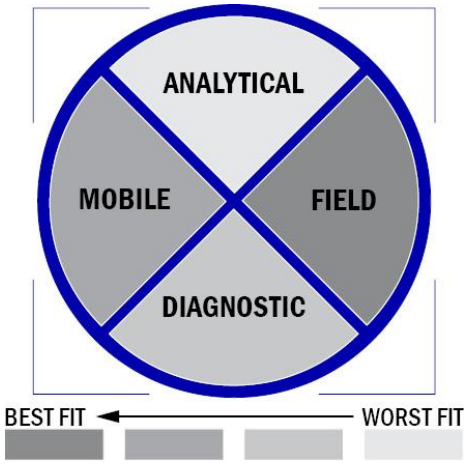
FIELD USE Ranking

Bio-Plex 200 Suspension ArraySystem ranked in the bottom third of all evaluated products for field use and earned 39% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
Bio-Plex 200	34.30
MINIMUM SCORE	26.53

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Bio-Rad Laboratories
2000 Alfred Nobel Drive
Hercules, CA 94547

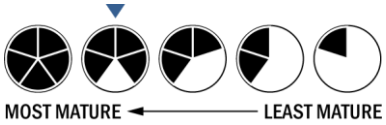
Point of Contact:
Michelle Heim, Bio-Plex Business Unit Manager
510-741-5382

COST

- $69,000.00/system or device
- ~$5.00/analysis

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- Screen not present
- Thermal output unknown

Training and Speed:
- A day of training and technical skills are required
- Greater than 20 minutes set up
- Almost no down time
- 3-5 steps are required
- Customer and manufacturer site training

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at 4°C
- Unknown influence of relative humidity
- Between 1 to 3 years

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Commercial carrier/ Fixed wing aircraft/ Ship transport
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Preventive maintenance serviceable by technician
- Expected life greater than 10 years
- 10-20 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Requires water aliquots
- External air or gas source not required
- External vacuum is required

Ease of Use:
- Real-time results available
- Data cannot be processed during a run.
- A single centrifugation step required
- Multiple shaking or vortexing, mixing, degassing or filtering steps required
- Software will not call final result

Sensitivity and Detection:
- 510K clearance N/A
- FDA approval N/A
- Less than 50 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- Network capable
- Wireless and wired connections
- Autonomous system with some effort
- Basic desktop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

BioPlex 2200

by BioRad Laboratories

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Demonstrated:
Blood

DESCRIPTION:

Fully automated, random access multiplex system designed for Autoimmune and Infectious disease testing in human serum or plasma. The system is designed to up to 22 specific analytes per assay panel. The system is utilized in diagnostic testing in hospital laboratories.

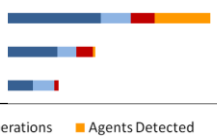
TECHNOLOGY:

BioPlex 2200 Immunoassay use heterogeneous sets of 8 micron paramagnetic Beads. The beads are infused with various ratios of fluorescent dyes creating unique bead sets. Beads are coated with recombinant and / or native antibodies, antigens specific to a certain assay. Bead sets are then mixed together into a single reagent pack for testing and the simultaneous detection of multiple analytes from a single sample The system uses a dual laser detection system to process a minimum 150 assay readings per analyte. Detection system is capable of reading 100,000 beads per minute.

ANALYTICAL Laboratory Ranking

BioPlex 2200 ranked in the bottom third of all evaluated products for analytical laboratories and earned 43% of the utility points of the best score.

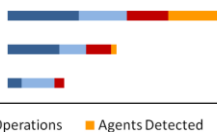
ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
BioPlex 2200	35.12
MINIMUM SCORE	20.38



DIAGNOSTIC Laboratory Ranking

BioPlex 2200 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 52% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
BioPlex 2200	42.68
MINIMUM SCORE	22.05



MOBILE Laboratory Ranking

BioPlex 2200 ranked in the bottom third of all evaluated products for mobile laboratories and earned 44% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
BioPlex 2200	36.10
MINIMUM SCORE	28.44

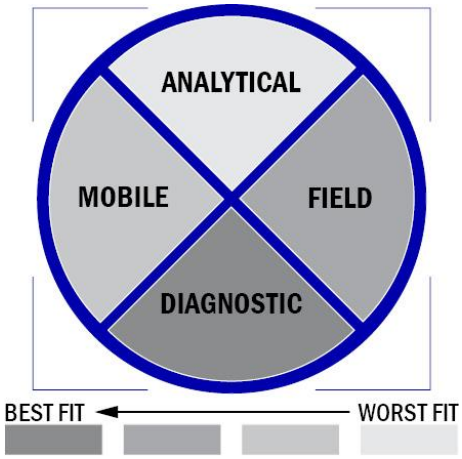
FIELD USE Ranking

BioPlex 2200 ranked in the bottom third of all evaluated products for field use and earned 45% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
BioPlex 2200	39.24
MINIMUM SCORE	26.53

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

BioRad Laboratories
5500 East 2nd St
Benicia Ca 94510 Email:

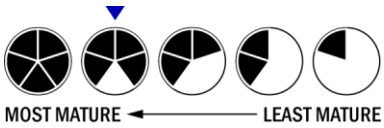
Point of Contact:
David Tomichek, Senior Product Manager
Ph:510-741-5119
david_tomichek@bio-rad.com

COST

- $385,000.00/system or device
- $1.00-15.00/analysis

SPECIFICITY

- False Positives: 0.1%-3%
- False Negatives: 0.1%-3%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30-60 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms present
- Screen cannot be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- More than a day of training and significant skills are required
- 5-10 minutes set up
- Almost no down time
- 0-2 steps are required
- Manufacturer site training

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be stored at room temp (27°C)
- Device must be used in a temperature stable, dry environment for optimum performance
- Between 1 to 3 years shelf life

Transportation:
- Larger than a home dishwasher
- Commercial carrier
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service more often than every 6 months
- Preventive maintenance serviceable by technician
- Maintenance is included
- Expected life 5-10 years
- Greater than 20 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1 hr

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Requires continual supply of water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed during analysis
- A single centrifugation step required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance shown
- FDA approval shown
- Less than 250 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Not network capable
- Wired connections
- System not capable of autonomy
- Onboard computer chip
- Automatically stores and archives data outputs but does not create an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

Bio-Seeq PLUS Biological Agent Identifier

by Smiths Detection, Inc

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e3-10e4 CFU/mL)
Virus (10e3-10e4 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Powder

DESCRIPTION:

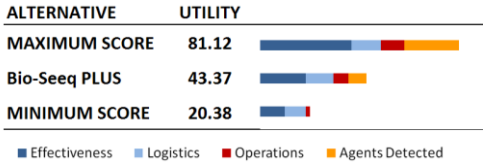
Bio-Seeq PLUS is a portable high precision instrument that detects and identifies trace levels of specific biological agents, both bacterial and viral, through DNA replication.

TECHNOLOGY:

Bio-Seeq PLUS utilizes Linear After The Exponential Polymerase Chain Reaction (LATE PCR)

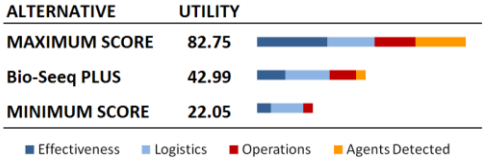
ANALYTICAL Laboratory Ranking

Bio-Seeq PLUS ranked in the middle third of all evaluated products for analytical laboratories and earned 53% of the utility points of the best score.



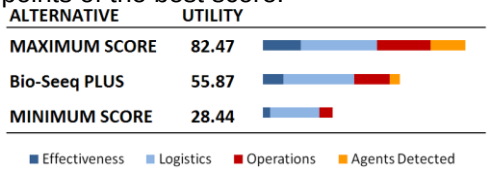
DIAGNOSTIC Laboratory Ranking

Bio-Seeq PLUS ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 52% of the utility points of the best score.



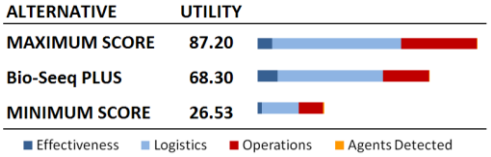
MOBILE Laboratory Ranking

Bio-Seeq PLUS ranked in the middle third of all evaluated products for mobile laboratories and earned 68% of the utility points of the best score.



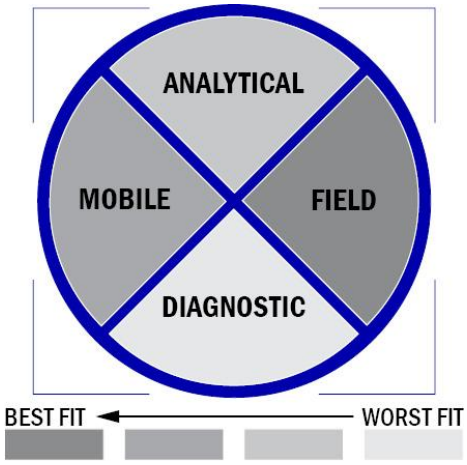
FIELD USE Ranking

Bio-Seeq PLUS ranked in the middle third of all evaluated products for field use and earned 78% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Smiths Detection, Inc.
2202 Lakeside Blvd.
Edgewood, MD 21040

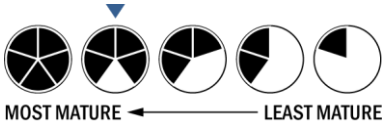
Point of Contact:
Ken Klein
Ken.klein@smithsdetection.com

COST

- $35,000.00/system or device
- $32.00/ analysis

SPECIFICITY

- False Positives: above MDL expect 0%
- False Negatives: Not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30-60 minutes for detection
- Multiple samples, single tests/ sample per run
- System not amenable to full or semi-automation

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set up
- Almost no down time
- 3-5 steps are required
- Customer and manufacturer sit training/ Hard copy manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be stored at room temperature but can withstand temperatures in excess of 45°C for periods of less than 24 hours
- Performance is not influenced by relative humidity
- Between 1 to 3 years

Transportation:
- Approximately the size of a toaster
- All means of transportation
- Weighs between 5 and 25kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Less than once a year
- Preventive maintenance N/A
- Maintenance is not included
- Expected life 5-10 years
- No QA required
- It likely that exposure to hazardous agent cannot be decontaminated

Physical System Requirements:
- System used batteries
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results not available
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance N/A
- FDA approval N/A
- Less than 10 ul for a test

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Not capable of autonomy
- Onboard computer chip
- Store and archive data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

BioSentryPlus

by JMAR

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Demonstrated:
Environmental water

DESCRIPTION:

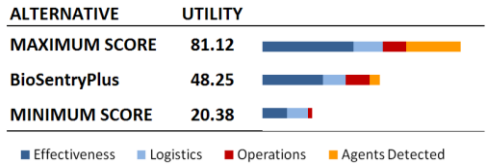
Product provides continuous monitoring of water for Biological and Chemical contamination events. Online, real time monitor for bacteria, spores, or cysts along with chemical sensors to provide a minute by minute measurement of the safety of water. The system can be operated autonomously and reports automatically when it detects an "out of normal" condition. No analysis consumables required.

TECHNOLOGY:

The biological sensor uses MIE light scattering detection and the chemical sensors include temperature, pH, conductivity, and Oxidation Reduction Potential (ORP). Additionally the system calculates a free chlorine reading.

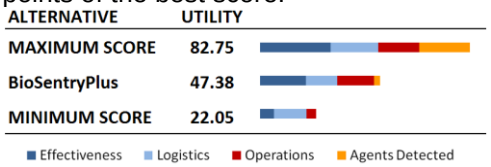
ANALYTICAL Laboratory Ranking

BioSentryPlus ranked in the middle third of all evaluated products for analytical laboratories and earned 59% of the utility points of the best score.



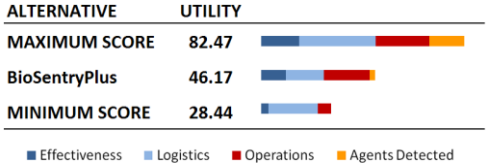
DIAGNOSTIC Laboratory Ranking

BioSentryPlus ranked in the middle third of all evaluated products for diagnostic laboratories and earned 57% of the utility points of the best score.



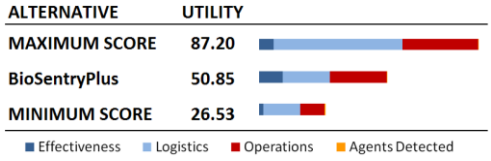
MOBILE Laboratory Ranking

BioSentryPlus ranked in the bottom third of all evaluated products for mobile laboratories and earned 56% of the utility points of the best score.



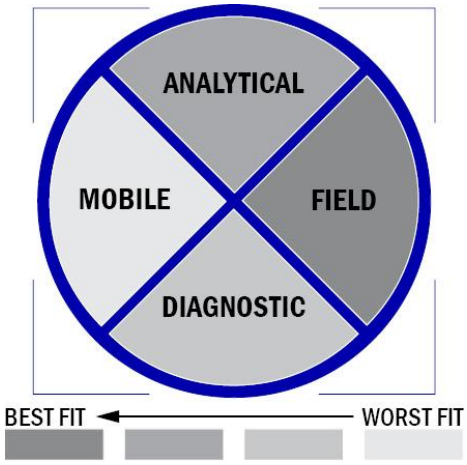
FIELD USE Ranking

BioSentryPlus ranked in the bottom third of all evaluated products for field use and earned 58% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

JMAR
10905 Technology Place
San Diego, CA 92127

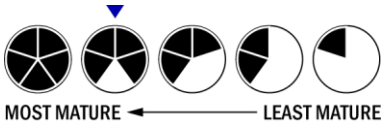
Point of Contact:
Liz Wessing
858-312-7769 ext 6837
lwessing@jmar.com

COST

- $24,990.00 - 29,990.00/system or device

SPECIFICITY

- False Positives: Not Available
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- Multiple samples, multiple tests/sample per run
- Fully automated

Signature:
- Sounds or alarms present
- Screen cannot be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 37°C
- Does not require consumables
- Peak performance at normal relative humidity conditions
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a home dishwasher
- Transport via commercial carrier
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 5-10 years
- No daily QA
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Requires a continual supply of water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Greater than 250 ul to test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless and wired connections
- Fully autonomous
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software is open but modification requires licensing
- System hardware is open but modification requires licensing

Biosignatures for Non-Invasive Detection of Exposure to Acute Radiation

by Battelle - Pacific Northwest National Laboratory

DETECTS THE FOLLOWING:
Nothing demonstrated.

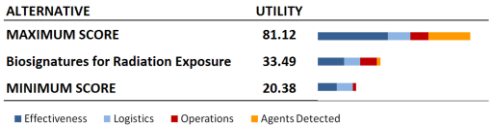
DETECTION MATRICES:
Nothing demonstrated.

DESCRIPTION:
We have been able to detect metabolites and protein modifications related to exposure to radiation.

TECHNOLOGY:
The key enabling technology is the ability to determine metabolites as well as protein modifications.

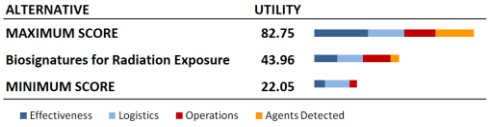
ANALYTICAL Laboratory Ranking

Biosignatures for Non-Invasive Detection of Exposure to Acute Radiation ranked in the bottom third of all evaluated products for analytical laboratories and earned 41% of the utility points of the best score.



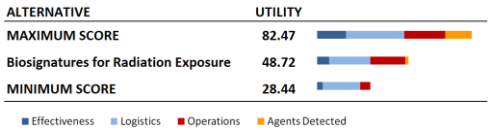
DIAGNOSTIC Laboratory Ranking

Biosignatures for Non-Invasive Detection of Exposure to Acute Radiation ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 53% of the utility points of the best score.



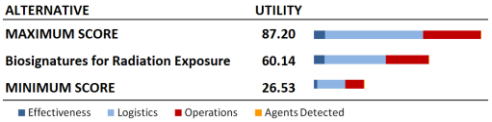
MOBILE Laboratory Ranking

Biosignatures for Non-Invasive Detection of Exposure to Acute Radiation ranked in the bottom third of all evaluated products for mobile laboratories and earned 59% of the utility points of the best score.



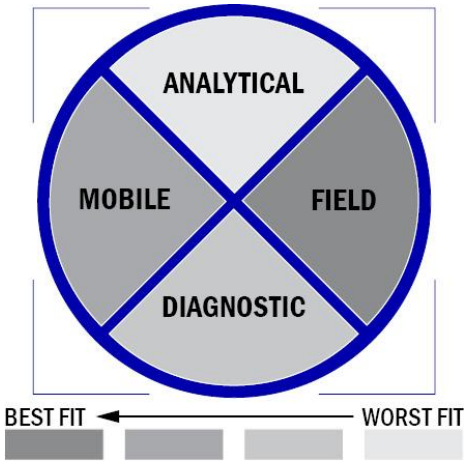
FIELD USE Ranking

Biosignatures for Non-Invasive Detection of Exposure to Acute Radiation ranked in the middle third of all evaluated products for field use and earned 69% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Battelle - Pacific Northwest National Laboratory
P.O. Box 999
Battelle Blvd.
Mail Stop P7-50
Richland, Washington 99352

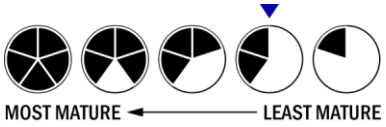
Point of Contact:
James Campbell
james.campbell@pnl.gov

COST

- Information not available

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, <10 tests/ sample per run
- Could be adapted to fully automated with some effort

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 5-10 minutes set-up required
- 1-3 minutes down time
- 3-5 steps required
- Customer site training

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours/ Must be stored at 4°C
- Performance is not influenced by relative humidity
- 6 months and 1 year shelf life

Transportation:
- Larger than a home dishwasher
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 3 solutions, buffer, and/or reagents
- 3 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life 3-5 years
- 10-20 minutes daily QA
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 100 ul to test liquids

System Maturity:
- Bread board
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB or single pos or neg response generated
- Not network capable
- Satellite, wireless and wired connections
- Could be fully autonomous with some effort
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software open and available for modification
- System hardware open and available for modification

Biosignatures for Non-Invasive Detection of Exposure to Organophosphate Pesticides

by Battelle - Pacific Northwest National Laboratory

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/ml of original sample)

DETECTION MATRICES:

Demonstrated:
Air

DESCRIPTION:

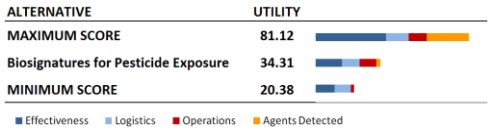
We have been able to detect the major metabolites of chlofpyrifos (CPF) In the saliva of rats exposed to CPF.

TECHNOLOGY:

The key enabling technology is the ability to determine metabolites as well as protein modifications.

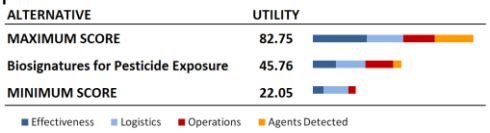
ANALYTICAL Laboratory Ranking

Biosignatures for Organophosphate Pesticides ranked in the middle third of all evaluated products for analytical laboratories and earned 74% of the utility points of the best score.



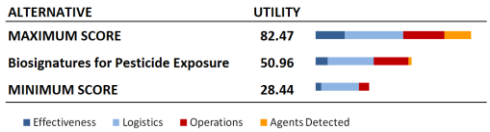
DIAGNOSTIC Laboratory Ranking

Biosignatures for Organophosphate Pesticides ranked in the top third of all evaluated products for diagnostic laboratories and earned 80% of the utility points of the best score.



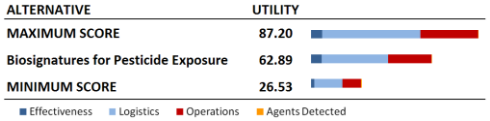
MOBILE Laboratory Ranking

Biosignatures for Organophosphate Pesticides ranked in the top third of all evaluated products for mobile laboratories and earned 87% of the utility points of the best score.



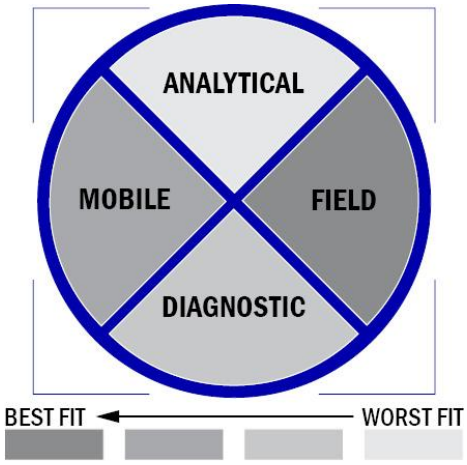
FIELD USE Ranking

Biosignatures for Organophosphate Pesticides ranked in the top third of all evaluated products for field use and earned 89% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Battelle - Pacific Northwest National Laboratory
P.O. Box 999
Battelle Blvd.
Mail Stop P7-50
Richland, Washington 99352

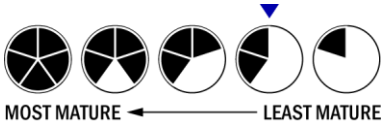
Point of Contact:
James Campbell
james.campbell@pnl.gov

COST

- Information not available

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, <10 tests/ sample per run
- Could be adapted to fully automated with some effort

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 5-10 minutes set-up required
- 1-3 minutes down time
- 3-5 steps required
- Customer site training

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours/ Must be stored at 4°C
- Performance is not influenced by relative humidity
- Between 6 months and 1 year

Transportation:
- Larger than a home dishwasher
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 3 solutions, buffer, and/or reagents
- 3 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life 3-5 years
- 10-20 minutes daily QA
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 100 ul to test liquids

System Maturity:
- Bread board
- Expected to be ready for commercialization within two calendar years
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB or single pos or neg response generated
- Not network capable
- Satellite, wireless and wired connections
- Could be fully autonomous with some effort
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- Software open and available for modification
- Hardware open and available for modification

BioThreat Alert ELISA Kit(s)

by Tetracore, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e4-10e5 CFU/mL)
Toxins (1-100 ng/mL)

DETECTION MATRICES:

Demonstrated:
Environmental Water, Soil, Food, Powder

DESCRIPTION:

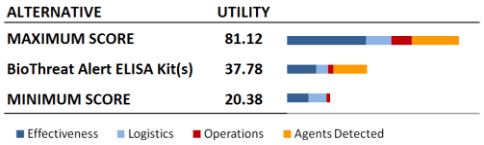
Antigen Capture ELISA kit for detection of biothreat agents; designed to be performed in the lab using a plate washer/reader for quantitative analysis. The kit can be adapted for field use for qualitative analysis with some effort. The kit is designed for environmental samples and the like, and can test samples in many matrices.

TECHNOLOGY:

ELISA: antigen capture employing capture and detector antibodies; most kits use monoclonal antibodies for detection.

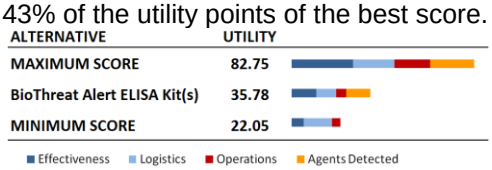
ANALYTICAL Laboratory Ranking

BioThreat Alert ELISA Kit(s) ranked in the bottom third of all evaluated products for analytical laboratories and earned 47% of the utility points of the best score.



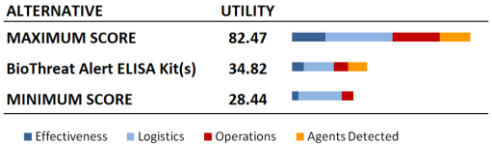
DIAGNOSTIC Laboratory Ranking

BioThreat Alert ELISA Kit(s) ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 43% of the utility points of the best score.



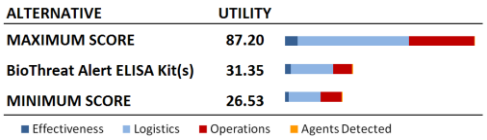
MOBILE Laboratory Ranking

BioThreat Alert ELISA Kit(s) ranked in the bottom third of all evaluated products for mobile laboratories and earned 42% of the utility points of the best score.



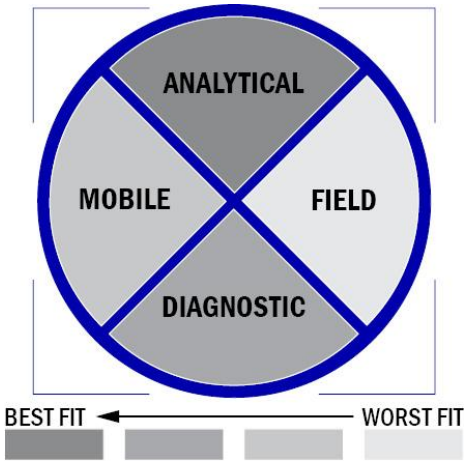
FIELD USE Ranking

BioThreat Alert ELISA Kit(s) ranked in the bottom third of all evaluated products for field use and earned 36% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Tetracore, Inc.
9901 Belward Campus Dr. Suite 300
Rockville, MD 20850

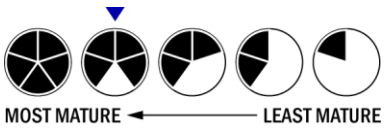
Point of Contact:
Tom O'Brien Ph.D.
240-268-5400
tobrien@tetracore.com

COST

- $575.00/kit

SPECIFICITY

- False Positives: <1%
- False Negatives: <1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, single tests/ sample per run
- Semi-automated system with some effort

Signature:
- Sounds or alarms not present
- No screen

Training and Speed:
- A day of training and technical skills are required
- No set up
- Greater than 12 steps are required
- Hard-copy manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at 4°C
- Performance is not influenced by relative humidity
- 1 to 6 months shelf life

Transportation:
- All means of transportation
- Weighs less than 1 kg

Re-use:
- Single detection assays
- 4 solutions, buffer, and/or reagents
- 5 components

Maintenance:
- No service required
- The device is single use and disposable so no decontamination is needed

Physical System Requirements:
- Not intended for portable use
- Water aliquots required
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results not available
- No centrifugation steps required
- A single shaking or vortexing, mixing, degassing or filtering steps required
- Software cannot call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Greater than 250 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- Not network capable
- No data transmission
- Autonomous system with significant effort
- Laptop computer
- No software
- Single use or this question does not apply to this device

BioThreat Integrated Detection System

by Tetracore, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Environmental water, Powder

DESCRIPTION:

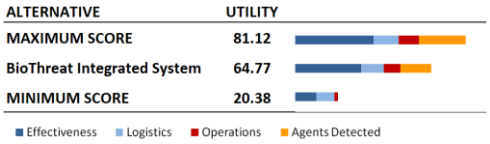
BioThreat Integrated Detection System provides quick, reliable screening and confirmatory analysis of biothreats for both biologists in the laboratory and First Responders in the field. The Rapid BioAlert reader and BioThreat Alert® strips provide a screening test for 9 different assays (Abrin, Anthrax, Bot Tox, Brucella, Orthopox, Plague, Ricin, SEB, and Tularemia) in less than 20 minutes. The reader is a fully functional ultra-mobile PC designed to enhance the speed and ease of testing. The interface has been designed to be large and simple, accommodating for various PPE worn by First Responders. Tetracore's T-COR 4TM Handheld Real-Time PCR Thermocycler provides superior confirmatory analysis for samples tested with BioThreat Alert® assays. The device operates connected to the Rapid BioAlert via USB and runs either standard TaqMan® real-time PCR or Isothermal real-time fluorescence based amplification, which delivers confirmatory analysis in 10 minutes. It can process four independent samples and is capable of analyzing two targets per sample. Tetracore produces 18 dry real-time PCR and 4 dry Isothermal Assays for the T-COR 4TM with shelf lives exceeding 18 months at room temperature. The T-COR 4TM is an open system capable of running any customer's assay in either a wet or dry formulation. Identification of agents in powder samples, agents in environmental samples, bacteria, and viruses has been demonstrated in both devices.

TECHNOLOGY:

Provides screening and confirmation of biothreat samples. BioThreat Alert® strips are handheld lateral-flow immunochromatographic assays that use colloidal gold labeled antibodies. Rapid BioAlert reader is a handheld PC coupled with additional hardware and software to allow analysis of the strips. T-COR 4TM is a handheld, battery-powered, peltier-based thermocycler designed for TaqMan® real-time PCR amplification and Isothermal real-time fluorescence based amplification. Designed with a proprietary, modular optical system, it can be modified to suit future requirements. The developed optical technology enables support of nucleic acid detection, polypeptide detection, and environmental sensing.

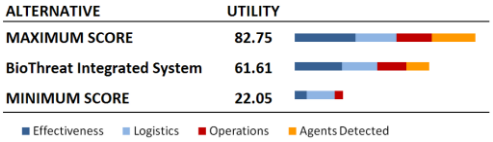
ANALYTICAL Laboratory Ranking

BioThreat Integrated Detection System ranked in the top third of all evaluated products for analytical laboratories and earned 80% of the utility points of the best score.



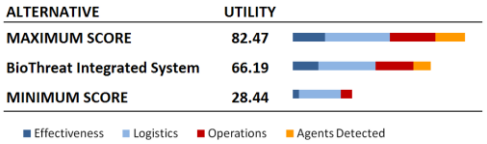
DIAGNOSTIC Laboratory Ranking

BioThreat Integrated Detection System ranked in the top third of all evaluated products for diagnostic laboratories and earned 74% of the utility points of the best score.



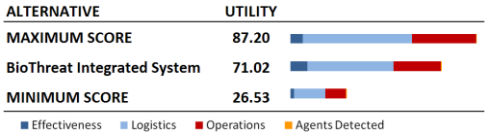
MOBILE Laboratory Ranking

BioThreat Integrated Detection System ranked in the top third of all evaluated products for mobile laboratories and earned 80% of the utility points of the best score.



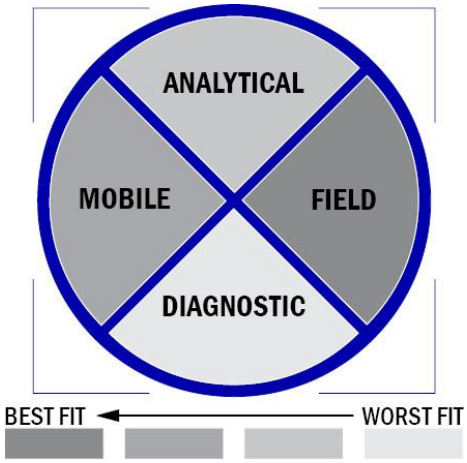
FIELD USE Ranking

BioThreat Integrated Detection System ranked in the top third of all evaluated products for field use and earned 81% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Tetracore, Inc.
9901 Belward Campus Drive
Suite 300
Rockville, MD, 20850

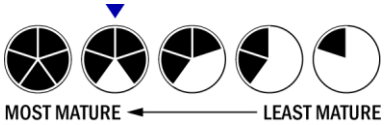
Point of Contact:
Tom O'Brien Ph.D.
240-268-5400
tobrien@tetracore.com

COST

- $21,500.00/system or device

SPECIFICITY

- False Positives: <0.1%
- False Negatives: Sample type, sample prep, assay, and concentration specific



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15 - 30 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 3-5 steps required
- DVD/ Web video/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for < 24 hours
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of carry-on luggage
- All modes of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 3 components

Maintenance:
- Service less than once a year
- Preventive maintenance not applicable
- One year warranty
- Expected life 3-5 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 4-8 hours battery life
- Requires water aliquots
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- Single centrifugation step
- Single shaking or vortexing, mixing, degassing or filtering step
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 250 ul required for test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property licensing is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless and wired connections
- Not autonomous
- On board computer chip
- Stores and archives data outputs and creates electronic records
- System software is closed and not available for modification
- System hardware is closed and not available for modification

BioTM-FD

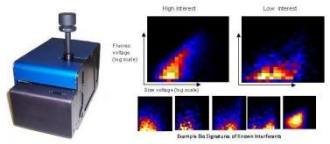
by Partner Airogistic, LLC

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)

DETECTION MATRICES:

Demonstrated:
Environmental air



DESCRIPTION:

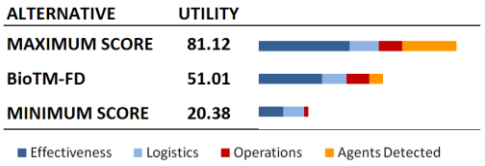
The BIOTM-FD is a laser induced florescence (LIF) detector that continuously analyzes air samples for airborne pathogens. The device is capable of alerting or triggering real-time air sample collection if a known and dangerous pathogen is present. This product is designed to be power efficient and operate as a standalone unit with minimal training or interaction. The detector employs a unique technology for determining the threat level based on characterized signatures of florescence vs. size and the statistical distributions for common pathogens. The system is flexible in that it can be trained to adapt to background particulates, look for new pathogens, and ignore known interferrents.

TECHNOLOGY:

The BioTM-FD LIF detector employs a unique design using an air inlet with and integrated aerosol concentrator for enriching the particle stream before interrogating the sampled air. The principle of detection is based on its use of Mie scattering, concurrently examining each particle for the presence of the metabolites NADH and riboflavin, which are necessary intermediates for metabolism of living organisms, such as bacteria and fungi. The detector simultaneously measures particle size and florescence with a single illumination correlating the two resulting signals in real time. The signals generated are processed statistically through maximum likelihood algorithms that compare samples to known bio-agent signatures.

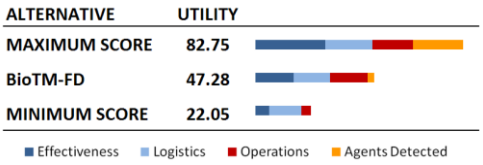
ANALYTICAL Laboratory Ranking

BioTM-FD ranked in the middle third of all evaluated products for analytical laboratories and earned 63% of the utility points of the best score.



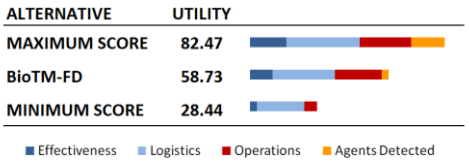
DIAGNOSTIC Laboratory Ranking

BioTM-FD ranked in the middle third of all evaluated products for diagnostic laboratories and earned 57% of the utility points of the best score.



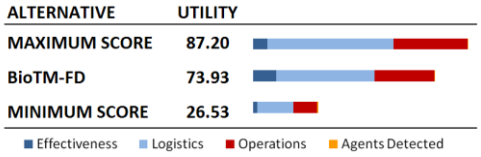
MOBILE Laboratory Ranking

BioTM-FD ranked in the middle third of all evaluated products for mobile laboratories and earned 71% of the utility points of the best score.



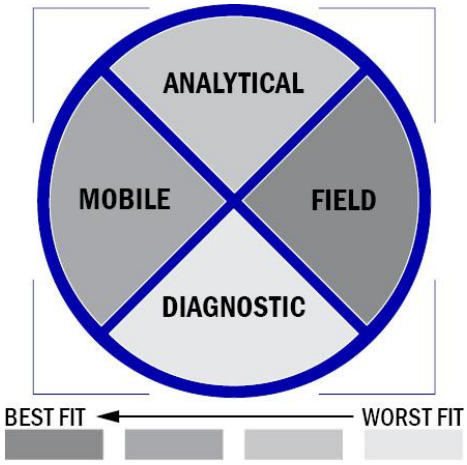
FIELD USE Ranking

BioTM-FD ranked in the top third of all evaluated products for field use and earned 85% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

BDST, Inc
1760 North Ranch Drive
Tucson, AZ 85715

Point of Contact:
Deward F. Manzer 520-971-1503
dmanzer@manzcorp.com

Airogistic, LLC
5204 Wheeler Branch Circle Ste 111L
Austin, TX 78701

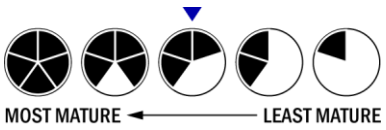
Point of Contact:
Jeff Michalski 512-743-3271
michalski@airogistic.com

COST

- $25,000.00 – 50,000.00/system or device

SPECIFICITY

- False Positives: 1 for 1000 hours of operation
- False Negatives: 1 for 1000 hours of operation



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- No screen
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- 5-10 minutes set-up
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 37°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size a toaster
- Transport via commercial carrier; tactical military wheeled and tracked vehicle; fixed wing military aircraft; ship
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- <5 minutes daily QA
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- 4-8 hours battery life
- Water requirements information not available
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Brass board
- Expected to be ready for commercialization within one calendar year
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is pending

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Wireless, wired connections
- Fully autonomous
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- Software open, modification requires licensing
- Hardware open, modification requires licensing

BIOWARD

by THALES Defense & Security

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

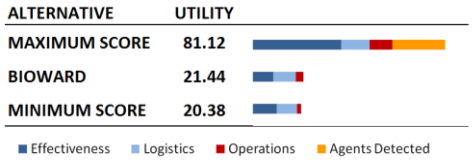
The BIOWARD is a portable aerosol dosimeter. It is designed to be carried by a non specialist soldier or a first responder all along his mission, even several days, to record a sample of the aerosols he is breathing. The device can be used for any kind a threat, be it biological, chemical or radiological, as long as it is present as aerosol.

TECHNOLOGY:

The BIOWARD use a filter sampling principal, with a flow rate mirroring human breath. it can achieve a operational autonomy of several days. the filter itself can be adapted to the threat.

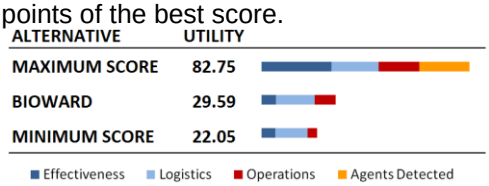
ANALYTICAL Laboratory Ranking

BIOWARD ranked in the bottom third of all evaluated products for analytical laboratories and earned 26% of the utility points of the best score.



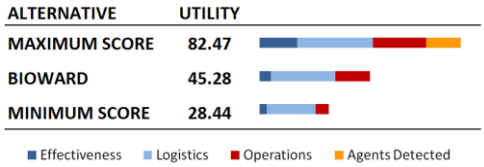
DIAGNOSTIC Laboratory Ranking

BIOWARD ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 36% of the utility points of the best score.



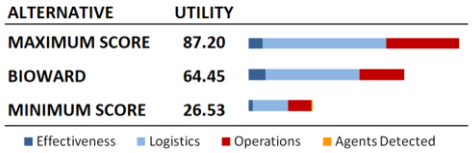
MOBILE Laboratory Ranking

BIOWARD ranked in the bottom third of all evaluated products for mobile laboratories and earned 55% of the utility points of the best score.



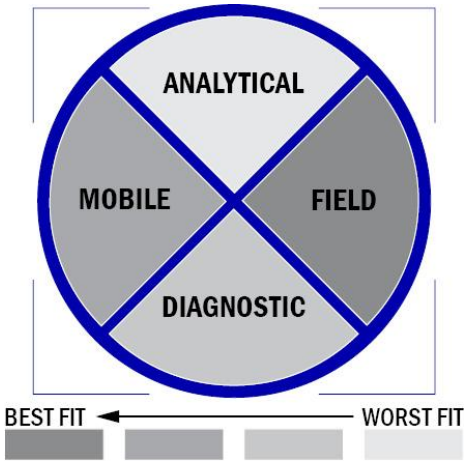
FIELD USE Ranking

BIOWARD ranked in the middle third of all evaluated products for field use and earned 74% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

THALES Defense & Security
C4I systems Division
20-22 rue Grange Dame Rose
CS 90519 78141

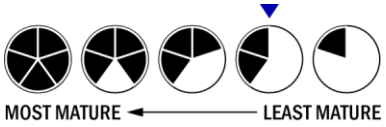
Point of Contact:
Jérôme LOUAT
jerome.louat@Thalesgroup.com

COST

- $2,000.00/system or device

SPECIFICITY

- False positives: Not applicable
- False negatives: Not applicable



Evaluation Criteria Provided by Vendor

Throughput of Product:
- Fully automated

Signature:
- Sounds or alarms can be deactivated
- No screen present
- Less than 200 BTU

Training and Speed:
- Very brief training and minimal technical skills
- No set up required
- < 1 minute down time
- Customer and manufacturer site training/ Hard-copy operators manual manuscript

Operational conditions:
- Can be used from < -21°C to > 41°C
- Components should be stored at room temperature but can withstand temperatures in excess of 45°C for periods of less than 24 hours
- Performance is not influenced by relative humidity
- > 3 years shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs <1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service < once per year
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 3-5 years
- No daily QA required

Physical System Requirements:
- Batteries
- Several days autonomy
- Does not require water
- External air or gas source is required
- External vacuum not required

Ease of Use:
- Real-time results not available
- No centrifugation steps are required
- No shaking or vortexing, mixing, degassing or filtering steps are required
- Software will not call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Does not test liquids

System Maturity:
- Only one incomplete device or system exist (bread board)
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- Not capable of transmitting data
- Fully autonomous
- No computational power needed
- The system does not contain internal memory for data storage or electronic record keeping
- The system does not employ any software
- The system hardware is closed and not available for modification

Blacklight (D1000)

by Thales Group

DETECTS THE FOLLOWING:

Demonstrated:
Aerosolized Chemical Agent (0.001-0.1 mg/mg^3)

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

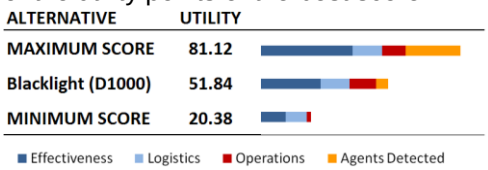
Blacklight is a man portable chemical sensor that can be rapidly mounted on to multiple platforms and/or networked as required. It allows first responders and military users to rapidly survey areas to identify and quantify industrial chemicals, warfare agents and novel threats. It is optimized for use in the field, although it can be used for monitoring within labs. It handles samples in the gas or suspended particle phase only, although liquid and solid samples can be processed using a headspace system.

TECHNOLOGY:

The system uses Differential Ultra Violet Absorption Spectroscopy in combination with an advanced signal processing routine to identify species. The species enter the system through an air inlet in to a cell to allow multiple passes through the air sample. The use of differentials rather than pure absorption allows simultaneous detection of multiple species, avoiding the usual masking. Infra-red and Combined UV-IR systems are also in development.

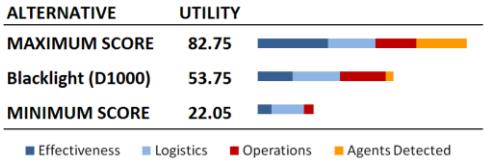
ANALYTICAL Laboratory Ranking

Blacklight (D1000) ranked in the middle third of all evaluated products for analytical laboratories and earned 64% of the utility points of the best score.



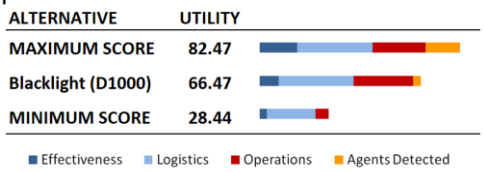
DIAGNOSTIC Laboratory Ranking

Blacklight (D1000) ranked in the middle third of all evaluated products for diagnostic laboratories and earned 65% of the utility points of the best score.



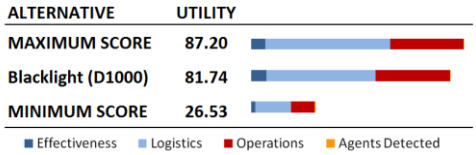
MOBILE Laboratory Ranking

Blacklight (D1000) ranked in the top third of all evaluated products for mobile laboratories and earned 81% of the utility points of the best score.



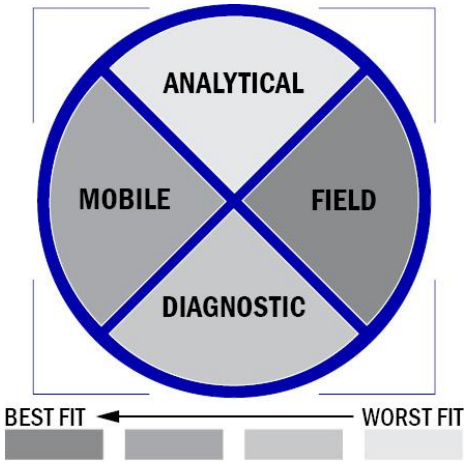
FIELD USE Ranking

Blacklight (D1000) ranked in the top third of all evaluated products for field use and earned 94% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Thales UK THALES,
Wookey Hole Road, Wells, Somerset,
BA5 1AA, United Kingdom
www.thalesgroup.com/uk

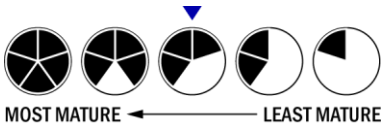
Point of Contact:
Thane Hall CBRN Business Lead
Tel: +44 (0)1749 682247.
Mob: +44 (0) 7971 679537.
thane.hall@uk.thalesgroup.com

COST

- $50,000.00/system or device

SPECIFICITY

- False Positives: <5%
- False Negatives: <5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- < 5 minutes set up
- Almost instantaneous down time
- 0-2 steps are required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from <-21°C to >42°C
- No consumable
- Performance is not influenced by relative humidity
- No consumable

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents

Maintenance:
- Once a year
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 5-10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Batteries
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance N/A
- FDA approval N/A
- Liquids not tested

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Satellite, wireless and wired connections
- Autonomous system
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

BoTest Botulinum Neurotoxin (BoNT) Detection Assays

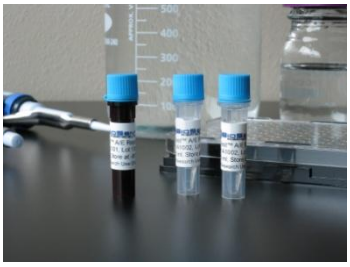
by BioSentinel

DETECTS THE FOLLOWING:

Demonstrated:
Toxins (Less than 1 ng/ml)

DETECTION MATRICES:

Demonstrated:
Blood, Environmental water, Food



DESCRIPTION:

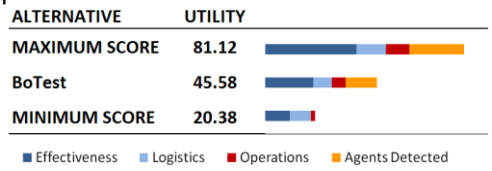
BioSentinel's BoTest™ Botulinum Neurotoxin (BoNT) Detection Assays offer the most sensitive system available for the routine detection of BoNT serotypes A and E (BoTest™ A/E); and serotypes B, D, F, and G (BoTest™ B/D/F/G). Intended uses include high throughput drug discovery; food, environmental, and water testing; and research. The assay detects and quantifies the activity of BoNT. In addition, the BoTest Matrix A assay can be used to detect botulinum activity in complex matrices.

TECHNOLOGY:

The BoTest™ Assays utilize fluorescent reporters that give a ratiometric response when specifically cleaved by BoNT. The assay is run in a mix-and-read, 96 – 1536-well plate format. The reporter uses native BoNT substrates for improved enzyme binding and sensitivity and can be coupled to antibody-conjugated magnetic beads to allow for the detection of BoNT in complex matrices. The assays provide up to a 300-fold increase in sensitivity for BoNT activity compared to other commercially available assays. The assays are provided in kits to ensure reagent consistency and reliability.

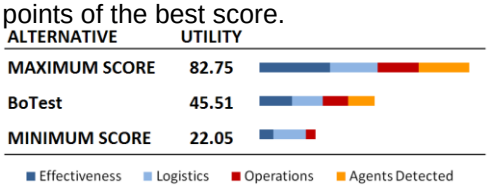
ANALYTICAL Laboratory Ranking

BoNT ranked in the middle third of all evaluated products for analytical laboratories and earned 56% of the utility points of the best score.



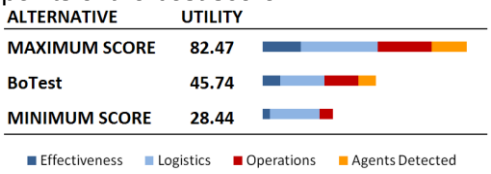
DIAGNOSTIC Laboratory Ranking

BoNT ranked in the middle third of all evaluated products for diagnostic laboratories and earned 55% of the utility points of the best score.



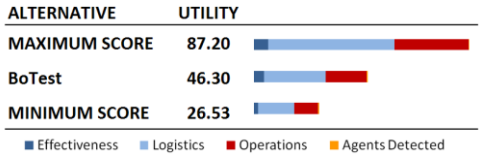
MOBILE Laboratory Ranking

BoNT ranked in the bottom third of all evaluated products for mobile laboratories and earned 55% of the utility points of the best score.



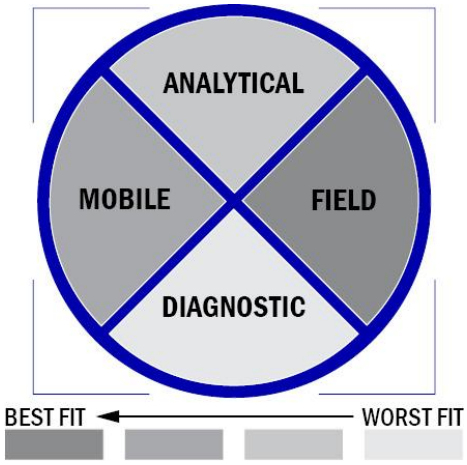
FIELD USE Ranking

BoNT ranked in the bottom third of all evaluated products for field use and earned 53% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

510 Charmany Drive
Madison, WI 53711

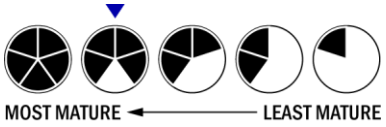
Point of Contact:
Ward Tucker
608.441.8174
866.807.0324

COST

- $395.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1 - 8 hours for detection
- Multiple samples, single tests/ sample per run
- Could easily be adapted into a fully automated system

Signature:
- Sounds or alarms not present
- No screen
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- >20 minutes set-up required
- Almost instantaneous down time
- 3-5 steps required
- Customer and manufacturer site training/ Hard copy and web-based operators manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be frozen at temps at or below -20°C (cryo-storage)
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of carry-on luggage
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 3 solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Requires water aliquots
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- Single centrifugation steps
- Multiple shaking or vortexing, mixing, degassing or filtering steps
- System will not call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Not network capable
- Wired connections
- Could be fully autonomous with significant effort
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- Software open, modification requires licensing
- Hardware open, modification requires licensing

BUILDING SENTRY ONE (BSO)

by BPSI

DETECTS THE FOLLOWING:

Demonstrated:
Toxins
Aerosolized chemical agent (0.000001-0.00003 mg/m3)

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

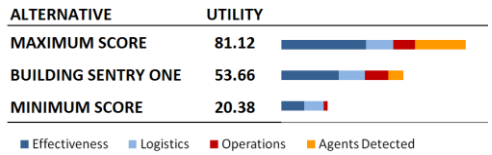
The Building Sentry One (BSO) is U.S. Department of Homeland Security SAFETY Act Designated technology installed to monitor terrorist concerns of a Commercial Office Building, Campus Complex or Stadium Environment. The BSO monitors both directly and remotely, airborne toxins in the fresh and return air supplies, lobbies and loading dock environments. If a toxin is detected, the BSO enacts a sequence of predetermined alerts and mechanical protocols to isolate toxins thus preventing continued distribution to prevent loss of life, preserve assets, and to provide an early warning system for first responders in the event of a targeted terrorist attack using chemical, radiological or biological (CBRN) materials or an accidental release. The BSO is installed as an all-in-one full backbone system and can integrate directly into an existing Building Management System (BMS) or security command center. The BSO detects a defined spectrum of chemical contaminants, a wide library of radiological isotopes and select biological agents with sensitivity levels customized for each specific toxin. The BSO has been designed in modular fashion to support continued advances in chemical, radiological and biological sensory technology, with a "Plug and Play" overlay into the Sentry One network. No known similar systems exist. The Building Sentry One is a fully functioning "Next Generation" detection backbone system that integrates sensory technology into just about any market ready project. With embedded controls, logic, software, mechanical protocols and remote monitoring coupled with multiple security means, this system is designed to operate 24/7/365 in the absence of false positive readings.

TECHNOLOGY:

BPSI's BSO is a COTS based system that detects a defined spectrum of toxic compounds, a 120+ library of radiological isotopes and select biological agents in a building's HVAC system on a continuous 24/7/365 basis with virtually zero false positive alarms. Through the integration of programmable logic controllers and sensor arrays, linked to a PC infrastructure with multi-layer communications protocols, the Building Sentry One solution offers a dynamic set of customized security measures. The BSO's backbone architecture mesh simply and easily with existing systems, in a seamless process that gives the end user virtually unlimited options for protection.

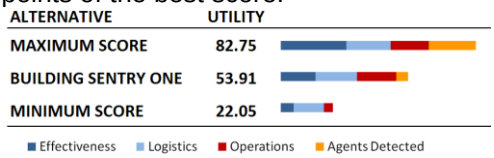
ANALYTICAL Laboratory Ranking

BSO ranked in the top third of all evaluated products for analytical laboratories and earned 66% of the utility points of the best score.



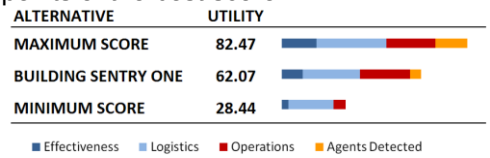
DIAGNOSTIC Laboratory Ranking

BSO ranked in the middle third of all evaluated products for diagnostic laboratories and earned 65% of the utility points of the best score.



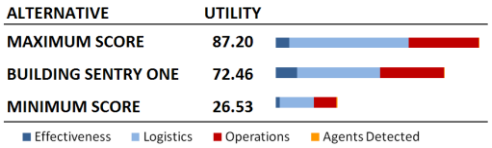
MOBILE Laboratory Ranking

BSO ranked in the top third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.



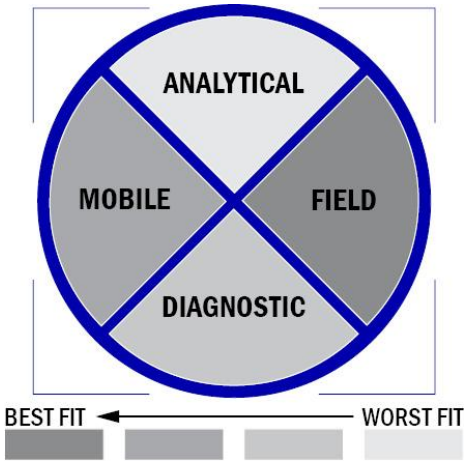
FIELD USE Ranking

BSO ranked in the top third of all evaluated products for field use and earned 83% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

BPSI
150 Post Street, Suite 750
San Francisco, CA 94108

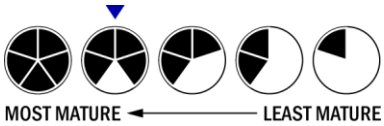
Point of Contact:
Greg Eiler
925-933-8600
geiler@bpsiglobal.com

COST

- $288,000.00/system or device

SPECIFICITY

- False Positives: .00005
- False Negatives: .000025



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- DVD/ Web video/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life >10 years
- No daily QA required
- Decontamination not applicable

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Water requirement information not available
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- Raw data information not available
- Network capable
- Wired connections
- Fully autonomous
- Basic desktop computer
- Stores and archives data outputs and creates an electronic record
- System software is open and available for modification
- System hardware is open and available for modification

C1000™ Thermal Cycler

by Bio-Rad Laboratories

DETECTS THE FOLLOWING:
Nothing demonstrated.

DETECTION MATRICES:
Nothing demonstrated.

DESCRIPTION:
This product is designed for laboratory analysis. This product amplifies DNA or cDNA extracted from any sample.

TECHNOLOGY:
This is a peltier-based system which amplifies DNA.

ANALYTICAL Laboratory Ranking

C1000™ Thermal Cycler ranked in the bottom third of all evaluated products for analytical laboratories and earned 37% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
C1000TM Thermal Cycler	29.85
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

C1000™ Thermal Cycler ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 37% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
C1000TM Thermal Cycler	30.96
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

C1000™ Thermal Cycler ranked in the bottom third of all evaluated products for mobile laboratories and earned 44% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
C1000TM Thermal Cycler	35.97
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

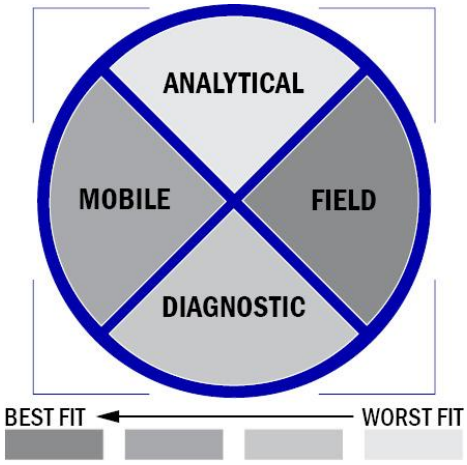
C1000™ Thermal Cycler ranked in the bottom third of all evaluated products for field use and earned 47% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
C1000TM Thermal Cycler	40.65
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Bio-Rad Laboratories
2000 Alfred Nobel Dr.
Hercules, CA 94547

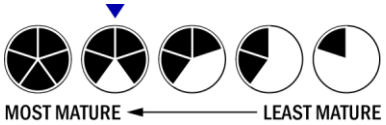
Point of Contact:
Pete Skirpstunas
510-741-4434

COST

- $8,000.00 - 8,700.00/system or device

SPECIFICITY

- False Positives: Assay dependent
- False Negatives: Assay dependent



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30- 60 minutes for detection
- # of tests depends on # of primer sets used per sample and between samples
- Could be semi-automated system with some effort

Signature:
- Sounds or alarms present
- Screen cannot be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- < 5 minutes set-up
- Almost instantaneous down time
- 3-5 steps required
- Customer site training/ Hard-copy and web manual

Operational conditions:
- Used from 25°C to 37°C
- Temp storage information not available
- Peak performance at normal relative humidity
- Shelf life information not available

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data processing while in progress information not available
- Single centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering steps
- System does not call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 50 ul to test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- No data generated
- Network capable
- Wired connection
- Not autonomous
- Laptop computer
- Does not store or archive data outputs but will create electronic record
- System software closed and not available for modification
- System hardware closed and not available for modification

Caliper LabChip GXII

by Microfluidics Caliper Life Sciences

DETECTS THE FOLLOWING:

Demonstrated:
Viruses
Toxins

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wounds

DESCRIPTION:

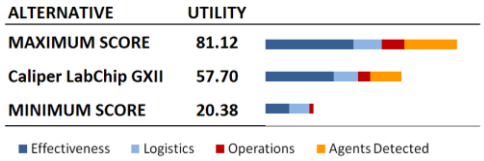
The LabChip GXII is a complete solution for consistent and precise analysis of protein, DNA, or RNA samples, and is an ideal instrument for protein research users. Whether it is quantitating monoclonal antibody titers, optimizing protein expression conditions, or rapidly screening IgG N-glycan profiles, the LabChip GXII is the perfect benchtop tool to accelerate your research and meet your goals. Leveraging microfluidics technology the LabChip GXII eliminates the need to handle time consuming SDS page gels, and provides superior results for less time and money.

TECHNOLOGY:

Electrophoretic separations of Protein, DNA, or RNA utilizing laser-induced fluorescence in a microfluidic channel.

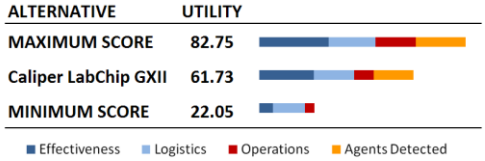
ANALYTICAL Laboratory Ranking

Caliper LabChip GXII ranked in the top third of all evaluated products for analytical laboratories and earned 55% of the utility points of the best score.



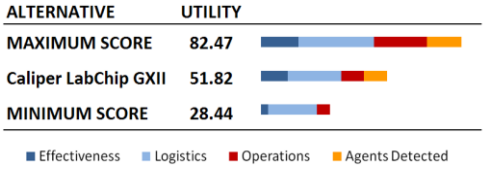
DIAGNOSTIC Laboratory Ranking

Caliper LabChip GXII ranked in the top third of all evaluated products for diagnostic laboratories and earned 63% of the utility points of the best score.



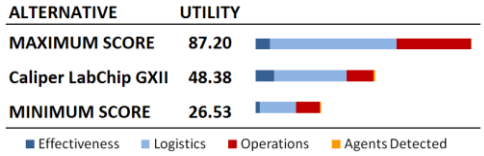
MOBILE Laboratory Ranking

Caliper LabChip GXII ranked in the middle third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.



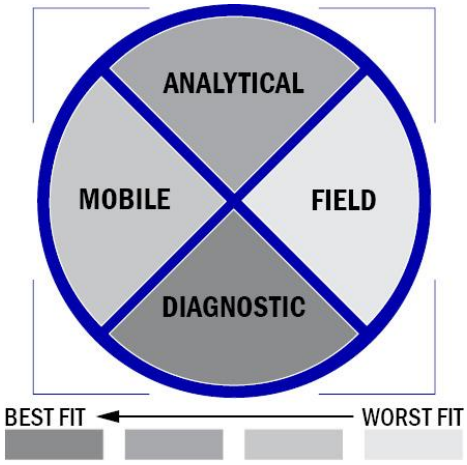
FIELD USE Ranking

Caliper LabChip GXII ranked in the bottom third of all evaluated products for field use and earned 71% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Microfluidics Caliper Life Sciences
68 Elm St
Hopkinton, MA 01748

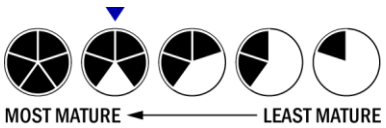
Point of Contact:
Richard P. Bunch
508-497-2237

COST

- $52,500.00 (GX for nucleic acids)
- $109,500.00 (GXII for nucleic acids and protein)

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- 5-10 minutes set-up required
- Almost instantaneous down time
- 0-2 steps required
- DVD/ Customer and manufacturer site training/ Web-based operators manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components should frozen but can stand temps >4°C for <24 hours/ Must be at room temp (27°C)/ Must be stored at 4°C
- Peak performance at normal relative humidity conditions
- 1 to 6 months shelf life

Transportation:
- Approximately the size of a carry-on luggage
- All modes of transportation
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 3 solutions and/or reagents
- 3 components

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by technician only
- Maintenance included
- Expected life 5-10 years
- 5-10 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- Single centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering steps
- System could call final result in the future

Sensitivity and Detection:
- 510K clearance pending
- FDA clearance capable
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connections
- Not autonomous
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software is closed and not available for modification
- System hardware is closed and not available for modification

CALS (Chemical Agent Line Sensor)

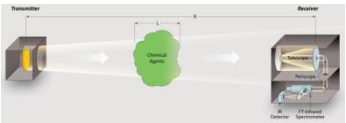
by Lincoln Laboratories

DETECTS THE FOLLOWING:

Demonstrated:
Aerosolized chemical agent

DETECTION MATRICES:

Demonstrated:
Environmental air



DESCRIPTION:

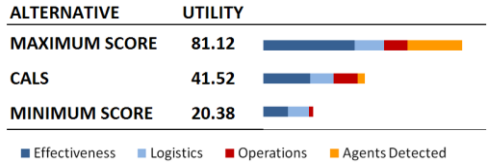
The Chemical Agent Line Sensor (CALS) detects and identifies releases of chemical warfare agents (CWAs) and toxic industrial agents (TICs) over a line path. The system can be used by several types of large open-volume facilities to determine whether a covert chemical release is occurring. It was specifically designed for low maintenance, no consumables, low cost, rapid deployment, and high detection performance to fit a wide array of facility constraints.

TECHNOLOGY:

The CALS system is an open path Fourier Transform Infrared (FTIR) chemical sensor. The system transmits Long Wave Infrared (LWIR) energy from a filament to a spectrometer spatially partitioned from the transmitter. The amount of absorbance at each wavelength is measured and used to identify the amount and type of agent present between the transmitter and receiver.

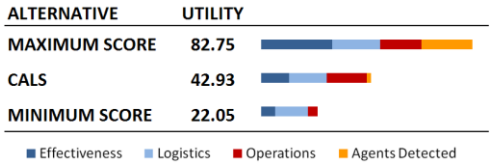
ANALYTICAL Laboratory Ranking

CALS ranked in the bottom third of all evaluated products for analytical laboratories and earned 51% of the utility points of the best score.



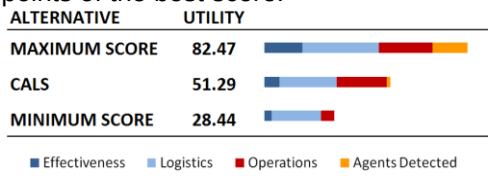
DIAGNOSTIC Laboratory Ranking

CALS ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 52% of the utility points of the best score.



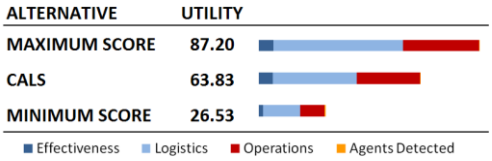
MOBILE Laboratory Ranking

CALS ranked in the middle third of all evaluated products for mobile laboratories and earned 62% of the utility points of the best score.



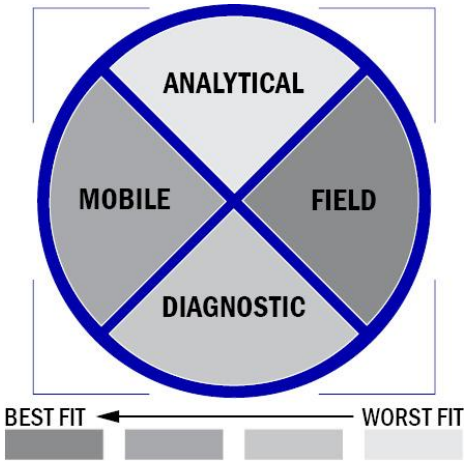
FIELD USE Ranking

CALS ranked in the middle third of all evaluated products for field use and earned 73% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

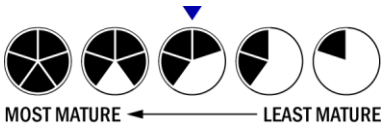
Point of Contact:
Benjamin L. Ervin, Ph.D.
Office: (781) 981-5124
Email: ben.ervin@LL.mit.edu
Address: 244 Wood Street, Lexington, MA 02420

COST

- $70,000.00/system or device
- $0.00/analysis

SPECIFICITY

- False Positives: Not Available
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, single tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Thermal output unknown

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- 10-20 minutes set up
- < 1 minute down time
- 0-2 steps are required
- Manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from <-21°C to >42°C
- Consumables not required
- Relative humidity influence unknown
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means of transportation
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- No consumables

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician
- Maintenance is not included
- Expected life greater than 10 years
- No QA required

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Liquids not tested

System Maturity:
- Brass board
- Has not appeared in peer reviewed publication or independent evaluation
- No technology ownership and intellectual property involved

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Satellite, wireless and wired connections
- Autonomous system
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

Capsenze Analyzer

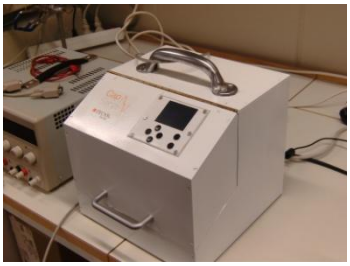
by Capsenze AB

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)
Toxins (<1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Environmental water, Insect vectors



DESCRIPTION:

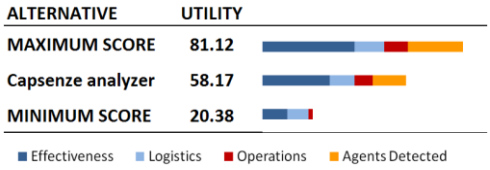
The sensor system is based on capacitive measurements. On the surface of the sensor is attached the recognition element. When a target molecule binds, a capacitance signal will be registered. We have analyzed bacterial toxins, vial capsid proteins, viruses, bacteria, various proteins etc. with a general detection limit of 10-17 moles per litre.

TECHNOLOGY:

The assaying principle is simple and no labeled compounds are required. An electrode surface made from high-purity gold is covered by an insulating layer of alkylthiols that have been functionalized by attaching terminal amino or carboxyl groups. Receptor molecules are then covalently bound to these groups to form an affinity surface, i.e. a biosensor transducer. With flow-injection analysis, the capacitance of the sensing surface is measured under certain conditions. When target molecules bind to the receptor, a subtle displacement of counter ions that form around the capacitive electrode takes place and the continuously measured capacitance signal decreases. In addition, the more target molecules that bind to the affinity layer, the more displacement is achieved, and a lower capacitance signal results. The decrease in measured capacitance can be correlated to the concentration target molecules near the transducer surface by comparing it to a calibration curve generated from control samples containing known target concentrations.

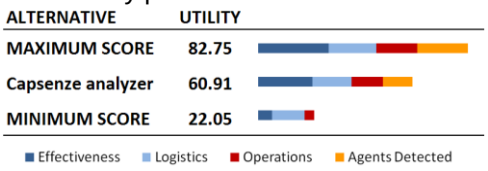
ANALYTICAL Laboratory Ranking

Capsenze Analyzer ranked in the top third of all evaluated products for analytical laboratories and earned 72% of the utility points of the best score.



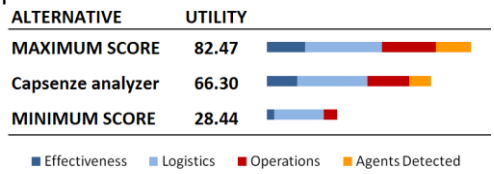
DIAGNOSTIC Laboratory Ranking

Capsenze Analyzer ranked in the top third of all evaluated products for diagnostic laboratories and earned 74% of the utility points of the best score.



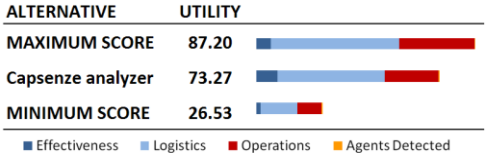
MOBILE Laboratory Ranking

Capsenze Analyzer ranked in the top third of all evaluated products for mobile laboratories and earned 80% of the utility points of the best score.



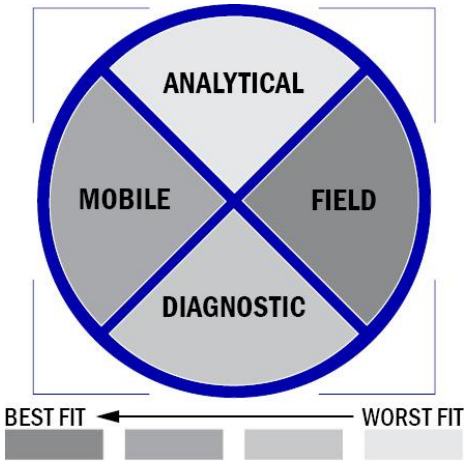
FIELD USE Ranking

Capsenze Analyzer ranked in the top third of all evaluated products for field use and earned 84% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

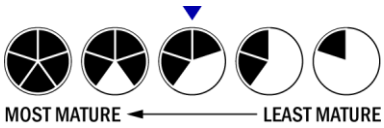
Capsenze AB

COST

- $25,000/system or device
- $10/analysis

SPECIFICITY

- False positives: Not available
- False negatives: Not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- 1 sample, single test/ sample per run
- Could easily be adapted into a fully automated system

Signature:
- Sounds or alarms can be deactivated
- Screen can be dimmed or turned off
- <200 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills are required
- 5-10 minutes set up
- <1 minute down-time
- 0-2 steps are required
- Customer and manufacturer site training/ Hard copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components must be stored at room temperature (27°C)
- Performance is not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a toaster
- Transport via tactical military wheeled and tracked vehicle
- Weighs 5-25 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance is not included
- Expected life 5-10 years
- 10-20 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 220V electrical requirement
- 4-8 hours battery life
- Requires water aliquots
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps are required
- Single shaking or vortexing, mixing, degassing or filtering step is required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval pending
- Less than 100 ul for a test

System Maturity:
- A few devices or systems exist (brass board)
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB
- Network capable
- Satellite, wireless and wired connections
- Fully autonomous
- On board computer chip in the system
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is open but modification requires licensing

Carbon14 Air Monitor

by Technical Associates

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types

DETECTION MATRICES:

Demonstrated:
Environmental Air

DESCRIPTION:

The Carbon14 Air Monitor is a sensitive, rugged, and portable instrument for detection and measurement of airborne C14. It is line operated with nominal 20 hour battery back-up. Optional inlet and outlet hoses allow monitoring interiors of fume hoods, exhaust stacks, etc. Features include: user settable units - uci/l or bq/m3 etc; wide range - digital accuracy; programmable digital readout; sensitive for occupational exposure dynamic background compensation; battery operation or ac operation; built-in high level alarm; built-in low flow alarm; built-in RS-232 computer interface. End Users: nuclear power plants, coal fired power plants, pharmaceutical labs, universities.

TECHNOLOGY:

The Carbon14 Air Monitor subtractive balanced chamber electrometer circuit decreases background effects to negligible levels and its deionized and filtered intake minimizes spurious effects from smoke, dust and existing ionization in the air. It will measure airborne C14 as CO2. gas or as volatile chemicals in concentrations as low as 1 x 10-4 uCi/l of air (3.7KBq/m3). Electrometer circuit amplifies net difference between 0.7 liter tritium internal chamber sealed background chamber of similar configuration. Battery Check, Set (calibration aid), Zero Adjust, Meter Programming. Internal or external calibration options.

ANALYTICAL Laboratory Ranking

Carbon14 Air Monitor ranked in the middle third of all evaluated products for analytical laboratories and earned 58% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
Carbon14 Air Monitor	46.67
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

Carbon14 Air Monitor ranked in the middle third of all evaluated products for diagnostic laboratories and earned 63% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
Carbon14 Air Monitor	52.06
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

Carbon14 Air Monitor ranked in the top third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
Carbon14 Air Monitor	61.80
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

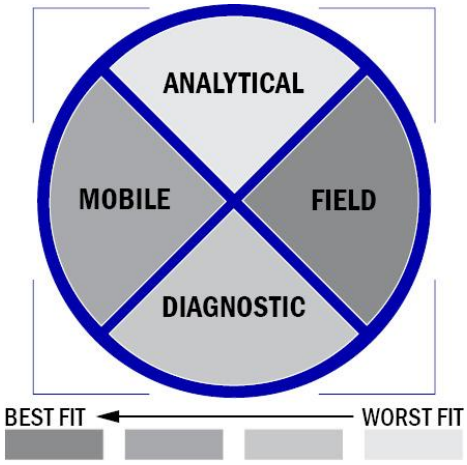
Carbon14 Air Monitor ranked in the top third of all evaluated products for field use and earned 88% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
Carbon14 Air Monitor	76.62
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Technical Associates
7051 Eton Ave.
Canoga Park, CA 91303

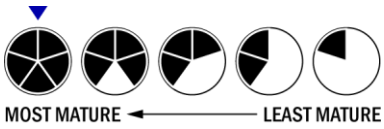
POC: Robert Goldstein
818-883-7043

COST

- $7,950.00/system or device

SPECIFICITY

- False Positives: <1:10,000
- False Negatives: <1:1,000



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, >10 tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 4°C to 41°C
- Consumables not required
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life >10 years
- <5 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System does not call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Does not test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connections
- Fully autonomous
- No computer required
- Stores and archives data outputs but not create an electronic record
- System does not employ software
- System hardware open and available for modification

CARD™ Device

by Rheonix, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Environmental water, Food

DESCRIPTION:

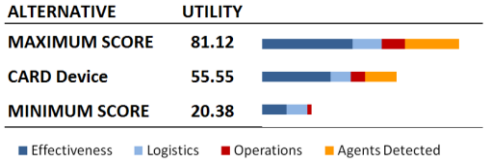
The Rheonix CARD™ device and EncompassMDx™ instrumentation system were developed to perform fully automated molecular and/or immunoassays. The unique design of the Rheonix CARD™ device allows up to four assays to be simultaneously run on a single disposable device. The Rheonix CARD™ contains all microfluidic channels, reservoirs, pumps, and valves required to perform sophisticated molecular analysis and/or immunoassays at the push of a button. Under the control of our intuitive Encompass MDx™ software, all assay steps are performed automatically once the "raw" sample is applied. No preanalytical steps are required. Due to the ability to perform sophisticated molecular and/or immunoassays without any user intervention, the Rheonix CARD™ platform is well suited for a broad spectrum of applications in either "point-of-care" or central laboratory settings. Thus far, "raw" clinical samples including whole blood, serum plasma, buccal swabs, vaginal swabs and saliva have been successfully tested. Some of the assays that have already been developed include a 20-plex PCR assay that can detect and distinguish 20 clinically relevant HPV subtypes in vaginal swabs and a simultaneous immunoassay/PCR-based assay for the direct detection of HIV-1 in human saliva samples. Other assays currently under development include multiplex PCR assays for the detection of sexually transmitted infections, sepsis detection directly from whole blood, EPA-funded efforts to detect Cryptosporidium parvum in drinking water and NSF-funded efforts to detect E. coli and various enterococci in recreational water samples.

TECHNOLOGY:

Our proprietary and patented lamination process permits us to produce a low cost, plastic CARD™ (Chemistry and Reagent Device) that contains all functionality required to perform automated molecular and/or immunoassays. The portable EncompassMDx™ controller processes one CARD™ and the EncompassMDx™ workstation processes up to six CARD™ devices per run. In either case, once a raw specimen is introduced into the CARD™ all steps are automatically performed under software control: cell lysis, DNA isolation/ purification, multiple-PCR, endpoint detection via an integrated reverse dot blot, and finally output of results. Where necessary, we can also magnetically concentrate either cells or nucleic acids.

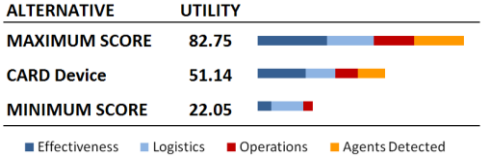
ANALYTICAL Laboratory Ranking

CARD Device ranked in the top third of all evaluated products for analytical laboratories and earned 68% of the utility points of the best score.



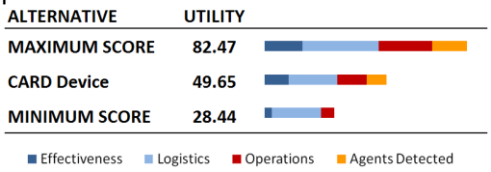
DIAGNOSTIC Laboratory Ranking

CARD Device ranked in the middle third of all evaluated products for diagnostic laboratories and earned 62% of the utility points of the best score.



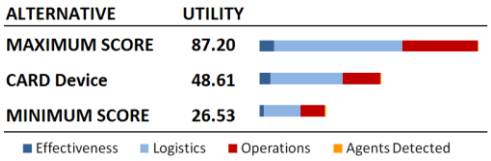
MOBILE Laboratory Ranking

CARD Device ranked in the bottom third of all evaluated products for mobile laboratories and earned 60% of the utility points of the best score.



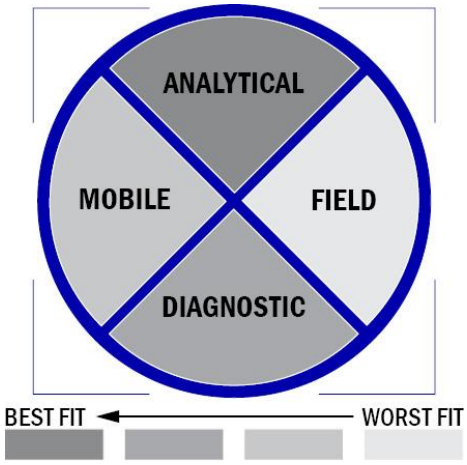
FIELD USE Ranking

CARD Device ranked in the bottom third of all evaluated products for field use and earned 56% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Rheonix, Inc.
22 Thornwood Drive
Ithaca, NY 14850

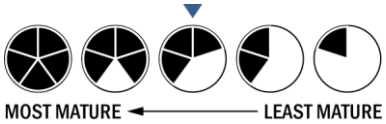
Point of Contact:
Tony Eisenhut, President
Phone: 607-257-1242, Ext 160
Email: Teisenhut@rheonix.com

COST

- Portable Encompass™ Controller: $ 7,500
- Bench top Encompass™ Workstation: $ 47,500
- $50.00/test

SPECIFICITY

- False Positives: <1%
- False Negatives: <1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- No sounds or alarms
- There is no screen
- Between 200-500 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- Less than 5 minutes for set up
- 3-5 minutes down time
- 0-2 steps are required
- Web video/ Customer and manufacturer site training/ Hard copy manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at room temp (27°C)/ Must be stored at 4°C
- Performance is not influenced by relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means on transportation
- Weighs between 5 and 25 kg

Re-use:
- Single use detection assay
- >5 solutions, buffer, and/or reagents
- 4 components

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by customer
- Maintenance not included
- System life not applicable
- 5-10 minutes QA required
- The device is single use and disposable so decontamination not needed

Physical System Requirements:
- 110V electrical requirement
- 2-4 hours battery use
- Does not require water
- External air or gas source is required
- External vacuum is required

Ease of Use:
- Real-time results not available
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering step required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 10 ul for a test

System Maturity:
- Brass board
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Satellite and wired connections
- Fully autonomous system
- Laptop computer
- Automatically stores and archives data outputs does not create an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

CBDS (Chemical-Biological Detection System)

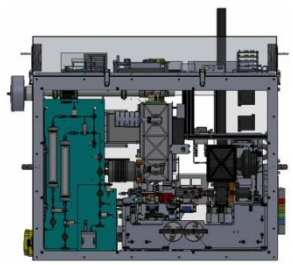
by Science & Engineering Services, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e3-10e4 CFU/mL)
Viruses (10e3-10e4 PFU/mL)
Toxins (1-100 ng/ml)
Aerosolized chemical agent (0.0001 – 0.001 mg/m3)
Liquid chemical agent (1 ppb – 1 ppm)

DETECTION MATRICES:

Nothing demonstrated.



DESCRIPTION:

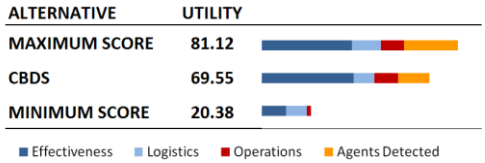
The Chemical-Biological Detection System (CBDS) is sized and designed to deliver next generation capabilities beyond the current CBMS Block II. CBDS utilizes an integrated mass analyzer for analysis and identification of CWA, TIC and BWA materials; with collection of CWA, TIC and BWA hazards accomplished via air-stack as well as collection of CWA and TIC hazards via ground probe and/or direct injection. A key attribute of CBDS is the ability to create and transfer library updates of new hazards and/or unknowns within a few hours. In terms of logistics, the consumables cost per sample is less than one dollar and train-up for non-technical users is one day.

TECHNOLOGY:

The Chemical-Biological Detection System (CBDS) uses a hexapole ion-trap mass spectrometer in which MS/MS is conducted either via AP-MALDI of biological samples or via chemical ionization of chemical samples. Biological materials undergo automated single-spot proteomic processing and MS/MS targeted bio-marker analysis to sift rapidly thru clutter against specialized-onboard and/or commercial internet-accessible databases. Chemical materials undergo similar steps, less single-spot proteomics processing.

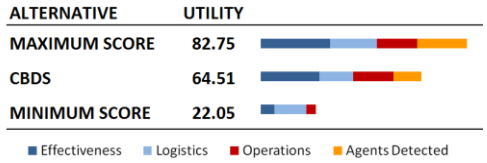
ANALYTICAL Laboratory Ranking

CBDS ranked in the top third of all evaluated products for analytical laboratories and earned 86% of the utility points of the best score.



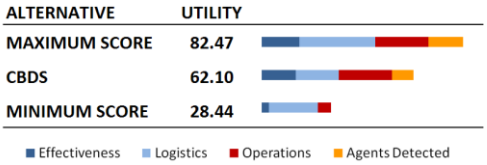
DIAGNOSTIC Laboratory Ranking

CBDS ranked in the top third of all evaluated products for diagnostic laboratories and earned 78% of the utility points of the best score.



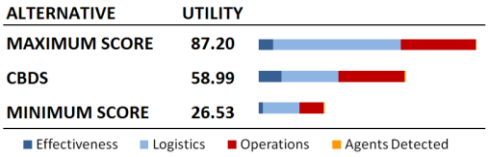
MOBILE Laboratory Ranking

CBDS ranked in the top third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.



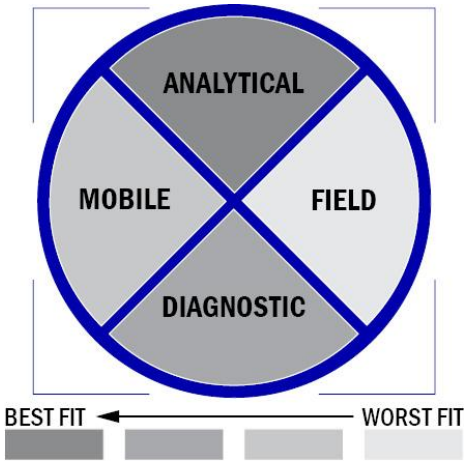
FIELD USE Ranking

CBDS ranked in the middle third of all evaluated products for field use and earned 68% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Science & Engineering Services, Inc.
6992 Columbia Gateway Drive
Columbia, Maryland 21046

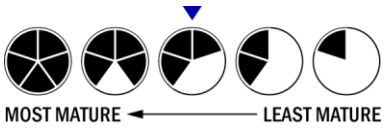
Point of Contact:
Robert M. Serino, Ph.D.
443.539.0139

COST

- $350,000.00/system or device

SPECIFICITY

- False Positives: 1%
- False Negatives: 1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 10-20 minutes set-up
- 1-3 minutes down time
- 0-2 steps required
- Customer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components must be stored at 4°C
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a home dishwasher
- Transport via tactical military wheeled and tracked vehicle
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 3 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance capable
- Less than 10 ul to test liquids

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless and wired connections
- Fully autonomous
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software open and available for modification
- System hardware open and available for modification

CBMS/CBDS (Chemical Biological Mass Spectrometer/Chemical Biological Detection System)

by Hamilton Sundstrand Corporation

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria
Viruses
Toxins
Liquid chemical agent

DETECTION MATRICES:

Demonstrated:
Environmental Air

DESCRIPTION:

The CBMS is a mass spectrometer for the detection of liquid Chemical Warfare Agents (CWAs) on the ground from a moving military reconnaissance vehicle via a ground sampling system. The CBDS version adds an air sampler and pyrolysis module to enable the detection of Biological Warfare Agents (BWAs) via an air intake. In either mode, the system operates continuously and autonomously, reporting alarms both on a display screen and electronically.

TECHNOLOGY:

CWA detection employs direct ion trap mass spectrometric analysis of the vapor molecules. BWA detection concentrates aerosols during a collection period and pyrolyzes the accumulated material, then the composite mass spectrum is analyzed for patterns indicating the presence of target BWAs.

ANALYTICAL Laboratory Ranking

CBMS/CBDS ranked in the middle third of all evaluated products for analytical laboratories and earned 58% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
CBMS/CBDS	47.43
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

CBMS/CBDS ranked in the middle third of all evaluated products for diagnostic laboratories and earned 55% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
CBMS/CBDS	45.21
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

CBMS/CBDS ranked in the bottom third of all evaluated products for mobile laboratories and earned 62% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
CBMS/CBDS	50.90
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

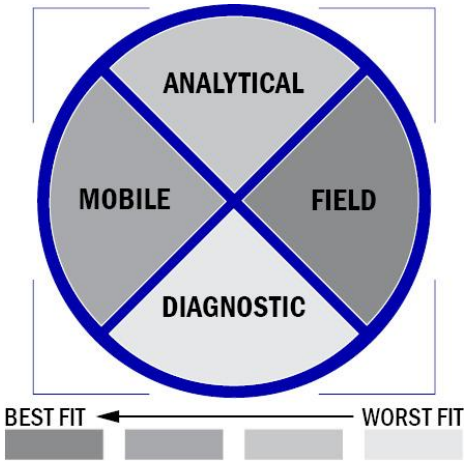
CBMS/CBDS ranked in the middle third of all evaluated products for field use and earned 66% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
CBMS/CBDS	57.36
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Hamilton Sundstrand Corporation
2771 N. Garey Avenue
Pomona, CA 91767

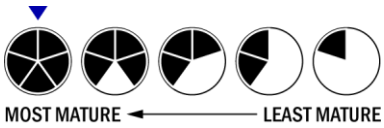
Point of Contact:
Gary R. Stewart
(909) 593-3581 Ext. 4499

COST

- $160,000.00-240,000.00/system or device
- $0.10/analysis

SPECIFICITY

- False Positives: Not Available
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- More than a day of training and significant skills are required
- >20 minutes set up
- Almost instantaneous down time
- 0-2 steps are required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from <-21°C to >42°C
- Components should be stored at room temp but can withstand temps > 45°C for periods of less than 24 hours
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a home dishwasher
- All means of transportation
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 3 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by technician
- Maintenance is not included
- Expected life > 10 years
- 5-10 minutes QA required
- Exposure to hazardous agent would require up to 1 day to decontaminate

Physical System Requirements:
- Multiple outlets or a dedicated circuit breaker
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can not be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance N/A
- FDA approval N/A
- Less than 10 ul for a test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Autonomous system
- No computational power
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

CBRN Water Purity Monitor

by Technical Associates

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria
Viruses
Toxins
Discrimination of radiation types
Identification of specific isotopes

DETECTION MATRICES:

Demonstrated:
Environmental water

DESCRIPTION:

The CBRN Water Purity Monitor is a state of the art integrated chemical, biological, & radiation continuous real-time water monitoring system. It combines several detection goals in one continuous, real-time, on-line monitor. • 7 Major Chemical Tests • Detects Alpha, Beta, Gamma, Tritium, Radon, Radium. • Detects More Than 12 Microbes • Customer Controlled Alarm Threshold • Calibration Can be Customized for Specific Contaminants • SCADA compatible • Remote Control & Communications The CBRN Water Purity Monitor is a multi detector water monitor /controller for simultaneous measuring of alpha, beta and gamma-emitting radio nuclides, chemical and biological contaminants. Color LCD display. The pre-amps are plug in modules for easy maintenance. Additional monitoring is avail-able tailored to specific needs upon request. Measurements are logged 24 hr/day - 7 day/week, with alarm capability and a universal read out adaptable to mainframe infrastructure computers. • Monitor drinking water for all radioactive contaminants. • Monitor for contamination in ground or surface water. • Monitor liquid-waste-stream from laboratory or plant. • Measures at or below EPA/DHS/PAG levels. • Protective action guideline levels and military drinking water limits. • Real time, in-line, continuous. • Detects alphas, betas and gammas. • No reagent tanks to fill. • No waste stream. • Easy calibration. End Users: • Military and Civilian • Ground and Surface Drinking Water and Wastewater • Reservoirs • High Profile Buildings: Convention Centers, Sports Arenas, Government Establishments • Industrial Contaminates: Laboratory, Power Plant, Agricultural • Residual Treatment Additives • Hospitals and Schools.

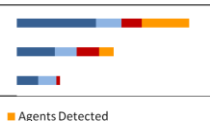
TECHNOLOGY:

Not Available

ANALYTICAL Laboratory Ranking

CBRN Water Purity Monitor ranked in the middle third of all evaluated products for analytical laboratories and earned 56% of the utility points of the best score.

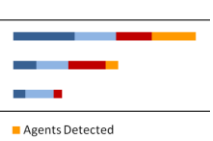
ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
CBRN Water Purity Monitor	45.76
MINIMUM SCORE	20.38



DIAGNOSTIC Laboratory Ranking

CBRN Water Purity Monitor ranked in the middle third of all evaluated products for diagnostic laboratories and earned 58% of the utility points of the best score.

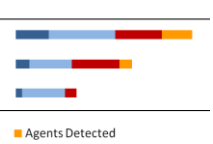
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
CBRN Water Purity Monitor	47.66
MINIMUM SCORE	22.05



MOBILE Laboratory Ranking

CBRN Water Purity Monitor ranked in the middle third of all evaluated products for mobile laboratories and earned 66% of the utility points of the best score.

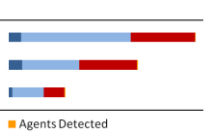
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
CBRN Water Purity Monitor	54.29
MINIMUM SCORE	28.44



FIELD USE Ranking

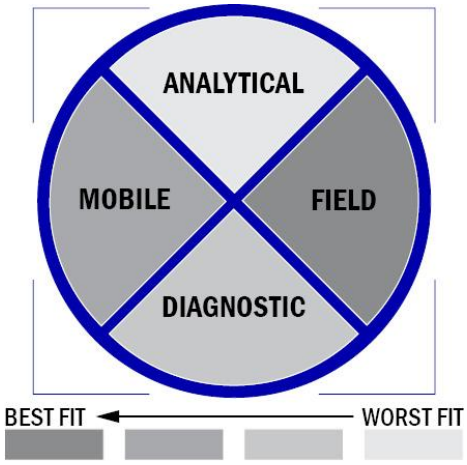
CBRN Water Purity Monitor ranked in the middle third of all evaluated products for field use and earned 69% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
CBRN Water Purity Monitor	60.35
MINIMUM SCORE	26.53



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Technical Associates
7051 Eton Ave.
Canoga Park, CA 91303

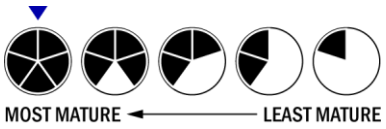
Point of Contact:
Robert Goldstein
818-883-7043

COST

- $380,000.00/system or device

SPECIFICITY

- False Positives: <1:10,000
- False Negatives: <1:1,000



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, >10 tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy and web-based operators manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Larger than a home dishwasher
- All modes of transportation
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 4 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Requires continual supply of water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Greater than 250 ul to test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- 100-149 GB generated
- Network capable
- Wireless and wired connections
- Could easily be adapted to fully autonomous system
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software closed but available for modification
- System hardware open and available for modification

CDS-100 (Compact Diagnostic System)

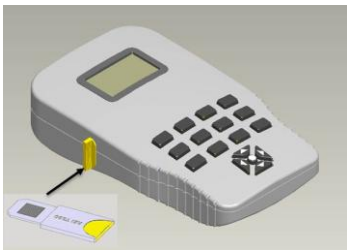
by Resonant Sensors Incorporated

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Toxins (100-1,000 ng/mL)
Aerosolized Chemical Agent (0.00003-0.0001 mg/m3)
Liquid Chemical Agent (1 ppb-1 ppm)

DETECTION MATRICES:

Demonstrated:
Blood, Environmental air, Environmental water, Food



DESCRIPTION:

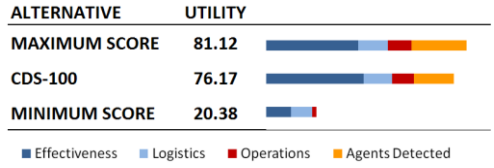
Resonant Sensors Incorporated (RSI) is developing a new compact photonic biosensor system for real time screening of an array of biotoxins, parasites and/or viruses in biological and environmental samples. Our products include a disposable sensor chip with an associated compact reader unit that can rapidly and simultaneously screen for an array of agents without requiring the use of chemical labels or post processing steps. This differentiating technology provides a new point-of-use diagnostic tool for first responders in the field. Our sensor platform can be applied to monitor an array of bio- or chemical reactions in a variety of matrices (including serum, environmental water samples, and food). Selectivity is imparted on the sensor element using conventional surface chemistries (such as silane) to covalently attach commercially available antibody, aptamer, or DNA layers. As a test begins, the analyte binds to the detection-layer target, and the system monitors instantaneous changes at the sensor surface, thus providing real-time data. Test time is limited only by chemical binding dynamics, and is typically less than 10-15 minutes. Qualitative data is available immediately after sample introduction. The RSI sensor chips are pre-sensitized to detect a target panel of 15 microbials and toxins in a single sample for applications such as infectious disease screening. The biochip will be operated without requiring any post-detection washing steps. This work is being performed in collaboration with our commercial partners at Raytheon ELCAN Optical Technologies in Richardson, Texas.

TECHNOLOGY:

RSI's products are based upon guided-mode resonance (GMR) sensor technology that occurs in subwavelength waveguide-gratings. When these sensors are illuminated with a light source, a specific wavelength of light is reflected (with a corresponding transmission null) at a particular angle. Interaction of a target analyte with a biochemical layer on the sensor surface yields measurable angular shifts that directly identify the binding event without additional processing or foreign tags. The GMR sensor surface may be optimized with an array of capture molecules, allowing rapid detection of multiple analytes in a single test.

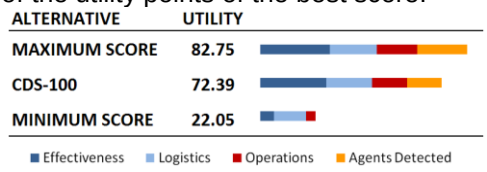
ANALYTICAL Laboratory Ranking

Compact Diagnostic System ranked in the top third of all evaluated products for analytical laboratories and earned 91% of the utility points of the best score.



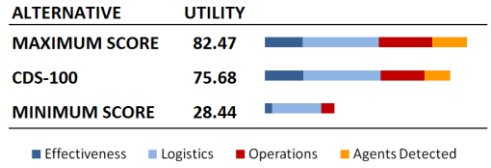
DIAGNOSTIC Laboratory Ranking

Compact Diagnostic System ranked in the top third of all evaluated products for diagnostic laboratories and earned 92% of the utility points of the best score.



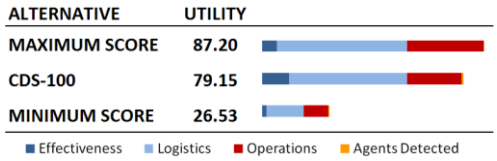
MOBILE Laboratory Ranking

Compact Diagnostic System ranked in the top third of all evaluated products for mobile laboratories and earned 87% of the utility points of the best score.



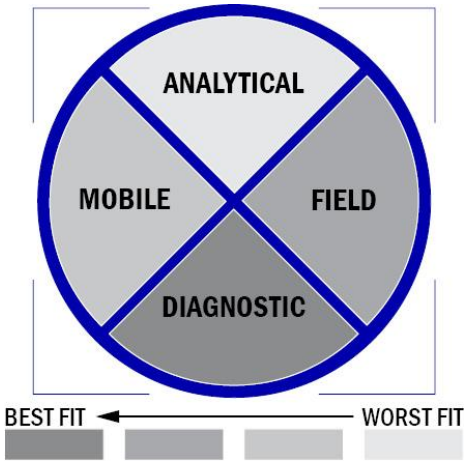
FIELD USE Ranking

Compact Diagnostic System ranked in the top third of all evaluated products for field use and earned 91% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Resonant Sensors Incorporated
416 Yates Street, NH518, Box 19016
Arlington, TX 76010

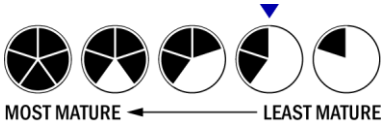
Point of Contact:
(817) 272-3450

COST

- $9,000/system or device
- $30/analysis

SPECIFICITY

- False positives: <5%
- False negatives: <5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Could easily be adapted into a fully automated system

Signature:
- Sounds or alarms deactivated
- Screen can be dimmed
- Less than 200 BTU

Training and Speed:
- Very brief training and minimal technical skills
- <5 minutes set up required
- 1-3 minutes down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components stored at room temp withstand temps > 45°C for < 24 hours/ Stored frozen withstand temps > 4°C for < 24 hours/ Stored at room temp (27°C)/ Stored at 4°C/ Must be frozen
- Performance is not influenced by relative humidity
- Between 1-6 months shelf life

Transportation:
- Approximately the size of a toaster
- All means of transportation
- Weighs between 1 to 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions and/or reagents
- 1 component

Maintenance:
- Service < once per year
- Preventive maintenance serviceable by technician
- Maintenance is included
- Expected life 3-5 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1 hr

Physical System Requirements:
- Batteries
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call the final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 50 ul for a test

System Maturity:
- Bread board
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- <100 GB
- Network capable
- Wireless and wired connections
- Fully autonomous system with some effort
- On board computer chip
- The system automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

C-FLAPS Biological Detection System

by Dycor Technologies Ltd.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria

DETECTION MATRICES:

Demonstrated:
Environmental Air

DESCRIPTION:

C-FLAPS is a non-specific bioaerosol detector which was specifically designed for use as a point detector, deployed either on mobile platforms (reconnaissance vehicles, naval ships) or networked in a fixed site (military critical infrastructure, sporting events, mass gatherings, etc) to assist in surveillance for the presence of anomalous bioaerosols. Operating on the principle of fluorescence of specific enzymes present only in living organisms, the C-FLAPS provides increased confidence in determining live particles as opposed to other aerosolized particles, and when coupled with automated sampling systems, becomes a key tool in enhancing situational awareness for military, civilian security, and public health surveillance capability. C-FLAPS is usually deployed as part of a custom-designed turnkey monitoring, detection, sampling and identification capability within either bio-specific or CBRNE surveillance requirements. C-FLAPS has been extensively and widely deployed, beginning with its role as a major component of the referee system at the US Army West Desert Test Center and DRDC Suffield in Canada, through operational deployments with North American and European defense, security and public health clients. An extensive library of background bioaerosol environments has been compiled, and continues to expand, providing continuous refinement of alarming algorithms for reduction of false alarms.

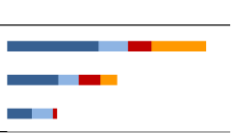
TECHNOLOGY:

Fluorescence excitation of NADH and Riboflavin, and measurement of their fluorescence emissions along two wavelengths, along with scattered light intensity readings, provide exceptional discrimination and rejection of interferrents. Integrated alarming algorithms give the operator the ability to vary parameters based on background conditions, minimize false alarms and differentiate between non-living/harmless interferrents and actual biological events.

ANALYTICAL Laboratory Ranking

C-FLAPS Biological Detection System ranked in the middle third of all evaluated products for analytical laboratories and earned 56% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
C-FLAPS	45.07
MINIMUM SCORE	20.38

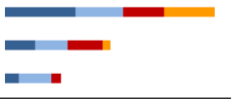


Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

C-FLAPS Biological Detection System ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 50% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
C-FLAPS	41.65
MINIMUM SCORE	22.05

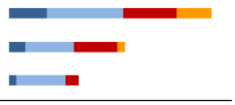


Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

C-FLAPS Biological Detection System ranked in the bottom third of all evaluated products for mobile laboratories and earned 57% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
C-FLAPS	47.34
MINIMUM SCORE	28.44

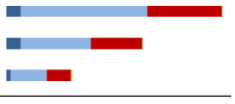


Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

C-FLAPS Biological Detection System ranked in the bottom third of all evaluated products for field use and earned 63% of the utility points of the best score.

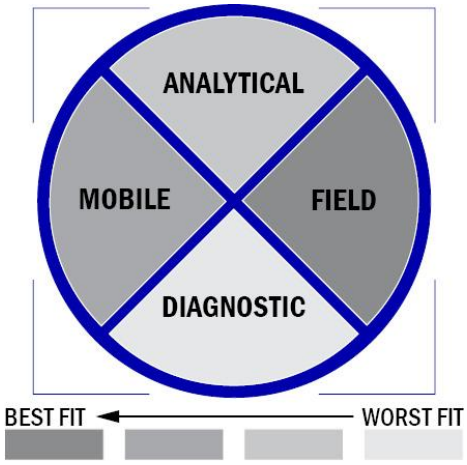
ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
C-FLAPS	55.03
MINIMUM SCORE	26.53



Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Dycor Technologies Ltd.
1851 - 94 Street NW
Edmonton, Alberta, Canada T6N 1E6

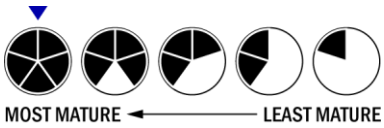
Point of Contact:
Markus Lemke, VP Business Development
markus.lemke@dycor.com
780-930-2387

COST

- Not Available

SPECIFICITY

- False Positives: Less than 5%
- False Negatives: Less than 5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- No screen on device
- Greater than 500 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- 10-20 minutes set up
- Almost instantaneous down time
- 3-5 steps are required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 37°C
- No consumables required
- Performance is not influenced by relative humidity
- No reagents

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means of transportation
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- No consumables

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance is included
- Expected life 5-10 years
- Less than 5 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Liquids not tested

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Satellite, wireless and wired connections
- Autonomous system
- Laptop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open but modification requires licensing
- The system hardware is open but modification requires licensing

CFX Real-Time PCR Detection Systems

by Bio-Rad Laboratories

DETECTS THE FOLLOWING:
Nothing demonstrated.

DETECTION MATRICES:
Nothing demonstrated.

DESCRIPTION:
Information not available

TECHNOLOGY:
The CFX Real-Time PCR detection systems are designed for real-time PCR amplification and detection of DNA or cDNA using fluorescence detection to determine target sample presence, absence or quantity. The systems combine a C1000 thermal cycler with interchangeable 96 well or 384 well modules for singleplex and multiplex detection of fluorophores. Purchase of this instrument conveys a limited non-transferable immunity from suit for the purchaser's own internal research and development and for use in human in vitro diagnostics and all other applied fields except veterinary diagnostics. The CFX Automation System enables the automated loading of multiple reaction plates into the CFX system allowing fully automated running sample amplification and detection.

ANALYTICAL Laboratory Ranking

CFX Real-Time PCR Detection Systems ranked in the middle third of all evaluated products for analytical laboratories and earned 52% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
CFX Real-Time PCR	42.33
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

CFX Real-Time PCR Detection Systems ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 48% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
CFX Real-Time PCR	39.57
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

CFX Real-Time PCR Detection Systems ranked in the bottom third of all evaluated products for mobile laboratories and earned 48% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
CFX Real-Time PCR	39.92
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

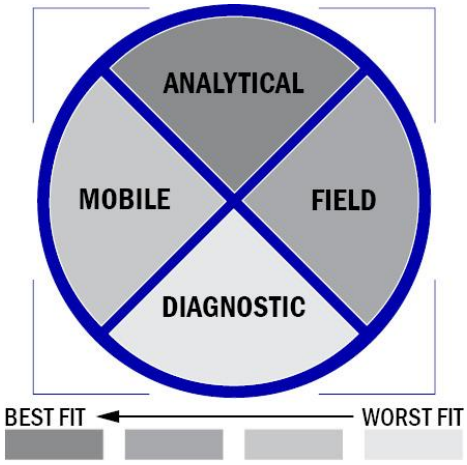
CFX Real-Time PCR Detection Systems ranked in the bottom third of all evaluated products for field use and earned 48% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
CFX Real-Time PCR	41.74
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

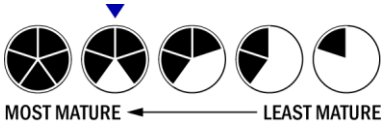
Bio-Rad Laboratories
2000 Alfred Nobel Dr.
Hercules, CA 94547

COST

- Information not available

SPECIFICITY

- False Positives: Assay dependent
- False Negatives: Assay dependent



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30 - 60 minutes for detection
- Multiple samples, multiple tests/samples per run
- Could easily be adapted to a fully automated system

Signature:
- Sounds or alarms present
- Screen cannot be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- < 5 minutes set-up
- Almost instant down time
- 3-5 steps required
- DVD/ Web video/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Used from 25°C to 37°C
- Temp storage information not available
- Peak performance at normal relative humidity
- Shelf life information not available

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life information not available
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- Single centrifugation step
- Single shaking or vortexing, mixing, degassing or filtering step
- System could call final result in the future

Sensitivity and Detection:
- 510K clearance information not available
- FDA clearance information not available
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connection
- Fully autonomous
- Basic desktop computer
- Stores and archives data outputs and creates electronic records
- System software is closed and not available for modification
- System hardware is closed and not available for modification

Chameleon

by Morphix Technologies

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

The Chameleon is hands-free, power-free chemical detection for gases and vapors in air. The Chameleon consists of an armband and disposable chemical detecting cassettes. The armband holds up to ten chemical cassettes to detect ten different chemicals or families of chemicals. The Chameleon is easy to use and provides a clear color change on half the sensor if the targeted chemical is present. The Chameleon has been successfully third party tested and is designed for use in a wide variety of operating environments including desert, arctic and tropic. The Chameleon can even be immersed in salt and fresh water for an hour under pressure. It is very rugged and accurate.

TECHNOLOGY:

The Chameleon utilizes sensitive, selective, low-cost, easy to use colorimetric chemistry sensors. The design of the Chameleon cassette allows the Chameleon to be completely water resistant and usable in a wide range of harsh environmental conditions.

ANALYTICAL Laboratory Ranking

Chameleon ranked in the middle third of all evaluated products for analytical laboratories and earned 58% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
Chameleon	46.94
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

Chameleon ranked in the middle third of all evaluated products for diagnostic laboratories and earned 55% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
Chameleon	45.82
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

Chameleon ranked in the middle third of all evaluated products for mobile laboratories and earned 68% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
Chameleon	56.16
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

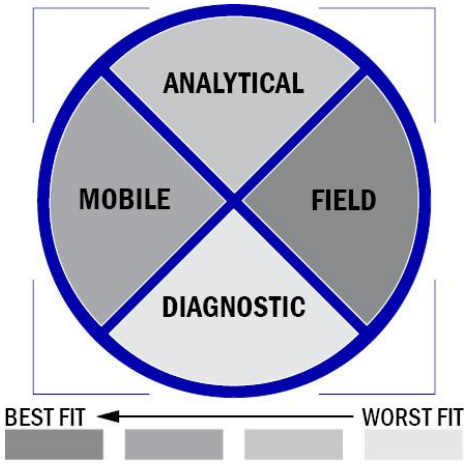
Chameleon ranked in the top third of all evaluated products for field use and earned 81% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
Chameleon	70.88
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Morphix Technologies, Inc
2557 Production Road
Virginia Beach, VA 23454

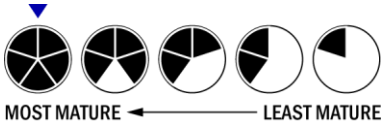
Point of Contact:
Kimberly Chapman
800-808-2234

COST

- $60.00/system or device

SPECIFICITY

- False Positives: <5%
- False Negatives: <1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, single tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- No screen
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- <1 minute down time
- 0-2 steps required
- DVD/ Web-based video/ Customer site training

Operational conditions:
- Can be used from -21°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Performance is not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Single use
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- No service required
- Preventive maintenance not applicable
- Maintenance not applicable
- Expected life not applicable
- No daily QA required
- No decon required

Physical System Requirements:
- No electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System could call final result in the future

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- Does not generate raw data
- Not network capable
- Could be adapted to a fully autonomous system with some effort
- No computer required
- Does not store or archive data outputs or create an electronic record
- System does not employ software
- System hardware not applicable

ChemPro 100i

by Environics USA

DETECTS THE FOLLOWING:
Nothing demonstrated.

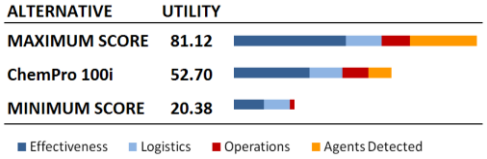
DETECTION MATRICES:
Demonstrated:
Environmental air, Soil

DESCRIPTION:
The CP100i is an Ion Mobility Spectrometer capable of classifying gas for the first responder community and war fighter.

TECHNOLOGY:
The CP100i uses Ion Mobility Spectrometer in conjunction with Electrochemical cells to classify chemicals.

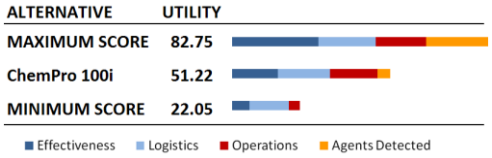
ANALYTICAL Laboratory Ranking

ChemPro 100i ranked in the middle third of all evaluated products for analytical laboratories and earned 65% of the utility points of the best score.



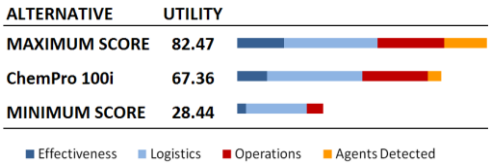
DIAGNOSTIC Laboratory Ranking

ChemPro 100i ranked in the middle third of all evaluated products for diagnostic laboratories and earned 62% of the utility points of the best score.



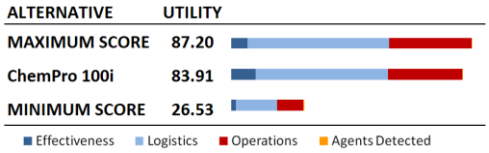
MOBILE Laboratory Ranking

ChemPro 100i ranked in the top third of all evaluated products for mobile laboratories and earned 82% of the utility points of the best score.



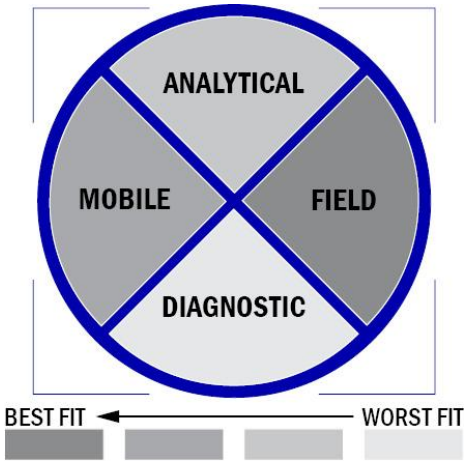
FIELD USE Ranking

ChemPro 100i ranked in the top third of all evaluated products for field use and earned 96% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Environics USA
1308 Continental Dr.
Suite J
Abingdon, MD 21009

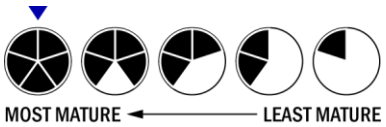
Point of Contact:
Tim Spaeder
240-683-1186
TSpaeder@EnvironicsUSA.com

COST

- $14,000.00/ system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- <5 minutes set-up required
- 1-3 minutes down time
- 0-2 steps required
- DVD/ Web video/ Customer manufacturer and site training/ Hard-copy and web manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Does not require consumables
- Performance not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs between 1 - 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- No service required
- Preventive maintenance serviceable by customer
- Expected life 3-5 years
- Less than 5 minutes daily QA
- Likely that exposure to hazardous agent cannot be decontaminated

Physical System Requirements:
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source information not available

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering step
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Satellite, wireless and wired connections
- Fully autonomous
- On board computer chip
- Stores and archives data outputs and creates electronic records
- System software is closed and not available for modification
- System hardware is closed and not available for modification

ChemPro PD

by Environics USA

DETECTS THE FOLLOWING:
Nothing demonstrated.

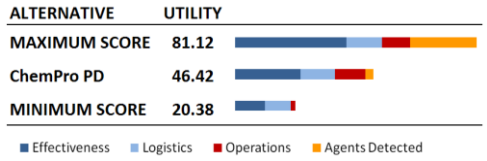
DETECTION MATRICES:
Nothing demonstrated.

DESCRIPTION:
Rugged TIC/ CWA detector for harsh environments.

TECHNOLOGY:
Ion mobility spectroscopy (IMS) and SC cell based technology using spectral matching software to locate, classify and identify TICs and CWAs.

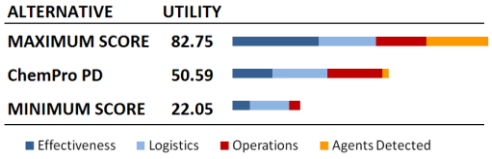
ANALYTICAL Laboratory Ranking

ChemPro PD System ranked in the middle third of all evaluated products for analytical laboratories and earned 57% of the utility points of the best score.



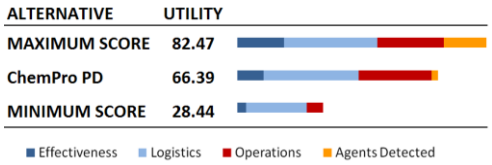
DIAGNOSTIC Laboratory Ranking

ChemPro PD System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 61% of the utility points of the best score.



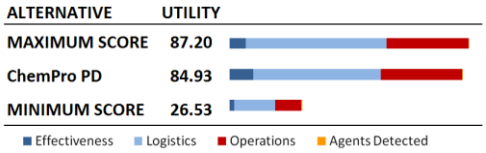
MOBILE Laboratory Ranking

ChemPro PD System ranked in the top third of all evaluated products for mobile laboratories and earned 81% of the utility points of the best score.



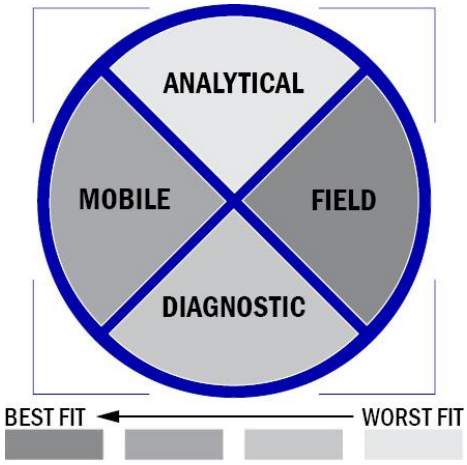
FIELD USE Ranking

ChemPro PD System ranked in the top third of all evaluated products for field use and earned 97% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Environics USA
1308 Continental Drive Suite J
Abingdon, MD 21009

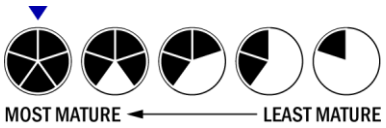
Point of Contact:
Tim Spaeder

COST

- $15,000/system or device
- $1.00/analysis

SPECIFICITY

- False positives: - 1%
- False negatives: - 1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Currently fully-automated

Signature:
- Sounds or alarms cannot be deactivated
- Screen can be dimmed or turned off
- <200 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills required
- < 5 minutes set up
- Minimal down time
- 0-2 steps are required
- DVD/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from <-21°C to >42°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Shelf life great than 3 years

Transportation:
- Approximately the size of a soda can
- All means of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- No service required
- Preventive maintenance serviceable by customer
- Maintenance is included
- Expected life 3-5 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Batteries
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps are required
- No shaking or vortexing, mixing, degassing or filtering steps are required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Does not test liquids

System Maturity:
- Is commercially available and meets military specifications
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB per response
- Network capable
- Wired and wireless connections
- Fully autonomous
- On-board computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

ChemSight

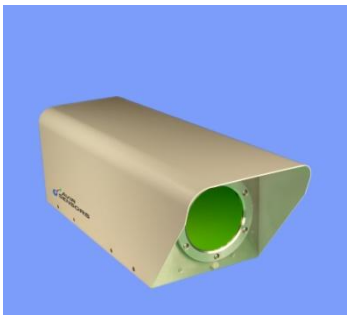
by Avir Sensors, LLC

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.



DESCRIPTION:

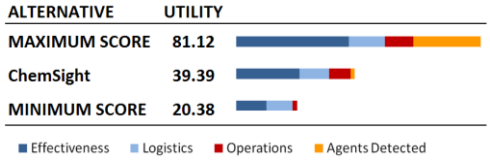
ChemSight® detector can identify minute quantities of hazardous gaseous chemicals (CWAs and TICs) over a wide coverage area, has minimal operating costs and is designated as a Qualified Anti-Terrorism Technology. ChemSight® Chemical detector from Avir Sensors puts unprecedented detection and identification capability into the hands of safety officers by delivering comprehensive information about chemical threats in a matter of seconds. ChemSight® is a continuously operating, open path detector that uses infrared spectroscopy. It can reliably monitor lines of sight of up to 45 meters and detect and identify multiple chemicals and interferrents. ChemSight® is particularly suitable to monitor large facilities military bases and perimeters, indoors or outdoors, that face constantly varying challenges by multiple threats. It is robust, easy to install and operate — even by untrained personnel. ChemSight's exceptionally low-maintenance schedule and no consumables make it the only "install-and-forget" detector in the field. Unlike point detectors that can provide only localized snapshot views of the protected area, the ChemSight® offers a global view and fast response to nearly all chemical challenges and interferrents. ChemSight® can be used with confidence in security applications because it detects and identifies a wide range of TICs and interferrents. Identify high and low concentrations without risking poisoning its detector elements. New signatures can be uploaded into ChemSight® through standard wired and wireless networks. SiteProtector™ software readily integrates with industry standard security network systems or can act as its own autonomous detector system.

TECHNOLOGY:

ChemSight® is an open-path chemical detector. It includes an eye-safe IR source that projects a collimated spectrally-broad beam (blackbody emission) towards the detector where the beam is analyzed spectroscopicly by a multi-spectral, room temperature detector array. Chemicals intercepting the IR beam absorb portion of the energy and are detected, identified and quantified by matching their IR absorption spectrum against signatures stored in the detector's digital library. It provides fast detection and recovery (1 sec), months - or even years - of continuous operation with no consumables and only minimal and infrequent maintenance.

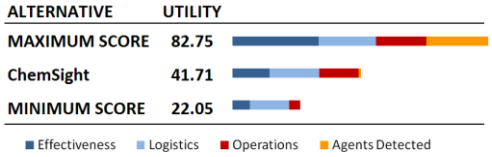
ANALYTICAL Laboratory Ranking

ChemSight ranked in the bottom third of all evaluated products for analytical laboratories and earned 49% of the utility points of the best score.



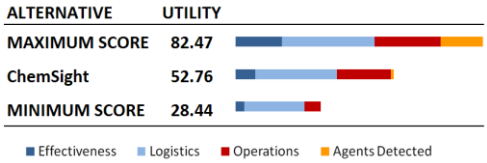
DIAGNOSTIC Laboratory Ranking

ChemSight ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 50% of the utility points of the best score.



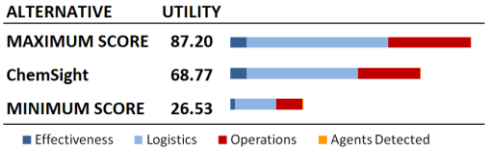
MOBILE Laboratory Ranking

ChemSight ranked in the middle third of all evaluated products for mobile laboratories and earned 64% of the utility points of the best score.



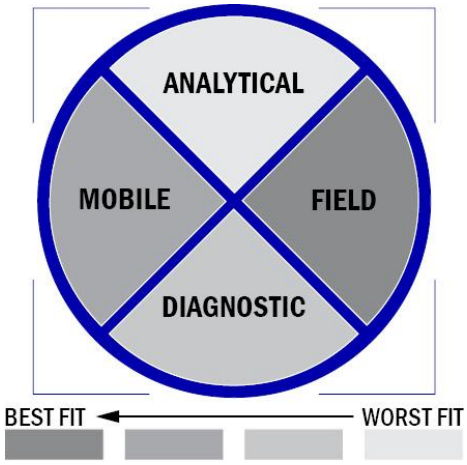
FIELD USE Ranking

ChemSight ranked in the middle third of all evaluated products for field use and earned 79% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

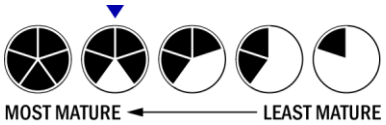
Avir Sensors, LLC
1484 Greenbrier Place
Charlottesville, VA, 22901

COST

- $31,000.00/system or device

SPECIFICITY

- False Positives: 1/year
- False Negatives: 0



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- >20 minutes set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy and web-based operators manual

Operational conditions:
- Can be used from 4°C to 41°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- Components not applicable

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life >10 years
- >5 minutes QA required
- Decon not applicable

Physical System Requirements:
- 110V electrical requirement
- 1-2 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless and wired connections
- Fully autonomous
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software closed and not available for modification
- System hardware is closed and not available for modification

Clinical Bio-Seeq System

by Smiths Detection, Inc

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1000 CFU/mL)
Viruses (1-100 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swab

DESCRIPTION:

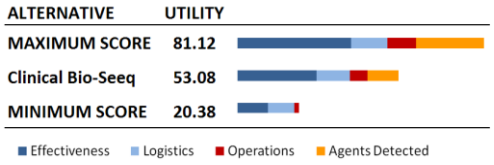
The Clinical Bio-Seeq™ System has been designed specifically for the identification of infectious diseases in human clinical samples and is comprised of three key components: the Bio-Seeq™ 2 instrumentation, an automated Sample Preparation Unit, and the Linear After The Exponential PCR (LATE-PCR) chemistry. The combination of these three technologies is designed to provide the capability for a user to perform multiplexed PCR in a point-of-care (POC) setting without any molecular biology training. The Clinical Bio-Seeq™ instrument is an evolution of the Bio-Seeq™ Vet instrument, using many of the same core components, and is therefore able to PCR diagnostics on a multitude of samples types, both clinical and non-clinical (i.e. blood, tissue, swabs, powders, soil). The Clinical Bio-Seeq™ is a desktop instrument with five independent, high speed, Peltier-based thermocyclers. This means that the machine can start a new assay as long as any one of the five thermocyclers is available. This ensures that the system can operate in an asynchronous mode and provide data with the shortest possible turnaround. Detection of nucleic acid amplification is based on multicolor fluorescence-based optics. The instrument has a touch screen, barcode scanner, a software package compatible with hospital information systems and hardened chemical resistant shell that permits very aggressive surface disinfection with microbicides. The Instrument has been developed in a modular fashion and will accept banks of additional thermocycler modules, providing the capability for increased throughput capacity.

TECHNOLOGY:

The Clinical Bio-Seeq™ System utilizes a proprietary automated Sample Preparation Unit to perform sample lysis and nucleic acid recovery, 4-color Peltier-based thermocyclers for PCR amplification, and Linear After The Exponential PCR (LATE-PCR) for highly multiplexed assays and qualitative/quantitative endpoint detection.

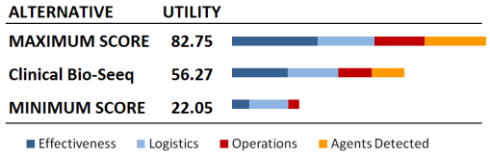
ANALYTICAL Laboratory Ranking

Clinical Bio-Seeq System ranked in the top third of all evaluated products for analytical laboratories and earned 65% of the utility points of the best score.



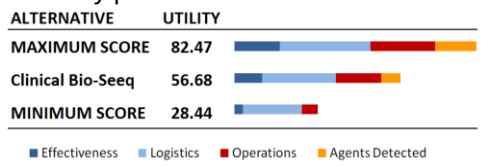
DIAGNOSTIC Laboratory Ranking

Clinical Bio-Seeq System ranked in the top third of all evaluated products for diagnostic laboratories and earned 68% of the utility points of the best score.



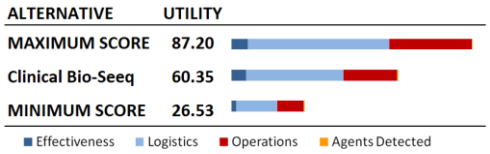
MOBILE Laboratory Ranking

Clinical Bio-Seeq System ranked in the middle third of all evaluated products for mobile laboratories and earned 69% of the utility points of the best score.



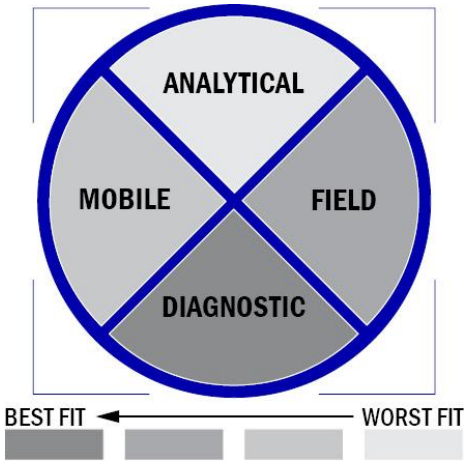
FIELD USE Ranking

Clinical Bio-Seeq System ranked in the middle third of all evaluated products for field use and earned 69% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Smiths Detection
459 Park Avenue, Bushey, Watford, WD23 2BW United Kingdom

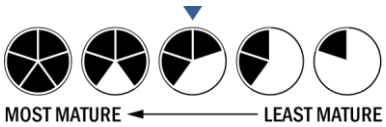
Point of Contact:
Dr. Carmelo Volpe
carmelo.volpe@smithsdetection.com

COST

- $35,000.00/system or device
- $50.00-80.00/ analysis

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- System fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes set up
- Almost no down time
- 0-2 steps are required
- Customer site training/ Hard copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temperature
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Commercial carrier/ Fixed wing aircraft/ Ship transport
- Weighs between 5 and 25kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 3 components

Maintenance:
- Service once a year
- Maintenance is not included
- Expected life 5-10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results not available
- No centrifugation steps required
- A single shaking or vortexing, mixing, degassing or filtering step required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 100 ul for a test

System Maturity:
- Brass board
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Not capable of autonomy
- Onboard computer chip
- Store and archive data outputs and creates an electronic record
- The system software is closed with no modification
- The system hardware is closed with no modification

CRITICAL Monitoring Badges and Taggants

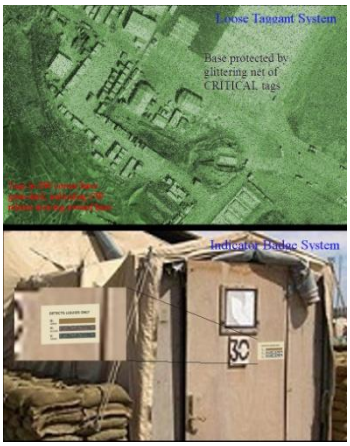
by Research Support Instruments, Inc.

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.



DESCRIPTION:

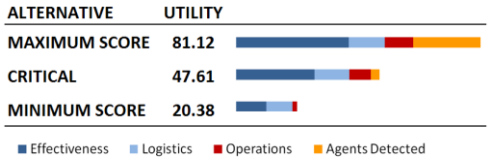
The Colorimetric Retroreflecting Indicator Tags for Identification of Chemical Agents at Locations (CRITICAL) system consists of indicator badges and loose taggants for monitoring for CWA releases in the field. The CRITICAL indicator badges can be placed at strategic locations at DOD or industrial facilities and continuously monitored with standard networked CMOS cameras or by facility personnel at a long range. Further, when dispersed uniformly over an open area, CRITICAL taggants can be monitored to indicate and track CWA releases real-time. The taggants will work for a long duration in a range of environments, with the ability to be tailored to rainy, snowy, or dusty locations if needed. Readout of the badges and taggants will be simple enough for facility personnel with minimal training, and will require standard cameras and light sources to minimize infrastructure costs. The fabrication protocols scale up to mass-production, resulting in low cost for large facilities.

TECHNOLOGY:

Colorimetric dyes on retroreflective microstructures and cheaply mass-fabricated retroreflector elements are the key technologies of the CRITICAL system. The dyes darken in the presence of various CWA's and TIC's. The resulting contrast on the retoreflector faces causes a sharp decrease in the returned signal from a broadband light source. The retroreflectors provide narrow reflected beam divergence, with correspondingly long detection range and the ability to operate covertly, and are easily mass-fabricated to cover large areas of installations or produce large quantities of indicator badges.

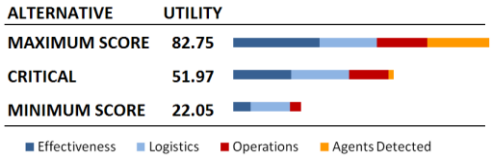
ANALYTICAL Laboratory Ranking

CRITICAL ranked in the middle third of all evaluated products for analytical laboratories and earned 59% of the utility points of the best score.



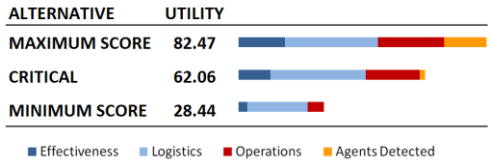
DIAGNOSTIC Laboratory Ranking

CRITICAL ranked in the middle third of all evaluated products for diagnostic laboratories and earned 63% of the utility points of the best score.



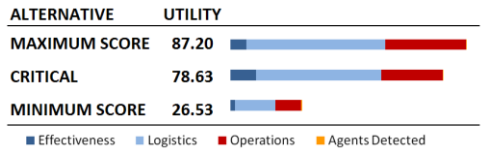
MOBILE Laboratory Ranking

CRITICAL ranked in the top third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.



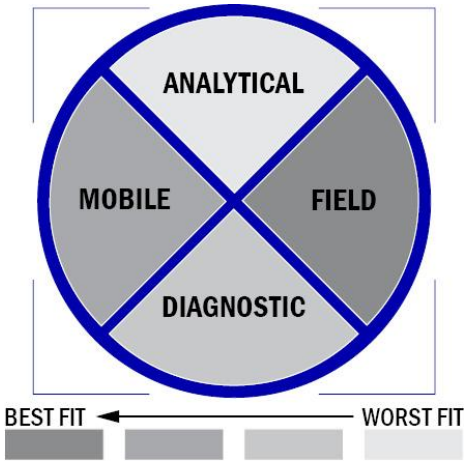
FIELD USE Ranking

CRITICAL ranked in the top third of all evaluated products for field use and earned 90% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Research Support Instruments, Inc.
57 Hamilton Ave., Suite 206
Hopewell, NJ 08525

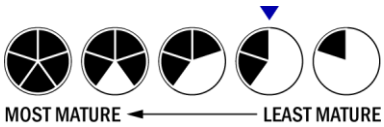
Point of Contact:
John Kline
609-429-0535
kline@researchsupport.com

COST

- Badges: <$200 for kit of 10
- Taggant: ~$8000/square mile

SPECIFICITY

- False Positives: System reduces failure rate
- False Negatives: System reduces failure rate



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Could easily be adapted into a fully automated system

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training

Operational conditions:
- Can be used from -21°C to >42°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Single use
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life not applicable
- <5 minutes daily QA
- Decontamination not applicable

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System could call final result in the future

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 50 ul to test liquids

System Maturity:
- Bread board
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Wireless, wired connections
- Could be fully autonomous system with some effort
- No computer required
- Could be adapted to store or archive data outputs or create an electronic record
- System does not employ software
- System hardware not applicable

DCI-I

by Airogistic, LLC

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (100-1,000 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

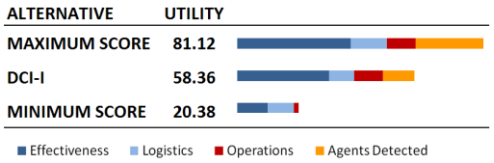
DCI-I is a complete biological, chemical and radiological detection, collection and Identification system. It combines into a 19" rack mount chassis a laser induced florescence (LIF) detector, wetted walled plastic cyclone collector (WWPC), a rapid presumptive identifier based on "Canary" technologies, and an interface to a confirmatory PCR identifier. This system also scales optional interfaces to government chemical detectors and industrial radiation detectors using existing and established software drivers to these devices. The DCI-I includes a video surveillance option that allows triggered events to be correlated with live video recording and real-time image recognition.

TECHNOLOGY:

A laser induced florescence detector (LIF) searches for bio signatures examining each particle for the presence of metabolites by correlating size and florescence. If a statistical match occurs, the detector triggers the presumptive "CANARY" identifier and a wetted wall plastic cyclone collector (WWPC), which efficiently collects airborne aerosolized particulates into a phosphate buffer solution. The system provided video monitoring of the location for play back and determining the source of the event. The system communicates to authorities through network software as it prepares samples for onsite confirmatory and forensic PCR analysis.

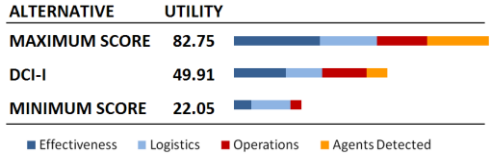
ANALYTICAL Laboratory Ranking

DCI-I ranked in the top third of all evaluated products for analytical laboratories and earned 72% of the utility points of the best score.



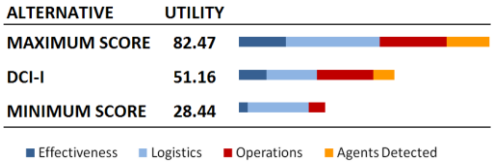
DIAGNOSTIC Laboratory Ranking

DCI-I ranked in the middle third of all evaluated products for diagnostic laboratories and earned 60% of the utility points of the best score.



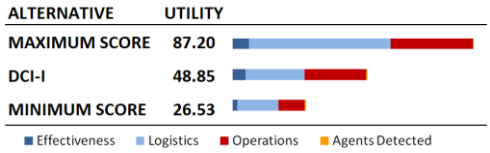
MOBILE Laboratory Ranking

DCI-I ranked in the middle third of all evaluated products for mobile laboratories and earned 62% of the utility points of the best score.



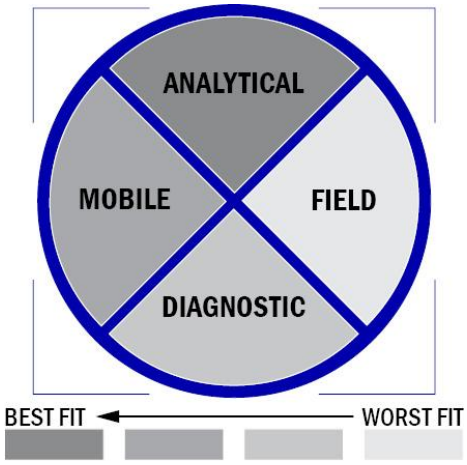
FIELD USE Ranking

DCI-I ranked in the bottom third of all evaluated products for field use and earned 56% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Airogistic, LLC
5204 Wheeler Branch Circle
Suite 111L
Austin, TX 78701

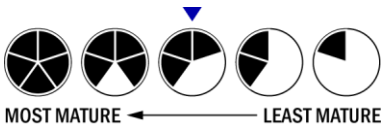
Point of Contact:
Jeff Michalski
michalski@airogistic.com
512-743-3271

COST

- $75,000.00 - 200,000.00/system or device

SPECIFICITY

- False Positives: LIF Detector 1 per 1000 hours, CANARY <.05% @ 50 ACPLA, HyBeacons PCR not known
- False Negatives: LIF Detector 1 per 1000 possible detections, CANARY <.05% @ 50 ACPLA, HyBeacons PCR not known



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 -15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms present
- Screen cannot be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- <5 minutes set-up
- 1-3 minutes down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored frozen but can stand temps >4°C for <24 hours
- Performance is not influenced by relative humidity
- 1 to 6 months shelf life

Transportation:
- Size information not available
- Transport via commercial carrier/ Tactical military wheeled and tracked vehicle/ Fixed wing military aircraft/ Ship
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 4 components

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 5-10 years
- <5 minutes daily QA
- Exposure to hazardous agent would require up to 4 hours to decon

Physical System Requirements:
- 110V electrical requirement
- 1-2 hours battery life
- Requires water aliquots
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 100 ul to test liquids

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is pending

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Wireless, wired connections
- Fully autonomous
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- Software open, modification requires licensing
- Hardware open, modification requires licensing

Defender TSR System

by Alexeter Technologies

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e4-10e5 CFU/mL)
Viruses (>10e5 PFU/mL)
Toxins (1-100 ng/mL)

DETECTION MATRICES:

Demonstrated:
Environmental air, Environmental water, Food, Powder

DESCRIPTION:

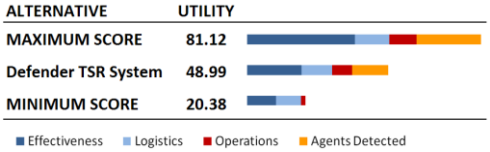
The Defender TSR System is designed to detect and identify the following biological agents, in the field, with a 15-minute test: anthrax, ricin, botulinum toxin, staphylococcal enterotoxin B, plague, tularemia, brucella and orthopox. The Defender TSR Reader, part of the system is an optical reader which evaluates the test strips, documents the results and delivers a report to the user. A protein detection test is also part of the system.

TECHNOLOGY:

Hand held immunochromatographic assays that use colloidal gold labeled antibodies, optional Reader for objective evaluation and documentation.

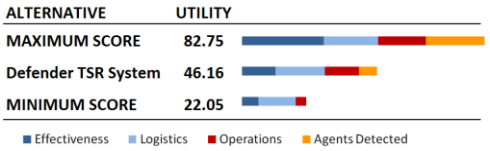
ANALYTICAL Laboratory Ranking

Defender TSR System ranked in the middle third of all evaluated products for analytical laboratories and earned 60% of the utility points of the best score.



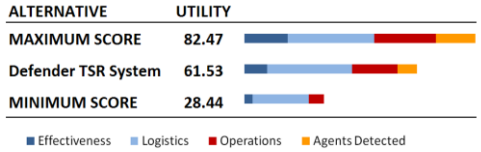
DIAGNOSTIC Laboratory Ranking

Defender TSR System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 56% of the utility points of the best score.



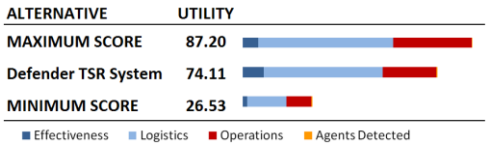
MOBILE Laboratory Ranking

Defender TSR System ranked in the top third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.



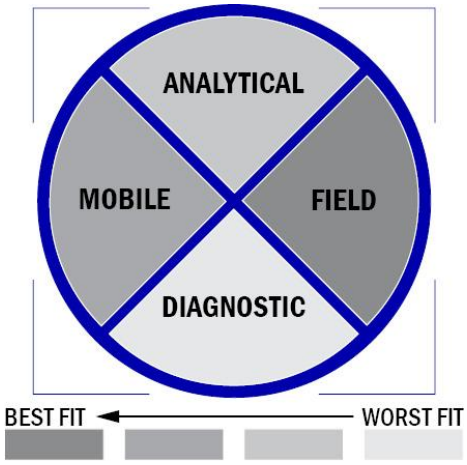
FIELD USE Ranking

Defender TSR System ranked in the top third of all evaluated products for field use and earned 85% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

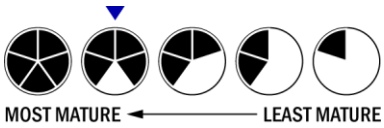
Alexeter Technologies

COST

- $15,000.00/system or device
- $26.00/analysis

SPECIFICITY

- False Positives: 0.2%
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15-30 minutes for detection
- 1 sample, >10 tests/ sample per run
- Adaptable with some effort to semi-automated

Signature:
- Sounds or alarms are present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- Less than 5 minutes set up
- Almost no down time
- 3-5 steps are required
- DVD/ Manufacturer site training

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temperature but can withstand temperatures > 45°C for periods of less than 24 hours
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All means of transport
- Weighs between 1 and 5 kg

Re-use:
- Single use detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service every 3 years
- Preventive maintenance serviceable by technician
- Maintenance is included
- Expected life N/A
- No QA required
- The device is single use and disposable so no decontamination is needed

Physical System Requirements:
- Batteries
- 4-8 hours battery use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps required
- A single shaking or vortexing, mixing, degassing or filtering step required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Less than 50 ul for a test

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Fully autonomous system with significant effort
- No computational power
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open but modification requires licensing
- The system hardware is open but modification requires licensing

DETECTIVE-EX-100T

by Advanced Measurement Technology

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types
Identification of specific isotopes

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

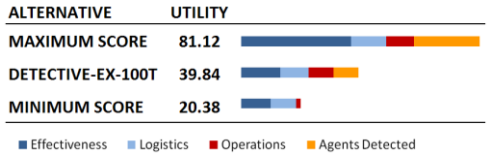
Detective-EX-100T has the largest detector of the highly successful ORTEC Detective range of high purity germanium (HPGe) based hand-held radioisotope identifiers (RIDs), for use in the detection and prevention of illicit trafficking of nuclear materials at ports and border crossings. It is one of the most advanced RID commercially available.

TECHNOLOGY:

Gamma and neutron, High Purity Germanium (HPGe) detector, high resolution, “gold standard” for identification

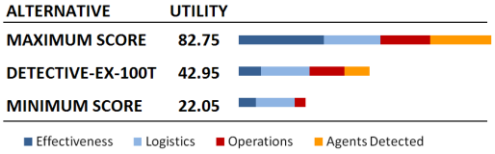
ANALYTICAL Laboratory Ranking

DETECTIVE-EX-100T System ranked in the bottom third of all evaluated products for analytical laboratories and earned 49% of the utility points of the best score.



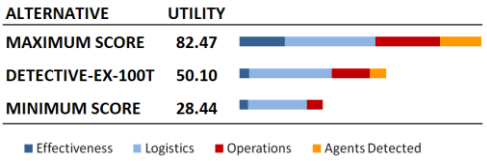
DIAGNOSTIC Laboratory Ranking

DETECTIVE-EX-100T System ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 52% of the utility points of the best score.



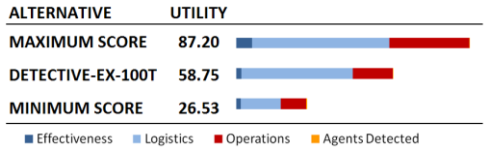
MOBILE Laboratory Ranking

DETECTIVE-EX-100T System ranked in the bottom third of all evaluated products for mobile laboratories and earned 61% of the utility points of the best score.

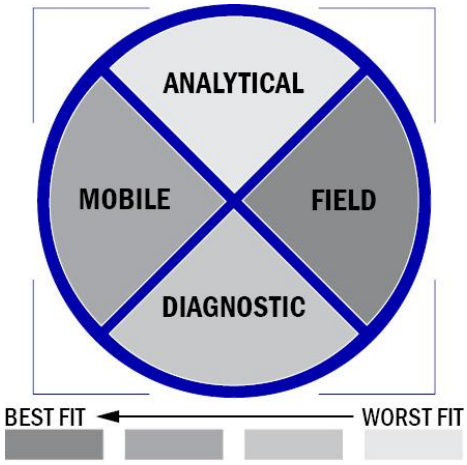


FIELD USE Ranking

DETECTIVE-EX-100T System ranked in the middle third of all evaluated products for field use and earned 67% of the utility points of the best score.



Summary of Analysis



CONTACT INFORMATION

Advanced Measurement Technology
7675 Edgewood Lane
Seven Hills, OH 44131

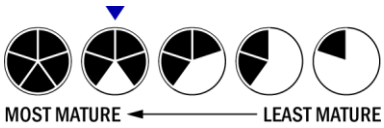
Point of Contact:
Ronald A. Zeszut
510-735-6923
ron.zeszut@ametek.com

COST

- $90,000/system or device

SPECIFICITY

- False positives: Not available
- False negatives: Not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms cannot be deactivated
- Screen can be dimmed or turned off
- Less than 200 BTU

Training and Speed:
- Very brief training and minimal technical skills
- > 20 minutes set up
- Minimal down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy operators manual manuscript

Operational conditions:
- Can be used from 4°C to 37°C
- Does not require consumables
- Performance is not known under relative humidity

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs 5-25 kg

Re-use:
- Multiple detection assays

Maintenance:
- No service required
- Preventive maintenance serviceable customer
- Maintenance is not included
- Expected life 5-10 years
- <5 minutes daily QA required

Physical System Requirements:
- Batteries
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call the final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Does not test liquids

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- <100 GB
- Network capable
- Wireless and wired connections
- Fully autonomous
- No computational power required
- The system automatically stores and archives data outputs and creates an electronic record
- The system hardware is closed and not available for modification

Diagnostic Biosensors Field System

by Diagnostic Biosensors, LLC

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria

DETECTION MATRICES:

Demonstrated:
Blood, Environmental water

DESCRIPTION:

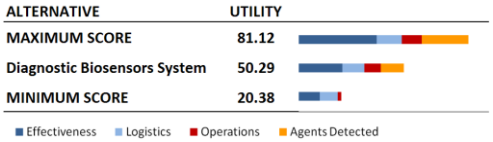
The system is designed for use in the field and by consumers. It generates quantitative assay results for samples from a broad range of complex liquid matrixes including blood, urine, and wastewater. Precision electronic detector elements are embedded into a single consumable sample handling cartridge. Customer-supplied capture molecules, and other dried assay reagents, are placed in the cartridge during production. Low cost per assay is achieved through design for manufacturing. Detection elements are commercially available for development of assays and systems. The detector element production process does not harm sensitive biomolecules. Finished detector elements can be machine - assembled into higher level systems without harming onboard biomolecules. The total system is available as a brass board assay development environment. The underlying commercial data acquisition system allows for configurations as a stand-alone custom device or as a user-configurable experimental station. The instrument communicates with a laptop or smart phone via standard USB 2.0 or Bluetooth. Battery power versions are available, standard is 110V AC.

TECHNOLOGY:

The fundamental detection element is a giant magnetoresistive (GMR) sensor array chip that counts the biospecifically bound magnetic labels at its surface. Magnetic labels are available for a wide range of detectable species including antibodies, DNA, RNA, proteins, toxins, bacteria, cells, and chemicals. The tiny plastic sample handling cartridge contains the detector elements and an interface to the handheld instrument. There are peer reviewed accounts of magnetoresistive biosensors detecting many analytes of interest including, Biological Warfare Agents, proteomic breast and colon cancer markers, food pathogens (e-coli, cryptosporidium), immunological lung cancer markers (IL-6), and more.

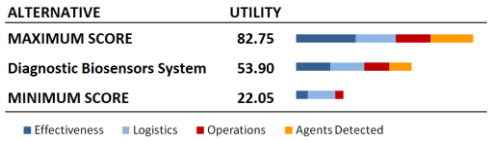
ANALYTICAL Laboratory Ranking

Diagnostic Biosensors Field System ranked in the middle third of all evaluated products for analytical laboratories and earned 62% of the utility points of the best score.



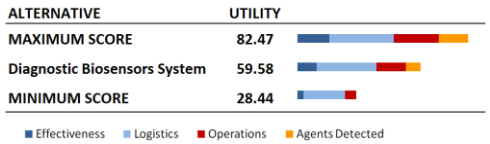
DIAGNOSTIC Laboratory Ranking

Diagnostic Biosensors Field System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 65% of the utility points of the best score.



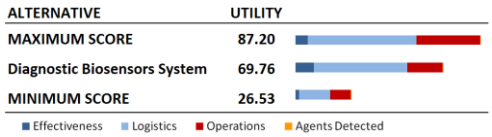
MOBILE Laboratory Ranking

Diagnostic Biosensors Field System ranked in the middle third of all evaluated products for mobile laboratories and earned 72% of the utility points of the best score.



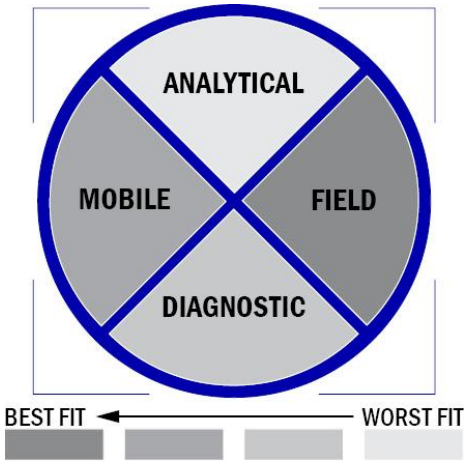
FIELD USE Ranking

Diagnostic Biosensors Field System ranked in the middle third of all evaluated products for field use and earned 80% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Diagnostic Biosensors, LLC
1712 Brook Ave. SE
Minneapolis, MN 55414-2422

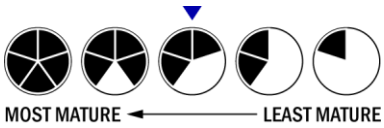
Point of Contact:
Mark Tondra
Mark@DiagnosticBiosensors.com
612 331-3584

COST

- $5,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, >10 tests/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- <5 minutes set-up
- <1 minute down time
- 0-2 steps required
- Customer and manufacturer site training/ Web-based operators manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Impact of relative humidity on performance unknown
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Single use
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 3-5 years
- >5 minutes daily QA
- No decon required

Physical System Requirements:
- 110V electrical requirement
- 4-8 hours battery life
- Requires water aliquots
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering step
- System could call final result in the future

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 10 ul to test liquids

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

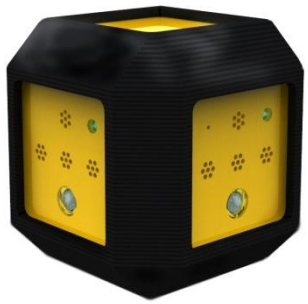
Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Satellite, wireless, wired
- Could easily be fully autonomous
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- Software open, available for modification
- Hardware open, available for modification

DISe

by Adaptive Methods

DETECTS THE FOLLOWING:
Nothing demonstrated.

DETECTION MATRICES:
Nothing demonstrated.

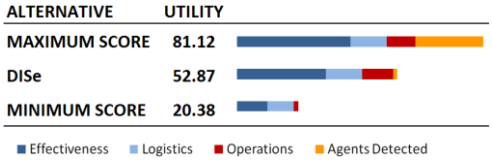


DESCRIPTION:
A rugged, portable, hand-deployable environmental sensor that provides remote situational awareness to damage control teams in hazardous areas by providing video, audio, and environmental data wirelessly.

TECHNOLOGY:
A rugged, portable, hand-deployable environmental sensor that provides remote situational awareness to damage control teams in hazardous areas by providing video, audio, and environmental data wirelessly.

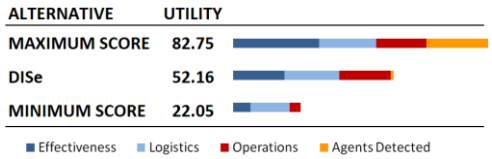
ANALYTICAL Laboratory Ranking

DISe System ranked in the middle third of all evaluated products for analytical laboratories and earned 65% of the utility points of the best score.



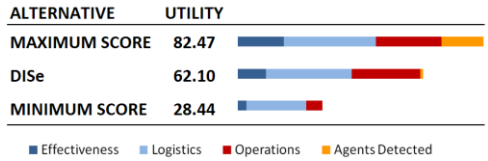
DIAGNOSTIC Laboratory Ranking

DISe System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 63% of the utility points of the best score.



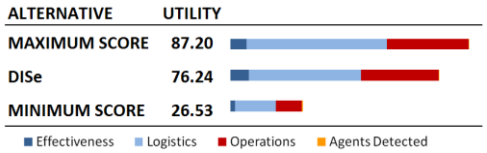
MOBILE Laboratory Ranking

DISe System ranked in the top third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.



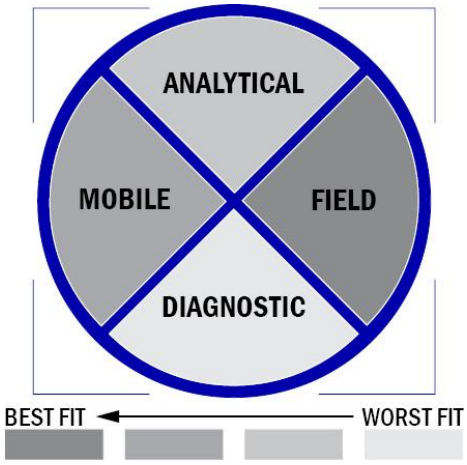
FIELD USE Ranking

DISe System ranked in the top third of all evaluated products for field use and earned 87% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Adaptive Methods
5885 Trinity Parkway
Centreville, VA 20120

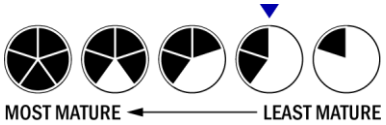
Point of Contact:
Fernando Aunon
571.217.7648

COST

- $8,000-15,000/system or device

SPECIFICITY

- False positives: - 0%
- False negatives: - 0%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully-automated

Signature:
- Sounds or alarms cannot be deactivated
- Screen can be dimmed
- 200-500 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills required
- No set up
- Minimal down time
- 0-2 steps are required
- DVD/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from <-21°C to >42°C
- All means of component storage is needed
- This system does not require consumables
- Performance is not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a soda can
- All means on transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service < every 6 months
- Preventive maintenance serviceable by technician only
- Maintenance is included
- Expected life 5-10 years
- No QA required
- It likely that exposure to hazardous agent cannot be decontaminated

Physical System Requirements:
- Batteries
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps are required
- No shaking or vortexing, mixing, degassing or filtering steps are required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Does not test liquids

System Maturity:
- Bread board
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- >250 GB
- Network capable
- Wired and wireless connections
- Could be adapted into fully autonomous system
- Basic desktop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

DNA PROfiler

by Advanced Analytical Technologies

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood

DESCRIPTION:

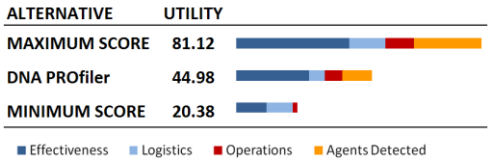
This product was designed primarily for laboratory analysis of DNA. It provides a simplified process for the identification of genus and species of microbes based on their DNA Sequence.

TECHNOLOGY:

The PROfiler enables identification of Genus/Species of microbes through a process of PCR amplification, followed by selective digestion of amplicons followed by capillary electrophoresis separation and recognition.

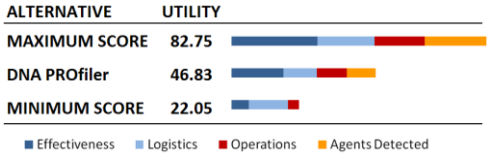
ANALYTICAL Laboratory Ranking

DNA PROfiler System ranked in the middle third of all evaluated products for analytical laboratories and earned 55% of the utility points of the best score.



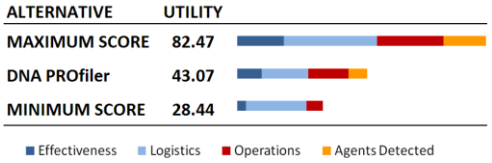
DIAGNOSTIC Laboratory Ranking

DNA PROfiler System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 57% of the utility points of the best score.



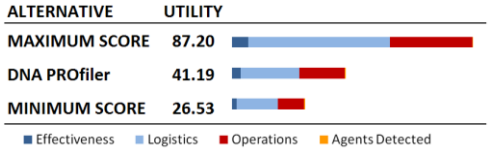
MOBILE Laboratory Ranking

DNA PROfiler System ranked in the bottom third of all evaluated products for mobile laboratories and earned 52% of the utility points of the best score.



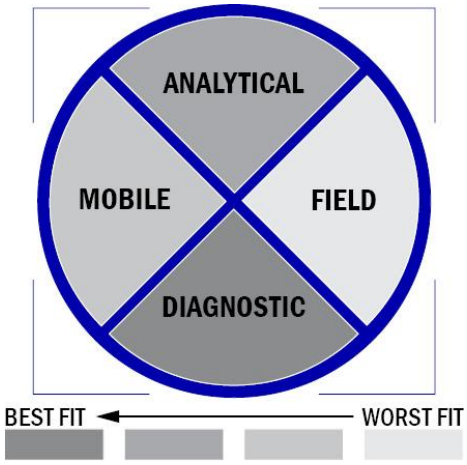
FIELD USE Ranking

DNA PROfiler System ranked in the bottom third of all evaluated products for field use and earned 47% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Advanced Analytical Technologies
Suite 2711 South Loop Drive
Ames, IA 5010

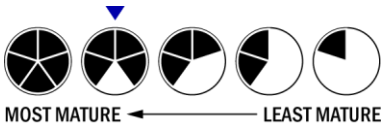
Point of Contact:
Steve Lasky

COST

- $100,000/system or device
- $5.00/analysis

SPECIFICITY

- False positives: - <3%
- False negatives: - <5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Currently semi-automated

Signature:
- Sounds or alarms can be deactivated
- Screen can be dimmed or turned off
- 200-500 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- >20 minutes set up
- <5 minutes down time
- 6-8 steps are required
- Customer site training

Operational conditions:
- Can be used from 4°C to 37°C
- Components must be stored at room temperature (27°C)
- Performance is not influenced by relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a home dishwasher
- All modes of transportation
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 5-10 years
- > 20 minutes QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- Multiple centrifugation steps are required
- Multiple shaking or vortexing, mixing, degassing or filtering steps are required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- <10 ul for a test

System Maturity:
- Commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB per pos or neg response
- Network capable
- Wired connections
- Could easily be adapted into fully autonomous system
- Laptop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is open but modification requires licensing

DOSE-GARD® Microelectronic Alarming Dosimeter

by General Atomics Electronic Systems Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

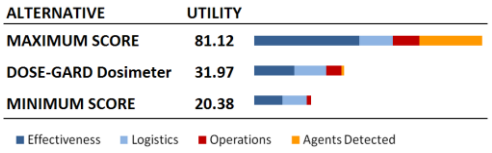
The DOSE-GARD® Microelectronic Alarming Dosimeter provides emergency responders with the ultimate in rugged, reliable, and affordable protection from excessive exposure to radiation. The DOSE-GARD® system was originally designed for military applications, with low cost, ease of use, and high reliability as the design goals, making the device accessible to every soldier or sailor or emergency responder, and assuring accurate and consistent performance under the extreme conditions that they encounter. DOSE-GARD® features: - a proprietary detector that is accurate to regulatory standards; - an IR computer interface and software; - dimensions of 1.5" diameter by 0.7" thick, and a weight of 1.2 oz; - a standard lithium disk battery good for 3 years of operation; - a 3-year calibration interval; - a large digital readout; - user-settable alarm; and, - a variety of mounting options. For easy and convenient use under extreme conditions, the DOSE-GARD® System can be deployed as a self-contained emergency kit, with dosimeters, computer interface, system software, and even the computer. During an incident, kits can be taken directly to the scene and a complete dose management set up instantly.

TECHNOLOGY:

DOSE-GARD® uses a proprietary ionization chamber to detect gamma and x-rays above 50 keV and up to 6 MeV. Calibration of the dosimeter is recommended every three years. The dosimeter is powered by a lithium disk battery good for three years to coincide with the calibration interval. Infrared communication provides a link with a computer to perform the calibrations and also to operate the dosimeter in the automated mode. In the manual mode, Menu and Select buttons on the dosimeter are used to operate it.

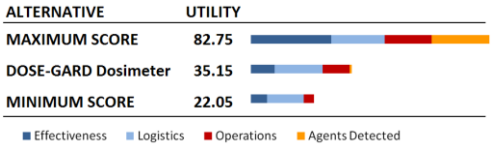
ANALYTICAL Laboratory Ranking

DOSE-GARD® ranked in the bottom third of all evaluated products for analytical laboratories and earned 39% of the utility points of the best score.



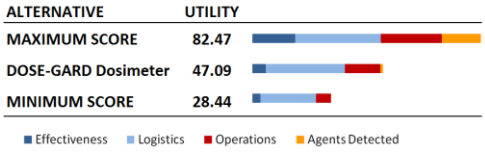
DIAGNOSTIC Laboratory Ranking

DOSE-GARD® ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 42% of the utility points of the best score.



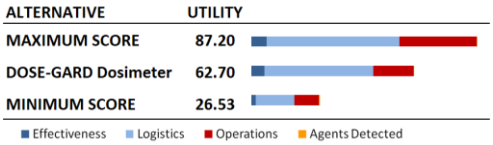
MOBILE Laboratory Ranking

DOSE-GARD® ranked in the bottom third of all evaluated products for mobile laboratories and earned 57% of the utility points of the best score.



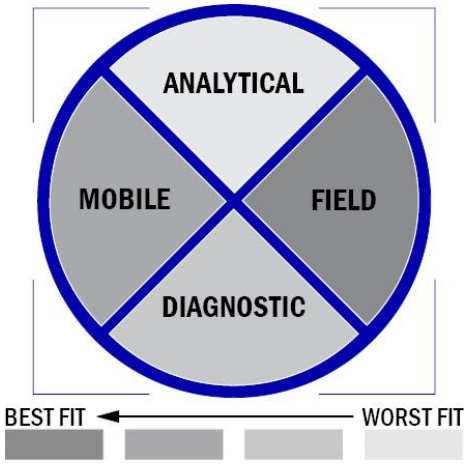
FIELD USE Ranking

DOSE-GARD® ranked in the middle third of all evaluated products for field use and earned 72% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

General Atomics Electronic Systems Inc.
4949 Greencraig Lane
San Diego, CA 92123

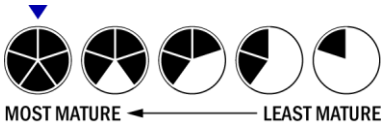
Point of Contact:
John Darrin
410-464-9125

COST

- $238.00/system or device

SPECIFICITY

- False Positives: 0%
- False Negatives: 0%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Number of samples, number of tests/sample per run not applicable
- Fully automated

Signature:
- Sounds or alarms present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- Web video/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components not applicable
- Performance is not influenced by relative humidity
- Shelf life not applicable

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- Components not applicable

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life >10 years
- No daily QA required
- Decon not applicable

Physical System Requirements:
- No electrical requirement
- Up to 3 years battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Processing data while in progress not applicable
- Centrifugation not applicable
- Shaking or vortexing, mixing, degassing or filtering not applicable
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- Raw data generated not applicable
- Not network capable
- Wireless and wired connections
- Fully autonomous
- No computer required
- Stores and archives data outputs and creates an electronic record
- System software closed and not available for modification
- System hardware closed and not available for modification

Drinking Water Safety Monitor

by Technical Associates

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types

DETECTION MATRICES:

Demonstrated:
Environmental Water

DESCRIPTION:

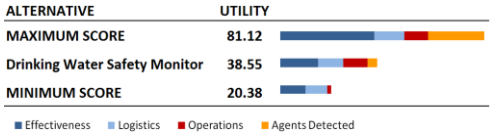
• Monitor drinking water for radioactive contaminants. • Monitor for contamination of inlet pipe water. • Measures at or below EPA/DHS/PAG levels. • Protective action guideline levels and military drinking water limits. • Real time, in-line, continuous. • Detects alphas, betas and gammas. • No reagent tanks to fill. • No waste stream. • Easy calibration. • Prevent acute health effects. • Reduce risk of chronic exposure. • World's only PAG-level alpha, beta, gamma water monitor. End Users: • Hospitals • Schools • Government Facilities • High Profile Buildings: Convention Centers, Sports Arenas

TECHNOLOGY:

The alpha, beta flow cell and gamma detector are changed via disconnect fittings. Water moves through the system with a high precision pump; 10 liter per minute capacity or it can be operated using city water pressure and no pump is required. The electronics are microprocessor with LED/LCD display in units of picoCuries per liter. 1. Alpha-Beta Detector: is a light-tight detector assembly interfacing with the sample via disconnect coax cables and medical grade hoses. The sample is viewed by a matched pair of 5'' diameter photo-multiplier tubes. 2. Gamma Scintillation detector has a sensitive 2" diameter crystal.

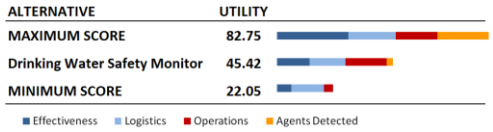
ANALYTICAL Laboratory Ranking

Drinking Water Safety Monitor ranked in the bottom third of all evaluated products for analytical laboratories and earned 48% of the utility points of the best score.



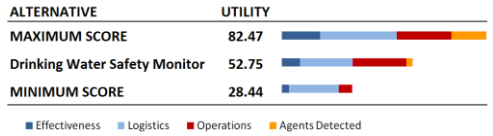
DIAGNOSTIC Laboratory Ranking

Drinking Water Safety Monitor ranked in the middle third of all evaluated products for diagnostic laboratories and earned 55% of the utility points of the best score.



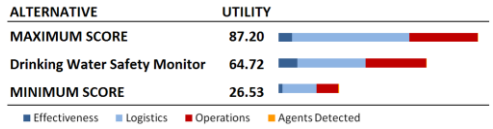
MOBILE Laboratory Ranking

Drinking Water Safety Monitor ranked in the middle third of all evaluated products for mobile laboratories and earned 64% of the utility points of the best score.



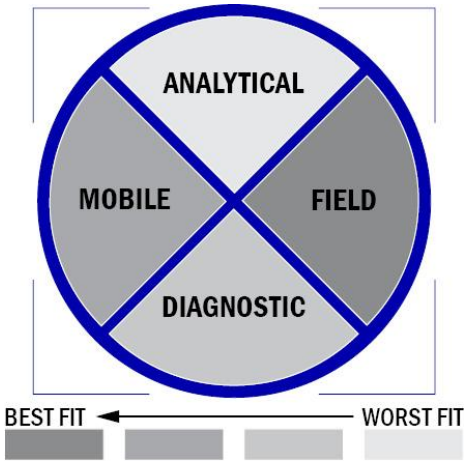
FIELD USE Ranking

Drinking Water Safety Monitor ranked in the middle third of all evaluated products for field use and earned 72% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Technical Associates
7051 Eton Ave.
Canoga Park, CA 91303

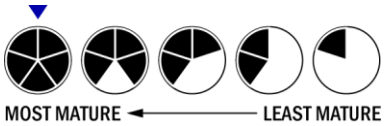
Point of Contact:
Robert Goldstein
818-883-7043

COST

- $35,000.00/system or device

SPECIFICITY

- False Positives: <1:10,000
- False Negatives: <1:1,000



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15 - 30 minutes for detection
- 1 sample, <10 tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- Almost instantaneous down time
- 0-2 steps required
- Manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of carry-on luggage
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Requires a continual supply of water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Greater than 250 ul to test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- > 250 GB generated
- Network capable
- Wired connections
- Fully autonomous
- On board computer chip
- Could be adapted to store and archive data outputs and create an electronic record
- System does not employ software
- System hardware is closed and not available for modification

DX-4030 Portable FTIR Multi-Component Gas Analyzer

by Gasmet Technologies Inc.

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

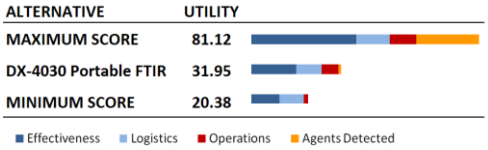
The DX-4030 Gas Analyzer is a field instrument designed for multi-component gas analysis of organic and inorganic gases in the air with sub-ppm detection levels.

TECHNOLOGY:

Gasmet Technologies new DX-4030 Gas Analyzer can measure 25 gases simultaneously using Fourier Transform Infrared technology (FTIR). An internal sample pump actively samples ambient air and all 25 gas concentrations are displayed and logged on a PDA (Personal Digital Assistant) with updated readings each 5 seconds. The library of gases can include CWA's, TIC's and/or other organic and inorganic gases. Identification of unknown gases can be performed by comparing the measured spectrum against the NIST/EPA in spectra library of over 5,000 gases.

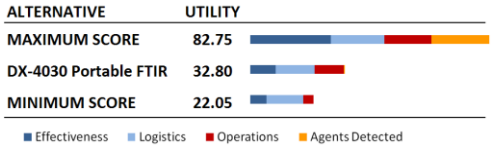
ANALYTICAL Laboratory Ranking

DX-4030 Gas Analyzer ranked in the bottom third of all evaluated products for analytical laboratories and earned 39% of the utility points of the best score.



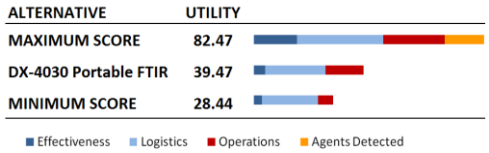
DIAGNOSTIC Laboratory Ranking

DX-4030 Gas Analyzer ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 40% of the utility points of the best score.



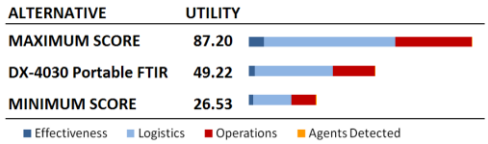
MOBILE Laboratory Ranking

DX-4030 Gas Analyzer ranked in the bottom third of all evaluated products for mobile laboratories and earned 48% of the utility points of the best score.



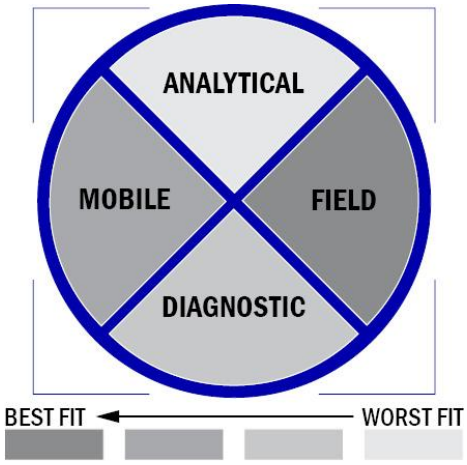
FIELD USE Ranking

DX-4030 Gas Analyzer ranked in the bottom third of all evaluated products for field use and earned 56% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Gasmet Technologies Inc.
1410 Taschereau, B-202
La Prairie, Qc J5R 4E8

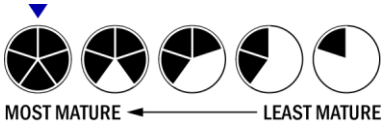
Point of Contact:
Jacques Bourbonnais
sales @gasmet.com
866-685.0050

COST

- Approx. $56,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Could easily be adapted to full automation

Signature:
- Sounds or alarms present
- Screen may be dimmed or turned off
- Thermal output information not available

Training and Speed:
- A day of training and technical skills are required
- 5-10 minutes set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard copy and web-based operators manual

Operational conditions:
- Can be used from 4°C - 41°C
- Does not require consumables
- Performance not influenced by relative humidity
- Does not have a shelf-life

Transportation:
- Approximately the size of carry-on luggage
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- Solutions, buffer, and/or reagents not applicable
- Consumables not applicable

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- 12 month warranty for defective parts
- Expected life >10 years
- <5 minutes daily QA required
- Hazardous agent isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 2-4 hour battery life
- Portable
- Does not require water
- External air or gas source required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- Centrifugation not applicable
- Shaking or vortexing, mixing, degassing or filtering step not applicable
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Gas samples only

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Autonomous
- Laptop computer
- Stores and archives data outputs and creates electronic records
- System software is closed and not available for modification
- System hardware is closed and not available for modification

EAGLE

by ChemImage Corporation

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e3-10e4 CFU/mL)
Toxins
Liquid chemical agent
(> 1 ppt)

DETECTION MATRICES:

Demonstrated:
Nasal and throat swabs, Environmental air, Environmental water, Soil, Food, Powder

DESCRIPTION:

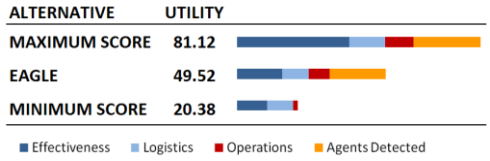
The EAGLE transportable chemical/biological threat detection system can rapidly identify organic and inorganic inorganic industrial chemicals, reveal the presence of chemical or biological weapons of mass destruction (WMD), and equally important, identify the presence of a hoax material. With this critical material identification information in hand, HAZMAT teams can make informed and accurate decisions in regard to potential evacuations of large numbers of people, extensive clean up and decontamination efforts.

TECHNOLOGY:

The EAGLE is the first transportable instrument to combine the strengths of three powerful techniques: microscopic examination, Raman spectroscopy and fluorescence spectroscopy for rapid identification of chemical and biothreats. The first step involves the coupling of fluorescence spectroscopy and microscopic image analysis in a process developed by ChemImage known as wide field Chemical Imaging. The EAGLE uses fluorescence chemical imaging to determine the presence and location of any small fluorescence particle (i.e. a biological). The EAGLE uses Raman spectroscopy to identify the agent by using the built in spectral library.

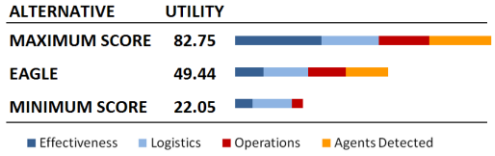
ANALYTICAL Laboratory Ranking

EAGLE ranked in the middle third of all evaluated products for analytical laboratories and earned 61% of the utility points of the best score.



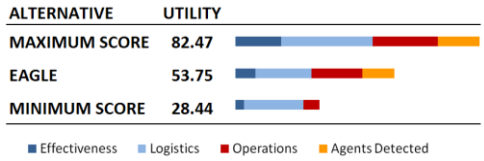
DIAGNOSTIC Laboratory Ranking

EAGLE ranked in the middle third of all evaluated products for diagnostic laboratories and earned 60% of the utility points of the best score.



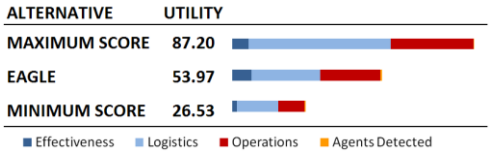
MOBILE Laboratory Ranking

EAGLE ranked in the middle third of all evaluated products for mobile laboratories and earned 65% of the utility points of the best score.



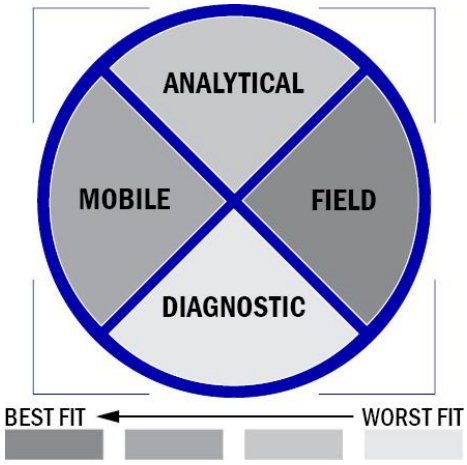
FIELD USE Ranking

EAGLE ranked in the bottom third of all evaluated products for field use and earned 62% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ChemImage Corporation
7301 Penn Ave
Pittsburgh, PA 15208

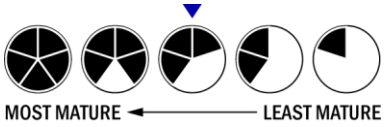
Point of Contact:
412-241-7335

COST

- $199,000.00/system or device

SPECIFICITY

- False Positives: Depends on sample and CONOPS
- False Negatives: Depends on sample and CONOPS



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, single test/ sample per run
- Could be adapted to semi-automated with some effort

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- 10-20 minutes set-up
- <1 minute down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours/ Must be stored at room temp
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of home dishwasher
- Transport via commercial carrier/ Fixed wing military and rotary wing aircraft/ Ship
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by technician only
- Maintenance included
- Expected life >10 years
- 10-20 minutes daily QA
- Exposure to hazardous agent requires up to 1 day to decon

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- Single centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 10 ul to test liquids

System Maturity:
- Brass board
- Expected to be ready for commercialization within one calendar year
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property owned

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Wireless, wired connections
- Could be fully autonomous with significant effort
- Laptop computer
- Could be adapted to store and archive data outputs and create an electronic record
- Software closed and not available for modification
- Hardware closed and not available for modification

EC BAND

by Early Warning Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)

DETECTION MATRICES:

Demonstrated:
Environmental water

DESCRIPTION:

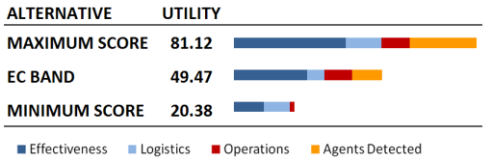
EC BAND is an automated field instrument with electrochemical nucleic acid detection that sequentially collects, extracts, detects and identifies up to 16 biological pathogens and toxins within 4 hours. System is designed to work as a bio-agent autonomous networked detector with no technician for up to 60 tests. EC BAND can be integrated with a third party aerosol collector or Early Warning's water collector/concentrator to process samples containing either airborne, waterborne or surface borne bio-agents. Collector output solutions exposed to immuno-magnetic beads to extract target biological agents from over 1 million inhibitor cells before detection to greatly reduce the incidence of false positives and negatives. Once extracted, target bio-agents are processed to deliver nucleic acid strands to a replaceable cartridge containing up to 60 single-use electrochemical biosensors. Each biosensor contains up to 16 independent working electrodes. Matching nucleic acids hybridize with highly specific DNA probes on individual working electrodes and voltammetry used to generate electrical current from guanine oxidation in proportion to a bio-agent's concentration. LOD limit is 1 cfu bacteria/100 mL of water (achieved) and 0.01 cfu bacteria/liter of air (determined) without PCR. Biosensors are produced on silicon wafers and a low cost per test will be achieved from volume semiconductor fabrication processing. Tests can be triggered by time, remote or local operator, or third party instrument. Test results, alarms transmitted electronically. The system is currently TRL-5.

TECHNOLOGY:

The core technology is an electrochemical biosensor licensed from NASA which redesigned a blood glucose enzyme-biosensor, the most common biosensor platform used in handheld devices. Sensitivity was improved by reducing surface area 5 orders of magnitude by using highly conductive carbon nanotubes to better distinguish guanine oxidation's nanoAmp electrical currents from background noise. Because of their small size, many working electrodes can fit on the same biosensor to allow multiplexing. DNA probes attached to carbon nanotubes on different working electrodes provide highly specific detection on multiple bio-agents. Proven biomolecular processing techniques including immuno-magnetic beads prepare samples for detection.

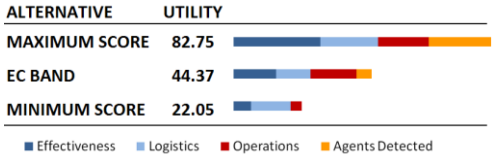
ANALYTICAL Laboratory Ranking

EC BAND ranked in the middle third of all evaluated products for analytical laboratories and earned 61% of the utility points of the best score.



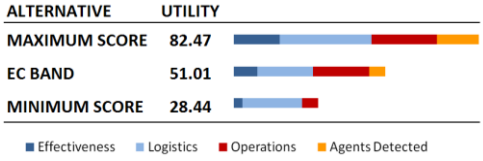
DIAGNOSTIC Laboratory Ranking

EC BAND ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 54% of the utility points of the best score.



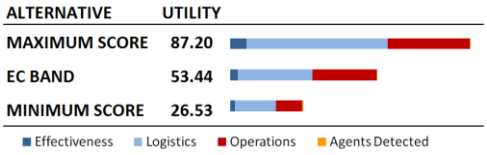
MOBILE Laboratory Ranking

EC BAND ranked in the bottom third of all evaluated products for mobile laboratories and earned 62% of the utility points of the best score.



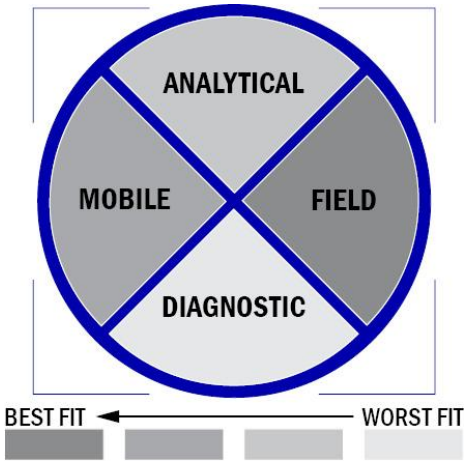
FIELD USE Ranking

EC BAND ranked in the bottom third of all evaluated products for field use and earned 61% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Early Warning Inc.
407 St. Laurent Blvd, Suite 500
Montreal, QC H2Y 2Y5

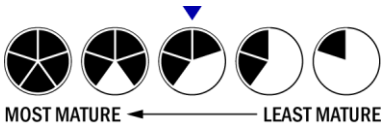
Point of Contact:
Neil Gordon
888.401.3834 ext 5222
Neil.Gordon@EarlyWarningInc.com

COST

- Information not available

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1 - 8 hours for detection
- 1 sample, >10 tests/ sample per run
- Could easily be adapted into a fully automated system

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- >1 day training and significant technical skills are required
- >20 minutes set-up
- >5 minute down time
- 0-2 steps required
- Customer site training

Operational conditions:
- Can be used from -21°C to 41°C
- Components stored at 4°C
- Performance not influenced by relative humidity
- 1 - 6 months shelf life

Transportation:
- Approximately the size of a home dishwasher
- All modes of transportation
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service more than twice a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 3-5 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Requires water aliquots
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 50 ul to test liquids

System Maturity:
- Brass board
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is pending

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Satellite, wireless, wired connections
- Could easily be adapted to fully autonomous
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- Software open, modification requires licensing
- Hardware open, modification requires licensing

EC Lab Analyzer

by Early Warning Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)

DETECTION MATRICES:

Demonstrated:
Environmental water

DESCRIPTION:

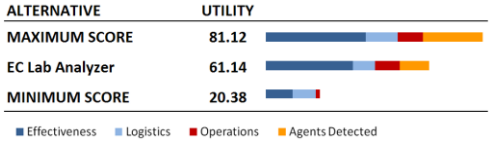
The EC Lab Analyzer is an automated lab instrument that uses electrochemical nucleic acid biosensors to detect up to 16 biological pathogens and toxins in multiple samples simultaneously within 5 minutes after hybridization. The EC Lab Analyzer is designed to work with a low-volume RNA/DNA preparation instrument in a standalone or integrated system for testing clinical or environmental samples. Purified nucleic acids are delivered to a consumable cartridge containing up to 60 single use electrochemical biosensors. Multiple cartridges can be used in parallel to process as many samples as the RNA/DNA preparation instrument can produce. Each biosensor contains up to 16 independent working electrodes. Matching nucleic acids hybridize with highly specific DNA probes on individual working electrodes and voltammetry is used to generate electrical current from guanine oxidation in proportion to a bio-agent's concentration. A greater number of targets can be processed in parallel on additional biosensors. The Level of detection limit is 1 cfu bacteria per 100 ml of water (achieved), 0.01 cfu bacteria per Liter of air (determined) and 1 - 10 cfu per mL blood (determined) without PCR. Biosensors are produced on silicon wafers and low cost per test will be achieved from volume semiconductor fabrication processing. An optional second test can distinguish viable cells from total cells by providing nutrients and heat to half the sample to allow viable cells to reproduce for about 1 1/2 hours and then measure for an increase electrical current from guanine oxidation compared to the untreated sample. The system is currently TRL-4.

TECHNOLOGY:

The core technology is an electrochemical biosensor licensed from NASA which redesigned a blood glucose enzyme-biosensor, the most common biosensor platform used in handheld devices. Sensitivity was improved by reducing the surface area 5 orders of magnitude by using highly conductive carbon nanotubes to better distinguish guanine oxidation's nanoAmp electrical currents from background noise. Because of their small size, many working electrodes can fit on the same biosensor to allow multiplexing. DNA probes attached to carbon nanotubes on different working electrodes provide highly specific detection on multiple bio-agents.

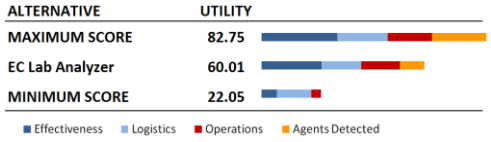
ANALYTICAL Laboratory Ranking

EC Lab Analyzer ranked in the top third of all evaluated products for analytical laboratories and earned 75% of the utility points of the best score.



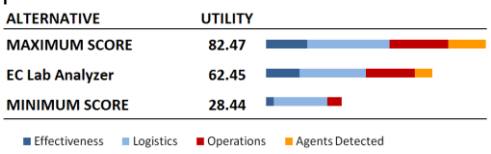
DIAGNOSTIC Laboratory Ranking

EC Lab Analyzer ranked in the top third of all evaluated products for diagnostic laboratories and earned 73% of the utility points of the best score.



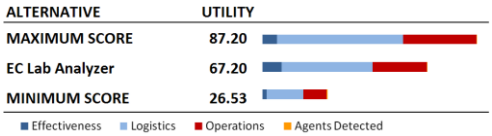
MOBILE Laboratory Ranking

EC Lab Analyzer ranked in the top third of all evaluated products for mobile laboratories and earned 76% of the utility points of the best score.



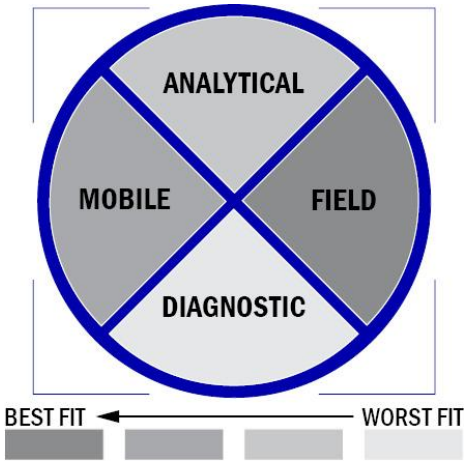
FIELD USE Ranking

EC Lab Analyzer ranked in the middle third of all evaluated products for field use and earned 77% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Early Warning Inc.
407 St. Laurent Blvd, Suite 500
Montreal, QC H2Y 2Y5

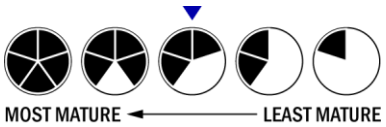
Point of Contact:
Neil Gordon
888.401.3834 ext 5222
Neil.Gordon@EarlyWarningInc.com

COST

- Information not available

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15 - 30 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Could easily be adapted into a fully automated system

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- <5 minutes set-up
- <5 minute down time
- 0-2 steps required
- Customer and manufacturer site training

Operational conditions:
- Can be used from 4°C to 41°C
- Components stored at 4°C
- Performance not influenced by relative humidity
- 1 - 6 months shelf life

Transportation:
- Approximately the size of a home dishwasher
- All modes of transportation
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service more than twice a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 3-5 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- 4-8 hours battery life
- Requires water aliquots
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 50 ul to test liquids

System Maturity:
- Brass board
- Ready for commercialization in 1 year
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is pending

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Satellite, wireless, wired connections
- Could easily be adapted to fully autonomous
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- Software open, modification requires licensing
- Hardware open,

Eco™ Real-Time PCR System

by Illumina Inc.

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

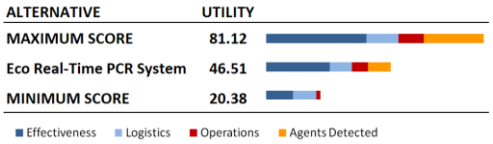
The instrument is an integrated system designed to perform Real-Time PCR. The instrument utilizes a custom plate allowing the researcher to analyze up to 48 samples simultaneously. An intuitive software interface supports all chemistries and Real-time PCR applications, including absolute quantification by standard curve, relative quantification with support for multiple reference gene normalization, allelic discrimination by end-point fluorescence and genotyping by High Resolution Melt(HRM) curve analysis.

TECHNOLOGY:

The instrument utilizes an advanced thermal design which incorporates a precisely electroformed hollow silver block that is heated and cooled by a single Peltier device. The hermetically sealed hollow block contains a conductive fluid and two opposing agitators driven by electromagnetic motors. During PCR cycling these agitators rapidly circulate the fluid, transferring heat from the peltier quickly and evenly throughout the hollow block. The optical system consists of two panels of 48 fixed LEDs, four emission filters in a linear filter slide, and a high performance CCD camera which detects the fluorescence for each well at each cycle.

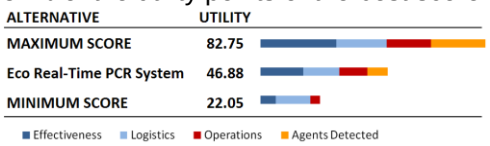
ANALYTICAL Laboratory Ranking

Eco™ Real-Time PCR System ranked in the middle third of all evaluated products for analytical laboratories and earned 57% of the utility points of the best score.



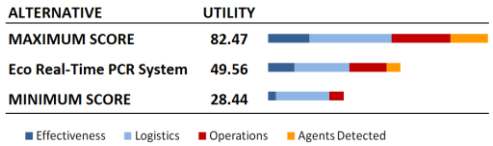
DIAGNOSTIC Laboratory Ranking

Eco™ Real-Time PCR System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 57% of the utility points of the best score.



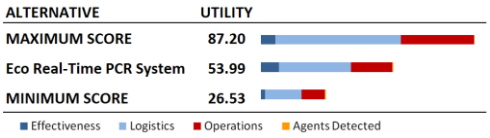
MOBILE Laboratory Ranking

Eco™ Real-Time PCR System ranked in the bottom third of all evaluated products for mobile laboratories and earned 60% of the utility points of the best score.



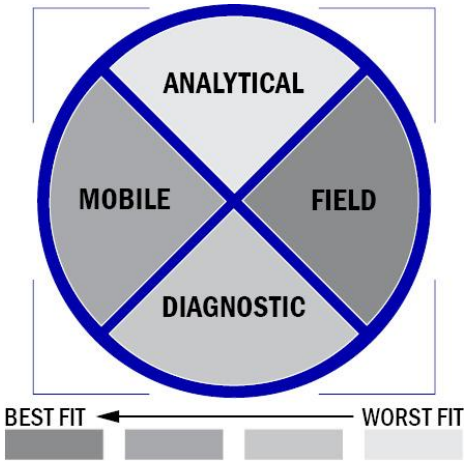
FIELD USE Ranking

Eco™ Real-Time PCR System ranked in the bottom third of all evaluated products for field use and earned 62% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Illumina Inc.
9885 Towne Centre Drive
San Diego, CA 92121

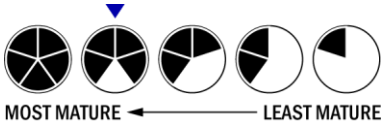
Point of Contact:
Dawn Barry
dbarry@illumina.com
1-800-809-4566

COST

- $13,900.00/system or device
- $1.07/analysis

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Could be semi-automated with some effort

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off

Training and Speed:
- An afternoon of training and some technical skills required
- 10-20 minutes set up
- 1-3 minutes down time
- 3-5 steps are required
- Web video/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be stored at 4°C/ Components must be frozen
- Performance is not influenced by relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a toaster
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by technician
- Maintenance is not included
- Expected life 5-10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can not be processed while in progress
- A single centrifugation steps required
- A single shaking or vortexing, mixing, degassing or filtering step required
- Software could call final result in future

Sensitivity and Detection:
- 510K clearance capable
- FDA approval not applicable
- Less than 10 ul for a test

System Maturity:
- Is commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Not capable of autonomy
- Laptop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is closed and not available for modification

Enigma FL (Field-Lab) System

by Enigma Diagnostics

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Urine, Environmental air, Environmental water, Soil

DESCRIPTION:

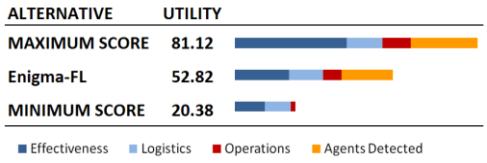
Enigma Diagnostics' rapid PCR system combines the speed and sensitivity of real-time PCR with the simplicity needed for field-based and point-of-care molecular tests. Portable and completely self-contained, every aspect of its operation has been fully automated to provide ultra-rapid, laboratory-standard results even when used in the field. The entire process from collection of the raw sample to delivery of an unequivocal end result can take less than 30 minutes. The system operates with ambient stored reagents in a single disposable cartridge and meets the need for diagnostic systems that are portable and easy to use with minimal operator training and expertise. This eliminates the logistics and training burden associated with traditional PCR instruments that require refrigerated reagents and time-consuming manual sample processing.

TECHNOLOGY:

Real-time PCR.

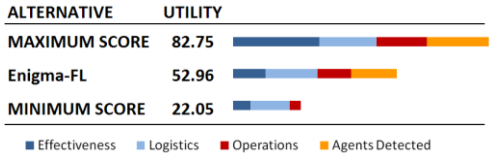
ANALYTICAL Laboratory Ranking

Enigma FL ranked in the middle third of all evaluated products for analytical laboratories and earned 65% of the utility points of the best score.



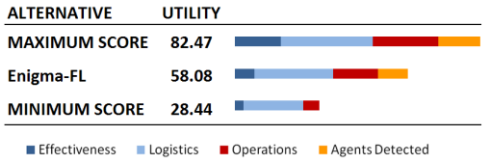
DIAGNOSTIC Laboratory Ranking

Enigma FL ranked in the middle third of all evaluated products for diagnostic laboratories and earned 64% of the utility points of the best score.



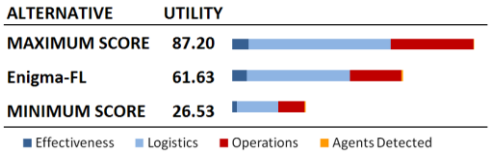
MOBILE Laboratory Ranking

Enigma FL ranked in the middle third of all evaluated products for mobile laboratories and earned 70% of the utility points of the best score.



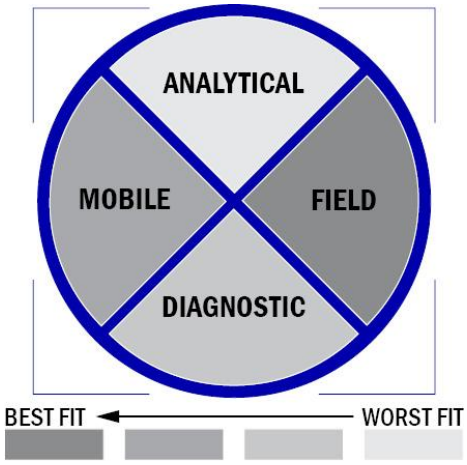
FIELD USE Ranking

Enigma FL ranked in the middle third of all evaluated products for field use and earned 71% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Enigma Diagnostics
Building 244, Tetricus Science Park
DSTL Porton Down,
Salisbury, Wiltshire, UK SP4 0JQ

COST

- $42,600.00/system or device
- $28.00-45.00/analysis

SPECIFICITY

- False Positives: 2-5%
- False Negatives: 1-2%

Maturity Not Available

Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30-60 minutes for detection
- 1 sample, >10 tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms present
- Screen cannot be dimmed or turned off

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes for set up
- < 1 minute down time
- 0-2 steps are required
- Customer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components must be stored at room temperature (27°C)
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 3 component

Maintenance:
- Preventive maintenance serviceable by customer
- Expected life unknown
- Less than 5 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time not available
- Software will call final result

Sensitivity and Detection:
- FDA approval capable
- Greater than 250 ul for a test

System Maturity:
Not Available

Interoperability and System Complexity:
- > 250 GB
- Wired connections
- Not capable of autonomy
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record

Enigma-ML

by Enigma Diagnostics Ltd

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e3-10e4 CFU/mL)
Viruses (10e3-10e4 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Nasal and Throat swabs, Food

DESCRIPTION:

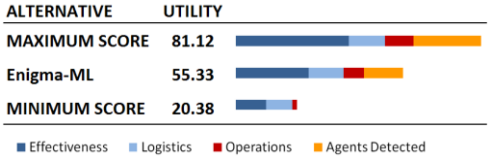
The Enigma-ML is the next generation of biological agent detection system. It combines the specificity and sensitivity of diagnostic laboratory PCR tests with the speed and simplicity needed for rapid, point-of-care diagnosis. Using Enigma's sample preparation and Electrically Conducting Polymer (ECP) thermocycling technology, the Enigma ML provides fully automated diagnostic testing without the need for laboratory facilities or specialist equipment. The instrument can process a range of clinical samples in addition to food and environmental matrices. Enigma-ML has a modular, easily scalable architecture providing the flexibility to analyse up to six tests in parallel with complete random access. A minimally trained user can perform analysis from raw sample to end result in under 60 minutes. Comprehensive data entry and traceability is assured using a virtual keyboard and integrated bar-code reader; POCT1-2A compliant Ethernet communication protocols provide connectivity with surveillance and information management systems for time-critical decision making. Ambient stable reagents are pre-packaged within a multi-functional consumable cartridge, eliminating the manual processing and refrigerated logistics burden of conventional PCR instruments. Complete sample analysis is a 3 step process. The test result is conveyed using an unambiguous on-screen dialogue with the option of hard-copy results via an integrated thermal printer. Enigma ML is designed to deliver gold-standard, on-site diagnostic capabilities to clinicians, first responders, homeland security and veterinary professionals.

TECHNOLOGY:

Enigma-ML automates all steps in the PCR process from raw sample to diagnostic result calling. Test reagents are self-contained within a disposible cartridge; sample processing ululitzing a chemical lysis with robust magnetic bead nucleic acid purification. Enigma's freeze-drying technology enables ambient storage stability of PCR reagents. The instrument has two LED excitation sources with six-channel detection optics supporting TaqMan®, HybProbe® and other fluoresence PCR assays. Direct-heating thermocycling using our proprietary ECP reaction vessel provides the rapid, precise thermal transitions required for highly multiplexed PCR and melt analyses. Test outcome is automatically determined using proprietary algorithms for data interpretation and result presentation.

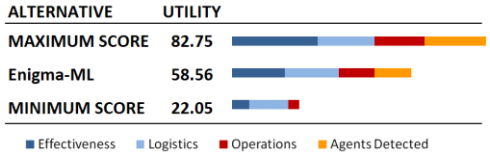
ANALYTICAL Laboratory Ranking

Enigma-ML ranked in the top third of all evaluated products for analytical laboratories and earned 68% of the utility points of the best score.



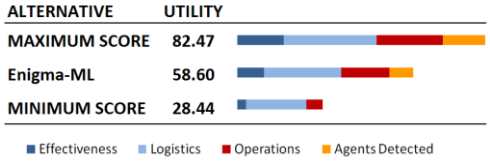
DIAGNOSTIC Laboratory Ranking

Enigma-ML ranked in the top third of all evaluated products for diagnostic laboratories and earned 71% of the utility points of the best score.



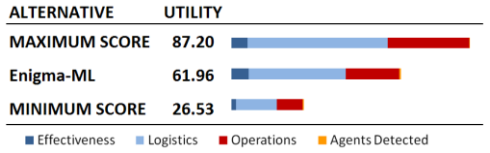
MOBILE Laboratory Ranking

Enigma-ML ranked in the middle third of all evaluated products for mobile laboratories and earned 71% of the utility points of the best score.



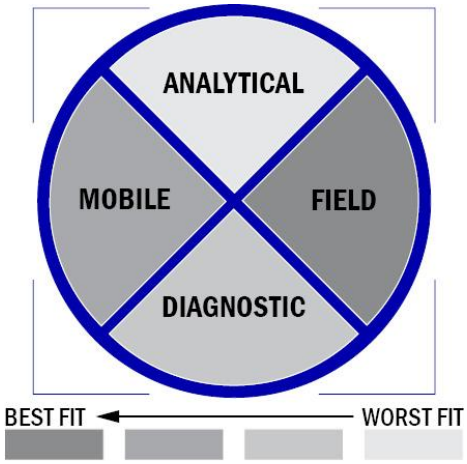
FIELD USE Ranking

Enigma-ML ranked in the middle third of all evaluated products for field use and earned 71% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Enigma Diagnostics Ltd
Tetricus Science Park DSTL
Porton Down Salisbury Wiltshire SP4 0JQ UK +44 (0)1235 854034

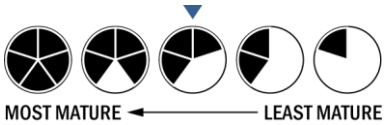
Point of Contact:
Dr Ian George Director, Business Development
ian.george@enigmadiagnostics.com

COST

- $25,000.00/system or device
- $20.00-25.00/analysis

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30-60 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- No sounds or alarms
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set up required
- Almost no down time
- 0-2 steps are required
- DVD/ Web video/ Customer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be stored at room temperature but can withstand temperatures > 45°C for periods < 24 hours
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Maintenance is included
- Expected life 3-5 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decon requires <1 hr

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time not available
- Data cannot be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 250 ul for a test

System Maturity:
- Brass board
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Not capable of autonomy
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

Envi Assay System and ChemPro Reader Module

by Environics

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (>100,000 CFU/mL)
Viruses (>100,000 PFU/mL)
Toxins (1-100 ng/mL)

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

Envi assay system is intended for rapid on-site identification of biological material. The system has manual test tickets for Ricin toxin, Botulinum toxin, SEB toxin, Anthrax and Smallpox. The system also contains a reader module that is used to read the test results.

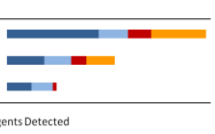
TECHNOLOGY:

The test tickets are based on Immunoassay technology that use either gold- or fluorescence labeled antibodies. The reader module has a two-wavelength camera that is capable of reading both labels. The Reader module can be connected to a ChemPro100 Chemical Detector or to a PC.

ANALYTICAL Laboratory Ranking

Envi Assay System ranked in the middle third of all evaluated products for analytical laboratories and earned 54% of the utility points of the best score.

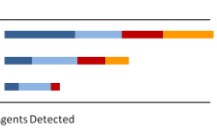
ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
Envi Assay and ChemPro Reader	43.88
MINIMUM SCORE	20.38



DIAGNOSTIC Laboratory Ranking

Envi Assay System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 60% of the utility points of the best score.

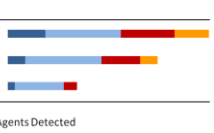
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
Envi Assay and ChemPro Reader	49.36
MINIMUM SCORE	22.05



MOBILE Laboratory Ranking

Envi Assay System ranked in the top third of all evaluated products for mobile laboratories and earned 74% of the utility points of the best score.

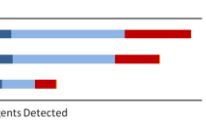
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
Envi Assay and ChemPro Reader	61.35
MINIMUM SCORE	28.44



FIELD USE Ranking

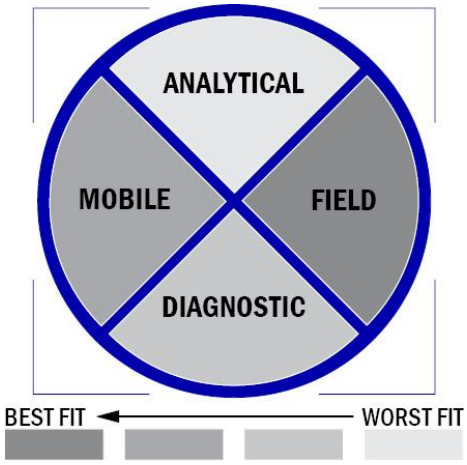
Envi Assay System ranked in the top third of all evaluated products for field use and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
Envi Assay and ChemPro Reader	73.14
MINIMUM SCORE	26.53



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Environics
Oy Graanintie 5 50100
Mikkeli, Finland

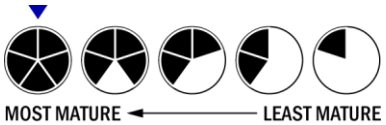
Point of Contact:
Timo Jaakkola
timo.jaakkola@environicsusa.com
443 703 8008

COST

- $15,000.00/system or device

SPECIFICITY

- False Positives: 0
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, single test/ sample per run
- Not amenable to full or semi-automation

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- <5 minutes set-up required
- <1 minute down time
- 3-5 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C - 41°C
- Components must be stored at room temp (27°C)
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Single use
- 0-1 solutions, buffer, and/or reagents
- 3 components

Maintenance:
- No service required
- Preventive maintenance not applicable
- Maintenance not included
- Expected life not applicable
- No daily QA required
- No decontamination required

Physical System Requirements:
- No electrical requirement
- Battery life 4-8 hours
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering step
- System calls final result

Sensitivity and Detection:
- 510K clearance not capable
- FDA clearance incapable
- Less than 10 ul required for test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connection
- Not autonomous
- On board computer chip
- Stores and archives data outputs and creates electronic records
- System software open and available for modification
- System hardware open and available for modification

Envi BioScout

by Environics

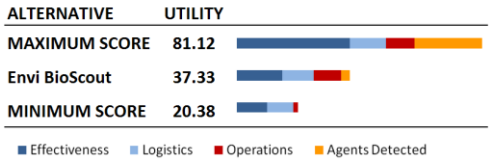
DETECTS THE FOLLOWING:
Nothing demonstrated.

DETECTION MATRICES:
Nothing demonstrated.

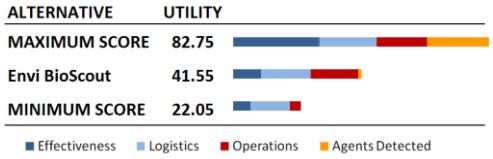
DESCRIPTION:
ENVI BioScout™ provides a robust and sensitive bioaerosol detection solution that monitors continuously ambient air, triggers early-warning for detected potential airborne biological threats and initiates automatic air sample collection when a biological alarm is issued.

TECHNOLOGY:
The bioaerosol detector is intended to operate as an integral part of fixed and mobile EnviScreen CBRN Monitoring Systems with Operix/Manifix 2010 software, but it is easy to integrate to 3rd party systems as well. ENVI BioScout™ is compatible with various communication methods and its modular design enables broadening of the device capabilities: an additional sample collector, a remote alarm unit, a BWA identifier or other optional modules can be connected to ENVI BioScout™ through various interface options. The device can be adapted to different outdoor and indoor environments through its adjustable, advanced alarm algorithm. It has been designed to tolerate demanding environmental conditions with continuous use, ease of maintenance and feasible lifecycle costs in mind. ENVI BioScout™ applications include both civilian and military protection in the form of building and area monitoring, mass event and critical infrastructure protection and NBC reconnaissance vehicles etc.

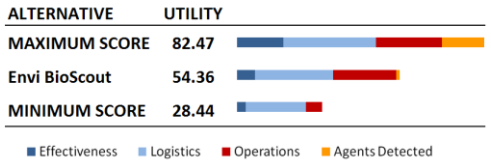
ANALYTICAL Laboratory Ranking
Envi BioScout ranked in the bottom third of all evaluated products for analytical laboratories and earned 46% of the utility points of the best score.



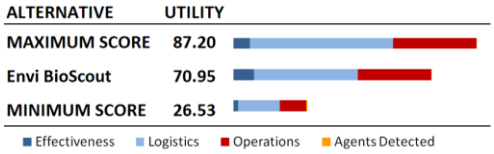
DIAGNOSTIC Laboratory Ranking
Envi BioScout ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 50% of the utility points of the best score.



MOBILE Laboratory Ranking
Envi BioScout ranked in the middle third of all evaluated products for mobile laboratories and earned 66% of the utility points of the best score.

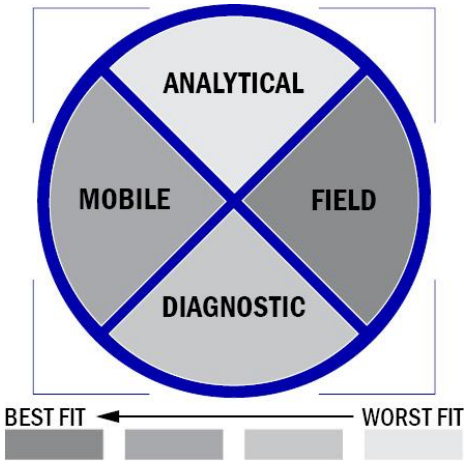


FIELD USE Ranking
Envi BioScout ranked in the top third of all evaluated products for field use and earned 81% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Environics
Oy Graanintie 5
50100 Mikkeli Finland

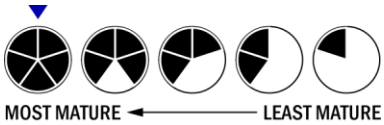
Point of Contact:
Timo Jaakkola
443 703 8008
timo.jaakkola@environicsusa.com

COST

- Approx. $ 55,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Number of tests/ sample per run not applicable
- Fully automated

Signature:
- Sounds or alarms not present
- No screen
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- <5 minutes set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site/ Hard-copy manual

Operational conditions:
- Used from < -21°C to > 42°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours/ Must be stored at room temp (27°C)/ Must be stored at 4°C
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of carry-on luggage
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by customer
- Maintenance not included
- Greater than 10 years
- No daily QA required
- Exposure to hazardous agent would require up to 1 day to decon

Physical System Requirements:
- 110V electrical requirement
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connection
- Could be adapted to fully autonomous with some effort
- No computer required
- Stores and archives data outputs and creates electronic records
- System software closed, not available for modification
- System hardware closed, not available for modification

EpiSENSE

by Episensor

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (100-1,000 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Environmental air, Environmental water, Soil, Food, Powder, Insect vectors

DESCRIPTION:

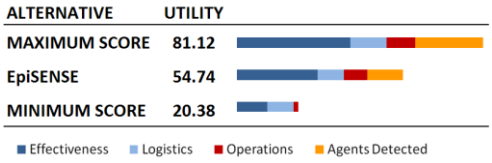
Episensors' EpiSENSE system is a biological detection platform that utilizes our unique Quantum Dot (QD) Forster Resonance Energy Transfer (FRET) detection technology. This technology uses antibodies to capture target antigens, triggering an optical response that is detected by the EpiSENSE system. The use of antibodies provides a high level of sensitivity, and allows for the simultaneous detection and identification of a wide variety of different biological pathogens including bacteria, viruses and toxins. The EpiSENSE system is designed to provide remote detection of airborne biological pathogens and reports their concentrations. Sample collection, liquid handling and optical measurements have been integrated to produce a low cost, stand-alone system that is currently capable of semi-autonomous remote operation. The system can operate continuously or on a set duty cycle. Its design allows for easy adaptation to accommodate a wide range of sample types including liquids, sample swipes and powders. EpiSENSE recently underwent field testing at Dugway Proving Ground's Joint Ambient Breeze Tunnel, where the detection of airborne biological pathogens was successfully demonstrated against a simulated real world background.

TECHNOLOGY:

EpiSENSE utilizes antibody functionalized QDs to detect, identify and quantify the presence of biological analytes. The QDs are initially functionalized in such a way that their optical emission is quenched. When the QD complexes are exposed to the analyte of interest, the quenching mechanism is disrupted and the QDs begin to fluoresce, which indicates the presence as well as the concentration of the analyte. Because the system is initially in a quenched state, the assay sensitivity is greatly increased and the false positive rate greatly decreased when compared to conventional FRET assays that begin in an unquenched state.

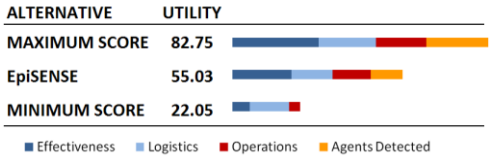
ANALYTICAL Laboratory Ranking

EpiSENSE ranked in the top third of all evaluated products for analytical laboratories and earned 67% of the utility points of the best score.



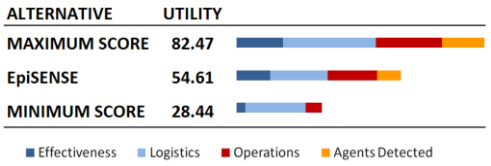
DIAGNOSTIC Laboratory Ranking

EpiSENSE ranked in the top third of all evaluated products for diagnostic laboratories and earned 67% of the utility points of the best score.



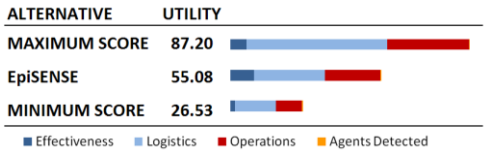
MOBILE Laboratory Ranking

EpiSENSE ranked in the middle third of all evaluated products for mobile laboratories and earned 66% of the utility points of the best score.



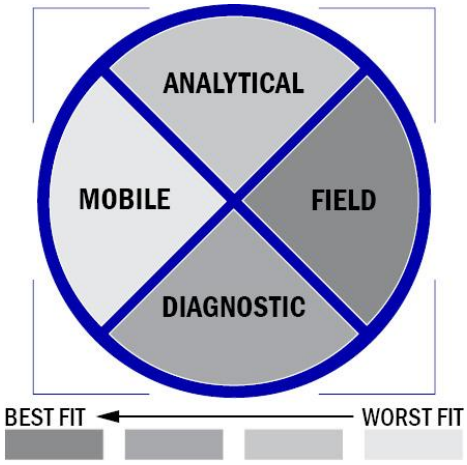
FIELD USE Ranking

EpiSENSE ranked in the middle third of all evaluated products for field use and earned 63% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

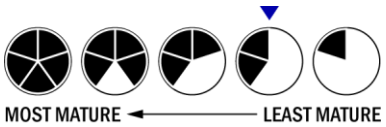
Episensor
590 Territorial Drive Unit H
Bolingbrook, IL 60440

COST

- $25,000.00/system or device
- $0.50/analysis

SPECIFICITY

- False Positives: 0.000001%
- False Negatives: 0.000001%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- 1 sample, <10 tests/ sample per run
- Currently semi-automated

Signature:
- Sounds or alarms present
- No screen present
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 10-20 minutes set up
- <1 minute down time
- 0-2 steps are required
- Manufacturer site training

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp
- Performance is not influenced by relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service more often that every 6 months
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 3-5 years
- Less than 5 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- A single shaking or vortexing, mixing, degassing or filtering step required
- Software could call final result in the future

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 10 ul for a test

System Maturity:
- Bread board
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Not network capable
- Wired connections
- Autonomous system with easy adaptation
- Laptop computer
- System could be adapted to store and archive data outputs and create an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

eSensor XT-8

by GenMark Diagnostics

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Food

DESCRIPTION:

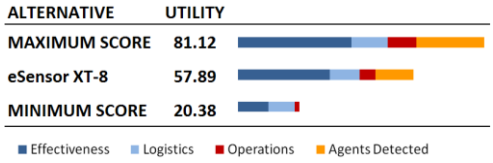
The eSensor XT-8 is a multiplex molecular diagnostics platform which utilizes GenMark's proprietary electrochemical detection technology. The system features random access, touch screen interface and requires no routine maintenance or calibration. The unit is field upgradeable to include 1, 2 or 3 analysis towers for a total of 8, 16 or 24 cartridges at one time.

TECHNOLOGY:

Multiplex assays for DNA/RNA, proteins or small molecules using electrochemical detection and AC voltametry. Electrochemical detection allows for low input levels and is highly resistant to interference from sample constituents.

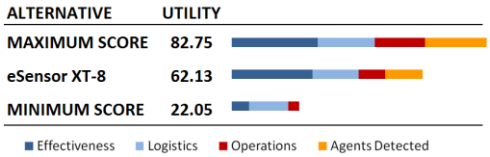
ANALYTICAL Laboratory Ranking

eSensor XT-8 ranked in the top third of all evaluated products for analytical laboratories and earned 71% of the utility points of the best score.



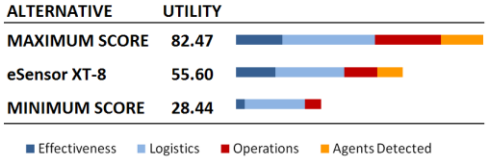
DIAGNOSTIC Laboratory Ranking

eSensor XT-8 ranked in the top third of all evaluated products for diagnostic laboratories and earned 75% of the utility points of the best score.



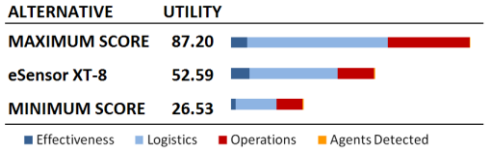
MOBILE Laboratory Ranking

eSensor XT-8 ranked in the middle third of all evaluated products for mobile laboratories and earned 67% of the utility points of the best score.



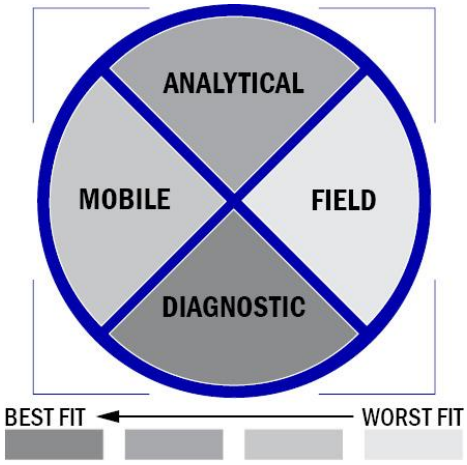
FIELD USE Ranking

eSensor XT-8 ranked in the bottom third of all evaluated products for field use and earned 60% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

GenMark Diagnostics
5964 La Place Court
Carlsbad, CA 92008

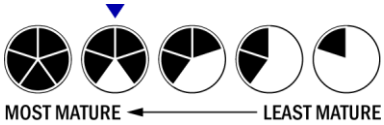
Point of Contact:
Jeff Hawkins SVP Marketing & Business Development
Office: 760-448-4310
jeff.hawkins@genmarkdx.com

COST

- $50,000.00/system or device
- $75.00-150.00/analysis

SPECIFICITY

- 510K cleared assays have accuracy of 99%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Adapted with some effort to fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed
- Thermal output unknown

Training and Speed:
- An afternoon of training
- < 5 minutes set up
- Almost no down time
- 3-5 steps are required
- Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components stored at room temp can withstand >45°C for <24 hours/ Components stored frozen can withstand >4°C for <24 hours
- Peak performance at normal relative humidity conditions
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Commercial/ Fixed wing aircraft/ Ship transport
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions and/or reagents
- 5 or more components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance is included
- Expected life 5-10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1hr

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results not available
- No centrifugation steps required
- Multiple shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance shown
- FDA approval shown
- Less than 250 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Not network capable
- Wired connections
- Not capable of autonomy
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

Exicycler 96

by Bioneer Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Environmental air, Environmental water, Soil, Food, Powder

DESCRIPTION:

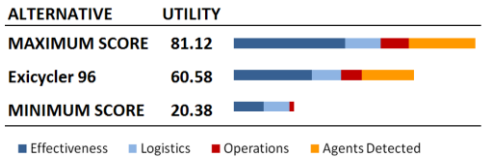
The Exicycler 96 is a standard format (96-well), thermal cycler that can be used to perform real-time PCR. The system used a thermal block whose temperature can be controlled, to drive an enzymatic reaction that duplicates DNA. It also contains an optical component that can quantify the amount of DNA in the reaction at a given time. As the amount of DNA increases, the optical sensor can detect this. Software included in the system allow detailed analysis of many kinds of experiments including: Absolute quantitation, Relative quantitation, SNP analysis, plus/minus assays and more.

TECHNOLOGY:

The Exicycler 96 supports two different reaction chemistries: Probe based chemistries and SYBR™ Green I double stranded DNA binding dye chemistry. The Exicycler 96 is a real-time thermal cycler that features a patented system of optics that drives the same amount of light to each well ensuring even fluorescent excitation without the need for a background "reference dye". This technology is called Light Tunnel Technology and exclusive to the Exicycler. The thermal cycler itself is driven by a peltier based 96-well block. The Exicycler 96 is a true 5 color system since there is no need for a reference dye, allowing the use of dyes that are well separated in multiplex experiments. The instrument has an a short arc lamp excitation source, and utilizes a 16-bit 2-D charge coupled device (CCD) camera to enable continuous wavelength detection from 520-680 nm.

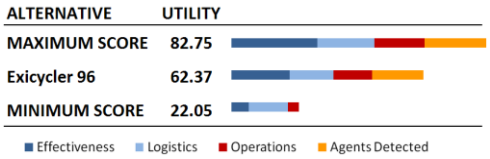
ANALYTICAL Laboratory Ranking

Exicycler 96 ranked in the top third of all evaluated products for analytical laboratories and earned 75% of the utility points of the best score.



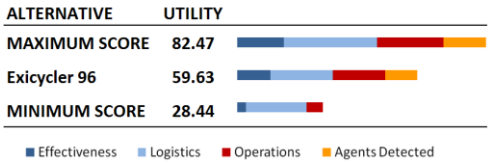
DIAGNOSTIC Laboratory Ranking

Exicycler 96 ranked in the top third of all evaluated products for diagnostic laboratories and earned 75% of the utility points of the best score.



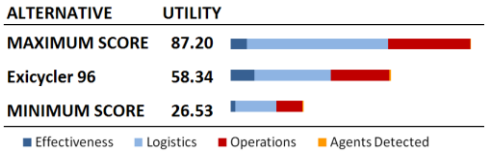
MOBILE Laboratory Ranking

Exicycler 96 ranked in the middle third of all evaluated products for mobile laboratories and earned 72% of the utility points of the best score.



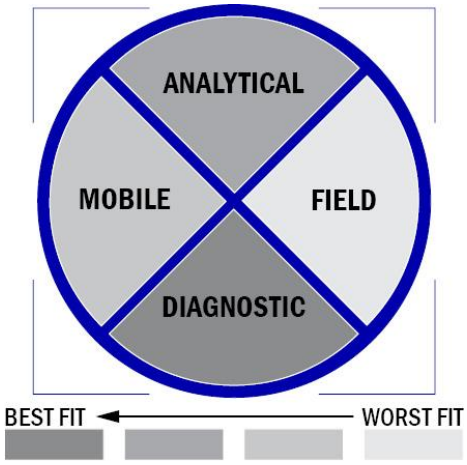
FIELD USE Ranking

Exicycler 96 ranked in the middle third of all evaluated products for field use and earned 67% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Bioneer Inc.
1000 Atlantic Avenue
Alameda, CA 94501

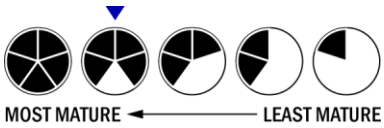
Point of Contact:
Dr. Vincent Prezioso
510-735-6932

COST

- $30,000/system or device
- $0.50/analysis

SPECIFICITY

- False positives: Not applicable
- False negatives: Not applicable



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Easily adapted into a fully automated system

Signature:
- Sounds or alarms cannot be deactivated
- No screen
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- >5 minutes set up required
- <1 minute down time
- 0-2 steps are required
- DVD/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be stored frozen but can with stand temperatures > 4°C for <24 hours/ Must be stored at room temperature (27°C)
- Performance is not influenced by relative humidity
- Shelf life greater than 3 years

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions and/or reagents
- 2 components

Maintenance:
- Service once per year
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1 hr

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source is required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- There is a single centrifugation step required
- There is a single shaking or vortexing, mixing, degassing or filtering step required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- <50 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB
- Network Capable
- Wired connections
- Could be adapted to a fully autonomous system with some effort
- Laptop computer
- The system automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

ExiStation Molecular Diagnostic Platform

by Bioneer, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Environmental air, Environmental water, Food

DESCRIPTION:

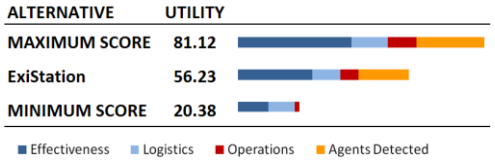
The ExiStation Molecular Diagnostic Platform is a semi-automated system that provides sample preparation and real-time diagnostics for a variety of clinical sample types and tests. The system allows for simultaneous parallel analysis of up to 6 different samples types and tests in under 4 hours making it the highest throughput system available.

TECHNOLOGY:

The ExiStation consists of 3 x ExiPrep 16 Dx systems, and ExiSpin and an Exicycler 96. The ExiPrep systems are sample prep devices capable of purifying DNA and RNA from a wide range of clinical samples and uses proprietary spherical magnetic nano-particles. Once the sample is purified, the ExiPrep 16 Dx will also set up the diagnostic qPCR reaction which is then taken to the ExiSpin. The ExiSpin is a combination centrifuge/vortexer that is used to mix and spin the reactions in a uniform manner ensuring world class reproducibility of the kits. Finally, after mixing and spinning in the ExiSpin, the samples are placed in the Exicycler 96 Real-Time thermal cycler. The Exicycler uses a peltier based thermal block and has 5-color optics with a 16 bit 2-d CCD camera for detection.

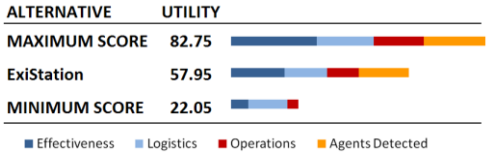
ANALYTICAL Laboratory Ranking

ExiStation Molecular Diagnostic ranked in the top third of all evaluated products for analytical laboratories and earned 69% of the utility points of the best score.



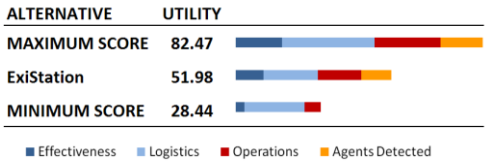
DIAGNOSTIC Laboratory Ranking

ExiStation Molecular Diagnostic ranked in the top third of all evaluated products for diagnostic laboratories and earned 70% of the utility points of the best score.



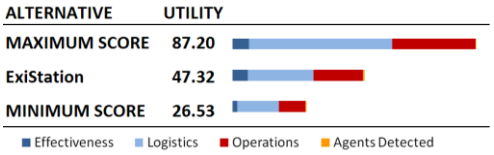
MOBILE Laboratory Ranking

ExiStation Molecular Diagnostic ranked in the middle third of all evaluated products for mobile laboratories and earned 63% of the utility points of the best score.



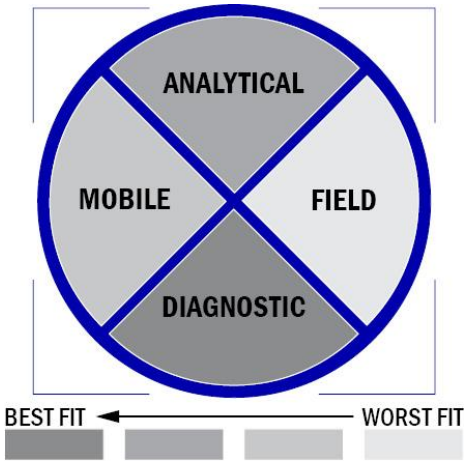
FIELD USE Ranking

ExiStation Molecular Diagnostic ranked in the bottom third of all evaluated products for field use and earned 54% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Bioneer, Inc.
1000 Atlantic Avenue
Alameda, CA 94501

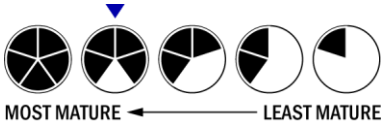
Point of Contact:
Dr. Vincent Prezioso
510-735-6923
vince@bioneer.us.com

COST

- $82,000/system or device
- $30/analysis

SPECIFICITY

- False positives: Not available
- False negatives: Not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Currently semi-automated

Signature:
- Sounds or alarms cannot be deactivated
- No screen
- Less than 200 BTU

Training and Speed:
- An afternoon of training and some technical skills required
- <5 minutes set up required
- Minimal down time
- 3-5 steps required
- DVD/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components stored at room temp but can with stand temps > 45°C for <24 hours
- Performance is not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of carry-on luggage suitcase
- All modes of transportation
- Weighs >50 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service less than once per year
- Preventive maintenance serviceable by technician only
- Maintenance is not included
- Expected life 5-10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1 hr

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- Multiple centrifugation steps are required
- Multiple shaking or vortexing, mixing, degassing or filtering steps are required
- Software will call the final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 250 ul for a test

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB
- Network capable
- Wired connections
- Fully autonomous
- Laptop computer
- The system automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

Experion Automated Electrophoresis System

by Bio-Rad Laboratories

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Demonstrated:
Food

DESCRIPTION:

Experion is a system based on microfluidic chip technology, automates electrophoretic separation, staining, destaining, imaging, band detection, quantitation and other data analysis of protein, RNA, or DNA molecules. Digitized data such as size (molecular weight), concentration, % total are displayed automatically during and after a run. Experion requires very small volumes of sample (1-4ul), uses small volumes of reagents, and thus produces very small waste volumes and minimizes exposure to reagents. People who normally use SDS-PAGE analysis can use Experion for their protein analysis (such as sizing and purity). People running gels to separate RNA or DNA can use Experion. People checking their RNA integrity for downstream applications such as RT-qPCR can use Experion.

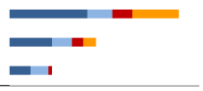
TECHNOLOGY:

Electrophoretic separation of protein, RNA, and DNA with detection based on laser induced fluorescence of the detection dyes used for each assay. The device is meant for laboratory use (not portable) and takes up a small amount of bench space. The microfluidic chip is based on the Lab-on-a-chip platform (from Caliper Life Sciences).

ANALYTICAL Laboratory Ranking

Experion Automated Electrophoresis System ranked in the bottom third of all evaluated products for analytical laboratories and earned 51% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
Experion Automated System	41.63
MINIMUM SCORE	20.38

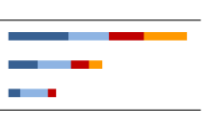


Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

Experion Automated Electrophoresis System ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 53% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
Experion Automated System	43.62
MINIMUM SCORE	22.05

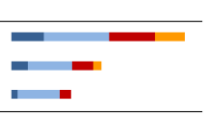


Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

Experion Automated Electrophoresis System ranked in the t bottom third of all evaluated products for mobile laboratories and earned 52% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
Experion Automated System	42.80
MINIMUM SCORE	28.44

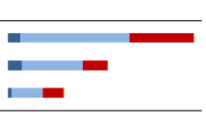


Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

Experion Automated Electrophoresis System ranked in the bottom third of all evaluated products for field use and earned 54% of the utility points of the best score.

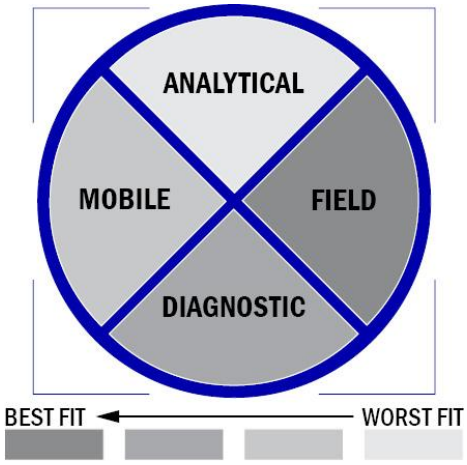
ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
Experion Automated System	46.97
MINIMUM SCORE	26.53



Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Bio-Rad Laboratories
6000 James Watson Dr.
Hercules, CA 94547

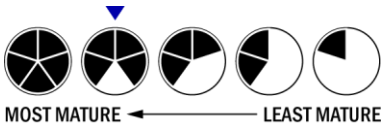
Point of Contact:
Marie Nguyen
510 741 5312

COST

- $16,234.00/system or device

SPECIFICITY

- False Positives: N/A
- False Negatives: N/A



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30 - 60 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- <5 minutes set-up required
- 1-3 minutes down time
- 3-5 steps required
- DVD/ Customer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 25°C - 37°C
- Components must be stored at room temp (27°C)/ Must be stored at 4°C/ Must be frozen at temps at or below -20°C (cryo-storage)
- Peak performance at normal relative humidity conditions
- Shelf life 6 months - 1 year

Transportation:
- Approximately the size of a carry-on luggage
- Transport via commercial carrier or ship
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 4 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- No service required
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- No decontamination required

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- Single centrifugation step
- Single shaking or vortexing, mixing, degassing or filtering step
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance capable
- Less than 10 ul required for test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Not network capable
- Not autonomous
- Laptop computer
- Stores and archives data outputs and creates electronic records
- System software closed and not available for modification
- System hardware closed and not available for modification

FABS (Fast Aerosol Bioclassification System)

by Hamilton Sundstrand Corp.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria
Viruses
Toxins

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

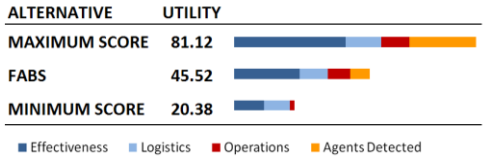
The Fast Aerosol Bioclassification Sensor (FABS) is a facility monitor device developed jointly by Hamilton Sundstrand and Smiths Detection for early detection of biological warfare agent (BWA) attacks. The FABS instrument is based upon chemistry that is indicative of classes of agents rather than specific to a particular genus/species. Thus it is a generic BWA detector that can serve as a trigger for a confirmatory analysis in a "Detect-to-Warn" architecture. Multiple FABS units controlled and monitored from a single computer station can be widely distributed throughout a facility to provide an initial, fast "low-regret" response to an alarm in the event of a potential hazardous aerosol release.

TECHNOLOGY:

A replaceable cartridge holds disposable sample "coupons" with 8 individual sensing areas. Each area is coated with an immobilized marker chemical or fluorophore that interacts with impinged aerosols. If a target class is recognized, the spot fluoresces proportional to the concentration of target when interrogated by a visible light LED. The disposable coupon acts as a sample archive for later gold-standard analysis.

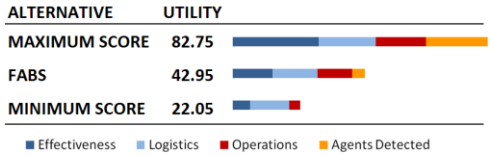
ANALYTICAL Laboratory Ranking

FABS ranked in the middle third of all evaluated products for analytical laboratories and earned 56% of the utility points of the best score.



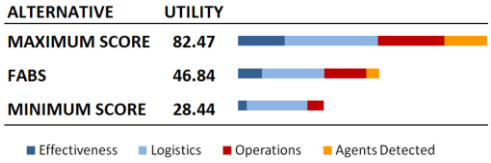
DIAGNOSTIC Laboratory Ranking

FABS ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 57% of the utility points of the best score.



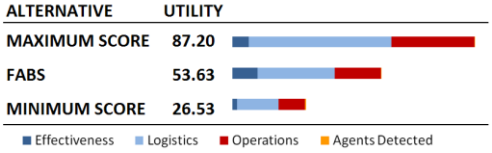
MOBILE Laboratory Ranking

FABS ranked in the bottom third of all evaluated products for mobile laboratories and earned 52% of the utility points of the best score.



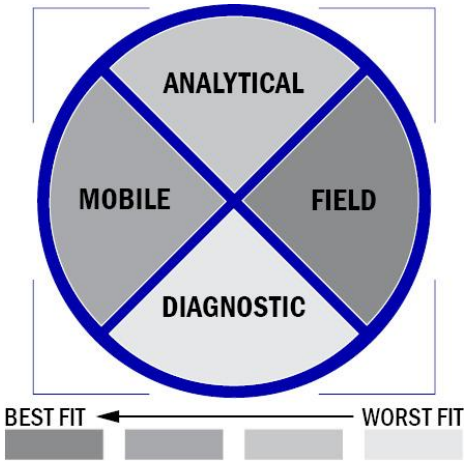
FIELD USE Ranking

FABS ranked in the bottom third of all evaluated products for field use and earned 56% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Hamilton Sundstrand Corp.
2771 N. Garey Ave.
Pomona, CA

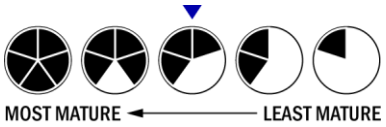
Point of Contact:
Dr. Michael Tissandier
(909) 593-3581 Ext. 4057

COST

- Approx. $22,000.00/system or device

SPECIFICITY

- False Positives: 2%
- False Negatives: 5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- No screen
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 10-20 minutes set-up
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components must be stored at 4°C
- Peak performance at normal relative humidity conditions
- 1 to 6 months shelf life

Transportation:
- Approximately the size of a toaster
- Transport via commercial carrier/ Tactical military wheeled and tracked vehicle/ Ship
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service > every 6 months
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connections
- Fully autonomous
- Basic desktop computer
- Stores and archives data outputs but does not create an electronic record
- System software closed, not available for modification
- System hardware is closed and not available for modification

Falcon II Wide-Field Raman Chemical Imaging System

by ChemImage Corporation

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e3-10e4CFU/mL)
Toxins
Liquid chemical agent
(> 1 ppt)

DETECTION MATRICES:

Demonstrated:
Nasal and throat swabs, Urine, Environmental air, Environmental water, Soil, Food, Powder

DESCRIPTION:

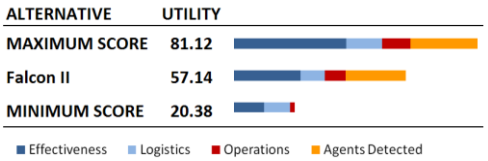
FALCON II combines benefits of wide-field Chemical Imaging with dispersive Raman spectroscopy. This combination of powerful analytical multiple hardware options and unique, easy-to-use software makes FALCON II the most versatile and feature-rich Raman microscope platform available. Chemical Imaging combines digital imaging and Raman spectroscopy to provide molecular images that reveal material morphology, composition, structure and concentration. Chemical Imaging takes advantage of the microscope user's natural visual senses and perception to make complex analysis more intuitive and straightforward. FALCON II produces 2-D and 3-D molecular images with unequaled speed and quality. Duet Vision Technology™ delivers real-time simultaneous imaging and spectroscopy, allowing users to quickly and easily identify critical regions of interest. ChemImage proprietary use of a liquid crystal imaging spectrometer provides unparalleled image fidelity, spatial and spectral resolution for high throughput hyperspectral screening of materials. FALCON II also performs dispersive Raman spectroscopy at high spectral resolution for microscopy applications. Limited or no sample preparation required. Raman spectroscopy and Raman Chemical Imaging are compatible with aqueous systems. Non-destructive sample characterization can be performed through glass containers, thin plastic bags, blister packs. Application areas include drug content uniformity, particle size distribution, polymorph characterization, water quality monitoring, cancer research, polymer characterization, biological and chemical agent detection and identification.

TECHNOLOGY:

Chemical Imaging combines digital imaging and Raman spectroscopy to provide molecular images that reveal material morphology, composition structure and concentration. Falcon II can be configured to operate in visible as well as Raman with optional fluorescence or Near Infrared (NIR) absorbance/reflectance capabilities. Falcon II consists of 3 major subsystems all package in one convenient unit. Subsystems are an excitement source to provoke material response, imaging optics to acquire sample response information and an optical detection system with optical filters to detect high resolution spatial and spectral information.

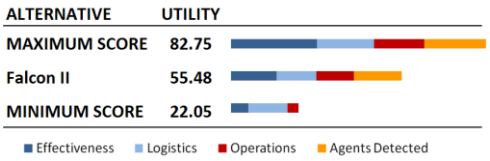
ANALYTICAL Laboratory Ranking

Falcon II ranked in the top third of all evaluated products for analytical laboratories and earned 70% of the utility points of the best score.



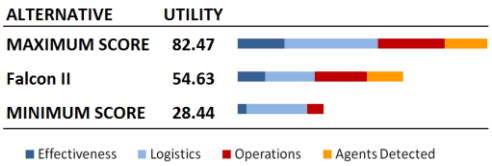
DIAGNOSTIC Laboratory Ranking

Falcon II ranked in the top third of all evaluated products for diagnostic laboratories and earned 67% of the utility points of the best score.



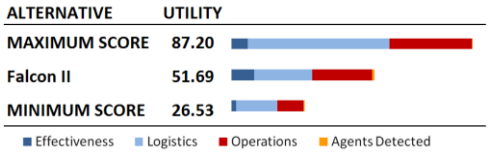
MOBILE Laboratory Ranking

Falcon II ranked in the middle third of all evaluated products for mobile laboratories and earned 66% of the utility points of the best score.



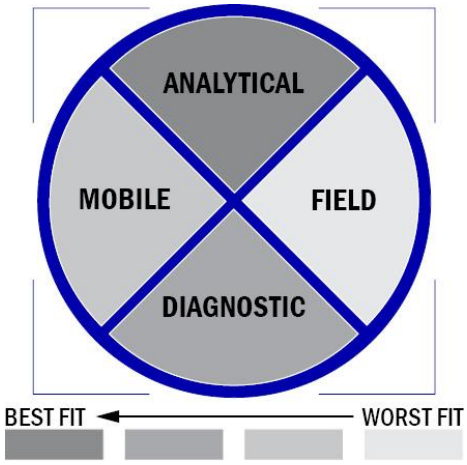
FIELD USE Ranking

Falcon II ranked in the bottom third of all evaluated products for field use and earned 59% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ChemImage Corporation
7301 Penn Ave
Pittsburgh, PA 15208

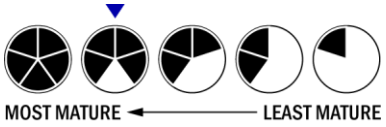
Point of Contact:
Steve Mitts
412-241-7335 x272
mittss@chemimage.com

COST

- Information not available

SPECIFICITY

- False Positives: Sample and CONOPS dependent
- False Negatives: Sample and CONOPS dependent



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Could easily be adapted to semi-automated with some effort

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Thermal output information not available

Training and Speed:
- A day of training and technical skills are required
- 10-20 minutes set-up required
- <1 down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Larger than home dishwasher
- Commercial carrier/ fixed wing military/rotary wing plane/ Ship
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by technician only
- Maintenance included
- Expected life >10 years
- 10-20 minutes QA required
- Exposure to hazardous agent requires >2 days to decon

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- Single centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance capable
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless and wired connections
- Could be adapted to fully autonomous with some effort
- On board computer chip
- Could be adapted to store and archive data outputs and create electronic record
- System software closed, not available for modification
- System hardware closed, not available for modification

FilmArray Pathogen Detection System

by Idaho Technology, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Viruses (10e3-10e4 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Environmental air, Soil, Food, Powder

DESCRIPTION:

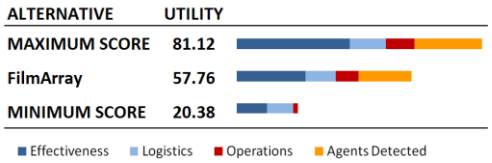
The FilmArray System is a user friendly automated pathogen identification system. The dual use platform with integrated sample preparation is capable of analyzing clinical and environmental samples automatically testing for multiple pathogens simultaneously from a raw sample. The lightweight, small footprint instrument processes a sample, analyzes the data and reports results in one hour. Consumable pouches are freeze dried and room temperature stable. ITI's current test panels are for respiratory disease and bio-threat with its development pipeline to include, gastrointestinal disease, sepsis, and sexually transmitted disease panels. The system is intended for clinical diagnostic use and environmental testing. It is simple to use requiring little training and net-work capable with connectivity to the national health information network and composite health care system available.

TECHNOLOGY:

The FilmArray integrates sample preparation into a highly multiplexed Polymerase Chain Reaction (PCR) system developed for the point-of-care diagnostic market. The single sample instrument uses a consumable pouch that integrates sample preparation and nested multiplex PCR. Integrated sample preparation provides ease-of-use while the highly multiplexed PCR provides both the sensitivity of PCR and the ability to test for up to 30 different organisms simultaneously.

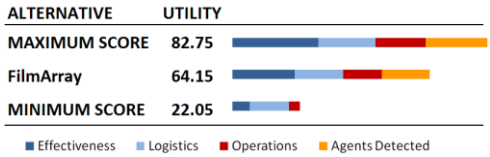
ANALYTICAL Laboratory Ranking

FilmArray ranked in the top third of all evaluated products for analytical laboratories and earned 71% of the utility points of the best score.



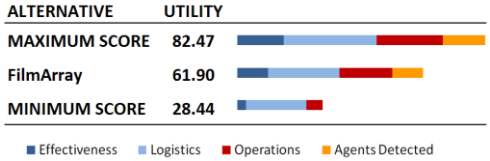
DIAGNOSTIC Laboratory Ranking

FilmArray ranked in the top third of all evaluated products for diagnostic laboratories and earned 78% of the utility points of the best score.



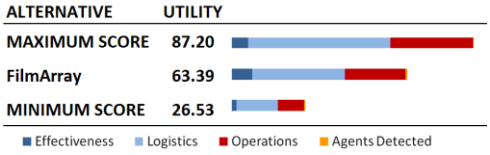
MOBILE Laboratory Ranking

FilmArray ranked in the top third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.



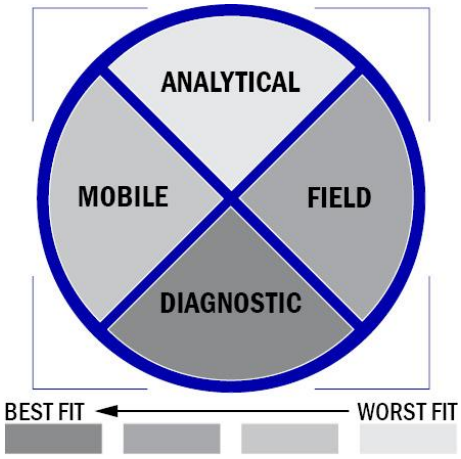
FIELD USE Ranking

FilmArray ranked in the middle third of all evaluated products for field use and earned 73% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Idaho Technology, Inc.
390 Wakara Way
Salt Lake City, UT 84108

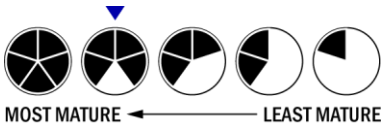
Point of Contact:
Matt Scullion
matts@idahotech.com

COST

- $49,500.00/system or device
- $130.00/respiratory disease panel (as an example)

SPECIFICITY

- False Positives: <1%
- False Negatives: Assay dependent



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30-60 minutes for detection
- 1 sample, >10 tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- < 5 minutes set up
- < 1 minute down time
- 3-5 steps are required
- DVD/ Web video/ Customer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can withstand temperatures in excess of 45°C for periods of less than 24 hours
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 3 components

Maintenance:
- Service less than once a year
- Preventive maintenance N/A
- Maintenance is not included
- Expected life unknown
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results not available
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance pending
- FDA approval pending
- Less than 250 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Autonomous system with some effort
- Laptop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

Firefly 2

by Charm Sciences, Inc.

DETECTS THE FOLLOWING:
Nothing demonstrated.

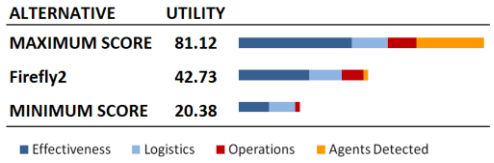
DETECTION MATRICES:
Nothing demonstrated.

DESCRIPTION:
The Firefly 2 device is a portable photomultiplier detector designed to detect light from bioluminescence tests kits.

TECHNOLOGY:
Photomultiplier detector using bioluminescence test kit, 5 second real-time analysis. Numeric RLU (relative light unit) results are provided for documentation purposes.

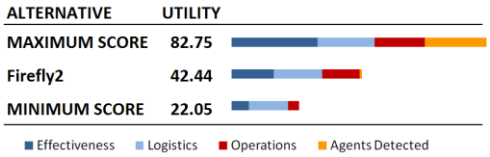
ANALYTICAL Laboratory Ranking

Firefly 2 ranked in the middle third of all evaluated products for analytical laboratories and earned 53% of the utility points of the best score.



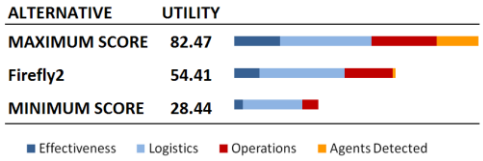
DIAGNOSTIC Laboratory Ranking

Firefly 2 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 51% of the utility points of the best score.



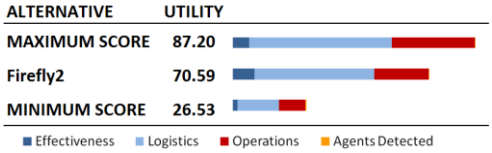
MOBILE Laboratory Ranking

Firefly 2 ranked in the middle third of all evaluated products for mobile laboratories and earned 66% of the utility points of the best score.



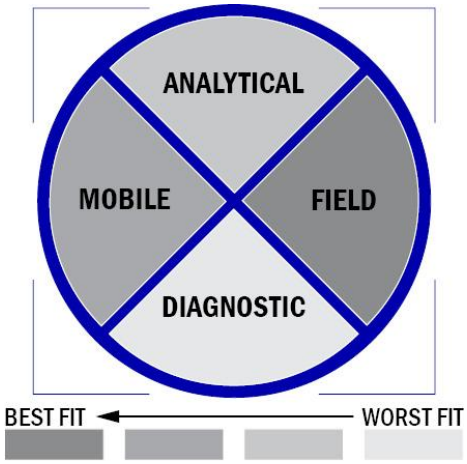
FIELD USE Ranking

Firefly 2 ranked in the top third of all evaluated products for field use and earned 81% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

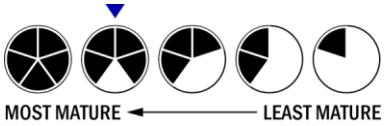
Charm Sciences, Inc.
659 Andover Street
Lawrence, MA 01843-1032

COST

- $2,695.00/system or device
- $3.00/ analysis

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Adaptable to full automation with some effort

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off

Training and Speed:
- Very brief training and minimal technical skills
- No set up required
- Almost no down time
- 3-5 steps are required
- DVD/ Web video/ Customer and manufacturer sit training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components must be stored at room temperature (27°C)/ Must be stored at 4°C
- Performance is not influenced by relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a soda can
- All means of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance is included
- Expected life 5-10 years
- No QA required
- The device is single use and disposable so no decontamination is needed

Physical System Requirements:
- Batteries
- 4-8 hours battery life
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps required
- A single shaking or vortexing, mixing, or filtering step required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Less than 50 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Wired connections
- Not capable of autonomy
- No computational power
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

First Responder's Radiation Detection Emergency Kit

by Technical Associates

DETECTS THE FOLLOWING:

Demonstrated:
Identification of radioisotopes
Discrimination between radiation types

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Environmental air, Environmental water, Soil, Food, Powder

DESCRIPTION:

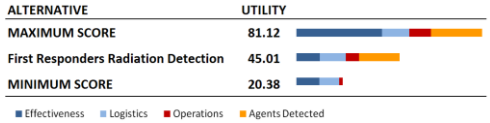
There are Five separate detectors detecting alpha, beta, gamma, x-rays, & neutrons in the First Responder's Radiation Detection Emergency Kit. Easy switch to change from internal to external probes. Lightweight - fits into the provided briefcase. It is also available with the mR/hour Scale, a single Counts Per Minute Scale or mR/hr Scale, or Both Scalers (upon request). End Users: Excellent for Fire Department, Ambulance, Police, First Responders and U.S Custom Personnel use for surveying people, cars, luggage, surface of room, etc.

TECHNOLOGY:

First Responder's Radiation Detection Emergency Kit features an internally mounted 2 inch Beta pancake GM detector (T-1190) with window looking downward from bottom of case and four external probes for detection of Alpha (PAS-8), low energy Gamma (PGS-3T), all Neutrons (PNS-20T), plus the Gamma Search Probe (PGS-3L). A sliding shield protects pancake detector when not in use. This system is half the weight of other systems.

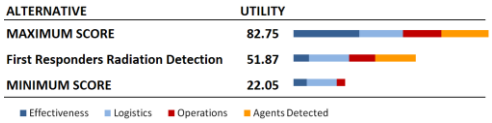
ANALYTICAL Laboratory Ranking

First Responder's Radiation Detection Emergency Kit ranked in the middle third of all evaluated products for analytical laboratories and earned 55% of the utility points of the best score.



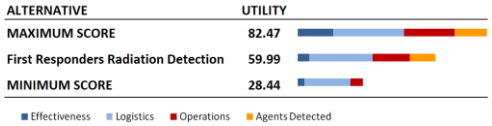
DIAGNOSTIC Laboratory Ranking

First Responder's Radiation Detection Emergency Kit ranked in the middle third of all evaluated products for diagnostic laboratories and earned 63% of the utility points of the best score.



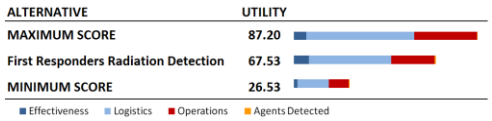
MOBILE Laboratory Ranking

First Responder's Radiation Detection Emergency Kit ranked in the top third of all evaluated products for mobile laboratories and earned 73% of the utility points of the best score.



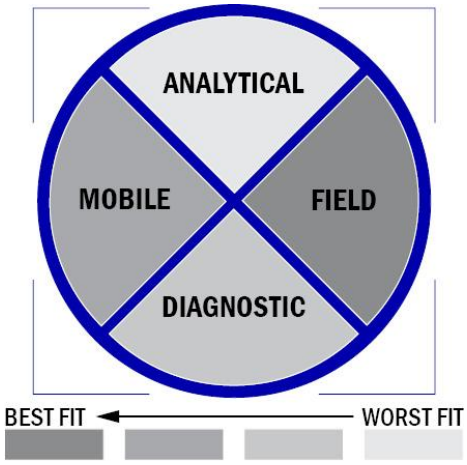
FIELD USE Ranking

First Responder's Radiation Detection Emergency Kit ranked in the middle third of all evaluated products for field use and earned 77% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Technical Associates
7051 Eton Ave.
Canoga Park, CA 91303

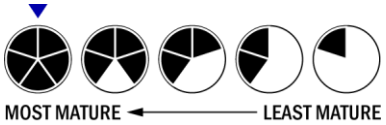
Point of Contact:
Robert Goldstein
818-883-7043

COST

- $3,950.00/system or device

SPECIFICITY

- False Positives: User makes determination
- False Negatives: User makes determination



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, >10 tests/ sample per run
- Not amenable to full or semi-automation

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from -21°C to 41°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance not applicable
- Maintenance not included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System does not call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Greater than 250 ul to test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Not network capable
- Not autonomous
- No computer required
- Does not store or archive data outputs or create an electronic record
- System does not employ software
- System hardware is closed and not available for modification

FirstDefender RM/RMX

by Thermo Scientific

DETECTS THE FOLLOWING:

Demonstrated:
Liquid chemical agent (<1 ppt)

DETECTION MATRICES:

Demonstrated:
Environmental air, Environmental water, Powder

DESCRIPTION:

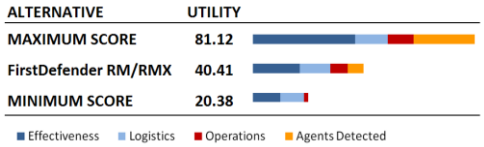
Thermo Scientific FirstDefender RM is the next generation Raman spectrometer for rapid, accurate identification of unknown chemicals directly in the field. Building on the award-winning, field proven FirstDefender®, significant improvements have been made in speed, performance, mixture analysis and user interface incorporating extensive user feedback and the latest technical advances. At 1.8 pounds (800g), the FirstDefender RM unit is less than half the size and weight of the first generation instrument, with a large, vivid display for ease of use in bulky protective gear. It is designed to meet the demanding requirements of elite military personnel and civilian first responders. The RMX expands on these capabilities with a flexible probe and select tactical robot integration through an integration kit. Key Benefits: • Faster, more accurate identification. Based on Raman spectroscopy, quickly identifies unknown solid and liquid chemicals. Unit stores all data and can export in multiple formats. • Built for field use. MIL-STD-810F and IP67 tested and certified. • Improved automatic mixture analysis. Sophisticated chemometric algorithms automatically determine presence of mixed and contaminated chemicals. • Point-and-shoot™ identification. Operates directly through sealed glass or plastic containers, avoiding exposure to potentially harmful substances. • Extensive substance library. Identifies explosives, toxic industrial chemicals (TICs), chemical warfare agents (CWAs), narcotics, precursors, white powders and more.

TECHNOLOGY:

Raman Spectroscopy Raman is a vibrational spectroscopy technique, where an intense single wavelength laser is focused on a sample. The laser energy excites the bonds of a molecule and generates or scatters measurable light to identify the material in question. Raman is highly effective at extracting a reliable and accurate identification of an unknown substance based on its underlying chemistry. Raman spectroscopy is best used as a primary analysis technique for sampling aqueous solutions and white or light colored powders and scanning through sealed containers.

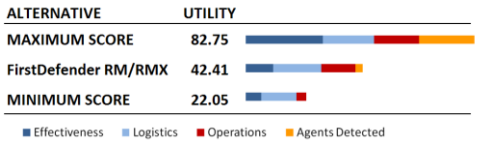
ANALYTICAL Laboratory Ranking

FirstDefender RM/RMX ranked in the bottom third of all evaluated products for analytical laboratories and earned 50% of the utility points of the best score.



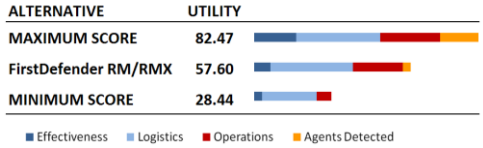
DIAGNOSTIC Laboratory Ranking

FirstDefender RM/RMX ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 51% of the utility points of the best score.



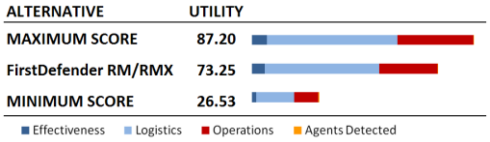
MOBILE Laboratory Ranking

FirstDefender RM/RMX ranked in the middle third of all evaluated products for mobile laboratories and earned 70% of the utility points of the best score.



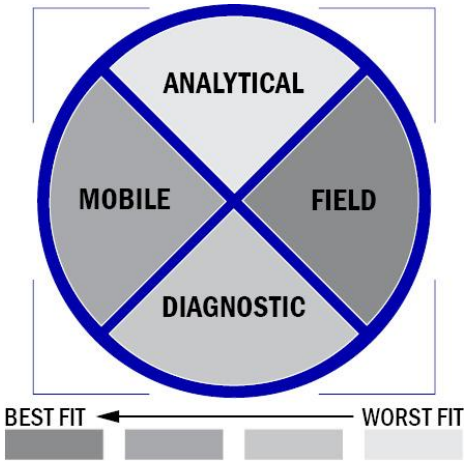
FIELD USE Ranking

FirstDefender RM/RMX ranked in the top third of all evaluated products for field use and earned 84% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Thermo Scientific Portable Optical Analysis
Part of Thermo Fisher Scientific
46 Jonspin Road
Wilmington, MA 01887

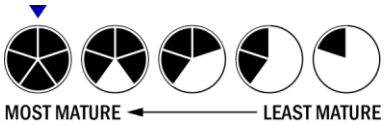
Point of Contact:
John Kenneweg
john.kenneweg@thermofisher.com
(301) 447-2331
www.thermoscientific.com/ahura

COST

- $50,000.00 - 55,000.00/system or device

SPECIFICITY

- False Positives: 1.1%
- False Negatives: 0%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- No set-up required
- Almost instantaneous down time
- 3-5 steps required
- DVD/ Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays.
- 0-1 solutions, buffer, and/or reagents
- 0 components

Maintenance:
- Service not required
- Preventive maintenance not applicable
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results not available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Not network capable
- Wired connections
- Not autonomous
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software closed, not available for modification
- System hardware is closed and not available for modification

FLAPS III™ Model 3317 (TSI Fluorescence Aerosol Particle Sensor)

by TSI Incorporated

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

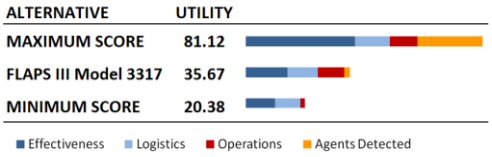
The TSI FLAPS III™ Model 3317 employs fluorescence measurements on individual airborne particles for rapid biological threat detection (under one minute response time) in military and homeland defense applications where a trigger detector is required for biological point detection systems. The instrument delivers exceptional threat discrimination and interference rejection using real-time processing of the data with advanced alarm algorithms. It has been tested with standard simulants for bio-threat agents (spore & vegetative bacteria, viruses and toxins), and has undergone significant field testing to verify its performance. Instrument is designed for field operation in terms of reliability, maintainability, and serviceability. (A predecessor instrument, the TSI UVAPS Model 3312A, has been fielded in the US Army P3I-BIDS enclosure.) The TSI FLAPS III™ Model 3317 system simultaneously measures for each individual airborne particle, the scattered-light intensity and the fluorescence emissions in two wavelength regions. These single particle measurements provide a robust data set for the rapid detection of airborne biological threat agents under various background environments. The instrument is generally used with a front-end aerosol concentrator to optimize performance, and is available in a stand-alone environmental enclosure with radio communications for remote operation. It has been in production since early 2004. The TSI FLAPS III™ Model 3317 is developed under sole license of U.S. patent numbers 5701012, 5895922 , and 6831279 from the Canadian Department of Defense.

TECHNOLOGY:

Detection of biological aerosols by the TSI FLAPS III™ Model 3317 is based on UV laser-induced fluorescence. The instrument uses a simplified optical train with a single, commercially available 405nm CW laser diode for both excitation and optical sizing (nominal lifetime 10,000 hours of continuous operation). An opposed nozzle design, consisting of an inlet nozzle and outlet nozzle, prevents particle recirculation in the optical chamber, and is used together with HEPA-filtered sheath air flow to eliminate fouling of the optical components. Measurements are taken on individual particles in the aerosol stream.

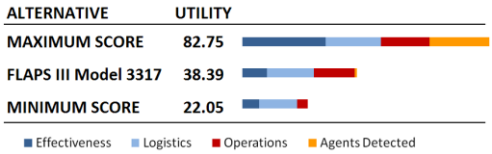
ANALYTICAL Laboratory Ranking

TSI FLAPS III™ Model 3317 ranked in the bottom third of all evaluated products for analytical laboratories and earned 44% of the utility points of the best score.



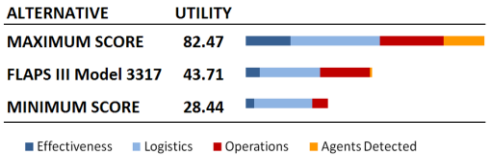
DIAGNOSTIC Laboratory Ranking

TSI FLAPS III™ Model 3317 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 46% of the utility points of the best score.



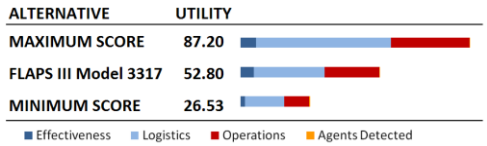
MOBILE Laboratory Ranking

TSI FLAPS III™ Model 3317 ranked in the bottom third of all evaluated products for mobile laboratories and earned 53% of the utility points of the best score.



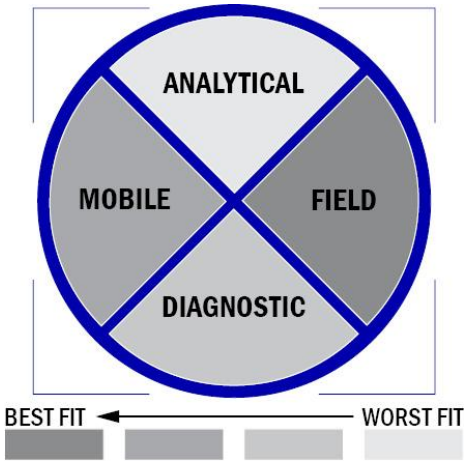
FIELD USE Ranking

TSI FLAPS III™ Model 3317 ranked in the bottom third of all evaluated products for field use and earned 61% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

TSI Incorporated
500 Cardigan Road
Shoreview, MN 55126

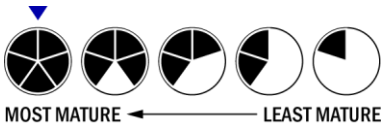
Point of Contact:
Richard Remiarz
richard.remiarz@tsi.com
651-490-2773

COST

- $100,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Individual assays or reactions not performed; instrument responds to variety of agents in real time
- Fully automated

Signature:
- Sounds or alarms not present
- No screen
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- No consumables required
- Performance not influenced by relative humidity
- Shelf life not applicable

Transportation:
- Larger than home dishwasher
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Trigger is designed for continuous use
- 0-1 solutions, buffer, and/or reagents
- No consumables required

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life >10 years
- No daily QA required
- Likely that exposure to hazardous agent cannot be decontaminated

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connections
- Fully autonomous
- Laptop computer chip
- Stores and archives data outputs and creates an electronic record
- System software closed and not available for modification
- System hardware closed and not available for modification

Food Safety Security Module (FSSM)

by Science & Engineering Services, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e3-10e4 CFU/mL)
Viruses (10e3-10e4 PFU/mL)
Toxins (1-100 ng/mL)

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

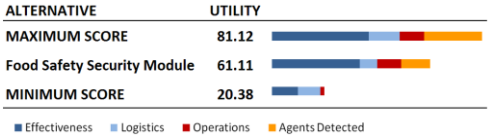
The Food-Safety Security Module (FSSM) is a scalable, integrated package that utilizes a commercial mass spectrometer, commercial AP-MALDI, and commercial databases to detect and identify food-borne pathogens in less than 24-hours total time; including enrichment. Processing can be either manual or automated with use of the supplemental auto-processing module. In terms of logistics, the consumables cost per sample is less than one dollar and train-up for non-technical users is one day.

TECHNOLOGY:

The Food-Safety Security Module (FSSM) builds on our Wide-Spectrum Bio-ID technologies and uses a commercial ion-trap mass spectrometer in which MS/MS is conducted via AP-MALDI of biological samples after enrichment. Biological materials undergo single-spot proteomic processing and MS/MS targeted bio-marker analysis to sift rapidly thru clutter against a commercial internet-accessible database such as MASCOT.

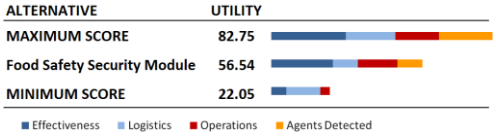
ANALYTICAL Laboratory Ranking

FSSM ranked in the top third of all evaluated products for analytical laboratories and earned 75% of the utility points of the best score.



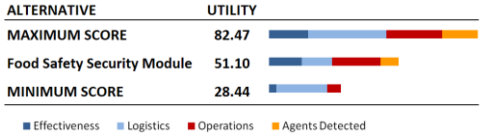
DIAGNOSTIC Laboratory Ranking

FSSM ranked in the top third of all evaluated products for diagnostic laboratories and earned 68% of the utility points of the best score.



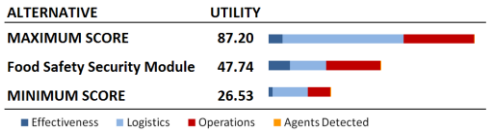
MOBILE Laboratory Ranking

FSSM ranked in the middle third of all evaluated products for mobile laboratories and earned 62% of the utility points of the best score.



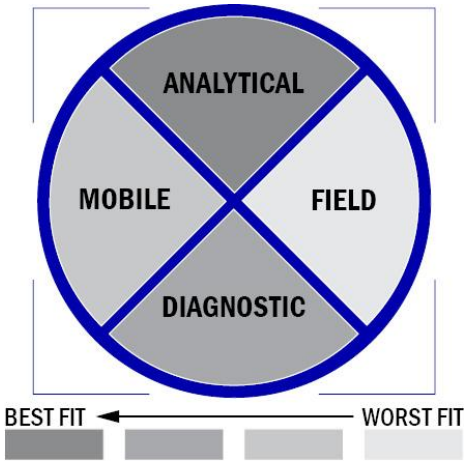
FIELD USE Ranking

FSSM ranked in the bottom third of all evaluated products for field use and earned 55% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Science & Engineering Services, Inc.
6992 Columbia Gateway Drive
Columbia, Maryland 21046

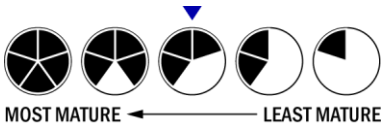
Point of Contact:
Robert M. Serino, Ph.D.
443.539.0139

COST

- $60,000/ manual system
- $150,000/ automated system

SPECIFICITY

- False Positives: 1%
- False Negatives: 1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 10-20 minutes set-up
- 1-3 minutes down time
- 3-5 steps required
- Customer site training/ Hard-copy manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at 4°C
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a home dishwasher
- Transport via tactical military wheeled and tracked vehicle
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 3 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- Requires both an external air and gas source
- External vacuum source required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 10 ul to test liquids

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless and wired connections
- Not autonomous
- Basic desktop computer
- Stores and archives data outputs and creates an electronic record
- System software open and available for modification
- System hardware open and available for modification

GammaRAE II R

by RAE Systems

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

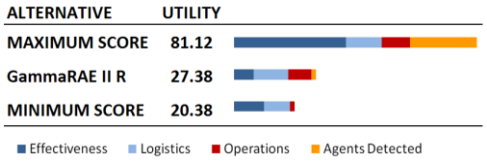
The GammaRAE II R is a gamma radiation detector and full-range dosimeter in a single instrument. Designed specifically to meet the needs of first responders, it has rapid response of a detection and the accurate dose measurement of a dosimeter.

TECHNOLOGY:

The GammaRAE II R uses a sensitive CsI scintillator for excellent search capability and fast response. It also has an energy-compensated PIN diode sensor for high dose rate range and accurate dosimeter capability.

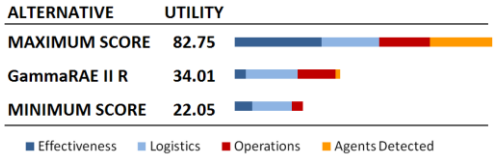
ANALYTICAL Laboratory Ranking

GammaRAE II R ranked in the bottom third of all evaluated products for analytical laboratories and earned 34% of the utility points of the best score.



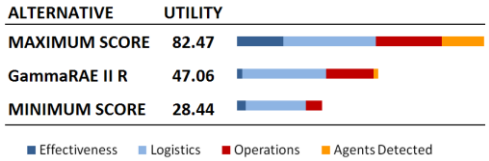
DIAGNOSTIC Laboratory Ranking

GammaRAE II R ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 41% of the utility points of the best score.



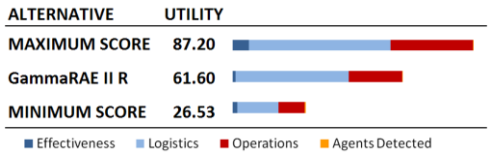
MOBILE Laboratory Ranking

GammaRAE II R ranked in the bottom third of all evaluated products for mobile laboratories and earned 57% of the utility points of the best score.



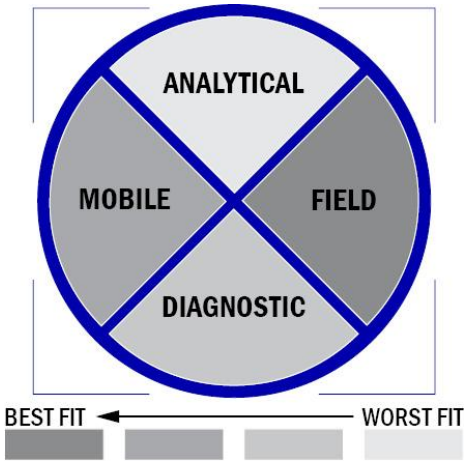
FIELD USE Ranking

GammaRAE II R ranked in the middle third of all evaluated products for field use and earned 71% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

RAE Systems
3775 North First Street
San Jose, CA 95134-1708

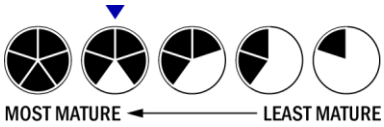
Point of Contact:
June Wang

COST

- $1,318.00/system or device

SPECIFICITY

- False Positives: ≤ 1 over 10 hrs.
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- Alarming in <2 seconds
- Samples not required
- Fully automated

Signature:
- Sounds or alarms present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- DVD/ Hard copy operators manual

Operational conditions:
- Can be used from -20°C to 50°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a soda can
- Transport via commercial carrier
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0 solutions, buffer, and/or reagents
- 0 components

Maintenance:
- Service not required
- Preventive maintenance not applicable
- Maintenance not included
- Expected life 1-3 years
- No daily QA required
- Decontamination not applicable

Physical System Requirements:
- No electrical requirement
- 600 hour battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- Raw data generated “in MB range”
- Not network capable
- Wireless and wired connections
- Fully autonomous
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software closed and not available for modification
- System hardware closed and not available for modification

Genedrive™

by Diagnostics Epistem

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Viruses (100-1,000 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Environmental water, Soil, Food

DESCRIPTION:

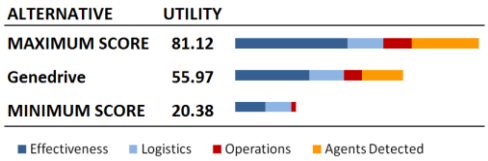
Genedrive™ offers rapid detection of NA targets in a fully integrated, compact (12cm x 17cm x 9cm) and lightweight (550g) unit. It can detect multiple targets simultaneously using room temperature stable reagents. Single button operation allows use by untrained operators.

TECHNOLOGY:

Genedrive™ uses hybrid thermal engine technology which enables rapid thermal cycling within a compact, low power unit.

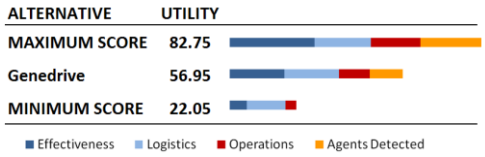
ANALYTICAL Laboratory Ranking

Genedrive ranked in the top third of all evaluated products for analytical laboratories and earned 69% of the utility points of the best score.



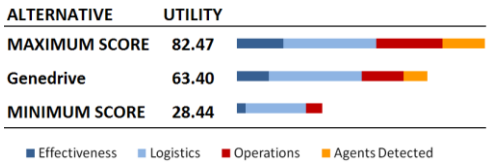
DIAGNOSTIC Laboratory Ranking

Genedrive ranked in the top third of all evaluated products for diagnostic laboratories and earned 69% of the utility points of the best score.



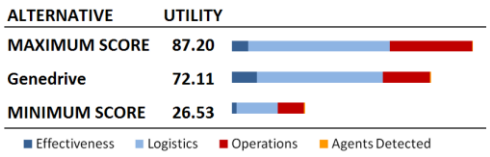
MOBILE Laboratory Ranking

Genedrive ranked in the top third of all evaluated products for mobile laboratories and earned 77% of the utility points of the best score.



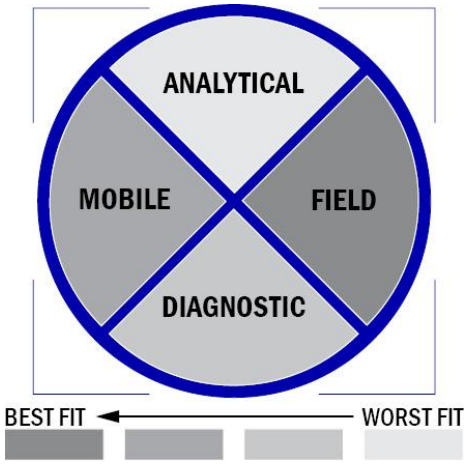
FIELD USE Ranking

Genedrive ranked in the top third of all evaluated products for field use and earned 83% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Diagnostics Epistem
48 Grafton Street
Manchester, M13 9XX, UK

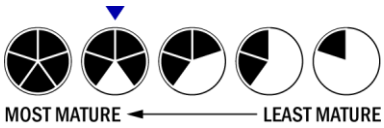
Point of Contact:
Ben Cobb
0161 606 7258
b.cobb@epistem.co.uk

COST

- $5,000.00/system or device
- $15.00-150.00/analysis

SPECIFICITY

- False positives: Not available
- False negatives: Not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15-30 minutes for detection
- 1 sample, >10 tests/ sample per run
- Semi-automated

Signature:
- Sounds or alarms cannot be deactivated
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- No set up
- Minimal down time
- 0-2 steps are required
- DVD/ Hard-copy operators manual manuscript

Operational conditions:
- Can be used from < -21°C to > 42°C
- Components must be stored at room temperature (27°C)
- Performance is not known under relative humidity
- Shelf life for reagents/test kits is 1-3 years

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- No service required
- Preventative maintenance serviceable by technician only
- Maintenance is included
- Expected life 3-5 years
- No daily QA required
- It likely that exposure to hazardous agent cannot be decontaminated

Physical System Requirements:
- 12VDC electrical requirement
- 1-2 hours of battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results not available
- No centrifugation steps are required
- No shaking or vortexing, mixing, degassing or filtering steps are required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 100 ul for a test

System Maturity:
- Commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB
- Not network capable
- Wireless and wired connections
- Not capable of autonomy
- On board computer chip in the system
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

GeneXpert ® System

by Cepheid

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (assay dependent)
Viruses (assay dependent)
Toxins (assay dependent)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Wound, Environmental water, Soil

DESCRIPTION:

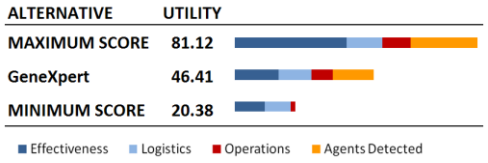
The GeneXpert System is a closed, self-contained, fully-integrated and automated platform that represents a paradigm shift in the automation of molecular analysis, producing accurate results in a timely manner with minimal risk of contamination. The GeneXpert System is the only system to combine on-board sample preparation with real-time PCR (polymerase chain reaction) amplification and detection functions for fully integrated and automated nucleic acid analysis. The system is designed to purify, concentrate, detect and identify targeted nucleic acid sequences thereby delivering answers directly from unprocessed samples. Modular in design, the GeneXpert System has a variety of configurations to meet the broad range of testing demands of any clinical environment. The Cepheid GeneXpert® System makes biothreat agent detection possible in minutes — all from unprepared samples. This easy-to-use, automated and highly accurate real-time PCR instrument combines the ingenuity of more than 30 patents into a sophisticated genetic tool for first responders. A patented, disposable, cartridge test for anthrax is available now, and can be performed on-site — delivering critical answers in critical situations.

TECHNOLOGY:

The GeneXpert® System fully integrates and automates the three processes required for real-time PCR-based molecular testing: sample preparation, amplification, and detection, all in one cartridge. On-demand. Just load a biological sample and the system does the rest.

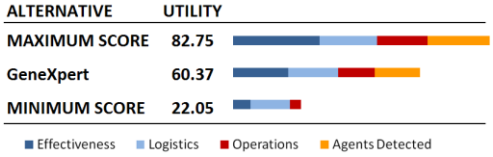
ANALYTICAL Laboratory Ranking

GeneXpert System ranked in the middle third of all evaluated products for analytical laboratories and earned 57% of the utility points of the best score.



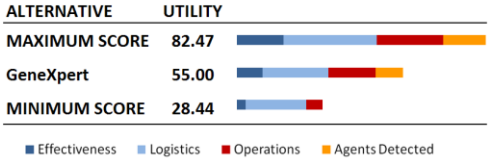
DIAGNOSTIC Laboratory Ranking

GeneXpert System ranked in the top third of all evaluated products for diagnostic laboratories and earned 73% of the utility points of the best score.



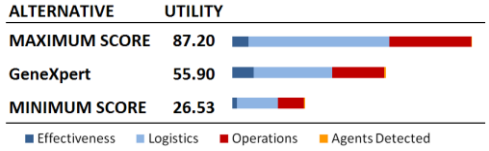
MOBILE Laboratory Ranking

GeneXpert System ranked in the middle third of all evaluated products for mobile laboratories and earned 67% of the utility points of the best score.



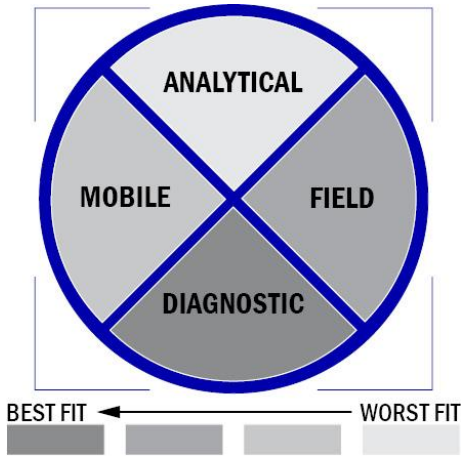
FIELD USE Ranking

GeneXpert System ranked in the bottom third of all evaluated products for field use and earned 64% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089

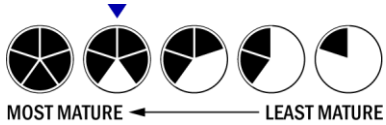
Point of Contact:
Chinmay Sheth

COST

- $79,200.00/system or device

SPECIFICITY

- Assay dependent



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1- 8 hours for detection
- 1 sample, <10 tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- No set up
- Almost no down time
- 0-2 steps are required
- DVD/ Web video/ Customer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can withstand temps > 45°C for periods < 24 hours/ Must be stored at room temp / 4°C
- Performance is not influenced by relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician
- Maintenance is not included
- Expected life >10 years
- <5 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1 hr

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance shown
- FDA approval shown
- Less than 250 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Not capable of an autonomous system
- Basic desktop computer
- store and archive data outputs but not create an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

Genome Analyzer IIx

by Illumina Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria
Viruses

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Environmental water, Soil

DESCRIPTION:

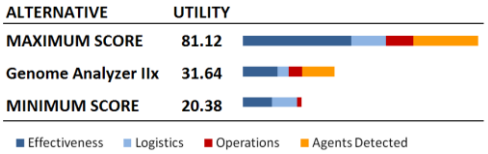
The Genome Analyzer IIx offers a powerful combination of 2 x 150 bp read lengths and up to 640 million paired-end reads per flow cell, enabling a broad range of high-throughput sequencing applications. Evidenced by a vast number of peer-reviewed publications in an ever-broadening range of applications, Illumina sequencing technology with the Genome Analyzer IIx is a proven platform for genomic discovery and validation.

TECHNOLOGY:

Illumina sequencing technology leverages clonal array formation and proprietary reversible terminator technology for rapid and accurate large-scale sequencing. The innovative and flexible sequencing system enables a broad array of applications in genomics, transcriptomics, and epigenomics.

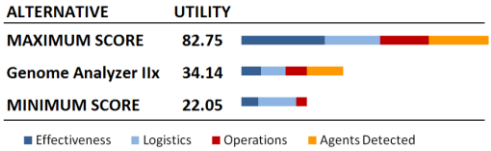
ANALYTICAL Laboratory Ranking

Genome Analyzer IIx ranked in the bottom third of all evaluated products for analytical laboratories and earned 39% of the utility points of the best score.



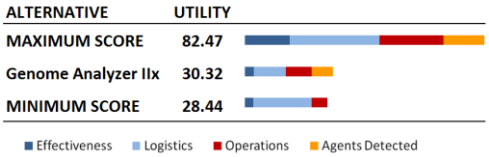
DIAGNOSTIC Laboratory Ranking

Genome Analyzer IIx ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 41% of the utility points of the best score.



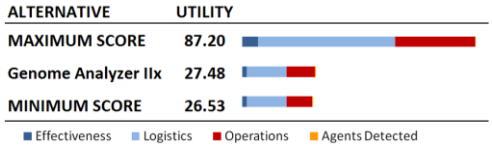
MOBILE Laboratory Ranking

Genome Analyzer IIx ranked in the bottom third of all evaluated products for mobile laboratories and earned 37% of the utility points of the best score.



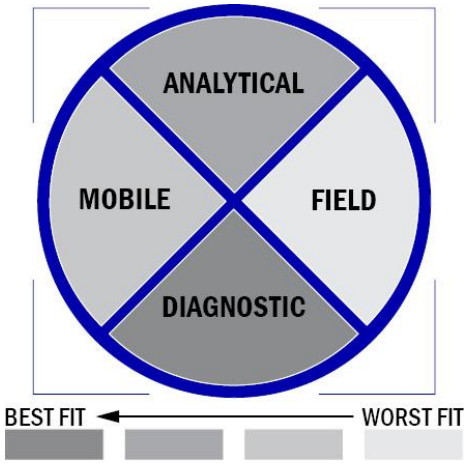
FIELD USE Ranking

Genome Analyzer IIx ranked in the bottom third of all evaluated products for field use and earned 32% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Illumina Inc.
9885 Towne Centre Drive
San Diego, CA 92121

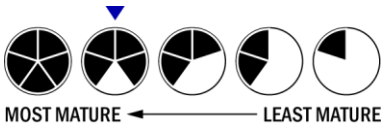
Point of Contact:
Dawn Barry
dbarry@illumina.com
203-296-0536

COST

- $250,000.00/system or device

SPECIFICITY

- False Positives: <3%
- False Negatives: <0.5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- Greater than 8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- >20 minutes set-up
- <5 minutes down time
- Greater than 12 steps required
- Customer site training/ Hard-copy and web-based operators manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at 4°C/ Must be frozen
- Peak performance at normal relative humidity conditions
- 6 months to 1 year shelf life

Transportation:
- Larger than a home dishwasher
- Commercial carrier; fixed wing military aircraft; ship
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service more than twice a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Requires water aliquots
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- Multiple centrifugation steps
- Multiple shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connections
- Not autonomous
- High end desktop computer
- Does not store or archive data outputs or create an electronic record
- System software open and available for modification
- System hardware closed and not available for modification

Guardian Predator®

by Nucsafe Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Identification of radioisotopes
Discrimination between radiation types
Identification of specific isotopes

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

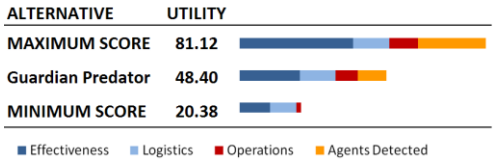
Nucsafe's Guardian Predator® is built to detect the presence of NORM, legal and illicit radioactive materials. The system incorporates state of the art passive scanning technology to detect changes in radiation levels emitted by gamma, high energy beta and neutron radionuclides contained on persons and in objects, vehicles, or containers.

TECHNOLOGY:

Gamma ray detection is based on PVT or NaI(Tl). Neutron detection utilizes 6Li glass fiber. Exposure rate via Geiger Muller Tube. Alpha and Beta particle detection.

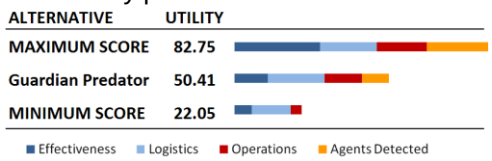
ANALYTICAL Laboratory Ranking

Guardian Predator® ranked in the middle third of all evaluated products for analytical laboratories and earned 60% of the utility points of the best score.



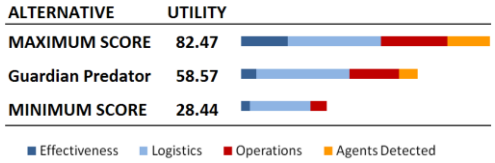
DIAGNOSTIC Laboratory Ranking

Guardian Predator® ranked in the middle third of all evaluated products for diagnostic laboratories and earned 61% of the utility points of the best score.



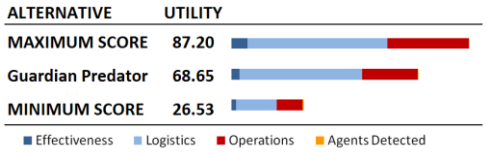
MOBILE Laboratory Ranking

Guardian Predator® ranked in the middle third of all evaluated products for mobile laboratories and earned 71% of the utility points of the best score.



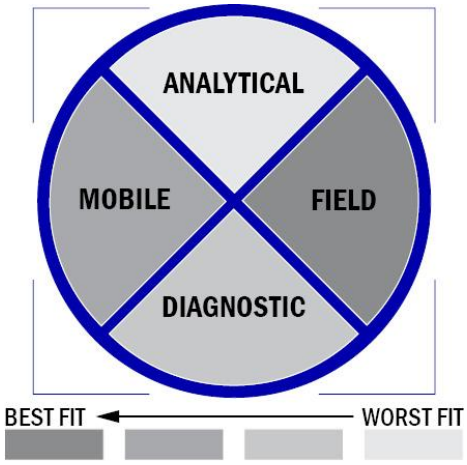
FIELD USE Ranking

Guardian Predator® ranked in the middle third of all evaluated products for field use and earned 79% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Nucsafe Inc. 601
Oak Ridge Turnpike
Oak Ridge, TN 37830

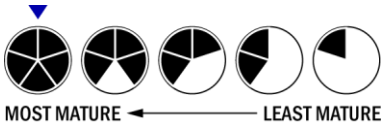
Point of Contact:
Stanley Cass
SCass@nucsafe.com
724-263-5500

COST

- $40,000.00-48,000.00/system or device

SPECIFICITY

- False Positives: Not Available
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- < 5 minutes set up
- Almost instantaneous down time
- 0-2 steps are required
- DVD/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Components should be stored at room temperature but can withstand temperatures in excess of 45°C for periods of less than 24 hours/ This system does not require consumables
- Performance is not influenced by relative humidity

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 5-10 years
- No QA required

Physical System Requirements:
- Batteries
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Satellite, wireless and wired connections
- Autonomous system
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

Guardian Reader System

by Alexeter Technologies

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e4-10e5 CFU/mL)
Viruses (>10e5 PFU/mL)
Toxins (1-100 ng/mL)

DETECTION MATRICES:

Demonstrated:
Environmental air, Environmental water, Food, Powder

DESCRIPTION:

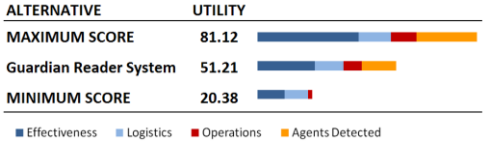
The Guardian Reader System is designed to detect and identify the following biological agents, in the field, with a 15-minute test: anthrax, ricin, botulinum toxin, staphylococcal enterotoxin B, plague, tularemia, brucella and orthopox. The Guardian Reader, part of the system is an optical reader which evaluates the test strips, documents the results and delivers a report to the user. Alternatively, the system may be supplied with the Defender TSR (Test Strip Reader) a hand-held optical reader. A protein detection test is also part of the system.

TECHNOLOGY:

Hand held immunochromatographic assays that use colloidal gold labeled antibodies, optional Reader for objective evaluation and documentation.

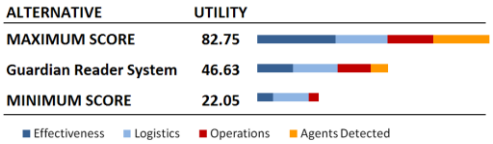
ANALYTICAL Laboratory Ranking

Guardian Reader System ranked in the middle third of all evaluated products for analytical laboratories and earned 63% of the utility points of the best score.



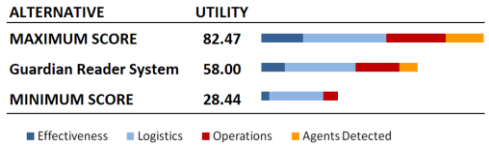
DIAGNOSTIC Laboratory Ranking

Guardian Reader System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 56% of the utility points of the best score.



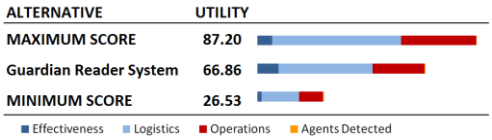
MOBILE Laboratory Ranking

Guardian Reader System ranked in the middle third of all evaluated products for mobile laboratories and earned 70% of the utility points of the best score.



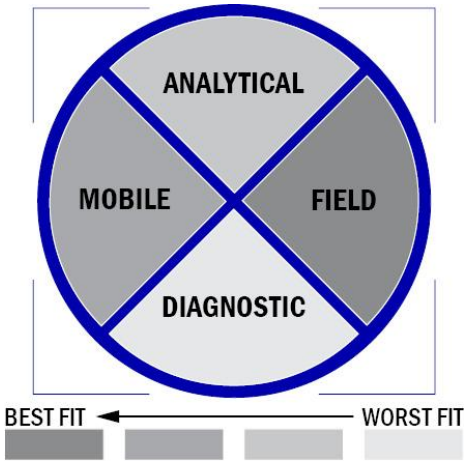
FIELD USE Ranking

Guardian Reader System ranked in the middle third of all evaluated products for field use and earned 77% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Alexeter Technologies
830 Seton Court, Suite 6
Wheeling, IL 60090

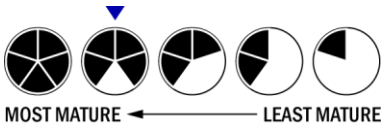
Point of Contact:
Tom Fryzel, Technical Director
877-591-5571
tfryzel@alexeter.com

COST

- $12,000.00/system or device
- $26.00/analysis

SPECIFICITY

- False Positives: 0.2%
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15-30 minutes for detection
- 1 sample, <10 tests/ sample per run
- Currently semi automated

Signature:
- Sounds or alarms are present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- No set up
- Almost no down time
- 3-5 steps are required
- DVD/ Manufacturer site training

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temperature but can withstand temperatures > 45°C for periods of less than 24 hours
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All means of transport
- Weighs between 5 and 25 kg

Re-use:
- Single use detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- No maintenance
- Preventive maintenance N/A
- Maintenance is not included
- Expected life N/A
- No QA required
- The device is single use and disposable so no decontamination is needed

Physical System Requirements:
- 110V electrical requirement
- 1-2 hours battery use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps required
- A single shaking or vortexing, mixing, degassing or filtering step required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Less than 50 ul for a test

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- No data transmission
- Fully autonomous system with significant effort
- No computational power
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open but modification requires licensing
- The system hardware is open but modification requires licensing

HAPSITE ER

by INFICON

DETECTS THE FOLLOWING:

Demonstrated:
Aerosolized chemical agent (0.0001 – 0.001 mg/m3)
Liquid chemical agent (< 1 ppb)

DETECTION MATRICES:

Demonstrated:
Environmental air, Environmental water, Soil, Food

DESCRIPTION:

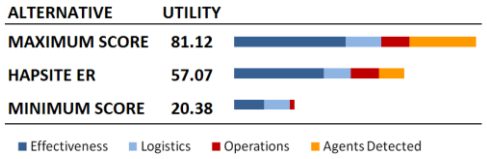
The HAPSITE ER is the only person-portable Gas Chromatograph/Mass Spectrometer (GC/MS) that requires minimal training to deliver qualitative and quantitative lab quality results—in the field, in less than 10 minutes. In fact, all the operator has to do is push a button to begin identifying and quantifying volatile organic compounds (VOCs), toxic industrial chemicals (TICs), toxic industrial materials (TIMs), chemical warfare agents (CWAs), and select semi-volatile organic compounds (SVOCs). HAPSITE ER has the capability to identify analytes in the PPM(parts per million) – PPT(parts per trillion) range. The GC column provides sharp chromatography and excellent resolution. During the quantitation method, the front panel clearly displays what chemicals are present, their concentration, and access to information regarding the degree of danger — to help make quick decisions affecting life, health and safety.

TECHNOLOGY:

Gas Chromatograph/Mass Spectrometer.

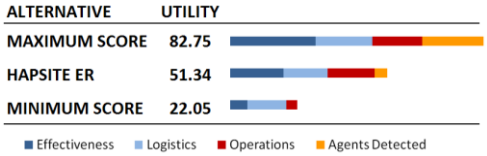
ANALYTICAL Laboratory Ranking

HAPSITE ER ranked in the top third of all evaluated products for analytical laboratories and earned 70% of the utility points of the best score.



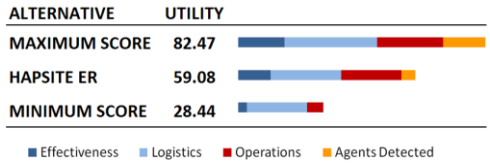
DIAGNOSTIC Laboratory Ranking

HAPSITE ER ranked in the middle third of all evaluated products for diagnostic laboratories and earned 62% of the utility points of the best score.



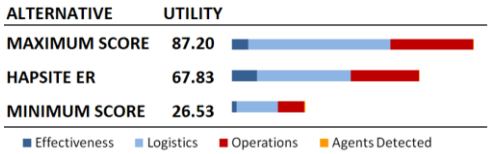
MOBILE Laboratory Ranking

HAPSITE ER ranked in the middle third of all evaluated products for mobile laboratories and earned 72% of the utility points of the best score.



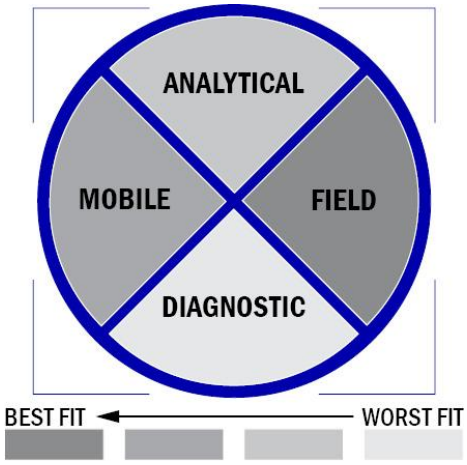
FIELD USE Ranking

HAPSITE ER ranked in the middle third of all evaluated products for field use and earned 78% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

INFICON
1326 Lovering Ave
Wilmington, DE 19806

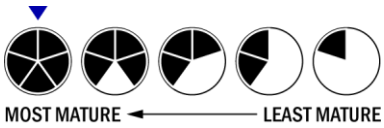
POC: 610-363-3342

COST

- $119,307.00/system or device

SPECIFICITY

- False Positives: Not applicable
- False Negatives: Not applicable



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 5-10 minutes set-up
- 1-3 minutes down time
- 0-2 steps required
- DVD/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- 18”x 17”x 7”
- All modes of transportation
- Between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless and wired connections
- Could be adapted to fully autonomous
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software closed, not available for modification
- Hardware closed, not available for modification

HAZMATCAD and HAZMATCAD Plus

by MSA

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

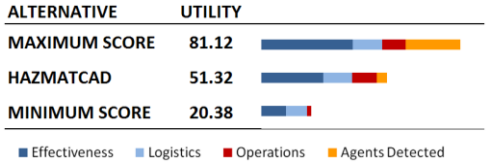
The HAZMACTAD series instruments are designed to detect chemical warfare agents (CWA) and toxic industrial chemicals (TICs). This product was designed for 1st responder application for an easy to operate instrument that can quickly determine to threats are present.

TECHNOLOGY:

The HAZMATCAD series uses a hybrid configuration of electrochemical cell array for the detection of blood (HCN), choke (COCl2), halogens (Cl2) and (Br2) and hydride gases (arsine, phosphine). It also use surface acoustic wave array for chemcial agent detectrion.

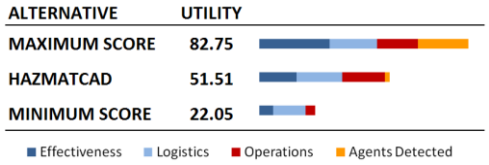
ANALYTICAL Laboratory Ranking

HAZMATCAD System ranked in the middle third of all evaluated products for analytical laboratories and earned 63% of the utility points of the best score.



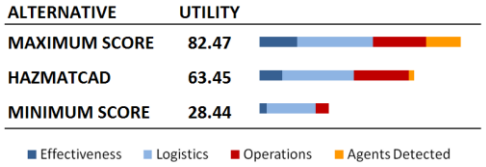
DIAGNOSTIC Laboratory Ranking

HAZMATCAD System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 62% of the utility points of the best score.



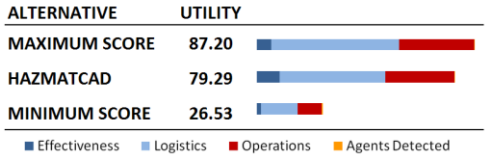
MOBILE Laboratory Ranking

HAZMATCAD System ranked in the top third of all evaluated products for mobile laboratories and earned 77% of the utility points of the best score.



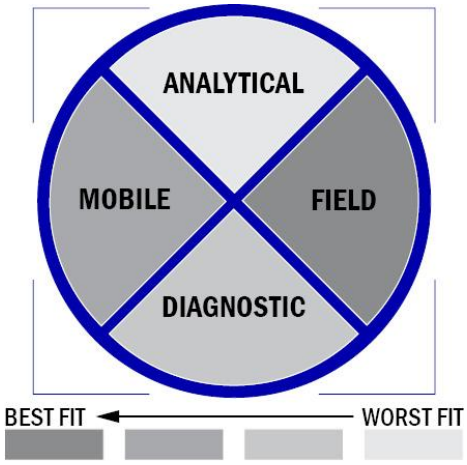
FIELD USE Ranking

HAZMATCAD System ranked in the top third of all evaluated products for field use and earned 91% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

MSA
1000 Cranberry Woods Drive
Cranberry Township, PA 16066

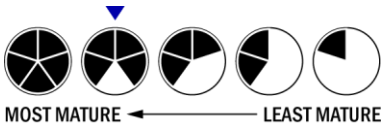
Point of Contact:
Norman Davis Jr.
norm.davis@MSAnet.com
724-776-8884

COST

- $8,000 for HAZMATCAD Plus
- $5,500 for HAZMATCAD
- <$1.00/analysis

SPECIFICITY

- False positives: <1%
- False negatives: <0.01%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully-automated

Signature:
- Sounds or alarms cannot be deactivated
- Screen can be dimmed or turned off
- < 200 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills required
- No set up
- Minimal down time
- 0-2 steps are required
- DVD/ Web video/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from -21°C to 41°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance is included
- Expected life 3-5 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Batteries
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps are required
- No shaking or vortexing, mixing, degassing or filtering steps are required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Does not test liquids

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- >250 GB
- Not network capable
- Wired and wireless connections
- Fully autonomous
- Basic desktop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

HazMatID 360

by Smiths Detection

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

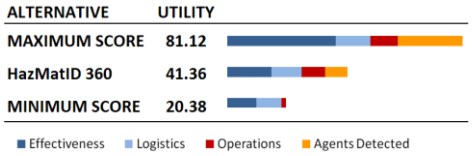
Uses Fourier-Transform Infrared (FTIR) Spectroscopy and an extensive on-board spectral library to rapidly ID solid and liquid chemicals based on distinct molecular fingerprints. Capable of identifying over 32,000 substances including nerve & blister agents, TICs, white powders, explosives & explosive precursors, drugs & drug precursors, common chemicals, and pesticides. Features mixture analysis which allows effective chemical assessment of samples that may have been contaminated with more than one material, like water or dirt. Mixture analysis, combined with chemical hazard classification capabilities enables advanced data handling and comprehensive analysis using ruggedized FTIR technology in the field. Built-in Bluetooth wireless communication to allow for immediate data transmission out of the hot zone to a command center and/or ReachBack™ support services to aid with information integration prior to decon. Also includes PEAC® decision support software, which provides users with detailed information regarding management of hazardous chemicals.

TECHNOLOGY:

Incorporates FTIR spectroscopy to ID a broad range of materials. In this technique, infrared (IR) optical radiation from 4000 to 650 wavenumbers (cm-1) passes through a chemical medium where it is absorbed by the oscillating electric fields of bonding electrons and lattice vibrations. As such, FTIR is applicable to virtually all covalent organic and inorganic compounds. It is particularly sensitive to polar functional groups associated with unsaturated and aromatic hydrocarbons (petroleum products), nitrates (explosives, fertilizers), organophosphates (pesticides, WMDs), hydroxyls and carbonyls (drugs, solvents), etc. Purely ionic compounds (e.g., sodium chloride) do not possess the requisite electronic structure to be identified by any FTIR system. The diamond attenuated total reflection (ATR) sample interface allows users to analyze materials with virtually no sample prep. The ATR measurement involves attenuation of the evanescent field of a totally internally-reflected IR beam emanating from the diamond sensor into a sample. Technique permits easy, reproducible measurements with minimal training. To identify a solid or liquid chemical, the user places a small portion (at least 1 mg) on to diamond sensor and cleans sensor with an alcohol swab when finished.

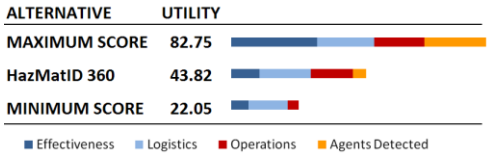
ANALYTICAL Laboratory Ranking

HazMatID 360 ranked in the bottom third of all evaluated products for analytical laboratories and earned 51% of the utility points of the best score.



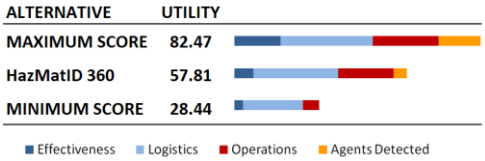
DIAGNOSTIC Laboratory Ranking

HazMatID 360 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 53% of the utility points of the best score.



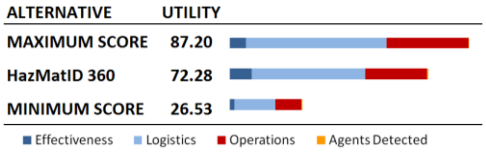
MOBILE Laboratory Ranking

HazMatID 360 ranked in the middle third of all evaluated products for mobile laboratories and earned 70% of the utility points of the best score.



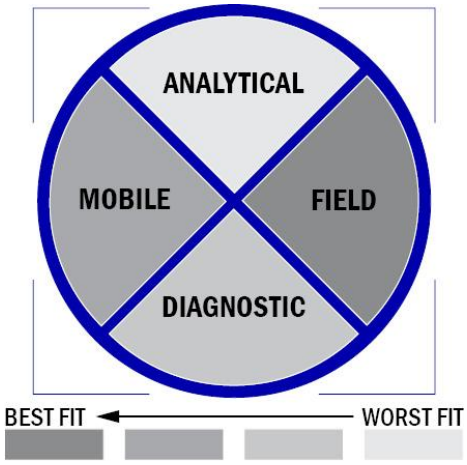
FIELD USE Ranking

HazMatID 360 ranked in the top third of all evaluated products for field use and earned 83% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Smiths Detection
21 Commerce Drive
Danbury, CT 06810

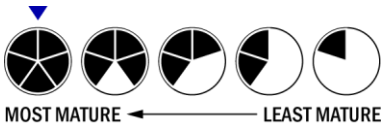
Point of Contact:
Dustin Levy
dustin.levy@smithsdetection.com

COST

- $55,000.00/system or device

SPECIFICITY

- False Positives: 5%
- False Negatives: 5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 5-10 minutes set-up
- Almost instantaneous down time
- 0-2 steps required
- Web-based video/ Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 4°C to 41°C
- Does not require consumables
- Performance not influenced by relative humidity
- Between 1 - 3 years shelf life

Transportation:
- Approximately the size of a toaster
- Transport via tactical military wheeled and tracked vehicle
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Less than once a year
- Preventive maintenance serviceable by technician only
- Maintenance included
- Expected life 5-10 years
- Less than 5 minutes daily QA
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- No electrical requirement
- 1-2 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 250 ul to test liquids

System Maturity:
- Is commercially available and meet mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless, wired connections
- Not autonomous
- No computer required
- Stores and archives data outputs and creates an electronic record
- System software closed , not available for modification
- System hardware closed , not available for modification

HDS-101GN Search and Identification

by Mirion Technologies (MGPI), Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Discriminates between radiation types
Identification of specific isotopes

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

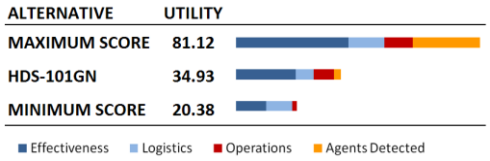
The HDS-101GN is designed to search for and identify radioactive materials and to respond to radiological threats such as illicit trafficking and RDDs. The HDS-101Gn can identify radionuclides and classify them as medical, industrial, naturally occurring radioactive materials (NORM) and special nuclear materials (SNM). The HDS-101G/GN are ideally suited for First Responders, Border & Customs inspectors, Law Enforcement Officers, Site Security in critical infrastructures, and for all applications related to the control of radioactive and nuclear materials.

TECHNOLOGY:

NORM Medical Discrimination algorithm (NMD) categorizes and identifies up to 4 isotopes simultaneously.

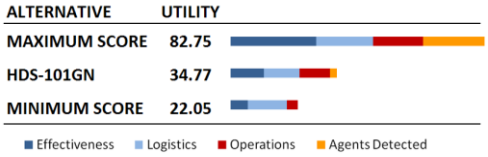
ANALYTICAL Laboratory Ranking

HDS-101GN Search and Identification ranked in the bottom third of all evaluated products for analytical laboratories and earned 43% of the utility points of the best score.



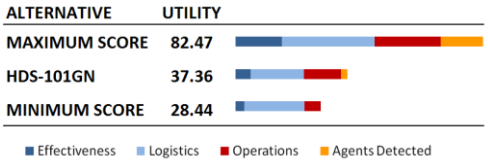
DIAGNOSTIC Laboratory Ranking

HDS-101GN Search and Identification ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 42% of the utility points of the best score.



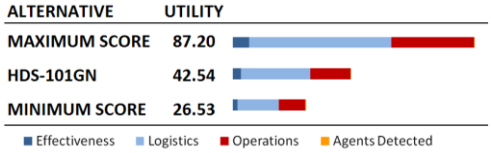
MOBILE Laboratory Ranking

HDS-101GN Search and Identification ranked in the bottom third of all evaluated products for mobile laboratories and earned 45% of the utility points of the best score.



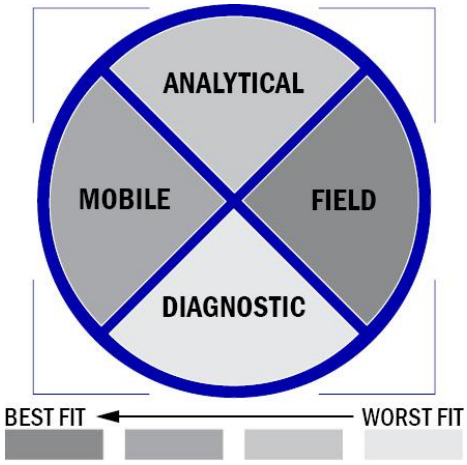
FIELD USE Ranking

HDS-101GN Search and Identification ranked in the bottom third of all evaluated products for field use and earned 49% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Mirion Technologies (MGPI), Inc.
5000 Highlands Parkway, Ste 150
Smyrna, GA 30082

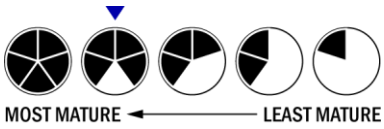
Point of Contact:
Keith Spero
770.432.2744 x163

COST

- $9,500/system or device

SPECIFICITY

- False positives: Less than 1/hr/week
- False negatives: Not applicable



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms can be deactivated
- Screen can be dimmed or turned off

Training and Speed:
- An afternoon of training and some technical skills required
- <5 minutes set up required
- Customer site training/ Hard-copy manual

Operational conditions:
- Can be used from -21°C to 41°C
- Does not require consumables
- < 90% at 42°C (108°F) relative humidity

Transportation:
- Size of system or device 280mm x 78 mm (11in x 3.1 in)
- All modes of transportation
- Weighs 1500 kg

Maintenance:
- Service less than once per year
- Maintenance is included
- No daily QA required
- Unit is able to be decontaminated

Physical System Requirements:
- 110V electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source is required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation step required

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Does not test liquids

System Maturity:
- Is commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB
- Network capable
- Wired and wireless connections
- Fully autonomous
- Laptop computer
- The system automatically stores and archives data outputs and creates an electronic record
- The system software is open but modification requires licensing
- The system hardware is open but modification requires licensing

High-Speed Resonant FTIR Spectrometer for Thermal Luminescence Detection of Liquids on Surfaces

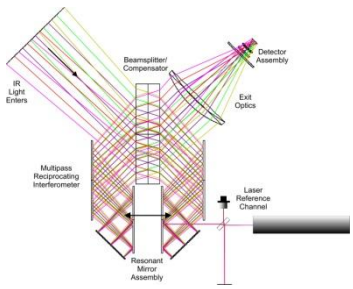
by OPTRA, Inc.

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.



DESCRIPTION:

This is an ultra-high measurement bandwidth infrared spectrometer intended for use in thermal luminescence (TL) measurements of unknown liquids or solids on surfaces. Specific application of this device is the detection and identification of chemical warfare agents (CWAs) and toxic industrial chemicals (TICs). TL technique illuminates a surface under suspicion with a light source whose spectrum is separate from the spectral range of the spectrometer. As contaminant heats up, dynamic properties of the molecular emission spectrum in the long-wave infrared region are observed by the spectrometer, thereby providing a new dimension of information with which to identify the contaminant and discriminate it from other spectral interferrents. This spectrometer offers a ten-fold spectral acquisition rate improvement over commercially available rapid scan infrared spectrometers with comparable sensitivity and specificity for detecting CWAs, TICs. TL measurement is non-contact & requires no sample preparation or consumables. Approach is capable of simultaneously detecting a number of contaminants; in its final format, the system will include fully automated detection and identification algorithms.

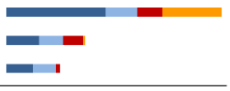
TECHNOLOGY:

A Fourier transform infrared spectrometer employing a multi-pass reciprocating interferometer and a resonant scanner to acquire 10,000, 8 cm-1 spectra per second over the 7-14 micron spectral range. The spectrometer will be used for time-resolved thermal luminescence measurements of CWAs and TICs on surfaces. This spectrometer offers a ten-fold spectral acquisition rate improvement over commercially available rapid scan infrared spectrometers with comparable sensitivity and specificity for detecting CWAs and TICs.

ANALYTICAL Laboratory Ranking

High-Speed Resonant FTIR ranked in the bottom third of all evaluated products for analytical laboratories and earned 37% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
High-Speed Resonant FTIR	29.64
MINIMUM SCORE	20.38

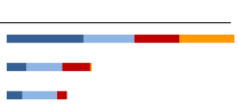


Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

High-Speed Resonant FTIR ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 37% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
High-Speed Resonant FTIR	30.96
MINIMUM SCORE	22.05

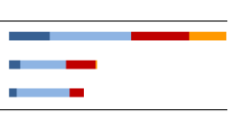


Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

High-Speed Resonant FTIR ranked in the bottom third of all evaluated products for mobile laboratories and earned 40% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
High-Speed Resonant FTIR	33.34
MINIMUM SCORE	28.44

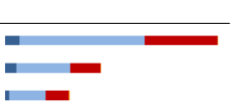


Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

High-Speed Resonant FTIR ranked in the bottom third of all evaluated products for field use and earned 45% of the utility points of the best score.

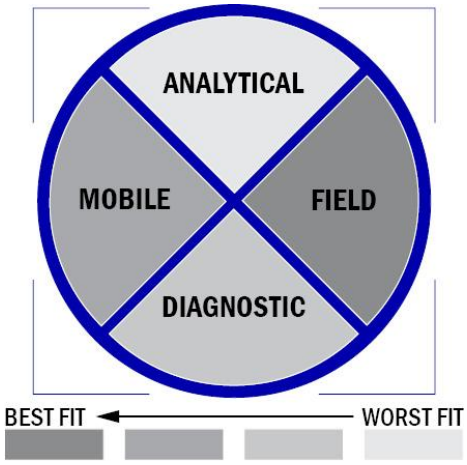
ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
High-Speed Resonant FTIR	39.23
MINIMUM SCORE	26.53



Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

OPTRA, Inc.
461 Boston St.
Topsfield, MA 01983

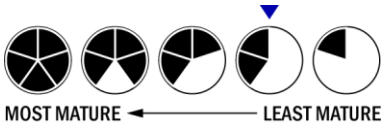
Point of Contact:
Julia Rentz Dupuis
978-887-6600 x125

COST

- Approx. $35,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, >10 tests/ sample per run
- Could be adapted to fully automated with some effort

Signature:
- User interface is still under development

Training and Speed:
- An afternoon of training and some technical skills required
- <5 minutes set-up required
- <1 minute down time
- 0-2 steps required
- Manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours/ Should be frozen but can stand temps >4°C for <24 hours
- Impact of relative humidity not known
- Shelf life not applicable

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Transport via commercial carrier/ Fixed wing military aircraft/ Ship
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- No consumables

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance not determined
- Expected life >10 years
- <5 minutes daily QA
- Decon not applicable

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System could call final result in the future

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Liquid test information not available

System Maturity:
- Bread board
- Technology ownership and intellectual property is pending

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Not network capable
- Could be fully autonomous with some effort
- Basic desktop computer
- Could be adapted to store and archive data outputs and create an electronic record
- System software open and available for modification
- System hardware open and available for modification

HiScanSQ Systems

by Illumina Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria
Viruses

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Environmental water, Soil

DESCRIPTION:

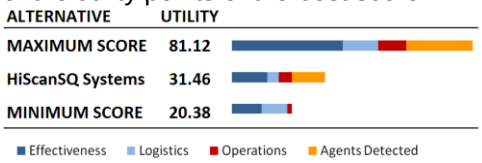
The HiScanSQ system integrates the power and resolution of next-generation sequencing with the high-throughput capacity of genotyping and gene expression arrays, delivering unprecedented flexibility for experimental design. The instrument features two distinct components, the HiScan Reader and the SQ Module. The HiScan Reader functions as a high-speed, precision imaging scanner for Illumina sequencing and microarray-based analyses. The SQ Module is reagent handling fluidics device needed to perform Illumina next-generation sequencing. Other components include the cBot Cluster Generation System, a suite of data collection and analysis software, and dedicated consumables. cBot provides automated clonal amplification of single molecules randomly distributed on a glass surface.

TECHNOLOGY:

The HiScan Reader is a high-speed, precision imaging scanner for Illumina sequencing and microarray-based analyses. The SQ Module is an add-on reagent handling fluidics device needed to perform Illumina next-generation sequencing on the HIScan reader. BeadArray technology is utilized in Illumina's HiScanSQ System for a broad range of DNA and RNA analysis applications. Illumina's BeadArray Technology is based on sub-micron silica beads that self assemble in microwells on planar silica slides. Each bead is covered with hundreds of thousands of copies of a specific oligonucleotide that act as the capture sequences in one of Illumina's assays. Illumina sequencing technology leverages clonal array formation and proprietary reversible terminator technology for rapid and accurate large-scale sequencing. The innovative and flexible sequencing system enables a broad array of applications in genomics, transcriptomics, and epigenomics.

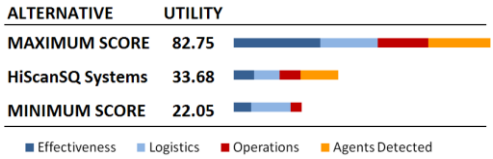
ANALYTICAL Laboratory Ranking

HiScanSQ Systems ranked in the bottom third of all evaluated products for analytical laboratories and earned 39% of the utility points of the best score.



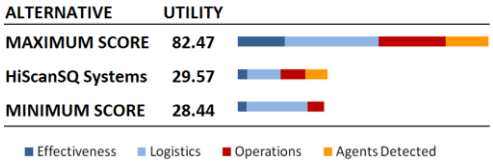
DIAGNOSTIC Laboratory Ranking

HiScanSQ Systems ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 41% of the utility points of the best score.



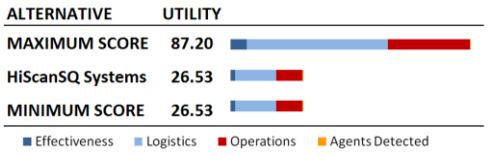
MOBILE Laboratory Ranking

HiScanSQ Systems ranked in the bottom third of all evaluated products for mobile laboratories and earned 36% of the utility points of the best score.



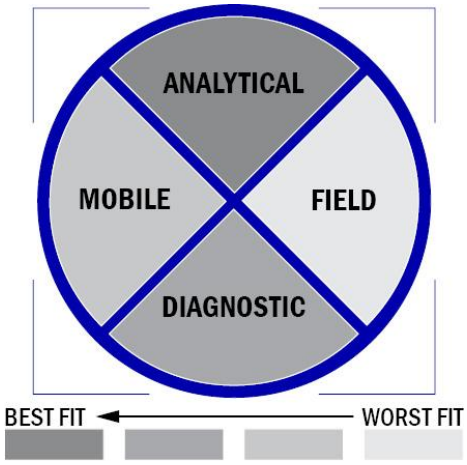
FIELD USE Ranking

HiScanSQ Systems ranked in the bottom third of all evaluated products for field use and earned 30% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Illumina Inc.
9885 Towne Centre Drive
San Diego, CA 92121

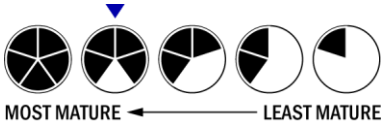
Point of Contact:
Dawn Barry
dbarry@illumina.com
203-296-0536

COST

- $405,500.00/system or device

SPECIFICITY

- False Positives: <3%
- False Negatives: <0.5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- More than 8 hrs for detection
- Multiple samples, multiple tests/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- An day of training and technical skills required
- >20 minutes set-up
- <5 minutes down time
- Greater than 12 steps required
- Customer site training/ Hard-copy and web-based operators manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at room temp (27°C)/ Must be stored at 4°C/ Must be frozen
- Peak performance at normal relative humidity conditions
- Between 1-6 months shelf life

Transportation:
- Larger than home dishwasher
- Transport via commercial carrier; Fixed wing military aircraft/ Ship
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service more than twice a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- <5 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Requires water aliquots
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- Multiple centrifugation steps
- Multiple shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connections
- Not autonomous
- High end desktop computer
- Does not store or archive data outputs or create an electronic record
- System software open and available for modification
- System hardware closed and not available for modification

HiSeq 1000 Sequencing System

by Illumina Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria
Viruses

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Environmental water, Soil

DESCRIPTION:

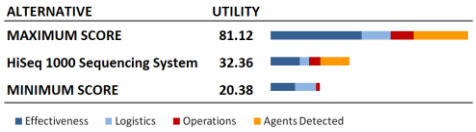
The Illumina HiSeq 1000 Sequencing System is an integrated platform that uses massively parallel sequencing technology for genetic analysis and functional genomics. It consists of the HiSeq 1000 sequencer, which uses TDI line scanning and dual surface imaging to generate up to 300 gigabases (Gb) per run and up to 30 Gb per day. Other components include the cBot Cluster Generation System, a suite of data collection and analysis software, and dedicated consumables. cBot provides automated clonal amplification of single molecules randomly distributed on a glass surface. Resulting DNA clusters are sequenced on the HiSeq 2000 using a sequencing by synthesis method with patented reversible terminator chemistry.

TECHNOLOGY:

Illumina sequencing technology leverages clonal array formation and proprietary reversible terminator technology for rapid and accurate large-scale sequencing. The innovative and flexible sequencing system enables a broad array of applications in genomics, transcriptomics, and epigenomics.

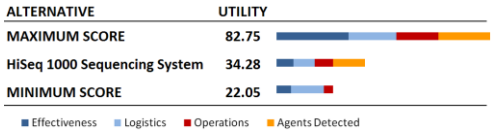
ANALYTICAL Laboratory Ranking

HiSeq 1000 Sequencing System ranked in the bottom third of all evaluated products for analytical laboratories and earned 40% of the utility points of the best score.



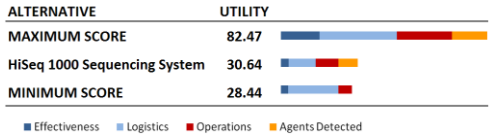
DIAGNOSTIC Laboratory Ranking

HiSeq 1000 Sequencing System ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 41% of the utility points of the best score.



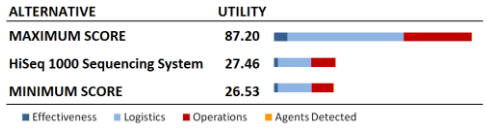
MOBILE Laboratory Ranking

HiSeq 1000 Sequencing System ranked in the bottom third of all evaluated products for mobile laboratories and earned 37% of the utility points of the best score.



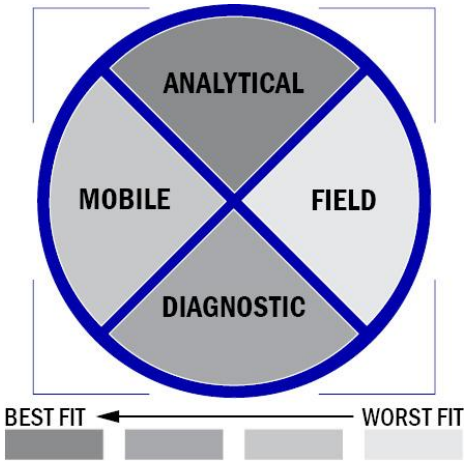
FIELD USE Ranking

HiSeq 1000 Sequencing System ranked in the bottom third of all evaluated products for field use and earned 31% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Illumina Inc.
9885 Towne Centre Drive
San Diego, CA 92121

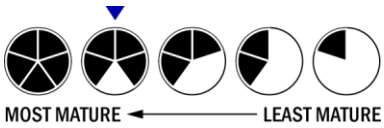
Point of Contact:
Dawn Barry
dbarry@illumina.com
203-296-0536

COST

- $560,000.00/system or devices

SPECIFICITY

- False Positives: 2-3%
- False Negatives: <0.5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- More than 8 hrs for detection
- Multiple samples, multiple tests/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- >20 minutes set-up
- <5 minutes down time
- Greater than 12 steps required
- Customer site training/ Hard-copy and web-based operators manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at 4°C/ Must be frozen
- Peak performance at normal relative humidity conditions
- 6 months to 1 year shelf life

Transportation:
- Larger than a home dishwasher
- Transport via commercial carrier/ Fixed wing military aircraft
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service more than twice a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 220V electrical requirement
- Not portable
- Requires water aliquots
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- Multiple centrifugation steps
- Multiple shaking or vortexing, mixing, degassing or filtering steps
- System could call final result in the future

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- > 250 GB raw data
- Network capable
- Wired connections
- Not autonomous
- High end desktop computer
- Does not store or archive data outputs or create an electronic record
- System software open and available for modification
- System hardware closed and not available for modification

HiSeq 2000 Sequencing System

by Illumina Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria
Viruses

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Environmental water, Soil

DESCRIPTION:

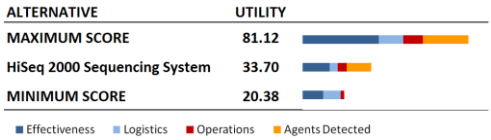
The Illumina HiSeq 2000 Sequencing System is an integrated platform that uses massively parallel sequencing technology for genetic analysis and functional genomics. It consists of the HiSeq 2000 sequencer, which uses TDI line scanning and dual surface imaging to generate up to 600 gigabases (Gb) per run and up to 60 Gb per day. Other components include the cBot Cluster Generation System, a suite of data collection and analysis software, and dedicated consumables. cBot provides automated clonal amplification of single molecules randomly distributed on a glass surface. Resulting DNA clusters are sequenced on the HiSeq 2000 using a sequencing by synthesis method with patented reversible terminator chemistry.

TECHNOLOGY:

Illumina sequencing technology leverages clonal array formation and proprietary reversible terminator technology for rapid and accurate large-scale sequencing. The innovative and flexible sequencing system enables a broad array of applications in genomics, transcriptomics, and epigenomics.

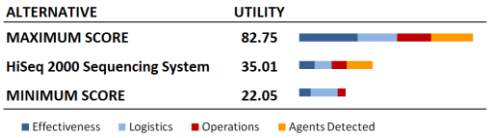
ANALYTICAL Laboratory Ranking

HiSeq 2000 Sequencing System ranked in the bottom third of all evaluated products for analytical laboratories and earned 42% of the utility points of the best score.



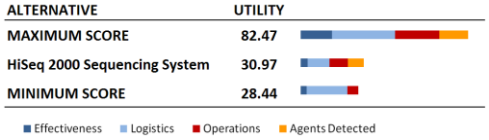
DIAGNOSTIC Laboratory Ranking

HiSeq 2000 Sequencing System ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 42% of the utility points of the best score.



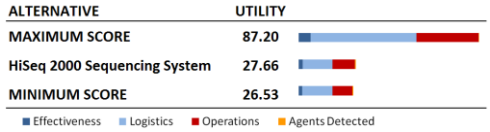
MOBILE Laboratory Ranking

HiSeq 2000 Sequencing System ranked in the bottom third of all evaluated products for mobile laboratories and earned 38% of the utility points of the best score.



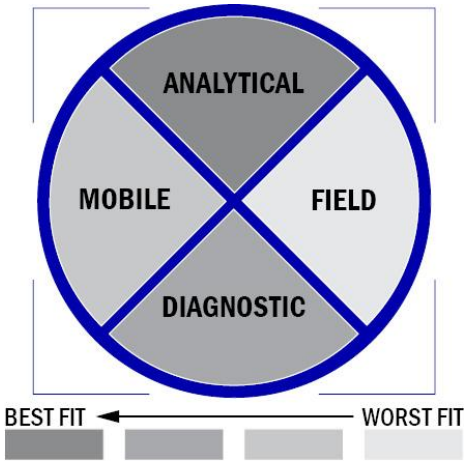
FIELD USE Ranking

HiSeq 2000 Sequencing System ranked in the bottom third of all evaluated products for field use and earned 32% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Illumina Inc.
9885 Towne Centre Drive
San Diego, CA 92121

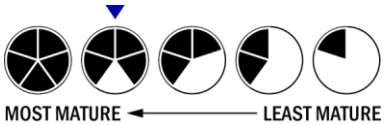
Point of Contact:
Dawn Barry
dbarry@illumina.com
203-296-0536

COST

- $690,000.00/system or device

SPECIFICITY

- False Positives: 2-3%
- False Negatives: <0.5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- More than 8 hrs for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- >20 minutes set-up
- <5 minutes down time
- Greater than 12 steps required
- Customer site training/ Hard-copy and web-based operators manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at 4°C/ Must be frozen
- Peak performance at normal relative humidity conditions
- 6 months to 1 year shelf life

Transportation:
- Larger than a home dishwasher
- Transport via commercial carrier; fixed wing military aircraft
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service more than twice a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 220V electrical requirement
- Not portable
- Requires water aliquots
- External air or gas source required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- Multiple centrifugation steps
- Multiple shaking or vortexing, mixing, degassing or filtering steps
- System could call final result in the future

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- > 250 GB raw data
- Network capable
- Wired connections
- Not autonomous
- High end desktop computer
- Does not store or archive data outputs or create an electronic record
- System software open and available for modification
- System hardware open and available for modification

HMT (Hardened MobileTrace®)

by MorphoDetection, Inc.

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

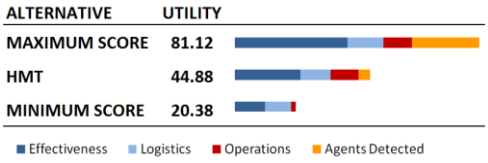
The Hardened MobileTrace® (HMT) is a handheld device that is a ruggedized and enhanced version of the MorphoDetection, Inc's., MobileTrace®. It is designed to bring laboratory grade capabilities to the most challenging field operations. The core technology is Ion Trap Mobility Spectrometry, allowing for high sensitivity detection of CWA's, TIC's, explosives, taggants, narcotics and precursors in a particle or vapor state. Developed as a collaborative effort with TSWG, the HMT has been tested to MIL-STD 810 F(G) for drop testing (three feet for unit alone, four feet in its case transport case), rain, salt fog, and dust. It is capable of operating in a temperature range of -20° C to 55° C, storage temperature range of -20° C to 70° C and up to 95% rH. The HMT also offers unique features such as; hot swappable batteries, automatic trap recognition (no additional triggering required) and the ability to go from particle mode to vapor mode without the need of any hardware changes. It is also equipped with a daylight readable 800 NIT color LCD display and has both Ethernet and USB ports for such options as; communications to a computer, data transfer to a USB memory stick, use of the included external keyboard and ease of performing software updates.

TECHNOLOGY:

The Hardened MobileTrace's detection technology is MorphoDetection, Inc.'s patented Ion Trap Mobility Spectroscopy. CWA's and TIC's are detected as vapor. In the HMT's Universal mode, the desorber temperature is lowered and a sample pump will draw vapors into the desorber where they collect on the heater plates. When sample collection is complete, the desorber will then flash heat and pass the vapors into the ITMS detector for analysis. The HMT utilizes a polymeric membrane to reduce the introduction of particle contaminants from entering the detector thereby reducing maintenance requirements.

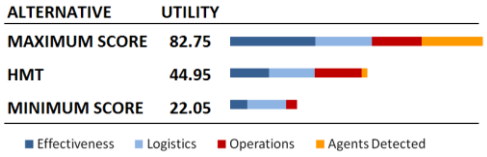
ANALYTICAL Laboratory Ranking

HMT ranked in the middle third of all evaluated products for analytical laboratories and earned 55% of the utility points of the best score.



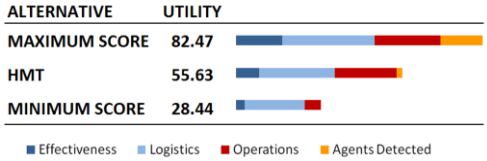
DIAGNOSTIC Laboratory Ranking

HMT ranked in the middle third of all evaluated products for diagnostic laboratories and earned 54% of the utility points of the best score.



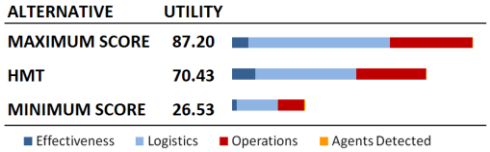
MOBILE Laboratory Ranking

HMT ranked in the middle third of all evaluated products for mobile laboratories and earned 67% of the utility points of the best score.



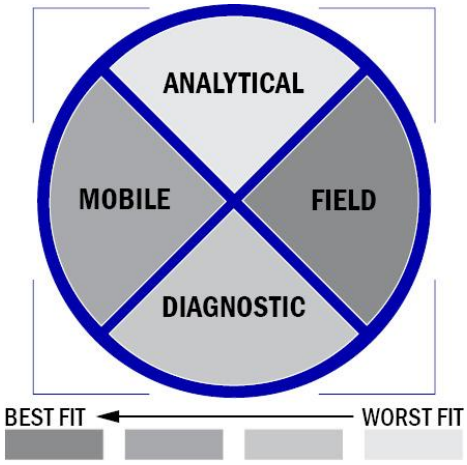
FIELD USE Ranking

HMT ranked in the top third of all evaluated products for field use and earned 81% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

MorphoDetection, Inc.
205 Lowell Street
Wilmington, MA 01887

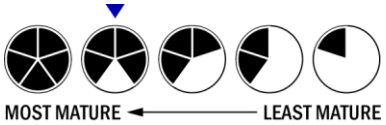
Point of Contact:
Ethan Sandahl
978-909-1287
ethan.sandahl@morphodetection.com

COST

- $39,500.00/system or device
- $3,000.00/year for system use

SPECIFICITY

- False positives: - <2%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- System is fully automated

Signature:
- Sounds or alarms can be deactivated
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- Less than 5 minutes set up
- Less than 1 minute down time
- 0-2 steps are required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from <-21°C to >41°C
- Components should be stored at room temp but can with stand temperatures >45°C for periods < 24 hours
- Performance is not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Less than once per year
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 5-10 years
- < 5 minutes daily QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps are required
- No shaking or vortexing, mixing, degassing or filtering steps are required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Does not test liquids

System Maturity:
- Commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB
- Network capable
- Wired connections
- Could be adapted to a fully autonomous system with some effort
- On board computer chip in the system
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

Home Healthcare Diagnostics

by MD Microscopes International

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Environmental air, Water, Soil, Food, Powder

DESCRIPTION:

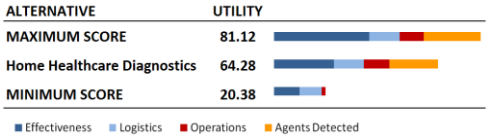
A patent pending technology will enable home healthcare diagnostics for everyone, reducing primary healthcare costs and increasing healthcare availability. Rural communities, the elderly, the military, veterans, and families will have the conveyance of low cost diagnostics in their home. Through the convergence of old and new technologies, diagnostic tests can now be run anywhere in the world, in a variety of environments, without any skill. For the first time ever, the full array of morphological (e.g., cell count, hematology, white cell differential, bacteria, fluorescent markers, tissue sample, etc.) and diagnostic tests (e.g., immunological, protein, hormonal, chemical, genetic, etc.) on the same drop of blood (or body fluid) at wavelength limited resolution and fully automated, can be run by a child on a USB plug-and-play system. The system is mobile, can be USB or battery powered, is the size of an external hard drive and has an overnight Fedex shipping weight of 3.5 lbs. The system receives a disposable carrier having a demographically or geographically derived matrix of 5-100 tests – demographically derived may focus on age, combat situations, exposure expectations; geographically derived may focus on a combination of demographics along with the unique issues associated with the location. A sample is added, no pre-processing, and placed in the unit for automated analysis. In the US it is expected to reduce primary health care costs by at least 50%; and to be sold in chain stores (e.g., Wal-Mart, Walgreens, etc.).

TECHNOLOGY:

The Home Healthcare Diagnostics provides fully automated wavelength limit analysis, brightfield and fluorescence, in a mobile USB plug-and-play device. This fundamental advance in technology is applicable across a multitude of applications. In one application, a carrier is inserted without pre-processing for healthcare diagnostics, chemical assays, immunoassays and biological assessments. Other uses include all fully automated microscopy needs and applications; genetic, microbiology, bacteriology, virology, etc. The full automation enables the data to be transmitted to experts anywhere in the world and remote from the test site.

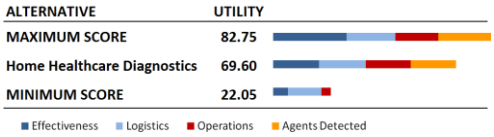
ANALYTICAL Laboratory Ranking

Home Healthcare Diagnostics ranked in the top third of all evaluated products for analytical laboratories and earned 79% of the utility points of the best score.



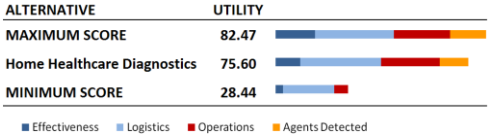
DIAGNOSTIC Laboratory Ranking

Home Healthcare Diagnostics ranked in the top third of all evaluated products for diagnostic laboratories and earned 84% of the utility points of the best score.



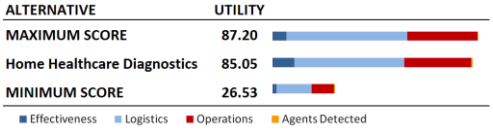
MOBILE Laboratory Ranking

Home Healthcare Diagnostics ranked in the top third of all evaluated products for mobile laboratories and earned 92% of the utility points of the best score.



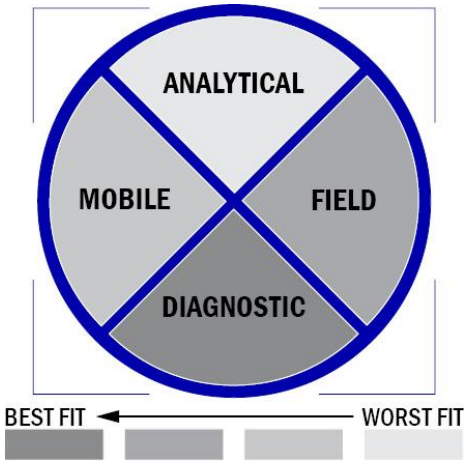
FIELD USE Ranking

Home Healthcare Diagnostics ranked in the top third of all evaluated products for field use and earned 98% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

MD Microscopes International
555 Republic Drive
Plano, TX 75074

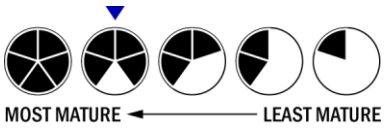
Point of Contact:
Dr. Glenn Spaulding
281-827-4707

COST

- $400.00 - $10,000.00/system or device

SPECIFICITY

- False Positives: Test dependent
- False Negatives: Test dependent



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/samples per run
- Could easily be adapted into a fully automated system

Signature:
- Sounds or alarms not present
- Optional screen can be turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- No set-up required
- <1 minute down time
- 0-2 steps required
- DVD/ Customer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Components should be stored at room temp but can stand temps >45°C for < 24 hours
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Preventive maintenance included
- Expected life not applicable
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 1-2 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering step
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 50 ul required for test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property licensing is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Satellite, wireless and wired connections
- Could easily be adapted to fully autonomous
- On board computer chip
- Could be adapted to store or archive data outputs or create electronic records
- System software is open and available for modification
- System hardware is open and available for modification

IBTIS (Instantaneous Bio Threat Identification System)

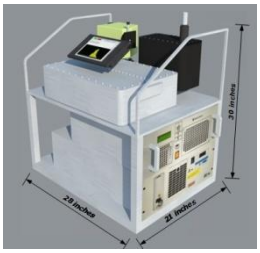
by Caribbean Biotechnologies Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria

DETECTION MATRICES:

Demonstrated:
Nasal and throat swabs, Environmental air



DESCRIPTION:

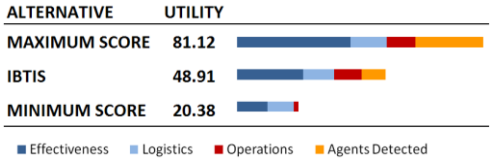
IBTIS was designed to test environmental samples from open spaces instantaneously, and alert first respondents of the presence of specific biological agents that may represent a health hazard. The system takes samples from the open environment at a specific location, and continuously test this air sample through a flow through system. The sample is tested optically for diameter and two-photon fluorescence response using unique optical devices and detectors. The response is compared with a bank of spectral responses, previously tested under lab conditions, and issues a warning of presence and concentration. The warning indicates the level of speciation in terms of %, if higher than 99% correlation, it is considered as positive. . The system is capable of detecting the presence of multiple agents from same air samples. IBTIS has been tested in the lab for a range of bacteria and fungus including; E-Aerogenes, B. thuringensis, M. Smegmatis, Aspergilus sp, M. Tuberculosis, S. Mitis, and B. Subtiulus, among others . The system is relatively portable, with physical dimensions of 3' high, 2' wide, and 2' deep. The system can be used for surveillance of public spaces, in hospitals to avoid contamination due to air flow infections, and could be adapted for industrial locations. IBTIS has been adapted as a medical device for M. Tuberculosis, by using a mouth piece that patients can use to deliver their breath to the testing section.

TECHNOLOGY:

The scientific principle of IBTIS is non-linear intrinsic fluorescence and particle sizing. Thus, signals and identifications are limited to biological agents. Two-photon fluorescence is a powerful diagnostic tool given the unique response of the fluorophores that are activated with this red-shifted signal. The light source used is a femtosecond infrared signal, capable of delivering two photons per pulse. This signal is the main detection source, and it is combined with particle sizing via Mie scattering of same red light. Those two signals are detected via a series of ultra-sensitive optical sensors (PMT) and in-house software to issue a diagnostic.

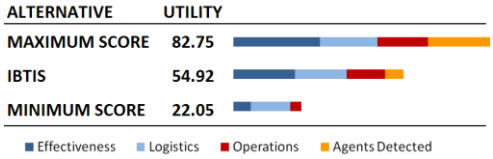
ANALYTICAL Laboratory Ranking

IBTIS ranked in the middle third of all evaluated products for analytical laboratories and earned 60% of the utility points of the best score.



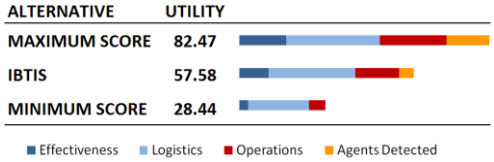
DIAGNOSTIC Laboratory Ranking

IBTIS ranked in the middle third of all evaluated products for diagnostic laboratories and earned 66% of the utility points of the best score.



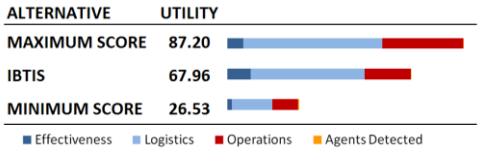
MOBILE Laboratory Ranking

IBTIS ranked in the middle third of all evaluated products for mobile laboratories and earned 70% of the utility points of the best score.



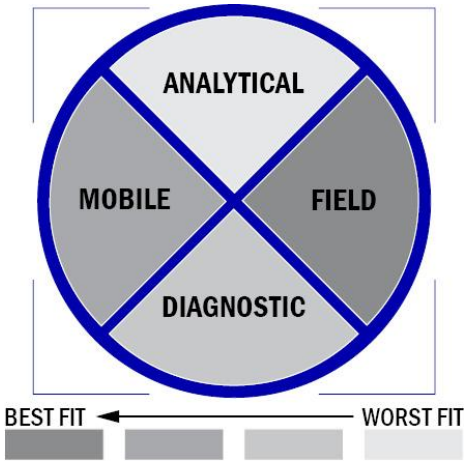
FIELD USE Ranking

IBTIS ranked in the middle third of all evaluated products for field use and earned 78% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Caribbean Biotechnologies Inc.
177 Balboa St.
La Quinta Industrial Park
Mayaguez, PR 00680

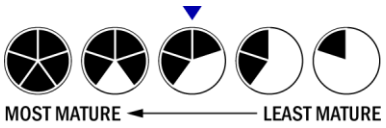
Point of Contact:
Jorge E. Gonzalez, Ph.D.
jegc@cbtpr.com
(516)-984-9613

COST

- $125,000.00 - $150,000.00/system or device

SPECIFICITY

- False Positives: < 5%
- False Negatives: < 5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/samples per run
- Fully automated system

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 5-10 minutes set-up
- < 1 minute down time
- 0-2 steps required
- Customer site training

Operational conditions:
- Can be used from 4°C to 37°C
- Does not require consumables
- Peak performance at normal relative humidity
- Shelf life information not applicable

Transportation:
- Approximately the size of carry-on luggage
- Transport via commercial carrier/ Fixed wing military aircraft/ Ship
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- < 5 minutes daily QA required
- Hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance pending
- FDA clearance pending
- Does not test liquids

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Satellite, wireless and wired connections
- Could easily be adapted to fully autonomous
- No computer required
- Stores and archives data outputs and creates electronic records
- System software open and available for modification
- System hardware open and available for modification

ICS-5000 Ion Chromatography system

by Dionex Corporation

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

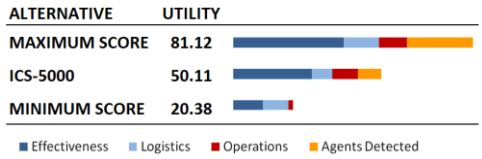
Dionex Corporation develops, manufactures, sells, and services chromatography and extraction systems for separating, isolating, and identifying the components of chemical mixtures. Our continuing leadership in chromatography helps us create powerful solutions to increase productivity for the industries that shape the world. Our solutions are used by the environmental, life sciences, pharmaceutical, food and beverage, chemicals, power generation, and electronics industries.

TECHNOLOGY:

Eluent Regeneration was developed for systems dedicated to high-throughput analyses of samples with low- to moderate-concentration matrices. Reagent-Free IC systems with Eluent Regeneration (RFIC-ER systems) are designed to use carbonate, carbonate/ bicarbonate, or MSA eluents for isocratic separations. Eluent Regeneration is available as an optional configuration or upgrade for ICS-1100, -1600, -2100, and -5000 systems.

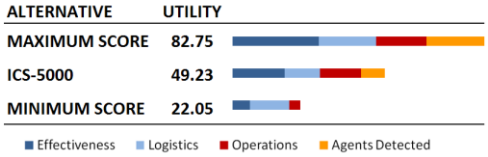
ANALYTICAL Laboratory Ranking

ICS-5000 Ion Chromatography system ranked in the middle third of all evaluated products for analytical laboratories and earned 62% of the utility points of the best score.



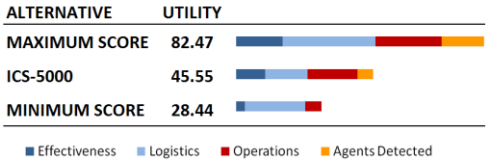
DIAGNOSTIC Laboratory Ranking

ICS-5000 Ion Chromatography system ranked in the middle third of all evaluated products for diagnostic laboratories and earned 59% of the utility points of the best score.



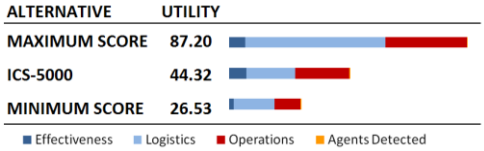
MOBILE Laboratory Ranking

ICS-5000 Ion Chromatography system ranked in the bottom third of all evaluated products for mobile laboratories and earned 55% of the utility points of the best score.



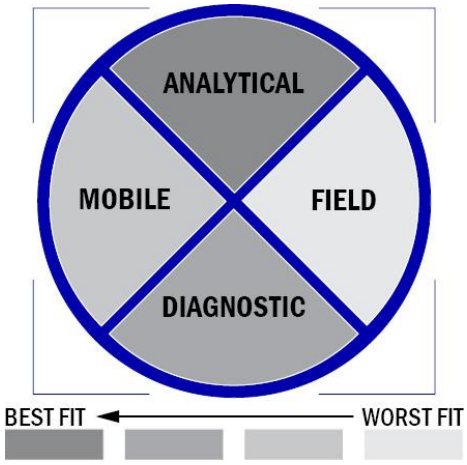
FIELD USE Ranking

ICS-5000 Ion Chromatography system ranked in the bottom third of all evaluated products for field use and earned 51% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

1228 Titan Way
P.O. Box 3603
Sunnyvale, CA 94088-3603

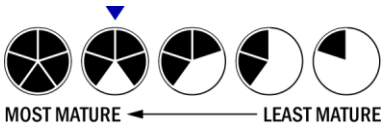
Point of Contact:
Osama El-badry
408 737 0700
elbadry@dionex.com

COST

- $35,000.00 - 50,000.00/system or device

SPECIFICITY

- False Positives: 1%
- False Negatives: 1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15 – 30 minutes for detection
- Multiple samples, multiple tests/samples per run
- Semi-automated

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- >1 day training and significant technical skills are required
- >20 minutes set-up required
- 1-3 minutes down time
- 0-2 steps required
- DVD/ Customer and manufacturer site training/ Hard copy and web manual

Operational conditions:
- Can be used from 4°C - 41°C
- Components should be stored at room temp but can stand temps > 45°C for <24 hours
- Optimum performance in temp stable, dry environment
- Between 1-3 years shelf life

Transportation:
- Approximately the size of dishwasher
- Transport via commercial carrier, fixed wing military or rotary wing aircraft, ship
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 5-10 years
- 10-20 mins daily QA required
- Hazardous agent isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110v electrical requirement
- Not portable
- Requires water aliquots
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering step
- System calls final result

Sensitivity and Detection:
- 510K clearance information not available
- FDA clearance capable
- Less than 250 ul required for test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- 200-249 GB
- Network capable
- Wired connection
- Could be fully autonomous with some effort
- Basic desktop computer
- Stores and archives data outputs and creates electronic records
- System software is open but modification requires licensing
- System hardware is open but modification requires licensing

ID-24

by Evogen, Inc.

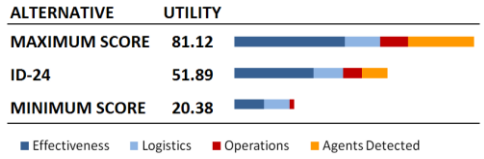
DETECTS THE FOLLOWING:
Nothing demonstrated.

DETECTION MATRICES:
Nothing demonstrated.

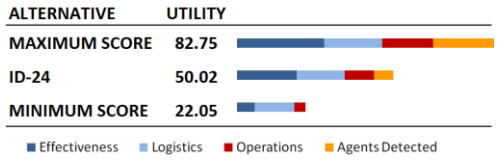
DESCRIPTION:
The Evogen ID-24 is a single channel PCR laboratory instrument. The instrument has 3 thermally and optically independent blocks at 8 wells each, allowing multiple PCR protocols to be run simultaneously on one instrument. The ID-24 uses Evogen HyBeacons probes to provide real-time amplification as well as high resolution melt analysis.

TECHNOLOGY:
The ID-24 uses a peltier-based thermal engine for each block of 8 wells. The optics are based on high-sensitivity photodiodes. These diodes read the fluorescent emission signal from each well that is produced when Evogen's proprietary HyBeacons probes bind to a specific target sequence during the annealing step of the PCR cycles.

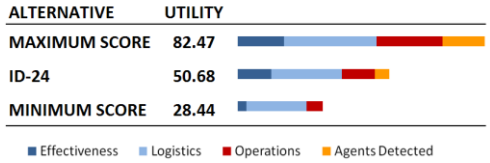
ANALYTICAL Laboratory Ranking
ID-24 ranked in the middle third of all evaluated products for analytical laboratories and earned 64% of the utility points of the best score.



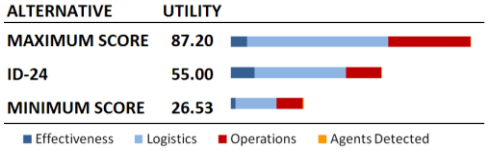
DIAGNOSTIC Laboratory Ranking
ID-24 ranked in the middle third of all evaluated products for diagnostic laboratories and earned 60% of the utility points of the best score.



MOBILE Laboratory Ranking
ID-24 ranked in the bottom third of all evaluated products for mobile laboratories and earned 61% of the utility points of the best score.

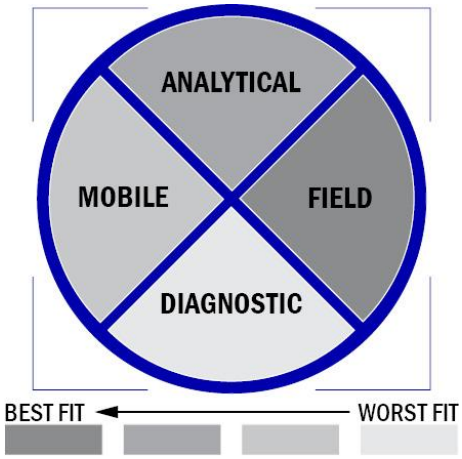


FIELD USE Ranking
ID-24 ranked in the bottom third of all evaluated products for field use and earned 63% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Evogen, Inc.
8301 State Line Road, Suite 101
Kansas City, Missouri 64110

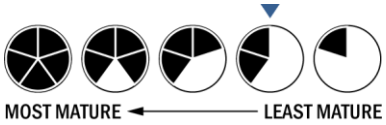
Point of Contact:
Jessica Chapman, Mechanical Engineer

COST

- $10,000.00/system or device
- $10.00-30.00/analysis

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1- 8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Currently semi-automated

Signature:
- No sounds or alarms
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- < 5 minutes set up
- 1-3 minutes down time
- 0-2 steps are required
- Hard-copy and web-based manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be stored at room
- Influence of humidity unknown
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of a toaster
- Commercial carrier
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- No service
- Preventive maintenance N/A
- Maintenance is not included
- 5-10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps required
- Single shaking or vortexing, mixing, degassing or filtering step required
- Software final call could be developed

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 10 ul for a test

System Maturity:
- Bread board
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed.

Interoperability and System Complexity:
- < 100 GB or single response generated
- Not network capable
- No data transmission
- Not capable of an autonomous system
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

identiFINDER

by ICx Radiation

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types
Identification of specific isotopes

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

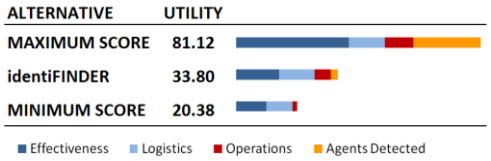
The identiFINDER™ instrument series is a family of handheld, digital gamma spectrometers. Every identiFINDER is able to rapidly locate, accurately measure and precisely identify sources or contaminations from gamma radiation. The ability to detect X-ray sources as well as the presence of neutrons in the radiation field via an optional neutron detector allows a wide application scope.

TECHNOLOGY:

identiFINDER instruments use either a LaBr or NaI detector to acquire a spectrum of the incoming gamma radiation. This spectrum is analyzed using a template matching algorithm that is capable of identifying the isotopes present in the sample.

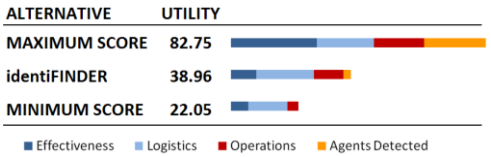
ANALYTICAL Laboratory Ranking

identiFINDER ranked in the bottom third of all evaluated products for analytical laboratories and earned 42% of the utility points of the best score.



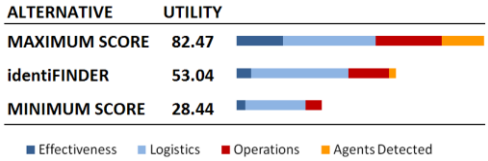
DIAGNOSTIC Laboratory Ranking

identiFINDER ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 47% of the utility points of the best score.



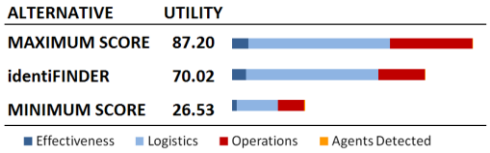
MOBILE Laboratory Ranking

identiFINDER ranked in the middle third of all evaluated products for mobile laboratories and earned 64% of the utility points of the best score.



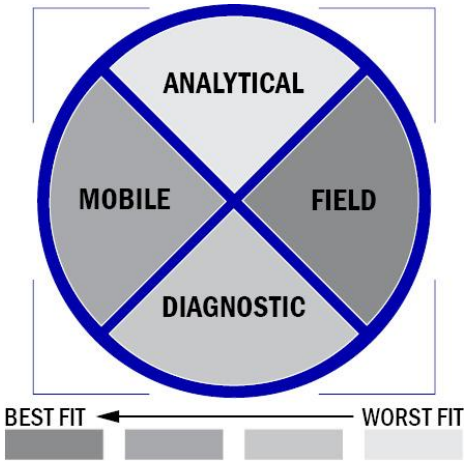
FIELD USE Ranking

identiFINDER ranked in the top third of all evaluated products for field use and earned 80% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ICx Radiation
100 Midland Rd
Oak Ridge, TN 37830

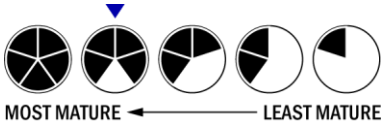
Point of Contact:
Jeff Perkins
Jeffrey.Perkins@icxt.com

COST

$11,000.00 - $33,000.00/system or device

SPECIFICITY

- False Positives: N/A
- False Negatives: N/A



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training

Operational conditions:
- Can be used from < -21°C to > 42°
- Components not applicable
- Performance is not influenced by relative humidity
- Shelf life not applicable

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- Components not applicable

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Decon not applicable

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Amount needed to test liquid not applicable

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Not network capable
- Wireless and wired connections
- Not autonomous
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software closed and not available for modification
- System hardware closed and not available for modification

identiFINDER 2

by ICx Radiation

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination of radiation types
Identification of specific isotopes

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

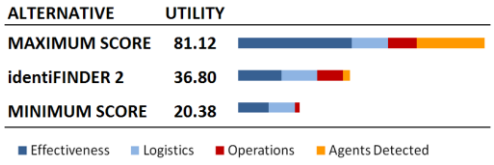
The ICx Technologies identiFINDER™ 2 is a logical extension of the original identiFINDER series of handheld radioisotope identification detector (RIID) instruments. The thousands of identiFINDERs currently deployed worldwide have provided ICx with a tremendous resource for suggestions and comments on how to improve the already exceptional identiFINDER. The identiFINDER 2 is the result of these comments and suggestions. The monochrome LCD display has been replaced with a TFT LCD, 64k color, 320 by 240 pixel display that is readable in virtually all light conditions. The spectrum is continuously LED peak stabilized to handle a wide range of count rates and conditions with no peak interference in the identification spectrum. Wired communication uses a micro USB connector, USB 2.0, or wireless via a Class 2.0 Bluetooth© interface, with a 33 ft(10m) range, which supports the reach-back capability, also provided. A Web interface is provided via USB emulated TCPIP (LAN) for monitoring and configuring the identiFINDER 2. A twelve channel, Sirf III GPS is included for incident location. Data storage has been enlarged to 1 GB to save more spectra and event information.

TECHNOLOGY:

Same as the original identiFINDER, this instrument uses either a LaBr or NaI detector to collect a gamma spectrum. This spectrum is run through a template matching algorithm to identify the isotopes present.

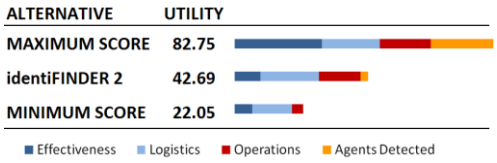
ANALYTICAL Laboratory Ranking

identiFINDER 2 ranked in the bottom third of all evaluated products for analytical laboratories and earned 45% of the utility points of the best score.



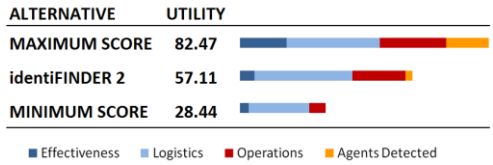
DIAGNOSTIC Laboratory Ranking

identiFINDER 2 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 52% of the utility points of the best score.



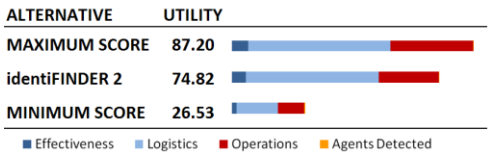
MOBILE Laboratory Ranking

identiFINDER 2 ranked in the middle third of all evaluated products for mobile laboratories and earned 69% of the utility points of the best score.



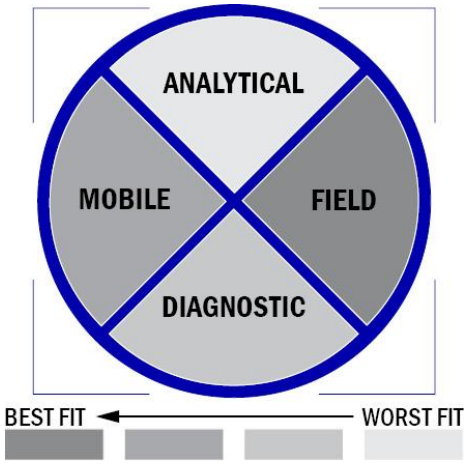
FIELD USE Ranking

identiFINDER 2 ranked in the top third of all evaluated products for field use and earned 86% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ICx Radiation
100 Midland Rd
Oak Ridge, TN 37830

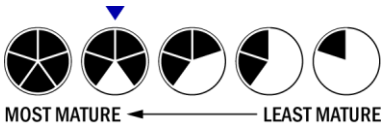
Point of Contact:
Jeff Perkins
Jeffrey.Perkins@icxt.com

COST

$12,000.00 - $35,000.00/system or device

SPECIFICITY

- False Positives: N/A
- False Negatives: N/A



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training

Operational conditions:
- Can be used from < -21°C to > 42°
- Does not require consumables
- Performance is not influenced by relative humidity
- Shelf life not applicable

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- Components not applicable

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Decon not applicable

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Amount needed to test liquid not applicable

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless and wired connections
- Fully autonomous
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software closed and not available for modification
- System hardware closed and not available for modification

IMMULITE® 2000 Immunoassay System

by Siemens Healthcare Diagnostics

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

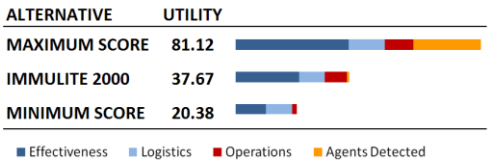
The IMMULITE 2000 immunoassay system has been designed specifically for optimum efficiency and consolidation in medium and high-volume laboratories. The IMMULITE 2000 intuitive software, and graphical user interface, offers streamlined information management, from remote test ordering to sophisticated analysis of results. Throughput of up to 200 tests/hour User-defined automatic dilution protocols Five hours of usable walk away time Third-generation assays for excellent sensitivity Comprehensive menu of more than 100* assays Easily automate through VersaCell™ or other ADVIA Automation Systems The IMMULITE 2000 analyzer combines allergy and specialty immunoassay testing on one platform with many features that provide greater efficiency in the lab. The IMMULITE sample types include serum, plasma, urine, and amniotic fluid but is assay specific.

TECHNOLOGY:

Chemilumenscent technology.

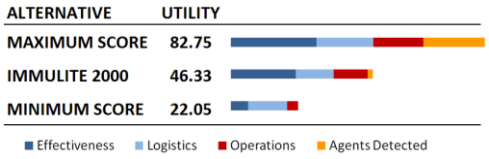
ANALYTICAL Laboratory Ranking

IMMULITE® 2000 Immunoassay System ranked in the bottom third of all evaluated products for analytical laboratories and earned 46% of the utility points of the best score.



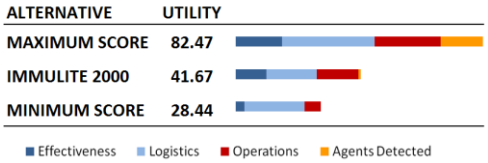
DIAGNOSTIC Laboratory Ranking

IMMULITE® 2000 Immunoassay System ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 56% of the utility points of the best score.



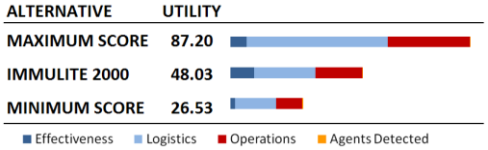
MOBILE Laboratory Ranking

IMMULITE® 2000 Immunoassay System ranked in the middle third of all evaluated products for mobile laboratories and earned 51% of the utility points of the best score.



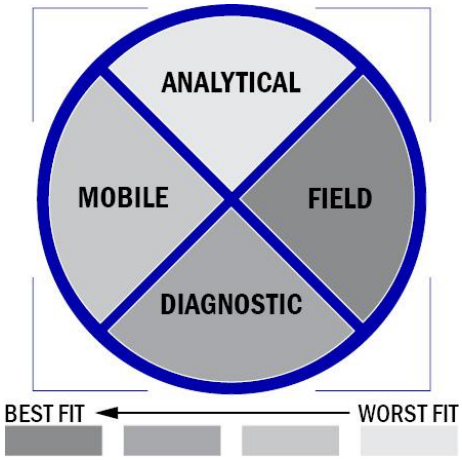
FIELD USE Ranking

IMMULITE® 2000 Immunoassay System ranked in the bottom third of all evaluated products for field use and earned 55% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

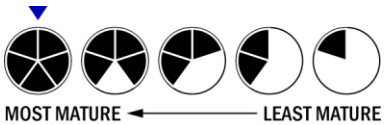
Siemens Healthcare Diagnostics
1717 Deerfield Road
Deerfield, IL 60015-0778
Phone: 847-267-5300

COST

- $157,200/system or device

SPECIFICITY

- Assay dependent



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30 - 60 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- No sounds or alarms
- Screen cannot be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- More than a day of training and significant technical skills are required
- Less than 5 minutes for set up
- Almost no down time
- 0-2 steps are required
- DVD/ Web video/ Customer and Manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 18°C to 32°C
- Components must be stored at 4°C
- Performance is not influenced by relative humidity
- 6 months - 1 year shelf life

Transportation:
- Larger than a home dishwasher
- Commercial carrier
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by technician
- Expected life 5-10 years
- Less than 5 minutes QA required

Physical System Requirements:
- 220V electrical requirement
- Not intended for portable use
- Requires water aliquots
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- A single centrifugation step required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance shown
- FDA approval shown
- Less than 250 ul for a test

System Maturity:
- Commercially available and meets milspecs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intel property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Fully autonomous system
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

Informant 15-Minute Black Mold Detection Test

by ADVNT Biotechnologies

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

Simple to use two channel immunochromatographic assay that test for Aspergillus, Stachybotrys and Penicillium Mold spores. the three types of black mold designated as a health hazard by the CDC.

TECHNOLOGY:

A triple-agent black mold detection system that employs hand held immunochromatographic assay that uses colloidal gold antibodies specific for the detection of hazardous black mold spores.

ANALYTICAL Laboratory Ranking

Informant 15-Minute Black Mold Detection Test ranked in the bottom third of all evaluated products for analytical laboratories and earned 35% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
Informant 15-Min Mold Test	28.28
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

Informant 15-Minute Black Mold Detection Test ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 39% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
Informant 15-Min Mold Test	32.60
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

Informant 15-Minute Black Mold Detection Test ranked in the bottom third of all evaluated products for mobile laboratories and earned 55% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
Informant 15-Min Mold Test	45.44
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

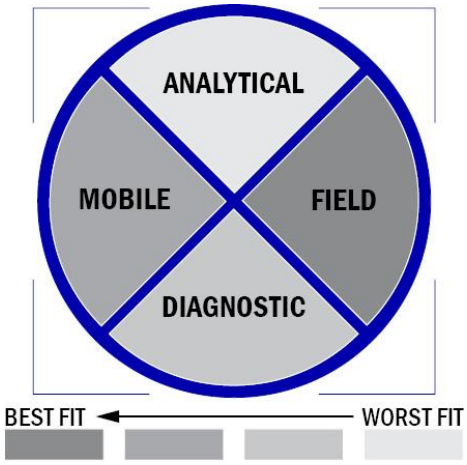
Informant 15-Minute Black Mold Detection Test ranked in the middle third of all evaluated products for field use and earned 70% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
Informant 15-Min Mold Test	60.68
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ADVNT Biotechnologies
22510 N. 18th Dr.
Phoenix, AZ. 85027

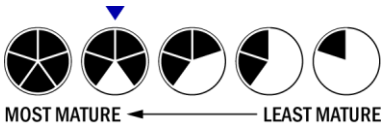
Point of Contact:
Kevin Borah
(888) 223 - 3269

COST

- $14.50/test

SPECIFICITY

- False Positives: Less than 1%
- False Negatives: Less than 1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, single test/sample per run
- Not amenable to full or semi-automation

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes set-up required
- Almost no down time
- 6-8 steps required
- Hard-copy operators manual

Operational conditions:
- Can be used from 25°C - 37°C
- Components should be stored at room temp but can stand temps >45°C for < 24 hours/ Must be stored at room temp (27°C)/ Must be stored at 4°C
- Performance not influenced by relative humidity
- Shelf life between 1-3 years

Transportation:
- Approximately the size of a soda can
- Transport via commercial carrier
- Weighs less than 1 kg

Re-use:
- Single use
- 2 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service not required
- Preventive maintenance information not available
- Warranty does not apply
- Expected life not applicable
- No daily QA required
- No decon required

Physical System Requirements:
- No electrical equipment
- Battery life information not available
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering step
- System does not call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 250 ul required for test

System Maturity:
- Is commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property licensing pending

Interoperability and System Complexity:
- Raw data size information not available
- Network capability information not available
- Not autonomous
- No computer required
- Does not store or archive data outputs or create electronic records
- Does not employ software
- System is single use

InnoScan

by Arrayit Corporation

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Demonstrated:
Blood

DESCRIPTION:

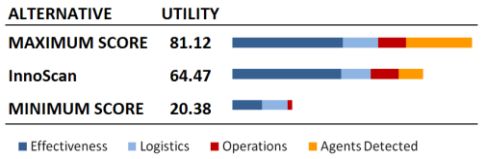
0.5 micron resolution microarray scanner, fluorescence based, designed for laboratory analysis.

TECHNOLOGY:

Next generation microarray scanning technology. World's only sub 1 µm microarray substrate slide scanner on the market. Proprietary rotary scanning architecture permits the fastest scanning speeds. 3 minutes to scan an entire 25 x 76 mm substrate slide. Scan 24 substrate slides in 100 minutes with autoload feature. Rotary scanning architecture reduces vibrational noise and increases image quality. Much greater reliability and longevity than conventional raster scanners. High resolution acquisition system: scans spot sizes down to 5 µm diameter. Real-time image acquisition for all microarray types including but not limited to in-situ high density glass slide microarrays, spotted microarrays of all kinds, tissue and cell microarrays. Low background noise and high sensitivity system. Uniform scanning across the entire microarray surface regardless of substrate type (glass, membrane and plastic). Not sensitive to shocks, vibrations and slide deformation (portable). Delivered with Mapix® software: an easy to use data acquisition and image analysis software including automatic spot recognition and powerful image analysis. Software for various OS environments (Linux, Windows). Ethernet interface allows easy data sharing (scanner can be shared over network by several users). Affordable price, low maintenance. Lightweight, robust structure makes it portable system. Small footprint for laboratory space saving.

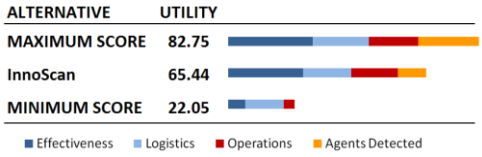
ANALYTICAL Laboratory Ranking

InnoScan ranked in the top third of all evaluated products for analytical laboratories and earned 79% of the utility points of the best score.



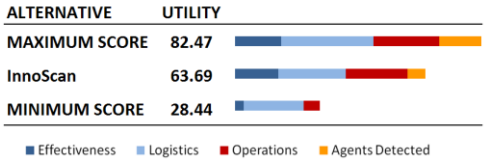
DIAGNOSTIC Laboratory Ranking

InnoScan ranked in the top third of all evaluated products for diagnostic laboratories and earned 79% of the utility points of the best score.



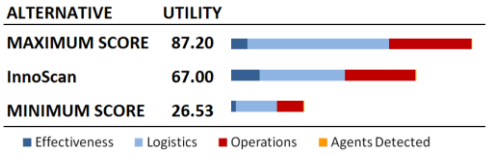
MOBILE Laboratory Ranking

InnoScan ranked in the top third of all evaluated products for mobile laboratories and earned 77% of the utility points of the best score.



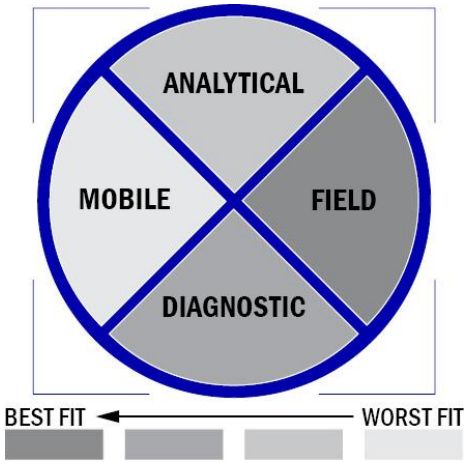
FIELD USE Ranking

InnoScan ranked in the middle third of all evaluated products for field use and earned 77% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Arrayit Corporation
524 East Weddell Drive
Sunnyvale CA 94089

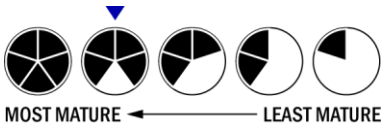
Point of Contact:
Rene Schena
408-744-1331

COST

- $125,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- <1 minute down time
- 3-5 steps required
- Customer and manufacturer site training/ Hard-copy and web-based operators manual

Operational conditions:
- Can be used from 4°C to 41°C
- Should be stored at room temp (27°C)
- Performance is not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of carry-on luggage
- Transport via commercial carrier
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- <5 minutes QA required
- Hazardous agent isolated to discrete elements and/or decon requires up to 1 hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Does not test liquids

System Maturity:
- Is commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- >250 GB raw data generated
- Network capable
- Wireless and wired connections
- Fully autonomous
- High end desktop computer
- Stores and archives data outputs and creates an electronic record
- System software is open and available for modification
- System hardware is open and available for modification

Instadose dosimeter

by Mirion Technologies

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

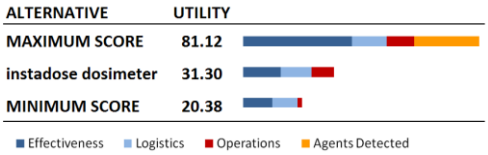
The instadose™ dosimeter brings radiation monitoring into the digital age. Smaller than a flash drive, this rugged dosimeter provides immediate dose readings when connected to any computer with internet access. Based upon patented direct ion storage technology, the instadose device includes access to each user's historical and current exposure readings online. There is no need to send badges to a processing center, simplifying administration and reducing costs. Benefits for your facility include: • NVLAP and HSE accredited • Unlimited real-time dose readings online • Online badge reassignment • Dose reports maintained online •Patient dose monitoring capabilities • NO badge collection • NO battery replacements or calibration

TECHNOLOGY:

The instadose dosimeter is based upon patented direct ion storage technology.

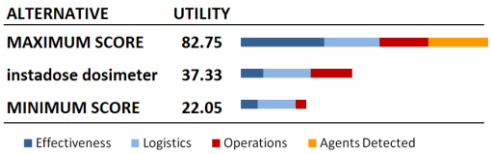
ANALYTICAL Laboratory Ranking

Instadose dosimeter system ranked in the bottom third of all evaluated products for analytical laboratories and earned 39% of the utility points of the best score.



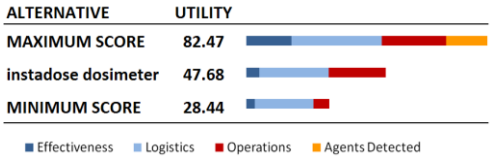
DIAGNOSTIC Laboratory Ranking

Instadose dosimeter system ranked in the middle third of all evaluated products for diagnostic laboratories and earned 45% of the utility points of the best score.



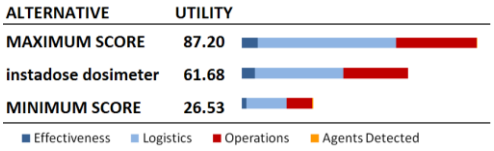
MOBILE Laboratory Ranking

Instadose dosimeter system ranked in the middle third of all evaluated products for mobile laboratories and earned 58% of the utility points of the best score.



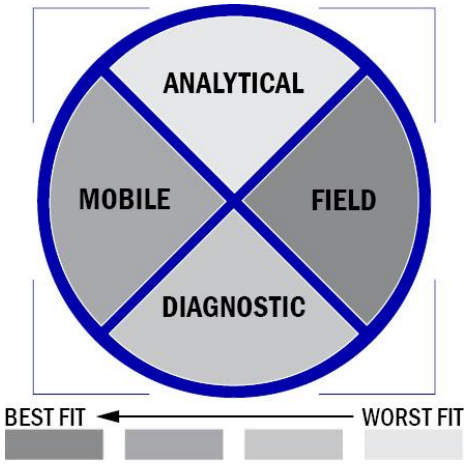
FIELD USE Ranking

Instadose dosimeter system ranked in the top third of all evaluated products for field use and earned 71% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Mirion Technologies
Dosimetry Services Division
2652 McGaw Ave
Irvine, CA 92614

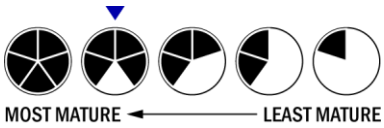
Point of Contact:
Lou Biacchi
949-419-1000

COST

- $172.00/ system or device

SPECIFICITY

- False positives: 1 per 9.5 hours
- False negatives: Surpass the ANSI N42.34-2006 requirements



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Semi-automated

Signature:
- Sounds or alarms can be deactivated
- Screen cannot be dimmed or turned off

Training and Speed:
- Very brief training and minimal technical skills
- Less than 5 minutes set up
- Minimal down time
- 0-2steps are required
- Customer site training/ Hard-copy and web-based operators manual manuscript

Operational conditions:
- Can be used from -21°C to 41°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Shelf life greater than 3 years

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- No additional components

Maintenance:
- No service required
- Maintenance is included
- Expected life 3-5 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour to decontaminate

Physical System Requirements:
- No electrical requirement
- No batteries required
- Does not require water
- External air or gas source is required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps are required
- No shaking or vortexing, mixing, degassing or filtering steps are required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Does not test liquids

System Maturity:
- Commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB
- Network capable
- Not capable of transmitting data
- Not capable of autonomy
- Basic desktop computer
- Does not contain internal memory for data storage or electronic record keeping
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

InSyte

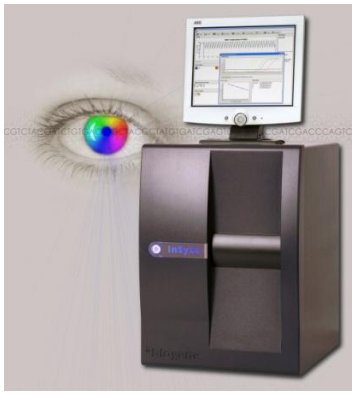
by BioGene Ltd

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.



DESCRIPTION:

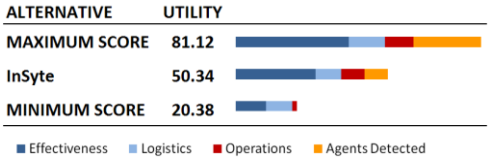
The InSyte is a laboratory based instrument for real-time amplification analysis of nucleic acid samples. It uses independent well control, meaning each vessel is individually monitored and can be controlled as such. The unique ability to perform the PCR process in a sub 15 minute time frame along, with laser based optics and photon counting detectors enabling capture of the full plate in under one second. The core technology is applicable to a point of care environment with subsequent further development.

TECHNOLOGY:

The system relies on ultra-rapid thermal cycling and the real-time PCR process in tandem with fast and sensitive laser and photon counting based optics. This allows the real-time detection of multiple nucleic acid target species in a single diagnostic run.

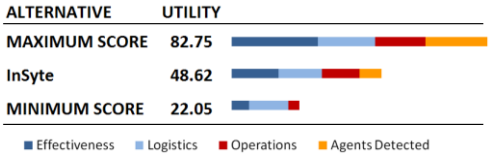
ANALYTICAL Laboratory Ranking

InSyte ranked in the middle third of all evaluated products for analytical laboratories and earned 62% of the utility points of the best score.



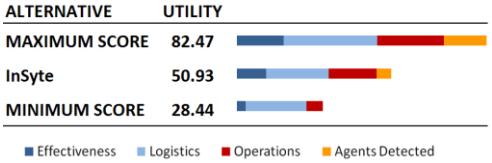
DIAGNOSTIC Laboratory Ranking

InSyte ranked in the middle third of all evaluated products for diagnostic laboratories and earned 59% of the utility points of the best score.



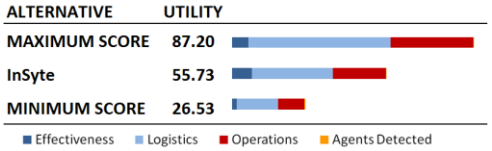
MOBILE Laboratory Ranking

InSyte ranked in the bottom third of all evaluated products for mobile laboratories and earned 62% of the utility points of the best score.



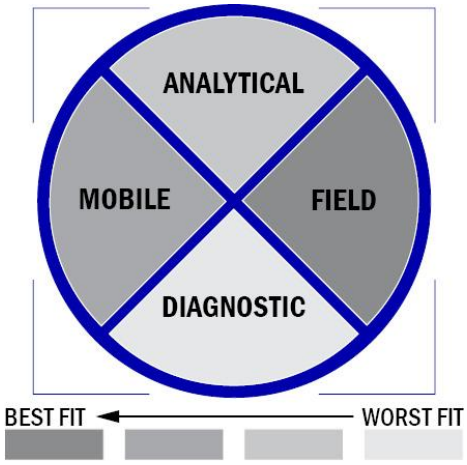
FIELD USE Ranking

InSyte ranked in the bottom third of all evaluated products for field use and earned 64% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

BioGene Ltd
BioGene House 6
The Business Centre Harvard Way
Kimbolton Cambs PE28 0NJ
United Kingdom

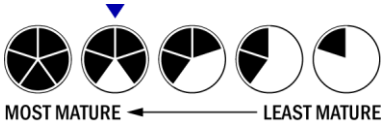
Point of Contact:
Mr. Nelson Nazareth

COST

- $93,300.00/system or device
- $2.25-3.00/test

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15-30 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated with some effort

Signature:
- No sounds or alarms
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 10-20 minutes for set up
- <1 minutes down time
- 3-5 steps are required
- Customer and manufacturer site training/ Hard copy manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components must be stored at 4°C
- Performance is not influenced by relative humidity
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of a home dishwasher
- Commercial carrier/ Tactical vehicle/ Fixed and rotary wing aircraft/ Ship transport
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 3 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service once a year
- Preventive maintenance N/A
- Maintenance not included
- Expected life 5-10 years
- No QA required
- Exposure to hazardous agent would require up to 1 day to decontaminate

Physical System Requirements:
- 220V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time not available
- Data can be processed while in progress
- No centrifugation steps required
- A single shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Less than 50 ul for a test

System Maturity:
- Commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Fully autonomous system with easy adaptation
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The software is closed, not available for modification
- The hardware is closed, not available for modification

Intelliprobe TM

by Rapid Diagnostek, Inc

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e3-10e4 CFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Urine

DESCRIPTION:

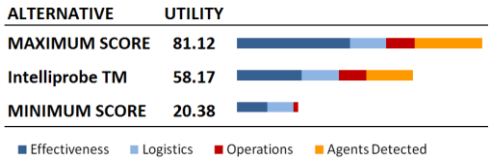
This is a highly versatile platform. The system consists of a cell phone-sized instrument that uses disposable sensors. Sensors can be for a single analyte or can be made as a multiplexed array on a single sensor. All sensor formats will be compatible with the same instrument. The system is intended for use at the point of sample collection, regardless of environment. Skills sufficient to use a cell phone are far above what is required to operate the system. While the first product will be a hand held device, the technology can also be configured as a low volume bench-top or a high throughput laboratory instrument. Test samples can be any untreated biological fluid, environmental sample, or a prepared solution or suspension of a material to be tested.

TECHNOLOGY:

A bulk acoustic shear-wave thin-film resonator coated with a capture ligand is operated at its fundamental resonance frequency as it is exposed to a test sample. As target analyte is captured the phase of the signal shifts. The rate of phase change is proportional to concentration of target analyte in the sample. A second identical resonator on the sensor is coated as a reference that is non reactive with the target analyte but will undergo any non-specific changes that the capture ligand on the test resonator experiences (pH, temperature, viscosity, non-specific protein binding, etc...). The net difference between the test and reference phase shifts is due solely to target analyte binding.

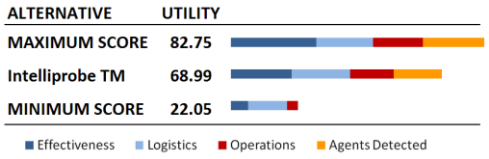
ANALYTICAL Laboratory Ranking

Intelliprobe TM ranked in the top third of all evaluated products for analytical laboratories and earned 72% of the utility points of the best score.



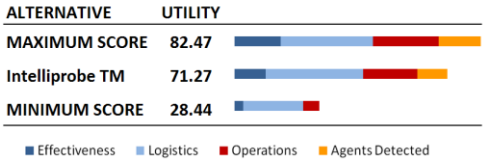
DIAGNOSTIC Laboratory Ranking

Intelliprobe TM ranked in the top third of all evaluated products for diagnostic laboratories and earned 83% of the utility points of the best score.



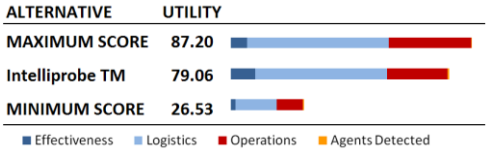
MOBILE Laboratory Ranking

Intelliprobe TM ranked in the top third of all evaluated products for mobile laboratories and earned 86% of the utility points of the best score.



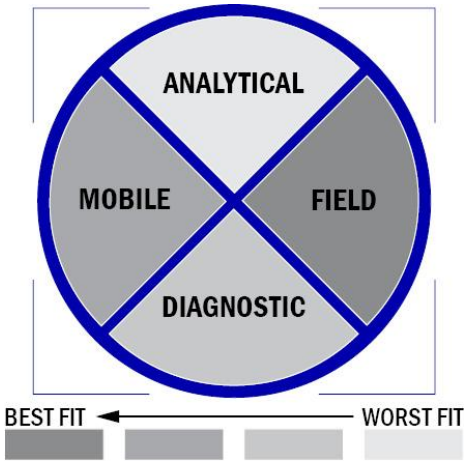
FIELD USE Ranking

Intelliprobe TM ranked in the top third of all evaluated products for field use and earned 91% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Rapid Diagnostek, Inc
1301 Gateway Circle, Suite 400
Hudson, WI 54016

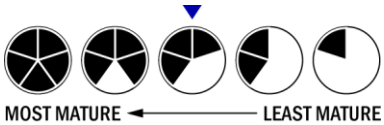
Point of Contact:
Richard A. Van Deusen, CTO

COST

- $250.00/system or device
- ≥$3.00/ analysis

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Currently semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set up
- Almost no down time
- 0-2 steps are required
- DVD/Web-based video

Operational conditions:
- Can be used from 4°C to 41°C
- Components storage unknown
- Performance is not influenced by relative humidity
- Shelf life unknown

Transportation:
- Approximately the size of a soda can
- All means of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 3-5 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1 hr

Physical System Requirements:
- System used batteries
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance pending
- FDA approval pending
- Less than 50 ul for a test

System Maturity:
- Brass board
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- > 250 GB
- Network capable
- Wired connections
- Fully autonomous system
- Onboard computer chip
- Store and archive data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is closed and not available for modification

Ion Torrent Personal Genome Machine

by Ion Torrent Systems, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 PFU/mL)

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

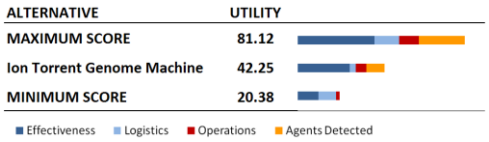
Ion Personal Genome Machine (PGM™) sequencer can do runs in about 2 hours, offers semiconductor scalability and is one tenth the price of other sequencers to buy and to run. A touch screen guides the user through every step of the run, making it simple to use. The PGM weighs less than 50 pounds and has a foot print that's no bigger than a desktop printer, so it can fit in any lab. The Ion Torrent Personal Genome Machine (PGM™) is simpler, more cost effective, and more scalable than any other sequencing technology. The PGM™ sequencer is a bench top system utilizing ground breaking and disruptive semiconductor technology that enables rapid and scalable sequencing experiments. Ion Torrent technology uses a massively parallel array of proprietary semiconductor sensors to perform direct real time measurement of the hydrogen ions produced during DNA replication. A high-density array of wells on the Ion semiconductor chips provide millions of individual reactors while integrated fluidics allow reagents to flow over the sensor array. This unique combination of fluidics, micromachining, and semiconductor technology enable the direct translation of genetic information (DNA) to digital information (DNA sequence) rapidly generating large quantities of high quality data. The Personal Genome Machine along with Ion Torrent semiconductor chips, Ion Torrent reagent kits, and the Torrent Server/Torrent Suite software allow Ion Torrent to deliver a cutting edge sequencing solution.

TECHNOLOGY:

Ion Torrent combines semiconductor sequencing technology with natural biochemistry. Ion Torrent produces proprietary semiconductor chips in standard CMOS factories. Ion leverages the $1 trillion investment that has been made in the semiconductor industry. Ion Torrent uniquely and directly benefits from four decades of exponential improvement in semiconductor technology, expressed as Moore's Law. Ion Torrent uses the simplest sequencing chemistry including natural nucleotides, no enzymatic cascade, no fluorescence, no chemiluminescence, no optics, no light, The Chip is the Machine. The Ion Chip directly detects, real-time, the natural release of the hydrogen ion as a nucleotide is incorporated into a DNA strand.

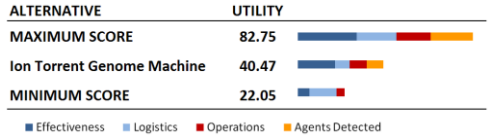
ANALYTICAL Laboratory Ranking

Ion Torrent Personal Genome Machine ranked in the middle third of all evaluated products for analytical laboratories and earned 52% of the utility points of the best score.



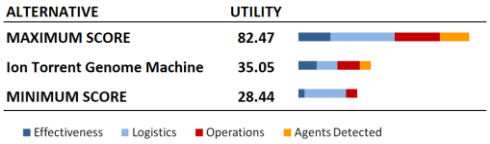
DIAGNOSTIC Laboratory Ranking

Ion Torrent Personal Genome Machine ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 49% of the utility points of the best score.



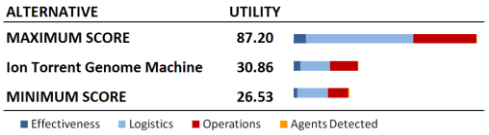
MOBILE Laboratory Ranking

Ion Torrent Personal Genome Machine ranked in the bottom third of all evaluated products for mobile laboratories and earned 43% of the utility points of the best score.



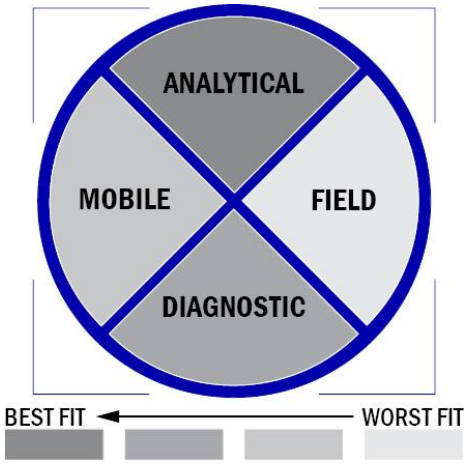
FIELD USE Ranking

Ion Torrent Personal Genome Machine ranked in the bottom third of all evaluated products for field use and earned 35% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

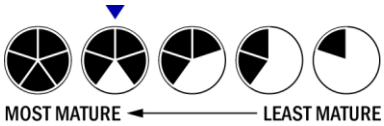
Ion Torrent Systems, Inc.
7000 Shoreline Court
Suite 201
South San Francisco, CA 94080

COST

- $49,500.00/system or device

SPECIFICITY

- False Positives: less than 1%
- False Negatives: less than 1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/sample per run
- Could easily be adapted into a fully automated system

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- >20 minutes set-up required
- <5 minutes down time
- Greater than 12 steps required
- Customer site training/ Hard-copy and web-based manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components must be stored at room temp/ Must be stored at 4°C
- Peak performance at normal relative humidity conditions
- 6 months and 1 year shelf life

Transportation:
- Approximately the size of home dishwasher
- All modes of transportation
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance included
- Expected life 3-5 years
- 10-20 minutes QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Requires water aliquots
- External air or gas source required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data processing while in progress information not available
- Multiple centrifugation steps
- Multiple shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connections
- Could be fully autonomous system with some effort
- High end computer
- Stores and archives data outputs and creates an electronic record
- System software is open and available for modification
- System hardware is open and available for modification

IPRL (Morpho Detection Inc. Intelligent Personal Radiation Locator)

by Morpho Detection Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types
Identification of specific isotopes

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

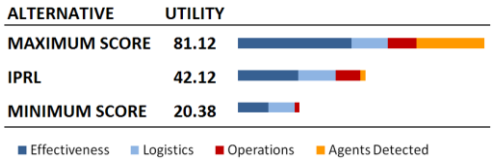
The IPRL system consists of multiple handheld radiation detectors used in conjunction with a base station. Each mobile unit utilizes a Cadmium Zinc Telluride (CZT) Compton camera gamma-ray detector that can identify isotopes and determine the direction from which the radiation originates. The inherent benefit of CZT is energy resolution less than 2%, compared to NaI, with resolution upwards of 9%. Better energy resolution translates to more accurate isotope identification and fewer false alarms. IPRL can determine the isotope, its direction, and intensity. Detected radiation from multiple units can either be wire or wirelessly transmitted to the mobile base station for system-wide analysis. In addition, data can be exchanged wirelessly between peer units and combined to improve the detection and identification of weak sources that individual modules cannot identify alone. The IPRL isotope identification algorithms can detect and identify a source from a very small number of total counts. The algorithm divides the spectrum into energy bins, and uses the method of projections onto convex sets to compare the measured spectrum to the library spectra. Once an isotope is identified, an estimate is made of confidence based on the peak/background ratio around prominent peaks in the spectrum. These advances in RIID algorithms allow the IPRL to have very rapid time-to-identification characteristics.

TECHNOLOGY:

IPRL utilizes a Cadmium Zinc Telluride (CZT) Compton camera gamma-ray detector that can identify isotopes and determine the direction from which the radiation originates. The IPRL was developed by GE GRC under a DNDO-funded Advanced Technology Demonstration (ATD) program (contract number HSHQDC-06-C-00089). Prototypes of the IPRL have undergone performance testing at Savannah River National Laboratory (SRNL) in September 2009. MDI is currently leveraging the prototype IPRL design to commercialize a Compact Directional RIID with Radiological Tripwire capability.

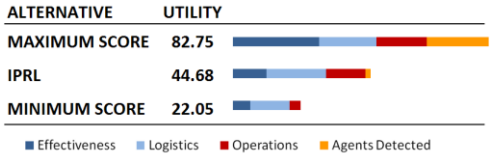
ANALYTICAL Laboratory Ranking

IPRL ranked in the bottom third of all evaluated products for analytical laboratories and earned 52% of the utility points of the best score.



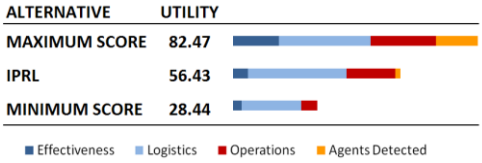
DIAGNOSTIC Laboratory Ranking

IPRL ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 54% of the utility points of the best score.



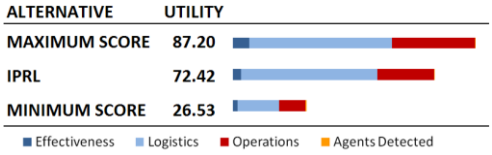
MOBILE Laboratory Ranking

IPRL ranked in the middle third of all evaluated products for mobile laboratories and earned 68% of the utility points of the best score.



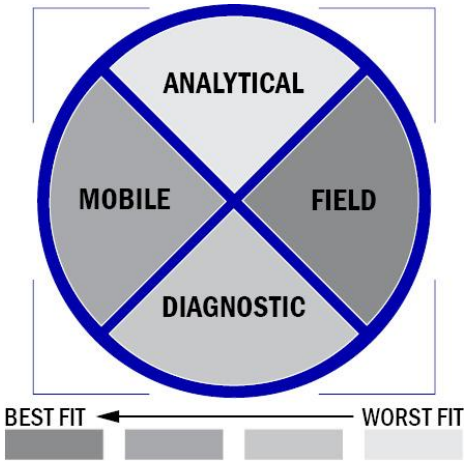
FIELD USE Ranking

IPRL ranked in the top third of all evaluated products for field use and earned 83% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Morpho Detection Inc.
7151 Gateway Blvd.
Newark, CA 94560

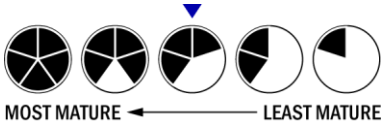
Point of Contact:
Lester Koga
lester.koga@morphodetection.com
510-739-3903

COST

- $28,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Thermal output information not available

Training and Speed:
- An afternoon of training and some technical skills required
- >5 minutes set-up
- Almost instantaneous down time
- Number of steps not applicable
- Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Shelf life not applicable

Transportation:
- Approximately the size of carry-on luggage
- Transport via commercial carrier/ Fixed wing military and rotary wing aircraft/ Ship
- Weighs between 5 and 25 kg

Re-use:
- On-going radiation detection
- Solutions, buffer, and/or reagents not applicable
- Components not applicable

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life >10 years
- >5 minutes daily QA
- Decon not applicable

Physical System Requirements:
- Operates from 10-40VDC (supplied w/ 110/220 adapter)
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property owned

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Wireless, wired connections
- Could be fully autonomous with some effort
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- Software closed and not available for modification
- Hardware closed and not available for modification

iScan System

by Illumina Inc.

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

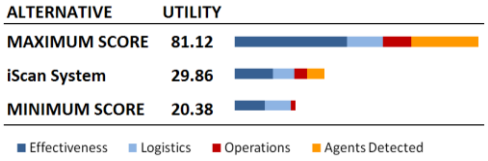
The iScan System is a cutting-edge, dedicated array scanner that supports rapid, sensitive, and accurate imaging of Illumina's array-based genetic analysis products. The system features a high signal-to-noise ratio, high sensitivity, an excellent limit of detection, and a broad dynamic range leading to exceptionally high data quality. •The iScan System supports Infinium, GoldenGate, DASL, Gene Expression (Direct Hybridization), and Methylation assays along with different multi-sample BeadChip formats.

TECHNOLOGY:

The iScan System is a cutting-edge, dedicated array scanner that supports rapid, sensitive, and accurate imaging of Illumina's array-based genetic analysis products. The system features a high signal-to-noise ratio, high sensitivity, an excellent limit of detection, and a broad dynamic range leading to exceptionally high data quality. •The iScan System supports Infinium, GoldenGate, DASL, Gene Expression (Direct Hybridization), and Methylation assays along with different multi-sample BeadChip formats.

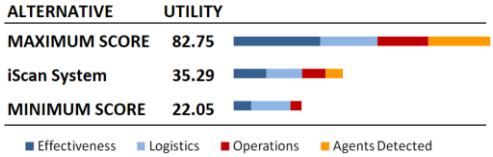
ANALYTICAL Laboratory Ranking

iScan System ranked in the bottom third of all evaluated products for analytical laboratories and earned 37% of the utility points of the best score.



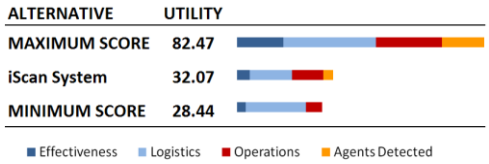
DIAGNOSTIC Laboratory Ranking

iScan System ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 43% of the utility points of the best score.



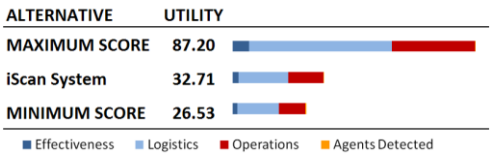
MOBILE Laboratory Ranking

iScan System ranked in the bottom third of all evaluated products for mobile laboratories and earned 39% of the utility points of the best score.



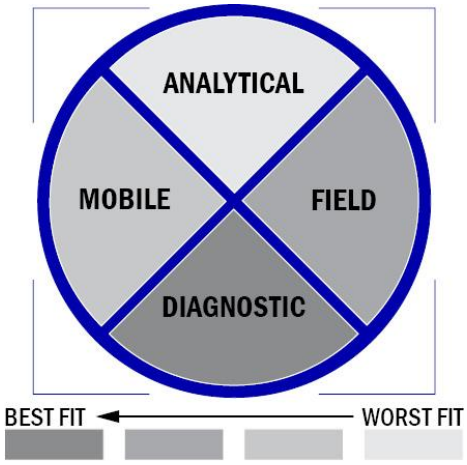
FIELD USE Ranking

iScan System ranked in the bottom third of all evaluated products for field use and earned 38% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Illumina Inc.
9885 Towne Centre Drive
San Diego, CA 92121

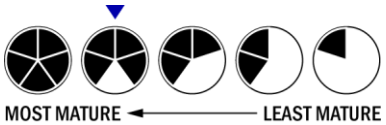
Point of Contact:
Dawn Barry
dbarry@illumina.com
203-296-0536

COST

- $230,000.00/system or device

SPECIFICITY

- False Positives: 1%
- False Negatives: 1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- More than 8 hrs for detection
- Multiple samples, multiple tests/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- <5 minutes set-up
- <1 minute down time
- Greater than 12 steps required
- Customer site training/ Hard-copy and web-based operators manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored room temperature (27°C)/ Must be frozen
- Performance not influenced by relative humidity
- Between 1-6 months shelf life

Transportation:
- Approximately the size of a home dishwasher
- All modes of transportation
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life >10 years
- <5 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Processing data while in progress information not available
- Multiple centrifugation steps
- Multiple shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Does not test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connections
- Could be adapted to fully autonomous with some effort
- High end desktop computer
- Stores and archives data outputs and creates an electronic record
- System software closed and not available for modification
- System hardware closed and not available for modification

IVDS (Integrated Virus Detection System)

by OpGen

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Viruses (100-1,000 CFU/mL)

DETECTION MATRICES:

Demonstrated:
Nasal and throat swabs,
Environmental air,
Environmental water, Soil,
Insect vectors

DESCRIPTION:

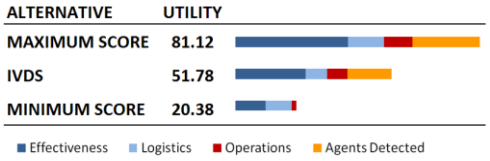
IVDS utilizes a particle counting technology to count whole viruses. IVDS determines the virus size and a quantitative concentration of the viruses per unit of sample. The major components are a Differential Mobility Analyzer (DMA) that determines the virus size and a Condensation Particle Counter (CCP) that determines the number of viruses in each size category. The four major steps in the process are (1) sample preparation that removes all contending particles that are larger and smaller than the viruses (creates a "virus window" from 10-600nm). This is done by ultra-filtration using tangential filters. (2) Sizing the viruses by using the DMA, (3) Counting the viruses by using the CPC and (4) recording the results in a computer file. In this manner viruses in the range from 10-600nm are separated, sized, counted and recoded in one minute intervals. No biochemical processes are used, this is a mechanical process for separation sizing and counting of viruses. IVDS is indicated for use when the detection of viruses in a sample is required. IVDS is indicated when detecting the absence viruses in a sample. IVDS is indicated when detecting unknown viruses in a sample. IVDS is indicated when quantifying virus titer and diversity in a sample.

TECHNOLOGY:

The principle of operation is mechanical separation and counting of the whole viruses in a liquid sample. The process utilizes four steps: (1) a mechanical filtration step using a hollow fiber tangential filter to separate particles larger and smaller than 10-600nm. (2) Differential Mobility Analyzer (DMA). (3) Condensation Particle Counter (CPC). (4) Software for recording size and concentration data to a computer file A unique feature of a mechanical means to count viruses is the absence of the typical spectral or chemical reactions associated with historical biochemical processes.

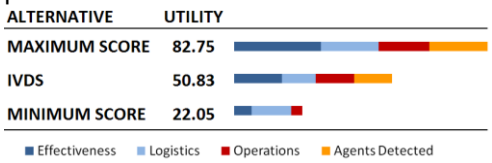
ANALYTICAL Laboratory Ranking

IVDS ranked in the middle third of all evaluated products for analytical laboratories and earned 64% of the utility points of the best score.



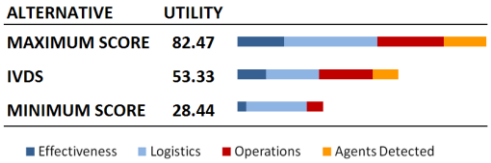
DIAGNOSTIC Laboratory Ranking

IVDS ranked in the middle third of all evaluated products for diagnostic laboratories and earned 61% of the utility points of the best score.



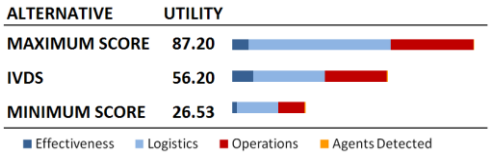
MOBILE Laboratory Ranking

IVDS ranked in the middle third of all evaluated products for mobile laboratories and earned 65% of the utility points of the best score.



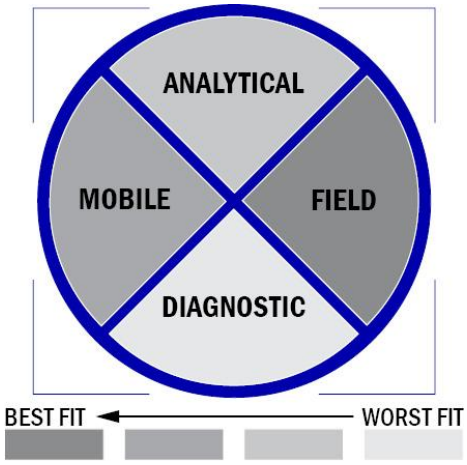
FIELD USE Ranking

IVDS ranked in the bottom third of all evaluated products for field use and earned 64% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

NanoEngineering Corporation
5501 Hwy 93 N.
Suite 6
Florence, MT 59833

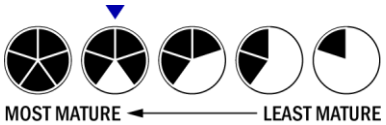
Point of Contact:
David Wick

COST

- $ 100,000.00/system or device

SPECIFICITY

- False Positives: 0
- False Negatives: 0



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15 - 30 minutes for detection
- 1 sample, >10 tests/ sample per run
- Could easily be adapted to fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Afternoon of training and some technical skills required
- 5-10 minutes set-up
- 3-5 minutes down time
- 3-5 steps required
- Customer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps in excess of 45°C for periods of less than 24 hours
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a carry-on suitcase
- Transport via tactical military wheeled and tracked vehicle
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 3 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 5-10 years
- 5-10 minutes daily QA required
- Hazardous agent isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air and gas source required
- External vacuum source required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- Single centrifugation step
- Single shaking or vortexing, mixing, degassing or filtering step required
- System could call final result in the future

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance capable
- Less than 50 ul required for test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Satellite, wireless and wired connections
- Could be fully autonomous with some effort
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software is closed and modification requires licensing
- System hardware is closed and modification requires licensing

JBAIDS (Joint Biological Agent Identification and Diagnostic System)

by Idaho Technology Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e3-10e4 PFU/mL)
Viruses (10e3-10e4PFU/mL)
Toxins (1-100 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Environmental air, Environmental water, Soil, Food, Powder

DESCRIPTION:

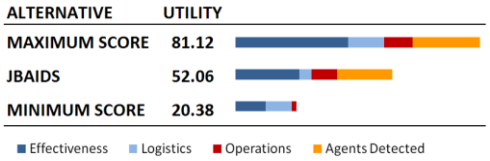
JBAIDS is the DoD standard platform used to positively identify specific biological warfare agents in a dual-purpose role: for diagnostic applications in a clinical environment and for environmental and food sample confirmatory testing. JBAIDS provides timely, reliable answers to field commanders and medical laboratory officers to support critical decision making and countermeasures and aid in determining appropriate medical intervention. The JBAIDS is an FDA cleared diagnostic system.

TECHNOLOGY:

The JBAIDS instrument is a ruggedized, portable real-time PCR instrument using TaqMan PCR amplification for detection of biological threat agents. The instrument is composed of an air thermocycler that amplifies specific DNA and RNA sequences using PCR and a fluorimeter that measures fluorescence signals associated with production of PCR product (amplicon) during the course of the reaction. Analysis of PCR data is achieved by associated software that automatically makes positive or negative calls for 16 biological threat agents.

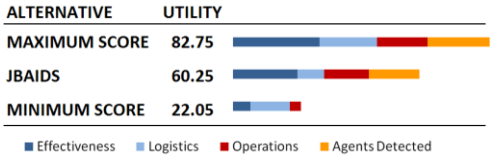
ANALYTICAL Laboratory Ranking

JBAIDS ranked in the middle third of all evaluated products for analytical laboratories and earned 64% of the utility points of the best score.



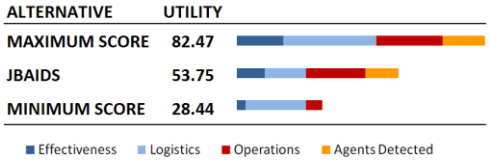
DIAGNOSTIC Laboratory Ranking

JBAIDS ranked in the top third of all evaluated products for diagnostic laboratories and earned 73% of the utility points of the best score.



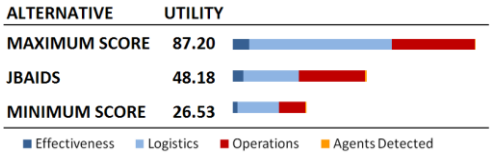
MOBILE Laboratory Ranking

JBAIDS ranked in the middle third of all evaluated products for mobile laboratories and earned 65% of the utility points of the best score.



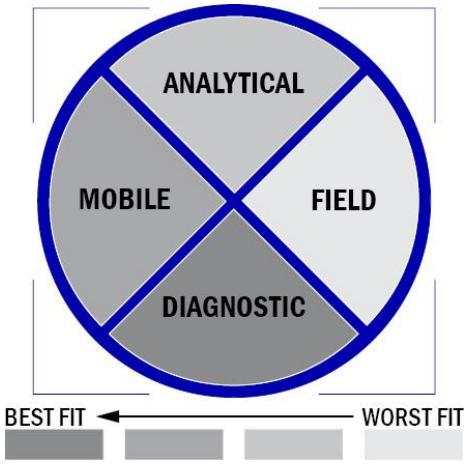
FIELD USE Ranking

JBAIDS ranked in the bottom third of all evaluated products for field use and earned 55% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Idaho Technology Inc.
390 Wakara Way
Salt Lake City, UT 84108

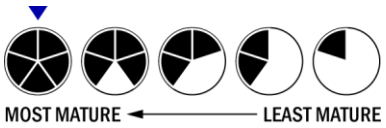
Point of Contact:
Gary Uzzell
slezak1@llnl.gov
801-736-635

COST

- $55,000.00/system or device

SPECIFICITY

- False Positives: <1%
- False Negatives: Organism dependent



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Could be adapted to semi-automated with some effort

Signature:
- Sounds or alarms present
- Screen may be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- <1 day training and significant technical skills are required
- 10-20 minutes set-up required
- < 5 minutes down time
- Greater than 12 steps required
- DVD/ Manufacturer site training/ Hard copy manual

Operational conditions:
- Can be used from 4°C - 41°C
- Components should be stored at room temp but can stand temps >45°C for periods <24 hours
- Performance not influenced by relative humidity
- Between 1 -3 years shelf life

Transportation:
- Approximately the size of carry-on luggage
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 4 solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life >10 years
- <5 minutes daily QA required
- Hazardous agent isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- Single shaking or vortexing, mixing, degassing or filtering step required
- System calls final result

Sensitivity and Detection:
- 510K cleared
- FDA cleared
- Greater than 250 ul required for test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Not network capable
- Not autonomous
- Laptop computer
- Stores and archives data outputs and creates electronic records
- System software is open and available for modification
- System hardware is open and available for modification

JBPDS (Joint Biological Point Detection System)

by General Dynamics Armament and Technical Products

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria
Viruses
Toxins

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

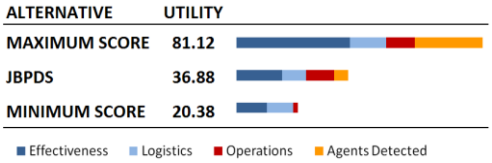
JBPDS provides automatic detection and identification of airborne biological agents at very low levels, triggers local and remote warning systems, and communicates threat information over standard communication systems. Using laser-induced fluorescence, the trigger/detector continuously evaluates the atmospheric background for traces of potential biological agents. When the system detects something of a suspicious nature, the collector/concentrator is initiated to sample hundreds of liters of air per minute, providing a small amount of liquid containing the collected aerosol sample. This sample is then evaluated for specific biological agents using immunoassays with an automated reader assembly. If the assay shows signs of biological agents, an alarm is sounded and a portion of the collected sample is provided for gold-standard laboratory analysis.

TECHNOLOGY:

Using laser-induced fluorescence, the trigger/detector continuously evaluates the atmospheric background for traces of potential biological agents. When the system detects something of a suspicious nature, the collector is initiated to sample hundreds of liters of air per minute, providing a small amount of liquid containing the collected aerosol sample. This sample is then evaluated for specific biological agents using immunoassay identification technology with an automated reader assembly. If the assay shows signs of biological agents, an alarm is sounded and a portion of the collected sample is provided for gold- standard laboratory analysis.

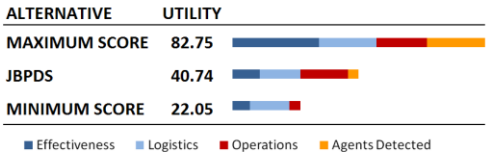
ANALYTICAL Laboratory Ranking

JBPDS ranked in the bottom third of all evaluated products for analytical laboratories and earned 45% of the utility points of the best score.



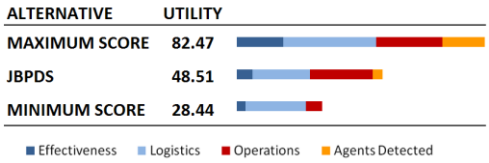
DIAGNOSTIC Laboratory Ranking

JBPDS ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 49% of the utility points of the best score.



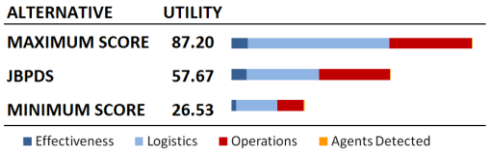
MOBILE Laboratory Ranking

JBPDS ranked in the bottom third of all evaluated products for mobile laboratories and earned 59% of the utility points of the best score.



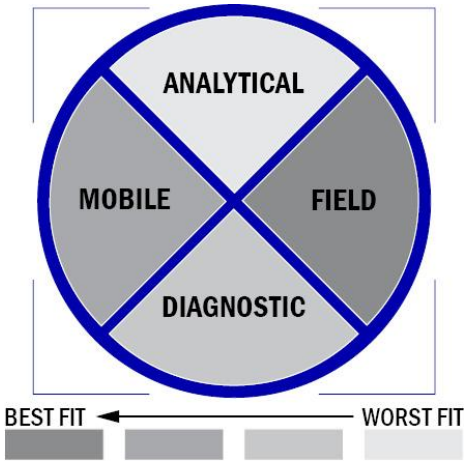
FIELD USE Ranking

JBPDS ranked in the middle third of all evaluated products for field use and earned 66% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

General Dynamics Armament and Technical Products
4205 Westinghouse Commons Blvd
Charlotte, NC 28273

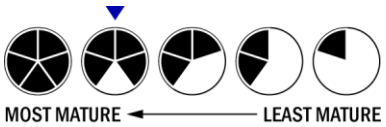
Point of Contact:
Doug Woody
980-235-2402
dwoody@gdatp.com

COST

- >$800,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15 - 30 minutes for detection
- 1 sample, >10 tests/ samples per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- More than a day of training and significant technical skills are required
- >20 minutes set-up
- <1 minute down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from -21°C to 41°C
- Components must be stored at 4°C
- Performance is not influenced by relative humidity
- 1 to 3 years shelf life

Transportation:
- Approximately the size of home dishwasher
- All modes of transportation
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 4 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service more often than every 6 months
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Greater than 250 ul to test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless, wired connections
- Fully autonomous
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software is closed and not available for modification
- System hardware is closed and not available for modification

JBSDS1 (Joint Biological Standoff Detection System, Increment 1)

by Science & Engineering Services, Inc.

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

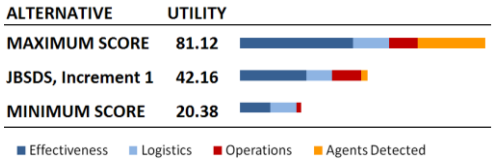
The Joint Biological Standoff Detection System (JBSDS) is considered by JPEO-CBD to be a major technology revolution and capability that responds to a validated DOD requirement. JBSDS is an eye-safe militarized Lidar that provides standoff detection of airborne Agents of Biological Origin to 3+ miles away and fits within a HMMWV. JBSDS is network-capable and has some ability for detecting chemical aerosols. In terms of logistics, the only daily-use consumable is electricity and train-up for non-technical users is within 2-3 days.

TECHNOLOGY:

The Joint Biological Standoff Detection System (JBSDS) started as a DARPA SBIR using a COTS-based Fluorescence Portable Digital Lidar open architecture via integrated transmitter-receiver with 355nm and 1067nm low-energy/high pulse-rate lasers. The output is eye-safe and all data processing is digital, with the discrimination algorithm based on pioneering work by MIT-LL using two orthogonal parameters: backscatter and fluorescence. The validated DOD requirement for operation is low-light conditions only, though JBSDS can be readily upgraded to 24/7 operations thru its open architecture.

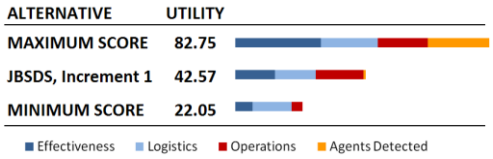
ANALYTICAL Laboratory Ranking

JBSDS ranked in the bottom third of all evaluated products for analytical laboratories and earned 52% of the utility points of the best score.



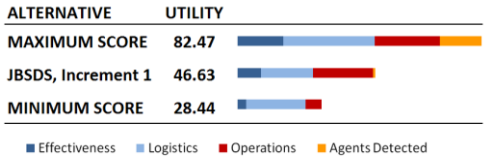
DIAGNOSTIC Laboratory Ranking

JBSDS ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 51% of the utility points of the best score.



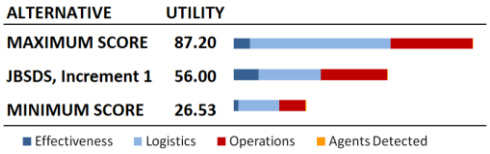
MOBILE Laboratory Ranking

JBSDS ranked in the bottom third of all evaluated products for mobile laboratories and earned 57% of the utility points of the best score.



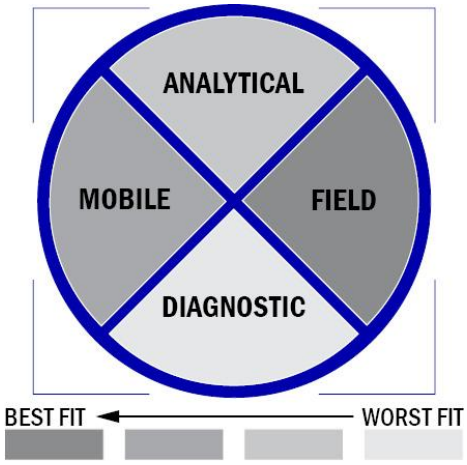
FIELD USE Ranking

JBSDS ranked in the bottom third of all evaluated products for field use and earned 64% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Science & Engineering Services, Inc.
6992 Columbia Gateway Drive
Columbia, Maryland 21046

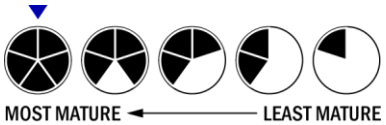
Point of Contact:
Robert M. Serino, Ph.D.
443.539.0139

COST

- $700,000.00/system or device

SPECIFICITY

- False Positives: 10%
- False Negatives: 10%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 10-20 minutes set-up
- 1-3 minutes down time
- 0-2 steps required
- Customer site training/Hard-copy operators manual

Operational conditions:
- Can be used from -21°C to 41°C
- Does not require consumables
- Peak performance at normal relative humidity conditions
- Between 1-3 years shelf life

Transportation:
- Larger than a home dishwasher
- Transport via commercial carrier/ Tactical military wheeled and tracked vehicle/ Fixed wing military aircraft
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless and wired connections
- Fully autonomous
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software open and available for modification
- System hardware open and available for modification

JBSDS2 (Joint Biological Standoff Detection System, Increment 2)

by Science & Engineering Services, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e3-10e4 CFU/mL)

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

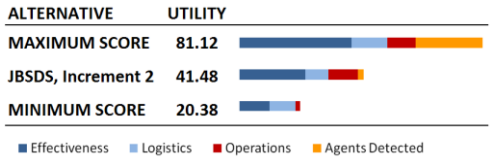
The Joint Biological Standoff Detection System 2 (JBSDS2) is an incremental improvement over the original JBSDS using an eye-safe militarized Lidar that provides standoff detection of airborne Agents of Biological Origin and fits within a HMMWV trailer or fixed-site. JBSDS2 is fully network-capable and has some ability for detecting chemical aerosols. In terms of logistics, the only daily-use consumable is electricity and train-up for non-technical users is within 2-3 days.

TECHNOLOGY:

The Joint Biological Standoff Detection System 2 (JBSDS2) builds on the original JBSDS COTS-based Fluorescence Portable Digital Lidar open architecture and integrated transmitter-receiver by using additional sensor orthogonality for improved performance, 24/7. The output is eye-safe and all data processing is digital.

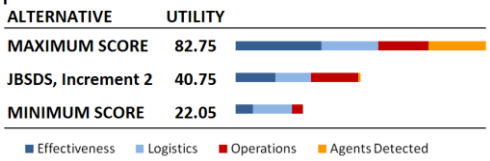
ANALYTICAL Laboratory Ranking

JBSDS2 ranked in the bottom third of all evaluated products for analytical laboratories and earned 51% of the utility points of the best score.



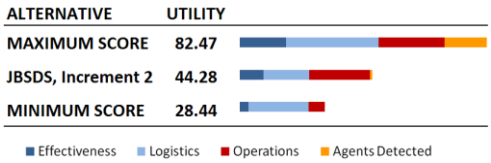
DIAGNOSTIC Laboratory Ranking

JBSDS2 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 49% of the utility points of the best score.



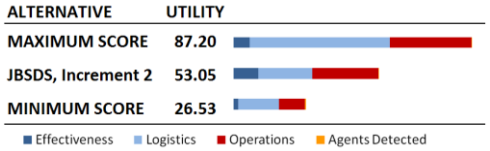
MOBILE Laboratory Ranking

JBSDS2 ranked in the bottom third of all evaluated products for mobile laboratories and earned 54% of the utility points of the best score.



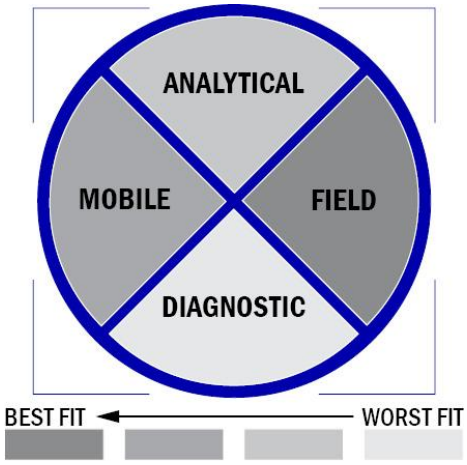
FIELD USE Ranking

JBSDS2 ranked in the bottom third of all evaluated products for field use and earned 61% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Science & Engineering Services, Inc.
6992 Columbia Gateway Drive
Columbia, Maryland 21046

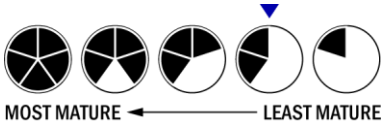
Point of Contact:
Robert M. Serino, Ph.D.
443.539.0139

COST

- $800,000.00/system or device

SPECIFICITY

- False Positives: 10%
- False Negatives: 10%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 10-20 minutes set-up
- 1-3 minutes down time
- 0-2 steps required
- Customer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from -21°C to 41°C
- Does not require consumables
- Peak performance at normal relative humidity conditions
- Between 1-3 years shelf life

Transportation:
- Larger than a home dishwasher
- Transport via commercial carrier/ Tactical military wheeled and tracked vehicle/ Fixed wing military aircraft
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Bread board
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless and wired connections
- Fully autonomous
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software open and available for modification
- System hardware open and available for modification

JCSD (Joint Contaminated Surface Detector)

by ITT Corporation

DETECTS THE FOLLOWING:

Demonstrated:
Liquid chemical agent
(> 1 ppt)

DETECTION MATRICES:

Demonstrated:
Soil

DESCRIPTION:

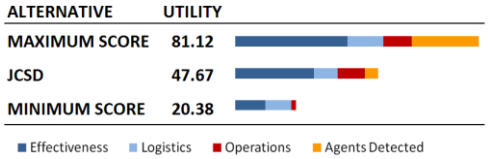
The JCSD is a non-contact optical sensor that provides real-time detection and identification of solid and liquid surface contamination from a host moving vehicle (at speeds up to 45mph) as it passes over the contamination.

TECHNOLOGY:

The JCSD employs standoff UV Raman spectroscopy using a high rep rate UV laser and spectrograph. A detection and identification algorithm reports detections in real time.

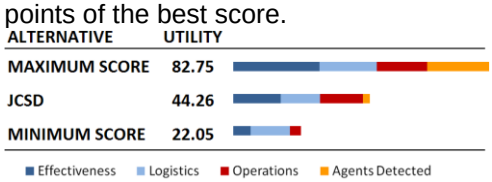
ANALYTICAL Laboratory Ranking

JCSD ranked in the middle third of all evaluated products for analytical laboratories and earned 59% of the utility points of the best score.



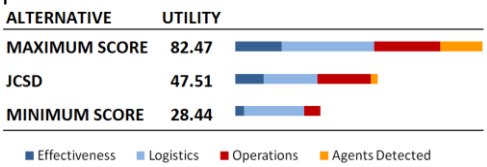
DIAGNOSTIC Laboratory Ranking

JCSD ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 53% of the utility points of the best score.



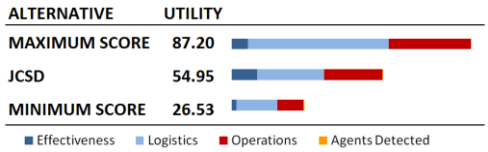
MOBILE Laboratory Ranking

JCSD ranked in the bottom third of all evaluated products for mobile laboratories and earned 58% of the utility points of the best score.



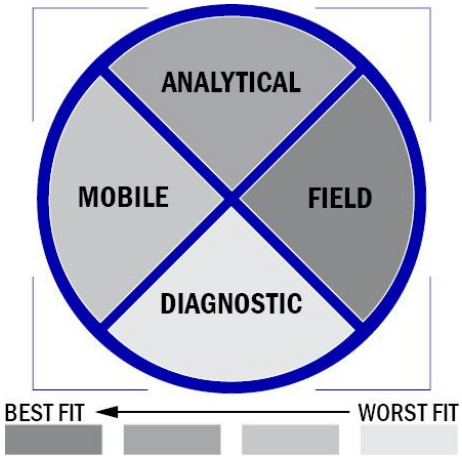
FIELD USE Ranking

JCSD ranked in the bottom third of all evaluated products for field use and earned 63% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ITT Corporation
5901 Indian School Rd NE
Albuquerque NM 87110

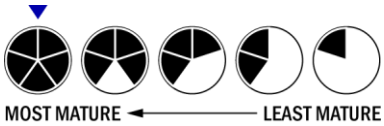
Point of Contact:
Thomas H. Chyba
tom.chyba@itt.com

COST

- Information not available

SPECIFICITY

- False Positives: 0.004%
- False Negatives: 6%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- 10-20 minutes set-up required
- Almost instantaneous down time
- 3-5 steps required
- DVD/ Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Peak performance at normal relative humidity conditions
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a home dishwasher
- All modes of transportation
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 5-10 years
- 5-10 minutes daily QA
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Requires multiple outlets or a dedicated circuit breaker
- Not portable
- Does not require water
- External air or gas source required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB or single pos or neg response generated
- Network capable
- Wired connections
- Could easily be adapted to fully autonomous
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software closed, not available for modification
- Hardware is closed and not available for modification

JSLSCAD

by General Dynamics Armament and Technical Products (GDATP)

DETECTS THE FOLLOWING:

Demonstrated:
Aerosolized chemical agent

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

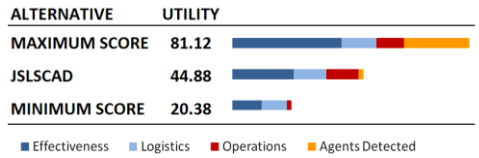
The Joint Service Lightweight Standoff Chemical Agent Detector developed and produced by General Dynamics Armament and Technical Products provides ground platforms of the 21st century with state-of-the-art remote chemical agent detection. The unit uses a passive infrared detection system that automatically searches the 7- to 14-micron region of the surrounding atmosphere for chemical agent vapor clouds. Using sophisticated pattern recognition algorithms, JSLSCAD detects, classifies and identifies chemical agents while discriminating against both natural and manmade battle space interferrents. Once detection is made, JSLSCAD identifies the agent cloud and alerts operators with audible and/or visual alarms. It also indicates the direction and extent of the agent cloud on a graphical computer display and forwards the Nuclear, Biological and Chemical report details through the Joint Warning and Reporting Network. The JSLSCAD is the first chemical detection system to furnish 360-degree coverage for ground platforms for a detection range of up to 2 kilometers, allowing personnel to avoid contaminated areas or don protective masks and clothing. The JSLSCAD is currently in full rate production and is fielded on the Stryker-NBCRV (Nuclear Biological Chemical Reconnaissance Vehicle).

TECHNOLOGY:

The JSLSCAD uses a passive Fourier Transform Infrared (FTIR) technology to allow detection of Chemical Warfare Agents (CWA) and Toxic Industrial Chemicals (TIC) at standoff distances.

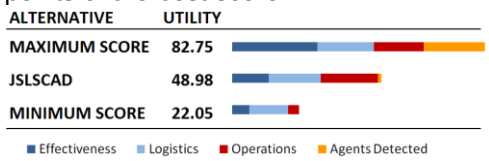
ANALYTICAL Laboratory Ranking

JSLSCAD ranked in the middle third of all evaluated products for analytical laboratories and earned 55% of the utility points of the best score.



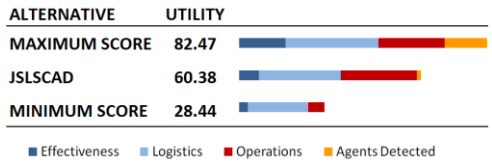
DIAGNOSTIC Laboratory Ranking

JSLSCAD ranked in the middle third of all evaluated products for diagnostic laboratories and earned 59% of the utility points of the best score.



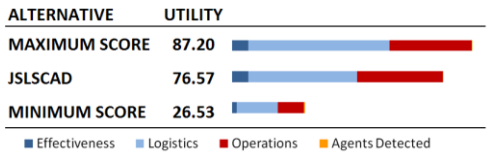
MOBILE Laboratory Ranking

JSLSCAD ranked in the top third of all evaluated products for mobile laboratories and earned 73% of the utility points of the best score.



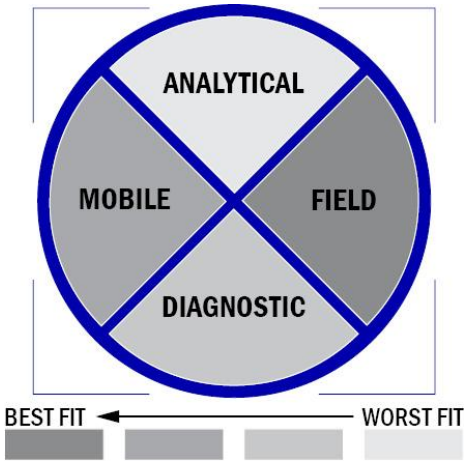
FIELD USE Ranking

JSLSCAD ranked in the top third of all evaluated products for field use and earned 88% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

General Dynamics Armament and Technical Products (GDATP)
4205 Westinghouse Commons Drive
Charlotte, NC 28273

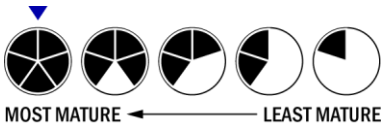
Point of Contact:
Boyd Despard
980.235.2348
bdespard@gdatp.com

COST

- $290,000.00-330,000.00/system or device
- No consumables

SPECIFICITY

- False Positives: Not Applicable
- False Negatives: Not Applicable



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- < 5 minutes set up
- Almost instantaneous down time
- 0-2 steps are required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from <-21°C to >42°C
- Consumables not requires
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents

Maintenance:
- No service required
- Preventive maintenance serviceable by customer
- Maintenance is included
- Expected life greater than 10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- System does not test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Satellite, wireless and wired connections
- Autonomous system
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is closed and not available for modification

JUNO™

by General Dynamics Armament and Technical Products (GDATP)

DETECTS THE FOLLOWING:

Demonstrated:
Aerosolized chemical agent
Liquid chemical agent

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

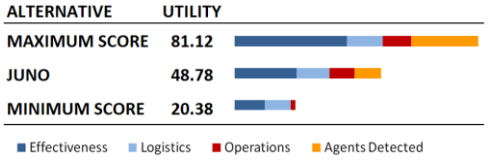
JUNO™ is a hand-held chemical detector that is capable of detecting, identifying, quantifying and alerting the user to the presence of chemical vapors. JUNO™ detects at levels significantly below immediately dangerous to life and health (IDLH) for chemical warfare agents (CWAs) and approaching the permissible exposure limits (PELs) for toxic industrial chemicals (TICs). The JUNO™ system utilizes a differential mobility spectrometry (DMS) sensor engine with a tunable ion mobility filter. The benefits of this technology are increased selectivity and sensitivity and simultaneous detection of nerve and blister agents. JUNO™ is a small sensor package with a low false alarm rate and high probability of detection that enables users to monitor chemical agent exposure levels and confirm decontamination effectiveness. Interaction with the system is simple. JUNO™ has a menu-driven interface that notifies users with audible and visual alarms when a threat is detected. The unit has increased sensitivity, one or two orders of magnitude superior to current handheld detectors. JUNO™ has been extensively tested at GDATP facilities and at various government laboratories including ECBC against a wide range of chemicals including CWAs, TICs, and explosives. JUNO™ has been validated to detect GA, GB, GD, GF, VX, AC, CK, HD, NH3, and Lewisite. The TICs that have been tested both at GDATP, Midwest Research Institute, and at Oak Ridge National Laboratories includes: chlorine, cyanogen chloride, hydrochloric acid, hydrogen cyanide, hydrogen sulfide, nitric acid, and phosgene. JUNO™ is not affected by common interferrents such as paint, Windex®, engine exhaust, and DEET.

TECHNOLOGY:

JUNO™ is based on differential ion mobility spectrometry (DMS) which uses the nonlinear dependence of ion mobility under high field conditions to separate ions with similar mobilities seen in low-fields of IMS. Ions within a DMS flow through an analyzer region where they are subjected to two electrical fields, a high frequency, high potential asymmetric waveform, and a low potential DC field. These two fields create a tunable filter that allows ions to be sorted. This yields improved selectivity and sensitivity over IMS and allows the simultaneous detection of both positive and negative ions.

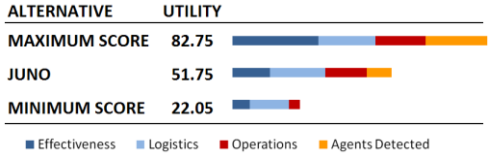
ANALYTICAL Laboratory Ranking

JUNO™ ranked in the middle third of all evaluated products for analytical laboratories and earned 60% of the utility points of the best score.



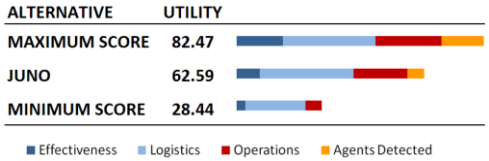
DIAGNOSTIC Laboratory Ranking

JUNO™ ranked in the middle third of all evaluated products for diagnostic laboratories and earned 66% of the utility points of the best score.



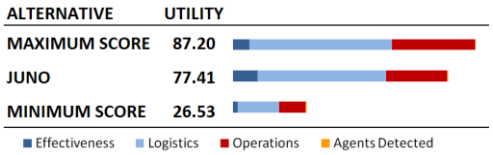
MOBILE Laboratory Ranking

JUNO™ ranked in the top third of all evaluated products for mobile laboratories and earned 76% of the utility points of the best score.



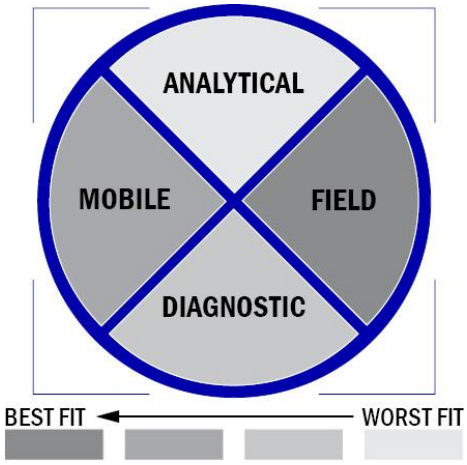
FIELD USE Ranking

JUNO™ ranked in the top third of all evaluated products for field use and earned 89% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

General Dynamics Armament and Technical Products (GDATP)
4205 Westinghouse Commons Drive
Charlotte, NC 28273

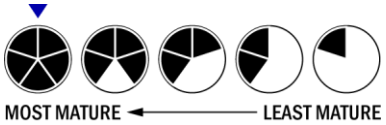
Point of Contact:
Doug Woody
980.235.2402
dwoody@gdatp.com

COST

- Not Available

SPECIFICITY

- False Positives: Not Applicable
- False Negatives: Not Applicable



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Currently semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- 5-10 minutes set up
- Less than 1 minute down time
- 0-2 steps are required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from <-21°C to >42°C
- No consumables
- Performance is not influenced by relative humidity
- No consumables

Transportation:
- Approximately the size of a soda can
- All means of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected greater than 10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Batteries
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance N/A
- FDA approval N/A
- System does not test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Autonomous system with some effort
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

KIM

by Bertin Technologies

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e4-10e5 CFU/mL)
Toxins (<1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Environmental air,
Environmental water, Powder

DESCRIPTION:

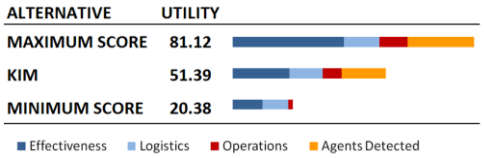
Bertin Technologies (France) has developed the system KIM (Kits of Immuno-agglutination on Microbeads) dedicated to the detection of warfare agents. The system is composed of a field analyzer and detection kits. KIM technology enables a rapid homogeneous and sensitive bioanalysis. Within 10 minutes, air samples (e.g. collected with Bertin's Coriolis® air-sampler) could be analyzed without any further preparation. Field-compatible preparation kits have been developed to ensure the compatibility of following samples with the system KIM: powders, surface swab samples, river waters. The KIM system is dedicated to first responders. Procedures have been simplified to be easily performed by users without technical expertise. The analyzer has been conceived for field application in terms of weight, solidity, autonomy, compatibility with standard decontamination procedures.

TECHNOLOGY:

The detection principle consists in accelerating traditional immuno-agglutination on antibody-grafted microbeads by using magnetic Brownian colloids. These microbeads have self-organization properties under a homogenous magnetic field: they self-assemble into linear chains, and the resulting one-dimensional confinement drastically speed-up the recognition rate between the grafted antibodies and the antigen (Baudry et al.. Proc Natl Acad Sci U S A. 2006 Oct 31;103(44):16076-8). The agglutination process can be monitored by the variation of the Optical Density after magnetic field application to the sample: this measurement relies on the fact that a doublet of microbeads scatters more light than two separate beads.

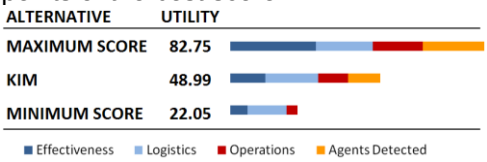
ANALYTICAL Laboratory Ranking

KIM ranked in the middle third of all evaluated products for analytical laboratories and earned 63% of the utility points of the best score.



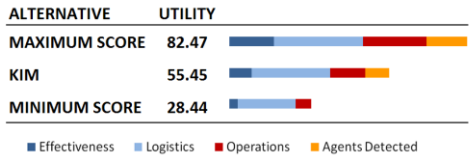
DIAGNOSTIC Laboratory Ranking

KIM ranked in the middle third of all evaluated products for diagnostic laboratories and earned 59% of the utility points of the best score.



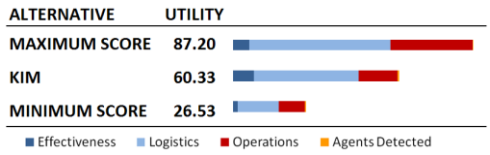
MOBILE Laboratory Ranking

KIM ranked in the middle third of all evaluated products for mobile laboratories and earned 67% of the utility points of the best score.



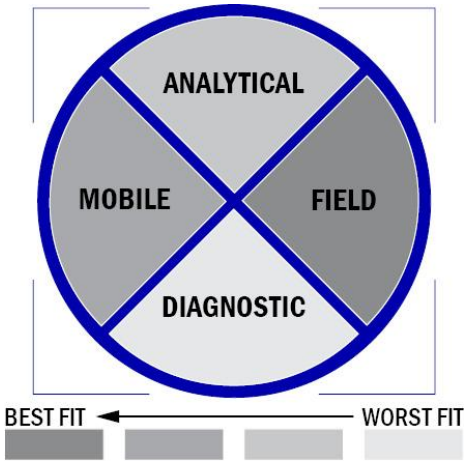
FIELD USE Ranking

KIM ranked in the middle third of all evaluated products for field use and earned 69% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Bertin Technologies - BP284 78053
Saint Quentin en Yvelines Cedex

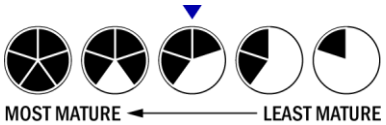
Point of Contact:
Antonin DUVAL, Sales Manager
+33 1 39 30 61 69
duval@bertin.fr

COST

- $60,000.00/system or device
- $100.00/analysis

SPECIFICITY

- False Positives: <5%
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- 1 sample, single test/ sample per run
- Currently semi-automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- < 5 minutes set up
- Almost instantaneous down time
- 0-2 steps are required
- Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components must be stored at room temperature (27°C)/ Components must be stored at 4°C
- Unknown influence of relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician
- Maintenance is included
- Expected life 5-10 years
- No QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- Batteries
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results not available
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Greater than 250 ul for a test

System Maturity:
- Brass board
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Not network capable
- Wired connections
- Fully autonomous system
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

Laser Photo-Acoustic Spectrometer (LPAS)

by Science & Engineering Services, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Aerosolized chemical agent (0.0001 – 0.001 mg/m3)
Liquid chemical agent (< 1 ppb)

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

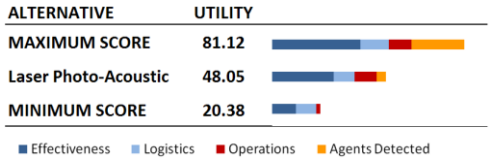
The Laser Photo-Acoustic Spectrometer (LPAS) is a high-sensitivity, optically-based sensor for detection and identification of trace levels of volatile explosives and chemicals. Developed as a commercial product by our Pranalytica partner www.prananytic.com, LPAS was originally created for environmental monitoring of semi-conductor manufacturing sites. The high sensitivity and reliability attributes of LPAS are now being ported to explosive and chemical sensing needs. In terms of logistics, the only daily-use consumable is electricity and train-up for non-technical users is one day.

TECHNOLOGY:

The Laser Photo-Acoustic Spectrometer (LPAS) was developed as a commercial product by our Pranalytica partner www.prananytic.com and utilizes multiple quantum cascade lasers combined with a smart algorithm for rapid detection and identification of chemicals or explosives to the ppb level. The optical system is open architecture and the smart algorithm is trainable within one day against new target analytes.

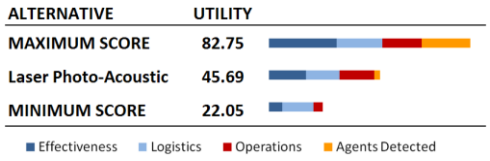
ANALYTICAL Laboratory Ranking

LPAS ranked in the middle third of all evaluated products for analytical laboratories and earned 59% of the utility points of the best score.



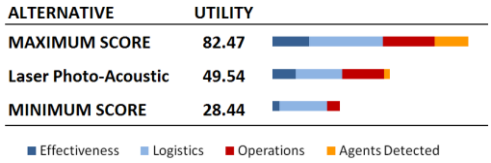
DIAGNOSTIC Laboratory Ranking

LPAS ranked in the middle third of all evaluated products for diagnostic laboratories and earned 55% of the utility points of the best score.



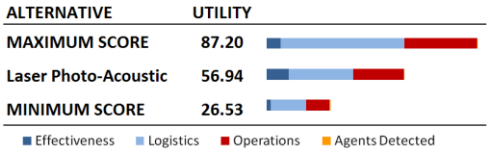
MOBILE Laboratory Ranking

LPAS ranked in the bottom third of all evaluated products for mobile laboratories and earned 60% of the utility points of the best score.



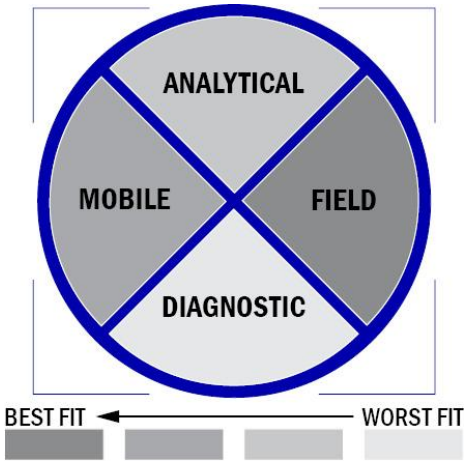
FIELD USE Ranking

LPAS ranked in the middle third of all evaluated products for field use and earned 65% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Science & Engineering Services, Inc.
6992 Columbia Gateway Drive
Columbia, Maryland 21046

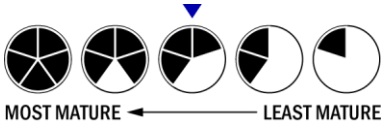
Point of Contact:
Robert M. Serino, Ph.D.
443.539.0139

COST

- $250,000.00/system or device

SPECIFICITY

- False Positives: 1%
- False Negatives: 1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Semi-automated

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 10-20 minutes set-up
- 1-3 minutes down time
- 0-2 steps required
- Customer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 25°C to 37°C
- Does not require consumables
- Peak performance at normal relative humidity condition
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage
- Transport via commercial carrier/ Tactical military wheeled and tracked vehicle/ Fixed wing military aircraft
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Brass board
- Expected to be ready for commercialization within two calendar years
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless and wired connections
- Fully autonomous
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software open and available for modification
- System hardware open and available for modification

LaserScan Analyzer

by Block Engineering

DETECTS THE FOLLOWING:

Demonstrated:
Liquid chemical agent
(1 ppb – 1 ppm)

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

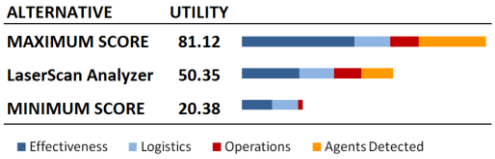
The LaserScan Analyzer is a handheld, battery-operated device that is capable of detecting surface contamination, due to the presence of chemical threats, within seconds and in a standoff mode. The system utilizes Quantum Cascade Lasers (QCLs) with the widest tuning range available today, covering the 6-12 microns infrared spectrum, and offers the chemical identification through the use of infrared spectroscopy. The current device, developed under funding from JIEDDO, Army SBIR and Congressional Adds, is capable of detecting trace explosives in the 1-10 micrograms/sq. cm from approximately 6-12 inches standoff distance. Longer distances could also be achieved with properly sized optics. The system has built-in libraries to detect and identify the explosives of interest and has been tested with numerous backgrounds and surfaces. A built-in LCD displays the identified chemical as well as the actual infrared spectrum, if needed. Furthermore, the same device, but with a different software package could be used for the detection of Chemical Warfare Agents (CWAs) and Toxic Industrial Chemicals (TICs) as Low Volatility Contaminants on surfaces. The system is currently at TRL6 or TRL7 levels. Alternative configurations include built-in gas and vapor detection capability, enabling the potential for LaserScan to detect both surface contaminations in standoff, as well as gases and vapors by collecting air samples. Infrared spectroscopy is also capable of detecting pathogens and other biological threats and feasibility has been demonstrated by several groups. LaserScan could potentially be able to identify such threats by developing appropriately prepared samples and software algorithms.

TECHNOLOGY:

The technology behind the operation of the LaserScan Analyzer is laser-based infrared spectroscopy. A Quantum Cascade Laser (QCL) in an External Cavity Configuration is used to tune across the infrared spectrum of 6-12 microns within a few seconds. A built-in infrared detector is used to collect the reflection of the infrared laser light as it bounces off the target and sophisticated, built-in, ultra-fast electronics generate an infrared spectrum of the chemical substance that was found on the target. High-speed, embedded software algorithms compare this spectrum to built-in infrared libraries and provide real-time identification of the chemical.

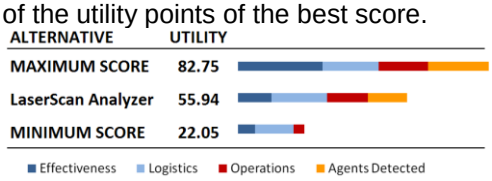
ANALYTICAL Laboratory Ranking

LaserScan Analyzer ranked in the middle third of all evaluated products for analytical laboratories and earned 62% of the utility points of the best score.



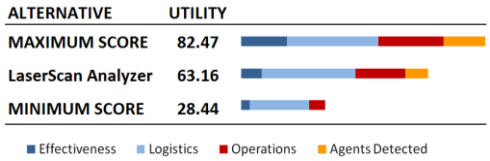
DIAGNOSTIC Laboratory Ranking

LaserScan Analyzer ranked in the top third of all evaluated products for diagnostic laboratories and earned 68% of the utility points of the best score.



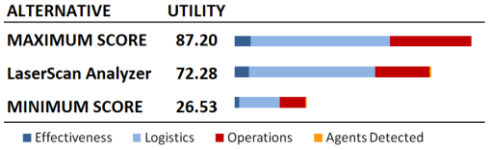
MOBILE Laboratory Ranking

LaserScan Analyzer ranked in the top third of all evaluated products for mobile laboratories and earned 77% of the utility points of the best score.



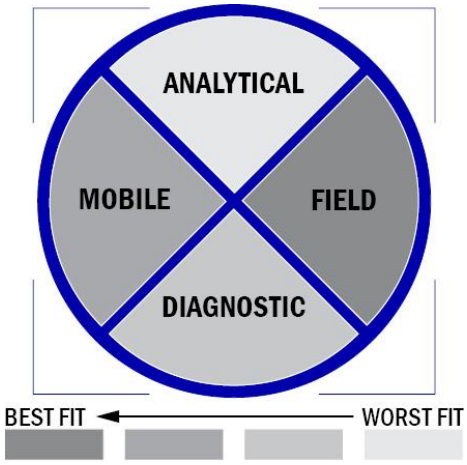
FIELD USE Ranking

LaserScan Analyzer ranked in the top third of all evaluated products for field use and earned 83% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

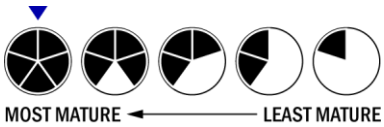
Block Engineering
377 Simarano Drive
Marlborough, MA 01752
Phone: (508) 251-3100
info@blockeng.com

COST

- $90,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/sample per run
- Could be adapted to fully automated with some effort

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- >5 minutes set-up
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 37°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Shelf life not applicable

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- No components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 3-5 years
- No daily QA
- Exposure to hazardous agent would require up to 1 day to decontaminate

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless, wired connections
- Could be fully autonomous system with some effort
- No computer required
- Stores and archives data outputs and creates an electronic record
- Software open, modification requires licensing
- Hardware closed, modification requires licensing

Liat™ Analyzer

by IQuum, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)
Toxins (<1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Urine, Environmental air

DESCRIPTION:

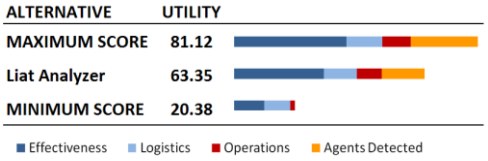
Liat™ systems enable minimally-trained operators to perform sophisticated biological sample testing in any setting in as little as 20 minutes. The Liat™ Analyzer refines nucleic acid testing to three simple steps: collecting a raw biological sample, such as whole blood or swab, into a Liat Tube; scanning the tube's barcode; and inserting the tube into the Liat Analyzer. The analyzer automatically executes all required assay processes from sample to result, including sample preparation, inhibitor removal, nucleic acid purification, amplification and real-time detection, in 20 minutes to 1 hour. No further operator intervention or manual processing is required. Multiple agents can be detected in one test. Interpreted results are displayed on the system's built-in touch screen and can be transmitted via integrated network connectivity. The system can also be battery powered for field operations. The performance of Liat test has been show to be substantially equivalent to that of laboratory based tests in clinical studies and independent third party testing. The Liat Influenza A/2009 H1N1 Assay received the FDA Emergency Use Authorization, and was the fastest of all tests to receive the authorization, taking only half the time of the next fastest competitor. Preparation for 510(k) submission is currently on-going. Liat tests for NIAID Class A priority pathogens have also been developed. The Liat Analyzer's compact size ease-of-use, full automation and rapid turnaround time will make it ideally suited for near-patient molecular diagnostics, field testing of environmental or industrial samples, and rapid onsite analysis for biodefense applications.

TECHNOLOGY:

The Liat system automates and integrates sample purification, nucleic acid amplification, and detection of the target sequence in biological samples using real-time polymerase chain reaction (PCR) assays. The system consists of an instrument and preloaded software for running tests and viewing the results, and single-use disposable Liat Tubes that hold the sample purification and PCR reagents, and hosts the sample preparation and PCR processes. Assay chemistries used are similar to that used in lab-based test, thus achieving the same quality of results, while automated Liat sample processing significantly accelerates time-to-result and enables used by minimally trained personnel.

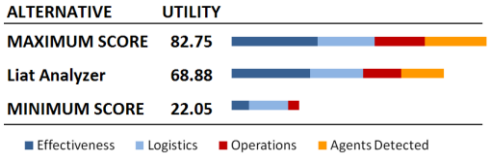
ANALYTICAL Laboratory Ranking

Liat™ Analyzer ranked in the top third of all evaluated products for analytical laboratories and earned 78% of the utility points of the best score.



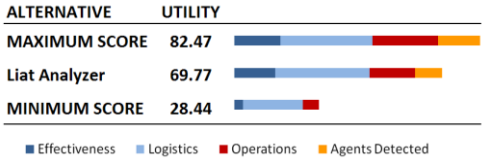
DIAGNOSTIC Laboratory Ranking

Liat™ Analyzer ranked in the top third of all evaluated products for diagnostic laboratories and earned 83% of the utility points of the best score.



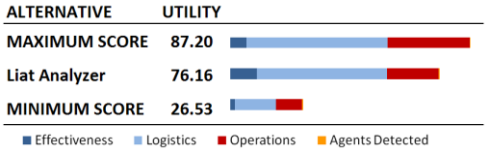
MOBILE Laboratory Ranking

Liat™ Analyzer ranked in the top third of all evaluated products for mobile laboratories and earned 85% of the utility points of the best score.



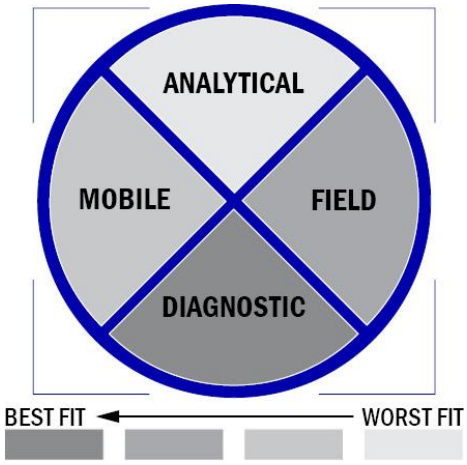
FIELD USE Ranking

Liat™ Analyzer ranked in the top third of all evaluated products for field use and earned 78% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

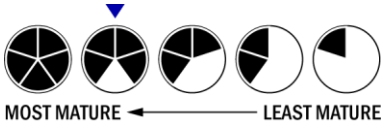
IQuum, Inc.
700 Nickerson Road
Marlborough, MA 01752
Tel: 508-970-0099
Web: www.IQuum.com

COST

- $25,000.00/system or device
- $40.00-80.00/analysis

SPECIFICITY

- False Positives: ~0%
- False Negatives: ~0%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15-30 minutes for detection
- 1 sample, <10 tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- < 5 minutes set up
- <1 minute down time
- 3-5 steps are required
- DVD/ Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at 4°C
- Performance is not influenced by relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a toaster
- All means of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Less than once a year
- Preventive maintenance N/A
- Maintenance is not included
- Expected life 3-5 years
- No QA required
- Exposure to hazardous agent would require up to 1 day to decontaminate

Physical System Requirements:
- Batteries
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance pending
- FDA approval shown
- Less than 250 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Satellite, wireless and wired connections
- Autonomous system with some effort
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

Liat™ WorkStation

by IQuum, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Viruses (10e3-10e4 PFU/mL)
Toxins (<1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Urine, Environmental air

DESCRIPTION:

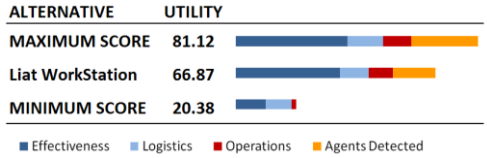
Liat™ systems enable minimally-trained operators to perform sophisticated biological sample testing in any setting in as little as 20 minutes. The Liat™ Workstation offers the same sample-to-result automation and rapid turnaround time as the Liat Analyzer, but enables 128 high-performance nucleic acid tests to be performed in an 8 hour shift. The Liat Workstation refines nucleic acid testing to three simple steps: collecting a raw biological sample, such as whole blood or swab, into a Liat Tube; scanning the tube's barcode; and inserting the tube into one of the 8 modules of the workstation. The workstation automatically executes all required assay processes, including sample preparation, inhibitor removal, nucleic acid purification, amplification and real-time detection, in 20 minutes to 1 hour. No further operator intervention is required. Multiple agents can be detected in one test. Results can be automatically displayed or transmitted via network connectivity. The performance of Liat test has been show to be substantially equivalent to that of lab-based tests in clinical studies and independent third-party testing. The Liat Influenza A/2009 H1N1 Assay and Liat Analyzer received the FDA Emergency Use Authorization, and was the fastest of all tests to receive the authorization, taking only half the time of the next fastest competitor. Liat tests for NIAID Class A priority pathogens have also been developed. The Liat Workstation's ease-of-use, full automation and rapid turnaround time will make it ideally suited for decentralized or near-patient molecular diagnostics, or mobile labs for fast onsite analysis for biodefense or environmental testing applications.

TECHNOLOGY:

The Liat system automates and integrates sample purification, nucleic acid amplification, and detection of the target sequence in biological samples using real-time polymerase chain reaction (PCR) assays. The system consists of an instrument and preloaded software for running tests and viewing the results, and single-use disposable Liat Tubes that hold the sample purification and PCR reagents, and hosts the sample preparation and PCR processes. Assay chemistries used are similar to that used in lab-based test, thus achieving the same quality of results, while automated Liat sample processing significantly accelerates time-to-result and enables used by minimally trained personnel.

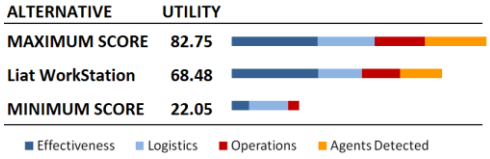
ANALYTICAL Laboratory Ranking

Liat™ WorkStation ranked in the top third of all evaluated products for analytical laboratories and earned 82% of the utility points of the best score.



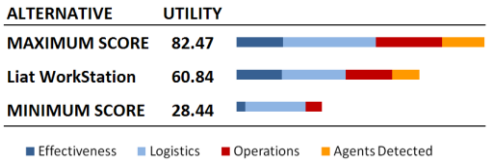
DIAGNOSTIC Laboratory Ranking

Liat™ WorkStation ranked in the top third of all evaluated products for diagnostic laboratories and earned 83% of the utility points of the best score.



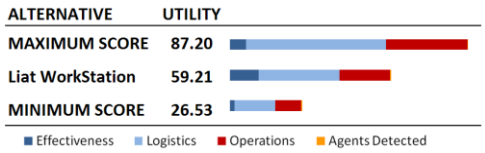
MOBILE Laboratory Ranking

Liat™ WorkStation ranked in the top third of all evaluated products for mobile laboratories and earned 74% of the utility points of the best score.



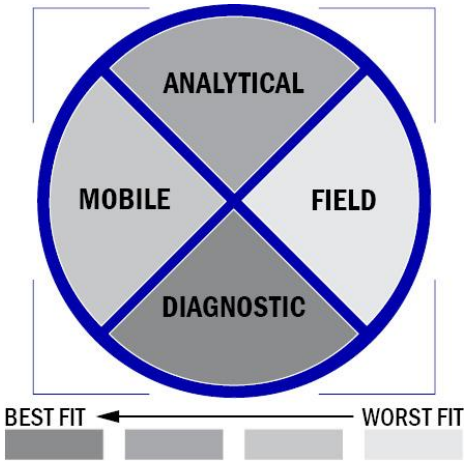
FIELD USE Ranking

Liat™ WorkStation ranked in the middle third of all evaluated products for field use and earned 68% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

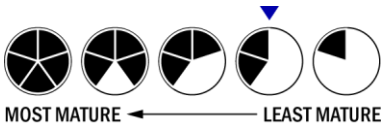
IQuum, Inc.
700 Nickerson Road
Marlborough, MA 01752
Tel: 508-970-0099
Web: www.IQuum.com

COST

- $120,000.00/system or device
- $40.00-80.00/analysis

SPECIFICITY

- False Positives: ~0%
- False Negatives: ~0%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15-30 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- < 5 minutes set up
- < 1 minute down time
- 3-5 steps are required
- DVD/ Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at 4°C
- Performance is not influenced by relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means of transportation
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service less than once a year
- Preventive maintenance N/A
- Maintenance is not included
- Expected life 3-5 years
- No QA required
- Exposure to hazardous agent would require up to 1 day to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance pending
- FDA approval shown
- Less than 250 ul for a test

System Maturity:
- Bread board
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Satellite, wireless and wired connections
- Autonomous system with some effort
- Laptop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

LightCycler® 2.0

by Roche Applied Sciences

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)
Toxins (<1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Environmental air, Environmental water, Soil, Food, Powder, Insect vectors

DESCRIPTION:

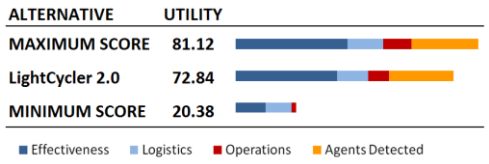
The LightCycler® Carousel-Based System has repeatedly set the standard for real-time PCR. It was the first system to introduce hybridization probes, melting curve analysis, automated absolute quantification, and relative quantification with efficiency correction. We now have two different instruments to meet your research needs. Choose the LightCycler® 1.5 Instrument if your work requires only single dye or duplex assays; step up to the LightCycler® 2.0 Instrument if you want to experience the power of multiplexing.

TECHNOLOGY:

The LightCycler® Carousel-Based System is used for: Accurate and reproducible quantification of nucleic acids Simple and precise qualitative PCR product detection Unambiguous identification and characterization of PCR products by melting point analysis Reliable SNP (Single Nucleotide Polymorphism) genotyping Convenient and exact determination of nucleic acid concentrations before setting the PCR reaction.

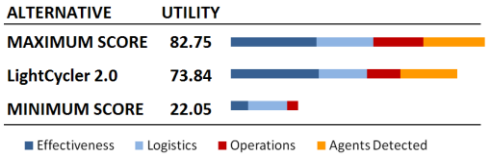
ANALYTICAL Laboratory Ranking

LightCycler 2.0 ranked in the top third of all evaluated products for analytical laboratories and earned 90% of the utility points of the best score.



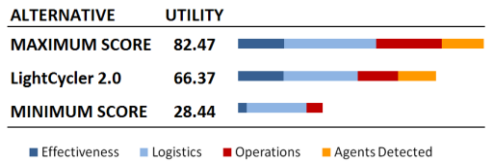
DIAGNOSTIC Laboratory Ranking

LightCycler 2.0 ranked in the top third of all evaluated products for diagnostic laboratories and earned 89% of the utility points of the best score.



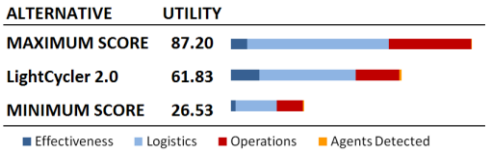
MOBILE Laboratory Ranking

LightCycler 2.0 ranked in the top third of all evaluated products for mobile laboratories and earned 80% of the utility points of the best score.



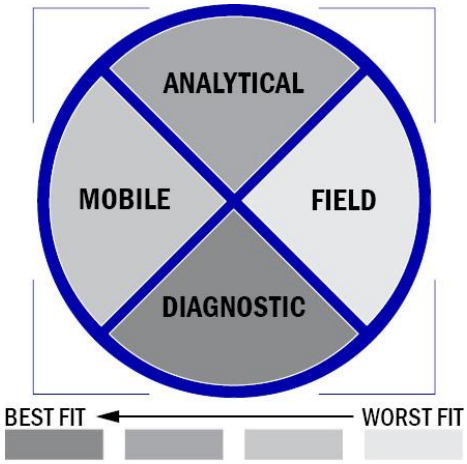
FIELD USE Ranking

LightCycler 2.0 ranked in the middle third of all evaluated products for field use and earned 71% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

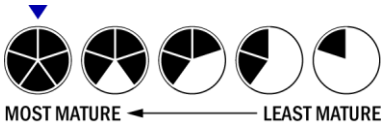
Roche Applied Sciences
9115 Hague Road PO Box 50414
Indianapolis, IN 46250-0414
Phone: 800-262-4911

COST

- $25,000.00/system plus cost of PC or laptop
- $2.00/ analysis

SPECIFICITY

- False Positives: 0
- False Negatives: 0



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30-60 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Easily adapted to full automation

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- Less than 5 minutes set up
- Less than 1 minute down time
- 0-2 step required
- DVD/ Web video/ Customer and manufacture site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be stored frozen but can with stand temps >4°C for < 24 hours
- Influenced of relative humidity unknown
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions and/or reagents
- 1 component

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by technician
- Maintenance is included
- Expected life 5-10 years
- < 5 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1 hr

Physical System Requirements:
- 110V electrical requirement
- 1-2 hours battery use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- A single centrifugation step
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance shown
- FDA approval shown
- Less than 10 ul for a test

System Maturity:
- Is commercially available and meets milspecs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- > 250 GB
- Not network capable
- Satellite, wireless and wired connections
- Not capable of autonomy
- High end desktop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

LightCycler 480

by Roche Applied Sciences

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL0
Toxins (<1ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Environmental air, Environmental water, Soil, Food, Powder, Insect vectors

DESCRIPTION:

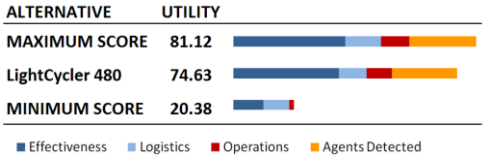
The LightCycler 480 Real-Time PCR System is a fully integrated multiwell-plate based real-time PCR platform for highly accurate qualitative and quantitative detection of nucleic acids. Building on the benefits of Roche's capillary-based LightCycler® Systems, it goes one step further in offering enhanced throughput, compatibility with automation equipment and maximum flexibility regarding hard- and software. Providing novel ways to combine speed and accuracy without compromises, the LightCycler® 480 Real-Time PCR System meets the needs of a broad range of applications in research fields such as gene expression studies, discovery and analysis of genetic variation or array data validation.

TECHNOLOGY:

The LightCycler 480 Real-Time PCR System is a fully integrated multiwell-plate based real-time PCR platform. Benefit from novel thermal cycling and data capture technologies to achieve outstanding temperature homogeneity and assay reproducibility. Increase the sensitivity and yield of your real-time PCR applications, with robust LightCycler® 480 reagents and specially engineered clear or white consumables. Analyze true raw data, breaking free from the need to use passive reference dyes or normalization plates to get accurate results. Flexibly switch between 96- or 384-well plate formats. Select from numerous assay formats and detection dyes, expanding the range of real-time PCR applications in your lab.

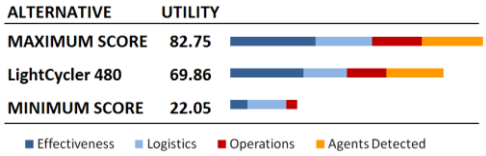
ANALYTICAL Laboratory Ranking

LightCycler 480 ranked in the top third of all evaluated products for analytical laboratories and earned 92% of the utility points of the best score.



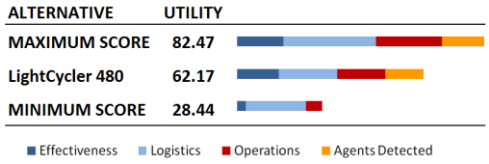
DIAGNOSTIC Laboratory Ranking

LightCycler 480 ranked in the top third of all evaluated products for diagnostic laboratories and earned 84% of the utility points of the best score.



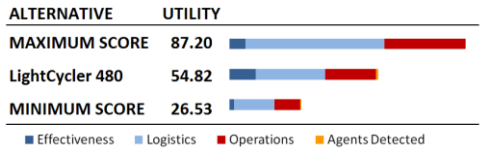
MOBILE Laboratory Ranking

LightCycler 480 ranked in the top third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.



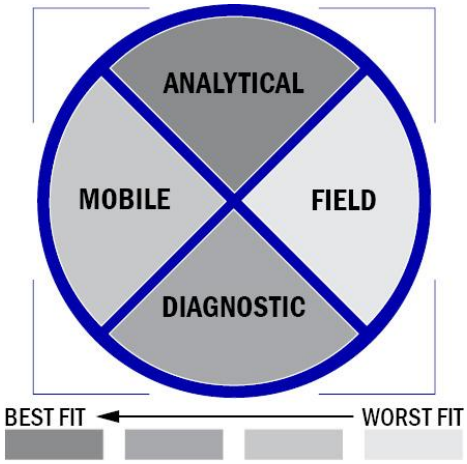
FIELD USE Ranking

LightCycler 480 ranked in the bottom third of all evaluated products for field use and earned 63% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

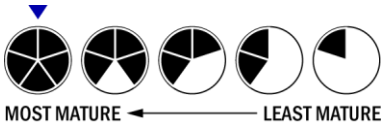
Roche Applied Sciences
9115 Hague Road PO Box 50414
Indianapolis, IN 46250-0414
Phone: 800-262-4911

COST

- $50,000.00/system or device
- $0.68/assay

SPECIFICITY

- False Positives: 0
- False Negatives: 0



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30-60 minutes for detection
- Multiple samples, multiple tests/ sample per run
- System fully automated

Signature:
- No sounds or alarms
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- 10-20 minutes set up
- Less than 1 minute down time
- 0-2 steps required
- DVD/ Web video/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be stored frozen but can with stand temps > 4°C for < 24 hours
- Influence of relative humidity unknown
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a home dishwasher
- All means of transportation
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance is included
- Expected life 5-10 years
- < 5 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1 hr

Physical System Requirements:
- 220V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 10 ul for a test

System Maturity:
- Is commercially available and meets milspecs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- > 250 GB
- Network capable
- Satellite, wireless and wired connections
- Not capable of autonomy
- High end desktop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

Lightning MVP

by BioControl Systems, Inc.

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Demonstrated:
Environmental water, Food, Powder

DESCRIPTION:

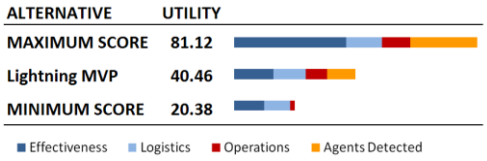
BioControl, a leading manufacturer of microbiology and food safety tests introduces the LIGHTNING MVP®, a breakthrough in HACCP and GMP compliance monitoring. LIGHTNING MVP is the first quality monitoring system utilizing one instrument platform to collect, analyze, and report data from quality and hygiene indicators including ATP, temperature, pH, conductivity and concentration. Results can be transferred to a PC for analysis and reporting. The highly accurate and reproducible platform allows for on-site calibration of all parameters, supporting SSOP and HACCP requirements and ensuring your hygiene and QA programs are effective and documented.

TECHNOLOGY:

The LIGHTNING MVP detects contamination by measuring adenosine triphosphate (ATP). The test uses the enzyme luciferase, which is highly sensitive to ATP. ATP is found in most food residues and all bacteria, yeast, and mold cells. The sampling devices, when used to obtain a sample and activated, emit light in proportion to the amount of ATP in the sample. The LIGHTNING MVP instrument measures the light output from an MVP sampling device.

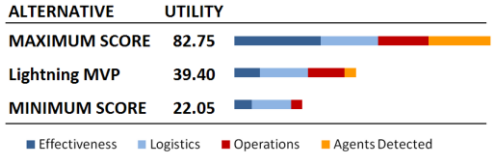
ANALYTICAL Laboratory Ranking

Lightning MVP ranked in the bottom third of all evaluated products for analytical laboratories and earned 50% of the utility points of the best score.



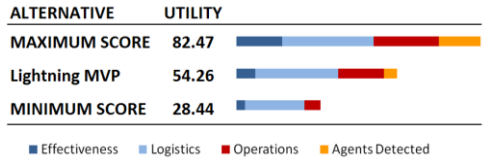
DIAGNOSTIC Laboratory Ranking

Lightning MVP ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 48% of the utility points of the best score.



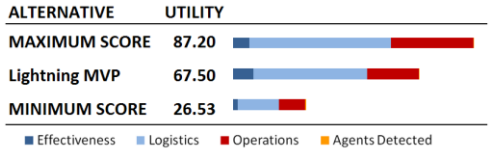
MOBILE Laboratory Ranking

Lightning MVP ranked in the middle third of all evaluated products for mobile laboratories and earned 66% of the utility points of the best score.



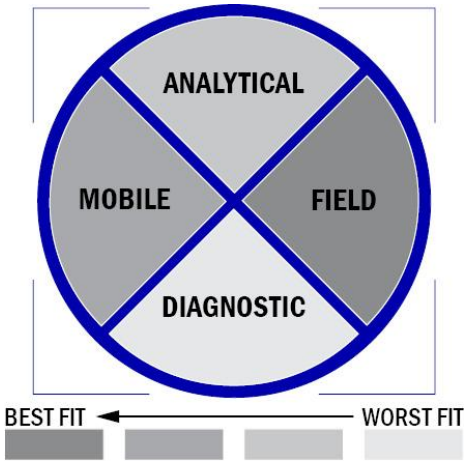
FIELD USE Ranking

Lightning MVP ranked in the middle third of all evaluated products for field use and earned 77% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

BioControl Systems, Inc.
12822 SE 32nd St.
Bellevue, WA 98005
info@biocontrolsys.com

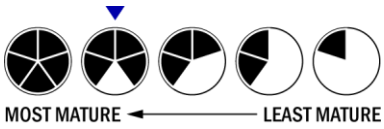
Point of Contact:
Sean Reichle - Product Manager

COST

- $3,495.00/system or device
- $3.20/analysis

SPECIFICITY

- False Positives: Not Applicable
- False Negatives: Not Applicable



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Not amenable to automation

Signature:
- Sounds or alarms present
- Screen cannot be dimmed or turned off
- Thermal output unknown

Training and Speed:
- Very brief training and minimal technical skills
- < 5 minutes set up
- Almost no down time
- 0-2 steps are required
- DVD/ Web video/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be stored at room temperature but can withstand temps > 45°C for periods < 24 hours
- Performance is not influenced by relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a soda can
- All means of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance is included
- Expected life 5-10 years
- < 5 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Batteries
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results not available
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Less than 250 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Not capable of autonomy
- No computational power
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

LISA® Manportable Standoff Chemical Detection System

by ITT Corporation

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

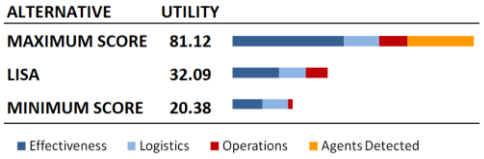
The LISA® Manportable system has been developed as part of the DHS S&T Low Vapor Pressure Chemical Detection Systems (LVPCDS) program. The system provides a capability to perform real-time sensitive site assessment (e.g., inspect buildings, roadside formations, equipment, vehicles, aircraft, and other manmade or natural surfaces) for the presence of low vapor pressure chemicals, other persistent chemical agents, and TICs, with the expanded capability to include explosives, homemade explosives and their precursors.

TECHNOLOGY:

LISA® Manportable is an ultraviolet Raman sensor technology for achieving real-time standoff detection and identification of surface-deposited contaminants. The advantage of this approach is the ability to directly interrogate liquid or solid phase contaminants on a surface in order to create the molecule-specific Raman spectral signatures. Distinct Raman peaks can clearly identify chemicals and distinguish them from a benign elements and backgrounds.

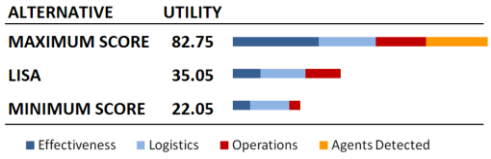
ANALYTICAL Laboratory Ranking

LISA® ranked in the bottom third of all evaluated products for analytical laboratories and earned 40% of the utility points of the best score.



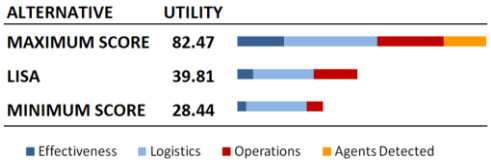
DIAGNOSTIC Laboratory Ranking

LISA® ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 42% of the utility points of the best score.



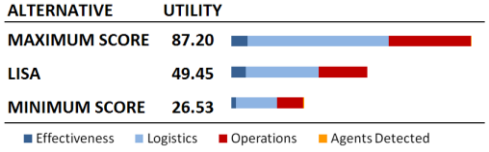
MOBILE Laboratory Ranking

LISA® ranked in the bottom third of all evaluated products for mobile laboratories and earned 48% of the utility points of the best score.



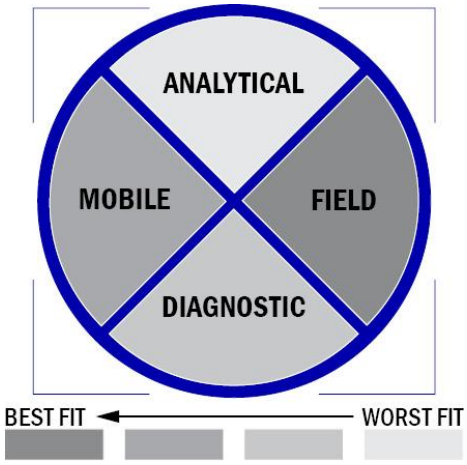
FIELD USE Ranking

LISA® ranked in the bottom third of all evaluated products for field use and earned 58% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ITT Corporation
5901 Indian School Rd
Albuquerque, NM 87110

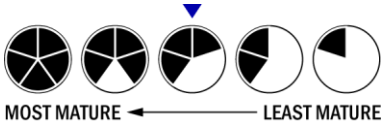
Point of Contact:
Howard LaValley
505-889-7002

COST

- $350,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Could be semi-automated system with some effort

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 10-20 minutes set-up
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Shelf life not applicable

Transportation:
- Approximately the size of a home dishwasher
- Transport via commercial carrier
- Weighs more than 50 kg

Re-use:
- Multiple detection assays.
- 0-1 solutions, buffer, and/or reagents
- 0 components

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by technician only
- Maintenance information not available
- Expected life unknown
- <5 minutes daily QA
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquid

System Maturity:
- Brass board
- Expected to be ready for commercialization within one calendar year
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property owned

Interoperability and System Complexity:
- Raw data information not available
- Network capability information not available
- Wireless, wired connections
- Could easily be a fully autonomous system
- Computing requirement information not available
- Stores and archives data outputs and creates an electronic record
- System software information not available
- System hardware information not available

LLMDA (Lawrence Livermore Microbial Detection Array)

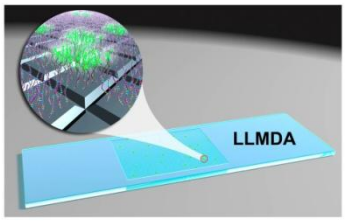
by Lawrence Livermore National Laboratory

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Viruses (100-1,000 CFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Environmental air, Environmental water, Soil



DESCRIPTION:

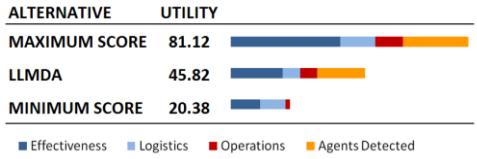
LLMDA is a pan-microbial microarray. It contains 388,000 DNA probes designed to detect all sequenced bacteria and viruses. It is designed for laboratory analysis and has been extensively tested on environmental samples, pure microbial samples, as well as human and animal clinical samples. It is adaptable for many matrices.

TECHNOLOGY:

The LLMDA has been tested using synthesized microarrays from both Roche/NimbleGen (using a photo-deprotection scheme) and Agilent (using an ink-jet deposition scheme.)

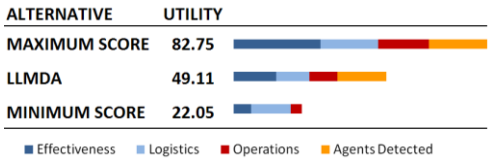
ANALYTICAL Laboratory Ranking

LLMDA ranked in the middle third of all evaluated products for analytical laboratories and earned 56% of the utility points of the best score.



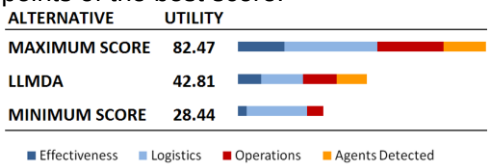
DIAGNOSTIC Laboratory Ranking

LLMDA ranked in the middle third of all evaluated products for diagnostic laboratories and earned 59% of the utility points of the best score.



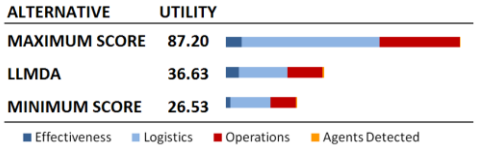
MOBILE Laboratory Ranking

LLMDA ranked in the bottom third of all evaluated products for mobile laboratories and earned 52% of the utility points of the best score.



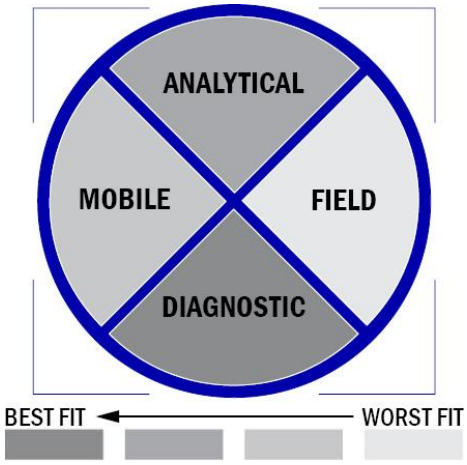
FIELD USE Ranking

LLMDA ranked in the bottom third of all evaluated products for field use and earned 42% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Lawrence Livermore National Lab
7000 East Avenue
Livermore, CA 94550

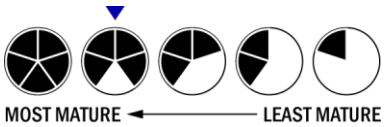
Point of Contact:
Tom Slezak
slezak1@llnl.gov
925-422-5746

COST

- Information not available

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- 1 sample, >10 tests/ sample per run
- Could be adapted to semi-automated with some effort

Signature:
- Sounds or alarms not present
- No screen
- Greater than 500 BTU/hour

Training and Speed:
- > 1 day training and significant technical skills required
- No set-up required
- < 5 minutes down time
- 9-12 steps required
- Customer and manufacturer site training

Operational conditions:
- Can be used from 25°C - 37°C
- Components must be stored at room temperature (27°C)/ Must be stored at 4°C
- Peak performance at normal relative humidity
- 6 months – 1 year shelf life

Transportation:
- Approximately the size of a home dishwasher
- Transport via commercial carrier or fixed wing military aircraft
- Weighs between 25 and 50 kg

Re-use:
- Designed for single use
- 4 solutions, buffer, and/or reagents
- 3 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance included
- Expected life 5-10 years
- 5-10 minutes daily QA required
- Hazardous agent isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results not available
- No centrifugation steps required
- Multiple shaking or vortexing, mixing, degassing or filtering step required
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 50 ul required for test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connection
- Not autonomous
- High-end desktop computer
- Stores and archives data outputs and creates electronic records
- System software is open but modification requires licensing
- System hardware is open but modification requires licensing

Low-Cost Biological Standoff Detection System (LC-BSDS)

by Science & Engineering Services, Inc.

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

The Low-Cost Biological Standoff Detection System (LC-BSDS) is a lower-costing, modified commercial product that provides JBSDS-like standoff detection capabilities without the military-rugged package at a smaller SWAP footprint. This open architecture, commercial approach results in a lower baseline price starting below 1/4th that of JBSDS, with scalable capabilities via insertion of custom modules. In terms of logistics, the only daily-use consumable is electricity and train-up for non-technical users is within 2-3 days.

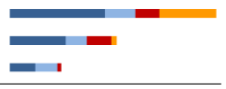
TECHNOLOGY:

The Low-Cost Biological Standoff Detection System (LC-BSDS) is a commercial lidar that uses an integrated transmitter-receiver with a 1067nm low-energy/high pulse-rate laser as a baseline capability. In support of customer needs, the scalable open architecture system can accept other laser wavelengths and/or software capabilities for added performance.

ANALYTICAL Laboratory Ranking

LC-BSDS ranked in the bottom third of all evaluated products for analytical laboratories and earned 52% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
Low-Cost Biological Standoff	41.98
MINIMUM SCORE	20.38

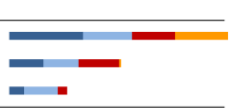


Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

LC-BSDS ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 51% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
Low-Cost Biological Standoff	42.36
MINIMUM SCORE	22.05

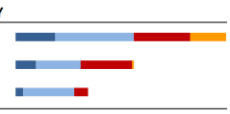


Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

LC-BSDS ranked in the bottom third of all evaluated products for mobile laboratories and earned 56% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
Low-Cost Biological Standoff	46.37
MINIMUM SCORE	28.44

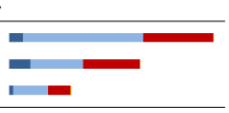


Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

LC-BSDS ranked in the bottom third of all evaluated products for field use and earned 64% of the utility points of the best score.

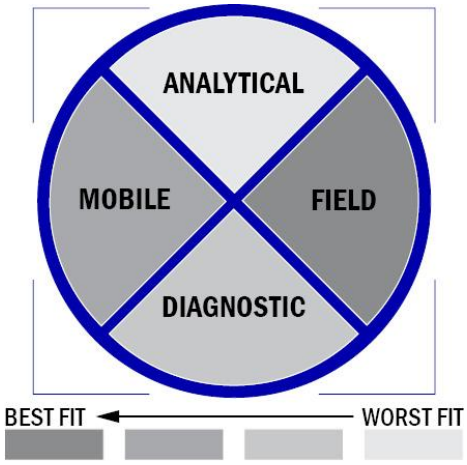
ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
Low-Cost Biological Standoff	55.70
MINIMUM SCORE	26.53



Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Science & Engineering Services, Inc.
6992 Columbia Gateway Drive
Columbia, Maryland 21046

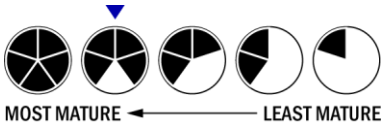
Point of Contact:
Robert M. Serino, Ph.D.
443.539.0139

COST

- $250,000.00/system or device

SPECIFICITY

- False Positives: 10%
- False Negatives: 10%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 10-20 minutes set-up
- 1-3 minutes down time
- 0-2 steps required
- Customer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from -21°C to 41°C
- Does not require consumables
- Peak performance at normal relative humidity conditions
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a home dishwasher
- Transport via commercial carrier/ Tactical military wheeled and tracked vehicle/ Fixed wing military aircraft
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless and wired connections
- Fully autonomous
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software open and available for modification
- System hardware open and available for modification

Low-cost Sagnac LWIR Interferometric HSI System

by Spectrum Photonics, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Aerosolized chemical agent

DETECTION MATRICES:

Demonstrated:
Environmental Air

DESCRIPTION:

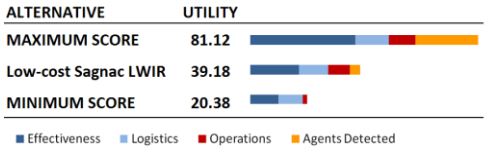
The objective of the ongoing research and development project is to develop a hyperspectral sensor system in the 8 to 14 micron wavelength region (long wave infrared or LWIR) capable of detecting chemical agents of DoD and civil interest via spectral measurements with spectral resolution as high as 4 cm-1. The Sagnac interferometer-based imaging technology is an evolution of a LWIR hyperspectral technology invented by Professor Paul Lucey (co-Founder of Spectrum Photonics and a key member of our project technical staff) and patented by the University of Hawaii. The patented Sagnac-based LWIR HSI system, to which Spectrum owns an exclusive license from the University of Hawaii, is particularly germane to the envisioned CBD Sponsor goal of developing a small, lightweight, low-cost LWIR HSI system because it is based on a static (no moving parts) interferometer design which is particularly well-suited to the use of uncooled microbolometer imaging detector technologies.

TECHNOLOGY:

The sensor is a spectral interferometer based on the Sagnac interferometer that contains no precision moving parts (distinguishing it from a scanning Michelson interferometer) and uses a microbolometer array as a LWIR scene-imaging camera which simultaneously capturing the interferometer's fringe structure output. Unlike a Michelson interferometer, our implementation of a Sagnac interferometer places an image of the complete interferogram on the detector array, so the pixels provide the sampling in space, rather than in time. The concept is based upon that of Horton 1996, and our innovation is applying this technique with uncooled LWIR arrays that utilize the multiplex advantage of interferometers to allow collection of quality data under substantial platform motion.

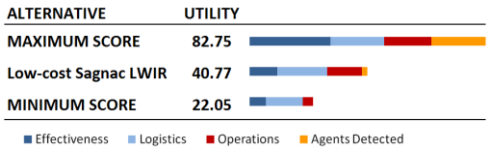
ANALYTICAL Laboratory Ranking

Low-cost Sagnac LWIR ranked in the bottom third of all evaluated products for analytical laboratories and earned 48% of the utility points of the best score.



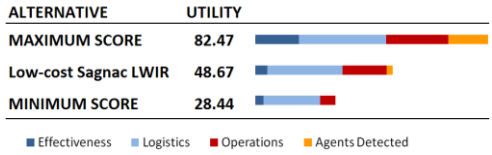
DIAGNOSTIC Laboratory Ranking

Low-cost Sagnac LWIR ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 49% of the utility points of the best score.



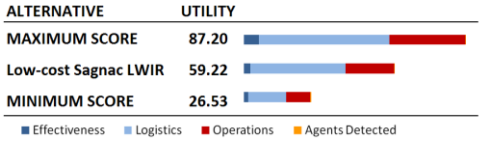
MOBILE Laboratory Ranking

Low-cost Sagnac LWIR ranked in the bottom third of all evaluated products for mobile laboratories and earned 59% of the utility points of the best score.



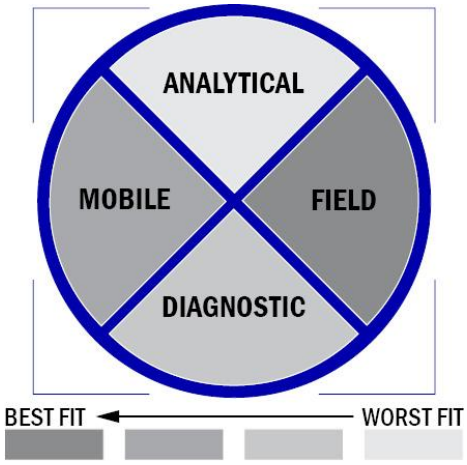
FIELD USE Ranking

Low-cost Sagnac LWIR ranked in the middle third of all evaluated products for field use and earned 68% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

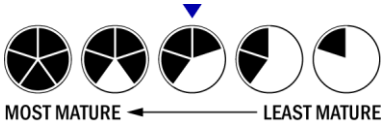
Spectrum Photonics, Inc.
2800 Woodlawn Drive, Suite 150
Honolulu, Hawaii 96822

COST

- $25,000.00/system or device
- $0.00/analysis

SPECIFICITY

- False Positives: Not Applicable
- False Negatives: Not Applicable



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Currently semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off

Training and Speed:
- A day of training and technical skills are required
- < 5 minutes set up
- Almost instantaneous down time
- 3-5 steps are required
- DVD/ Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Consumables not required
- Performance is not influenced by relative humidity
- Shelf life not applicable

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays

Maintenance:
- Service more often than every 6 months
- Preventive maintenance serviceable by customer
- Expected life greater than 10 years
- 5-10 minutes QA required

Physical System Requirements:
- Batteries
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can not be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- System does not test liquids

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Autonomous system with some effort
- Laptop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open but modification requires licensing

LP-CBRSS (Longreach-Project Chem/Bio/Rad Surveillance System)

by Longreach-Project DBA/Warren Parish

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

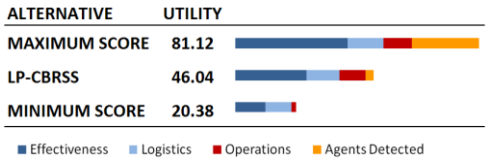
A SUAS (Unmanned Air System platform) with Chem/Bio touch sensors sends streaming data on contacts to remote sources in real time, where they are registered and set into 3D image exploitation maps. The air platform is under three pounds, remote control, flies for one hour, hand or air vehicle launched, drone. Tactical use is to fly through suspect space taking real time positive/neg readings and relay via comms to data center using MIL communications.

TECHNOLOGY:

Touch sensors are proven in production micro sensors carried by the air vehicle TL-6 or better, software is used in Military C4ISR operations.

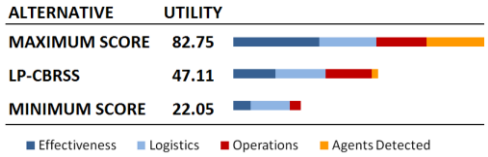
ANALYTICAL Laboratory Ranking

LP-CBRSS ranked in the middle third of all evaluated products for analytical laboratories and earned 57% of the utility points of the best score.



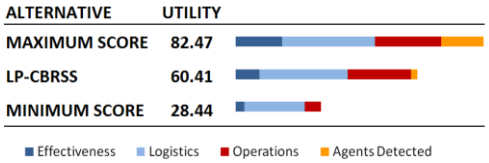
DIAGNOSTIC Laboratory Ranking

LP-CBRSS ranked in the middle third of all evaluated products for diagnostic laboratories and earned 57% of the utility points of the best score.



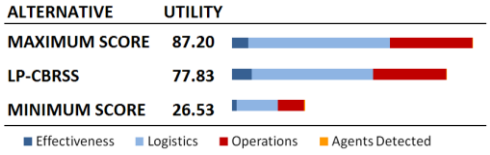
MOBILE Laboratory Ranking

LP-CBRSS ranked in the top third of all evaluated products for mobile laboratories and earned 73% of the utility points of the best score.



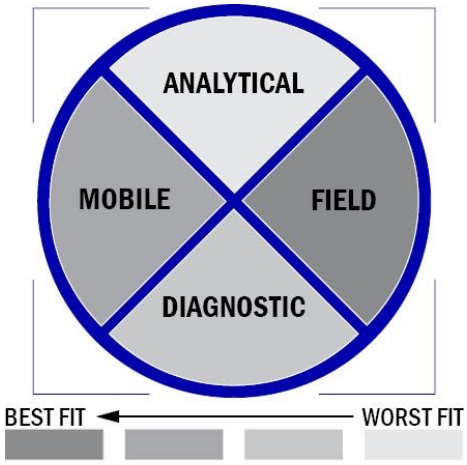
FIELD USE Ranking

LP-CBRSS ranked in the top third of all evaluated products for field use and earned 89% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Longreach-Project DBA/Warren Parish
3838 Warren Ridge
Sarasota, FL 34233

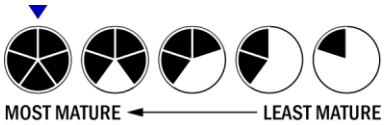
Point of Contact:
Warren Parrish
202-558-2452
Longreach-Project@attglobal.net

COST

- $200,000.00 - 60,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Thermal output not applicable

Training and Speed:
- >1 day training and significant technical skills are required
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer site training

Operational conditions:
- Can be used from < -21°C to > 42°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Performance not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 4 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life not applicable
- No daily QA required
- Decon not applicable

Physical System Requirements:
- No electrical requirement
- <1 hour battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is pending

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Satellite, wireless and wired connections
- Fully autonomous
- On board computer chip
- Could be adapted to store and archive data outputs and create an electronic record
- Software open, modification requires licensing
- Hardware open, modification requires licensing

LuBEA

by Precision System Science USA, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Viruses (100-1,000 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood

DESCRIPTION:

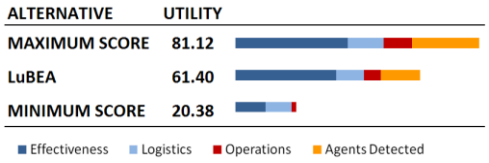
Small footprint, fully automated system from sample handling, reaction, washing and detection through to analysis. All reagents and reagents are pre-filled in a cartridge. Infectious disease, HLA & Bacterial typing, Food allergen, Bacterial & Viral contamination.

TECHNOLOGY:

Beads array In Single Tip for multiplex signal detection. Multiplex ELISA/EIA Multiplex DNA typing.

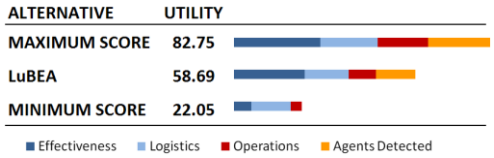
ANALYTICAL Laboratory Ranking

LuBEA ranked in the top third of all evaluated products for analytical laboratories and earned 62% of the utility points of the best score.



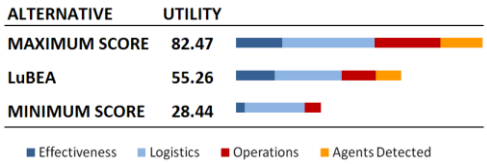
DIAGNOSTIC Laboratory Ranking

LuBEA ranked in the top third of all evaluated products for diagnostic laboratories and earned 67% of the utility points of the best score.



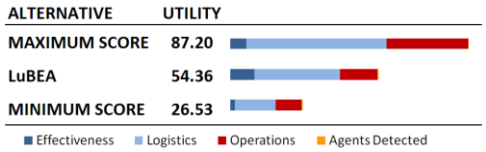
MOBILE Laboratory Ranking

LuBEA ranked in the middle third of all evaluated products for mobile laboratories and earned 71% of the utility points of the best score.



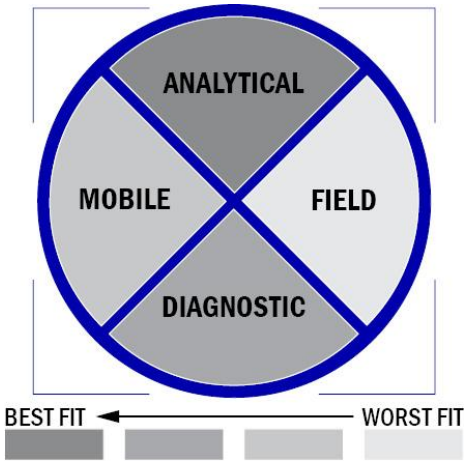
FIELD USE Ranking

LuBEA ranked in the bottom third of all evaluated products for field use and earned 76% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Precision System Science USA, Inc.
5673 W. Las Positas Blvd.
Suite 202
Pleasanton CA 94588

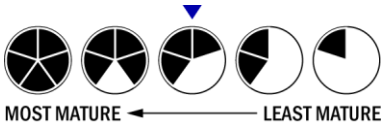
Point of Contact:
Chris Kusumoto
925-960-9183
chrisks@pssbio.com
925-960-9180
contact@pssbio.com

COST

- $10,000.00/system or device

SPECIFICITY

- False Positives: ~0.1%
- False Negatives: ~0.1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- Multiple samples, single tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- <5 minutes set-up required
- <1 minute down time
- 3-5 steps required
- DVD/ Web video/ Customer site training/ Hard copy manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Impact of relative humidity unknown
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of carry-on luggage
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 3 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 3-5 years
- No daily QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- 1-2 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results not available
- Data processing while in progress information not available
- No centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 250 ul to test liquids

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Not network capable
- Could be fully autonomous with some effort
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software open and available for modification
- System hardware open and available for modification

Luminex 100/200 System

by Luminex Corporation

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)
Toxins (1-100 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Environmental air, Environmental water, Soil, Food

DESCRIPTION:

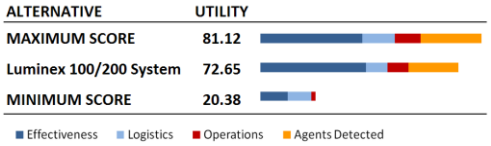
The Luminex 100/200 System is designed to meet the multiplexing needs of clinical and research laboratory professionals. The System is a versatile multiplexing platform capable of performing qualitative and quantitative analysis of proteins and nucleic acids in a variety of sample matrices. The Luminex 100/200 is a flexible analyzer based on the principles of flow cytometry. The System enables you to multiplex (simultaneously measure) up to 100 analytes in a single microplate well, using very small sample volumes. The system delivers fast and cost-effective bioassay results on many assay formats including nucleic acid assays, receptor-ligand assays, immunoassays and enzymatic assays. The Luminex 100/200 System is the combination of three core xMAP technologies. The first is xMAP microspheres, a family of 100 fluorescently dyed 5.6 micron-sized polystyrene microspheres that act as both the identifier and the solid surface to build the assay. Suspended microspheres give consistent, reproducible results and allow for easy quality control. The second is the flow cytometry-based Luminex 100/200 analyzer, which integrates key xMAP detection components such as lasers, optics, fluidics and high-speed digital signal processors. The third component is the xPONENT software, which is designed for protocol-based data acquisition with robust data regression analysis. The total system includes the Luminex 100/200 instrument, the Luminex XY plate handling platform, and the Luminex SD sheath fluid delivery system, software, and PC. A professional Training Session for one person is included.

TECHNOLOGY:

The system includes the Luminex 100/200 instrument, the XY plate handling platform, and the SD sheath fluid delivery system, software and PC. The System comprises three core xMAP technologies: 1. The xMAP microspheres, a family of 100 fluorescently dyed 5.6 micron-sized polystyrene microspheres that act as both the identifier and the solid surface to build the assay. 2. The flow cytometry-based Luminex 100/200 analyzer, which integrates key xMAP detection components such as lasers, optics, fluidics and high-speed digital signal processors. 3. The xPONENT® software, which is designed for protocol-based data acquisition with robust data regression analysis.

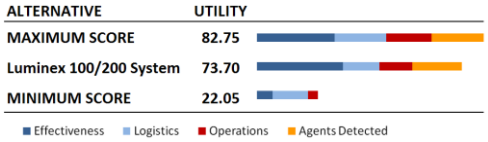
ANALYTICAL Laboratory Ranking

Luminex 100/200 System ranked in the top third of all evaluated products for analytical laboratories and earned 90% of the utility points of the best score.



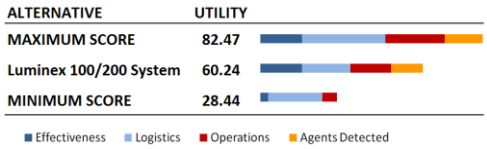
DIAGNOSTIC Laboratory Ranking

Luminex 100/200 System ranked in the top third of all evaluated products for diagnostic laboratories and earned 89% of the utility points of the best score.



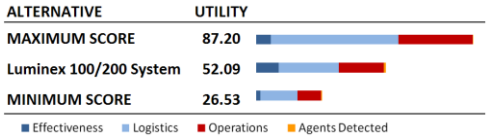
MOBILE Laboratory Ranking

Luminex 100/200 System ranked in the top third of all evaluated products for mobile laboratories and earned 73% of the utility points of the best score.



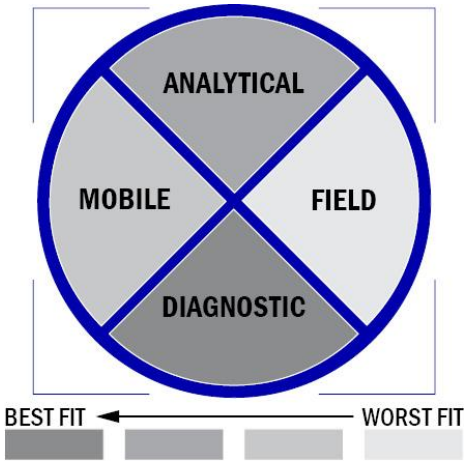
FIELD USE Ranking

Luminex 100/200 System ranked in the bottom third of all evaluated products for field use and earned 60% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Luminex Corporation
12212 Technology Blvd.
Austin, TX 78727

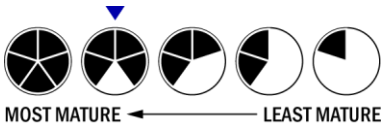
Point of Contact:
Amy Altman
aaltman@luminexcorp.com
(512) 219-8020

COST

- $75,000.00/system or device

SPECIFICITY

- False Positives: System reduces failure rate
- False Negatives: System reduces failure rate



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- >20 minutes set-up
- Almost instantaneous down time
- 3-5 steps required
- Web video/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components must be stored at 4°C
- Peak performance at normal relative humidity conditions
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of carry-on luggage
- Transport via commercial carrier/ Ship
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 4 solutions, buffer, and/or reagents
- 1 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 5-10 years
- 5-10 minutes daily QA
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Requires water aliquots
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- Multiple shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance shown
- FDA clearance shown
- Less than 50 ul to test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable.
- Wired connections
- Could easily be adapted into a fully autonomous system
- No computer required
- Stores and archives data outputs and creates an electronic record
- System software is closed and not available for modification
- System hardware is closed and not available for modification

Luminex MAGPIX System

by Luminex Corporation

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)
Toxins (1-100 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Environmental air, Environmental water, Soil, Food

DESCRIPTION:

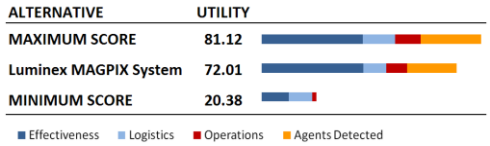
The MAGPIX system is a versatile multiplexing platform capable of performing qualitative and quantitative analysis of proteins and nucleic acids in a variety of sample matrices. This affordable system requires small sample input and can perform up to 50 tests in a single reaction volume, greatly reducing sample input, reagents and labor while improving productivity. The MAGPIX analyzer is based on CCD imaging technology, which allows for a compact, more robust system. Streamlined start-up and shut-down protocols and minimal maintenance requirements make the system easy to operate and maintain. MAGPIX was designed to meet the needs of laboratory medicine and the care of patients, as well as the research environment. It can be ruggedized for biodefense field applications; a ruggedized prototype of MAGPIX was field tested in a Technology Readiness Evaluation by the US Army Research, Development and Engineering Command Edgewood Chemical and Biological Center. Testing was done at the Dugway Proving Ground, UT. System performance on an antibody-based test of seven agents of biological origin was run over a 3 month period. Although assay-level performance information is proprietary, the system proved to be adequately rugged with no performance faults throughout the testing period.

TECHNOLOGY:

The Luminex MAGPIX system comprises three components: 1. The MAGPIX instrument, which integrates key components such as LED CCD cameras, optics, and high-speed digital signal processors. 2. The MagPlex microspheres, 50 fluorescently dyed 6.5 micron-sized polystyrene paramagnetic microspheres, each with a distinct spectral address, that act as both the identifier and the solid surface to build the assay. They may be multiplexed together up to 50 per well and can be used for many assay formats such as nucleic acid assays and immunoassays. 3. The xPONENT software, a modular, flexible, software package for control of the MAGPIX and data analysis.

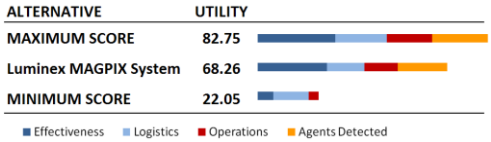
ANALYTICAL Laboratory Ranking

MAGPIX System ranked in the top third of all evaluated products for analytical laboratories and earned 89% of the utility points of the best score.



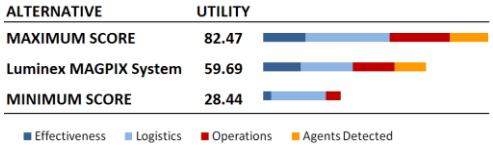
DIAGNOSTIC Laboratory Ranking

MAGPIX System ranked in the top third of all evaluated products for diagnostic laboratories and earned 82% of the utility points of the best score.



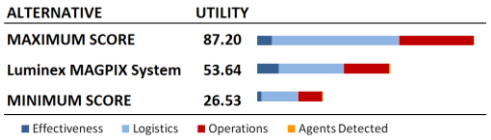
MOBILE Laboratory Ranking

MAGPIX System ranked in the top third of all evaluated products for mobile laboratories and earned 72% of the utility points of the best score.



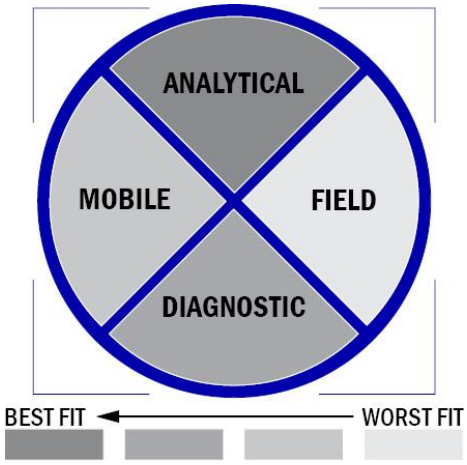
FIELD USE Ranking

MAGPIX System ranked in the bottom third of all evaluated products for field use and earned 62% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Luminex Corporation
12212 Technology Blvd.
Austin, TX 78727
(512) 219-8020
www.luminexcorp.com

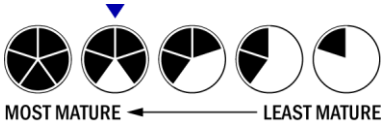
Point of contact:
Amy Altman, Ph.D. VP, Biodefense
aaltman@luminexcorp.com

COST

- $35,000.00/system or device

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- No sounds or alarms
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 10-20 minutes for set up
- Almost instantaneous down time
- 3-5 steps are required
- Web video/ Customer and Manufacturer site training/ Hard-copy and Web manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components must be stored at 4°C
- Peak performance at normal relative humidity conditions
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Commercial carrier/Ship transport
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 4 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 5-10 years
- 5 to 10 minutes QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Requires water aliquots
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- Multiple shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- Capable of 510K clearance
- Capable of FDA approval
- Less than 50 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Easily adapted into a fully autonomous system
- Basic desktop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

M3IB

by THALES Defense & Security

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria
Viruses
Toxins

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

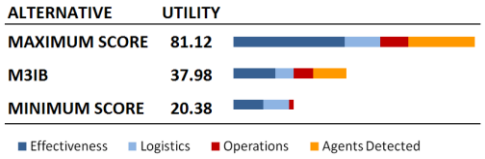
The M3IB is an air transportable automated field laboratory that, once deployed, is capable of identifying biological agents through the use of two distinct technologies. The fully automated laboratory module is very easy to be use even for non specialist staff. The analytical chain includes sample preparation steps that make the system suitable for many kind of environmental samples, and its "open" concept make it easy to adapt new protocols for more specific samples.

TECHNOLOGY:

The M3IB uses of the two main proven technologies for rapid biological identification, which are PCR and ELISA. The PCR, based on nucleic acids amplification, can identify viruses and bacteria's with a high sensitivity. ELISA, adapted for automated and rapid results, can identify all kind of biological threats, bacteria's, viruses or toxins.

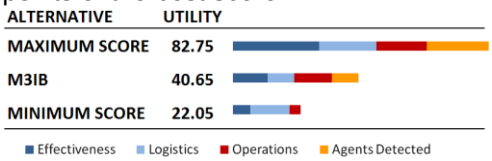
ANALYTICAL Laboratory Ranking

M3IB ranked in the bottom third of all evaluated products for analytical laboratories and earned 47% of the utility points of the best score.



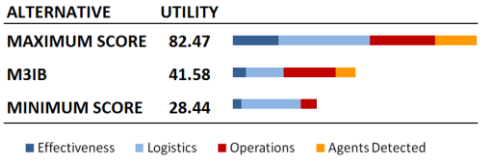
DIAGNOSTIC Laboratory Ranking

M3IB ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 49% of the utility points of the best score.



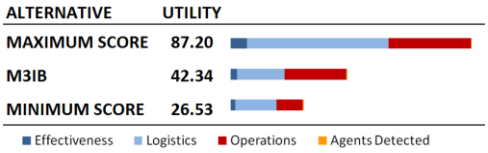
MOBILE Laboratory Ranking

M3IB ranked in the bottom third of all evaluated products for mobile laboratories and earned 50% of the utility points of the best score.



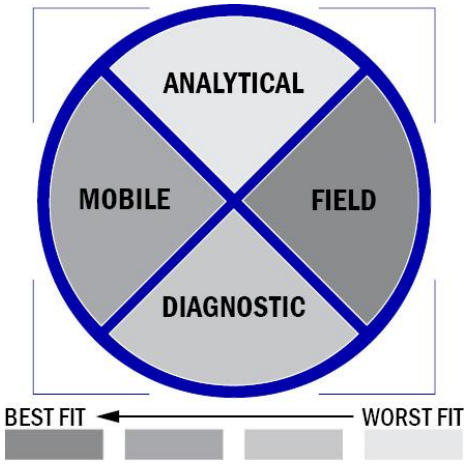
FIELD USE Ranking

M3IB ranked in the bottom third of all evaluated products for field use and earned 49% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

THALES Defense & Security
C4I systems Division
20-22 rue Grange Dame Rose
CS 90519 78141

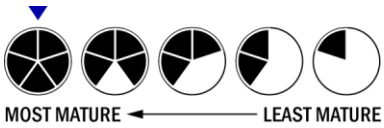
Point of Contact:
Jérôme LOUAT
jerome.louat@Thalesgroup.com

COST

- Not available

SPECIFICITY

- False positives: Not available
- False negatives: Not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms can be deactivated
- Screen cannot be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- More than a day of training and significant skills are required
- >20 minutes set up required
- Minimal down time
- 0-2 steps are required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used <-21°C to >42°C
- Components stored at room temp but can withstand temps > 45°C for < 24 hours/ Must be stored at 4°C/ Must be frozen
- Performance is not influenced by relative humidity
- Shelf life 1-3 years

Transportation:
- Larger than a home dishwasher
- Tactical military wheeled and tracked vehicle/ Fixed wing military aircraft/ Ship transport
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by technician only
- Maintenance is not included
- Expected life >10 years
- 10-20 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1 hr

Physical System Requirements:
- Requires multiple outlets or a dedicated circuit breaker
- Not intended for portable use
- Requires water aliquots
- Requires an external air source
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- > 250 ul for a test

System Maturity:
- Is commercially available and meets military specs
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB
- Network capable
- Wired connections
- Easily be adapted into a fully autonomous system
- On board computer chip
- The system automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

Mass Spectrometry-Based Detection of Host Protein Response

by Battelle - Pacific Northwest National Laboratory

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

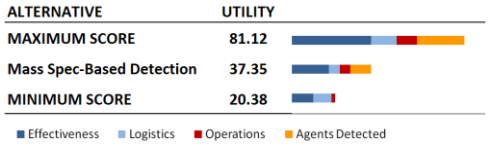
A wide variety of commercial mass spectrometers are available, specifically we have used a Orbi trap electrospray tandem mass spectrometers (Thermo Inc) and MALDI-TOF MS system (Bruker Daltonics). These systems are strictly laboratory-based systems commonly used for protein characterization and proteomics in basic research environments.

TECHNOLOGY:

Protein identification by mass spectrometry has continued to mature over the last 15 years. The method relies on ionization and fragmentation of sample peptides (often produced by enzymatic digestion). The peptide fragment data is compared to predicted protein sequences for identification using either vendor-supplied or open-source computational tools. The profile of identified proteins varies in response to the type of agent exposure.

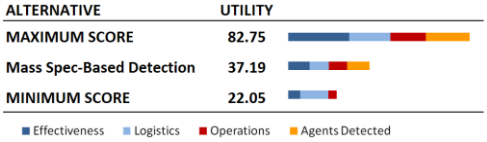
ANALYTICAL Laboratory Ranking

Mass Spectrometry-Based Detection of Host Protein Response ranked in the bottom third of all evaluated products for analytical laboratories and earned 46% of the utility points of the best score.



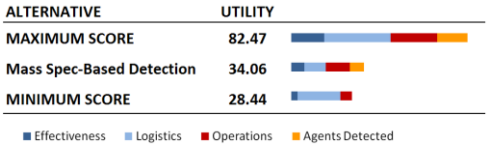
DIAGNOSTIC Laboratory Ranking

Mass Spectrometry-Based Detection of Host Protein Response ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 45% of the utility points of the best score.



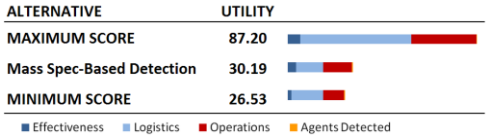
MOBILE Laboratory Ranking

Mass Spectrometry-Based Detection of Host Protein Response ranked in the bottom third of all evaluated products for mobile laboratories and earned 41% of the utility points of the best score.



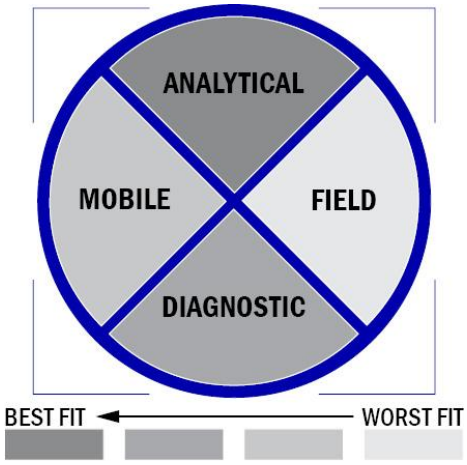
FIELD USE Ranking

Mass Spectrometry-Based Detection of Host Protein Response ranked in the bottom third of all evaluated products for field use and earned 35% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Battelle - Pacific Northwest National Laboratory
P.O. Box 999
Battelle Blvd.
Mail Stop P7-50
Richland, WA 99352

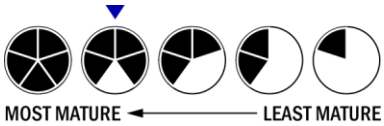
Point of Contact:
Dr. David S. Wunschel
david.wunschel@pnl.gov

COST

- $250,000.00 - 600,000.00/system or device

SPECIFICITY

- False Positives: <10%
- False Negatives: <10%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- > 8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Could be adapted to fully automated with some effort

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- >1 day training and significant technical skills required
- 10-20 minutes set-up required
- <5 minute down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at 4°C/ Must be frozen at temps at/below -20°C (cryo-storage)
- Must be temp stable, dry environment for optimum performance
- Greater than 3 years shelf life

Transportation:
- Larger than home dishwasher
- All modes of transportation
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 3 solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life 5-10 years
- >20 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Requires water aliquots
- External air or gas source required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- Multiple centrifugation steps
- Multiple shaking or vortexing, mixing, degassing or filtering steps
- System could call final result in the future

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is not involved

Interoperability and System Complexity:
- 150-199 GB raw data generated
- Network capable
- Not autonomous
- High end desktop computer
- Stores and archives data outputs and creates an electronic record
- System software is closed and not available for modification
- System hardware is closed and not available for modification

M-BAND (Microfluidic Bioagent Autonomous Detector)

by Microfluidic Systems

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)
Toxins (1-100 ng/ml)

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

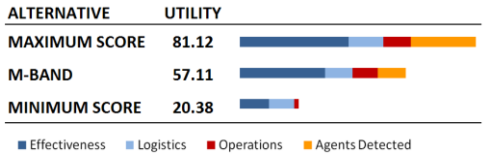
The Microfluidic Bioagent Autonomous Networked Detector (M-BAND) is a fully automated, wirelessly networked airborne pathogen detection and identification system designed to run for up to 1 month continuously without human intervention. It can specifically identify bacteria, viruses, and toxins at threat levels indoors and outdoors. It has been field tested for over 2 years by several independent agencies domestically and internationally.

TECHNOLOGY:

The M-BAND is a modular and fully integrated system that includes a high volume air collector, sample processing, Taqman PCR for bacteria and viruses, and chemiluminescence immunoassays for toxins. It includes a 17-plex Taqman PCR for 6 agents and immunoassays for 3 toxins. It is wirelessly networked and remotely operable.

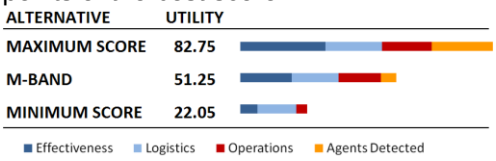
ANALYTICAL Laboratory Ranking

M-BAND ranked in the top third of all evaluated products for analytical laboratories and earned 70% of the utility points of the best score.



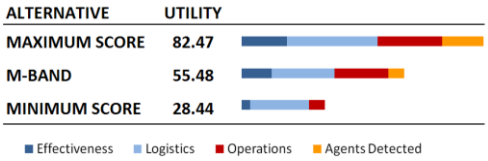
DIAGNOSTIC Laboratory Ranking

M-BAND ranked in the middle third of all evaluated products for diagnostic laboratories and earned 62% of the utility points of the best score.



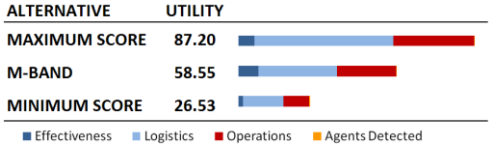
MOBILE Laboratory Ranking

M-BAND ranked in the middle third of all evaluated products for mobile laboratories and earned 67% of the utility points of the best score.



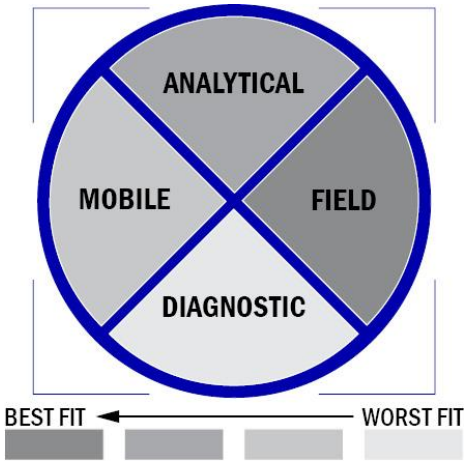
FIELD USE Ranking

M-BAND ranked in the middle third of all evaluated products for field use and earned 67% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Microfluidic Systems
47790 Westinghouse Dr
Fremont, CA 94563

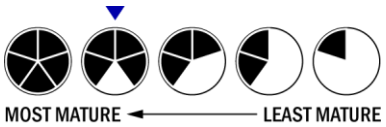
Point of Contact:
M. Allen Northrup PhD
northrup@microfluidicsystems.com
510-933-1501

COST

- $190,000.00/system or device

SPECIFICITY

- False Positives: Achieved 0% at LOD of 4-100 copies (depends on organism)
- False Negatives: Achieved 0% at LOD of 4-100 copies (depends on organism)



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30 - 60 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- >20 minutes set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer site training

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours/ Must be stored at room temp (27°C)/ Must be stored at 4°C
- Performance is not influenced by relative humidity
- 6 months - 1 year shelf life

Transportation:
- Larger than a home dishwasher
- Transport via commercial carrier
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 4 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life 3-5 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results not available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Greater than 250 ul to test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- 100-149 GB raw data generated
- Network capable
- Satellite, wireless and wired connections
- Fully autonomous
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software open and available for modification
- System hardware open and available for modification

MBio MQ

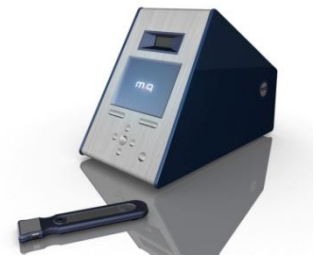
by MBio Diagnostics, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Toxins (1-100 ng/ml)

DETECTION MATRICES:

Demonstrated:
Blood



DESCRIPTION:

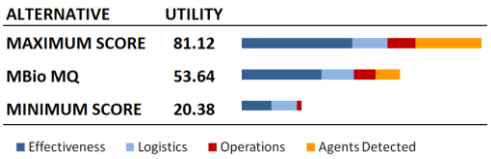
The MBio MQ multiplexed assay system delivers quantitative fluorescence immunoassay results for panels of analytes – all from a single drop of blood, plasma, or serum. MQ is a simple reader and disposable cartridge system for point-of-care testing. MQ provides the data quality and multiple results of a clinical laboratory analyzer in an inexpensive format with workflow comparable to single analyte rapid diagnostic tests. Under design for a CLIA-waiver, the simple system uses minimal sample (5 to 10 microliters) and delivers results in less than 30 minutes. The MBio technologies fill an unmet need for near patient disease panels.

TECHNOLOGY:

MBio's diagnostic systems are all built on the company's LightDeck™ technology, a patent-protected fluorescence assay illumination method that is simultaneously simple, inexpensive and robust. It is a variation on planar waveguide technology, an approach that has been used for performing sensitive biological assays for over two decades. MBio's innovation has been to solve the light coupling reproducibility problem that has limited widespread use of the technology. The MBio MQ incorporates low cost consumer electronics (laser diodes and imagers) to create a robust reader device and for the MQ's single-use test cartridges.

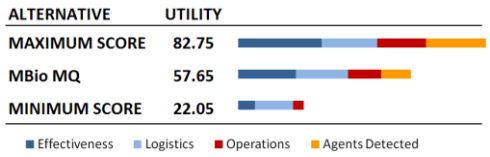
ANALYTICAL Laboratory Ranking

MBio MQ ranked in the top third of all evaluated products for analytical laboratories and earned 66% of the utility points of the best score.



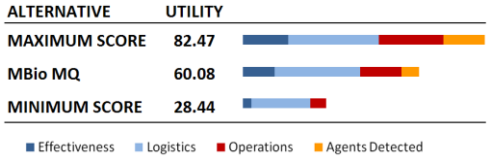
DIAGNOSTIC Laboratory Ranking

MBio MQ ranked in the top third of all evaluated products for diagnostic laboratories and earned 70% of the utility points of the best score.



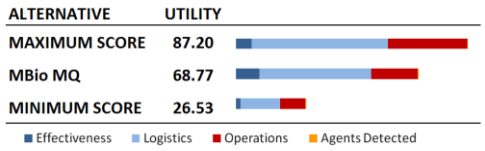
MOBILE Laboratory Ranking

MBio MQ ranked in the top third of all evaluated products for mobile laboratories and earned 73% of the utility points of the best score.



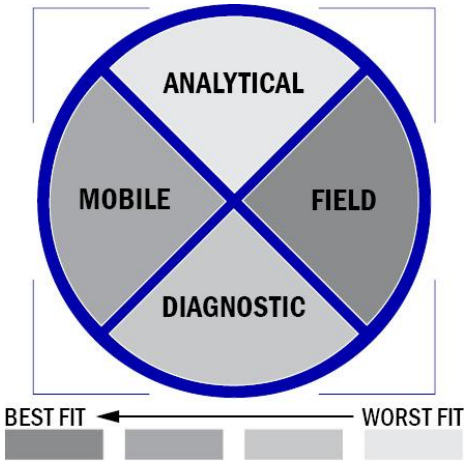
FIELD USE Ranking

MBio MQ ranked in the middle third of all evaluated products for field use and earned 79% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

MBio Diagnostics, Inc.
3122 Sterling Circle
Boulder, CO 80301

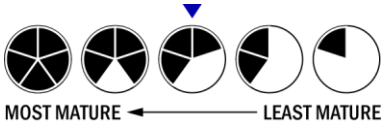
Point of Contact:
Michael J. Lochhead, Ph.D. Vice President
303-952-2810
mike.lochhead@mbiodx.com

COST

- $5,000.00/system or device

SPECIFICITY

- False Positives: < 1% for HIV Ab (pre-clinical)
- False Negatives: < 1% for HIV Ab (pre-clinical)



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15 - 30 minutes for detection
- Multiple samples, multiple tests/sample per run
- Semi-automation

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- <1 minute down time
- 0-2 steps required
- Customer site training/ Hard copy operators manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Performance is not influenced by relative humidity
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 1 and 5 kg

Re-use:
- Single use
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service once a year
- Preventive maintenance not applicable
- Maintenance not included
- Expected life unknown
- 10-20 minutes QA
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 50 ul to test liquids

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Not autonomous
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software is open and available for modification
- System hardware is open and available for modification

MENTOR-100

by Menon & Associates

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e3-10e4 CFU/mL)

DETECTION MATRICES:

Demonstrated:
Environmental air,
Environmental water, Powder

DESCRIPTION:

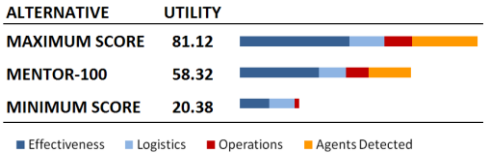
The MENTOR-100 biodetector is a compact, portable system that uses a patented nucleic-acid based assay ('NMR Bioassay') to detect and identify biological agents. Currently the system is configured to detect aerosolized agents in the atmosphere. The system is fully automated from sample collection to detection, has automated decontamination, and is fully reusable. The results are presented in a simple no threat/threat format that requires no operator interpretation. The system can also accept liquid samples for detection which could include spores or other solid threats suspended in liquid. Clinical samples can be handled by developing and interfacing the appropriate sample processing module. Currently the MENTOR-100 can detect the biothreats Bacillus anthracis, Francisella tularensis, Yersinia pestis and the controls Bacillus thuringiensis and Bacillus subtilis. The system is capable of multiplexed detection. Other biothreats including viruses and other bacteria can be added to the system library by developing the appropriate NMR Bioassay. The system is also capable of adapting existing nucleic acid assays developed for other detection platforms. Applications include threat monitoring and biosurveillance, clinical diagnosis, and food and water safety. The small footprint of the system will allow it to be used in a wide variety of locations, including public buildings, transportation centers, clinics and food processing establishments. The development of the MENTOR-100 has been supported by the Department of Homeland Security (DHS) and the Defense Threat Reduction Agency (DTRA). The MENTOR-100 has successfully detected blind assays at the Edgewood Chemical Biological Center (ECBC).

TECHNOLOGY:

The MENTOR-100 biodetector uses the properties of paramagnetic nanoparticles to change the nuclear magnetic resonance (NMR) relaxation time of protons in an aqueous solution. Paramagnetic nanoparticles coated with a molecular binding agent together with specialized nucleic acid probes are introduced into the assay and processed. The interaction of the nanoparticles, probes and the target's nucleic acid causes a change in the NMR relaxation time when the target is present compared to when it is absent. This change in relaxation time is used to indicate the presence of the target.

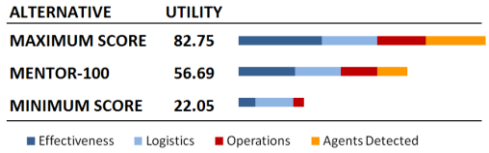
ANALYTICAL Laboratory Ranking

MENTOR-100 ranked in the top third of all evaluated products for analytical laboratories and earned 72% of the utility points of the best score.



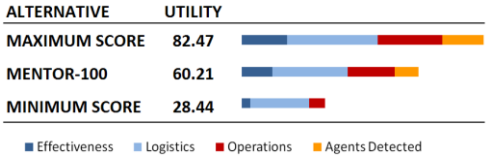
DIAGNOSTIC Laboratory Ranking

MENTOR-100 ranked in the top third of all evaluated products for diagnostic laboratories and earned 69% of the utility points of the best score.



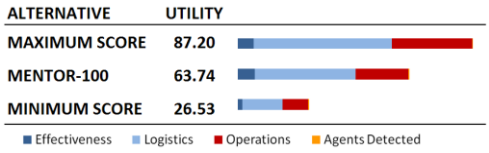
MOBILE Laboratory Ranking

MENTOR-100 ranked in the top third of all evaluated products for mobile laboratories and earned 73% of the utility points of the best score.



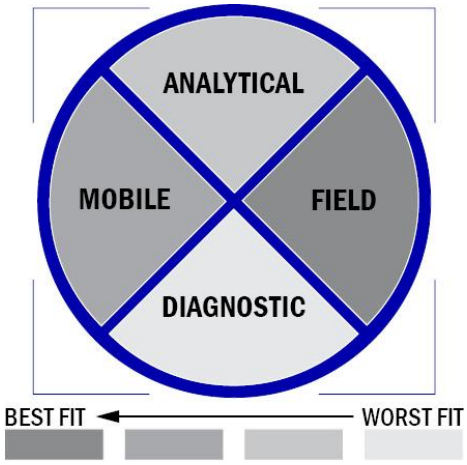
FIELD USE Ranking

MENTOR-100 ranked in the middle third of all evaluated products for field use and earned 73% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

6199 Cornerstone Ct. Ste 109-111
San Diego, CA 92121

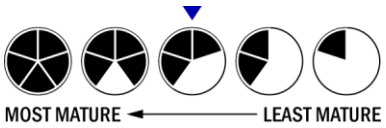
Point of Contact:
Sankaran Kumar

COST

- $120,000.00/system or device
- $2.50/ analysis

SPECIFICITY

- False Positives: <5%
- False Negatives: <10%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15-30 minutes for detection
- 1 sample, <10 tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- No set up
- Less than 5 minutes down time
- 0-2 steps are required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components stored at room temp can withstand temps >45°C for periods < 24 hours/ Must store at room temp / 4°C
- Performance is not influenced by relative humidity
- Between 1 to 6 months shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service more often that every 6 months
- Preventive maintenance serviceable by technician
- Maintenance is included
- Expected life >10 years
- 10-20 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1 hr

Physical System Requirements:
- 110V electrical requirement
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 10 ul for a test

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Fully autonomous system
- Onboard computer chip
- Store and archive data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

METRO SENTRY ONE (MSO)

by BPSI

DETECTS THE FOLLOWING:

Demonstrated:
Toxins
Aerosolized chemical agent (0.000001-0.00003 mg/m3)

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

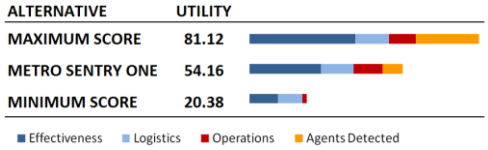
The Metro Sentry One (MSO) is a mechanical system installed to monitor areas of terrorist concerns such as an underground Metro Transit Authority station environment. The MSO monitors both directly and remotely, airborne toxins in the fresh air supply, points of ingress and egress and the ambient platform environment. If a toxin is detected, the MSO enacts a sequence of predetermined alerts and mechanical protocols to isolate toxins thus preventing continued distribution to prevent loss of life, preserve assets, and to provide an early warning system for first responders in the event of a targeted terrorist attack using chemical, radiological or biological materials or an accidental release. The MSO is installed as an all-in-one full backbone system and can integrate directly into an existing security command platform or into BPSI's extensive fusion platform. The MSO detects a defined spectrum of chemical contaminants, a wide library of radiological isotopes and select biological agents with sensitivity levels customized for each specific toxin. The MSO has been designed in modular fashion to support continued advances in chemical, radiological and biological sensory technology, with a "Plug and Play" overlay into the Sentry One network. No known similar systems exist. The Metro Sentry One is a fully functioning "Next Generation" detection backbone system that integrates sensory technology into a market ready transit retrofit project. With embedded controls, logic, software, mechanical protocols and remote monitoring coupled with multiple security means, this system is designed to operate 24/7/365 in the absence of false positive readings.

TECHNOLOGY:

BPSI's Metro Sentry One (MSO) is a COTS based system that detects a defined spectrum of toxic compounds, a 120+ library of radiological isotopes and select biological agents in a transit environment on a continuous 24/7/365 basis with virtually zero false positive alarms. Through the integration of programmable logic controllers and sensor arrays, linked to a PC infrastructure with multi-layer communications protocols, the Metro Sentry One solution offers a dynamic set of customized security measures. The MSO's backbone architecture mesh simply and easily with existing systems, in a seamless process that gives the end user virtually unlimited options for protection.

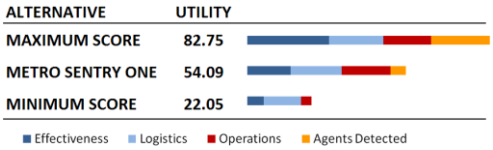
ANALYTICAL Laboratory Ranking

MSO ranked in the top third of all evaluated products for analytical laboratories and earned 67% of the utility points of the best score.



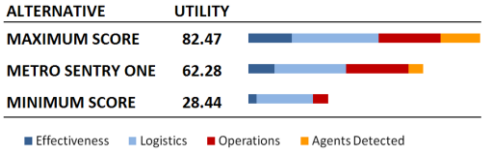
DIAGNOSTIC Laboratory Ranking

MSO ranked in the middle third of all evaluated products for diagnostic laboratories and earned 65% of the utility points of the best score.



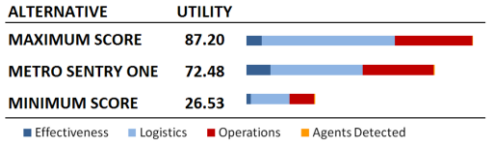
MOBILE Laboratory Ranking

MSO ranked in the top third of all evaluated products for mobile laboratories and earned 76% of the utility points of the best score.



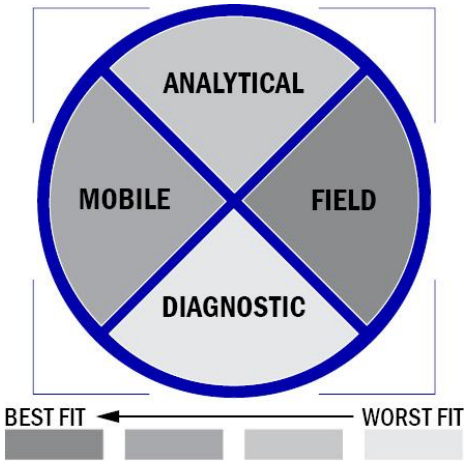
FIELD USE Ranking

MSO ranked in the top third of all evaluated products for field use and earned 83% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

BPSI
150 Post Street, Suite 750
San Francisco, CA 94108

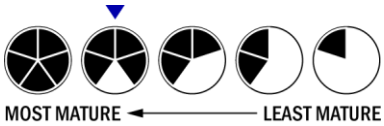
Point of Contact:
Greg Eiler
925-933-8600
geiler@bpsiglobal.com

COST

- $295,000.00/system or device

SPECIFICITY

- False Positives: .00005
- False Negatives: .000025



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- DVD/ Web video/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life >10 years
- No daily QA required
- Decontamination not applicable

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance information not available
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- Raw data information not available
- Network capable
- Wired connections
- Fully autonomous
- Basic desktop computer
- Stores and archives data outputs and creates an electronic record
- System software is open and available for modification
- System hardware is open and available for modification

MICRO-DETECTIVE

by AMETEK Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types
Identification of specific isotopes

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

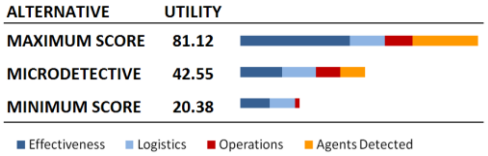
The Micro-Detective is a hand-held portable Radioisotope Identifiers (RID's) that utilize a high purity germanium detector (HPGe) to identify radioactive sources. The Micro-Detective can accurately detect and identify the specific type of radiation emanating from a person, a package, a cargo container or a vehicle.

TECHNOLOGY:

The High Purity Germanium (HPGe) Detector used in the MicroDetective is considered the "gold standard" for radiation identification, and is the only radiation detection technology that provides sufficient information to accurately and reliably identify radionuclides using their passive gamma ray emissions.

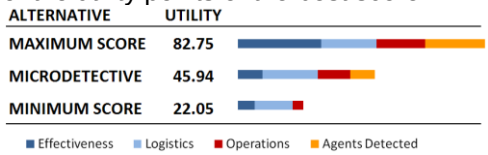
ANALYTICAL Laboratory Ranking

Micro-Detective ranked in the middle third of all evaluated products for analytical laboratories and earned 52% of the utility points of the best score.



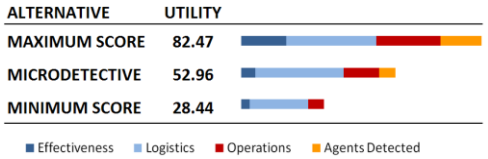
DIAGNOSTIC Laboratory Ranking

Micro-Detective ranked in the middle third of all evaluated products for diagnostic laboratories and earned 56% of the utility points of the best score.



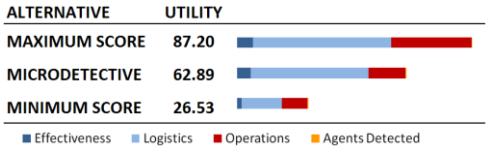
MOBILE Laboratory Ranking

Micro-Detective ranked in the middle third of all evaluated products for mobile laboratories and earned 64% of the utility points of the best score.



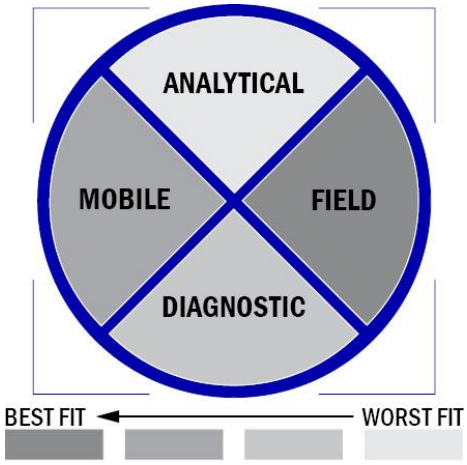
FIELD USE Ranking

Micro-Detective ranked in the middle third of all evaluated products for field use and earned 72% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

AMETEK Inc.
ORTEC Products Advanced Measurement Technology, Inc.
801 S. Illinois Avenue
Oak Ridge, TN 37831

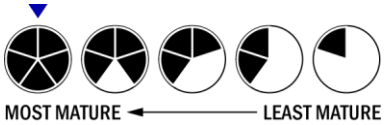
Point of Contact:
Ronald A. Zeszut
216-328-1404
ron.zeszut@ametek.com

COST

- $95,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from -10°C to 40°C
- Does not require consumables
- Peak performance at <90% at 35°C
- Shelf life not applicable

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 0 components

Maintenance:
- Service less than once a year
- Preventive maintenance not applicable
- Maintenance not included
- Expected life 5-10 years
- <5 minutes daily QA
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110VAC or 220VAC for line power and battery charging
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Liquid testing not applicable

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- <100 GB or single pos or neg response generated
- Network capable
- Wireless, wired connections
- Could easily be adapted to fully autonomous
- On board computer chip
- Does not store or archive data outputs or create an electronic record
- Software open, modification requires licensing
- Hardware open, modification requires licensing

MICRO-DETECTIVE-HX

by Advanced Measurement Technology

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

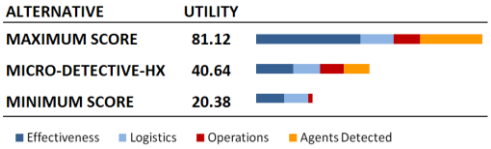
Micro-Detective-HX is the latest addition to the highly successful ORTEC Detective range of high purity germanium (HPGe) basedhand-held radioisotope identifiers (RIDs), for use in the detection and prevention of illicit trafficking of nuclear materials at ports and border crossings. It is the most advanced RID commercially available.

TECHNOLOGY:

Gamma and neutron, High Purity Germanium (HPGe) detector, high resolution, “gold standard” for identification

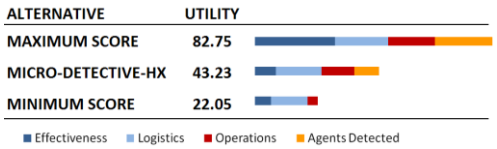
ANALYTICAL Laboratory Ranking

MICRO-DETECTIVE-HX System ranked in the bottom third of all evaluated products for analytical laboratories and earned 50% of the utility points of the best score.



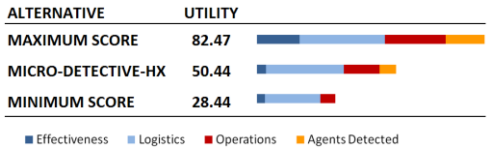
DIAGNOSTIC Laboratory Ranking

MICRO-DETECTIVE-HX System ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 52% of the utility points of the best score.



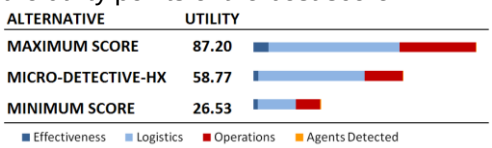
MOBILE Laboratory Ranking

MICRO-DETECTIVE-HX System ranked in the bottom third of all evaluated products for mobile laboratories and earned 61% of the utility points of the best score.



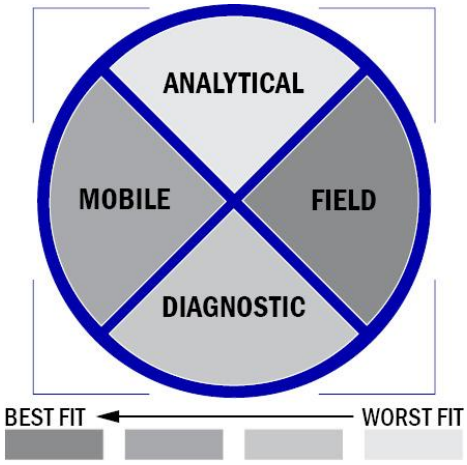
FIELD USE Ranking

MICRO-DETECTIVE-HX System ranked in the middle third of all evaluated products for field use and earned 67% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Advanced Measurement Technology
7675 Edgewood Lane
Seven Hills, OH 44131

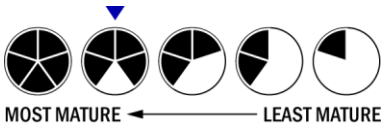
Point of Contact:
Ronald A. Zeszut
510-735-6923
ron.zeszut@ametek.com

COST

- $100,000/system or device

SPECIFICITY

- False positives: Not available
- False negatives: Not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms cannot be deactivated
- Screen can be dimmed or turned off
- Less than 200 BTU

Training and Speed:
- Very brief training and minimal technical skills
- > 20 minutes set up
- Minimal down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 37°C
- Does not require consumables
- Performance is not known under relative humidity

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays

Maintenance:
- No service required
- Preventive maintenance serviceable customer
- Maintenance is included
- Expected life 5-10 years
- <5 minutes daily QA required

Physical System Requirements:
- Batteries
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call the final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Does not test liquids

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- <100 GB
- Network capable
- Wireless and wired connections
- Fully autonomous
- No computational power required
- The system automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

microRaider

by ICx Radiation

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types
Identification of specific isotopes

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

The microRaider™ is a state-of-the-art Spectroscopic Personal Radiation Detector (SPRD) with solid state, CZT detectors. It combines the capabilities of a Personal Radiation Detector (PRD) with the radionuclide identification capabilities of a Radio-Isotope Identification Detector (RIID) into one conveniently small package. The microRaider provides great sensitivity along with realtime, accurate radionuclide identification. The microRaider is operated through three, easy to use buttons: on/off on top, select and execute on either side, with informative display prompts shown in the display header. High-intensity status LEDs are visible from the top and front of the unit with a large, bright, full-color display. In addition to the visible alarms the microRaider also features a speaker for alarm tones and a proportional vibration alarm.

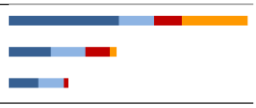
TECHNOLOGY:

The microRAIDER uses solid state, CZT detectors to acquire a gamma spectrum. This spectrum is analyzed using a template matching software to identify the isotopes present in the sample.

ANALYTICAL Laboratory Ranking

microRaider ranked in the bottom third of all evaluated products for analytical laboratories and earned 45% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
microRaider	36.70
MINIMUM SCORE	20.38

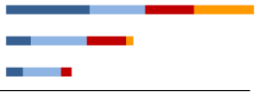


Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

microRaider ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 51% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
microRaider	42.55
MINIMUM SCORE	22.05



Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

microRaider ranked in the middle third of all evaluated products for mobile laboratories and earned 69% of the utility points of the best score.

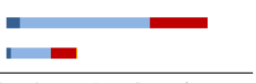
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
microRaider	57.20
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

microRaider ranked in the top third of all evaluated products for field use and earned 86% of the utility points of the best score.

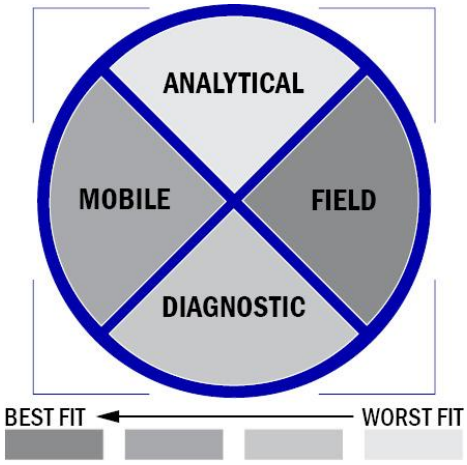
ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
microRaider	75.17
MINIMUM SCORE	26.53



Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ICx Radiation
100 Midland Rd
Oak Ridge, TN 37830

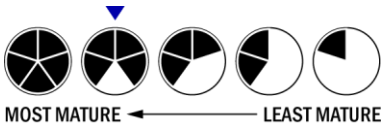
Point of Contact:
Jeff Perkins
Jeffrey.Perkins@icxt.com

COST

$8,000.00 - 10,000.00/system or device

SPECIFICITY

- False Positives: N/A
- False Negatives: N/A



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training

Operational conditions:
- Can be used from < -21°C to > 42°
- Does not require consumables
- Performance is not influenced by relative humidity
- Shelf life not applicable

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- Components not applicable

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Decon not applicable

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Amount needed to test liquid not applicable

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless and wired connections
- Could easily be adapted to fully autonomous system
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software closed, not available for modification
- System hardware closed and not available for modification

MICT Platform (Magnetic ImmunoChromatographic Test System)

by MagnaBioSciences

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (100-1,000 PFU/mL)
Toxins (<1 ng/mL)
Liquid chemical (1ppb-1ppm)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Urine, Environmental water, Soil, Food, Powder

DESCRIPTION:

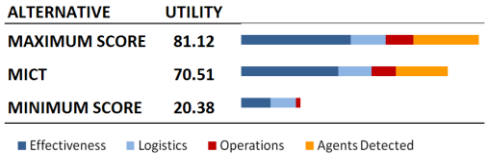
MagnaBioScienses, LLC, has developed a small Magnetic Detection Assay Instrument, with Cassette based assays for the detection of Chemical/Biological Warfare (CBW) agents. The Magnetic Assay Reader (MAR) platform is an electronic device that quantifies biochemical analytes that have been selectively and specifically bound to magnetic nanoparticles acting as reporter elements. The technology employed in the MAR detection scheme is that of magnetic induction, based on the susceptibility of superparamagnetic particles in a rapidly oscillating magnetic field. The use of magnetic particles in the Magnetic Immuno- Chromatograph Test, MICT, system provides a fast and low cost platform for biochemical assays which offer considerable advantages over visual and light-based (fluorophors, fluorescence, chemiluminescence) methods of detection. Sensor Advantages: 1. MAR Technology is reproducible, linear, and extremely sensitive. 2. Contaminates and biological fluids produce little or no background interference. 3. Magnetic reporters are chemically stable over long time periods allowing extended storage in extreme variations of temperature and humidity. 4. Assays using a magnetic reporter do not have to be optically seen or read, eliminating subjective interpretation. 5. Magnetic detection provides for a quantitative result. 6. Speed—with minimal sample preparation time, MAR measurements are preformed in less than 10 seconds The MAR technology has been demonstrated as working prototypes into lightweight, portable, handheld devices that maintain the performance the bench top instruments. The handheld devices use the identical MICT Cassettes. Such an advance would result in an instrument with significant benefits in Defense Applications: 1. Carried by and dedicated to individual Warfighters 2. Suitable for field use in hostile environments. 3. Ready for immediate use as may be required by the individual's environment 4. Applied to a wide variety of environmental matrices such as water, air, and food. 5. Used as a human diagnostic to test for infected or exposed individuals.

TECHNOLOGY:

Analyte detection using disposable immunochromatographic cassettes with magnetic colloids/labeled antibodies Bench top and handheld.

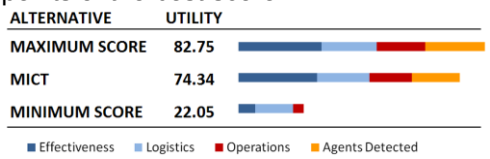
ANALYTICAL Laboratory Ranking

MICT Platform ranked in the top third of all evaluated products for analytical laboratories and earned 87% of the utility points of the best score.



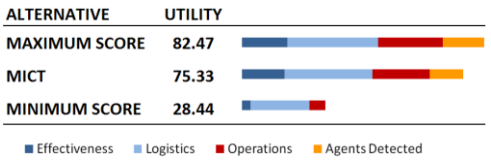
DIAGNOSTIC Laboratory Ranking

MICT Platform ranked in the top third of all evaluated products for diagnostic laboratories and earned 90% of the utility points of the best score.



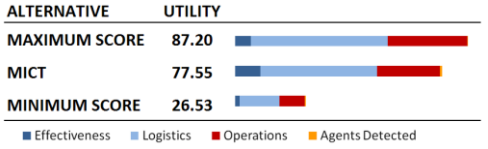
MOBILE Laboratory Ranking

MICT Platform ranked in the top third of all evaluated products for mobile laboratories and earned 91% of the utility points of the best score.



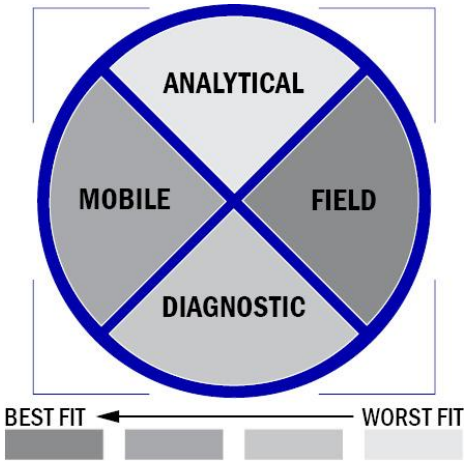
FIELD USE Ranking

MICT Platform ranked in the top third of all evaluated products for field use and earned 89% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

MagnaBioSciences
6325 Lusk Blvd suite 206
San Diego CA 9221
www.magnabiosciences.com

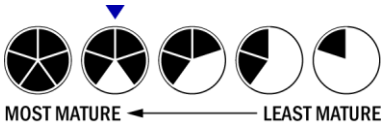
Point of Contact:
Ronald La Borde
858 481-4400 ext. 264
Jerry Daviess
858 481-4400 ext 104
Bruce Gardner
858-4400 ext 510

COST

- $5,000.00/system or device
- $2.50-3.00/assay

SPECIFICITY

- False Positives: <1%
- False Negatives: <1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- 1 sample, <10 tests/ sample per run
- Currently semi-automated

Signature:
- No sounds or alarms present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- Less than 5 minutes for set up
- Less than 1 minute down time
- 0-2 steps are required
- DVD/ Customer and Manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temperature (27°C)
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a toaster
- Commercial carrier/ Fixed and rotary wing aircraft / Ship
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- No service
- Preventive maintenance serviceable by customer
- Maintenance is included
- Expected life 5-10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires < 1hr

Physical System Requirements:
- 110V and batteries
- 4-8 hour battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time not available
- Data cannot be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance pending
- FDA approval pending
- Less than 100 ul for a test

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Not capable of autonomy
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open but modification requires licensing
- The system hardware is open but modification requires licensing

MiSeq System

by Illumina Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria
Viruses

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Environmental water, Soil

DESCRIPTION:

MiSeq is a next generation sequencer design for individual research labs. Key characteristics include rapid turnaround times, a simple workflow from sample prep to data analysis, high accuracy and output in excess of 1GB.

TECHNOLOGY:

MiSeq leverages standard molecular biology techniques to yield adapter ligated products that are then loaded onto the MiSeq system. There, the fragments are clonally amplified by bridge amplification and then sequenced using a sequencing by synthesis reversible terminator chemistry. Each based is imaged, processed and reported out as a variant call all on the same instrument.

ANALYTICAL Laboratory Ranking

MiSeq System ranked in the bottom third of all evaluated products for analytical laboratories and earned 39% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
MiSeq System	31.61
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

MiSeq System ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 44% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
MiSeq System	36.58
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

MiSeq System ranked in the bottom third of all evaluated products for mobile laboratories and earned 45% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
MiSeq System	37.24
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

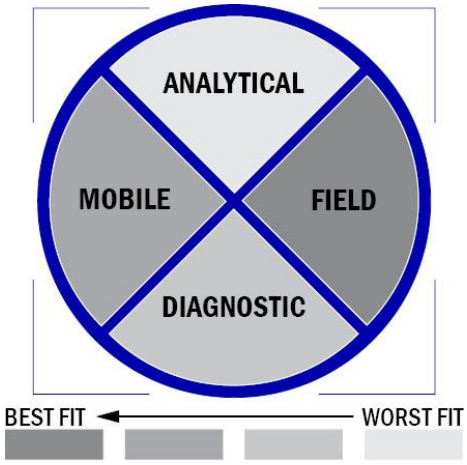
FIELD USE Ranking

MiSeq System ranked in the bottom third of all evaluated products for field use and earned 46% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
MiSeq System	39.97
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

Summary of Analysis



CONTACT INFORMATION

Illumina Inc.
9885 Towne Centre Drive
San Diego, CA 92121

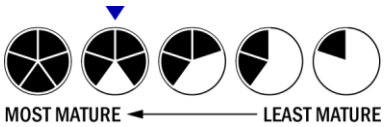
Point of Contact:
Dawn Barry
dbarry@illumina.com
203-296-0536

COST

- $125,000.00/system or device

SPECIFICITY

- False Positives: 2-3%
- False Negatives: <0.5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Could be adapted to semi-automated with some effort

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 10-20 minutes set-up
- <5 minutes down time
- 9-12 steps required
- Web video/ Customer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at room temp (27°C); must be frozen
- Impact of humidity unknown
- 6 months - 1 year shelf life

Transportation:
- Approximately the size carry-on luggage
- Transport via commercial carrier; fixed wing military and rotary wing aircraft; ship
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 2 solutions and/or reagents
- 5 or more components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance included
- Expected life 3-5 years
- 10-20 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- Single centrifugation step
- Multiple shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connections
- Not autonomous
- On board computer chip
- Will not store or archive data outputs but will create an electronic record
- System software open and available for modification
- System hardware closed and not available for modification

Mobile Laboratory

by Microscopes International

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Environmental water, Soil, Food

DESCRIPTION:

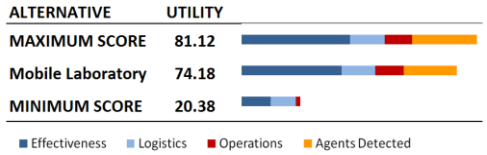
For the first time ever (patents pending), the full array of morphological (e.g., cell count, hematology, white cell differential, bacteria, fluorescent markers, tissue sample, etc.) and diagnostic tests (e.g., immunological, protein, hormonal, chemical, genetic, etc.) on the same drop of blood (or body fluid) at wavelength limited resolution and fully automated, can be run by a child on a USB plug-and-play system. The system is mobile, can be USB or battery powered, is the size of an external hard drive and has an overnight FedEx shipping weight of 3.5 lbs.

TECHNOLOGY:

The system receives a disposable carrier having a demographically or geographically derived matrix of 5-100 tests – demographically derived may focus on age, combat situations, exposure expectations; geographically derived may focus on a combination of demographics along with the unique issues associated with the location. A sample is added, no pre-processing, and placed in the unit for automated analysis. In the US it is expected to reduce primary health care costs by at least 50%; and to be sold in chain stores (e.g., Wal-Mart, Walgreens, etc.).

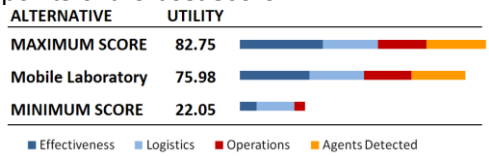
ANALYTICAL Laboratory Ranking

Mobile Laboratory ranked in the top third of all evaluated products for analytical laboratories and earned 91% of the utility points of the best score.



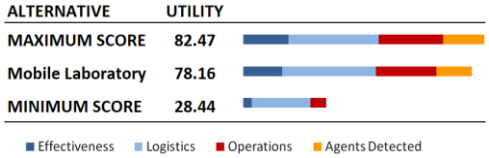
DIAGNOSTIC Laboratory Ranking

Mobile Laboratory ranked in the top third of all evaluated products for diagnostic laboratories and earned 92% of the utility points of the best score.



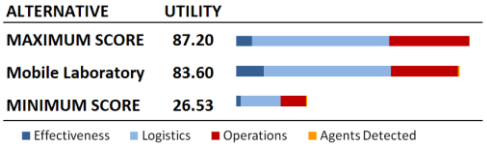
MOBILE Laboratory Ranking

Mobile Laboratory ranked in the top third of all evaluated products for mobile laboratories and earned 95% of the utility points of the best score.



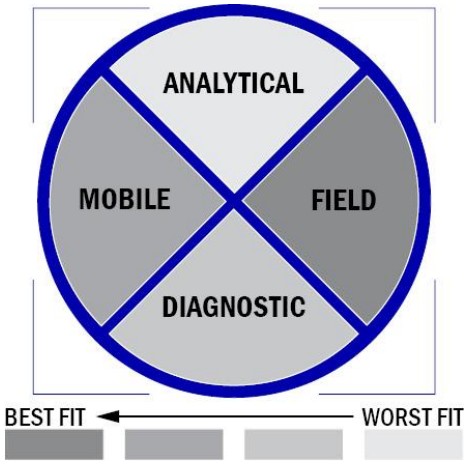
FIELD USE Ranking

Mobile Laboratory ranked in the top third of all evaluated products for field use and earned 96% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Microscopes International
555 Republic Drive, MS 105
Plano, TX 75074

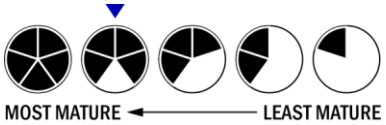
Point of Contact:
Glenn Spaulding
281-827-4707

COST

- $10,000.00/system or device
- $20.00/analysis

SPECIFICITY

- False Positives: Not Applicable
- False Negatives: Not Applicable



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- < 5 minutes set up
- < 1 minute down time
- 0-2 steps are required
- Customer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be stored at room temperature but can withstand temps > 45°C for periods < 24 hours
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All means of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance is included
- Expected life greater than 10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Batteries
- < 1 hour battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software could call final result in future

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 50 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Satellite, wireless and wired connections
- Autonomous system with easy adaptation
- Onboard computer chip
- Could be adapted to store and archive data outputs and create an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

Mobile Radiation Detection & Monitoring System

by Radiation Solutions Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Identification of specific isotopes

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

The RS-700 Series are self-contained gamma-ray and neutron (optional) radiation detection and monitoring systems. They can be used in land vehicles, helicopters or at a fixed site. The system has a built in GPS receiver to accurately locate each measurement. It is also supplied with the RadAssist survey program for user control, monitoring and recording. The system is flexible enough to permit real-time monitoring with a computer or operate in a stand alone configuration with the data being recorded internally and later retrieved. Alternatively, the data can be transmitted to a central command point in real time stored and transmitted at a later time. The RS-700 utilizes advanced DSP / FPGA technology and software techniques that provide laboratory levels of spectral performance that were previously unachievable on mobile platforms. Despite its state-of-the-art technology, the RS-700 is extremely operator friendly and can be rapidly deployed. The system provides - full 1024 channel spectrum - navigation track with 'breadcrumb' trail - Mapping displays - nuclide identification - alarm capability.

TECHNOLOGY:

A basic RS-700 system uses a 256 or 128 cubic inch sodium iodide detector as its primary detector. Other types are optionally available. Up to five detectors can be placed on the system The heart of the system is the Advanced Digital Spectrometer (ADS) module. Each individual NaI crystal detector has its own high speed analog to digital converter and a DSP / FPGA processor assembly. This module converts the analog signal from the detector to a digital spectrum with a 1,000,000 channel resolution. Using a unique detector energy calibration curve stored in the ADS assembly, the spectrum is linearized and compressed to the system's active 1024 channel resolution.

ANALYTICAL Laboratory Ranking

Mobile Radiation Detection & Monitoring System ranked in the middle third of all evaluated products for analytical laboratories and earned 40% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
Mobile Radiation Detection System	32.42
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

Mobile Radiation Detection & Monitoring System ranked in the top third of all evaluated products for diagnostic laboratories and earned 43% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
Mobile Radiation Detection System	35.89
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

Mobile Radiation Detection & Monitoring System ranked in the top third of all evaluated products for mobile laboratories and earned 55% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
Mobile Radiation Detection System	45.84
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

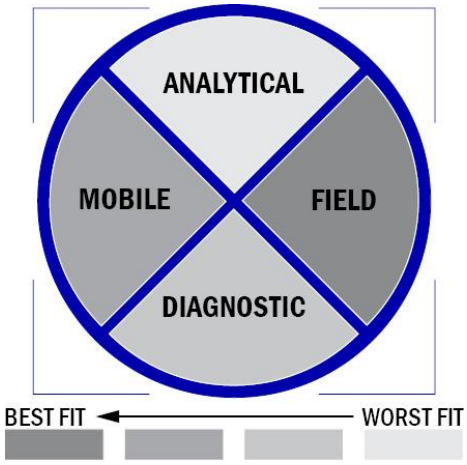
Mobile Radiation Detection & Monitoring System ranked in the top third of all evaluated products for field use and earned 64% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
Mobile Radiation Detection System	56.21
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

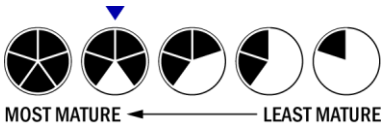
Radiation Solutions Inc.
386 Watline Ave
Mississauga, Ontario
Canada L4Z 1X2

COST

- Information not available

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, single tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Thermal output information not available

Training and Speed:
- An afternoon of training and some technical skills required
- >5 minutes set-up
- Almost instantaneous down time
- Number of manual steps information not available
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Used from < -21°C to > 42°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Shelf life not applicable

Transportation:
- Approximately the size of carry-on luggage
- Transport via commercial carrier; fixed wing military and rotary wing aircraft; ship
- Weighs between 5 and 25 kg

Re-use:
- On-going radiation detection
- Number of solutions, buffer, and/or reagents not applicable
- Number of components not applicable

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life >10 years
- <5 minutes daily QA
- Decon not applicable

Physical System Requirements:
- Operates from 10-40VDC (also supplied with 110/220 adapter)
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Nuclide Identification is occurring simultaneously with general monitoring
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Amount to test liquids information not available

System Maturity:
- Is commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property owned

Interoperability and System Complexity:
- < 250 GB raw data generated
- Network capable
- Wireless, wired connections
- Could easily be adapted to fully autonomous system
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software closed, not available for modification
- Hardware closed, not available for modification

Modernized AN/ PDR-75 Radiac

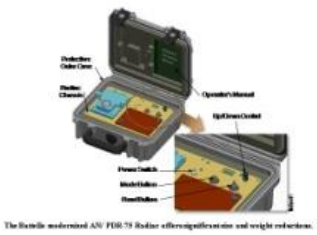
by Battelle Memorial Institute

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types

DETECTION MATRICES:

Nothing demonstrated.



The Battelle modernized AN/ PDR-75 Radiac offers significant size and weight reductions.

DESCRIPTION:

The AN/ PDR-75 Radiac measures the radiation exposure recorded by the DT-236 Dosimeter. The modernized AN/ PDR-75 radiac provides full compatibility with the DT-236 Dosimeter to improve reliability and operations, mitigate obsolescence, reduce size, weight, and power, and lower cost.

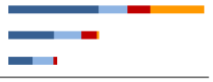
TECHNOLOGY:

The Battelle Modernized AN/ PDR-75 Radiac uses and ultraviolet light emitting diode to illuminate the DT-236 Dosimeter and modern, rugged, solid-state circuitry to perform calibration and operations. Similar to the AN/ PDR-75 Radiac, the modernized radiac includes a gamma channel, a neutron channel, operator controls, and a display.

ANALYTICAL Laboratory Ranking

Modernized AN/ PDR-75 Radiac ranked in the bottom third of all evaluated products for analytical laboratories and earned 46% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
Modernized AN/ PDR-75 Radiac	37.61
MINIMUM SCORE	20.38

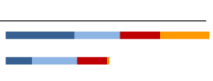


Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

Modernized AN/ PDR-75 Radiac ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 51% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
Modernized AN/ PDR-75 Radiac	42.10
MINIMUM SCORE	22.05

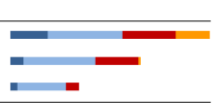


Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

Modernized AN/ PDR-75 Radiac ranked in the middle third of all evaluated products for mobile laboratories and earned 65% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
Modernized AN/ PDR-75 Radiac	53.82
MINIMUM SCORE	28.44



Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

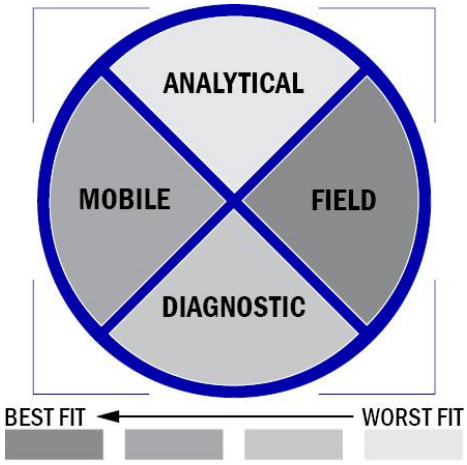
Modernized AN/ PDR-75 Radiac ranked in the middle third of all evaluated products for field use and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
Modernized AN/ PDR-75 Radiac	69.81
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Battelle Memorial Institute
505 King Avenue
Columbus, OH 43201-2693

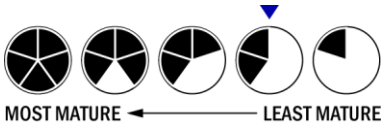
Point of Contact:
Ron Gorenflo

COST

- $5,800.00/system or device

SPECIFICITY

- False Positives: Not applicable
- False Negatives: Not applicable



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, single tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- <5 minutes set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard copy manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Will read multiple dosimeters
- 3 solutions, buffer, and/or reagents
- No consumables

Maintenance:
- Service not required
- Preventive maintenance not applicable
- Maintenance not included
- Expected life >10 years
- <5 minutes QA required
- Decontamination not applicable

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System could call final result in the future

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Bread board
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Not autonomous
- No computer required
- Could be adapted to store and archive data outputs, create an electronic record
- Software open, modification requires licensing
- Hardware open, modification requires licensing

Morphix ChemBio Detector

by Morphix Technologies

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

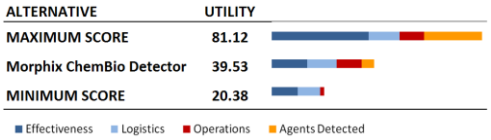
In January 2005, Morphix Technologies was awarded a contract by the Defense Threat Reduction Agency (DTRA) to develop a hand-held chemical / biological detection unit for use by the military and first responders. After completion of this two-year program, three prototypes have been developed. The wireless, electronic, chemical biological agent detector is very small (35mm x 85mm x 105mm) and weighs less than 400 grams. The Morphix chem/bio detector is easy to use. Simply insert the colorimetric coupon coated with chemical formulations specific for classes of chemical and biological agents, into the Morphix chem/bio detector and turn the unit on. Optoelectronic sensing of the coupon occurs at a predetermined rate. Upon detection of a color change on the coupon, the results are communicated wirelessly. The modular net-centric wireless communication technology is adaptable to multiple communication protocols. The modularity of this device makes it adaptable to many applications including as a personal detection badge, perimeter detection, standoff detection and mounted on an unmanned aerial vehicle or unmanned ground vehicle. Given it is the only known device capable of detecting both chemical and biological threats in such a compact package, the Morphix chem/bio detector is an excellent screening tool. This device has broad applicability within the military and first responder communities. The wireless, electronic, chemical, biological agent detection module provides broad chemical and biological agent class detection with significantly smaller size, weight, cost, training requirements and power requirements than current technologies.

TECHNOLOGY:

Generic biological agent class detection (e.g. bacterial vegetative cells or bacterial endospores) is achieved through the use of colorimetric, labeled antibodies, and fluorescence-on chemistries coupled with optical spectroscopy. Chemistries are contained in stable, proprietary formulations which have been hardened to perform under mil-spec environmental conditions.

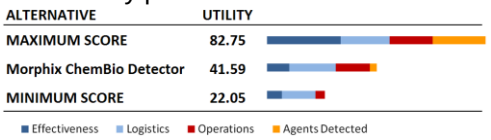
ANALYTICAL Laboratory Ranking

Morphix ChemBio Detector ranked in the bottom third of all evaluated products for analytical laboratories and earned 49% of the utility points of the best score.



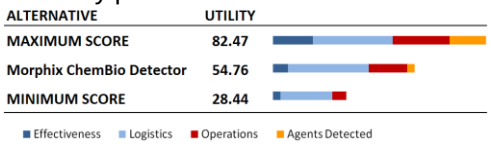
DIAGNOSTIC Laboratory Ranking

Morphix ChemBio Detector ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 50% of the utility points of the best score.



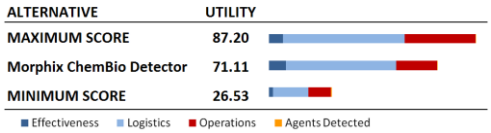
MOBILE Laboratory Ranking

Morphix ChemBio Detector ranked in the middle third of all evaluated products for mobile laboratories and earned 66% of the utility points of the best score.



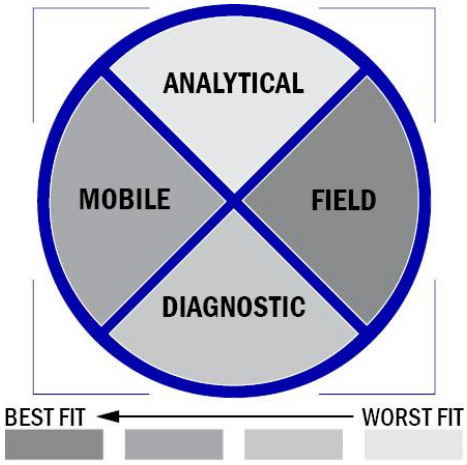
FIELD USE Ranking

Morphix ChemBio Detector ranked in the top third of all evaluated products for field use and earned 82% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Morphix Technologies
2557 Production Road
Virginia Beach VA 23454

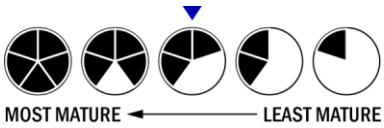
Point of Contact:
Kim Chapman

COST

- $1,500.00/system or device
- $25.00/analysis

SPECIFICITY

- False Positives: Not Available
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- 1 sample, single test/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- No screen present
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- < 5 minutes set up
- Almost instantaneous down time
- 0-2 steps are required
- Manufacturer site training

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at room temperature (27°C)
- Unknown influence of relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a soda can
- Commercial carrier
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service more often than every 6 months
- Preventive maintenance serviceable by customer
- Maintenance is included
- Expected life 1-3 years
- Less than 5 minutes QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- Batteries
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Liquids not tested

System Maturity:
- Brass board
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Autonomous system
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

MS-200 Microarray Scanner

by Roche Diagnostics Corporation Roche Applied Science

DETECTS THE FOLLOWING:
Nothing demonstrated.

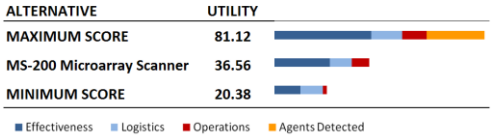
DETECTION MATRICES:
Nothing demonstrated.

DESCRIPTION:
The device accepts up to 48 microarray slides, and scans them automatically; with advanced image processing/storage functions.

TECHNOLOGY:
Ozone protection for the slides.

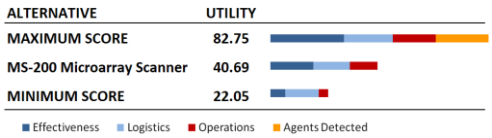
ANALYTICAL Laboratory Ranking

MS-200 Microarray Scanner System ranked in the bottom third of all evaluated products for analytical laboratories and earned 45% of the utility points of the best score.



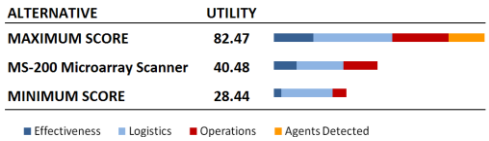
DIAGNOSTIC Laboratory Ranking

MS-200 Microarray Scanner System ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 49% of the utility points of the best score.



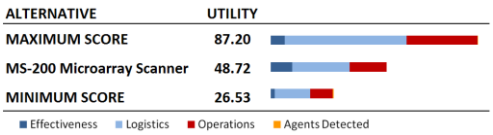
MOBILE Laboratory Ranking

MS-200 Microarray Scanner System ranked in the bottom third of all evaluated products for mobile laboratories and earned 49% of the utility points of the best score.



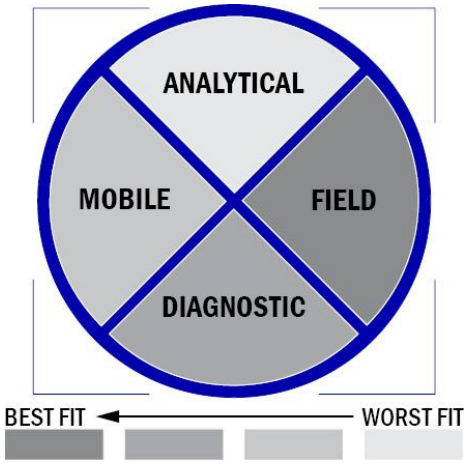
FIELD USE Ranking

MS-200 Microarray Scanner System ranked in the bottom third of all evaluated products for field use and earned 56% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Roche Diagnostics Corporation Roche Applied Science
9115 Hague Road
Indianapolis, IN 46256

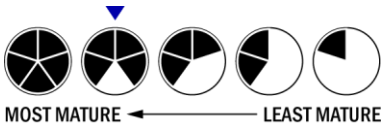
Point of Contact:
800-262-4911

COST

- $160,000/system or device
- Varies/analysis

SPECIFICITY

- False positives: Not applicable
- False negatives: Not applicable



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms can be deactivated
- Screen can be dimmed
- 200-500 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- 10-20 minutes set up
- Minimal down-time
- 3-5 steps are required
- Web video/ Customer and manufacturer site training/ Hardcopy and web manual

Operational conditions:
- Can be used from 25°C to 37°C
- Does not require consumables
- Device must be used in a temperature stable, dry environment
- > 3 years shelf life

Transportation:
- Approximately the size of a carry on suitcase
- Transport via commercial carrier/ Fixed wing military aircraft/ Ship transport
- Weighs 25-50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance is included
- Expected life 5-10 years
- No daily QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps are required
- No shaking or vortexing, mixing, degassing or filtering steps are required
- Software will not call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Does not test for liquids

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- 150-199 GB
- Network capable
- Not capable of transmitting data
- Not capable of autonomy
- High end desktop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

MSA Biosensor 2200R

by MSA

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Viruses (100-1,000 PFU/mL)
Toxins (<1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Environmental water, Powder

DESCRIPTION:

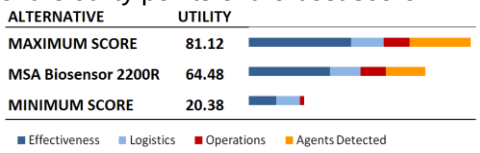
The BIOSENSOR 2200R biological agent detector is a handheld, portable, on-site instrument for rapid detection, analysis, and identification of biological agents. Unique bioassay technology offers excellent sensitivity and low false positives while offering ease of use in the field. This highly accurate detection method provides rapid measurement of biohazards such as anthrax, ricin, botulism, SEB, and plague. Exclusive five minute time-to-answer allows first responders to make informed critical decisions more rapidly than any other biological agent detector. The BIOSENSOR 2200R employs dynamic surface generation, a patent pending type of immunomagnetic assay detection technology. This technology offers significant advantages over other field-based assay methods by combining the benefits of both the free solution and lateral flow types. The result is more rapid analysis, a user-friendly format, and detector stability within a wide range of climates. Both wet and dry samples may be tested and results are displayed with a simple red (target present) or green (no target present) indication. As tests are nondestructive, samples may be retained as evidence. Single-test, disposable cartridges with on-board reagents have a 16 month shelf life. This instrument is IP 67 certified and permanently housed in a sturdy, light weight fully decon-able Pelican case. Recent research and development has demonstrated that the Biosensor 2200R can identify targets in whole blood and can be utilized as a human diagnostic device.

TECHNOLOGY:

The BIOSENSOR 2200R employs dynamic surface generation, a patent pending type of immunomagnetic sandwich assay technology. 1. MIX Sample is mixed with the sensing solution which contains: a magnetic component, a fluorescent component and receptors for the biological agent(s) of interest. 2. BIND Sensing materials bind to target during incubation. 3. MAGNETIZE All bound and unbound magnetic material is pulled to surface. 4. WASH All remaining sensing and non-target material is washed away. False positives are virtually eliminated by removing potential interferants. 5. READ Concentrated sample (pellet) is illuminated and emits a signal if target is present.

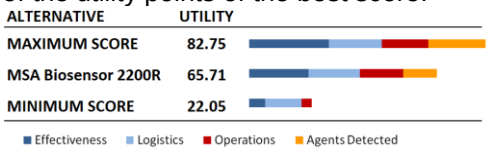
ANALYTICAL Laboratory Ranking

MSA Biosensor 2200R ranked in the top third of all evaluated products for analytical laboratories and earned 79% of the utility points of the best score.



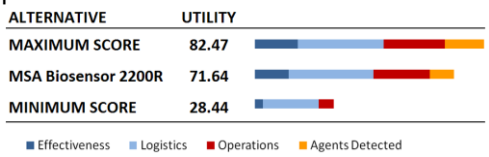
DIAGNOSTIC Laboratory Ranking

MSA Biosensor 2200R ranked in the top third of all evaluated products for diagnostic laboratories and earned 79% of the utility points of the best score.



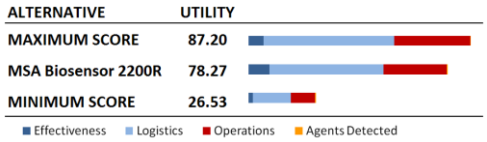
MOBILE Laboratory Ranking

MSA Biosensor 2200R ranked in the top third of all evaluated products for mobile laboratories and earned 87% of the utility points of the best score.



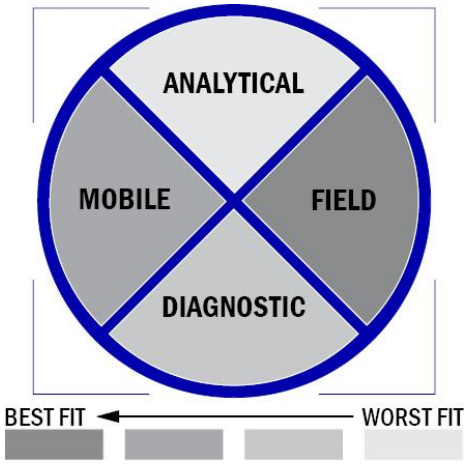
FIELD USE Ranking

MSA Biosensor 2200R ranked in the top third of all evaluated products for field use and earned 90% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

MSA
1000 Cranberry Woods Drive
Cranberry Township PA 16066

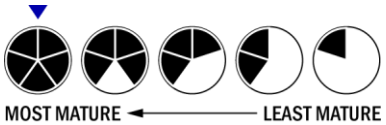
Point of Contact:
Norm Davis
Norm.Davis@MSAnet.com
w (724) 776-8884
c (412) 551-1017

COST

- $15,995.00/system or device
- <$50.00/analysis

SPECIFICITY

- False Positives: 0.0001%
- False Negatives: 0.01%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- 1 sample, <10 tests/ sample per run
- Currently semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- No set up required
- Almost no down time
- 6-8 steps are required
- DVD/ Web video/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can withstand temps > 45°C for periods of less than 24 hours
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All means of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 3 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- No service required
- Preventive maintenance N/A
- Maintenance is included
- Expected life greater than 10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Batteries
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- A single shaking or vortexing, mixing, degassing or filtering step required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 10 ul for a test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Not network capable
- Wired connections
- Not capable of autonomy
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

MSA BIOSENSOR 4000

by MSA

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Viruses (100-1,000 PFU/mL)
Toxins (<1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Environmental water, Soil, Powder, Insect vectors

DESCRIPTION:

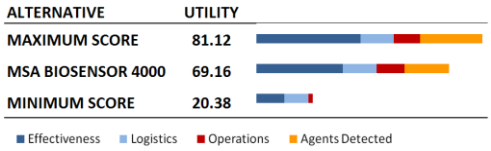
The BIOSENSOR 4000, built on the proven technology of the Biosensor 2200R, offers first responders and emergency medical technicians an automated instrument to further advance biological agent detection in the field, on the ambulance and in the laboratory. The BIOSENSOR 4000 fully automates the detection process from wet or dry sample introduction to result with no other user interaction required. The assay cartridge enables users to test simultaneously for up to eight pathogens. Unique bioassay technology offers excellent sensitivity and low false positives while offering ease of use in the field. This highly accurate detection method provides rapid measurement of multiple biohazards such as anthrax, ricin, botulism, SEB, tularemia, plague, smallpox and West Nile virus. Exclusive five minute time-to-answer allows first responders to make informed critical decisions more rapidly than any other biological agent detector. The BIOSENSOR 4000 employs dynamic surface generation, a patent pending type of immunomagnetic assay detection technology. The instrument and technology offer significant advantages over other field and lab based assay methods including better sensitivity, faster analysis, a user-friendly format, and detector stability within a wide range of climates. Results are displayed with a simple red (target present) or green (no target present) indication. As tests are nondestructive, samples may be retained as evidence. This instrument is IP 67 certified and permanently housed in a sturdy, light weight fully decon-able Pelican case. Research and development has demonstrated that the BIOSENSOR 4000 can identify targets in whole blood and can be utilized as a human diagnostic device.

TECHNOLOGY:

The BIOSENSOR 4000 employs dynamic surface generation, a patent pending type of immunomagnetic sandwich assay technology. 1. MIX Sample is mixed with the sensing solution which contains: a magnetic component, a fluorescent component and receptors for the biological agent(s) of interest. 2. BIND Sensing materials bind to target during incubation. 3. MAGNETIZE All bound and unbound magnetic material is pulled to surface. 4. WASH All remaining sensing and non-target material is washed away. False positives are virtually eliminated by removing potential interferants. 5. READ Concentrated sample (pellet) is illuminated and emits a signal if target is present.

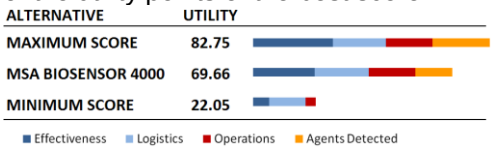
ANALYTICAL Laboratory Ranking

MSA BIOSENSOR 4000 ranked in the top third of all evaluated products for analytical laboratories and earned 85% of the utility points of the best score.



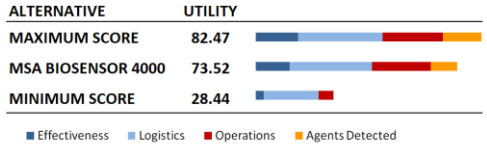
DIAGNOSTIC Laboratory Ranking

MSA BIOSENSOR 4000 ranked in the top third of all evaluated products for diagnostic laboratories and earned 84% of the utility points of the best score.



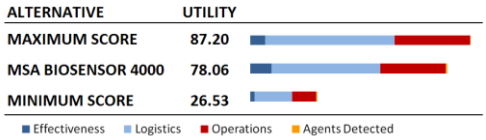
MOBILE Laboratory Ranking

MSA BIOSENSOR 4000 ranked in the top third of all evaluated products for mobile laboratories and earned 89% of the utility points of the best score.



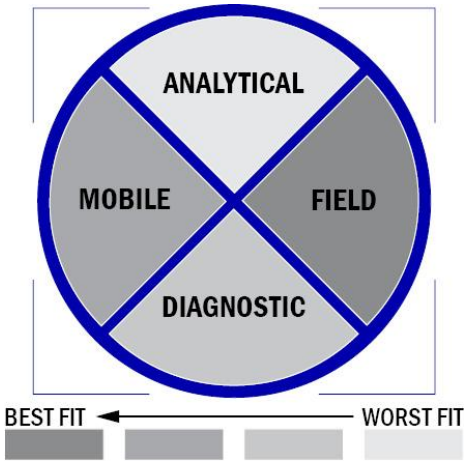
FIELD USE Ranking

MSA BIOSENSOR 4000 ranked in the top third of all evaluated products for field use and earned 90% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

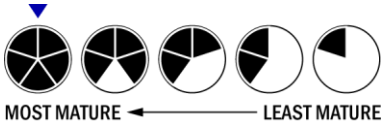
MSA
1000 Cranberry Woods Drive
Cranberry Township PA 16066
(724) 776-8884

COST

- $17,995.00/system or device
- <$75.00/8 agent analysis

SPECIFICITY

- False Positives: 0.0001%
- False Negatives: 0.01%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- 1 sample, <10 tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- No set up required
- Almost no down time
- 0-2 steps are required
- DVD/ Web video/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can withstand temps > 45°C for periods of less than 24 hours
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 3 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- No service required
- Preventive maintenance N/A
- Maintenance is included
- Expected life greater than 10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Batteries
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 10 ul for a test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Not network capable
- Wired connections
- Autonomous system with some effort
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

MSD® Cartridge Reader

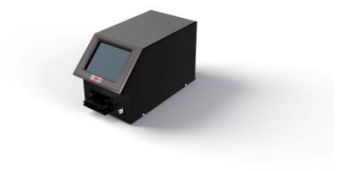
by Meso Scale Defense, a division of Meso Scale Diagnostics (MSD®)

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e3-10e4 CFU/mL)
Viruses (10e5-10e6 PFU/mL)
Toxins (<1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Urine, Environmental water, Soil, Powder



DESCRIPTION:

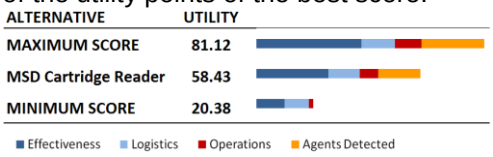
The Cartridge Reader system uses MSD's MULTI-ARRAY® electrochemiluminescence (ECL) technology to enable highly sensitive multiplexed immunoassay measurements in a compact, fully-automated format. The Cartridge Reader system consists of a compact reader instrument (12.5 lbs., 9" H x 8" W x 14" D) and single-use disposable cartridges that can conduct multiplexed measurements of up to 20 targets or controls per sample. The cartridges include integrated microfluidics to allow for fully automated sample processing and analysis without user intervention. Two cartridges types are available: one for analyzing liquid samples and the other for swab samples. To run an assay, the sample (liquid or swab) is inserted into the appropriate cartridge and the cartridge is then capped and loaded into the reader. All subsequent processing steps, including swab extraction (swab cartridge) and multiplexed ECL detection, are fully automated. The system can detect and measure bacteria, viruses, and toxins with limits of detection many times lower than lateral flow immunoassays. The system is extremely simple to operate and provides a result in about 15 minutes. The Cartridge Reader system is still under development for laboratory and point-of-care clinical and environmental testing applications and is not yet commercially released. However, the instrument has been tested at DoD technology readiness evaluations (TREs) and has been through clinical evaluations in the U.S. and other locations worldwide for influenza diagnostics.

TECHNOLOGY:

MSD's PR2 and Cartridge Reader instruments employ MSD's MULTI-ARRAY® technology that combines electrochemiluminescence (ECL) detection and array-based multiplexed measurements. ECL immunoassays enable highly sensitive measurement of samples for the presence of bacteria, viruses, and toxins. The measurements are performed on arrays printed on carbon ink electrodes that are incorporated into multi-well assay plates and cartridges. MULTI-ARRAY technology consistently has been demonstrated to provide high performance measurement capability in a wide range of matrices and in the presence of many interferents. While MULTI-ARRAY technology is primarily used for immunoassays, the technology can also be used for multiplexed nucleic acid measurements.

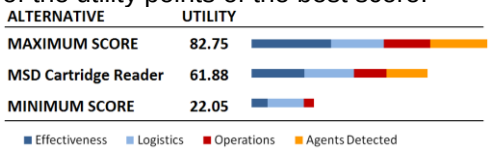
ANALYTICAL Laboratory Ranking

MSD Cartridge Reader ranked in the top third of all evaluated products for analytical laboratories and earned 72% of the utility points of the best score.



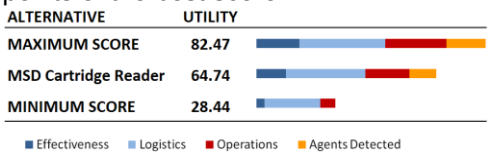
DIAGNOSTIC Laboratory Ranking

MSD Cartridge Reader ranked in the top third of all evaluated products for diagnostic laboratories and earned 75% of the utility points of the best score.



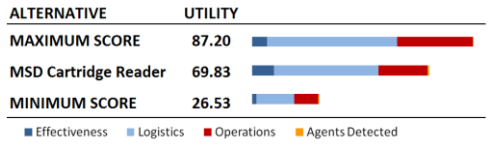
MOBILE Laboratory Ranking

MSD Cartridge Reader ranked in the top third of all evaluated products for mobile laboratories and earned 79% of the utility points of the best score.



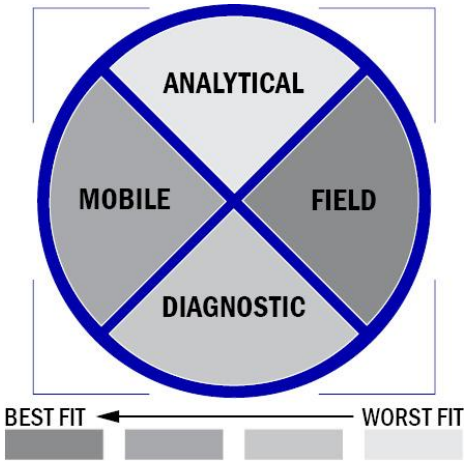
FIELD USE Ranking

MSD Cartridge Reader ranked in the top third of all evaluated products for field use and earned 80% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Meso Scale Defense, a division of Meso Scale Diagnostics (MSD®), LLC.
9238 Gaither Road
Gaithersburg, MD 20877

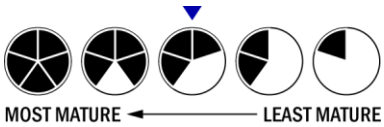
Point of Contact:
Charles Clinton
cclinton@mesoscale.com
240-631-2522 x4617

COST

- To Be Determined

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15-30 minutes for detection
- 1 sample, >10 tests/ sample per run
- Currently fully automated

Signature:
- No sounds or alarms
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes for set up
- < 1 minute down time
- 0-2 steps are required
- Customer and Manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components must be stored at 4°C / Components must be stored at room temp
- performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a toaster
- Commercial carrier
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service once a year
- Preventive maintenance unknown
- Expected life 5-10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- 4-8 hours battery power
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time not available
- Data cannot be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 250 ul for a test

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Fully autonomous system with some effort
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

MSD SECTOR® PR2 Model 1500

by Meso Scale Defense, a division of Meso Scale Diagnostics (MSD®)

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Viruses (100-1,000 PFU/mL)
Toxins (<1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Urine, Environmental air, Environmental water, Soil, Food, Powder

DESCRIPTION:

The SECTOR® PR2 instrument product line uses MSD's MULTI-ARRAY® electrochemiluminescence (ECL) technology to carry out highly sensitive, multiplexed immunoassays for biothreat agents. The PR2 instruments work with MSD's MULTI-ARRAY® 96-well assay plates. Each well of the plate has an array of up to 25 different antibodies to enable multiple targets (including bacteria, viruses, toxins and internal process controls) to be measured simultaneously. To provide stability and ease of use, the plates are sealed and contain all the required antibody reagents in dry format. The PR2 product line has been used to test a wide variety of sample types including many clinical sample types, dry filter unit extracts, aerosol samples, food and beverage samples, water, and soil samples. MSD's MULTI-ARRAY biodefense assays have undergone a range of sensitivity, near neighbor, interferent, and suspicious powder testing. The PR2 Model 1500 instrument is designed for OEM use in aerosol, water, or other sampling applications where autonomous sample analysis is desired. The Model 1500 includes a sample reservoir that accepts a 1mL liquid sample from the host system. The Model 1500 can then be commanded via the instrument's Ethernet interface to analyze the sample and provide results back to the host system in XML format. Time to result can be as short as 15 minutes. The instrument can accept a new liquid sample every five minutes and process multiple samples in parallel.

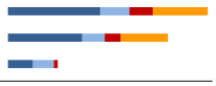
TECHNOLOGY:

MSD's PR2 and Cartridge Reader instruments employ MSD's MULTI-ARRAY® technology that combines electrochemiluminescence (ECL) detection and array-based multiplexed measurements. ECL immunoassays enable highly sensitive measurement of samples for the presence of bacteria, viruses, and toxins. The measurements are performed on arrays printed on carbon ink electrodes that are incorporated into multi-well assay plates and cartridges. MULTI-ARRAY technology consistently has been demonstrated to provide high performance measurement capability in a wide range of matrices and in the presence of many interferents. While MULTI-ARRAY technology is primarily used for immunoassays, the technology can also be used for multiplexed nucleic acid measurements.

ANALYTICAL Laboratory Ranking

MSD Sector PR2 Model 1500 ranked in the top third of all evaluated products for analytical laboratories and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
MSD SECTOR PR2 Model 1500	65.00
MINIMUM SCORE	20.38

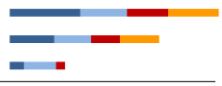


Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

MSD Sector PR2 Model 1500 ranked in the top third of all evaluated products for diagnostic laboratories and earned 72% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
MSD SECTOR PR2 Model 1500	59.30
MINIMUM SCORE	22.05

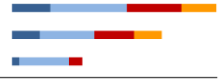


Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

MSD Sector PR2 Model 1500 ranked in the top third of all evaluated products for mobile laboratories and earned 73% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
MSD SECTOR PR2 Model 1500	60.55
MINIMUM SCORE	28.44

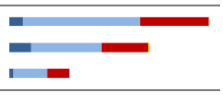


Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

MSD Sector PR2 Model 1500 ranked in the middle third of all evaluated products for field use and earned 70% of the utility points of the best score.

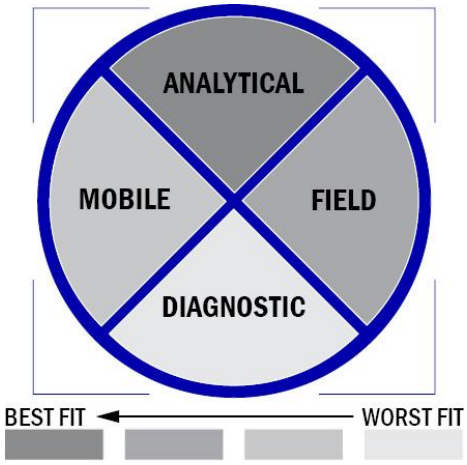
ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
MSD SECTOR PR2 Model 1500	61.24
MINIMUM SCORE	26.53



Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Meso Scale Defense, a division of
Meso Scale Diagnostics (MSD®), LLC.
9238 Gaither Road
Gaithersburg, MD 20877

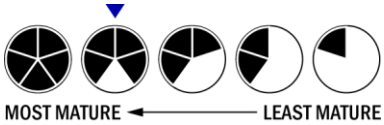
Point of Contact:
Charles Clinton
cclinton@mesoscale.com
240-631-2522 x4617

COST

- $90,000.00/system or device
- $4.50/10-plex assay

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15-30 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- No sounds or alarms
- Screen can be dimmed
- Between 200-500 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- Less than 5 minutes for set up
- 3-5 minutes down time
- 0-2 steps are required
- Customer and Manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temperature but can withstand temperatures > 45°C for periods of less than 24 hours/ Components must be stored at 4°C
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Commercial carrier
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician
- Maintenance not included
- Expected life 5-10 years
- 10-20 minutes QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time not available
- Data cannot be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Greater than 250 ul for a test

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Fully autonomous system
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

MSD SECTOR® PR2 Model 1800

by Meso Scale Defense, a division of Meso Scale Diagnostics (MSD®)

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Viruses (100-1,000 PFU/mL)
Toxins (<1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Urine, Environmental air, Environmental water, Soil, Food, Powder

DESCRIPTION:

The SECTOR® PR2 instrument product line uses MSD's MULTI-ARRAY® electrochemiluminescence (ECL) technology to carry out highly sensitive, multiplexed immunoassays for biothreat agents. The PR2 instruments work with MSD's MULTI-ARRAY® 96-well assay plates. Each well of the plate has an array of up to 25 different antibodies to enable multiple targets (including bacteria, viruses, toxins and internal process controls) to be measured simultaneously. To provide stability and ease of use, the plates are sealed and contain all the required antibody reagents in dry format. The PR2 product line has been used to test a wide variety of sample types including many clinical sample types, dry filter unit extracts, aerosol samples, food and beverage samples, water, and soil samples. MSD's MULTI-ARRAY biodefense assays have undergone a range of sensitivity, near neighbor, interferent, and suspicious powder testing. The PR2 Model 1800 instrument is a plate reader that is used for final readout of MULTI-ARRAY plates. Assay processing consists of sample introduction into the plate (125 µL), incubation (15-30 minutes), and wash steps prior to readout on the PR2 Model 1800 instrument. Using this semi-automated approach enables very high throughput testing of samples. With a 5 minute read time for 96-well plates, the PR2 Model 1800 instrument can test 1000+ samples per hour each in multiplex format up to 25-plex. The instrument includes a graphical user interface for analysis of results and an on-board database for storage of results.

TECHNOLOGY:

MSD's PR2 and Cartridge Reader instruments employ MSD's MULTI-ARRAY® technology that combines electrochemiluminescence (ECL) detection and array-based multiplexed measurements. ECL immunoassays enable highly sensitive measurement of samples for the presence of bacteria, viruses, and toxins. The measurements are performed on arrays printed on carbon ink electrodes that are incorporated into multi-well assay plates and cartridges. MULTI-ARRAY technology consistently has been demonstrated to provide high performance measurement capability in a wide range of matrices and in the presence of many interferrents. While MULTI-ARRAY technology is primarily used for immunoassays, the technology can also be used for multiplexed nucleic acid measurements.

ANALYTICAL Laboratory Ranking

MSD Sector PR2 Model 1800 ranked in the top third of all evaluated products for analytical laboratories and earned 79% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
MSD SECTOR PR2 Model 1800	63.89
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

MSD Sector PR2 Model 1800 ranked in the top third of all evaluated products for diagnostic laboratories and earned 70% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
MSD SECTOR PR2 Model 1800	58.06
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

MSD Sector PR2 Model 1800 ranked in the middle third of all evaluated products for mobile laboratories and earned 72% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
MSD SECTOR PR2 Model 1800	59.16
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

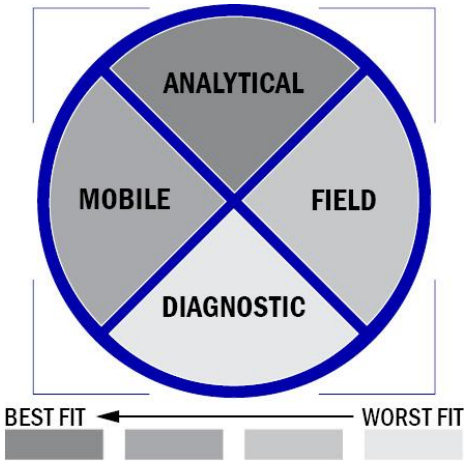
MSD Sector PR2 Model 1800 ranked in the middle third of all evaluated products for field use and earned 67% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
MSD SECTOR PR2 Model 1800	58.50
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Meso Scale Defense, a division of
Meso Scale Diagnostics (MSD®), LLC.
9238 Gaither Road
Gaithersburg, MD 20877

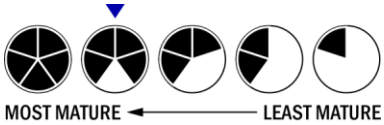
Point of Contact:
Charles Clinton
cclinton@mesoscale.com
240-631-2522 x4617

COST

- $80,000.00/system or device
- $4.50/10-plex assay

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15-30 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Currently semi-automated

Signature:
- No sounds or alarms
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- Less than 5 minutes for set up
- < 1 minute down time
- 3-5 steps are required
- Customer and Manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components stored at room temperature but can withstand temperatures > 45°C for periods of less than 24 hours/ Components stored at 4°C
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Commercial carrier
- Weighs between 25 and 0 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 3 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician
- Maintenance not included
- Expected life 5-10 years
- 10-20 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1hr

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time not available
- Data cannot be processed while in progress
- No centrifugation steps required
- Multiple shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Less than 250 ul for a test

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Fully autonomous system with easy adaptation
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The software is closed, not available for modification
- The hardware is closed, not available for modification

MSD SECTOR® PR2 Model 1900

by Meso Scale Defense, a division of Meso Scale Diagnostics (MSD®)

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Viruses (100-1,000 PFU/mL)
Toxins (<1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Urine, Environmental air, Environmental water, Soil, Food, Powder

DESCRIPTION:

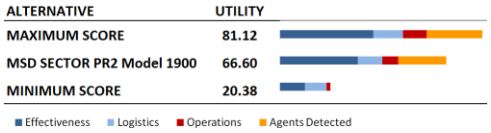
The SECTOR® PR2 instrument product line uses MSD's MULTI-ARRAY® electrochemiluminescence (ECL) technology to carry out highly sensitive, multiplexed immunoassays for biothreat agents. The PR2 instruments work with MSD's MULTI-ARRAY® 96-well assay plates. Each well of the plate has an array of up to 25 different antibodies to enable multiple targets (including bacteria, viruses, toxins and internal process controls) to be measured simultaneously. To provide stability and ease of use, the plates are sealed and contain all the required antibody reagents in dry format. The PR2 product line has been used to test a wide variety of sample types including many clinical sample types, dry filter unit extracts, aerosol samples, food and beverage samples, water, and soil samples. MSD's MULTI-ARRAY biodefense assays have undergone a range of sensitivity, near neighbor, interferent, and suspicious powder testing. The PR2 Model 1900 instrument is designed for automated sample processing and readout using MSD's MULTI-ARRAY assay plates in laboratory environments. The Model 1900 can accept multiple test tubes containing 250 µL liquid samples in the instrument's sample rack. The instrument can then be commanded via the graphical user interface to process and analyze the samples in a completely automated manner. This automation provides for very simple operation and enables multiplexed ECL testing with minimal user effort and training. The instrument can process 12 samples per hour all in multiplexed format with up to 25 assays per sample.

TECHNOLOGY:

MSD's PR2 and Cartridge Reader instruments employ MSD's MULTI-ARRAY® technology that combines electrochemiluminescence (ECL) detection and array-based multiplexed measurements. ECL immunoassays enable highly sensitive measurement of samples for the presence of bacteria, viruses, and toxins. The measurements are performed on arrays printed on carbon ink electrodes that are incorporated into multi-well assay plates and cartridges. MULTI-ARRAY technology consistently has been demonstrated to provide high performance measurement capability in a wide range of matrices and in the presence of many interferents. While MULTI-ARRAY technology is primarily used for immunoassays, the technology can also be used for multiplexed nucleic acid measurements.

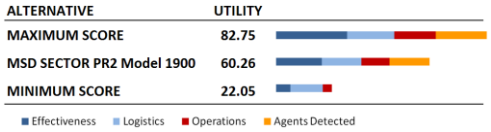
ANALYTICAL Laboratory Ranking

MSD Sector PR2 Model 1900 ranked in the top third of all evaluated products for analytical laboratories and earned 82% of the utility points of the best score.



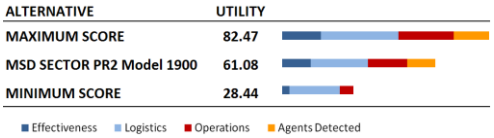
DIAGNOSTIC Laboratory Ranking

MSD Sector PR2 Model 1900 ranked in the top third of all evaluated products for diagnostic laboratories and earned 73% of the utility points of the best score.



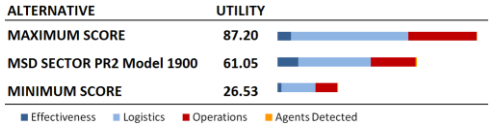
MOBILE Laboratory Ranking

MSD Sector PR2 Model 1900 ranked in the top third of all evaluated products for mobile laboratories and earned 74% of the utility points of the best score.



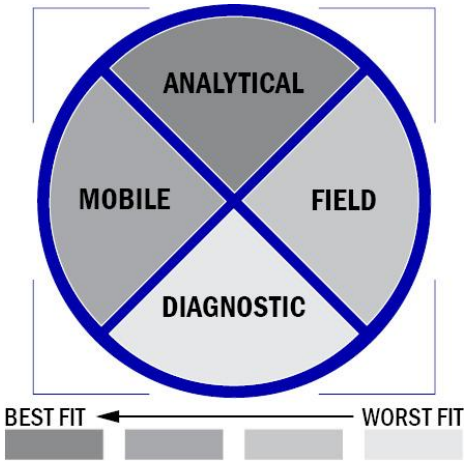
FIELD USE Ranking

MSD Sector PR2 Model 1900 ranked in the middle third of all evaluated products for field use and earned 70% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Meso Scale Defense, a division of Meso Scale Diagnostics (MSD®), LLC.
9238 Gaither Road
Gaithersburg, MD 20877

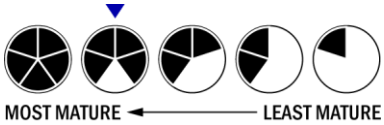
Point of Contact:
Charles Clinton
cclinton@mesoscale.com
240-631-2522 x4617

COST

- $98,000.00/system or device
- $4.50/10-plex assay

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15-30 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- No sounds or alarms
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- Less than 5 minutes for set up
- 3-5 minutes down time
- 0-2 steps are required
- Customer and Manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components stored at room temp but can withstand in excess of 45°C for < 24 hours/ Components stored at 4°C
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Commercial carrier
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician
- Maintenance not included
- Expected life 5-10 years
- 10-20 minutes QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time not available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Less than 250 ul for a test

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Fully autonomous system with some effort
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

Multiplexed Pathogen Detection at Point-Of-Use

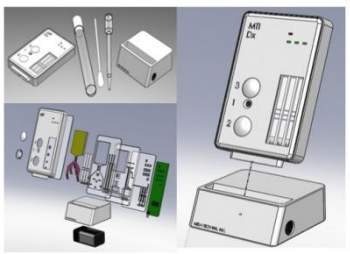
by Mesa Tech International Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swab



MESA TECH INTL INC

DESCRIPTION:

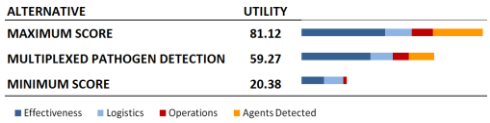
Mesa Tech International, Inc. (MTI) is maturing the disposable MTIDx (Multiple Target Identification Diagnostic) platform that integrates instrumentation-independent means of conducting all requisite steps of a nucleic acid-based molecular assay for point of use applications. MTI's instrument-independent platform, the size of an a deck of cards, will offer rapid (45 minutes), sample-to result, molecular diagnostics in a simple, self-contained disposable product that does not require investments in instruments and laboratory infrastructure. It will expand the current immuno-lateral flow rapid test market to a new generation of NA tests offering more informative (e.g. subtype, drug resistance) and sensitive diagnostic tests. It will facilitate the broader use of rapid nucleic acid diagnostics in small clinics and resource-limited settings where infectious disease diagnosis is most likely to have the greatest impact given >70% world population can't afford current PCR diagnostics. Moreover, the completely self-contained, disposable product will also enable a much higher "surge capacity" by allowing parallel tests to be run without instrumentation or "docking station" imposed bottlenecks.

TECHNOLOGY:

MTIDx incorporates nucleic acid extraction, amplification and detection into one simple stand-alone disposable device. Specifically, nucleic acids are extracted/purified using a passive buffer exchange-based sample preparation system that eliminates instrumentation and user interventions. Purified nucleic acids are rapidly amplified in low thermal mass chambers using an inexpensive microheater system. Robust amplification enzymatic reaction condition was developed suitable for use with the low cost microheaters. Amplification reaction products are detected using visual lateral flow hybridization-based detection that provides sequence specific detection amplicon. A fluidic system integrates the sample preparation, amplification and detection using the same microcontroller employed for microheater regulation.

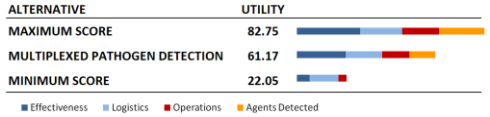
ANALYTICAL Laboratory Ranking

Multiplexed Pathogen Detection at Point-Of-Use ranked in the top third of all evaluated products for analytical laboratories and earned 73% of the utility points of the best score.



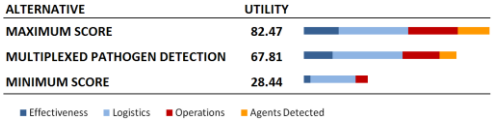
DIAGNOSTIC Laboratory Ranking

Multiplexed Pathogen Detection at Point-Of-Use ranked in the top third of all evaluated products for diagnostic laboratories and earned 74% of the utility points of the best score.



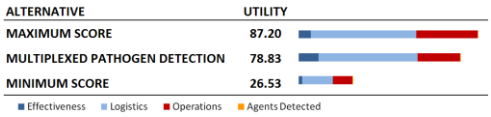
MOBILE Laboratory Ranking

Multiplexed Pathogen Detection at Point-Of-Use ranked in the top third of all evaluated products for mobile laboratories and earned 82% of the utility points of the best score.



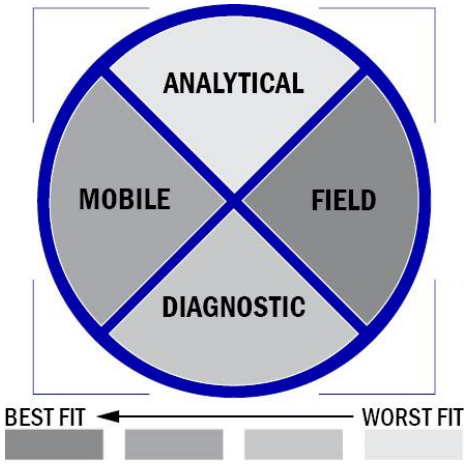
FIELD USE Ranking

Multiplexed Pathogen Detection at Point-Of-Use ranked in the top third of all evaluated products for field use and earned 90% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Mesa Tech International Inc.
Santa Fe, NM 87507

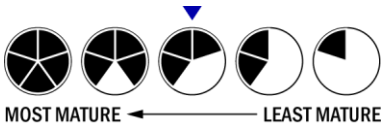
Point of Contact:
Dr. Hong Cai
hcai@mesabiotech.com
505-424-1114

COST

- $30-50/unit for the stand alone disposable test

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30 - 60 minutes for detection
- Multiple samples, multiple tests/sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- No screen
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- Down time not applicable
- 0-2 steps required
- CD/DVD

Operational conditions:
- Can be used from < -21°C to > 42°C
- Components should be stored at room temp but can stand temps > 45°C for <24 hours
- Performance is not influenced by relative humidity
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Single use
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service not required
- Preventive maintenance not applicable
- Maintenance not applicable
- Expected life not applicable
- No daily QA
- Decon not required

Physical System Requirements:
- No electrical requirement
- 1-2 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 250 ul to test liquids

System Maturity:
- Brass board
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Satellite, wireless and wired connections
- Could be fully autonomous system with some effort
- No computer required
- Does not store or archive data outputs or create an electronic record
- System does not employ software
- System hardware not applicable

MultiRAE Plus

by RAE Systems Inc.

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

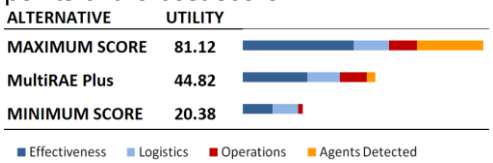
The MultiRAE Plus is a hand-held, portable gas detector containing 3 electrochemical sensors for the detection and measurement of hazardous atmospheres. The electrochemical sensors supported are oxygen and any two of the following toxic gas sensors: hydrogen sulfide gas (H2S), carbon monoxide gas (CO), Sulfur Dioxide gas (SO2), Nitric Oxide gas (NO), Nitrogen Dioxide gas (NO2), Chlorine gas (Cl2), Hydrogen Cyanide gas (HCN), Ammonia gas (NH3), and Phosphine gas (PH3). The MultiRAE Plus has a photoionization detector (PID) which uses an ultraviolet lamp and sensor to detect volatile organic compounds (VOCs) and halocarbons. The MultiRAE Plus also has a protected catalytic bead sensor for the detection of combustible gases and vapors. The MultiRAE Plus is used for gas detection in HazMat/Homeland Security, Confined Space Entry, Environmental, and Industrial Hygiene.

TECHNOLOGY:

The MultiRAE Plus has a photoionization detector (PID) which uses an ultraviolet lamp and sensor to detect volatile organic compounds (VOCs) and halocarbons.

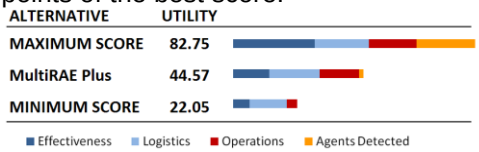
ANALYTICAL Laboratory Ranking

MultiRAE Plus ranked in the middle third of all evaluated products for analytical laboratories and earned 55% of the utility points of the best score.



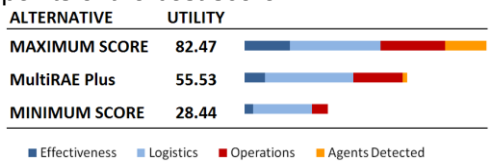
DIAGNOSTIC Laboratory Ranking

MultiRAE Plus ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 54% of the utility points of the best score.



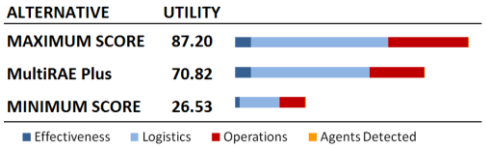
MOBILE Laboratory Ranking

MultiRAE Plus ranked in the middle third of all evaluated products for mobile laboratories and earned 67% of the utility points of the best score.



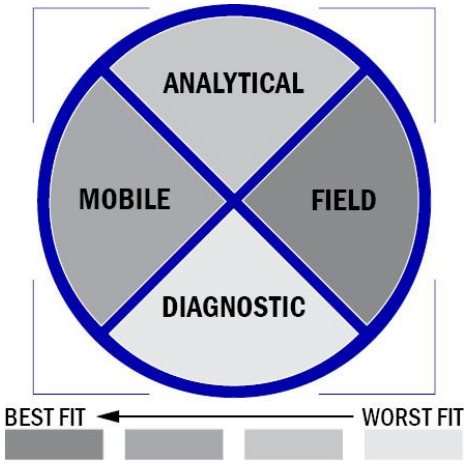
FIELD USE Ranking

MultiRAE Plus ranked in the top third of all evaluated products for field use and earned 81% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

RAE Systems Inc.
3775 N. First Street
San Jose, CA 95134

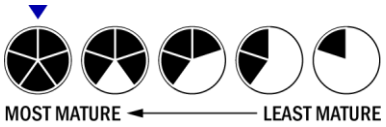
Point of Contact:
Jim Kane
757-746-5554
jkane@raesystems.com

COST

- $4,620.00/system or device

SPECIFICITY

- False Positives: Less than 5%
- False Negatives: Less than 5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, single tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- <5 minutes set-up required
- <1 minutes down time
- 3-5 steps required
- DVD/ Customer and manufacturer site training

Operational conditions:
- Can be used from -21°C to 41°C
- Components must be stored at 4°C
- Peak performance at normal relative humidity conditions
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weigh less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service more than every 6 months
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 5-10 years
- <5 minutes daily QA
- Likely that exposure to hazardous agent cannot be decontaminated

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Commercially available and meets military specifications
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- > 250 GB raw data generated
- Network capable
- Satellite, wireless and wired connections
- Fully autonomous
- Basic desktop computer
- Stores and archives data outputs and creates an electronic record
- System software open but modification requires licensing
- System hardware closed and not available for modification

MX300

by CustomArray, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)
Toxins (< 1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Urine, Environmental water, Soil, Food, Powder, Insect vectors

DESCRIPTION:

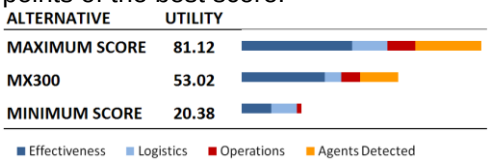
System for automating hybridization and reading of CustomArray DNA arrays, which can be used to detect organisms and genetic variants in laboratory settings. It is adaptable to any sample that has genetic material in it (either DNA or RNA).

TECHNOLOGY:

Samples must be processed to extract nucleic acid material (using third-party kits), that material is then amplified (using a standard thermocycler), and the amplified material is put into the MX300 for hybridization to a DNA array and reading of results.

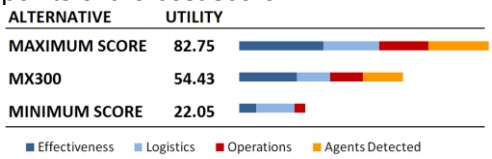
ANALYTICAL Laboratory Ranking

MX300 ranked in the middle third of all evaluated products for analytical laboratories and earned 65% of the utility points of the best score.



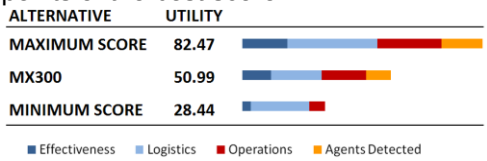
DIAGNOSTIC Laboratory Ranking

MX300ranked in the middle third of all evaluated products for diagnostic laboratories and earned 66% of the utility points of the best score.



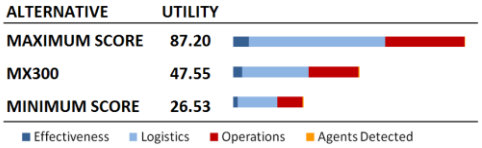
MOBILE Laboratory Ranking

MX300ranked in the bottom third of all evaluated products for mobile laboratories and earned 62% of the utility points of the best score.



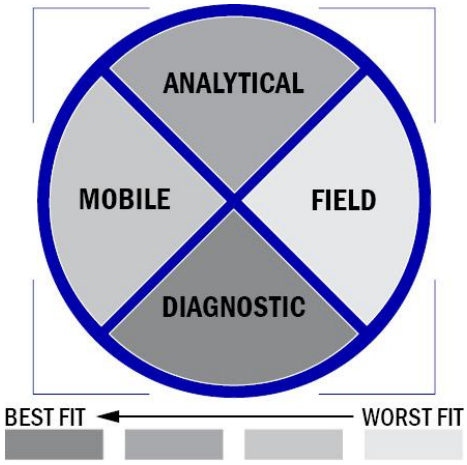
FIELD USE Ranking

MX300ranked in the bottom third of all evaluated products for field use and earned 55% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

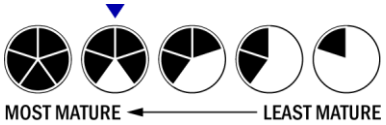
CustomArray, Inc.
6500 Harbour Hts Pkway, Suite 202
Mukilteo, WA 98275

COST

- $40,000.00/system or device
- $170.00/analysis

SPECIFICITY

- False Positives: Not Available
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated with some effort

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- More than a day of training and significant skills are required
- < 5 minutes set up
- < 5 minutes down time
- Greater than 12 steps are required
- DVD/ Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored frozen but can with stand temps > 4°C for < 24 hours
- Performance is not influenced by relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a home dishwasher
- All means of transportation
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service required once a year
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 3-5 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1 hr

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results not available
- Data can not be processed while in progress
- No centrifugation required
- Multiple shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 10 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Satellite, wireless and wired connections
- Fully autonomous system with significant effort
- Laptop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open but modification requires licensing
- The system hardware software is open but modification requires licensing

Mx3000P Mx3005P

by Agilent Technologies

DETECTS THE FOLLOWING:
Demonstrated:
Bacteria (1-100 CFU/mL)

DETECTION MATRICES:
Demonstrated:
Environmental water, Soil, Food, Powder, Insect vectors

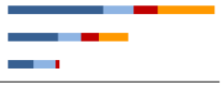
DESCRIPTION:
The Mx family of real-time cyclers delivers high-performance qPCR across multiple applications and probe chemistries. Rely on Agilent for the performance-and confidence-your work requires.

TECHNOLOGY:
An instrument used for conducting real time polymerase chain reaction assays.

ANALYTICAL Laboratory Ranking

Mx3000P Mx3005P ranked in the middle third of all evaluated products for analytical laboratories and earned 58% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
Mx3000P Mx3005P	47.31
MINIMUM SCORE	20.38

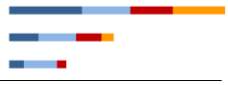


Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

Mx3000P Mx3005P ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 49% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
Mx3000P Mx3005P	40.13
MINIMUM SCORE	22.05

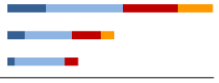


Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

Mx3000P Mx3005P ranked in the bottom third of all evaluated products for mobile laboratories and earned 52% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
Mx3000P Mx3005P	42.90
MINIMUM SCORE	28.44

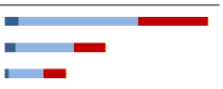


Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

Mx3000P Mx3005P ranked in the bottom third of all evaluated products for field use and earned 50% of the utility points of the best score.

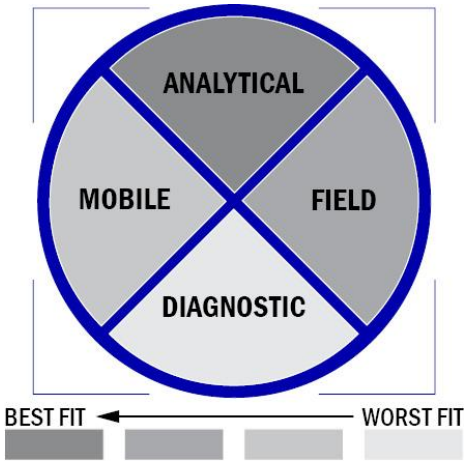
ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
Mx3000P Mx3005P	43.43
MINIMUM SCORE	26.53



Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

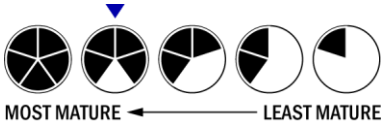
Agilent Technologies

COST

- $29,995.00/system or device

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30-60 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Adapted to semi-automated system with some effort

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Thermal output unknown

Training and Speed:
- An afternoon of training and some technical skills required
- 5-10 minutes set up
- Almost no down time
- 3-5 steps are required
- Web video/ Hard-copy manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at 4°C/ Components must be frozen
- peak performance at normal relative humidity conditions
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Ship transport
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician
- Maintenance is not included
- Expected life 5-10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software could call final result in the future

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Less than 10 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Not network capable
- No data transmission
- System not capable of autonomy
- Laptop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

nanoRaider

by ICx Radiation

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types
Identification of specific isotopes

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

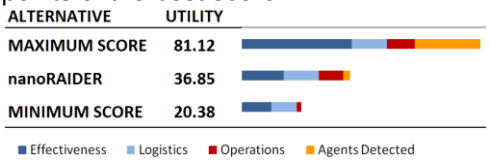
The ICx Technologies nanoRaider is a state-of-the-art Spectroscopic Personal Radiation Detector (SPRD) with solid-state, CZT detectors. The microRaider is operated through three, easy to use buttons: on/off on top, select, and execute on either side, with informative display prompts shown in the display header. As the next generation of SPRD instruments, the nanoRaider provides fast accurate identifications of isotopes.

TECHNOLOGY:

The ICx Technologies nanoRaider is a state-of-the-art Spectroscopic Personal Radiation Detector (SPRD) with solid-state, CZT detectors. The unit collects a gamma spectrum and analyzes this spectrum using a template matching algorithm to identify the isotopes in the sample.

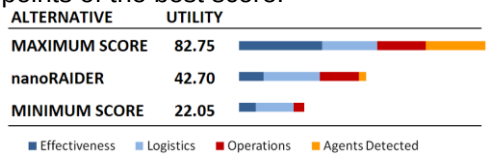
ANALYTICAL Laboratory Ranking

nanoRaider ranked in the bottom third of all evaluated products for analytical laboratories and earned 45% of the utility points of the best score.



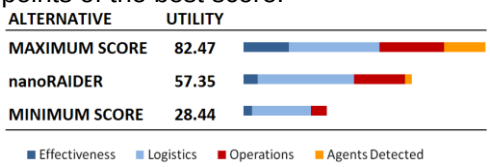
DIAGNOSTIC Laboratory Ranking

nanoRaider ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 62% of the utility points of the best score.



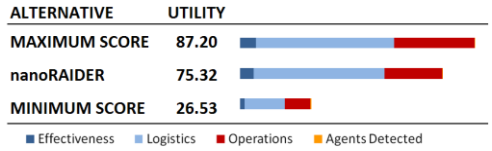
MOBILE Laboratory Ranking

nanoRaider ranked in the middle third of all evaluated products for mobile laboratories and earned 70% of the utility points of the best score.



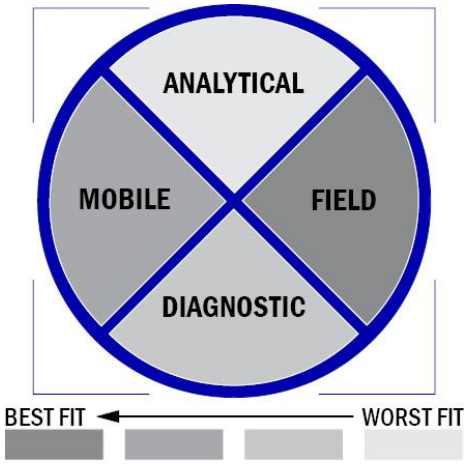
FIELD USE Ranking

nanoRaider ranked in the top third of all evaluated products for field use and earned 86% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ICx Radiation
100 Midland Rd
Oak Ridge, TN 37830

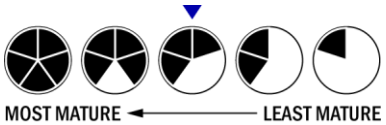
Point of Contact:
Jeff Perkins
Jeffrey.Perkins@icxt.com

COST

$6,000.00 - 8,000.00/system or device

SPECIFICITY

- False Positives: N/A
- False Negatives: N/A



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training

Operational conditions:
- Can be used from < -21°C to > 42°
- Does not require consumables
- Performance is not influenced by relative humidity
- Shelf life not applicable

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- Components not applicable

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Decon not applicable

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing, filtering
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Amount needed to test liquid not applicable

System Maturity:
- Brass board
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless and wired connections
- Could easily be adapted to fully autonomous system
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software closed, not available for modification
- Hardware closed, not available for modification

Nanosecond X-Ray Detector

by Technical Associates

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

The Nanosecond X-Ray Detector will accurately measure the integrated total dose from pulsed x-ray machines over a wide range of pulse widths and repetition rates. This monitor also measures low energies and short pulses that other survey meters ignore to the detriment of worker health. Digital readout: 6 digit-rate, 8 digits integrate dose rate and total dose read out, flat response. Sealed air ion chamber sees axially below 5 kev gamma or x-ray. Detects beta, gamma, x-ray, positrons with a fast response and wide range. Especially useful in Non-Destructive Testing or other Industrial or Medical applications where pulsed x-rays are used. End Users: US Military, Hospitals, Aircraft and Other Manufacturing.

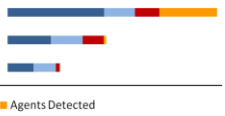
TECHNOLOGY:

The Nanosecond X-Ray Detector consists of a 2" diameter air ion chamber coupled to a stable solid state MOSFET input electrometer with built in A to D converter to read out directly in mR/h or total mR. Rate range is 0.01 R/h to 100 R/h in a single range. Dose range is 0.001R - 100R in a single range. Other Ranges are also available. Options include: Other Rate or Integrated Ranges; Other Readout Units such as Si units: Sv and Sv/h.

ANALYTICAL Laboratory Ranking

Nanosecond X-Ray Detector ranked in the bottom third of all evaluated products for analytical laboratories and earned 47% of the utility points of the best score.

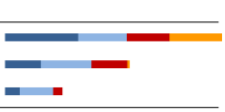
ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
Nanosecond X-Ray Detector	38.18
MINIMUM SCORE	20.38



DIAGNOSTIC Laboratory Ranking

Nanosecond X-Ray Detector ranked in the middle third of all evaluated products for diagnostic laboratories and earned 58% of the utility points of the best score.

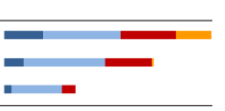
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
Nanosecond X-Ray Detector	47.63
MINIMUM SCORE	22.05



MOBILE Laboratory Ranking

Nanosecond X-Ray Detector ranked in the middle third of all evaluated products for mobile laboratories and earned 72% of the utility points of the best score.

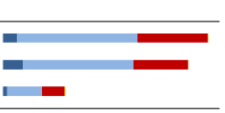
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
Nanosecond X-Ray Detector	59.59
MINIMUM SCORE	28.44



FIELD USE Ranking

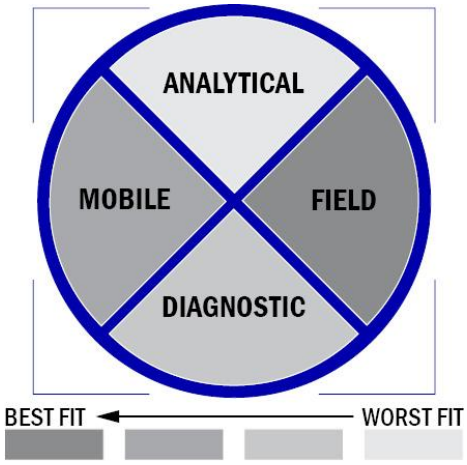
Nanosecond X-Ray Detector ranked in the top third of all evaluated products for field use and earned 90% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
Nanosecond X-Ray Detector	78.82
MINIMUM SCORE	26.53



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Technical Associates
7051 Eton Ave.
Canoga Park, CA 91303

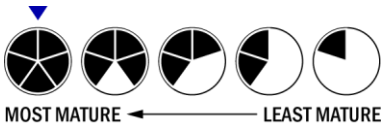
Point of Contact:
Robert Goldstein
818-883-7043

COST

- $ 3,500.00/system or device

SPECIFICITY

- False Positives: User makes determination
- False Negatives: User makes determination



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, >10 tests/ sample per run
- Could easily be adapted into a fully automated system

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 4°C to 41°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance not applicable
- Maintenance not included
- Expected life >10 years
- <5 minutes daily QA
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Does not test liquid

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB or single positive or negative response generated
- Network capable
- Wired connections
- Not autonomous
- On board computer chip
- Could be adapted to store and archive data outputs and create an electronic record
- System does not employ software
- System hardware is closed and not available for modification

NetBio Rapid DNA Analysis Systems

by NetBio, Inc

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood

DESCRIPTION:

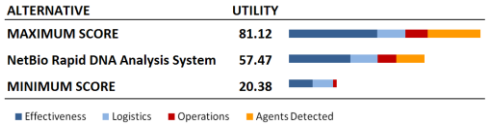
NetBio is developing a series of modular systems for biothreat detection. These field-hardened, portable instruments will provide self-verified, actionable data from clinical and environmental and samples in less than one hour. Use of DNA sequence to identify and characterize biothreats in real-time in the field will far surpass the breadth, scale, accuracy, and utility of existing technologies and will enable military and public health decisions to be made with greater speed and certainty than currently possible ConOps. System has been developed for field-forward operation by non-technical operators. All reagents are present within the consumable, and absolutely no user manipulations of reagents or sample are required. System will interrogate clinical and environmental samples. Autonomous system for routine envt'l monitoring is also in development. Biothreat platform is based on the ANDE system for human identification, a product being developed for DDR&E, FBI, and DHS, among others. Assay. System accepts a sample, and, based on microfluidic technology, purifies nucleic acids and performs DNA sequencing. System will interrogate a sample for 24 or more pathogens and sequence approximately 10 loci per pathogen. Resulting data clearly distinguishes pathogens from non-pathogenic near neighbors. System will be capable of identifying genetically modified agents, antibiotic susceptibility and viability of bacterial pathogens, and antiviral susceptibility of viral pathogens. This approach allows for the rapid (<1 hour) generation of self-verifying, actionable data.

TECHNOLOGY:

Composed of ruggedized instrument, disposable biochipset containing all required reagents, security and analytical software. Assay based on microfluidic PCR amplification, Sanger sequencing, and electrophoresis. Integrated system includes Peltier-based thermal cyclers, 488 nm laser, series of pneumatic drives to transfer materials, on-board computer for process control and analysis. Both liquid and lyophilized reagents are utilized, and the current system has been designed to meet MIL-STD-810F. Modular design allows customization based on stakeholder requirements.

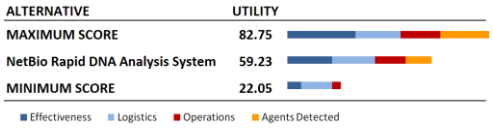
ANALYTICAL Laboratory Ranking

NetBio Rapid DNA Analysis Systems ranked in the top third of all evaluated products for analytical laboratories and earned 71% of the utility points of the best score.



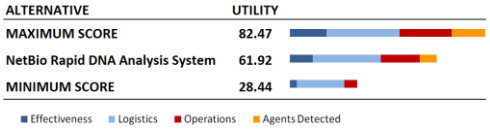
DIAGNOSTIC Laboratory Ranking

NetBio Rapid DNA Analysis Systems ranked in the top third of all evaluated products for diagnostic laboratories and earned 72% of the utility points of the best score.



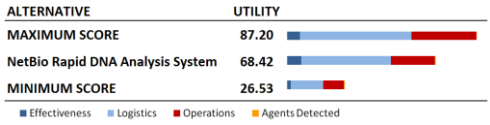
MOBILE Laboratory Ranking

NetBio Rapid DNA Analysis Systems ranked in the top third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.



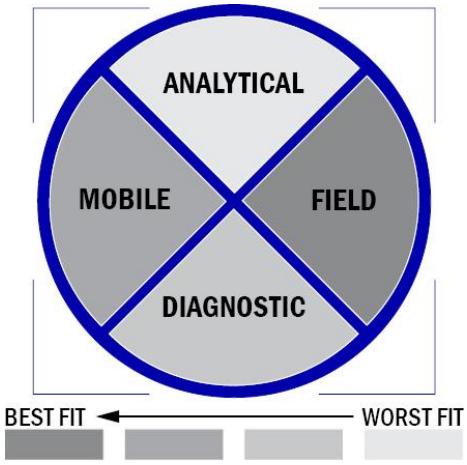
FIELD USE Ranking

NetBio Rapid DNA Analysis Systems ranked in the middle third of all evaluated products for field use and earned 78% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

NetBio, Inc
830 Winter Street
Waltham, MA 02451

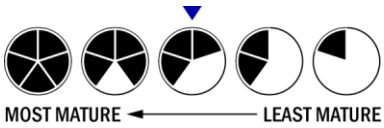
Point of Contact:
Dr. Richard F Selden
richard.selden@netbio.com
781-810-4904

COST

- $275,000.00/system or device

SPECIFICITY

- False Positives: 0
- False Negatives: 0



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30-60 minute for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps > 45°C for <24 hours
- Performance not influenced by relative humidity
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of carry-on luggage
- All modes of transportation
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life information not available
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Greater than 250 ul to test liquids

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Satellite, wireless and wired connections
- Could be fully autonomous system with some effort
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software closed, not available for modification
- System hardware closed, not available for modification

NeutronRAE II

by RAE Systems

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

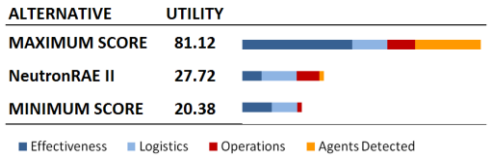
NeutronRAE II is a radiation detector to provide rapid detection of both gamma and neutron radiations. It was designed specifically to meet the needs of first responders.

TECHNOLOGY:

It uses a CsI scintillation detector for gamma detection and a LiI scintillator for neutron detection.

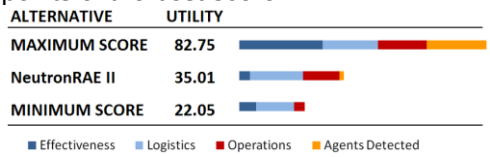
ANALYTICAL Laboratory Ranking

NeutronRAE II ranked in the bottom third of all evaluated products for analytical laboratories and earned 34% of the utility points of the best score.



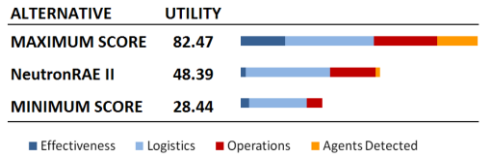
DIAGNOSTIC Laboratory Ranking

NeutronRAE II ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 42% of the utility points of the best score.



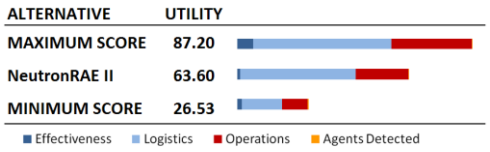
MOBILE Laboratory Ranking

NeutronRAE II ranked in the bottom third of all evaluated products for mobile laboratories and earned 59% of the utility points of the best score.



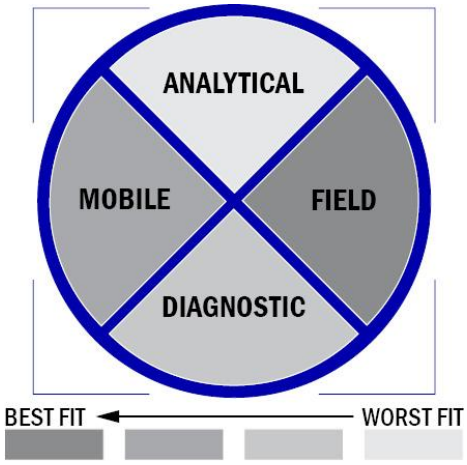
FIELD USE Ranking

NeutronRAE II ranked in the middle third of all evaluated products for field use and earned 73% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

RAE Systems
3775 North First Street
San Jose, CA 95134-1708

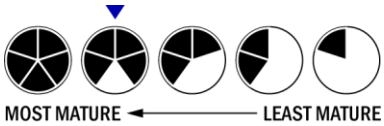
Point of Contact:
June Wang

COST

- $2,200.00/system or device

SPECIFICITY

- False Positives: <= 1 over 10 hrs.
- False Negatives: Not applicable



Evaluation Criteria Provided by Vendor

Throughput of Product:
- Alarming in 2 seconds
- No samples
- Fully automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- DVD/ Hard copy manual

Operational conditions:
- Can be used from 20°C to 50°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a soda can
- Transport via commercial carrier
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0 solutions, buffer, and/or reagents
- 0 components

Maintenance:
- Service not required
- Preventive maintenance not applicable
- Maintenance not included
- Expected life 1-3 years
- No daily QA required
- Decontamination not applicable

Physical System Requirements:
- No electrical requirement
- 500 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- Raw data generated “in MB range”
- Not network capable
- Wireless and wired connections
- Fully autonomous
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software is closed and not available for modification
- System hardware is closed and not available for modification

NIDS Auto-Reader

by ANP Technologies, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e4-10e5 CFU/mL)
Viruses (>10e5 PFU/mL)
Toxins (1-100 ng/mL)

DETECTION MATRICES:

Demonstrated:
Environmental air, Environmental water, Soil, Powder

DESCRIPTION:

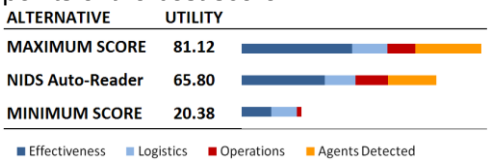
The kit consists of hand held assays and a reader for the point detection of biothreat agents. The assays are multiplexed, meaning each can detect 5 different agents with a single sample addition. The handheld reader automatically interprets assay results with the push of a single button, presenting results on a color LCD screen. An electronic record is also saved with both an image of the developed assay and numeric results for positive signal intensities. The system was originally developed for use by military first responders with light, low powder source, easy to use/maintain/decon, and rugged features that meet DOD requirements. Designed as a point detection device, a liquid sample is generated from the environment and then added to the handheld assay, allowed to develop for 15 minutes, and the results then read. Assays have been developed in both buffer and various water matrices including RO, tap and chlorinated or brominated water.

TECHNOLOGY:

The handheld assays are nanomanipulation based immunochromatographic assays using colloidal gold as a label. The nanomanipulation technology allows the antibodies to be oriented at nanoscale so that the assay sensitivity can be significantly enhanced and false positive rates can be dramatically reduced. With the incorporation of nanomanipulation technology, multiplexed assays with no Hook/Prozone effect and superior room temperature stability (i.e., over three years) can be readily produced in large quantities.

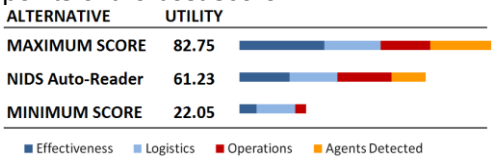
ANALYTICAL Laboratory Ranking

NIDS Auto-Reader ranked in the top third of all evaluated products for analytical laboratories and earned 81% of the utility points of the best score.



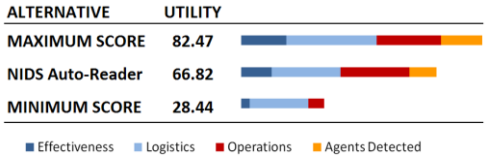
DIAGNOSTIC Laboratory Ranking

NIDS Auto-Reader ranked in the top third of all evaluated products for diagnostic laboratories and earned 74% of the utility points of the best score.



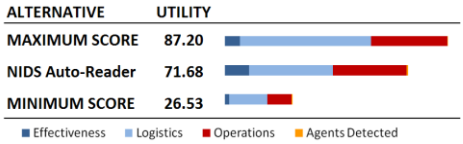
MOBILE Laboratory Ranking

NIDS Auto-Reader ranked in the top third of all evaluated products for mobile laboratories and earned 81% of the utility points of the best score.



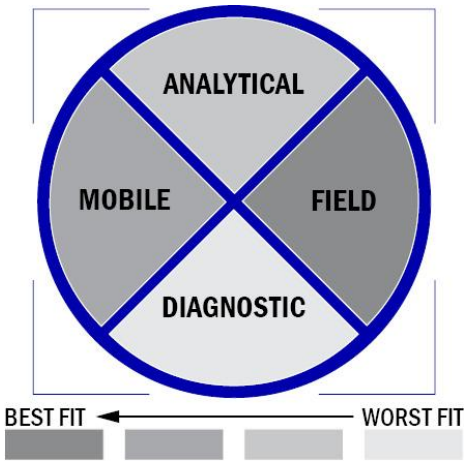
FIELD USE Ranking

NIDS Auto-Reader ranked in the top third of all evaluated products for field use and earned 82% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ANP Technologies, Inc.
824 Interchange Boulevard
Newark, DE 19711
302-283-1730

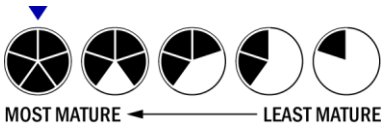
Point of Contact:
Robert Daniel

COST

- $30,000.00/system or device
- $5.00-$9.00/per target

SPECIFICITY

- False Positives: <1%
- False Negatives: <1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- No sounds or alarms
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- <5 minutes set up
- <1 minute down time
- 0-2 steps are required
- Customer and Manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can withstand temperatures in excess of 45°C for periods of less than 24 hours
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance is included
- Expected life 5-10 years
- No QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Less than 100 ul for a test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Fully autonomous system
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

NIDS Biothreat Detection Kit

by ANP Technologies, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e4-10e5 CFU/mL)
Viruses (10e4-10e5 PFU/mL)
Toxins (1-100 ng/mL)
Chemical

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Environmental air, Environmental water, Soil, Food, Powder

DESCRIPTION:

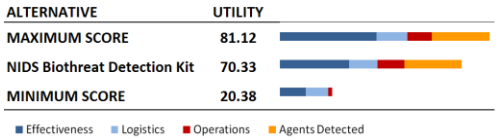
The kit consists of hand held assays and a reader for the point detection of biothreat agents. The assays are multiplexed, meaning each can detect 5 different agents with a single sample addition. The handheld reader automatically interprets assay results with the push of a single button, presenting results on a color LCD screen. An electronic record is also saved with both an image of the developed assay and numeric results for positive signal intensities. The system was originally developed for use by military first responders with light, low powder source, easy to use/maintain/decon, and rugged features that meet DOD requirements. Designed as a point detection device, a liquid sample is generated from the environment and then added to the handheld assay, allowed to develop for 15 minutes, and the results then read. Assays have been developed in both buffer and various water matrices including RO, tap and chlorinated or brominated water.

TECHNOLOGY:

The handheld assays are nanomanipulation based immunochromatographic assays using colloidal gold as a label. The nanomanipulation technology allows the antibodies to be oriented at nanoscale so that the assay sensitivity can be significantly enhanced and false positive rates can be dramatically reduced. With the incorporation of nanomanipulation technology, multiplexed assays with no Hook/Prozone effect and superior room temperature stability (i.e., over three years) can be readily produced in large quantities.

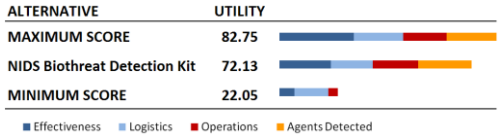
ANALYTICAL Laboratory Ranking

NIDS Biothreat Detection Kit ranked in the top third of all evaluated products for analytical laboratories and earned 87% of the utility points of the best score.



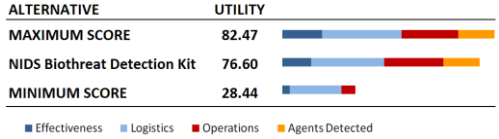
DIAGNOSTIC Laboratory Ranking

NIDS Biothreat Detection Kit ranked in the top third of all evaluated products for diagnostic laboratories and earned 87% of the utility points of the best score.



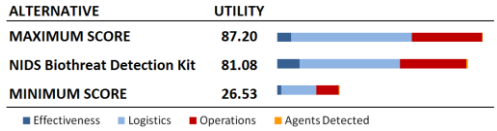
MOBILE Laboratory Ranking

NIDS Biothreat Detection Kit ranked in the top third of all evaluated products for mobile laboratories and earned 93% of the utility points of the best score.



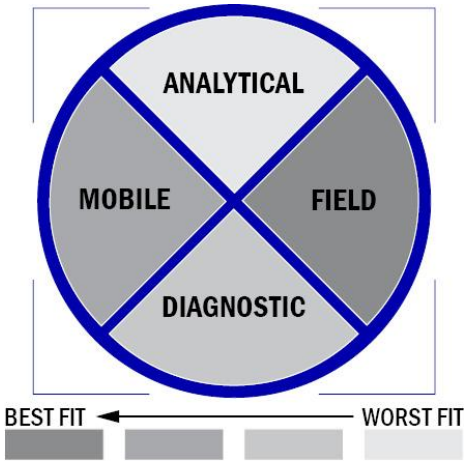
FIELD USE Ranking

NIDS Biothreat Detection Kit ranked in the top third of all evaluated products for field use and earned 93% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ANP Technologies, Inc.
824 Interchange Boulevard
Newark, DE 19711
302-283-1730

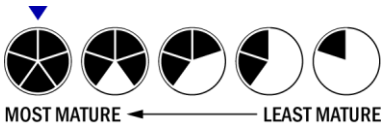
Point of Contact:
Robert Daniel

COST

- $6,500.00/system or device
- $5.00-$9.00/per target

SPECIFICITY

- False Positives: <1%
- False Negatives: <1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- 1 sample, >10 tests/ sample per run
- Currently fully automated

Signature:
- No sounds or alarms
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- No set up
- Almost no down time
- 0-2 steps are required
- Customer and Manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can withstand temps > 45°C for periods < 24 hours
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a soda can
- All means of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance is included
- Greater than 10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1 hr

Physical System Requirements:
- Batteries
- 4-8 hours battery use
- Does not require water
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- A single shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 100 ul for a test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Fully autonomous system with easy adaptation
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

NIDS Medical Reader System

by ANP Technologies, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e4-10e5 CFU/mL)
Viruses (10e4-10e5 PFU/mL)
Toxins (1-100 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Environmental air, Environmental water, Soil, Food, Powder

DESCRIPTION:

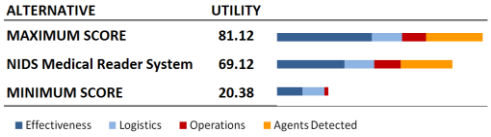
The kit consists of hand held assays and a reader for the point detection of biothreat agents. The assays are multiplexed, meaning each can detect 5 different agents with a single sample addition. The handheld reader automatically interprets assay results with the push of a single button, presenting results on a color LCD screen. An electronic record is also saved with both an image of the developed assay and numeric results for positive signal intensities. The system was originally developed for use by military first responders with light, low powder source, easy to use/maintain/decon, and rugged features that meet DOD requirements. Designed as a point detection device, a liquid sample is generated from the environment and then added to the handheld assay, allowed to develop for 15 minutes, and the results then read. Assays have been developed in both buffer and various water matrices including RO, tap and chlorinated or brominated water. The system has been modified to serve as a POC type medical assay reader.

TECHNOLOGY:

The handheld assays are nanomanipulation based immunochromatographic assays using colloidal gold as a label. The nanomanipulation technology allows the antibodies to be oriented at nanoscale so that the assay sensitivity can be significantly enhanced and false positive rates can be dramatically reduced. With the incorporation of nanomanipulation technology, multiplexed assays with no Hook/Prozone effect and superior room temperature stability (i.e., over three years) can be readily produced in large quantities.

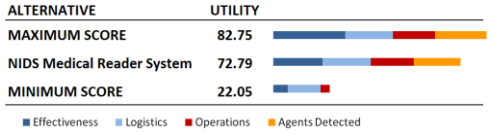
ANALYTICAL Laboratory Ranking

NIDS Medical Reader System ranked in the top third of all evaluated products for analytical laboratories and earned 85% of the utility points of the best score.



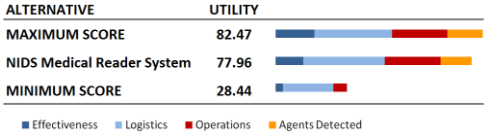
DIAGNOSTIC Laboratory Ranking

NIDS Medical Reader System ranked in the top third of all evaluated products for diagnostic laboratories and earned 88% of the utility points of the best score.



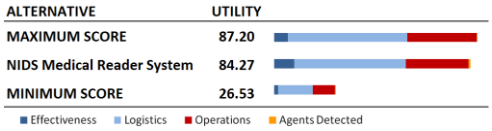
MOBILE Laboratory Ranking

NIDS Medical Reader System ranked in the top third of all evaluated products for mobile laboratories and earned 95% of the utility points of the best score.



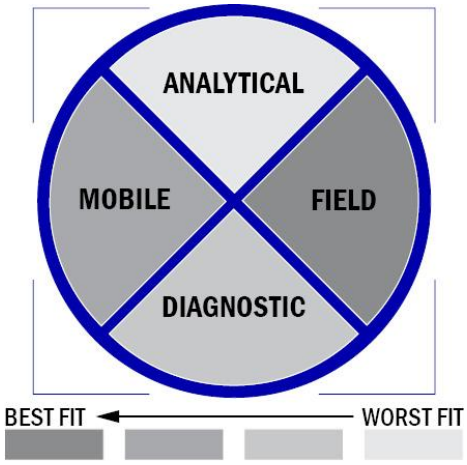
FIELD USE Ranking

NIDS Medical Reader System ranked in the top third of all evaluated products for field use and earned 97% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ANP Technologies, Inc.
824 Interchange Boulevard
Newark, DE 19711
302-283-1730

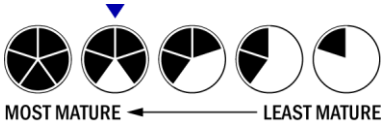
Point of Contact:
Robert Daniel

COST

- $2,500.00/system or device
- $9.00-15.00/per assay

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- 1 sample, <10 tests/ sample per run
- Currently fully automated

Signature:
- No sounds or alarms
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- No set up
- <1 minute down time
- 0-2 steps are required
- Customer and Manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can withstand temperatures in excess of 45°C for periods of less than 24 hours
- Performance is not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a soda can
- All means of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance is included
- Expected life >10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1hr

Physical System Requirements:
- Batteries
- 4-8 hours battery use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- A single shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 10 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Fully autonomous system with easy adaptation
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

NucliSens easyQ

by bioMerieux. Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (100-1,000 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swab, Stool, Urine, Wound, Environmental air, Soil, Food, Powder, Insect vectors

DESCRIPTION:

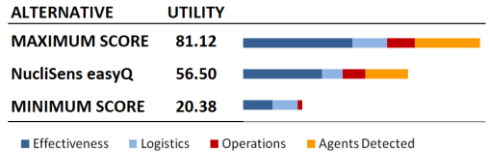
Amplification and Detection of RNA and DNA using NASBA technology of clinical specimens from body fluids.

TECHNOLOGY:

Amplification and Detection of RNA and DNA using NASBA technology of clinical specimens from body fluids.

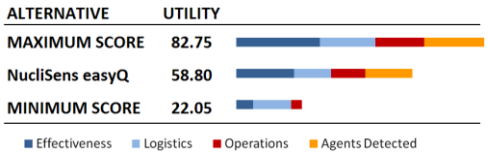
ANALYTICAL Laboratory Ranking

NucliSens easyQ ranked in the top third of all evaluated products for analytical laboratories and earned 57% of the utility points of the best score.



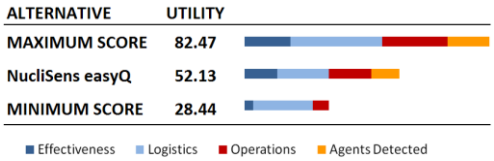
DIAGNOSTIC Laboratory Ranking

NucliSens easyQ ranked in the top third of all evaluated products for diagnostic laboratories and earned 63% of the utility points of the best score.



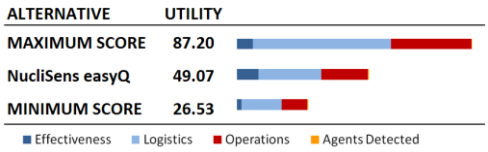
MOBILE Laboratory Ranking

NucliSens easyQ ranked in the bottom third of all evaluated products for mobile laboratories and earned 71% of the utility points of the best score.



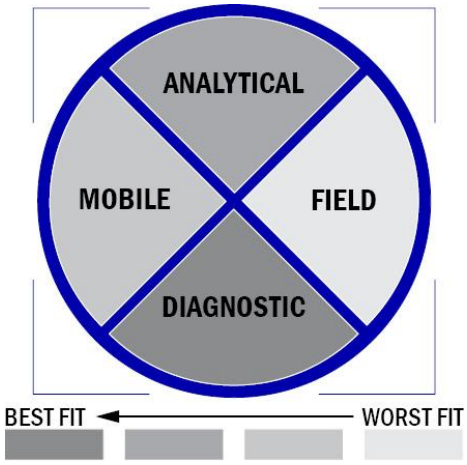
FIELD USE Ranking

NucliSens easyQ ranked in the middle third of all evaluated products for field use and earned 70% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

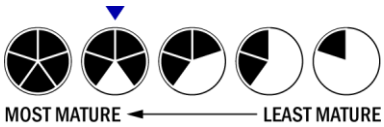
bioMerieux. Inc
100 Rodolohe St.
Durham, NC 27712

COST

- $38,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1 - 8 hours for detection
- Multiple samples, single tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- >20 minutes set-up
- 1-3 minutes down time
- 6-8 steps required
- Customer site training

Operational conditions:
- Can be used from 25°C to 37°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Peak performance at normal relative humidity conditions
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size carry-on luggage
- Via commercial carrier/ Fixed wing military aircraft
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays.
- 0-1 solutions, buffer, and/or reagents
- 3 components

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by technician only
- Maintenance included
- Expected life 3-5 years
- >5 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not requires water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- Single centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance pending
- Amount to test liquid information not available

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- 200-249 GB raw data generated
- Not network capable
- Not autonomous
- Basic desktop computer
- Stores and archives data outputs and creates an electronic record
- System software is closed and not available for modification
- System hardware is closed and not available for modification

Octet

by ForteBio

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria
Viruses
Toxins (Less than 1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Insect vectors

The Octet RED96 System

DESCRIPTION:

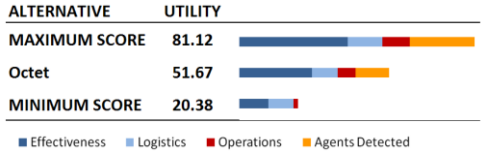
The Octet platform is intended to measure molecular binding interactions and protein concentration in crude or pure samples. It does not alter and does not consume the sample that it is measuring. It is intended for laboratory use but because it tolerates very crude samples and is somewhat compact it can be used in the field.

TECHNOLOGY:

The Octet platform uses Biolayer Interferometry. A molecular binding even on the tip of the biosensor causes a change in the optical thickness, which is read by the instrument.

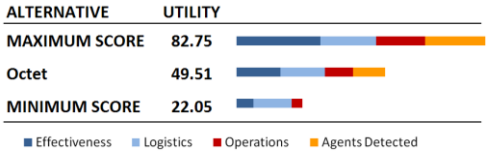
ANALYTICAL Laboratory Ranking

Octet ranked in the middle third of all evaluated products for analytical laboratories and earned 64% of the utility points of the best score.



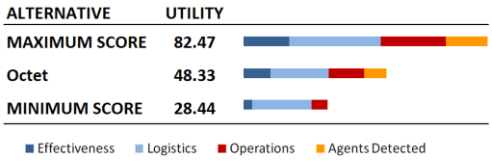
DIAGNOSTIC Laboratory Ranking

Octet ranked in the middle third of all evaluated products for diagnostic laboratories and earned 60% of the utility points of the best score.



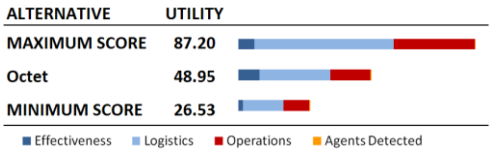
MOBILE Laboratory Ranking

Octet ranked in the bottom third of all evaluated products for mobile laboratories and earned 59% of the utility points of the best score.



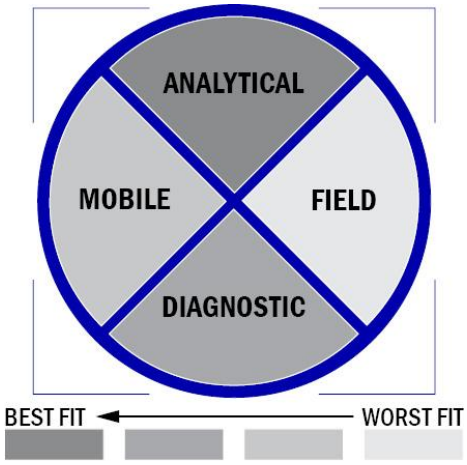
FIELD USE Ranking

Octet ranked in the bottom third of all evaluated products for field use and earned 56% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

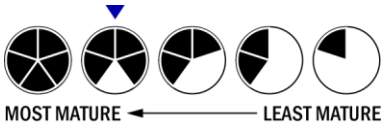
ForteBio
1360 Willow Road, Suite 201
Menlo Park, CA 94025
USA
Tel: 650.322.1360

COST

- $100,000 - 300,000/system or device

SPECIFICITY

- False Positives: <1%
- False Negatives: <1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Could easily be adapted into a fully automated system

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- >20 minutes set-up required
- Almost no down time
- 0-2 steps required
- Web video/ Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be room temp but can stand temps >45°C for <24 hours/ Must be at 27°C/ Must be at 4°C
- Impact of relative humidity unknown
- Between 1-3 years shelf life

Transportation:
- Approximately the size home dishwasher
- All modes of transportation
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life unknown
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 50 ul to test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Not network capable
- Wireless and wired connections
- Could easily be adapted into a fully autonomous system
- High end desktop computer
- Does not store or archive data outputs or create an electronic record
- System software closed and not available for modification
- Hardware closed and not available for modification

Overhoff Model 357RM Tritium Monitor

by Overhoff Technology Corporation

DETECTS THE FOLLOWING:

Demonstrated:
Identification of specific isotopes

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

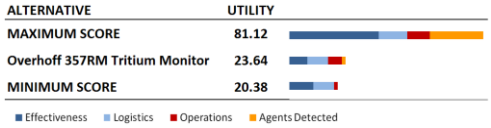
Low cost monitor for the detection and measurement of airborne Tritium. 19" rack mount configuration and also suited for table top use.

TECHNOLOGY:

Ionization chamber and electrometer technology with radon rejection circuitry.

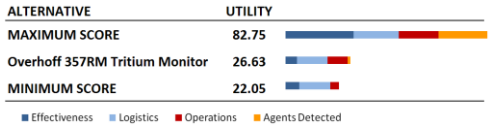
ANALYTICAL Laboratory Ranking

Model 357RM Tritium Monitor ranked in the bottom third of all evaluated products for analytical laboratories and earned 29% of the utility points of the best score.



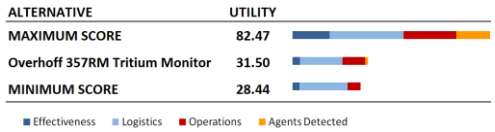
DIAGNOSTIC Laboratory Ranking

Model 357RM Tritium Monitor ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 32% of the utility points of the best score.



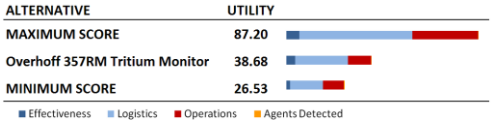
MOBILE Laboratory Ranking

Model 357RM Tritium Monitor ranked in the bottom third of all evaluated products for mobile laboratories and earned 38% of the utility points of the best score.



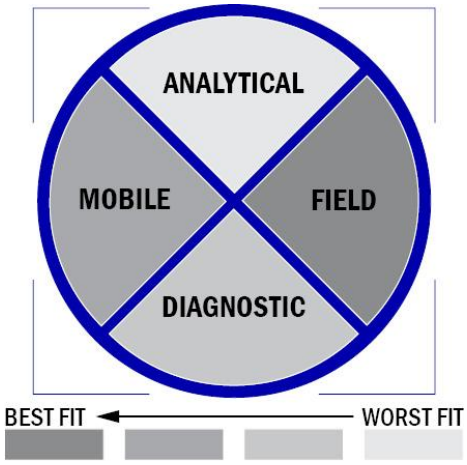
FIELD USE Ranking

Model 357RM Tritium Monitor ranked in the bottom third of all evaluated products for field use and earned 44% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Overhoff Technology Corporation
1160 U.S. Route 50
Milford, Ohio 45150

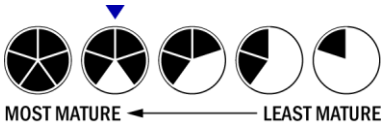
Point of Contact:
Dell Williamson

COST

- $13,250.00/system or device

SPECIFICITY

- False Positives: 0
- False Negatives: 0



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Not amenable to full or semi-automation

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- <5 minutes set-up required
- <1 minute down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard copy operators manual

Operational conditions:
- Can be used from 0°C to 50°C
- Components must be stored at room temperature (27°C)
- Peak performance at normal relative humidity conditions
- Shelf life not applicable

Transportation:
- Approximately the size of carry-on luggage
- Transport via commercial carrier/ Fixed wing military or rotary wing aircraft/ Ship
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 0 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life >10 years
- No daily QA required
- Decontamination parameters unknown

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering steps
- Final result call information not available

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Wired connections
- Not autonomous
- Computing requirement information not available
- Does not store or archive data outputs or create an electronic record
- System software closed and not available for modification
- System hardware closed and not available for modification

Overhoff Model 400AC

by Overhoff Technology Corporation

DETECTS THE FOLLOWING:

Demonstrated:
Identification of specific isotopes

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

The Model 400AC portable tritium monitor is a small, high sensitivity, hand held, battery (rechargeable) operated, fully gamma-compensated survey meter with RS232 serial data output and user recalibration features.

TECHNOLOGY:

Ionization chamber and electrometer with radon rejection circuitry.

ANALYTICAL Laboratory Ranking

Overhoff Technology Model 400AC ranked in the bottom third of all evaluated products for analytical laboratories and earned 37% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
Overhoff Model 400AC	30.28
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

Overhoff Technology Model 400AC ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 41% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
Overhoff Model 400AC	34.14
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

Overhoff Technology Model 400AC ranked in the bottom third of all evaluated products for mobile laboratories and earned 54% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
Overhoff Model 400AC	44.28
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

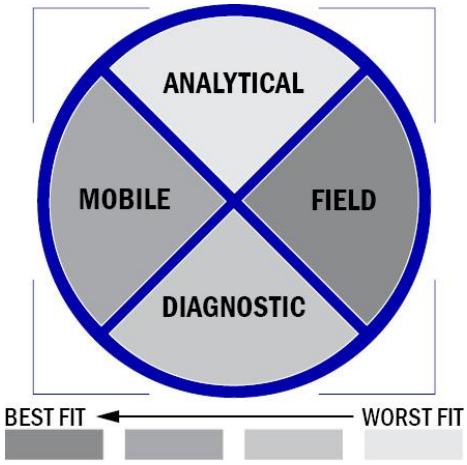
Overhoff Technology Model 400AC ranked in the middle third of all evaluated products for field use and earned 66% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
Overhoff Model 400AC	57.63
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Overhoff Technology Corporation
1160 U.S. Route 50
Milford, OH 45150

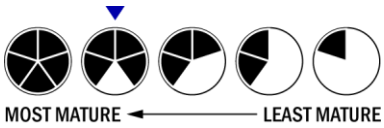
Point of Contact:
Dell Williamson
(513)248-2400
sales@overhoff.com

COST

- $12,500.00/system or device

SPECIFICITY

- False Positives: Zero
- False Negatives: Zero



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- 5-10 minutes set-up
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp (27°C)
- Impact of relative humidity on performance unknown
- Shelf life not applicable

Transportation:
- Approximately the size a toaster
- Transport via commercial carrier; fixed wing military and rotary wing aircraft; ship
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- Solutions, buffer, and/or reagents not applicable
- 1 components

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life >10 years
- <5 minutes daily QA
- Decontamination depends on concentration of tritium in the sample at the time of release

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property status unknown

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connections
- Not autonomous
- On board computer chip
- Does not store or archive data outputs or create an electronic record
- System software is closed and not available for modification
- System hardware is closed and not available for modification

Palladium Diagnostic System

by Integrated Nano-Technologies, LLC

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (100-1,000 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Environmental air, Soil, Insect vectors

DESCRIPTION:

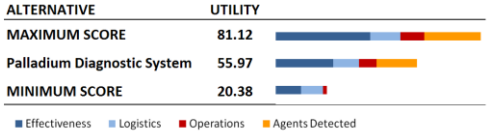
INT's Palladium System is an automated field deployable DNA based diagnostic and biological identification system. The unit can be used by first responders or as a point of care diagnostic system. The system utilizes a novel electronic array which allows for identification of multiple sequences within a sample. The current prototype system has a separate sample preparation unit. It uses PCR to amplify target sequences which provides a high degree of sensitivity and specificity. The system is designed for field use. It is under six pounds and is battery powered. Reagents do not need refrigeration. The sample preparation process is versatile and has been used to prepare target material from biological samples, such as blood, tissue, and whole insects, or environmental samples such as air filter washes or soil. Target materials evaluated on the system include DNA and RNA targets from bacteria and viruses. A second generation system is currently being engineered which will integrate all steps from sample preparation to reporting of results into a single handheld unit. The unit will also have GPS, wireless and cellular capability in order to record time, and location and report results.

TECHNOLOGY:

INT's Palladium System utilizes a novel electronic nucleic acid sensor. Target nucleic acids bind to sensors forming a bridge between electrodes. The presence of a target is determined electrically. This approach allows for a multiplexed array of sensors, for simultaneous testing for a number of targets. The system also incorporates a sample preparation process which uses nano-magnetic particles to separate and concentrate target molecules. The sample preparation process works with a wide variety of sample matrixes and with high yields using nucleic acid concentrations from femto-moles to milli-moles. Finally, the system uses a unique rotary vale disposable cartridge which is low cost and easy to manufacture. The rotary valve design allows for valving of multiple reagents with only one valve. The design of the cartridge provides flexibility to modify processing steps without the need to rework the cartridge.

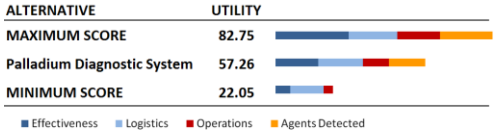
ANALYTICAL Laboratory Ranking

Palladium Diagnostic System ranked in the top third of all evaluated products for analytical laboratories and earned 70% of the utility points of the best score.



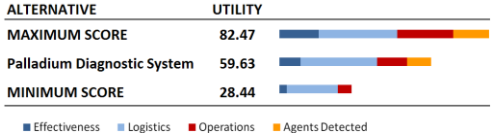
DIAGNOSTIC Laboratory Ranking

Palladium Diagnostic System ranked in the top third of all evaluated products for diagnostic laboratories and earned 69% of the utility points of the best score.



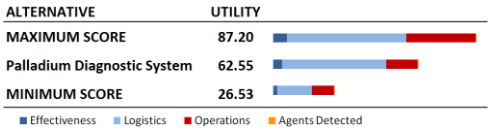
MOBILE Laboratory Ranking

Palladium Diagnostic System ranked in the middle third of all evaluated products for mobile laboratories and earned 72% of the utility points of the best score.



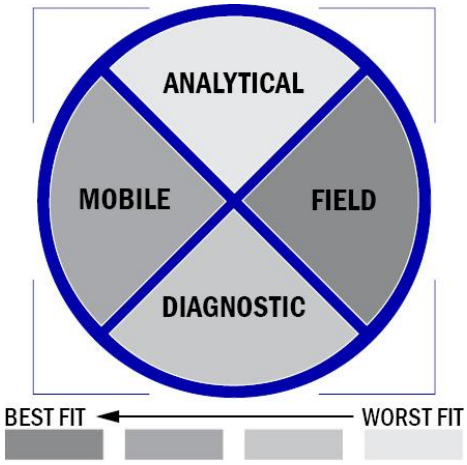
FIELD USE Ranking

Palladium Diagnostic System ranked in the middle third of all evaluated products for field use and earned 72% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Integrated Nano-Technologies, LLC
999 Lehigh Station Road
Henrietta, NY 14467

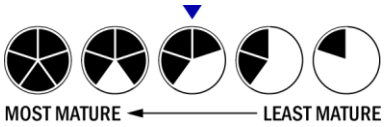
Point of Contact:
Dr. Michael Connolly
mconnolly@integratednano.com
585-334-0170 ext. 202

COST

- Approx. $10,000.00/system or device

SPECIFICITY

- False Positives: <5%
- False Negatives: <5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30 - 60 minutes for detection
- 1 sample, >10 tests/ sample per run
- Could easily be adapted into a fully automated system

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- <5 minutes set-up time
- <1 minute down time
- 6-8 steps required
- Customer site training

Operational conditions:
- Can be used from 25°C to 37°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Impact of relative humidity unknown
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 4 components

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life 3-5 years
- No daily QA required
- Likely that exposure to hazardous agent cannot be decontaminated

Physical System Requirements:
- No electrical requirement
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results not available
- Data processing while in progress information not available
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 10 ul to test liquids

System Maturity:
- Brass board
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property owned

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Wireless, wired connections
- Could be fully autonomous system with some effort
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- Software open, modification requires licensing
- Hardware open, modification requires licensing

PanNAT system

by Micronics, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1000 CFU/mL)
Viruses (100-1000 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Stool

DESCRIPTION:

The PanNAT system is a sample-to-solution, man-portable, PCR-based instrument that is mains and/or battery powered, lightweight and WiFi-enabled. It processes a microfluidics-enabled cartridge into which all reagents are integrated for extraction, amplification and detection of multiple targets from a single sample. Waste is captured on cartridge. Designed for lowest cost, the system employs molecular beacon probe technology and BTI dyes and quenchers together with Micronics' novel heating and cooling method for end point detection. It is real time capable. The system is designed for use at ambient temp; no refrigeration is required. The system is designed to meet the FDA's 510(k) Class II device and CLIA Waiver guidelines.

TECHNOLOGY:

Microfluidics-enabled sample processing of all nucleic acid assay steps with reagents integrated into the disposable cartridge for multiplex end point polymerase chain reaction detection in a man-portable point of care instrument. Novel heating and cooling platform and lowest cost fluorescent detection.

ANALYTICAL Laboratory Ranking

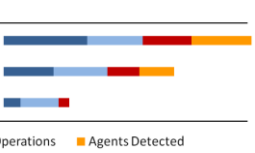
PanNAT ranked in the middle third of all evaluated products for analytical laboratories and earned 61% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
PanNAT system	49.68
MINIMUM SCORE	20.38

DIAGNOSTIC Laboratory Ranking

PanNAT ranked in the top third of all evaluated products for diagnostic laboratories and earned 69% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
PanNAT system	57.06
MINIMUM SCORE	22.05



MOBILE Laboratory Ranking

PanNAT ranked in the top third of all evaluated products for mobile laboratories and earned 76% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
PanNAT system	62.57
MINIMUM SCORE	28.44

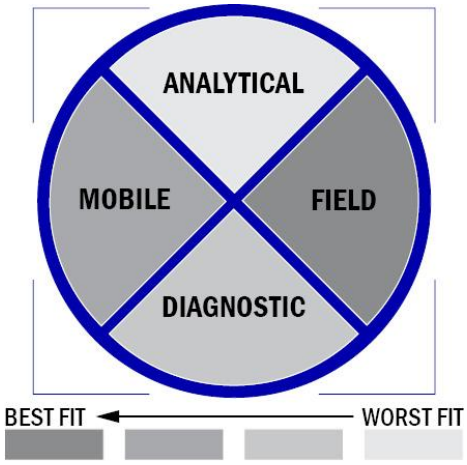
FIELD USE Ranking

PanNAT ranked in the top third of all evaluated products for field use and earned 83% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
PanNAT system	72.53
MINIMUM SCORE	26.53

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Micronics, Inc.
8463 154th Avenue N.E.
Redmond, WA 98052

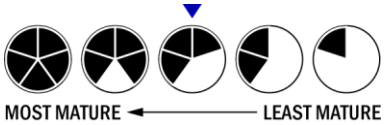
Point of Contact:
Reed Simmons VP, Manufacturing
(425)895-9197 x 141
rsimmons@micronics.net

COST

- <$8,000.00/system or device
- $4.00/ analysis

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30-60 minutes for detection
- 1 sample, >10 tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes set up
- 1-3 minutes down time
- 0-2 steps are required
- Hard copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components must be stored at room temperature (27°C)
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All means of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 4 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- No service needed
- Preventive maintenance serviceable by technician
- Maintenance is not included
- Expected life unknown
- No QA required
- The device is single use and disposable so no decontamination is needed

Physical System Requirements:
- System used batteries
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results not available
- Data cannot be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 250 ul for a test

System Maturity:
- Brass board
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Not capable of autonomy
- Onboard computer chip
- Store and archive data outputs and creates an electronic record
- The system software is open and available for modification with licensing
- The system hardware is closed and not available for modification

PASS (Product Acoustic Signature System)

by Spearhead Innovations

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

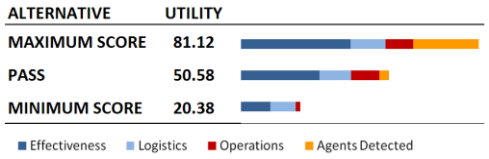
PASS uses acoustic inspection technology to rapidly, reliably, and safely interrogate sealed, liquid-filled containers and bulk solid commodities to: · Detect submerged contraband or hidden compartments · Classify/Identify material contents (by name if in database) · Expose containers/commodities that have been fraudulently labeled · Flag containers with contents different from surrounding containers · Determine container fill levels Handheld and battery-operated, PASS is designed for fast and easy use on sealed containers of various sizes, including large jugs, propane tanks, 55-gallon drums, tanker trucks, and railroad cars. Since the device makes its determinations without opening containers, its handlers and the public are protected from potentially disastrous exposure to lethal or otherwise hazardous materials and vapors. It is sensitive enough to distinguish between different grades of fuel.

TECHNOLOGY:

How it works: PASS measures the speed of sound through an unknown material at a known distance and temperature. This acoustic velocity is compared with values in a database to identify or classify material. When a signal does not reach a known distance, contraband or a hidden compartment is indicated.

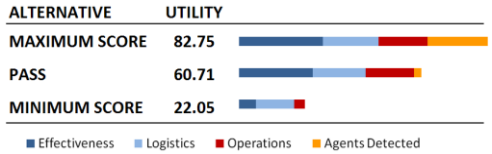
ANALYTICAL Laboratory Ranking

PASS ranked in the middle third of all evaluated products for analytical laboratories and earned 62% of the utility points of the best score.



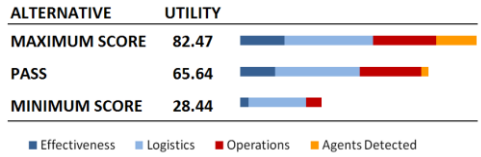
DIAGNOSTIC Laboratory Ranking

PASS ranked in the top third of all evaluated products for diagnostic laboratories and earned 73% of the utility points of the best score.



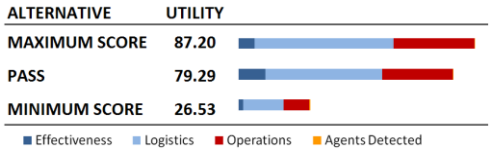
MOBILE Laboratory Ranking

PASS ranked in the top third of all evaluated products for mobile laboratories and earned 80% of the utility points of the best score.



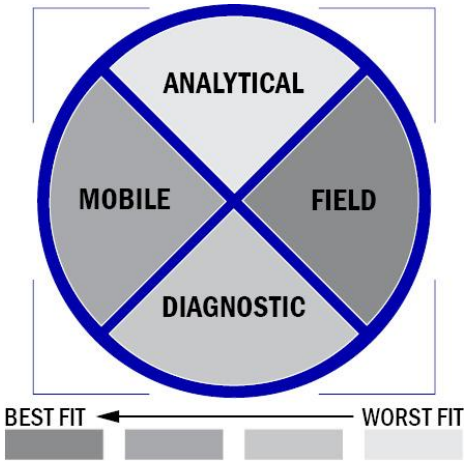
FIELD USE Ranking

PASS ranked in the top third of all evaluated products for field use and earned 91% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

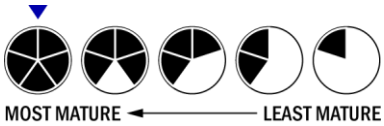
Spearhead Innovations
191 Main Street
Annapolis, MD 21401

COST

- $ 29,995.00/system or device

SPECIFICITY

- False Positives: Less than 5%
- False Negatives: Less than 5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, single tests/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- <5 minutes set-up required
- Almost instantaneous down time
- 3-5 steps required
- Customer site training

Operational conditions:
- Can be used from -21°C to 41°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weights between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life 5-10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- No electrical requirement
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance shown
- FDA clearance shown
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Not network capable
- Wireless, wired connections
- Could be fully autonomous with some effort
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software open but modification requires licensing
- System hardware open but modification requires licensing

PathSensors BioFlash-E®

by PathSensors

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (100-1,000 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

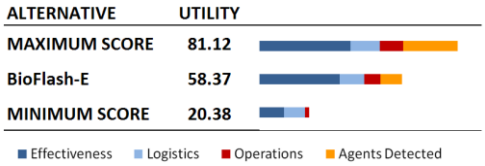
Incorporating the CANARY® technology, the BioFlash-E® Biological Identifier provides rapid, sensitive and specific identification of up to 21 biological threat agents. The portable and compact BioFlash-E® Biological Identifier offers breakthrough capabilities in sampling performance, reliability and operational cost.

TECHNOLOGY:

The BioFlash-E® Biological Identifier uses proprietary aerosol collection technology and MIT Lincoln Labs developed CANARY® detection technology to offer a complete, stand-alone solution for biological identification.

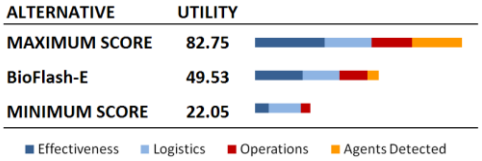
ANALYTICAL Laboratory Ranking

BioFlash-E® ranked in the top third of all evaluated products for analytical laboratories and earned 72% of the utility points of the best score.



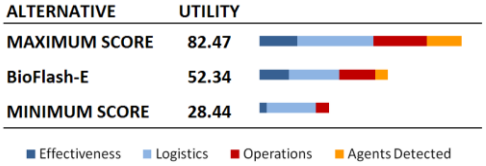
DIAGNOSTIC Laboratory Ranking

BioFlash-E® ranked in the middle third of all evaluated products for diagnostic laboratories and earned 60% of the utility points of the best score.



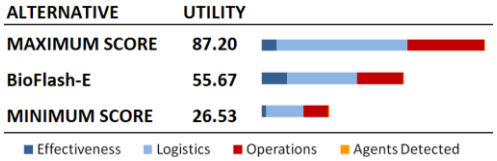
MOBILE Laboratory Ranking

BioFlash-E® ranked in the middle third of all evaluated products for mobile laboratories and earned 64% of the utility points of the best score.



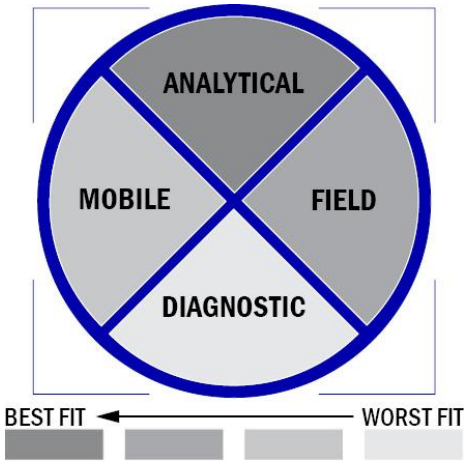
FIELD USE Ranking

BioFlash-E® ranked in the bottom third of all evaluated products for field use and earned 64% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

PathSensors
800 West Baltimore Street
Baltimore, MD 21201

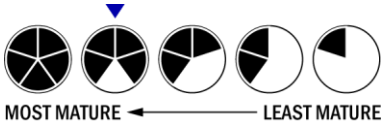
Point of Contact:
David Parrish

COST

- $35,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, single tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- No set-up required
- 1-3 minutes down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy and web-based operators manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components must be stored at room temp (27°C); must be stored at 4°C
- Performance is not influenced by relative humidity
- 1 to 6 months shelf life

Transportation:
- Approximately the size of carry-on luggage
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service not required
- Preventive maintenance not applicable
- Maintenance not included
- Expected life 5-10 years
- No daily QA
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data processing while in progress information not available
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 50 ul to test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connections
- Could easily be a fully autonomous system
- Laptop computer
- Stores and archives data outputs but does not create an electronic record
- Software closed and not available for modification
- Hardware closed and not available for modification

PINS-2

by Advanced Measurement Technology, ORTEC

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types
Identification of specific isotopes

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

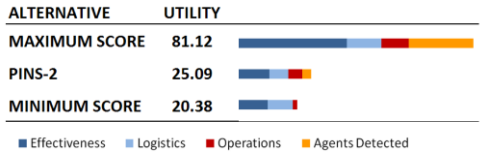
Portable Isotopic Neutron Spectroscopy (PINS) is an R&D 100 awardwinning technology employed originally to identify the contents of old munitions suspected of containing chemical agents. PINS Systems have been deployed world-wide since their introduction 10 years ago.Increasingly, PINS systems are being deployed as part of national counter-terrorist equipment providing a non contact and nondestructive means of identifying the contents of "suspect" packages.

TECHNOLOGY:

PINS is a novel application of a well-understood technique, involving the interrogation of a container, using neutrons from a small moderated source (the general arrangement is shown in Figure 2). The neutrons pass through the wall of the container and collide with the atomic nuclei of the contents. The ensuing nuclear reactions ("neutron capture" and "inelastic scattering") produce gamma rays, which when appropriately detected and recorded using an HPGe (High Purity Germanium) detector produce a gamma-ray spectrum. The gamma-ray spectrum peaks are found at channel numbers corresponding to energies associated with specific nuclear de-excitations characteristic of the chemical element concerned. The relative heights of the peaks are related to the ratios of the elements inside the container. These energies and ratios are in themselves UNIQUELY characteristic of the contents of the container, whether high explosive, nerve gas, or other. In this way, with a "library" of known signatures, it is possible to determine unambiguously the contents of the container.

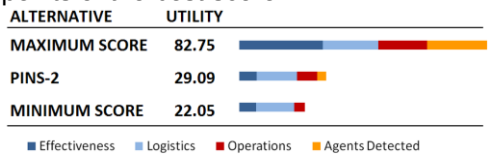
ANALYTICAL Laboratory Ranking

PINS-2 ranked in the bottom third of all evaluated products for analytical laboratories and earned 31% of the utility points of the best score.



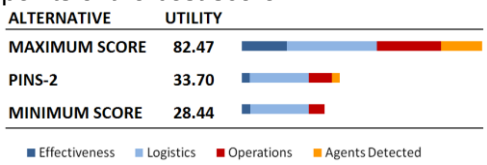
DIAGNOSTIC Laboratory Ranking

PINS-2 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 35% of the utility points of the best score.



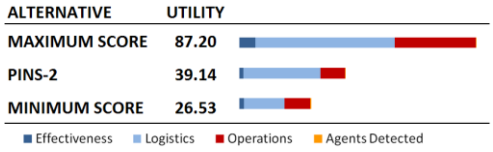
MOBILE Laboratory Ranking

PINS-2 ranked in the bottom third of all evaluated products for mobile laboratories and earned 41% of the utility points of the best score.



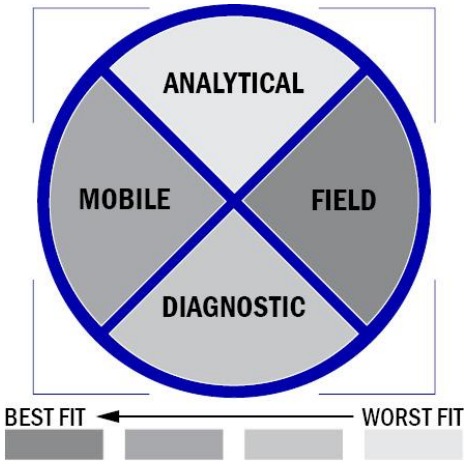
FIELD USE Ranking

PINS-2 ranked in the bottom third of all evaluated products for field use and earned 45% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Advanced Measurement Technology, ORTEC
801 S. Illinois Ave.
Oak Ridge, TN 37831

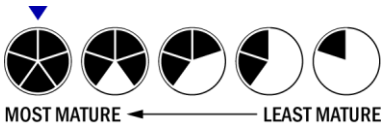
Point of Contact:
Ronald A. Zeszut
216-328-1404
ron.zeszut@ametek.com

COST

- $110,000.00/system or device

SPECIFICITY

- False Positives: Not Available
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15-30 minutes for detection
- 1 sample, single test/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- Greater than 20 minutes set up
- Less than 5 minutes down time
- 3-5 steps are required
- Customer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 37°C
- This system does not require consumables
- Influence of relative humidity unknown

Transportation:
- Larger than a home dishwasher
- All means of transportation
- Weighs more than 50 kg

Re-use:
- Multiple detection assays

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by technician
- Maintenance is not included
- Expected life 5-10 years
- 5-10 minutes QA required
- No sample introduced into device

Physical System Requirements:
- Batteries
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results not available
- Data can not be processed while in progress
- No centrifugation required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Liquids not tested

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Not network capable
- Wireless and wired connections
- Autonomous system with some effort
- Laptop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

PLEX-ID System

by Abbott Molecular, Inc

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Viruses (100-1,000 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Environmental air, Environmental water, Soil, Food, Powder, Insect vector

DESCRIPTION:

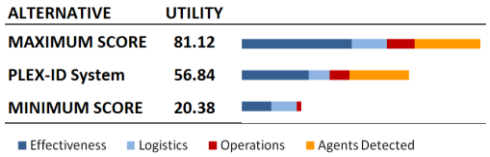
Ibis personnel invented and developed the Ibis TIGER/T5000 Universal Biosensor, which has been further developed into the Abbott/Ibis PLEX-ID. The biosensor originated from a DARPA program to develop revolutionary sensor technology to meet the needs of the Department of Defense. The technology that resulted from this program is widely held to be a major DARPA success story and the fundamentals of the technology and its validation have been documented in peer-reviewed publications. The Ibis Technology (now commercially available as the PLEX-ID) represents a universal pathogen detection platform capable of identification and strain typing of a broad range of pathogens. The platform employs the PCR (polymerase chain reaction) with primers that amplify relatively conserved regions of the genome(s) present in a sample. Using high-performance electrospray ionization mass spectrometry (ESI-MS), the base composition (i.e., the number of A's, G's, C's, and T's) of each amplicon is determined and the combination of base compositions from multiple primer pairs is assembled to yield the identity of the organism (s) in the sample. The platform has far-reaching applications in areas such as food safety, biological products screening, and clinical diagnostics. Initial deployments are for the purpose of identification and strain-typing of pathogens associated with biowarfare/bioterrorism events and naturally occurring emerging infectious disease.

TECHNOLOGY:

In each PCR/ESI-MS assay, multiple pairs of primers are used to amplify carefully selected regions of pathogen genomes; the primer target sites are broadly conserved, but the amplified region carries information on the microbe's identity in its unique nucleotide base composition. Regions of this nature appear in the DNA that encodes ribosomal RNA and in housekeeping genes that encode essential proteins. Following PCR amplification, a fully automated ESI-MS analysis is performed. The base compositions are compared to a database of over 750,000 calculated base compositions derived from the sequences of known organisms to determine the identities of any microorganisms present. This PCR/ESI-MS technology has been successfully used to identify pathogenic bacteria and viruses from a variety of clinical and environmental samples.

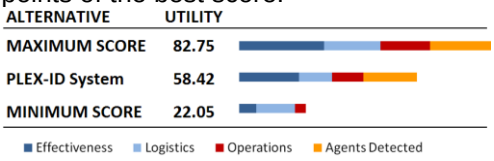
ANALYTICAL Laboratory Ranking

PLEX-ID System ranked in the top third of all evaluated products for analytical laboratories and earned 70% of the utility points of the best score.



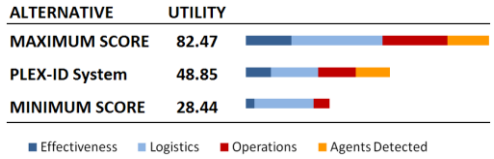
DIAGNOSTIC Laboratory Ranking

PLEX-ID System ranked in the top third of all evaluated products for diagnostic laboratories and earned 71% of the utility points of the best score.



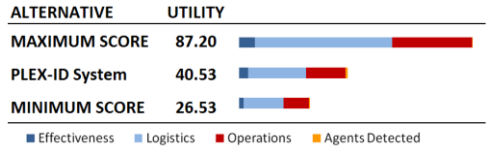
MOBILE Laboratory Ranking

PLEX-ID System ranked in the bottom third of all evaluated products for mobile laboratories and earned 59% of the utility points of the best score.



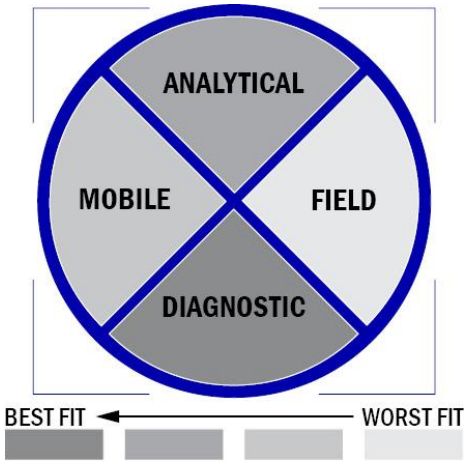
FIELD USE Ranking

PLEX-ID System ranked in the bottom third of all evaluated products for field use and earned 46% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Abbott Molecular, Inc
1300 E. Touhy
Des Plaines, IL 60018

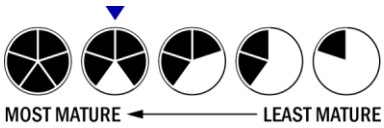
Point of Contact:
David Kowalski
David.Kowalski@abbott.com

COST

- $450,000.00/system or device
- $50.00-90.00/analysis

SPECIFICITY

- False Positives: <1%
- False Negatives: <1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Currently semi-automated

Signature:
- Sounds or alarms are present
- Screen cannot be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- More than a day of training and significant skills required
- 5-10 minutes for set up
- < 1 minute down time
- 6-8 steps are required
- Customer and Manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components stored at room temp but can withstand temps > 45°C for < 24 hours/ Components must be frozen
- Peak performance at normal relative humidity
- 6 months - 1 year shelf life

Transportation:
- Larger than a home dishwasher
- Commercial carrier/ Fixed wing aircraft/ Ship transport
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by technician
- Maintenance is included
- Expected life 5-10 years
- No QA required
- Exposure to hazardous agent would require up to 1 day to decontaminate

Physical System Requirements:
- 220V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- A centrifugation step required
- Single shaking or vortexing, mixing, degassing or filtering step required
- Software will call final result

Sensitivity and Detection:
- 510K clearance pending
- FDA approval pending
- Less than 250 ul for a test

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Not capable of autonomy
- No computational power needed
- Automatically stores and archives data outputs but does not create an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

PM1603A(B) Wrist Gamma Dosimeter

by Polimaster Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

Wrist Gamma Dosimeters are miniature, energy-compensated dosimeters designed to monitor the gamma radiation environment as well as precisely measure the ambient dose equivalent and ambient dose equivalent rate. The instruments' ability to compensate for energy variations allows these wrist gamma dosimeters to accurately measure the dose and dose rate of gamma radiation in a wide energy range. The range of the possible applications varies from the health physics needs and the personnel acute dose monitoring to the security applications and area monitoring. Thus the product designed for everyday and/or emergency use by Police, Security guards, Customs officers, First responders, HazMat teams, Firefighters, Militaries, etc. The instrument automatically compares the average dose rate of gamma radiation from the detector with the alarm threshold value chosen by the user. If the threshold value is exceeded, the instrument triggers an audible alarm. The user interface has friendly controls for routine operation and is characterized by simplicity, as well as by the convenient location of control buttons to switch between modes and settings. Thus the device can be operated even by the non-trained users, without any experience in radiation control.

TECHNOLOGY:

The dosimeters used for automatic control of radiation environment and measurement of the ambient dose and dose rate in a wide range The functionality of the devices based on the principle that some materials (radiation detectors) can register and detect gamma radiation. Production technology utilizes Geiger-Muller counters. Geiger-Muller counter utilizes small metal tubes filled with inert gas. When gas molecules inside the tube are excited by the incident radiation, they create an electrical current for the readout. The magnitude of the current is proportional to the energy of a gamma photons and therefore of dose of incident radiation.

ANALYTICAL Laboratory Ranking

Wrist Gamma Dosimeter PM1603A(B) ranked in the bottom third of all evaluated products for analytical laboratories and earned 74% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
PM1603A(B) Wrist Dosimeter	41.69
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

Wrist Gamma Dosimeter PM1603A(B) ranked in the middle third of all evaluated products for diagnostic laboratories and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
PM1603A(B) Wrist Dosimeter	45.03
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

Wrist Gamma Dosimeter PM1603A(B) ranked in the middle third of all evaluated products for mobile laboratories and earned 87% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
PM1603A(B) Wrist Dosimeter	57.74
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

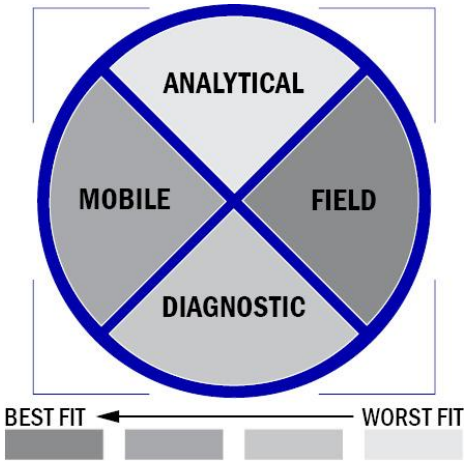
Wrist Gamma Dosimeter PM1603A(B) ranked in the top third of all evaluated products for field use and earned 89% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
PM1603A(B) Wrist Dosimeter	75.95
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Polimaster Inc.
2300 Clarendon Blvd.
Suite 708
Arlington VA, 22201

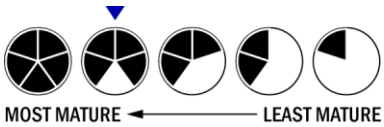
Point of Contact:
Vladimir Kanevsky
office (703) 525-5075
mobile(703) 608-3850
kanevsky@polimaster.us

COST

- $611.00 - $700.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- Almost instant down time
- 0-2 steps required
- DVD/ Hard-copy and web-based operators manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- No electrical requirement
- 1000 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquid

System Maturity:
- Is commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- <100 GB or single positive or negative response generated
- Not network capable
- Wireless, wired connections
- Fully autonomous
- No computer required
- Stores and archives data outputs and creates an electronic record
- System software is closed and not available for modification
- System hardware is closed and not available for modification

PM1603B Wrist Gamma Dosimeter

by Polimaster Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

PM1603B Wrist Gamma Dosimeters are miniature, energy-compensated dosimeters designed to monitor the gamma radiation environment as well as precisely measure the ambient dose equivalent H*(10) and ambient dose equivalent rate H*(10). The instruments' ability to compensate for energy variations allows these wrist gamma dosimeters to accurately measure the dose and dose rate of gamma radiation in a wide energy range. Recommended for professionals who work with or around the radioactive materials, for special forces, emergency services, miners and other professional exposed to radiation.

TECHNOLOGY:

For PM1603B Wrist Gamma Dosimeters: A Geiger-Muller tube with a filter for spatial-energy formation of sensitivity, which converts gamma radiation quanta to electric pulses, is used as a radiation detector. The detector has a high-voltage power supply. The microprocessor controls the dosimeter's operating modes, backlight device, audible alarm device, infrared communication channel, LCD, non-volatile memory, high-voltage power supply of the detector, operates the control buttons, performs all the necessary calculations, self-diagnostics. The dosimeter's operating algorithm ensures continuity of the measurement process, statistical processing of the measurement results, a prompt adaptation to the variation of level of the gamma radiation dose rate (setting the time of measurement in inverse dependence on the dose rate) and effective output of the information obtained to the LCD. The IR-communication channel provides an exchange of information with PC.

ANALYTICAL Laboratory Ranking

Wrist Gamma Dosimeter ranked in the bottom third of all evaluated products for analytical laboratories and earned 51% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
PM1603B Wrist Dosimeter	41.74
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

Wrist Gamma Dosimeter ranked in the middle third of all evaluated products for diagnostic laboratories and earned 54% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
PM1603B Wrist Dosimeter	45.08
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

Wrist Gamma Dosimeter ranked in the middle third of all evaluated products for mobile laboratories and earned 70% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
PM1603B Wrist Dosimeter	57.79
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

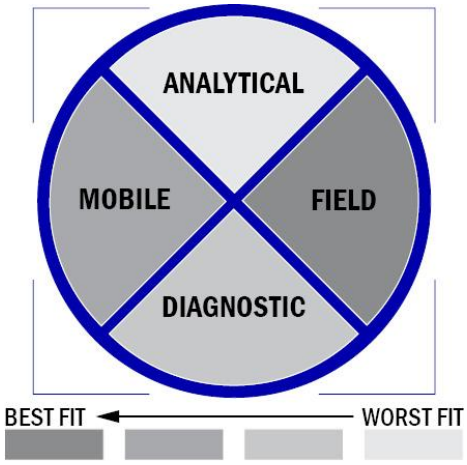
Wrist Gamma Dosimeter ranked in the top third of all evaluated products for field use and earned 87% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
PM1603B Wrist Dosimeter	76.00
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Polimaster Inc.
112 M. Bogdanovich str.
Minsk 220040
Republic of Belarus

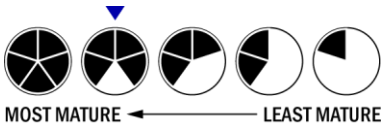
Point of Contact:
Mr. Yury Kurlovich
+375 17 2177083
polimaster@polimaster.com

COST

- $700.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- Almost instant down time
- 0-2 steps required
- DVD/ Hard-copy and web-based operators manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- Component information not available

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- No electrical requirement
- 9 month battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquid

System Maturity:
- Is commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB or single positive or negative response generated
- Not network capable
- Wireless, wired connections
- Fully autonomous
- No computer required
- Stores and archives data outputs and creates an electronic record
- System software is closed and not available for modification
- System hardware is closed and not available for modification

PM1604A (B) Personal compact dosimeter

by Polimaster Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

The compact personal dosimeter PM1604A(B) is a miniature energy-compensated personal dosimeter that measures both personal dose equivalent and personal dose equivalent rate of both gamma and X-ray radiation. Recommended for professionals who work with or around the radioactive materials. The instrument automatically compares the average dose and dose rate of gamma radiation from the detector with the alarm threshold value chosen by the user. If the threshold value is exceeded, the instrument triggers an audible alarm. The user interface has friendly controls for routine operation and is characterized by simplicity, as well as by the convenient location of control buttons to switch between modes and settings. Thus the device can be operated even by the non-trained users, without any experience in radiation control.

TECHNOLOGY:

The dosimeter measures personal dose equivalent and personal dose equivalent rate of both gamma and X-ray radiation in a wide range. The functionality of the device based on the principle that some materials (radiation detectors) can register and detect gamma radiation. Production technology utilizes Geiger-Muller counters. Geiger-Muller counter utilizes small metal tubes filled with inert gas. When gas molecules inside the tube are excited by the incident radiation, they create an electrical current for the readout. The magnitude of the current is proportional to the energy of a incident photons and therefore of dose of incident radiation.

ANALYTICAL Laboratory Ranking

Personal compact dosimeter PM1604A (B) ranked in the bottom third of all evaluated products for analytical laboratories and earned 51% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
1604A (B) Personal dosimeter	41.69
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

Personal compact dosimeter PM1604A (B) ranked in the middle third of all evaluated products for diagnostic laboratories and earned 54% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
1604A (B) Personal dosimeter	45.03
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

Personal compact dosimeter PM1604A (B) ranked in the middle third of all evaluated products for mobile laboratories and earned 70% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
1604A (B) Personal dosimeter	57.74
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

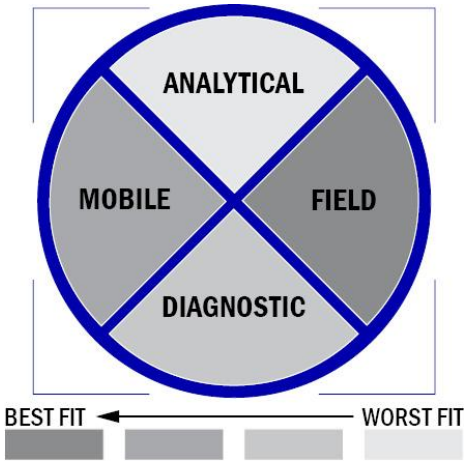
Personal compact dosimeter PM1604A (B) ranked in the top third of all evaluated products for field use and earned 87% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
1604A (B) Personal dosimeter	75.95
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Polimaster Inc.
2300 Clarendon Blvd.
Suite 708
Arlington VA, 22201

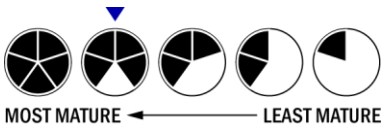
Point of Contact:
Vladimir Kanevsky
office (703) 525-5075
mobile(703) 608-3850
kanevsky@polimaster.us

COST

- $611.00 - 700.00/system or device

SPECIFICITY

- False Positives: Device measures personal radiation dose and dose rate
- False Negatives: Device measures personal radiation dose and dose rate



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- Almost instant down time
- 0-2 steps required
- DVD/ Hard-copy and web-based operators manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- No electrical requirement
- 1000 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquid

System Maturity:
- Is commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- <100 GB or single positive or negative response generated
- Not network capable
- Wireless, wired connections
- Fully autonomous
- No computer required
- Stores and archives data outputs and creates an electronic record
- System software is closed and not available for modification
- System hardware is closed and not available for modification

PM1703GN Personal Radiation Detector

by Polimaster Inc.

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

Personal Radiation Detector is a pager-size high sensitive device for the search for the nuclear and radioactive materials. Device ensures gamma and neutron radiation detection, radioactive source location and measures dose equivalent rate. Device is intended for use in any area where the radiation dose rate is required to be measured, where exceeding the default dose rate values requires an alarm. In addition, the instrument provides analysis of the gathered dosimetric information. The range of the possible applications varies from the health physics needs and to the security applications and area monitoring. The product designed for everyday and/or emergency use by Police, Security guards, Customs officers, First responders, HazMat teams, Firefighters, Militaries, etc. The instrument automatically compares the average count rate of gamma and neutron radiation from the detector with the alarm threshold value. The value calculated based on the background radiation measured during calibration and the set by the user coefficient (i.e. the number of mean deviation of current radiation background). If the threshold value is exceeded, the instrument triggers an alarm (light, audible and/or vibration). The user interface has friendly controls for routine operation and is characterized by simplicity, as well as by the convenient location of control buttons to switch between modes and settings. The device can be operated even by the non-trained users, without any experience in radiation control.

TECHNOLOGY:

Personal Radiation Detector performs gamma and neutron radiation detection, radioactive source location and provides fast radiation dose rate measurement. The functionality of the device based on the principle that some materials (radiation detectors) can register and detect gamma radiation. Production technology utilizes CsI(Tl) (for gamma radiation detection) and a LiI(Eu) (for neutron radiation detection) Scintillation Crystal detectors. Scintillation detector relies on the generation of light pulses by gamma-ray (neutron) interaction, which are then detected by a photodiode, and converted to a voltage pulse for further signal processing.

ANALYTICAL Laboratory Ranking

Personal Radiation Detector PM1703GN ranked in the bottom third of all evaluated products for analytical laboratories and earned 51% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
PM1703GN Radiation Detector	41.69
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

Personal Radiation Detector PM1703GN ranked in the middle third of all evaluated products for diagnostic laboratories and earned 54% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
PM1703GN Radiation Detector	45.03
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

Personal Radiation Detector PM1703GN ranked in the middle third of all evaluated products for mobile laboratories and earned 70% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
PM1703GN Radiation Detector	57.74
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

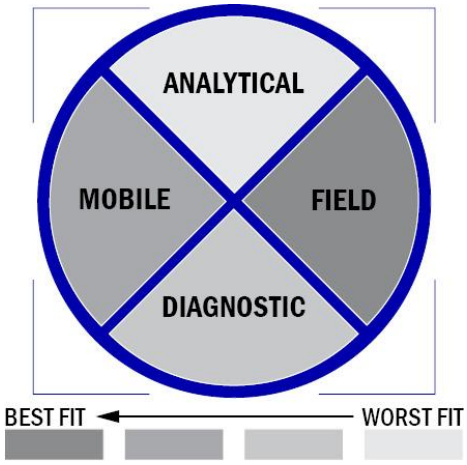
Personal Radiation Detector PM1703GN ranked in the top third of all evaluated products for field use and earned 87% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
PM1703GN Radiation Detector	75.95
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Polimaster Inc.
2300 Clarendon Blvd. Suite 708
Arlington VA, 22201

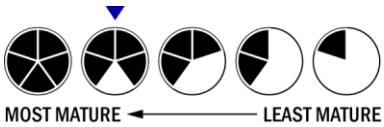
Point of Contact:
Vladimir Kanevsky
(703) 525-5075
kanevsky@polimaster.us

COST

- $3,120.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- Almost instant down time
- 0-2 steps required
- DVD/ Hard-copy and web-based operators manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- No electrical requirement
- 1000 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquid

System Maturity:
- Is commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- <100 GB or single pos or neg response generated
- Not network capable
- Wireless, wired connections
- Fully autonomous
- No computer required
- Stores and archives data outputs and creates an electronic record
- Software closed, not available for modification
- Hardware closed, not available for modification

PM1703M-O1 (MO-2) Personal Combined Radiation Detector/ Dosimeter

by Polimaster

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

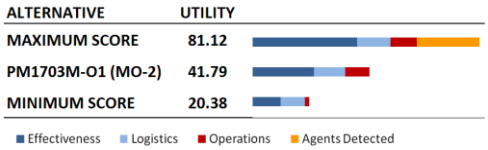
Personal Radiation Detector is a pager-size high sensitive device for nuclear and radioactive materials. Device ensures gamma radiation detection, radioactive source location and enables fast precise radiation dose rate measurement. Device intended for use in any area where radiation dose and dose rate need to be measured, where exceeding the default dose and dose rate values requires an alarm. Instrument provides accumulated information about accumulated dose and system analysis of gathered dosimetric information. Range of possible applications varies from health physics needs and personal acute dose monitoring to security applications and area monitoring. Product designed for everyday and/or emergency use by Police, Security, Firefighters, Militaries, etc. Automatically compares average count rate of gamma radiation from the detector with the alarm threshold value. Value calculated based on background radiation measured during calibration and the set by user coefficient. If threshold value is exceeded, instrument triggers an alarm. User interface has friendly controls for routine operation and is characterized by simplicity, as well as by the convenient location of control buttons to switch between modes and settings. Device can be operated even by the non-trained users, without any experience in radiation control.

TECHNOLOGY:

Personal Radiation Detector performs gamma radiation detection, radioactive source location and provides fast precise radiation dose rate measurement. Functionality of the device based on principle that some materials can register and detect gamma radiation. Production technology utilizes Geiger-Muller counters and High Sensitive Scintillation Crystal detectors. Scintillation detector relies on generation of light pulses by gamma-ray interaction, converted to a voltage pulse for further signal processing. Geiger-Muller counter utilizes small metal tubes filled with inert gas. When gas molecules inside the tube are excited by incident radiation, they create an electrical current for readout. Magnitude of current is proportional to energy of a gamma photons and of dose of incident radiation.

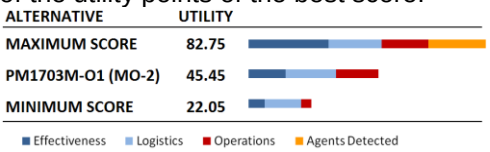
ANALYTICAL Laboratory Ranking

PM1703M-O1 (MO-2) ranked in the bottom third of all evaluated products for analytical laboratories and earned 52% of the utility points of the best score.



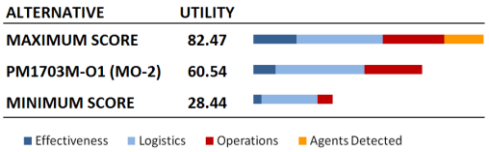
DIAGNOSTIC Laboratory Ranking

PM1703M-O1 (MO-2) ranked in the middle third of all evaluated products for diagnostic laboratories and earned 55% of the utility points of the best score.



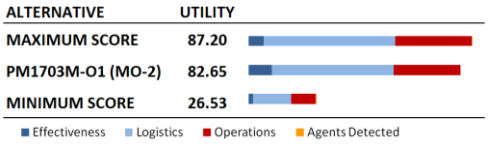
MOBILE Laboratory Ranking

PM1703M-O1 (MO-2) ranked in the top third of all evaluated products for mobile laboratories and earned 73% of the utility points of the best score.



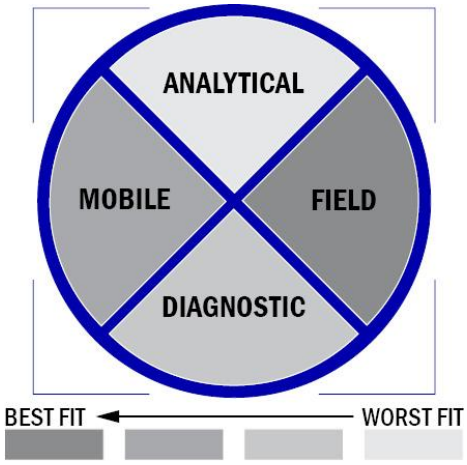
FIELD USE Ranking

PM1703M-O1 (MO-2) ranked in the top third of all evaluated products for field use and earned 95% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Kalvariju str. 125
3P3/p building
LT-08221
Vilnius, Republic of Lithuania

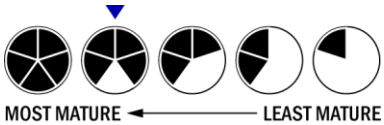
Point of Contact:
Mr. Michael Semeniuk
+370 5 2102323 +370 5 2102324
polimaster@polimaster.lt

COST

- $1,304.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up
- Almost instantaneous down time
- 0-2 steps required
- DVD/ Customer and manufacturer site training/ Hard-copy and web-based operators manual

Operational conditions:
- Can be used from -21°C to >42°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- <5 minutes QA
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Not network capable.
- Wireless and wired connections
- Fully autonomous
- No computer required
- Stores and archives data outputs and creates an electronic record
- System software closed and not available for modification
- System hardware closed and not available for modification

PM2012M – Combined Gamma Dosimeter and Chemical Agent Detector

by Polimaster Inc.

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

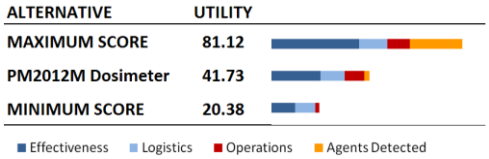
Combined Gamma Dosimeter and Chemical Agent Detector PM2012M is a two-in-one instrument featuring chemical detector and gamma radiation detector in one unit. The device is designed to detect chemical warfare agents and toxic compounds and differentiate between organophosphorus and arsenic containing compounds, as well as continuously monitor radiation background, measure gamma dose and dose rate and provide audible, visual alarms when preset thresholds are exceeded. is invaluable for first responders, police officers, military, and customs and border patrol services in the day-to-day monitoring of public safety as well as in special HazMat operations. It can be used as a personal detector, a monitor for surveying contaminated areas, or as a fixed-installed detector

TECHNOLOGY:

For Combined Gamma Dosimeter and Chemical Agent Detector PM2012M: Instrument's operation principle in the TCV air presence detection mode is based on toxic chemical vapors detection module. Instrument measures current strength of the ionization chamber with beta-source 63Ni. Analyzed air at that is forcedly pumped through the chamber by micro purge pump. Microprocessor-based controller with internal analog-digital converter controls GEDM and TCVDM modules. Instrument operation algorithm enables continuous measurement of ambient dose equivalent of gamma- and roentgen radiation H*(10 , measurement of photon emission ambient dose equivalent H*(10) and detection of toxic vapors air presence, statistical analysis of measurement data, and quick adaptation to variations of radiation strength (setting of measurement time periods irreversibly to radiation strength). Internal non-volatile instrument's memory accumulates and stores information. IR-link is used for MPC-PC information communication.

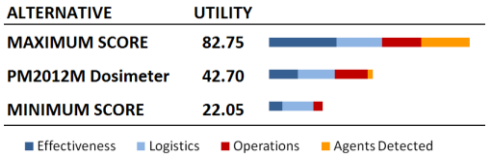
ANALYTICAL Laboratory Ranking

PM2012M Detector ranked in the bottom third of all evaluated products for analytical laboratories and earned 51% of the utility points of the best score.



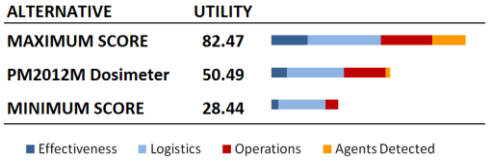
DIAGNOSTIC Laboratory Ranking

PM2012M Detector ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 52% of the utility points of the best score.



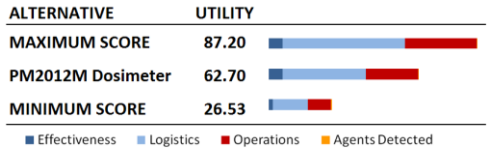
MOBILE Laboratory Ranking

PM2012M Detector ranked in the bottom third of all evaluated products for mobile laboratories and earned 61% of the utility points of the best score.



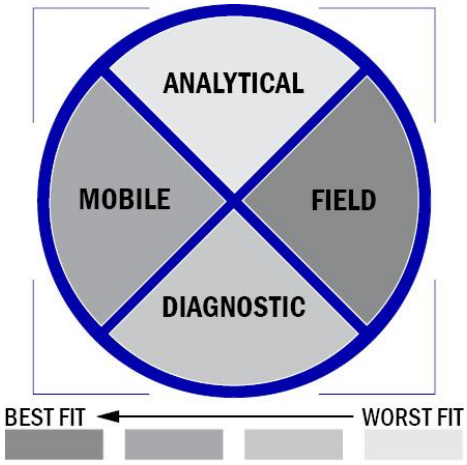
FIELD USE Ranking

PM2012M Detector ranked in the middle third of all evaluated products for field use and earned 72% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Polimaster, Inc.
112 M. Bogdanovich str.
Minsk 220040
Republic of Belarus

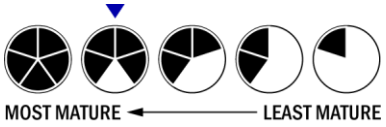
Point of Contact:
Mr. Yury Kurlovich
+375 17 2177083
polimaster@polimaster.com

COST

- $7,282.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- Almost instant down time
- 0-2 steps required
- DVD/ Hard-copy and web-based operators manual

Operational conditions:
- Can be used from -10°C to 50°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Dimensions: 66x47x195mm
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- Component information not available

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 220V electrical requirement
- 150 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquid

System Maturity:
- Is commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB or single positive or negative response generated
- Not network capable
- Wireless, wired connections
- Fully autonomous
- No computer required
- Stores and archives data outputs and creates an electronic record
- System software is closed and not available for modification
- System hardware is closed and not available for modification

Portable Air Monitor

by Technical Associates

DETECTS THE FOLLOWING:

Demonstrated:
Viruses
Toxins
Aerosolized chemical agent (< 0.000001 mg/m3)

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

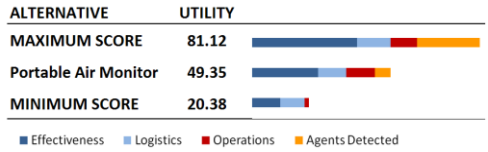
The Portable Air Monitor assures safety against airborne radioactivity contamination of airborne chemicals, vapors, and particulates by means of constant check with alarm and record capability. It provides integrated exposure information and can provide hard copy via external printer or computer. It is a complete system but may be expanded per need with additional modules. The Portable Air Monitor is more sensitive and versatile version of the broadly used long time standard. It may be used to monitor stack effluent down to EPA levels as well as hoods, glove box or workplace air. Data logger is built in. The end users are hospitals, PET treatment centers, state and federal EPA air quality departments, and the US military: Laboratory and Theatre.

TECHNOLOGY:

The Portable Air Monitor uses a standard charcoal filter in TA's unique quick change, no leak holder to trap any airborne Radio Iodine, PET positron emitters, other radioactive aerosols. The filter is under constant surveillance via a thin window scintillation detector. Air is drawn by a regulated pump through a three-foot inlet hose and exhausted via a flow meter through another three-foot hose. These may be extended to allow monitoring of hoods, glove boxes, stacks, etc. Time is recorded by an odometer type timer wired into the pump circuit. The unit is completely self-contained and portable. Complete with 10 filter cartridges.

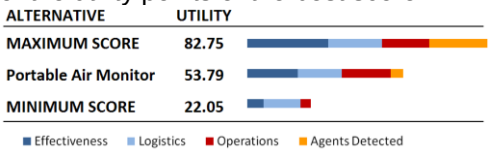
ANALYTICAL Laboratory Ranking

Portable Air Monitor ranked in the middle third of all evaluated products for analytical laboratories and earned 61% of the utility points of the best score.



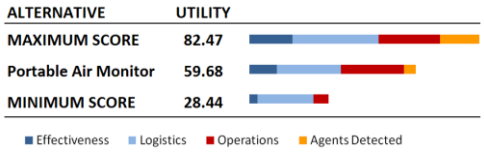
DIAGNOSTIC Laboratory Ranking

Portable Air Monitor ranked in the middle third of all evaluated products for diagnostic laboratories and earned 65% of the utility points of the best score.



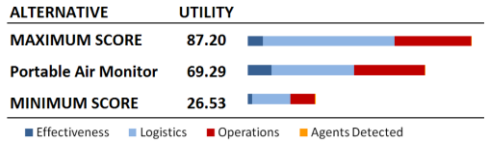
MOBILE Laboratory Ranking

Portable Air Monitor ranked in the middle third of all evaluated products for mobile laboratories and earned 72% of the utility points of the best score.



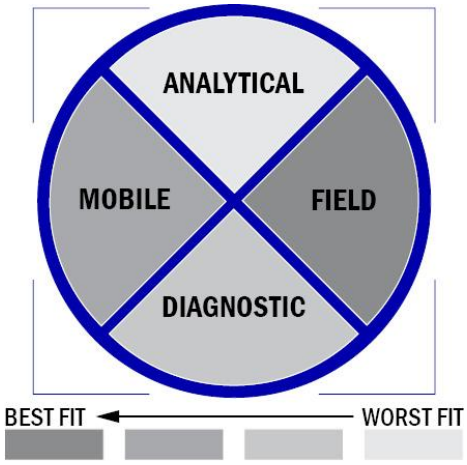
FIELD USE Ranking

Portable Air Monitor ranked in the middle third of all evaluated products for field use and earned 80% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Technical Associates
7051 Eton Ave.
Canoga Park, CA 91303

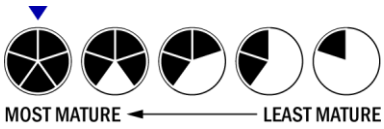
Point of Contact:
Robert Goldstein
818-883-7043

COST

- $14,500.00/system or device

SPECIFICITY

- False Positives: <1:10,000
- False Negatives: <1:1,000



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, >10 tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 5-10 minutes set-up
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 4°C to 41°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of carry-on luggage
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Does not test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connections
- Fully autonomous
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software is open but modification requires licensing
- System hardware is open and available for modification

Portable Liquid Scintillation Counter

by Technical Associates

DETECTS THE FOLLOWING:

Demonstrated:
Liquid chemical agent
(1 ppm – 100 ppm)
Identification of radioisotopes in tissue/ tissue damage
Discrimination between radiation types

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Environmental water, Soil, Food, Powder

DESCRIPTION:

The Portable Liquid Scintillation Counting System accurately quantitatively measures Carbon-14, Tritium and most other radioactive materials. Gamma ray counting is optional. PC interface and hard copy printer are optional. The Portable Liquid Scintillation Counter has a 3 Vial capacity for faster thru-put and easy comparison sample to calibration standard or to background. This is an all-in-one unit thus enhancing portability. End Users: state and federal health agencies, nuclear power plants, small labs, us military drinking water quality units, citizen groups, municipal utilities.

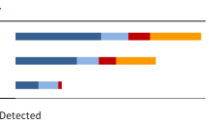
TECHNOLOGY:

Using the most sensitive method of detecting and quantitating beta emitting isotopes mixing the sample with liquid scintillation fluor and counting each individual scintillation event with a photomultplier counter. An energy analyzer further selects the pulses and delivers the true signal. Optionally, gamma ray counting is achieved by inserting and optically coupling an NaI(Tl) scintillation well crystal on the PM tube. Scintillation counts which are detected by PM tubes are processed by a fully adjustable single channel analyzer which is centered on the energy peak of the isotope being measured.

ANALYTICAL Laboratory Ranking

Portable Liquid Scintillation Counter ranked in the top third of all evaluated products for analytical laboratories and earned 76% of the utility points of the best score.

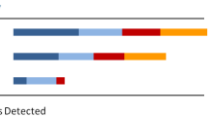
ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
Portable Liquid Scintillation Counter	61.32
MINIMUM SCORE	20.38



DIAGNOSTIC Laboratory Ranking

Portable Liquid Scintillation Counter ranked in the top third of all evaluated products for diagnostic laboratories and earned 79% of the utility points of the best score.

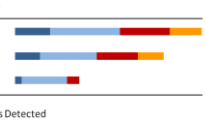
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
Portable Liquid Scintillation Counter	65.15
MINIMUM SCORE	22.05



MOBILE Laboratory Ranking

Portable Liquid Scintillation Counter ranked in the top third of all evaluated products for mobile laboratories and earned 80% of the utility points of the best score.

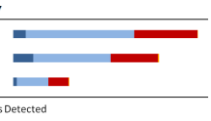
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
Portable Liquid Scintillation Counter	65.64
MINIMUM SCORE	28.44



FIELD USE Ranking

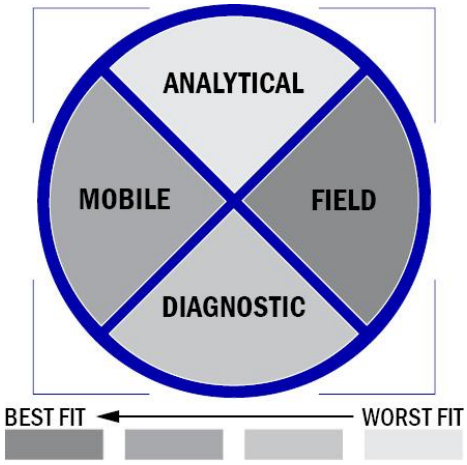
Portable Liquid Scintillation Counter ranked in the middle third of all evaluated products for field use and earned 79% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
Portable Liquid Scintillation Counter	68.93
MINIMUM SCORE	26.53



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Technical Associates
7051 Eton Ave.
Canoga Park, CA 91303

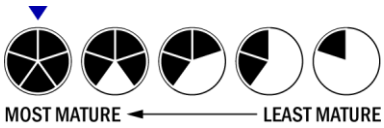
Point of Contact:
Robert Goldstein
818-883-7043

COST

- $11,500.00/system or device

SPECIFICITY

- False Positives: User makes determination
- False Negatives: User makes determination



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- Multiple samples, multiple tests/sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- <5 minutes set-up
- 1-3 minutes down time
- 3-5 steps required
- Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps > 45°C for <24 hours
- Performance is not influenced by relative humidity
- 1-3 years shelf life

Transportation:
- Approximately the size of carry-on luggage
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life >10 years
- <5 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Requires water aliquots
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering step
- System does not call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Greater than 250 ul to test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connections
- Not autonomous
- No computer required
- Stores and archives data outputs and creates an electronic record
- System does not employ software
- System hardware is open and available for modification

Prime Alert Biodetection System

by GenPrime, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (>100,000 CFU /mL)
Viruses (>100,000 CFU/mL)
Toxins (100-1,000 ng/mL)

DETECTION MATRICES:

Demonstrated:
Powder

DESCRIPTION:

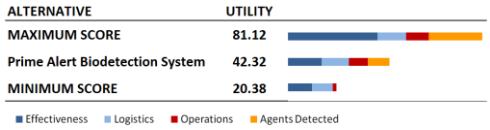
The Prime Alert Biodetection/Threat Verification System is designed to allow First Responders to perform a rapid, on-site test to determine if a substance is a potential biohazard or merely a hoax. The simple and reliable technology alerts the responder to the presence of suspicious levels of any microbe in one five-minute test. A negative result is quickly followed by tests for ricin and botulinum toxins. In less than 15 minutes reliable information is obtained, allowing the First Response team to make an informed decision regarding incident closure. The Microbe Screen™ is performed using a proven fluorescent-based technology in a hand-held reader and the Toxin Screen™ is carried out using lateral flow antibody tests.

TECHNOLOGY:

The Prime Alert is a broad spectrum point detection device designed for screening unknown substances for the presence of microbes. It employs a fluorescent nucleic acid stain with high affinity binding to DNA/RNA. The amount of fluorescence in a sample is correlative to the CFU's, and is reported digitally on a handheld battery powered fluorometer. This value is used to make a qualitative assessment of the presence or absence of microbes in a sample.

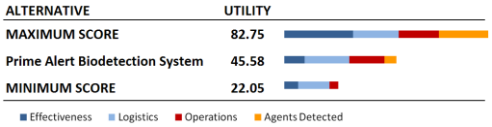
ANALYTICAL Laboratory Ranking

Prime Alert Biodetection System ranked in the middle third of all evaluated products for analytical laboratories and earned 52% of the utility points of the best score.



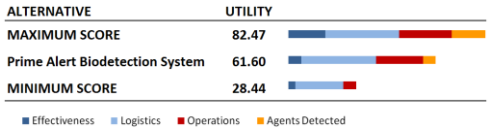
DIAGNOSTIC Laboratory Ranking

Prime Alert Biodetection System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 55% of the utility points of the best score.



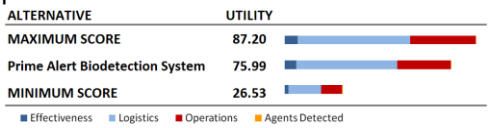
MOBILE Laboratory Ranking

Prime Alert Biodetection System ranked in the top third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.



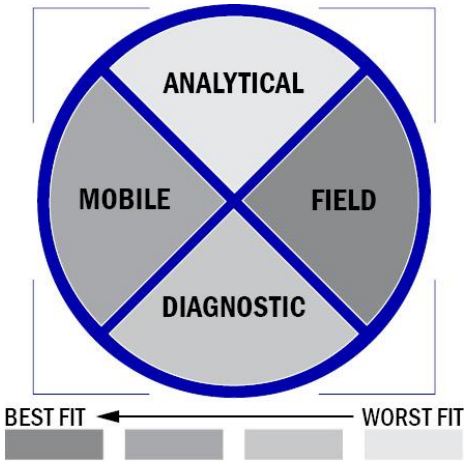
FIELD USE Ranking

Prime Alert Biodetection System ranked in the top third of all evaluated products for field use and earned 87% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

157 S. Howard, Ste. 605
Spokane, WA 99201

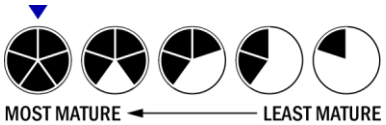
Point of Contact:
Buck Somes, 866-624-9855
Darby McLean, 866-624-9855

COST

- $10,500.00/system or device

SPECIFICITY

- False Positives: <1%
- False Negatives: <1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, <10 tests/ sample per run
- Could be semi-automated with some effort

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief training and minimal tech skills
- <5 minutes set-up required
- Almost no down time
- 3-5 steps required
- DVD/ Customer and manufacturer site training; Hard-copy operators manual

Operational conditions:
- Can be used from <-21°C to >42°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Performance not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs between 1 - 5 kg

Re-use:
- Multiple detection assays
- 3 solutions, buffer, and/or reagents
- 3 components

Maintenance:
- Maintenance not required
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Hazardous agent isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source information not available

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- Multiple shaking or vortexing, mixing, degassing or filtering step
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Not network capable
- Wired connections
- Not capable of autonomy
- On board computer chip in the system
- Stores and archives data outputs and creates electronic records
- System software is closed and not available for modification
- System hardware is closed and not available for modification

Pro-Strips® Multi-Agent Detection Test

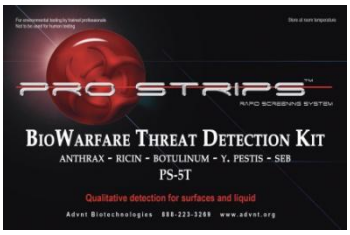
by ADVNT Biotechnologies

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e4-10e5 CFU/mL)

DETECTION MATRICES:

Nothing demonstrated.



DESCRIPTION:

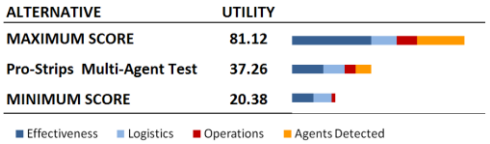
Pro-Strips® Multi-Agent Detection test. One devices is capable of detecting Anthrax, Ricin, Botulinum, SEB and Y. Pestis. Rapid and accurate result from one sample. Designed for environmental use to test surface and liquid.

TECHNOLOGY:

A 5 multi-agent detection system that employs hand held immunochromatographic assay that uses colloidal gold antibodies for rapid detection. This uses the same technology that supports our BADD single agent detection devices. 5 test from one sample.

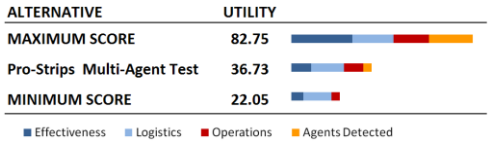
ANALYTICAL Laboratory Ranking

Pro-Strips® Multi-Agent Detection Test ranked in the bottom third of all evaluated products for analytical laboratories and earned 43% of the utility points of the best score.



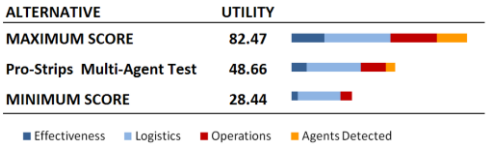
DIAGNOSTIC Laboratory Ranking

Pro-Strips® Multi-Agent Detection Test ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 44% of the utility points of the best score.



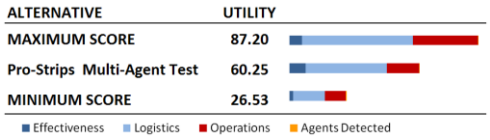
MOBILE Laboratory Ranking

Pro-Strips® Multi-Agent Detection Test ranked in the bottom third of all evaluated products for mobile laboratories and earned 53% of the utility points of the best score.



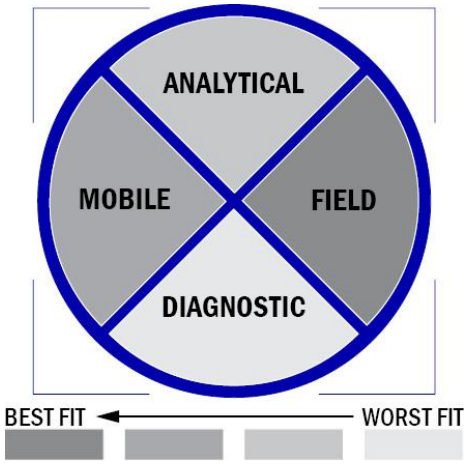
FIELD USE Ranking

Pro-Strips® Multi-Agent Detection Test ranked in the bottom third of all evaluated products for field use and earned 61% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ADVNT Biotechnologies
22510 N. 18th Dr.
Phoenix, AZ. 85027

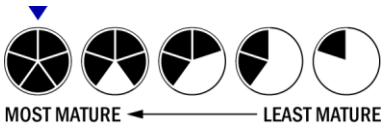
Point of Contact:
YP@advnt.org

COST

- $24.50/test

SPECIFICITY

- False Positives: Less than 1%
- False Negatives: Less than 1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, single test/sample per run
- Not amenable to full or semi-automation

Signature:
- Sounds or alarms not present
- No screen
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 6-8 steps required
- CD or DVD training

Operational conditions:
- Can be used from 25°C - 37°C
- Components should be stored at room temp but can stand temps >45°C for < 24 hours/ Must be stored at room temp (27°C)/ Must be stored at 4°C
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a soda can
- Transport via commercial carrier
- Weighs less than 1 kg

Re-use:
- Single use
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service not required
- Preventive maintenance not applicable
- Warranty does not apply
- Expected life does not apply
- No daily QA required
- No decon required

Physical System Requirements:
- No electrical equipment
- Does not use batteries
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering step
- System does not call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 250 ul required for test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property licensing not possible

Interoperability and System Complexity:
- Raw data size not applicable
- Network capability not applicable
- Not autonomous
- No computer required
- Does not store or archive data outputs or create electronic records
- System does not employ software
- System is single use

ProteOn(TM) XPR36 Interaction Array System

by Bio-Rad Laboratories

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

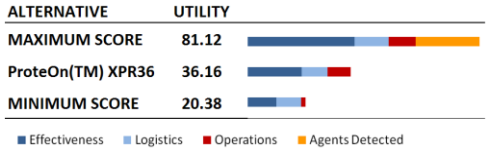
The ProteOn XPR36 protein interaction array system is an SPR optical biosensor that provides real-time data on the affinity, specificity, and interaction kinetics of protein interactions. Using proprietary XPR(TM) technology, a unique approach to multiplexing, this system generates a 6 x 6 interaction array for the simultaneous analysis of up to six ligands with up to six analytes. This system increases the throughput, flexibility, and versatility of experiment design, enabling the completion of more experiments in less time: analyze up to 36 different protein interactions in a single run, on a single chip; perform a complete kinetic analysis in a single run; measure a variety of experimental conditions simultaneously in parallel; screen multiple panels of analytes.

TECHNOLOGY:

Label-free, real-time evaluation of up to 36 unique protein interactions in a single run, yielding complete kinetic profile, binding affinity and analyte concentrations. With novel referencing capabilities and novel experimental design capabilities achieve robust data in less time.

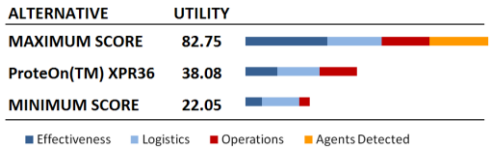
ANALYTICAL Laboratory Ranking

ProteOn(TM) XPR36 ranked in the bottom third of all evaluated products for analytical laboratories and earned 45% of the utility points of the best score.



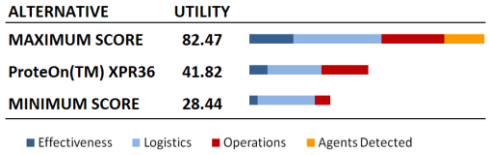
DIAGNOSTIC Laboratory Ranking

ProteOn(TM) XPR36 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 46% of the utility points of the best score.



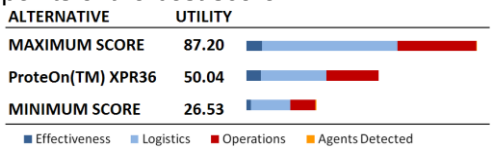
MOBILE Laboratory Ranking

ProteOn(TM) XPR36 ranked in the bottom third of all evaluated products for mobile laboratories and earned 51% of the utility points of the best score.



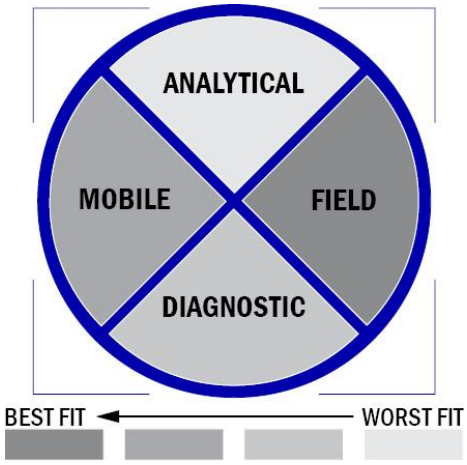
FIELD USE Ranking

ProteOn(TM) XPR36 ranked in the bottom third of all evaluated products for field use and earned 57% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Bio-Rad Laboratories
2000 Alfred Nobel Drive
Hercules, California 94547

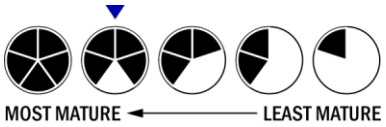
Point of Contact:
Candice Cox
Phone: (510)741-4788

COST

- $285,000.00/system or device

SPECIFICITY

- False Positives: Low
- False Negatives: Low



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30 - 60 minutes for detection
- Multiple samples, single tests/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- 5-10 minutes set-up
- > 1 minute down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be frozen but can stand temps >4°C <24 hours/ Must be stored at room temp (27°C)/ Must be stored at 4°C; must be frozen
- Performance is not influenced by relative humidity
- 6 months - 1 year shelf life

Transportation:
- Approximately the size home dishwasher
- Transport via commercial carrier or ship
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by technician only
- Maintenance included
- Expected life 5-10 years
- No daily QA
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System could call final result in the future

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 50 ul to test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Could be fully autonomous system with significant effort
- No computer required
- Stores and archives data outputs and creates an electronic record
- System software closed and not available for modification
- Hardware closed and not available for modification

Proteus and Asklepios

by GeneFluidics

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Viruses (1-100 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Urine, Wound, Environmental air, Environmental water, Food

DESCRIPTION:

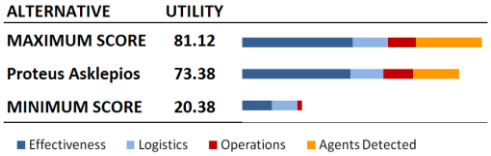
Proteus a new affordable automated molecular analysis platform: Proteus. This modular robotic system can be configured for nearly any fluid-handling application, and with the use of the Genefluidics Electrochemical Sensor module, becomes an all-in-one molecular analysis platform -- No PCR required! Proteus' automated operations include pipetting, serial dilution, mixing, spotting, washing, drying, incubation, sensor chip reading and more! Asklepios is a miniature microfluidics portable system, showcases the GeneFluidics' electrochemical sensor technology for multiplexed genetic assay and immunoassay in resource-limited settings. The result is a revolution in molecular analysis - complete automated sample preparation and detection in a small, portable package.Within the microfluidics cartridge, Asklepios performs the same sample preparation steps that would normally be performed on the laboratory bench: reagent delivery, washing, mixing, and target molecule detection. The Asklepios portable system utilizes a modular microfluidics cartridge with configurable functional components. Application-specific components are inserted into the universal cartridge case. A single cartridge configuration can run a variety of assays. By interchanging the modular components, the possible assay configurations are limitless. The universal electrochemical sensor array allows detection of multiple targets from a single sample. The revolutionary sensor technology allows any combination of different RNA, DNA, and protein targets to be detected simultaneous in the same cartridge. After the cartridge has been loaded into the system, the onboard process control runs the entire assay within the cartridge. Typical experiments are complete with results in less than 90 minutes.

TECHNOLOGY:

GeneFluidics' direct detection module measures health-specific and disease-specific biomolecules (DNAs, RNAs, proteins, and ions) in raw samples with ultra-high non-target amplified sensitivity. Sub-femtomolar (genetic) and sub-pg/mL (protein) sensitivities are made possible by taking advantage of high turnover enzyme cycling. Cycling occurs when an enzyme is immobilized onto our sensors via an anchor probe/target/signal probe hybrid, substrate solution introduced, and a control bias potential applied at the sensor surface. This enables a signal to be measured with just a few targets present.

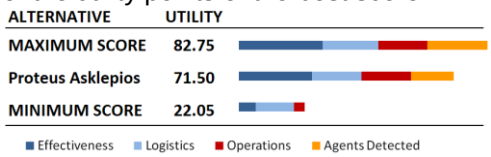
ANALYTICAL Laboratory Ranking

Proteus and Asklepios ranked in the top third of all evaluated products for analytical laboratories and earned 90% of the utility points of the best score.



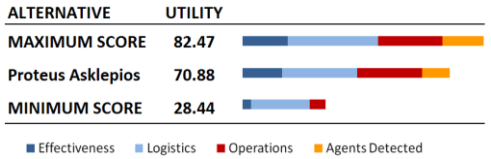
DIAGNOSTIC Laboratory Ranking

Proteus and Asklepios ranked in the top third of all evaluated products for diagnostic laboratories and earned 86% of the utility points of the best score.



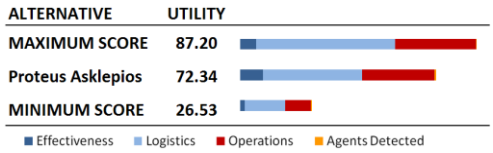
MOBILE Laboratory Ranking

Proteus and Asklepios ranked in the top third of all evaluated products for mobile laboratories and earned 86% of the utility points of the best score.



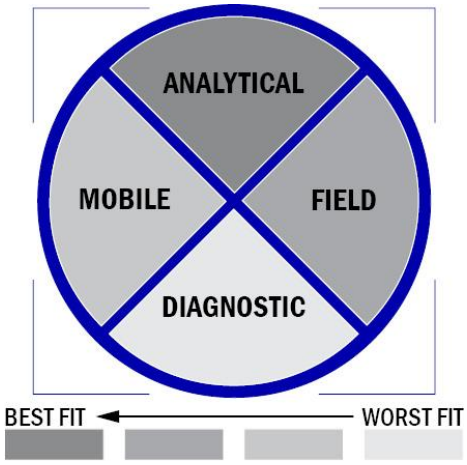
FIELD USE Ranking

Proteus and Asklepios ranked in the top third of all evaluated products for field use and earned 83% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

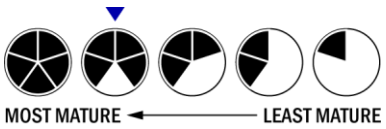
Genefluidics
2540 Corporate Place, B101
Monterey Park CA 91754

COST

- $8,000.00-15,000.00/Asklepios system
- $24,900.00-50,000.00/Proteus system
- $15.00-25.00/analysis

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- No sounds or alarms
- Screen cannot be dimmed
- Less than 200 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- Less than 5 minutes for set up
- Almost no down time
- 0-2 steps are required
- DVD/ Web video/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components stored at room temp can withstand temps >45°C for <24 hours/ Components must be stored at room temp and at 4°C
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All means of transport
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 4 solutions and/or reagents
- 1 component

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance is included
- Expected life 5-10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1 hr

Physical System Requirements:
- 110V electrical requirement
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 10 ul for a test

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Fully autonomous system
- Laptop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

pTD

by Bruker Detection

DETECTS THE FOLLOWING:

Demonstrated:
Toxins (Less than 1ng/ml)

DETECTION MATRICES:

Demonstrated:
Environmental air, Environmental water, Soil, Food, Powder

DESCRIPTION:

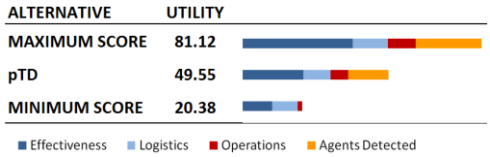
The portable Toxin Detector (pTD) allows the rapid, specific and sensitive identification of toxins, which are relevant as biological warfare agents. Application of the ready-to-use pTD Toxin Test Kit BWA I allows the parallel detection of botulinum neurotoxins (BoNT/A, BoNT/B, BoNT/E), staphylococcal enterotoxin B and ricin within less than 25 min in an automated process. A decontamination procedure is integrated in the assay ensuring secure operation of pTD. The system is intended for the on-site analysis of toxins in mobile labs and on-board vehicles. pTD Control is the control and analysis software of the pTD system. The user monitors and controls the start up and shut down of the device as well as the selection and the progress of methods via pTD Control. The results of each analysis are displayed automatically in pTD Control using a traffic light-based colour code. Red traffic light is shown together with the warning note that a target was found after identification of a toxin. Data evaluation is realized automatically. Integrated positive and negative control electrodes allow normalization of target electrode signals. This ensures reproducibility of electrochemical toxin detection within different chip batches. The pTD is a platform technology and extendable to address new threats. In addition to toxin detection, first promising results for detection of bacteria and viruses via PCR and nucleic acid hybridization were obtained. Integration of a PCR chamber in pTD will allow nucleic acid amplification and detection of several BWA related microorganisms in parallel.

TECHNOLOGY:

The detection principle is based on an ELISA procedure. Capture antibodies immobilized on gold electrodes facilitate the specific binding of corresponding toxins. Detection of bound toxins is realized by application of a detector-antibody-enzyme conjugate and measurement of the electrical current of an enzymatic redox reaction. The detection event is strongly amplified in this system and allows sensitive toxin identification (low ng/mL-range) in less than 25 minutes. First, the high turnover of enzymatic reaction contributes to the signal amplification and second, a redox recycling procedure built into the experimental procedure, provides a second signal amplification.

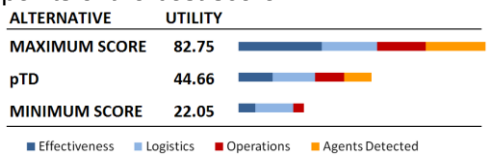
ANALYTICAL Laboratory Ranking

pTD ranked in the middle third of all evaluated products for analytical laboratories and earned 61% of the utility points of the best score.



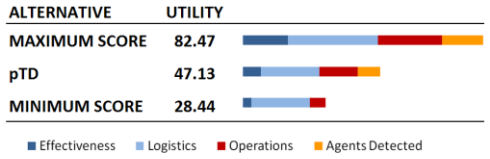
DIAGNOSTIC Laboratory Ranking

pTD ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 54% of the utility points of the best score.



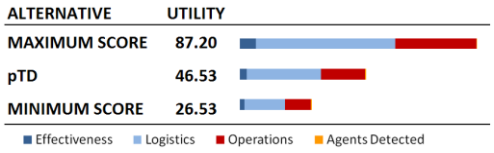
MOBILE Laboratory Ranking

pTD ranked in the bottom third of all evaluated products for mobile laboratories and earned 57% of the utility points of the best score.



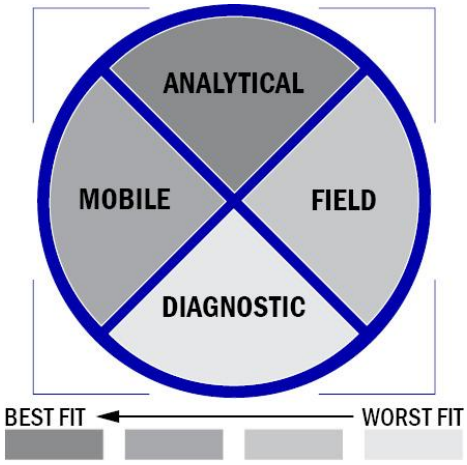
FIELD USE Ranking

pTD ranked in the bottom third of all evaluated products for field use and earned 53% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Bruker Detection
Division of Bruker Daltonik GmbH
Permosersr. 15
Leipzig, D-04318
Germany

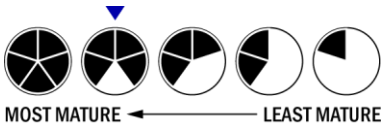
Point of Contact:
Dr. Thomas Elbner
+49 341 2431 366
the@bdal.de

COST

- $80,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15 - 30 minutes for detection
- 1 sample, >10 tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- No screen
- Between 200-500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- <5 minutes set-up required
- <1 minute down time
- 3-5 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components must be stored at 4°C
- Performance is not influenced by relative humidity
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Transport via commercial carrier
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service less than once a year
- Preventive maintenance not applicable
- Maintenance not included
- Expected life unknown
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results not available
- Data cannot be processed while in progress
- No centrifugation steps
- Multiple shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connections
- Not autonomous
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software is closed and not available for modification
- System hardware is closed and available for modification

QFlu Combo Test for POC Flu Diagnosis and Drug Resistance Detection

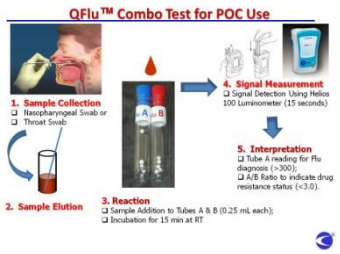
by Cellex, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Viruses (100-1,000 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Nasal and throat swabs



DESCRIPTION:

The QFlu Combo Test is designed for point-of-care use. It can simultaneously detect influenza virus in a sample and determine drug (e.g., Tamiflu) resistance within 15 minutes. The test uses a small, handheld detector that is powered with two AA batteries.

TECHNOLOGY:

The QFlu test detects influenza viral neuraminidase activity using a novel, biochemiluminescent substrate, a luciferin-neuraminic acid conjugate. In the presence of the influenza virus, the substrate is cleaved to release luciferin, which is immediately metabolized by luciferase in the reaction mix to generate detectable light. All reagents are formulated as a master mix. One only needs to add a sample (0.25 mL) into the reagent tube and, after 15 min incubation, detect the light signal using a handheld luminometer. For detection of drug resistance, an additional reagent tube is used, which contains the drug (Tamiflu or Relenza). The signal difference between reagents with and without the drug is used to indicate drug resistance status. The instrument would be able to interpret the test results.

ANALYTICAL Laboratory Ranking

QFlu Combo Test ranked in the middle third of all evaluated products for analytical laboratories and earned 56% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
QFlu - Flu and Drug	45.47
MINIMUM SCORE	20.38

■ Effectiveness ■ Logistics ■ Operations ■ Agents Detected

DIAGNOSTIC Laboratory Ranking

QFlu Combo Test ranked in the top third of all evaluated products for diagnostic laboratories and earned 68% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
QFlu - Flu and Drug	55.92
MINIMUM SCORE	22.05

■ Effectiveness ■ Logistics ■ Operations ■ Agents Detected

MOBILE Laboratory Ranking

QFlu Combo Test ranked in the top third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
QFlu - Flu and Drug	61.69
MINIMUM SCORE	28.44

■ Effectiveness ■ Logistics ■ Operations ■ Agents Detected

FIELD USE Ranking

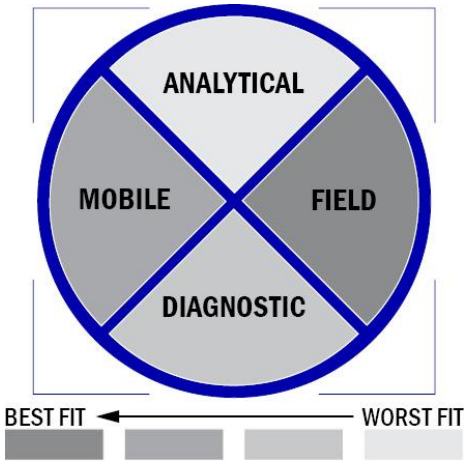
QFlu Combo Test ranked in the top third of all evaluated products for field use and earned 88% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
QFlu - Flu and Drug	76.83
MINIMUM SCORE	26.53

■ Effectiveness ■ Logistics ■ Operations ■ Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Cellex, Inc.
9700 Great Seneca Highway
Rockville, MD 20850

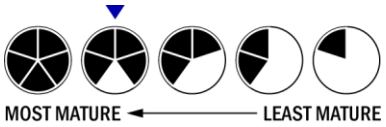
Point of Contact:
X. James Li
(301) 905-7269
lix@cellexinc.com

COST

- $500.00/system or device

SPECIFICITY

- False Positives: 5% (expected)
- False Negatives: 8% (expected)



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- Multiple samples, multiple tests/sample per run
- Could easily be adapted into a fully automated system

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- No set-up required
- <1 minute down time
- 0-2 steps required
- Customer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at 4°C/ Must be frozen
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a soda can
- Transport via commercial carrier
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life 3-5 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- No electrical requirement
- 4-8 hour battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results not available
- Data processing while in progress information not available
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance pending
- FDA clearance pending
- Less than 250 ul to test liquids

System Maturity:
- Is commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Not network capable
- Not autonomous
- No computer required
- Stores and archives data outputs and creates an electronic record
- System software is open and available for modification
- System hardware is open and available for modification

QFlu Combo Test for Rapid and Flu Diagnosis and Drug Resistance Detection

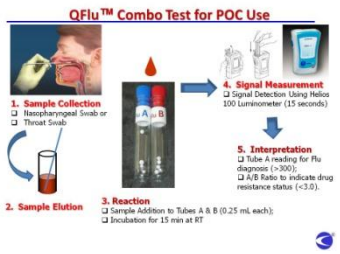
By Cellex, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Viruses (100-1,000 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Nasal and throat swabs



DESCRIPTION:

The QFlu Combo Test is intended to be used in point-of-care setting (initial response) for simultaneous diagnosis of influenza and drug resistance. There is only one key reagent, the master mix, and a handheld device for detection of the light signal. The assay is essentially a one-step assay (sample addition), which can be completed in 17 minutes with approximately 2 minute manual time. Analytical studies show that the test is at least 100,000 as sensitive as the lateral flow based flu test.

TECHNOLOGY:

The QFlu Combo Test uses a specific substrate for detection of influenza viral neuraminidase activity (hence diagnosis of influenza) and inhibition of this enzyme (hence determination of resistance to Tamiflu and Relenza). The substrate is a conjugate between luciferin and modified neuraminic acid. In the presence of flu virus, the substrate is cleaved to liberate luciferin, which is immediately oxidized by luciferase to generate light signal. The reagents are formulated as a master mix. Sample testing involves sample addition and signal detection using a handheld luminometer.

ANALYTICAL Laboratory Ranking

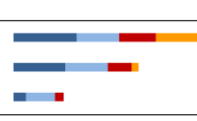
QFlu Combo Test ranked in the middle third of all evaluated products for analytical laboratories and earned 60% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
QFlu - Rapid Flu and Drug	46.18
MINIMUM SCORE	20.38

DIAGNOSTIC Laboratory Ranking

QFlu Combo Test ranked in the top third of all evaluated products for diagnostic laboratories and earned 67% of the utility points of the best score.

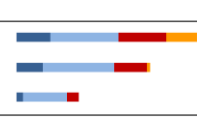
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
QFlu - Rapid Flu and Drug	55.12
MINIMUM SCORE	22.05



MOBILE Laboratory Ranking

QFlu Combo Test ranked in the top third of all evaluated products for mobile laboratories and earned 74% of the utility points of the best score.

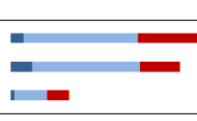
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
QFlu - Rapid Flu and Drug	61.11
MINIMUM SCORE	28.44



FIELD USE Ranking

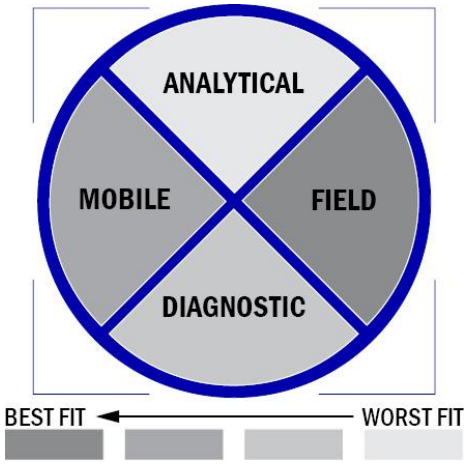
QFlu Combo Test ranked in the top third of all evaluated products for field use and earned 87% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
QFlu - Rapid Flu and Drug	76.00
MINIMUM SCORE	26.53



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Cellex, Inc.
104 Alexander Dr.
Building 6
PO 12808
Research Triangle Park, NC 27709

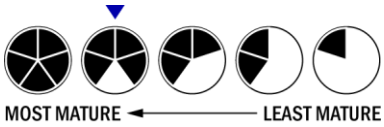
Point of Contact:
X. James Li

COST

- $500.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Could easily be adapted into a fully automated system

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- 1-3 minutes down time
- 0-2 steps required
- Hard-copy operators manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at 4°C
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a soda can
- Transport via commercial carrier
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 1-3 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results not available
- Data processing while in progress information not available
- Multiple centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System does not call final result

Sensitivity and Detection:
- 510K clearance pending
- FDA clearance pending
- 500 ul to test liquids

System Maturity:
- Is commercially available
- Appearance in peer reviewed publication or independent evaluation information not available
- Technology ownership and intellectual property owned

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Not network capable
- Wired connections
- Could be fully autonomous system with some effort
- No computer required
- Stores and archives data outputs and creates an electronic record
- Software open and available for modification
- System hardware open and available for modification

qNano

by Izon Science USA

DETECTS THE FOLLOWING:
Demonstrated:
Viruses

DETECTION MATRICES:
Demonstrated:
Urine, Environmental water

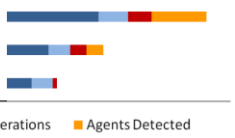
DESCRIPTION:
Particle analyzer capable of characterizing pathogens such as bacteria and virus particles.

TECHNOLOGY:
System uses adjustable nanopore to characterize single particles as they flow along an electric and pressure gradient.

ANALYTICAL Laboratory Ranking

qNano ranked in the bottom third of all evaluated products for analytical laboratories and earned 49% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
qNano	39.41
MINIMUM SCORE	20.38



DIAGNOSTIC Laboratory Ranking

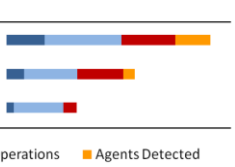
qNano ranked in the middle third of all evaluated products for diagnostic laboratories and earned 55% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
qNano	45.83
MINIMUM SCORE	22.05

MOBILE Laboratory Ranking

qNano ranked in the middle third of all evaluated products for mobile laboratories and earned 63% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
qNano	52.00
MINIMUM SCORE	28.44



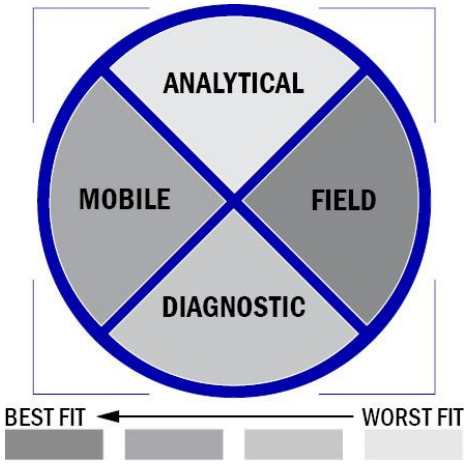
FIELD USE Ranking

qNano ranked in the middle third of all evaluated products for field use and earned 71% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
qNano	61.65
MINIMUM SCORE	26.53

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Izon Science USA
4841 International Blvd. Suite 105
Frederick, MD 21703

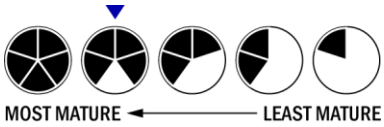
Point of Contact:
dietrich@izon.com

COST

- $20,000.00/system or device

SPECIFICITY

- False Positives: < 0.1% false positives in the field with over 100,000 tests
- False Negatives: False negatives cannot be reported as a single number because it is sample type, sample prep, assay, and concentration specific.



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15 - 30 minutes for detection
- Multiple samples, multiple tests/samples per run
- Could be adapted to fully automated with some effort

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- A day of training and technical skills required
- 5-10 minutes set-up required
- 1-3 minutes down time
- 3-5 steps required
- DVD/ Web video/ Customer and manufacturer site training/ Web-based manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Components should be stored at room temp but can stand temps >45°C for < 24 hours
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- No service required
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life unknown
- 5-10 minutes daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- Single centrifugation step
- Single shaking or vortexing, mixing, degassing or filtering step
- System could call final result in future

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 50 ul required for test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Could be adapted to a fully autonomous system with significant effort
- Laptop computer
- Stores and archives data outputs and creates electronic records
- System software open and available for modification
- System hardware open but modification requires licensing

QTL Biosensor 2200R

by QTL Biosystems

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Viruses (100-1000 PFU/mL)
Toxins (<1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Environmental Water, Powder

DESCRIPTION:

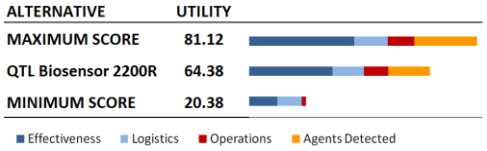
The BIOSENSOR 2200R biological agent detector is a handheld, portable, on-site instrument for rapid detection, analysis, and identification of biological agents. Unique bioassay technology offers excellent sensitivity and low false positives while offering ease of use in the field. This highly accurate detection method provides rapid measurement of biohazards such as anthrax, ricin, botulism, SEB, and plague. Exclusive five minute time-to-answer allows first responders to make informed critical decisions more rapidly than any other biological agent detector. The BIOSENSOR 2200R employs dynamic surface generation, a patent pending type of immunomagnetic assay detection technology. This technology offers significant advantages over other field-based assay methods by combining the benefits of both the free solution and lateral flow types. The result is more rapid analysis, a user-friendly format, and detector stability within a wide range of climates. Both wet and dry samples may be tested and results are displayed with a simple red (target present) or green (no target present) indication. As tests are nondestructive, samples may be retained as evidence. Single-test, disposable cartridges with on-board reagents have a 16 month shelf life. This instrument is IP 67 certified and permanently housed in a sturdy, light weight fully decon-able Pelican case. Recent research and development has demonstrated that the Biosensor 2200R can identify targets in whole blood and can be utilized as a human diagnostic device.

TECHNOLOGY:

The BIOSENSOR 2200R employs dynamic surface generation, a patent pending type of immunomagnetic sandwich assay technology. 1. MIX Sample is mixed with the sensing solution which contains: a magnetic component, a fluorescent component and receptors for the biological agent(s) of interest. 2. BIND Sensing materials bind to target during incubation. 3. MAGNETIZE All bound and unbound magnetic material is pulled to surface. 4. WASH All remaining sensing and non-target material is washed away. False positives are virtually eliminated by removing potential interferrents. 5. READ Concentrated sample (pellet) is illuminated and emits a signal if target is present.

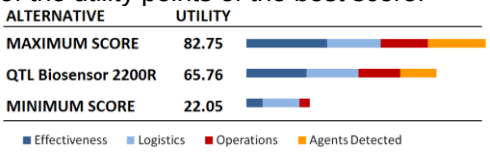
ANALYTICAL Laboratory Ranking

QTL Biosensor 2200R ranked in the top third of all evaluated products for analytical laboratories and earned 79% of the utility points of the best score.



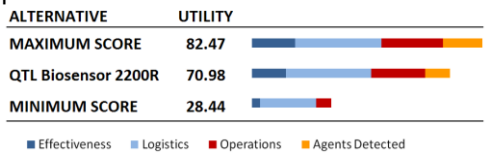
DIAGNOSTIC Laboratory Ranking

QTL Biosensor 2200R ranked in the top third of all evaluated products for diagnostic laboratories and earned 79% of the utility points of the best score.



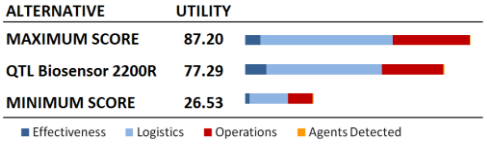
MOBILE Laboratory Ranking

QTL Biosensor 2200R ranked in the top third of all evaluated products for mobile laboratories and earned 86% of the utility points of the best score.



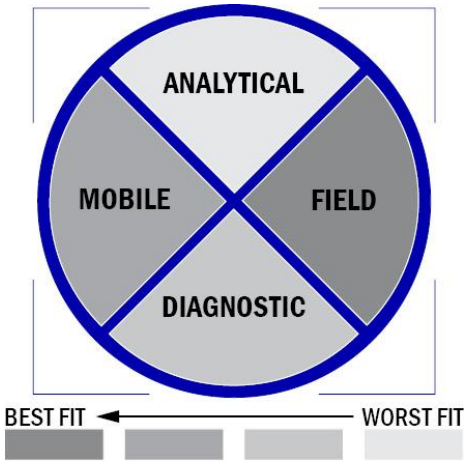
FIELD USE Ranking

QTL Biosensor 2200R ranked in the top third of all evaluated products for field use and earned 89% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

QTL Biosystems
935 4th Ave.
New Kensington PA 15068

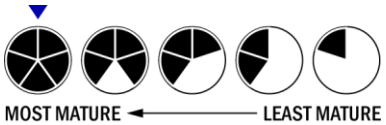
Point of Contact:
Brian Oswalt
(724) 575-0033
boswalt@qtlbio.com

COST

- $15,995.00/system or device
- <$50.00/analysis

SPECIFICITY

- False Positives: 0.0001%
- False Negatives: 0.01%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- 1 sample, <10 tests/ sample per run
- Currently semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- No set up
- Almost no down time
- 6-8 steps are required
- DVD/ Web video/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components stored at room temp but can withstand temp in excess of 45°C for periods of less than 24 hours
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All means of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 3 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- No service required
- Preventive maintenance N/A
- Expected life >10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Batteries
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- A single shaking or vortexing, mixing, degassing or filtering step required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 10 ul for a test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Not network capable
- Wired connections
- Not capable of autonomy
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

QTL Biosensor 4000

by QTL Biosystems

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Viruses (100-1000 PFU/mL)
Toxins (<1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Environmental Water, Soil, Powder

DESCRIPTION:

The BIOSENSOR 4000 offers first responders and emergency medical technicians an automated instrument to further advance biological agent detection in the field, on the ambulance and in the laboratory. The BIOSENSOR 4000 fully automates the detection process from wet or dry sample introduction to result with no other user interaction required. The assay cartridge enables users to test simultaneously for up to eight pathogens. Unique bioassay technology offers excellent sensitivity and low false positives while offering ease of use in the field. This detection method provides rapid measurement of multiple biohazards such as anthrax, ricin, plague, smallpox and West Nile virus. Exclusive five minute time-to-answer allows first responders to make informed critical decisions more rapidly than any other biological agent detector. The BIOSENSOR 4000 employs dynamic surface generation, a patent pending type of immunomagnetic assay detection technology. The instrument offer significant advantages over other field and lab based assay methods including better sensitivity, faster analysis, and detector stability within a wide range of climates. Results are displayed with a simple red (target present) or green (no target present) indication. As tests are nondestructive, samples may be retained as evidence. This instrument is IP 67 certified and permanently housed in a sturdy, light weight fully decon-able Pelican case. R&D has demonstrated that the BIOSENSOR 4000 can identify targets in whole blood and can be utilized as a human diagnostic device.

TECHNOLOGY:

The BIOSENSOR 4000 employs dynamic surface generation, a patent pending type of immunomagnetic sandwich assay technology. 1. MIX Sample is mixed with the sensing solution which contains: a magnetic component, a fluorescent component and receptors for the biological agent(s) of interest. 2. BIND Sensing materials bind to target during incubation. 3. MAGNETIZE All bound and unbound magnetic material is pulled to surface. 4. WASH All remaining sensing and non-target material is washed away. False positives are virtually eliminated by removing interferants. 5. READ Concentrated sample (pellet) is illuminated and emits a signal if target is present.

ANALYTICAL Laboratory Ranking

QTL Biosensor 4000 ranked in the top third of all evaluated products for analytical laboratories and earned 79% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
QTL BIOSENSOR 4000	68.56
MINIMUM SCORE	20.38

DIAGNOSTIC Laboratory Ranking

QTL Biosensor 4000 ranked in the top third of all evaluated products for diagnostic laboratories and earned 79% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
QTL BIOSENSOR 4000	68.94
MINIMUM SCORE	22.05

MOBILE Laboratory Ranking

QTL Biosensor 4000 ranked in the top third of all evaluated products for mobile laboratories and earned 86% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
QTL BIOSENSOR 4000	72.80
MINIMUM SCORE	28.44

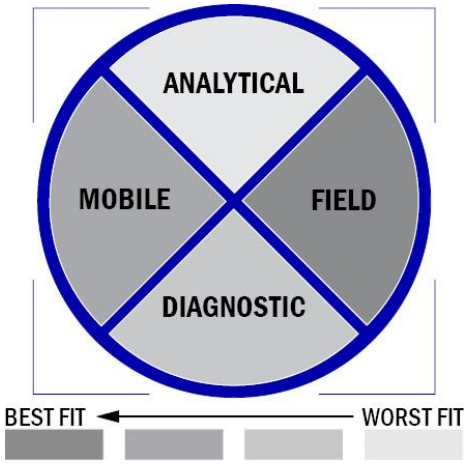
FIELD USE Ranking

QTL Biosensor 4000 ranked in the top third of all evaluated products for field use and earned 89% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
QTL BIOSENSOR 4000	77.22
MINIMUM SCORE	26.53

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

QTL Biosystems
935 4th Ave.
New Kensington PA 15068

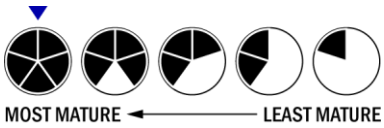
Point of Contact:
Brian Oswalt
(724) 575-0033
boswalt@qtlbio.com

COST

- $17,995.00/system or device
- <$75.00/ for analysis of up to 8 agents

SPECIFICITY

- False Positives: 0.0001%
- False Negatives: 0.01%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- 1 sample, <10 tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- No set up
- Almost no down time
- 0-2 steps are required
- DVD/ Web video/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components stored at room temp but can withstand temp in excess of 45°C for periods of less than 24 hours
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 3 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- No service required
- No preventive maintenance
- Expected life >10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Batteries
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- A single shaking or vortexing, mixing, degassing or filtering step required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 10 ul for a test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Not network capable
- Wired connections
- Fully autonomous system with some effort
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

Quant NQAD QT-500 Detector

by Quant Technologies

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

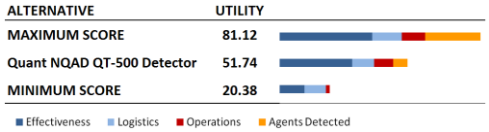
The NQAD is a Universal HPLC detector that can be used in-line with other detectors or as the detector of choice for various HPLC analyses including UHPLC, HPLC, GPC, and SFC. The NQAD line of detectors utilizes water condensation nucleation technology which does not rely on a specific characteristic of the compound to be detected. The detector first nebulizes the HPLC stream then, second, evaporates the mobile phase leaving a dried aerosol particle. Third, water is condensed on the particle to increase its size. Only then is each particle individually counted. At a basic level, the NQAD is a particle counter that works well as a mass counter as well. With a strong separation method, the NQADs high sensitivity, linearity, wide dynamic range and high reproducibility lead to nanogram on column sensitivity. Detection does not rely on a specific characteristic of the compound; therefore, no derivitazion is needed. The detector works well with gradient methods, mobile phases of any pH, is linear over 3-4 orders of magnitude and displays a peak reading in real time.

TECHNOLOGY:

The Quant line of NQAD detectors utilizes “Water Condensation Nucleation” technology. This technology has been used in air particle analyzers, which are generally used for clean room analysis and environmental monitoring. In addition, it has been used as a nonvolatile residue monitor that tests the amount of nonvolatile residue in ultrapure water system (crucial in the semiconductor industry). The NQAD line of detectors was created by taking this robust technology and applying it to chromatography.

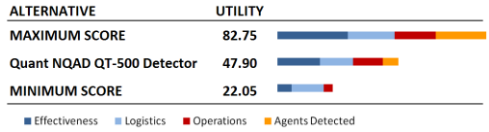
ANALYTICAL Laboratory Ranking

NQAD ranked in the middle third of all evaluated products for analytical laboratories and earned 64% of the utility points of the best score.



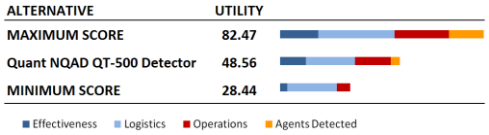
DIAGNOSTIC Laboratory Ranking

NQAD ranked in the middle third of all evaluated products for diagnostic laboratories and earned 58% of the utility points of the best score.



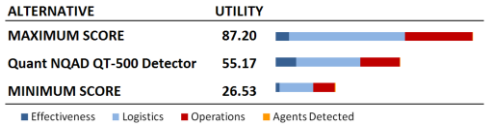
MOBILE Laboratory Ranking

NQAD ranked in the bottom third of all evaluated products for mobile laboratories and earned 59% of the utility points of the best score.



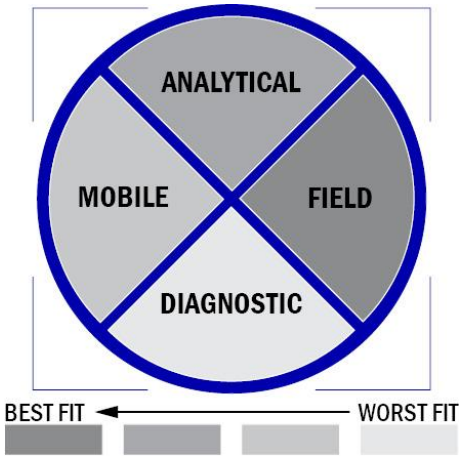
FIELD USE Ranking

NQAD ranked in the bottom third of all evaluated products for field use and earned 63% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Quant Technologies
1463 94th Lane NE
Blaine, MN 55449

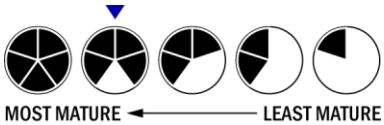
Point of Contact:
Melissa Tucker Nelson
MelissaN@QuantTechnologies.com
763/398.0508

COST

- $25,500.00 - 36,500.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- 10-20 minutes set-up
- Almost instantaneous down time
- 0-2 steps required
- DVD/ Web video/ Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at room temperature (27°C)
- Performance not influenced by relative humidity
- 1 to 6 months shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life >10 years
- 10-20 minutes daily QA
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Requires water aliquots
- External air or gas source required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System could call final result in the future

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connection
- Could easily be adapted to fully autonomous
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- Does not employ software
- System hardware is open but modification requires licensing

R.A.P.I.D. BioThreat Detection System

by Idaho Technology, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Viruses (10e3-10e4 PFU/mL)
Toxins (1-100 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Environmental air, Environmental water, Soil, Food, Powder

DESCRIPTION:

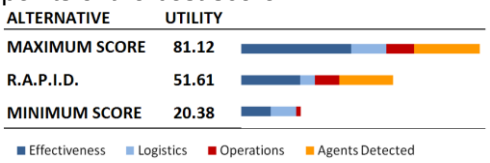
The Ruggedized Advanced Pathogen Identification Device (R.A.P.I.D.) is a portable real-time PCR system designed to identify biological agents. Because of its rugged design, reliability, and sensitivity it has become the standard for the U.S. DoD and other militaries around the world. The R.A.P.I.D. is the ideal choice for mobile analytical labs and field hospitals. The instrument integrates Idaho Technology's LightCycler ® Instrument technology into a portable, impact resistant package. Distinctive software allows simple "push-button" use of the R.A.P.I.D. System by military field personnel with minimal training. R.A.P.I.D.'s open platform supports multiple chemistries and sample matrices including environmental and food samples. Used with Idaho Technology's commercial freeze-dried pathogen test kits or customized reactions, R.A.P.I.D. provides quick, safe, and accurate field identification of pathogens.

TECHNOLOGY:

Real-time Polymerase Chain Reaction (PCR).

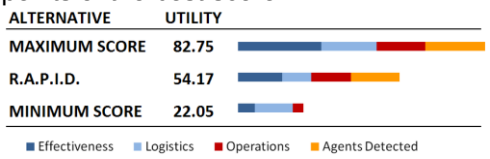
ANALYTICAL Laboratory Ranking

R.A.P.I.D. ranked in the middle third of all evaluated products for analytical laboratories and earned 64% of the utility points of the best score.



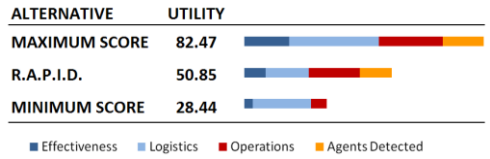
DIAGNOSTIC Laboratory Ranking

R.A.P.I.D. ranked in the middle third of all evaluated products for diagnostic laboratories and earned 65% of the utility points of the best score.



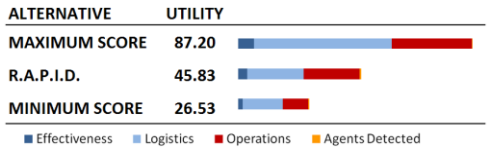
MOBILE Laboratory Ranking

R.A.P.I.D. ranked in the bottom third of all evaluated products for mobile laboratories and earned 62% of the utility points of the best score.



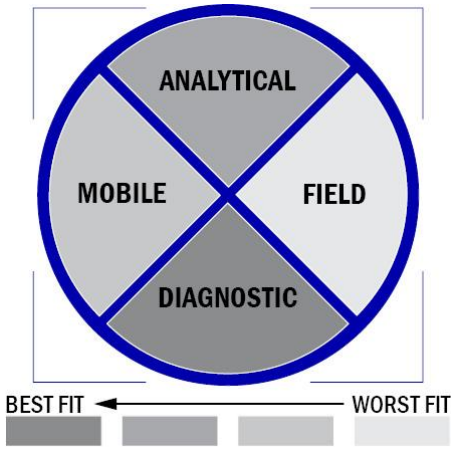
FIELD USE Ranking

R.A.P.I.D. ranked in the bottom third of all evaluated products for field use and earned 53% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Idaho Technology, Inc.
390 Wakara Way
Salt Lake City, UT 84108

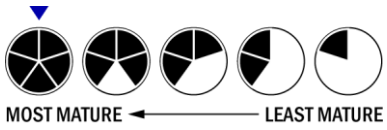
Point of Contact:
Lou Banks

COST

- $55,000.00/system or device
- $24.75/assay

SPECIFICITY

- False Positives: <1%
- False Negatives: assay dependent



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Semi-automated with some effort

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- More than a day of training and technical skills are required
- 10-20 minutes set up
- 3-5 minutes down time
- >12 steps are required
- DVD/ Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components stored at room temp but can withstand >45°C for periods of < 24 hours
- Performance is not influenced by relative humidity
- 1 to 6 months shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 4 solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service less than one a year
- Preventive maintenance by customer
- Maintenance is included
- Expected life 5-10 years
- Less than 5 minutes required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can not be processed while in progress
- No centrifugation steps required
- A single shaking or vortexing, mixing, degassing or filtering step required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Greater than 250 ul for a test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Not network capable
- No data transmission
- Not capable of autonomous system
- Laptop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

radHUNTER

by ICx Radiation

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

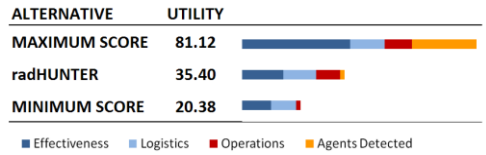
The radHUNTER is an extremely sensitive and accurate digital hand-held gamma radionuclide identification device (RID). It is the culmination of over eight years of development of micro-miniature, digital signal processing electronics; operating power conservation; and advancements in the scintillation detector, radionuclide template matching identification algorithm. The radHUNTER development was supported in part by the U.S. Department of Homeland Security (DHS) / Domestic Nuclear Detection Office (DNDO), Human Portable Radiation Detection System (HPRDS) program. Available in two configurations (NaI and LaBr), the radHUNTER is able to quickly detect, rapidly locate, accurately measure and precisely identify sources of contamination from their gamma radiation signature.

TECHNOLOGY:

The instrument uses either a LaBr or NaI detector to gather a gamma spectrum. This spectrum is analyzed by a template matching algorithm that identifies the isotopes present in the sample.

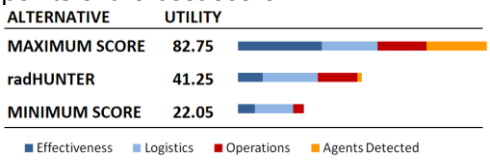
ANALYTICAL Laboratory Ranking

radHUNTER ranked in the bottom third of all evaluated products for analytical laboratories and earned 44% of the utility points of the best score.



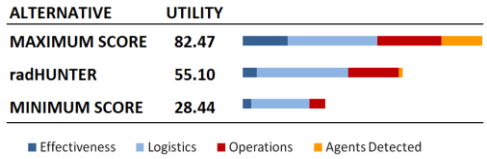
DIAGNOSTIC Laboratory Ranking

radHUNTER ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 50% of the utility points of the best score.



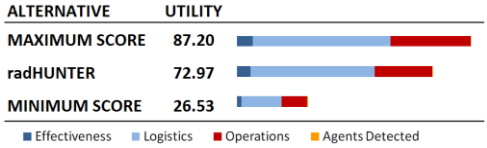
MOBILE Laboratory Ranking

radHUNTER ranked in the middle third of all evaluated products for mobile laboratories and earned 67% of the utility points of the best score.



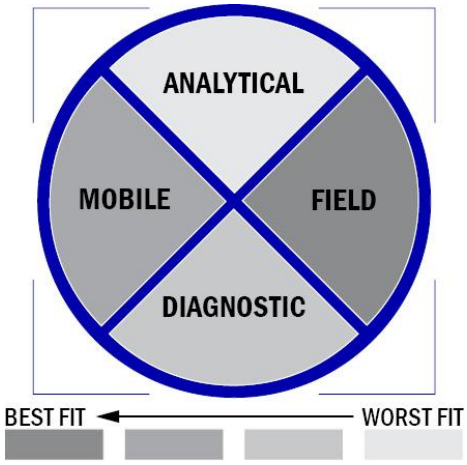
FIELD USE Ranking

radHUNTER ranked in the top third of all evaluated products for field use and earned 94% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ICx Radiation
100 Midland Rd
Oak Ridge, TN 37830

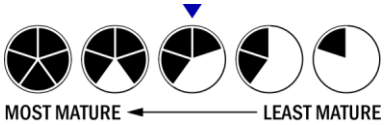
Point of Contact:
Jeff Perkins
Jeffrey.Perkins@icxt.com

COST

- $20,000.00/system or device

SPECIFICITY

- False Positives: Not available
- False Negatives: Not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- 5-10 minutes set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training

Operational conditions:
- Can be used from < -21°C to > 42°
- Does not require consumables
- Performance is not influenced by relative humidity
- Shelf life not applicable

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- Components not applicable

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Decon not applicable

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing, filtering
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Amount needed to test liquid not applicable

System Maturity:
- Brass board
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property owned

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Wireless and wired connections
- Could easily be adapted to fully autonomous system
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software closed, not available for modification
- System hardware closed, not available for modification

Radiation Alert Inspector

by S.E. International, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Toxins (Less than 1ng/ml)

DETECTION MATRICES:

Demonstrated:
Environmental air, Environmental water, Soil, Food, Powder

DESCRIPTION:

The Inspector is a small, handheld, microprocessor-based instrument which offers excellent sensitivity to low levels of alpha, beta, gamma, and x-rays. The digital readout is displayed with a red count light and a beeper sounds with each count detected. Other features include an adjustable timer, external calibration controls and adjustable alert.

TECHNOLOGY:

Gieger Mueller Tube based hand held radiation detector for alpha, beta, gamma, and x-ray.

ANALYTICAL Laboratory Ranking

Radiation Alert Inspector ranked in the bottom third of all evaluated products for analytical laboratories and earned 48% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
Radiation Alert Inspector	39.15
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

Radiation Alert Inspector ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 53% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
Radiation Alert Inspector	43.47
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

Radiation Alert Inspector ranked in the middle third of all evaluated products for mobile laboratories and earned 69% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
Radiation Alert Inspector	56.89
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

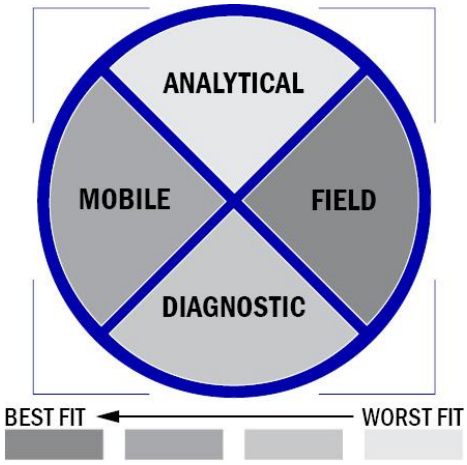
Radiation Alert Inspector ranked in the top third of all evaluated products for field use and earned 83% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
Radiation Alert Inspector	72.38
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

S.E. International, Inc.
P.O. Box 39, 436 Farm Rd.
Summertown, TN 38483
1.800.293.5759

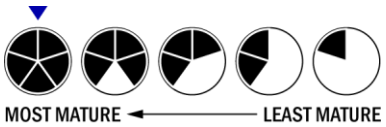
Point of Contact:
Chris Thomas

COST

- $540.00/system or device

SPECIFICITY

- False Positives: 1%
- False Negatives: 1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, single tests/ sample per run
- Not amenable to full or semi-automation

Signature:
- Sounds or alarms present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- DVD/ Web-based video/ Hard-copy and web-based manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transport
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- No additional components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life >10 years
- No daily QA required
- Likely that exposure to hazardous agent cannot be decontaminated

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Not network capable
- Wired connections
- Could be adapted to fully autonomous with some effort
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software closed, not available for modification
- Hardware closed, not available for modification

Radiation Control Monitor

by Technical Associates

DETECTS THE FOLLOWING:

Demonstrated:
Identification of radioisotopes in tissue/ tissue damage
Discrimination between radiation types
Identification of specific isotopes

DETECTION MATRICES:

Demonstrated:
Blood, Environmental air, Environmental water

DESCRIPTION:

The Radiation Control Monitor can be tailored to at least 50 configurations meeting a variety of objectives in monitoring radioactivity including: -exit/doorway monitor - package/mail monitor - vehicle monitor -laundry monitor. To maintain control of radioactive materials it is absolutely essential to control and to know when and where radioactivity is entering or leaving the area where it is used. The Radiation Control Monitor consists of: •Multi-channel systems •Highly sensitive (50 detector models) •Alarms with detection of radiation •Relay control can lock doors and trigger a Siren or autodialer or e-mail Two of the many radiation control monitor systems are high sensitivity monitors which are easily placed at entrance and exits and other strategic locations.

TECHNOLOGY:

The Radiation Control Monitor includes: •Engineering Units: User can input correct conversion factor and change to any units. •Controls: Front Panel: On-Off, Alarm-mute, Rate, Integrate, Reset. •Recessed or Internal: Discriminator level, high voltage. •Detectors: Any GM or alpha, beta, gamma or neutron scintillator. Over 50 probes and sample detectors to chose from. •Input Sensitivity: Adjustable from less than 1 millivolt to 100 millivolt •Anti-saturation and Dead-time Corrections are available. •Power: 105-125 volts, 50-60 Hz (220 V optional)

ANALYTICAL Laboratory Ranking

Radiation Control Monitor ranked in the middle third of all evaluated products for analytical laboratories and earned 60% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
Radiation Control Monitor	48.92
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

Radiation Control Monitor ranked in the top third of all evaluated products for diagnostic laboratories and earned 69% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
Radiation Control Monitor	56.87
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

Radiation Control Monitor ranked in the top third of all evaluated products for mobile laboratories and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
Radiation Control Monitor	63.34
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

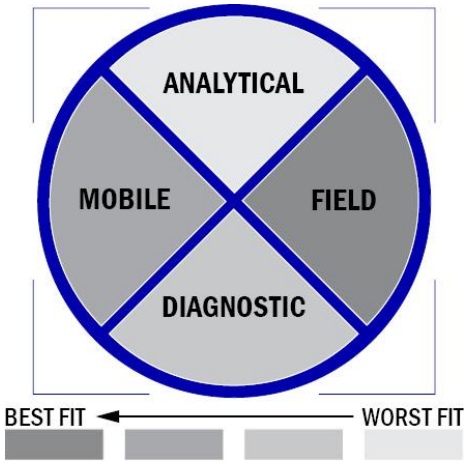
Radiation Control Monitor ranked in the top third of all evaluated products for field use and earned 83% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
Radiation Control Monitor	72.52
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Technical Associates
7051 Eton Ave.
Canoga Park, CA 91303

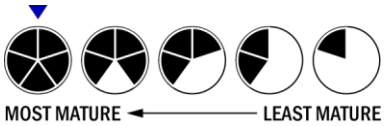
Point of Contact:
Robert Goldstein
818-883-7043

COST

- $9,500 - 60,000/system or device

SPECIFICITY

- False Positives: <1:10,000
- False Negatives: <1:1,000



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, <10 tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- <5 minutes set-up required
- Almost instantaneous down time
- 0-2 steps required
- Manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of carry-on luggage
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Does not test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property owned

Interoperability and System Complexity:
- 150-199 GB raw data generated
- Network capable
- Wired connections
- Fully autonomous
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software is closed and not available for modification
- System hardware is closed and not available for modification

Radiation Pager

by Sensor Technology Engineering, Inc.

DETECTS THE FOLLOWING:
Demonstrated:
Discrimination between radiation types

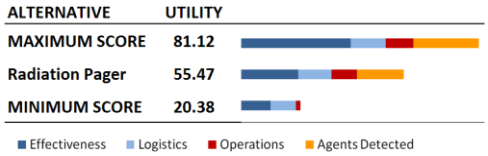
DETECTION MATRICES:
Demonstrated:
Blood, Nasal and throat swab, Stool, Urine, Wound, Environmental air, Environmental water, Soil, Food, Powder

DESCRIPTION:
Handheld gamma detector for interdiction.

TECHNOLOGY:
CsI scintillator with PMT.

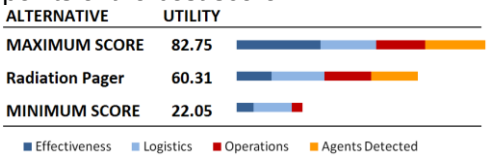
ANALYTICAL Laboratory Ranking

Radiation Pager ranked in the top third of all evaluated products for analytical laboratories and earned 68% of the utility points of the best score.



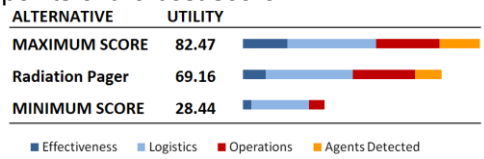
DIAGNOSTIC Laboratory Ranking

Radiation Pager ranked in the top third of all evaluated products for diagnostic laboratories and earned 73% of the utility points of the best score.



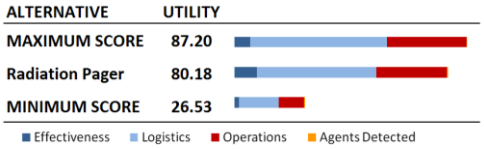
MOBILE Laboratory Ranking

Radiation Pager ranked in the top third of all evaluated products for mobile laboratories and earned 84% of the utility points of the best score.



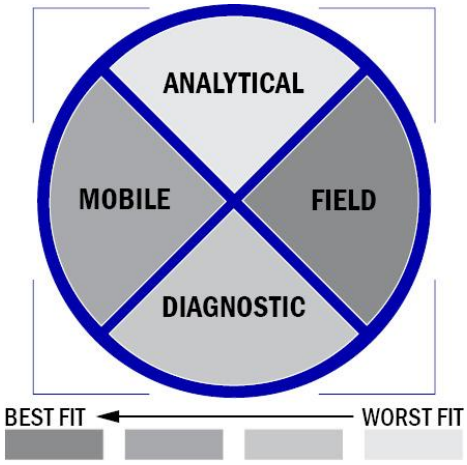
FIELD USE Ranking

Radiation Pager ranked in the top third of all evaluated products for field use and earned 92% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

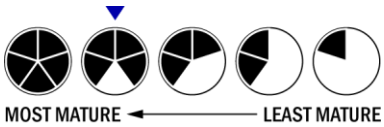
Sensor Technology Engineering, Inc.
5553 Hollister Ave. #1
Santa Barbara, CA 93117
805-964-9507
sb_sensor_tech@email.msn.com

COST

- $1,300.00/system or device

SPECIFICITY

- False Positives: Test every 0.5 sec, one false alarm every 8 hours
- False Negatives: Test every 0.5 sec, one false alarm every 8 hours



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, single tests/ sample per run
- Not amenable to full or semi-automation

Signature:
- Sounds or alarms not present
- No screen
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- >5 minutes set-up
- Almost instantaneous down time
- 0-2 steps required
- DVD/ Hard-copy manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life >10 years
- No daily QA
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Not network capable
- Not autonomous
- No computer required
- Does not store or archive data outputs or create an electronic record
- System software closed and not available for modification
- System hardware closed and not available for modification

Radiation Survey Meter and Surface Monitor

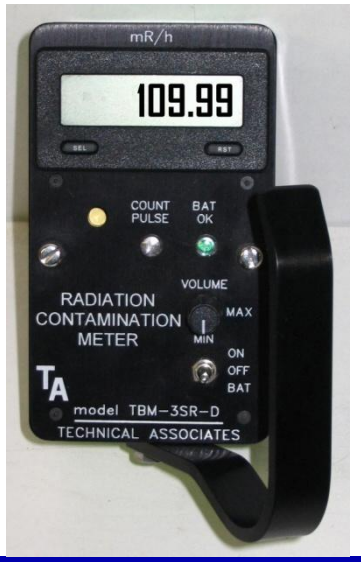
by Technical Associates

DETECTS THE FOLLOWING:

Demonstrated:
Identification of radioisotopes in tissue/ tissue damage
Discrimination between radiation types

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Soil, Food, Powder



DESCRIPTION:

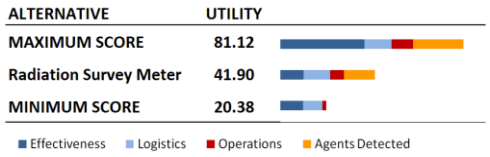
The Radiation Survey Meter and Surface Monitor's small size, light weight, one hand operation, digital display, built in speaker, and large detector area make this a very useful monitor for surveying bench tops or checking hands and clothes for almost any radioactive contamination. It is also available with the mR/hour Scale, uSv/hscale Counts Per Minute Scale or Both Scalers (upon request). End Users: Fire Department, Ambulance, Police, First Responders and U.S Custom Personnel use for surveying people, cars, luggage, surface of room, etc.

TECHNOLOGY:

The Radiation Survey Meter and Surface Monitor is a Small Digital Ratemeter with built in 2" diameter pancake tube and speaker. Reads out in mR/hr (or counts per minute). Thin window recessed and protected by sturdy grill. Additionally TBM-3SR-D has sliding methacrylate beta shield which also acts as additional protection for thin GM tube window. Instrument will see alpha, beta and gamma radiation. Anti-saturation circuit will not fall below full scale in high fields. Tested to 100R/h. It is also available with the mR/hour Scale, uSv/hscale Counts Per Minute Scale or Both Scalers (upon request).

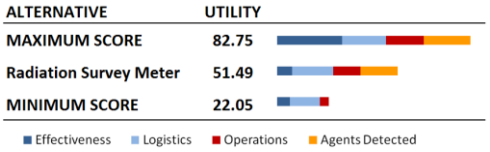
ANALYTICAL Laboratory Ranking

Radiation Survey Meter ranked in the bottom third of all evaluated products for analytical laboratories and earned 52% of the utility points of the best score.



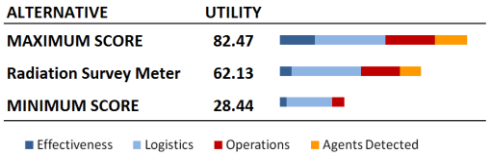
DIAGNOSTIC Laboratory Ranking

Radiation Survey Meter ranked in the middle third of all evaluated products for diagnostic laboratories and earned 62% of the utility points of the best score.



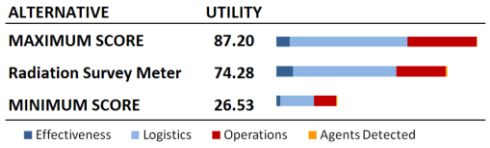
MOBILE Laboratory Ranking

Radiation Survey Meter ranked in the top third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.



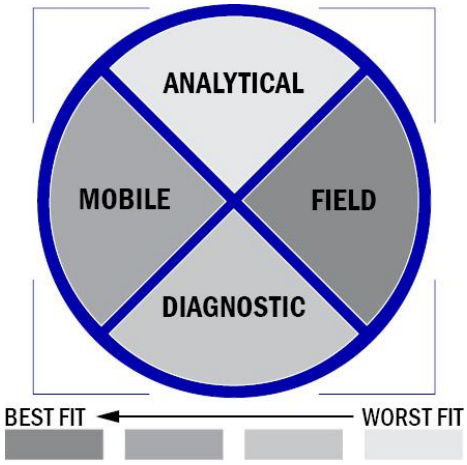
FIELD USE Ranking

Radiation Survey Meter ranked in the top third of all evaluated products for field use and earned 85% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Technical Associates
7051 Eton Ave.
Canoga Park, CA 91303

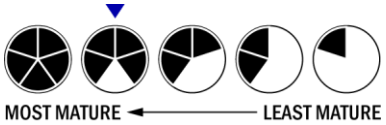
Point of Contact:
Robert Goldstein
818-883-7043

COST

- $585.00/system or device

SPECIFICITY

- False Positives: User makes determination
- False Negatives: User makes determination



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, >10 tests/ sample per run
- Not amenable to full or semi-automation

Signature:
- Sounds or alarms present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy and web-based operators manual

Operational conditions:
- Can be used from -21°C to 41°C
- Consumables not required
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance not applicable
- Maintenance not included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results not available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System does not call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connections
- Not autonomous
- No computer required
- Does not store or archive data outputs or create an electronic record
- System does not employ software
- System hardware closed and available for modification

Radio Frequency Phase Shift Sensor Platform

by Rapid Diagnostek, Inc.

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

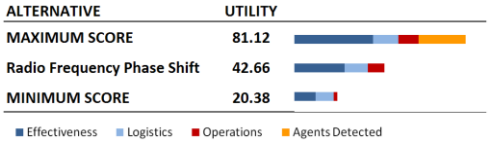
An inexpensive handheld instrument uses disposable sensors. Sensors are specific to one or several targets. After easy mounting of a sensor, untreated liquid sample (blood, urine, saliva, water, etc.) is taken into the disposable sensor/collection device and instrument reports results (target(s) detected including quantity). Data stored and uploaded to central system as needed.

TECHNOLOGY:

Direct detection of target binding to capture molecules on the surface of a piezeoelctric bulk acoustic shear-wave resonator cause changes in phase of the signal proportional to target analyte concentration. Reference (control) resonator included on the sensor is used to account for all non-specific signal changes resulting in rapid, specific target detection and quantification.

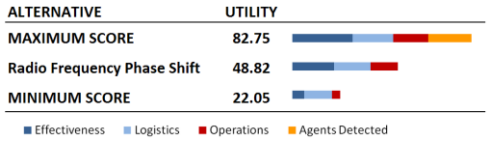
ANALYTICAL Laboratory Ranking

Radio Frequency Phase Shift Sensor Platform ranked in the middle third of all evaluated products for analytical laboratories and earned 53% of the utility points of the best score.



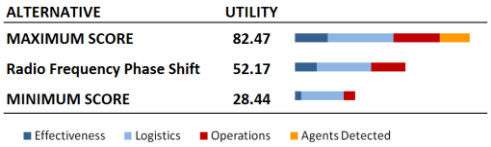
DIAGNOSTIC Laboratory Ranking

Radio Frequency Phase Shift Sensor Platform ranked in the middle third of all evaluated products for diagnostic laboratories and earned 59% of the utility points of the best score.



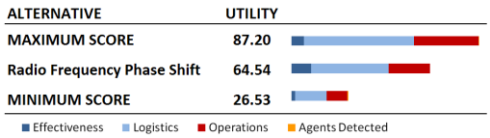
MOBILE Laboratory Ranking

Radio Frequency Phase Shift Sensor Platform ranked in the middle third of all evaluated products for mobile laboratories and earned 63% of the utility points of the best score.



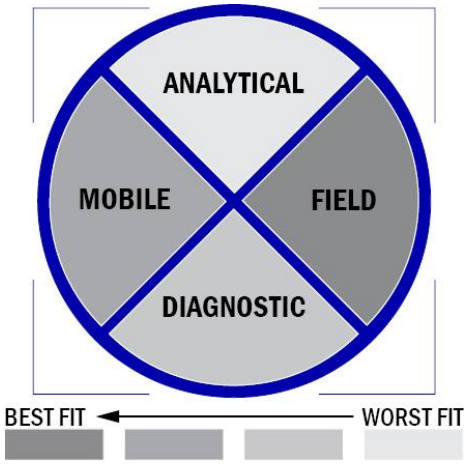
FIELD USE Ranking

Radio Frequency Phase Shift Sensor Platform ranked in the middle third of all evaluated products for field use and earned 74% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Rapid Diagnostek, Inc.
1301 Gateway Circle, Suite 400
Hudson, WI 54016

Point of Contact:
Richard A. Van Deusen
715-808-0568
dick@rapiddiagnostek.com

COST

- $250/system or device

SPECIFICITY

- False Positives: Less than 1%
- False Negatives: Less than 1%

Maturity Not Available

Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, >10 tests/sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be custom ordered to dim or turn off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- CD/DVD/ Web-based video

Operational conditions:
- Can be used from 4°C - 41°C
- Storage and shelf life not yet fully determined
- Performance not influenced by relative humidity
- Shelf life not yet determined

Transportation:
- Approximately the size of a soda can
- Transport via commercial carrier
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Preventive maintenance not included
- Expected life 1-3 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- No electrical equipment
- 4-8 hour battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering step
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 50 ul required for test

System Maturity:
- Information not available

Interoperability and System Complexity:
- Information not available

Radiological Contaminant Water Monitor

by Technical Associates

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types
Identification of specific isotopes

DETECTION MATRICES:

Demonstrated:
Environmental water

DESCRIPTION:

Radiological Contaminant Water Monitor is a multi detector water monitor /controller for simultaneous measuring of alpha, beta and gamma-emitting radio nuclides. Microprocessor with color LCD display. Pre-amps are plug in modules allowing change or addition of functions at a later date, and allow rapid repair by module replacement in the field. Additional monitoring is available and will be tailored upon request. Measurements logged 24 hr/day-7 day/week, with alarm capability and universal read out adaptable to mainframe infrastructure computers. Peak Detection and Isotope Identification TA SMART-PEAK™ Software detects radiation peaks at very low gamma concentration. Tritium and radon detectors optional. Monitor drinking water for all radioactive contaminants; for contamination in ground or surface water; liquid-waste-stream from laboratory or plant. Measures at or below EPA/DHS/PAG levels. Protective action guideline levels and military drinking water limits. Real time, in-line, continuous. Detects alphas, betas, gammas. No reagent tanks to fill. No waste stream. Easy calibration. Prevent acute health effects. Reduce risk of chronic exposure. World's only PAG-level alpha, beta, gamma water monitor. End Users: Military and Civilian; Ground and Surface Drinking Water and Wastewater; Reservoirs; High Profile Buildings: Convention Centers, Sports Arenas, Government Establishments; Industrial Contaminates: Lab, Power Plant, Agricultural; Residual Treatment Additives

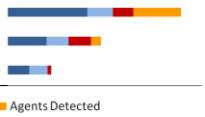
TECHNOLOGY:

1. Alpha Detectors: Anthracene scintillator consists of light-tight detector assembly. 2. Beta Scintillation detectors with 1,000cm2 sensitive area. The beta pulse analysis conditions, analyzes output from photo-multiplier tubes by pulse height, duration and coincidence, eliminating most background and noise counts. 3. Water measured for Gamma-emitter content, uses MCA analyzer with greater than 1,000 channels. Gamma energy of 10 kev to 3 mev, with isotope identification. Peak Detection and Isotope Identification TA SMART-PEAKTM Software detects radiation peaks at very low gamma concentration. Tritium and radon detectors are optional.

ANALYTICAL Laboratory Ranking

Radiological Contaminant Water Monitor ranked in the middle third of all evaluated products for analytical laboratories and earned 54% of the utility points of the best score.

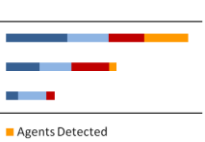
ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
Radiological Water Monitor	43.65
MINIMUM SCORE	20.38



DIAGNOSTIC Laboratory Ranking

Radiological Contaminant Water Monitor ranked in the middle third of all evaluated products for diagnostic laboratories and earned 61% of the utility points of the best score.

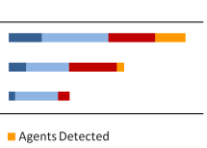
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
Radiological Water Monitor	50.10
MINIMUM SCORE	22.05



MOBILE Laboratory Ranking

Radiological Contaminant Water Monitor ranked in the middle third of all evaluated products for mobile laboratories and earned 65% of the utility points of the best score.

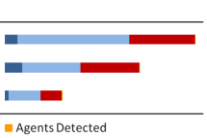
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
Radiological Water Monitor	53.79
MINIMUM SCORE	28.44



FIELD USE Ranking

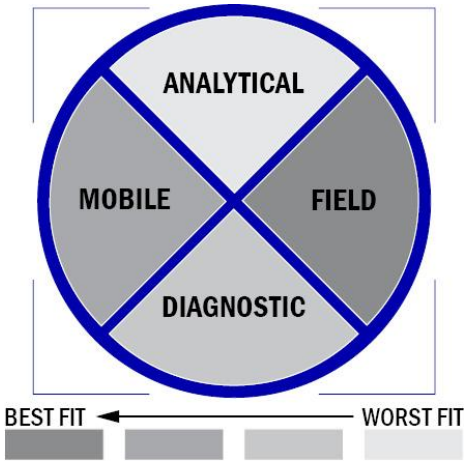
Radiological Contaminant Water Monitor ranked in the middle third of all evaluated products for field use and earned 71% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
Radiological Water Monitor	61.98
MINIMUM SCORE	26.53



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Technical Associates
7051 Eton Ave.
Canoga Park, CA 91303

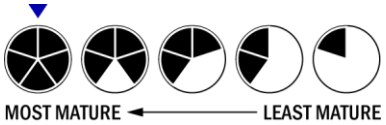
Point of Contact:
Robert Goldstein
818-883-7043

COST

- $125,000.00/system or device

SPECIFICITY

- False Positives: <1:10,000
- False Negatives: <1:1,000



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 and 15 minutes for detection
- 1 sample, >10 tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy and web-based operators manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Larger than a home dishwasher
- All modes of transportation
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Requires continual supply of water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance shown
- FDA clearance not applicable
- Greater than 250 ul to test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- 100-149 GB generated
- Network capable
- Wireless and wired connections
- Could easily be adapted to fully autonomous system
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software is closed but available for modification
- System hardware is open and available for modification

RADIR

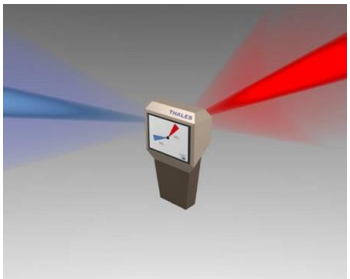
by Thales Group

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types
Identification of specific isotopes

DETECTION MATRICES:

Nothing demonstrated.



DESCRIPTION:

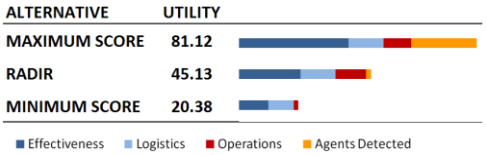
A handheld system for the military or first responder which allows the rapid detection, identification and geo-location of multiple radiation sources (Gamma). The system works with gamma radiation predominantly although a neutron module is available. The system uses an innovative processing system that allows the rapid discrimination, location and tracking of multiple sources simultaneously.

TECHNOLOGY:

The system uses a multiple chipset of CZT crystals (exact configuration and numbers is proprietary) which have been bonded in such a way to allow cell discrimination - in a similar manner to the medical imaging industry. this is combined with highly advanced processing software used in advanced sonar systems for detecting and tracking multiple sources.

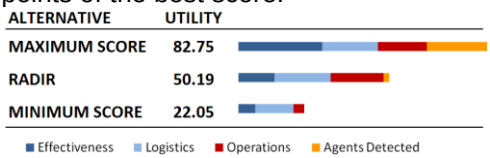
ANALYTICAL Laboratory Ranking

RADIR ranked in the middle third of all evaluated products for analytical laboratories and earned 56% of the utility points of the best score.



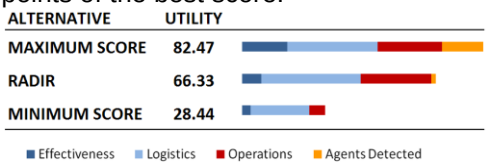
DIAGNOSTIC Laboratory Ranking

RADIR ranked in the middle third of all evaluated products for diagnostic laboratories and earned 61% of the utility points of the best score.



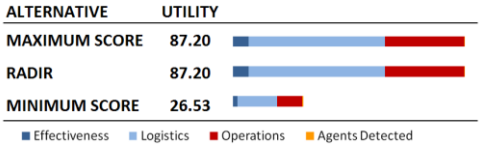
MOBILE Laboratory Ranking

RADIR ranked in the top third of all evaluated products for mobile laboratories and earned 80% of the utility points of the best score.



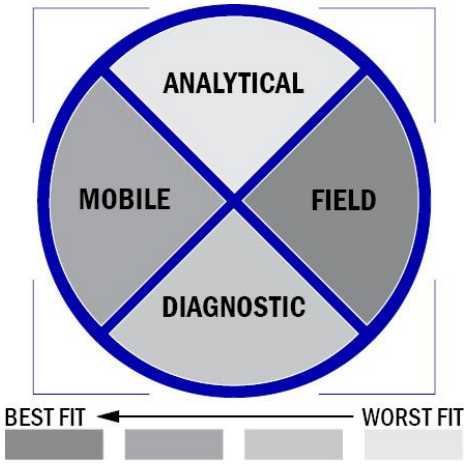
FIELD USE Ranking

RADIR ranked in the top third of all evaluated products for field use and earned 100% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Thales Group
Wookey Hole Road,
Wells, Somerset, BA5 1AA, United Kingdom
www.thalesgroup.com/uk

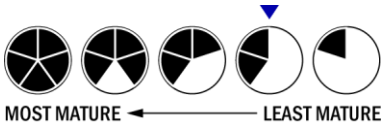
Point of Contact:
Thane Hall CBRN Business Lead
Tel: +44 (0)1749 682247.
Mob: +44 (0) 7971 679537.
thane.hall@uk.thalesgroup.com

COST

- $20,000.00-25,000.00/system or device

SPECIFICITY

- False Positives: Not Available
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- < 5 minutes set up
- Almost instantaneous down time
- 0-2 steps are required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from <-21°C to >42°C
- No consumables
- Performance is not influenced by relative humidity
- No reagents

Transportation:
- Approximately the size of a soda can
- All means of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- Components not applicable

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 5-10 years
- Less than 5 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Batteries
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Liquids not tested

System Maturity:
- Bread board
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Satellite, wireless and wired connections
- Autonomous system with easy adaptation
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

RadSeeker CS

by Smiths Detection, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Identification of radioisotopes in tissue/ tissue damage
Discrimination between radiation types
Identification of specific isotopes

DETECTION MATRICES:

Demonstrated:
Soil, Powder

DESCRIPTION:

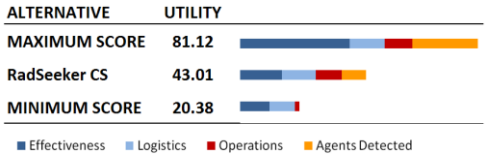
The Smiths Detection RadSeeker CS is a Radioisotope Identification Device (RIID) specifically designed to meet or exceed homeland security, emergency response and defense mission requirements (including ANSI N42.34-2006) for a next-generation field-deployed system capable of detecting and identifying nuclear threat materials. The RadSeeker's significant increase in identification capabilities over currently fielded systems is based on advanced spectrum processing and identification algorithms, coupled with a highly sensitive 2" x 2" Sodium Iodide (NaI) gamma detector. A moderated Helium-3 tube provides neutron detection. The RadSeeker CS is based on a modular design that has high reliability, includes an extensive Built-in-Test (BIT) capability, and requires no calibration. User-designed menus, a high resolution color display, and prioritization of threats were incorporated into the overall design, along with communications via USB, Ethernet, 802.11 Wi-Fi, and direct reachback over SATCOM. The RadSeeker CS is simple to use and supplies the operator with specific information for threat assessment. The user interface is intuitive providing clear and concise details. Pertinent data, such as dose rate, gamma counts per second, and neutron counts per second, are displayed to the user at all times. The RadSeeker CS is designed to be used as either a primary search (detection) device to effectively search pedestrians, packages, cargo, and motor vehicles or a secondary search device for verification of alarms obtained with fixed installations or PRDs. The RadSeeker CS is also an ideal tool for use during a radiological emergency response.

TECHNOLOGY:

The RadSeeker employs Symetrica Ltd's Discovery Technology, which features advanced spectrum processing and identification algorithms to transform the highly sensitive 2"x2" NaI detector in the RadSeeker into a high resolution spectrometer capable of identifying challenging radionuclides such as masked or shielded Special Nuclear Materials. Discovery Technology processes the gamma spectrum through a series of steps to de-convolve the observed spectrum, analyze it for spectral features, and identify the radionuclides present. The proprietary deconvolution technique can increase the effective resolution of a NaI detector from 7% to 2% Full-Width Half-Max (FWHM) at 662keV.

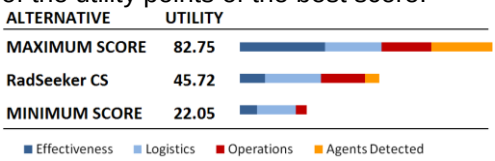
ANALYTICAL Laboratory Ranking

RadSeeker CS System ranked in the middle third of all evaluated products for analytical laboratories and earned 53% of the utility points of the best score.



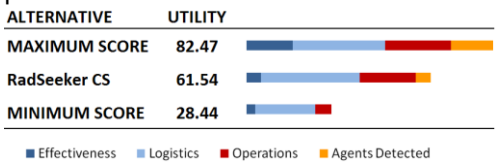
DIAGNOSTIC Laboratory Ranking

RadSeeker CS System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 55% of the utility points of the best score.



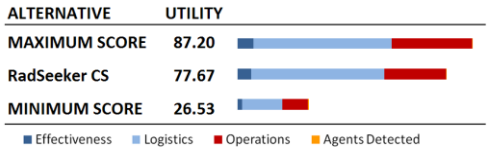
MOBILE Laboratory Ranking

RadSeeker CS System ranked in the top third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.



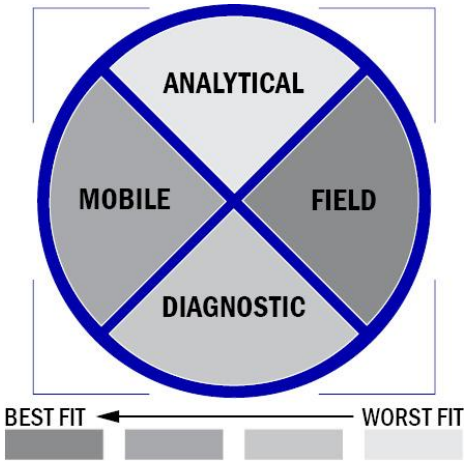
FIELD USE Ranking

RadSeeker CS System ranked in the top third of all evaluated products for field use and earned 89% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Smiths Detection, Inc.
60A Columbia Rd
Morristown, NJ 07960
973 496 9200

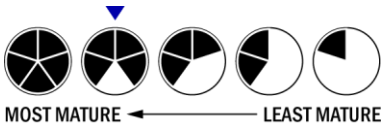
Point of Contact:
Stephanie White
(905) 817-5946
stephanie.white@smithsdetection.com

COST

- $24,000.00/system or device

SPECIFICITY

- False positives: 1 per 9.5 hours
- False negatives: Surpass the ANSI N42.34-2006 requirements



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Fully automated

Signature:
- Sounds or alarms can be deactivated
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- Less than 5 minutes set up
- Minimal down time
- 0-2 steps are required
- Customer and manufacturer site training/ Hard-copy operators manual manuscript

Operational conditions:
- Can be used from < -21°C to > 42°C
- Does not require consumables
- Performance is not influenced by relative humidity

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs 1-5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- No additional components

Maintenance:
- Service less than once a year
- Maintenance is not included
- Expected life 5-10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Batteries
- 4-8 hours of battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps are required
- No shaking or vortexing, mixing, degassing or filtering steps are required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- No specific liquid sample volume is required

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- <100 GB
- Network capable
- Satellite, wireless and wired connections
- Fully autonomous
- On board computer chip in the system
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

RADSticker

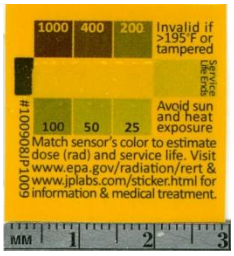
by JP Laboratories, Inc

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types

DETECTION MATRICES:

Nothing demonstrated.



DESCRIPTION:

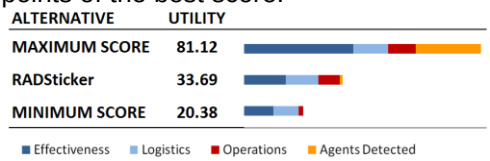
RADSticker is a peel-&-stick postage stamp sized (3cm x 3cm x 0.2mm, weight: 0.2g), instantly color developing, casualty dosimeter which costs a dollar, can be carried 24/7 and always ready. Needs no power, has no electronics or moving parts, reliable, robust, rugged and useful for triaging radiation exposure information and medical treatment in a major radiological incident, such as a nuclear or dirty bomb explosion, nuclear power plant accident or mishandling of radiation sources. It can be applied on many objects and carried for a few years. RADSticker monitors high dose (25 – 1,000 rad) in an event of a radiological incident. When exposed to ionizing radiation, the sensor of the dosimeter develops blue color instantly and the color intensifies as the dose increases. Radiation exposure can be estimated simply by matching the colors of the sensor with the adjacent color reference bars. Thus it provides the wearer and first responder instantaneous information on cumulative radiation exposure of the victim to prioritize and guide medical treatment, if required. If used as per instruction, RADSticker will not give false signals. The operating temperature range is from -30oC to 90oC. All essential information is printed on the front and back of the dosimeter. Additional information is provided in one page manual. By carrying a RADSticker, one minimizes the possibility of becoming a dosimeter (e.g., by taking and analyzing a blood sample). The first generation of the dosimeter was field tested by DHS with 800 first responders for one year (http://www.eml.st.dhs.gov/publications/reports/EML627.pdf).

TECHNOLOGY:

The materials used for monitoring radiation are fine particles of colorless solid diacetylenes dispersed in a polymeric binder. Upon exposure to ionizing radiation, diacetylenes polymerize to blue colored polymers. The reaction is irreversible. As radiation dose increases more monomeric diacetylene molecules polymerize and color of the sensor intensifies. Sensor is calibrated and color reference bars are printed on each side of the sensor for estimation of the dose.

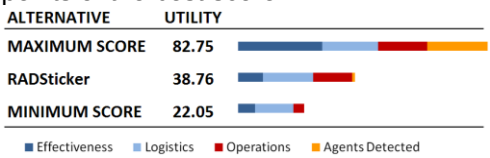
ANALYTICAL Laboratory Ranking

RADSticker ranked in the bottom third of all evaluated products for analytical laboratories and earned 42% of the utility points of the best score.



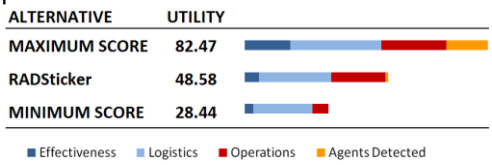
DIAGNOSTIC Laboratory Ranking

RADSticker ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 47% of the utility points of the best score.



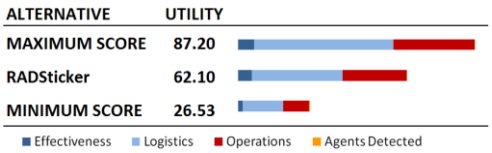
MOBILE Laboratory Ranking

RADSticker ranked in the bottom third of all evaluated products for mobile laboratories and earned 59% of the utility points of the best score.



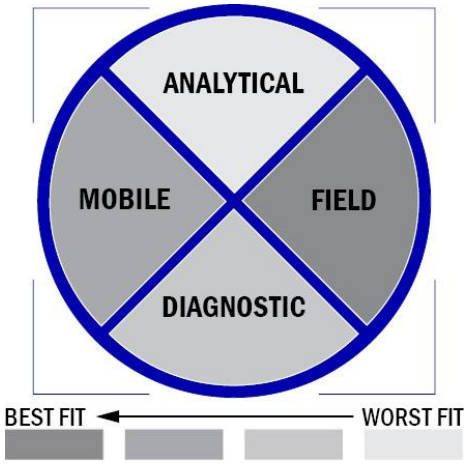
FIELD USE Ranking

RADSticker ranked in the middle third of all evaluated products for field use and earned 71% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

JP Laboratories, Inc
120 Wood Avenue
Middlesex, NJ 08846

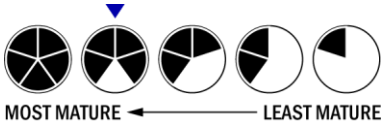
Point of Contact:
Dr. Gordhan Patel
gnpatel@jplabs.com
(732) 469 6670

COST

- Under $2.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- No screen
- Thermal output not applicable

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- Web-based video/ Hard copy and web-based manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Components should be stored at room temp but can withstand temps >45°C for periods < 24 hours
- Performance not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a postage stamp
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Designed for single use
- 0-1 solutions, buffer, and/or reagents
- Consumables not required

Maintenance:
- Service not required
- Preventive maintenance not applicable
- Replacement warranty for defective parts
- Expected life not applicable
- No daily QA required
- No decon required

Physical System Requirements:
- No electrical equipment or power source required
- Portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- Centrifugation not applicable
- Shaking or vortexing, mixing, degassing or filtering step not applicable
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- System memory not applicable
- Network not applicable
- Could be adapted to fully autonomous with some effort
- No computer required
- No internal memory
- No software employed
- Single use

RADTriage

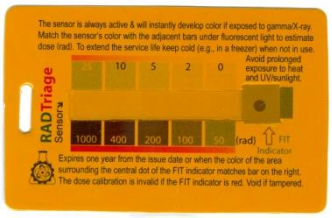
by JP Laboratories, Inc

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types

DETECTION MATRICES:

Nothing demonstrated.



DESCRIPTION:

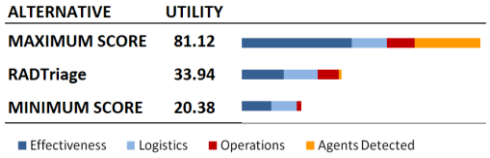
RADTriage™ radiation dosimeter is a credit card sized, self-indicating, user friendly, practically non-destructible, casualty personal dosimeter that reliably monitors harmful high dose (2 – 1,000 rad) in an event of a radiological incident. It is a color developing, disposable, pre-calibrated and affordable (under $15) radiation dosimeter. It has no moving or electronic parts, needs no battery and is always ready. When exposed to ionizing radiation, the sensor of the dosimeter develops blue color instantly and the color intensifies as the dose increases. Radiation exposure can be estimated simply by matching the colors of the sensor with the adjacent color reference bars. Thus it provides the wearer and first responder instantaneous information on cumulative radiation exposure of the victim to prioritize and guide medical treatment, if required. If used as per instruction, RADTriage will not give false signals. If false positives or negatives occur due to abnormal use, the user can monitor them with the multi-purpose FIT™ indicator which also indicates when to replace your badge. The operating temperature range is from -30oC to 90oC. All essential information is printed on the front and back of the dosimeter. Additional information is provided in one page manual. RADTriage can minimize the panic, worry and triages exposure information in an event of a radiological incident. The first generation of the dosimeter was field tested by DHS with 800 first responders for one year (http://www.eml.st.dhs.gov/publications/reports/EML627.pdf).

TECHNOLOGY:

The materials used for monitoring radiation are fine particles of colorless solid diacetylenes dispersed in a polymeric binder. Upon exposure to ionizing radiation, diacetylenes polymerize to blue colored polymers. The reaction is irreversible. As radiation dose increases more monomeric diacetylene molecules polymerize and color of the sensor intensifies. Sensor is calibrated and color reference bars are printed on each side of the sensor for estimation of the dose.

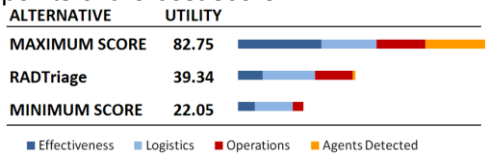
ANALYTICAL Laboratory Ranking

RADTriage ranked in the bottom third of all evaluated products for analytical laboratories and earned 42% of the utility points of the best score.



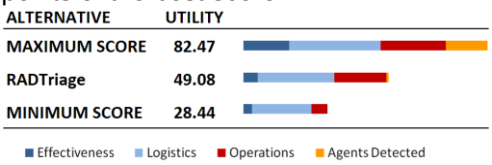
DIAGNOSTIC Laboratory Ranking

RADTriage ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 48% of the utility points of the best score.



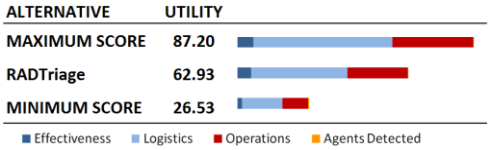
MOBILE Laboratory Ranking

RADTriage ranked in the bottom third of all evaluated products for mobile laboratories and earned 60% of the utility points of the best score.



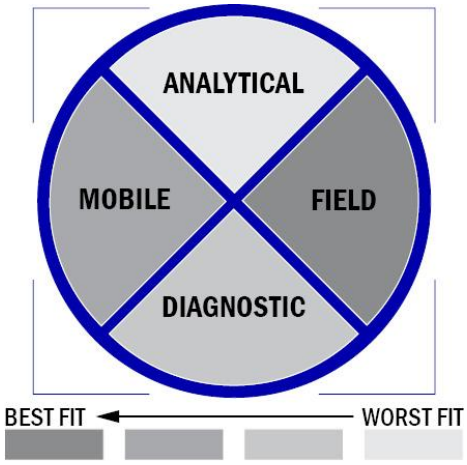
FIELD USE Ranking

RADTriage ranked in the middle third of all evaluated products for field use and earned 72% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

JP Laboratories, Inc
120 Wood Avenue
Middlesex, NJ 08846

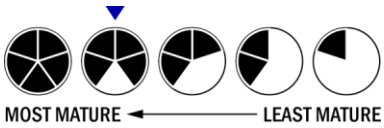
Point of Contact:
Dr. Gordhan Patel
gnpatel@jplabs.com
(732) 469 6670

COST

- Under $15.00/system or device

SPECIFICITY

- False Positives: None
- False Negatives: None



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen may be dimmed or turned off
- Thermal output not applicable

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- Web-based video/ Hard copy and web-based manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Components should be stored at room temp but can withstand temps >45°C for periods < 24 hours
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a credit card
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Designed for single use
- 0-1 solutions, buffer, and/or reagents
- Consumables not required

Maintenance:
- Service not required
- Preventive maintenance not applicable
- Replacement warranty for defective parts
- Expected life not applicable
- No daily QA required
- No decon required

Physical System Requirements:
- No electrical equipment or power source required
- Portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- Centrifugation not applicable
- Shaking or vortexing, mixing, degassing or filtering step not applicable
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- System memory not applicable
- Network not applicable
- Could be adapted to fully autonomous with some effort
- No computer required
- No internal memory
- No software employed
- Single use

Raider

by ICx Radiation

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types
Identification of specific isotopes

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

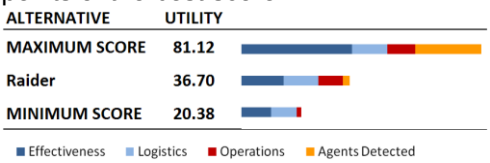
The Raider™ is a state-of-the-art handheld instrument in a class of its own. It is designed to uniquely meet or exceed the performance requirements of ANSI N42-34 (RID) and ANSI N42-48 (SPRD) standards. The instrument utilizes an innovative array of solid-state CZT detectors and (optional) He3 tubes to provide superior gamma and neutron sensitivities resulting in a rapid identification and verification of radioactive materials. The Raider is small and light enough to be held and operated with one hand and can be conveniently clipped to the user's belt in the holster provided. Two bi-directional buttons, one on each side, are all that are required to access every feature of this instrument. It is both water and drop resistant, making it rugged and ideal for strenuous operating situations. The Raider records, displays and analyzes spectral information in real time, providing quick and accurate radionuclide identification. This is made possible through high resolution semiconductor CZT detectors and state-of- the-art micro-miniature electronics utilizing modern digital signal processing.

TECHNOLOGY:

The Raider records, displays and analyzes spectral information in real time, providing quick and accurate radionuclide identification. This is made possible through high resolution semiconductor CZT detectors and state-of-the-art micro-miniature electronics utilizing modern digital signal processing. The spectrum is analyzed using a template matching algorithm to identify the isotopes present in the sample.

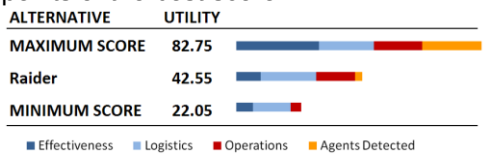
ANALYTICAL Laboratory Ranking

Raider ranked in the bottom third of all evaluated products for analytical laboratories and earned 45% of the utility points of the best score.



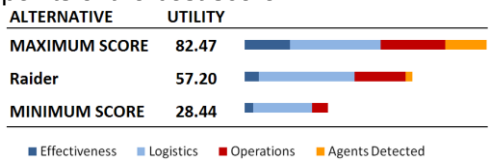
DIAGNOSTIC Laboratory Ranking

Raider ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 51% of the utility points of the best score.



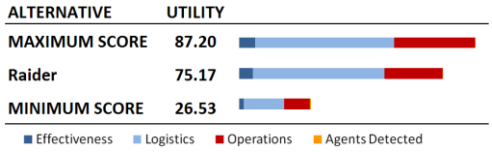
MOBILE Laboratory Ranking

Raider ranked in the bottom third of all evaluated products for mobile laboratories and earned 69% of the utility points of the best score.



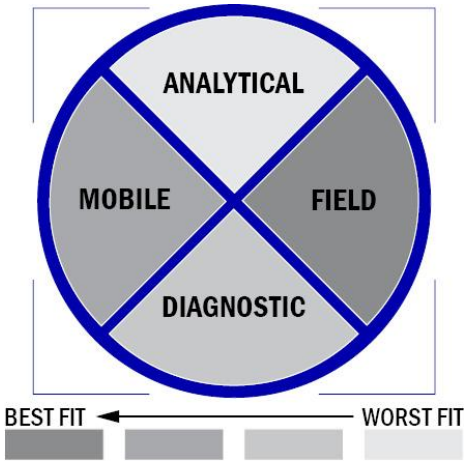
FIELD USE Ranking

Raider ranked in the bottom third of all evaluated products for field use and earned 86% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ICx Radiation
100 Midland Rd
Oak Ridge, TN 37830

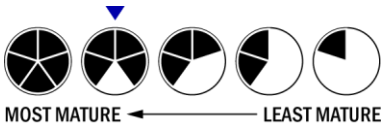
Point of Contact:
Jeff Perkins
Jeffrey.Perkins@icxt.com

COST

- $20,000.00-25,000.00/system or device

SPECIFICITY

- False Positives: Not available
- False Negatives: Not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training

Operational conditions:
- Can be used from < -21°C to > 42°
- Does not require consumables
- Performance is not influenced by relative humidity
- Shelf life not applicable

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- Components not applicable

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Decon not applicable

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Amount needed to test liquid not applicable

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless and wired connections
- Could easily be adapted to fully autonomous system
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software closed, not available for modification
- System hardware closed and not available for modification

RAMP

by Response Biomedical Corporation

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e3-10e4 CFU/mL)
Viruses (10e4-10e5 PFU/mL)
Toxins (1-100 ng/mL)

DETECTION MATRICES:

Demonstrated:
Environmental air, Environmental water, Soil, Food, Powder, Insect vectors

DESCRIPTION:

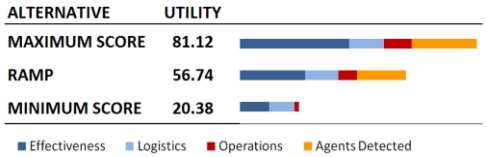
The RAMP System is designed to provide First Responders, Military Personnel, and Public Safety Workers with rapid, on-site, reliable diagnostic information for biological testing. The RAMP System is utilized by First Responder Teams world-wide. The RAMP System consists of a portable scanning fluorescence Reader and single-use, disposable test cartridges. To use, a small sample is added to the test cartridge and then inserted into the Reader. RAMP provides a positive or negative result in minutes, with no additional user intervention. Tests are available for anthrax, ricin, botulinum and pox. RAMP is used for testing liquid, powder or invisible surface samples. A suspect surface, powder or liquid is sampled using a swab and then added to the supplied sample buffer. Then a portion of the sample is placed into the Test Cartridge that is then inserted into the RAMP Reader. There is no regular calibration or maintenance required with the RAMP system and the cartridges have an internal standard system that runs concurrently with every assay to eliminate environmental and assay-to-assay variability. This internal standard system is not available in earlier generation flow assays and is unique to the RAMP system. The system has consistently demonstrated to be 100% reliable in detecting anthrax at or above 4,000 spores and does not cross-react with interfering substances, such as baking powder, or with non-pathogenic strains of anthrax.

TECHNOLOGY:

RAMP is a system for testing the presence of B. anthracis spores, ricin, botulinum toxin and orthopox viruses. The Reader is a scanning immunoassay and data analysis system measuring fluorescence in RAMP cartridges. The Reader can be operated on battery power or AC. The RAMP Test Cartridge is a single-use analyte-specific test used to detect the presence of analyte in a sample. The operator prepares the sample, places an aliquot into the sample well of the Test Cartridge, inserts Cartridge into the RAMP Reader, which analyzes the sample and provides a result.

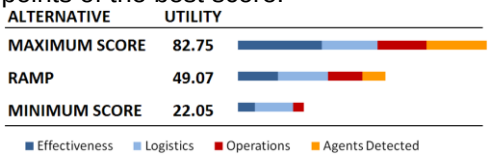
ANALYTICAL Laboratory Ranking

RAMP ranked in the top third of all evaluated products for analytical laboratories and earned 70% of the utility points of the best score.



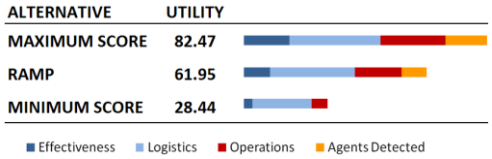
DIAGNOSTIC Laboratory Ranking

RAMP ranked in the middle third of all evaluated products for diagnostic laboratories and earned 59% of the utility points of the best score.



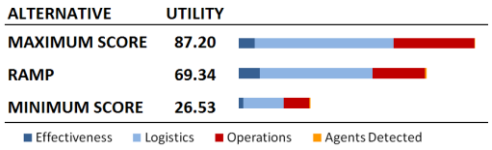
MOBILE Laboratory Ranking

RAMP ranked in the top third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.



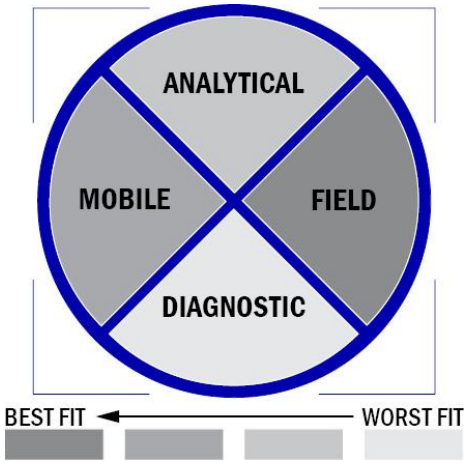
FIELD USE Ranking

RAMP ranked in the middle third of all evaluated products for field use and earned 80% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Response Biomedical Corporation
1781-75th Avenue W.
Vancouver, BC, Canada, V6P 6P2
www.responsebio.com

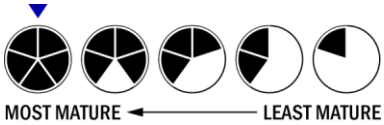
Point of Contact:
Michael Bayliss
Phone: (604)456-6010 (Ext. 6057) Fax: 604.456-6083
Email: mbayliss@responsebio.com

COST

- $11,000.00/system or device
- $25.00/analysis

SPECIFICITY

- Available upon request from manufacturer



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15-30minutes for detection
- 1 sample, single test/ sample per run
- System fully automated

Signature:
- Sounds or alarms are present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- No set up
- Almost no down time
- 0-2 steps are required
- DVD/ Web video/ Customer site training/ Hard copy manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components stored at room temp can withstand >45°C for < 24 hours/ Stored frozen can with stand >4°C for <24 hours
- Performance is not influenced by relative humidity conditions
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All means of transportation
- Weights between 1 and 5kg

Re-use:
- Single use detection assay
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- No maintenance
- No preventive maintenance
- No maintenance
- Expected life greater than 10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1hr

Physical System Requirements:
- Batteries
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results not available
- No centrifugation steps
- A single shaking or vortexing or filtering step required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Less than 100 ul for a test

System Maturity:
- Commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- System fully autonomous with easy adaptation
- Onboard computer chip
- Store and archive data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system is single use or this question does not apply to this device

RANIDPRO 200

by Environics

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types
Identification of specific isotopes

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

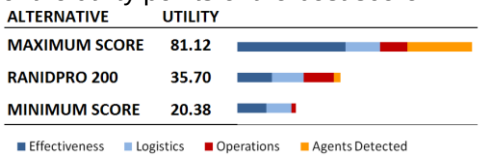
RanidPro 200 is a mobile radiation detection, identification, and data collection system. It consists of a rugged laptop computer, a gamma radiation detector and a neutron radiation detector with their associated electronics. Data and analyses may be viewed on-board with the laptop user screen or transmitted digitally/electronically to a remote station. In addition, a mobile telephone or PDA may be used as an additional remote device to control and monitor the system in operation. The RanidPro 200 is designed to be used in the field unnoticeably and it utilizes a conventional rugged laptop computer and smart telephone as easy user interfaces. It may be powered by a variety of AC or DC supplies. The RanidPro 200 system continuously collects, analyzes, and displays radiation information that is acquired by its detectors. All of the collected data is also stored into an on-board database for later review and/or more detailed analyses. The fully integrated system is driven by the RanidPro 200 software which has been specifically developed for ease of use and to provide high quality field spectroscopy, real-time monitoring, and quick efficient data communication with low identification false alarm rates. Although the system is designed to be very easy to use after a short training period by non-technical users it also contains an expert mode including analysis tools for the advanced user. Bluetooth connections between the laptop computer and a smart telephone with graphical interface forms a reliable communication link to, for example, a remote operation center.

TECHNOLOGY:

The RanidPro 200 uses employs quality detectors (Lanthanum Bromide for gamma and Li-6 enriched crystals in a matrix of Zinc Sulfide phosphor for neutrons) to provide high resolution information. These detectors may be exposed to a changing environment during use, which could cause energy calibrations to drift. RanidPro 200 addresses this with continuous internal calibrations. The detector data are analyzed using the software suite specifically developed for the RanidPro 200. The gamma analysis is performed using a hypothesis test, analyzing for specific radionuclides. The device contains an extensive radioisotope energy library and also performs ROI summations and count rate normalization.

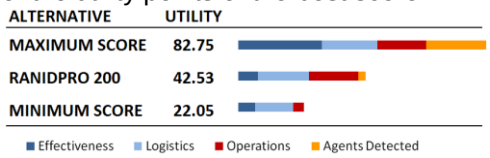
ANALYTICAL Laboratory Ranking

RANIDPRO 200 ranked in the bottom third of all evaluated products for analytical laboratories and earned 44% of the utility points of the best score.



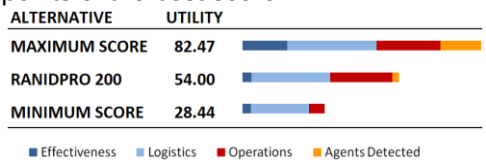
DIAGNOSTIC Laboratory Ranking

RANIDPRO 200 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 51% of the utility points of the best score.



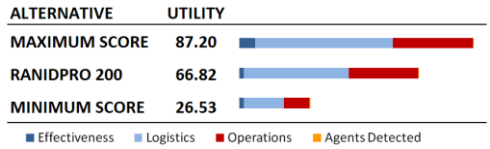
MOBILE Laboratory Ranking

RANIDPRO 200 ranked in the middle third of all evaluated products for mobile laboratories and earned 65% of the utility points of the best score.



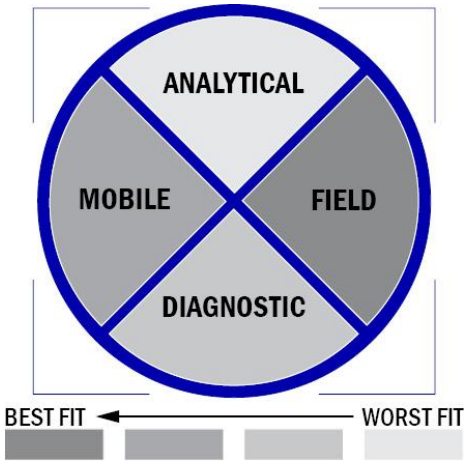
FIELD USE Ranking

RANIDPRO 200 ranked in the middle third of all evaluated products for field use and earned 77% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Environics
Oy Graanintie 5
PL 349 50101
Mikkeli Finland

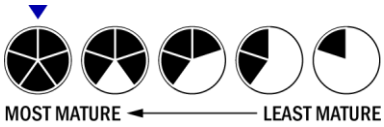
Point of Contact:
Timo Jaakkola
1308 Continental Drive, Suite J
Abingdon, MD 21009
410-612-1250

COST

- $53,000.00-65,000.00/system or device

SPECIFICITY

- False Positives: Less than 1 in a million
- False Negatives: Very low depending on the nuclide and its activity+



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up
- Almost instantaneous down time
- 0-2 steps required
- Customer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Does not require consumables
- Performance not influenced by relative humidity
- Shelf life not applicable

Transportation:
- Approximately size of carry-on luggage
- Mode information not available
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- Solutions, buffer, and/or reagents not applicable
- Components not applicable

Maintenance:
- No service required
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life > 10 years
- No daily QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 220V electrical requirement
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 50 ul to test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Satellite, wireless, wired connections
- Could easily be adapted to fully autonomous
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- Software open and available for modification
- Hardware open and available for modification

Rapid BioAlert Reader and BioThreat Alert Assays

by ADVNT Biotechnologies

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (>100,000 CFU/mL)

DETECTION MATRICES:

Demonstrated:
Soil, Food, Powder

DESCRIPTION:

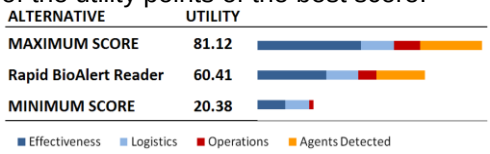
This new reader boasts many features designed to enhance the speed and the ease of testing for biological warfare agents. The Rapid BioAlert is a fully functional ultra-mobile PC (UMPC), running Windows XP and capable of connecting to WiFi and Bluetooth signals. Users can interact with the reader with its touch screen or by connecting via USB with a keyboard/mouse. The user interface has been designed to be large and simple in order to aid First Responders who may be using various forms of PPE. Coupling this new reader with Tetracore's BioThreat Alert® strips creates a quick, reliable system for biodetection. BioThreat Alert® strips have been on the market for over 10 years and offer assays to detect Abrin, Anthrax, Bot Tox, Brucella, Orthopox, Plague, Ricin, SEB, and Tularemia. These robust handheld assays are capable of testing samples from a variety of matrices (soil, air, liquid, powder) in a matter of 15 minutes. Upon the completion of an assay, the Rapid BioAlert can perform and record an accurate and objective analysis in merely 20 seconds. The software is also capable of generating a detailed report for each sample tested, which includes numerical output and a graphical representation of the results. The report can also be printed directly from the unit.

TECHNOLOGY:

This detection system consists of two separate parts. The BioThreat Alert® strips are handheld lateral-flow immunochromatographic assays that use colloidal gold labeled antibodies for detection. The Rapid BioAlert reader is a handheld PC coupled with additional hardware and software to allow for the analysis of the aforementioned strips. A camera attached to the rear of the device analyzes the strips' surface, measuring the optical density (reflection) and then determining a positive/ negative result. The tray attached to the unit is capable of being modified to suit new assay types and designs in the future.

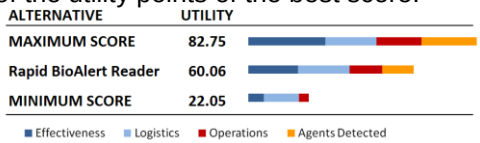
ANALYTICAL Laboratory Ranking

Rapid BioAlert Reader ranked in the top third of all evaluated products for analytical laboratories and earned 74% of the utility points of the best score.



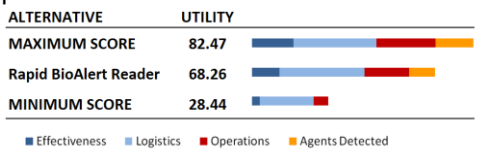
DIAGNOSTIC Laboratory Ranking

Rapid BioAlert Reader ranked in the top third of all evaluated products for diagnostic laboratories and earned 73% of the utility points of the best score.



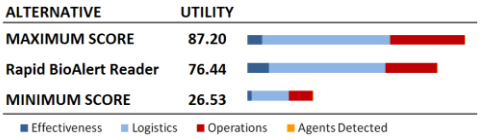
MOBILE Laboratory Ranking

Rapid BioAlert Reader ranked in the top third of all evaluated products for mobile laboratories and earned 83% of the utility points of the best score.



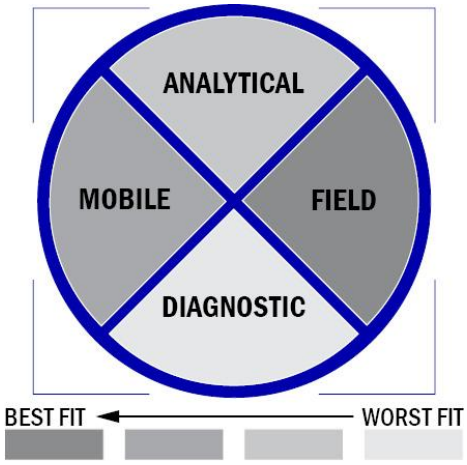
FIELD USE Ranking

Rapid BioAlert Reader ranked in the top third of all evaluated products for field use and earned 88% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

TetraCore
9901 Belward Campus Dr
STE 300
Rockville, MD 20850

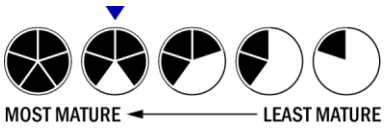
Point of Contact:
Dr. Tom O'Brien

COST

- $5,500.00/system or device

SPECIFICITY

- False Positives: < 0.1% false positives in the field with over 100,000 tests
- False Negatives: False negatives cannot be reported as a single number because it is sample type, sample prep, assay, and concentration specific.



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15 - 30 minutes for detection
- Multiple samples, multiple tests/samples per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 3-5 steps required
- DVD/ Web video/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C - 41°C
- Components should be stored at room temp but can stand temps >45°C for < 24 hours
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 1 -5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service less than once a year
- Preventive maintenance not applicable
- 1 year warranty
- Expected life 3-5 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results not available
- Data cannot be processed while in progress
- No centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering step
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 250 ul required for test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless and wired connections
- Could be adapted to a fully autonomous system with significant effort
- On board computer chip
- Stores and archives data outputs and creates electronic records
- System software is closed and not available for modification
- System hardware is closed and not available for modification

Rapid Detection of Ultra-Trace Levels of Pathogens (Listeria monocytogenes)

by Battelle - Pacific Northwest National Laboratory

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)

DETECTION MATRICES:

Demonstrated:
Food

DESCRIPTION:

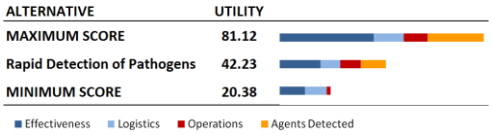
A protocol has been optimized to enable rapid enrichment, concentration, purification and polymerase chain reaction (PCR) detection of pathogenic organisms. While the developed protocol is specifically for Listeria monocytogenes, other pathogenic organisms could also be processed with variations to the protocol. The sample preparation and detection approach is amenable to multiplexing to allow detection of multiple pathogens (bacterial and viral) in a single sample. The protocol was developed specifically for analyzing surface swabs from food processing plant surfaces, but could be adapted to other surfaces, bodily fluids, environmental samples, and foodstuffs.

TECHNOLOGY:

We have investigated and developed unique enrichment broths to enable rapid enrichment (4-6 hours) of pathogenic organisms. We have also developed protocols to remove debris and interfering substances using a combination of filtration and immunomagnetic beads, which also provide a high degree of pathogen concentration and sample purification. We have also optimized PCR detection of Listeria monocytogenes.

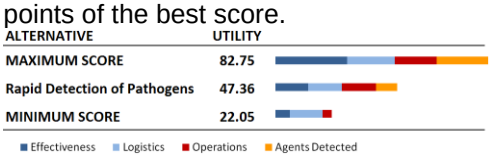
ANALYTICAL Laboratory Ranking

Rapid Detection of Ultra-Trace Levels of Pathogens ranked in the middle third of all evaluated products for analytical laboratories and earned 52% of the utility points of the best score.



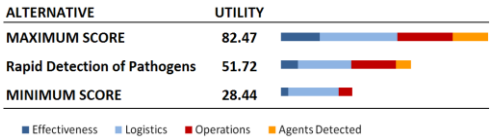
DIAGNOSTIC Laboratory Ranking

Rapid Detection of Ultra-Trace Levels of Pathogens ranked in the middle third of all evaluated products for diagnostic laboratories and earned 57% of the utility points of the best score.



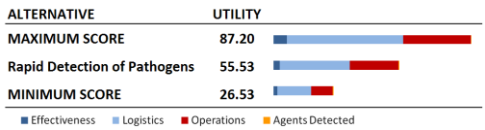
MOBILE Laboratory Ranking

Rapid Detection of Ultra-Trace Levels of Pathogens ranked in the middle third of all evaluated products for mobile laboratories and earned 63% of the utility points of the best score.



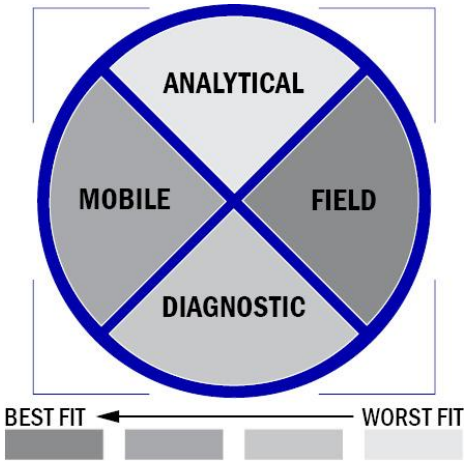
FIELD USE Ranking

Rapid Detection of Ultra-Trace Levels of Pathogens ranked in the bottom third of all evaluated products for field use and earned 64% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Battelle - Pacific Northwest National Laboratory
P.O. Box 999
Battelle Blvd.; Mail Stop P7-50
Richland, WA 99354

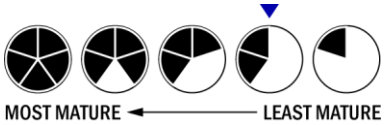
Point of Contact:
Dr. Richard M. Ozanich
richard.ozanich@pnl.gov

COST

- $30,000.00 - 40,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1 - 8 hours for detection
- 1 sample, single test/sample per run
- Could be adapted to semi-automated with some effort

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- <5 minutes set-up required
- 1-3 minutes down time
- Greater than 12 steps required
- Customer site training

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours/ Must be stored at 4°C/ Must be frozen at temps at or below -20°C (cryo-storage)
- Performance is not influenced by relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size carry-on luggage
- All modes of transport
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 4 solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life 3-5 years
- >20 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- Multiple shaking or vortexing, mixing, degassing or filtering steps
- System could call final result in the future

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 10 ul to test liquids

System Maturity:
- Bread board
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Satellite, wireless and wired connections
- Could be fully autonomous with significant effort
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software open and available for modification
- System hardware open and available for modification

Rapid Portable Biosensor

by Adaptive Methods

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (100-1,000 PF/mL)

DETECTION MATRICES:

Demonstrated:
Environmental water, Powder

DESCRIPTION:

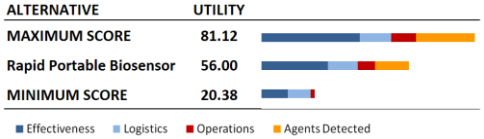
Economical, rapid (i.e., near real time), sensitive, and specific detection or diagnosis of exposure to biowarfare agents (i.e., bacteria, virus, toxins). With little or no sample-prep and minimal training required, the shirt-pocket size "reader" with disposable sample cartridge facilitates use in the field (including austere environments) or point-of-care settings. Supports single analyte or multiplex testing, in complex matrices including environmental or human derived samples.

TECHNOLOGY:

Our device is based on surface acoustic wave (SAW)-based sensor technology that directly detects virus, bacteria, or toxin through binding of the target agent to an antibody or peptide coupled to a piezoelectric surface. This binding results in a change to the electrical transfer function of the device which can be measured at its output. Sensitivity and selectivity are conferred through the use of selected ligands.

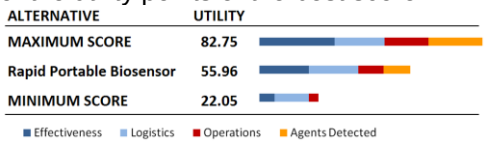
ANALYTICAL Laboratory Ranking

Rapid Portable Biosensor ranked in the top third of all evaluated products for analytical laboratories and earned 69% of the utility points of the best score.



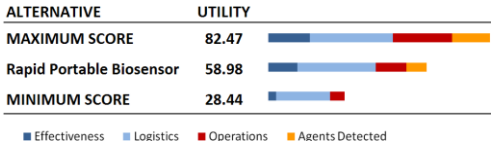
DIAGNOSTIC Laboratory Ranking

Rapid Portable Biosensor ranked in the top third of all evaluated products for diagnostic laboratories and earned 68% of the utility points of the best score.



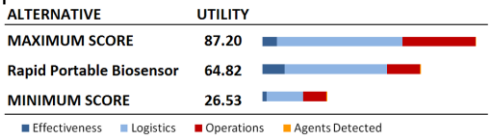
MOBILE Laboratory Ranking

Rapid Portable Biosensor ranked in the middle third of all evaluated products for mobile laboratories and earned 72% of the utility points of the best score.



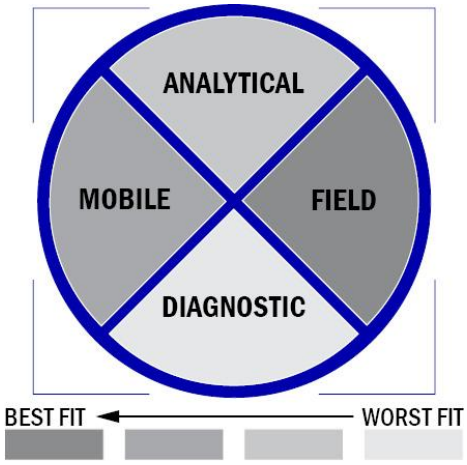
FIELD USE Ranking

Rapid Portable Biosensor ranked in the middle third of all evaluated products for field use and earned 74% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Adaptive Methods
15825 Shady Grove Road, Suite 135
Rockville, Maryland 20854

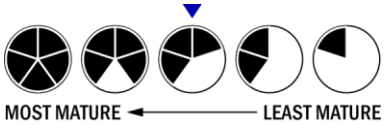
Point of Contact:
Mark Meister
mmeister@adaptivemethods.com
301.840.9722 x107

COST

- Estimated at $1,000 or less/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, <10 tests/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- <5 minutes set-up required
- <1 minute down time
- 0-2 steps required

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours/ Must be stored at room temp (27°C)/ Must be stored at 4°C
- Influence of relative humidity unknown
- 1 to 6 months shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 1 - 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance not applicable
- Expected life information not available
- Less than 5 minutes daily QA
- Hazardous agent isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source information not available

Ease of Use:
- Real-time results available
- Whether data can be processed while in progress is TBD
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering step
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- <250 ul to test liquids

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless and wired connections
- Could be fully autonomous with significant effort
- Basic desktop computer
- Stores and archives data outputs and creates electronic records
- System software closed, available for modification
- System hardware closed, not available for modification

RapidPlex

by ICx Biosystems

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1000 CFU/mL)
Viruses (10e3-10e4 PFU/mL)
Toxins (1-100 ng/mL)

DETECTION MATRICES:

Demonstrated:
Nasal and throat swabs,
Environmental water,
Environmental air, Powder

DESCRIPTION:

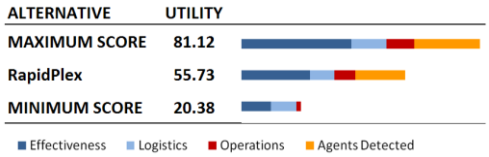
RapidPlex is a fully automated system for environmental monitoring of bacteria, viruses, and toxins. This advanced system has automated sample preparation, detects with high sensitivity, and identifies with high accuracy up to 20 different pathogens at once. Detected threats include toxins, DNA viruses, RNA viruses, bacteria, and bacterial spores. The RapidPlex identifier is capable of detecting at least 10-20 threat targets in a single test and utilizes multiple (2-3) independent biomarkers per threat target to ensure high levels of detection confidence and to minimize false positives, especially from non-pathogenic near-neighbors that are often present in the environment. The analyzer's total analysis time is configurable dependent on sensitivity requirements, but in its most sensitive mode, provides sample-to-answer times of less than 30 minutes. RapidPlex was developed initially for unattended environmental monitoring, but is adaptable to other biodetection applications such as clinical diagnostics and food/water testing.

TECHNOLOGY:

RapidPlex employs fast multiplex PCR to amplify DNA and RNA target sequences and a rapid multiplexed antibody sandwich assay for detection of toxins and surface proteins on viruses and bacteria. DNA amplicons and protein targets are detected by capturing them with specific capture probes on tens of thousands of microbeads. Each microbead is color coded to identify which threat hypothesis is being tested. This fluorescent imaging readout of thousands of assay microbeads enables coverage of a long threat list without the loss of sensitivity associated with sample splitting. The analyzer uses multiple molecular markers per threat to reduce false positives.

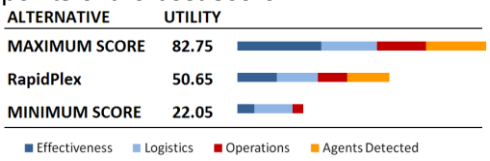
ANALYTICAL Laboratory Ranking

RapidPlex ranked in the top third of all evaluated products for analytical laboratories and earned 69% of the utility points of the best score.



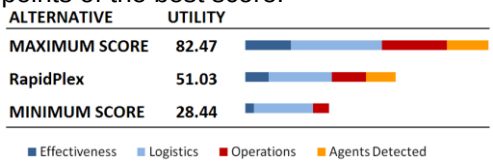
DIAGNOSTIC Laboratory Ranking

RapidPlex ranked in the middle third of all evaluated products for diagnostic laboratories and earned 61% of the utility points of the best score.



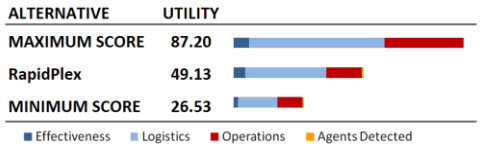
MOBILE Laboratory Ranking

RapidPlex ranked in the bottom third of all evaluated products for mobile laboratories and earned 62% of the utility points of the best score.



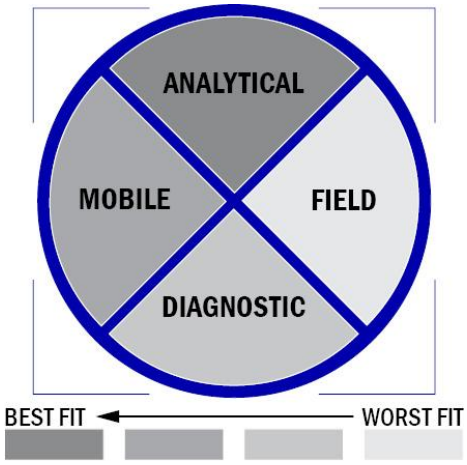
FIELD USE Ranking

RapidPlex ranked in the bottom third of all evaluated products for field use and earned 56% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ICx Biosystems
505 Coast Boulevard South, Suite 309
La Jolla, CA 92037

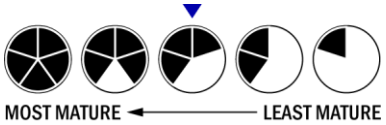
Point of Contact:
Michael Meyer
858-551-8827, x102
michael.meyer@icxt.com

COST

- $45,000/system or device
- $70/ analysis

SPECIFICITY

- False Positives: <2%
- False Negatives: <5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15-30 minutes for detection
- 1 sample, single test/ sample per run
- Currently fully automated

Signature:
- No sounds or alarms
- Screen can be dimmed or turned off

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- 5-10 minutes for set up
- < 5 minute down time
- 0-2 steps are required
- Customer site training

Operational conditions:
- Can be used from 25°C to 37°C
- Components should be stored at room temperature but can withstand temperatures in excess of 45°C for periods of less than 24 hours
- Influence of relative humidity unknown
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means of transportation
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 3 component

Maintenance:
- Service more often than every 6 months
- Preventive maintenance serviceable by customer
- Expected life unknown
- < 5 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time not available
- Data cannot be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Less than 100 ul for a test

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Fully autonomous system with some effort
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

RAPTOR

by Research International, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e4-10e5 CFU/mL)
Viruses (>10e5PFU/mL)
Toxins (<1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Urine, Environmental water, Food, Powder

DESCRIPTION:

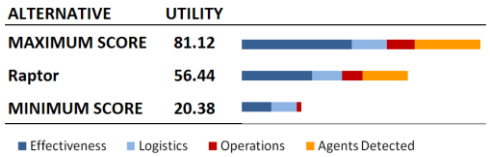
This rapid, automatic fluorometric assay system is a portable (6.45 kg) 4-channel system for monitoring toxins, viruses, bacteria, spores, fungi and other diverse targets. An extremely reliable third-generation product introduced in 2000, users have found these instruments will operate for two years or more with no breakdowns or leaks, and that they will tolerate debris-laden samples (such as are produced in mailrooms and food processing facilities) - impressive feats for a fully automated wet assay system. Although designed for the military, it works well in the laboratory too. The completely self-contained instrument is the culmination of a careful integration of optics, fluidics, electronics, and software into one compact system for laboratory and field assays. It performs user-defined, multi-step, assay protocols for monitoring fluorescently-labeled chemical reactions occurring on the surface of each of the system's four disposable optical waveguide sensors. Toxins and bacteria such as ricin and B. anthracis have been detected at levels below <1.0 ng/ml and 100 CFU/ml, respectively. Four sensors are mounted in a disposable plastic coupon allowing four different pathogens to be detected in a sample; or multiple channels may target the same pathogen to improve statistical certainty. Each coupon may be used for up to 30 assays if negative results are obtained. A bar code on each coupon identifies the type of assay to be run by the instrument and allows very sophisticated assays to be performed by unskilled persons. A computer embedded within the RAPTOR™ performs and controls all steps in the assay procedure.

TECHNOLOGY:

Research International's biosensor systems are based on 'sandwich format' fluoroimmunoassay reactions taking place on the surface of injection molded polystyrene waveguides. All fluidic and optoelectronic steps associated with the assay are performed automatically. In a typical waveguide-based sandwich immunoassay, the waveguide has a monolayer of capture antibody immobilized on its surface. The waveguide is first incubated with sample, washed, then incubated with fluorophore-labeled antibody to form an antibody/antigen/labeled-antibody sandwich. Excitation light is injected into the waveguide and fluorescence emission is collected by a sensitive photodetector that looks down the waveguide axis.

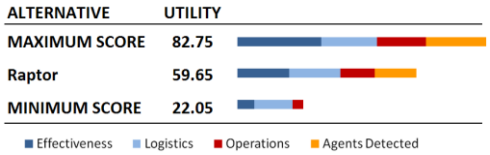
ANALYTICAL Laboratory Ranking

RAPTOR ranked in the top third of all evaluated products for analytical laboratories and earned 70% of the utility points of the best score.



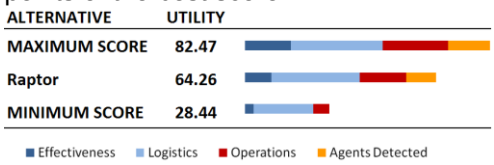
DIAGNOSTIC Laboratory Ranking

RAPTOR ranked in the top third of all evaluated products for diagnostic laboratories and earned 72% of the utility points of the best score.



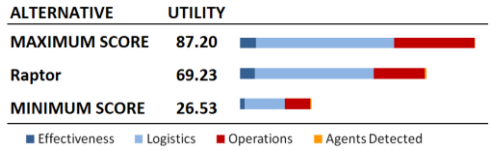
MOBILE Laboratory Ranking

RAPTOR ranked in the top third of all evaluated products for mobile laboratories and earned 78% of the utility points of the best score.



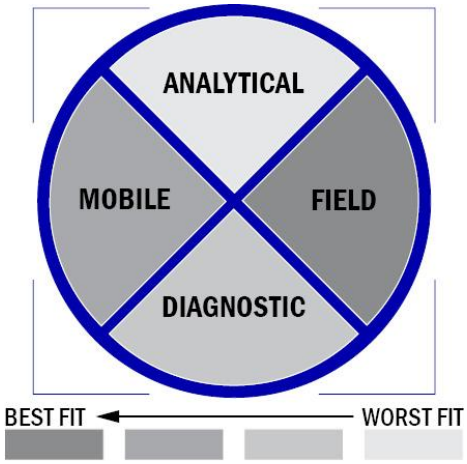
FIELD USE Ranking

RAPTOR ranked in the middle third of all evaluated products for field use and earned 79% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Research International, Inc.
17161 Beaton Road SE
Monroe, WA 98272

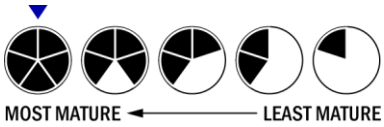
Point of Contact:
Jonathon Tobelmann
co. phone: 360-805-4930
direct 703-625-8381
jontobelmann@resrchintl.com

COST

- $49,500.00/system or device
- $210.00/30 samples

SPECIFICITY

- False Positives: ~1% per channel
- False Negatives: ~1% per channel



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- 1 sample, <10 tests/ sample per run
- Currently fully automated

Signature:
- No sounds or alarms
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- >20 minutes for set up
- Almost no down time
- 0-2 steps are required
- Customer and Manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components must be stored at 4°C
- Performance is not influenced by relative humidity
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of a toaster
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician
- Maintenance not included
- Expected life 5-10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Batteries
- 4-8 hours battery use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time not available
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Greater than 250 ul for a test

System Maturity:
- Commercially available and meets milspecs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Fully autonomous system
- No computational power needed
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

RAZOR EX BioThreat Detection System

by Idaho Technology, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Viruses (10e3-10e4 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Environmental water, Food, Powder

DESCRIPTION:

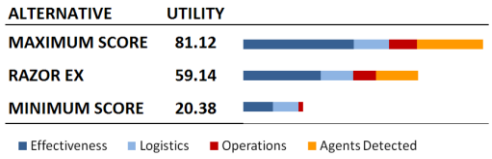
The advanced RAZOR EX BioThreat Detection System utilizes Real-time PCR technology to deliver the most reliable and sensitive field detection and identification of biological pathogens. Designed specifically for use in the field, the RAZOR EX' compact and lightweight design allows it to be hand carried and minimal sample preparation requirements make it easy to use. Powder, swab, water, dry filter, or culture sample types work ideally with the RAZOR EX. Used with The 10™ Target Screen Kit, the RAZOR EX simultaneously tests environmental samples for ten Category A and B BioThreat pathogens with reliable DNA-based results available in less than 30 minutes. Created for first responders and front line military troops, it is easily operated while working in protective equipment under extreme conditions. The new stand-alone, battery powered instrument includes Bluetooth® capabilities for wireless data transmission, bar code reader for data input, and a bright, easy to read color screen. The RAZOR EX utilizes Idaho Technology's patented reagent pouch system—integrated freeze-dried reagents packaged in durable plastic pouches for incomparable ease of use. A variety of pre-formatted pouch configurations are available for biothreat, food screening, or water testing applications.

TECHNOLOGY:

Real-time Polymerase Chain Reaction (PCR) - a molecular, enzymatic reaction that in the presence of a targeted pathogen, amplifies the amount of target DNA. The reaction is coupled with fluorescent probes that provide real-time detection.

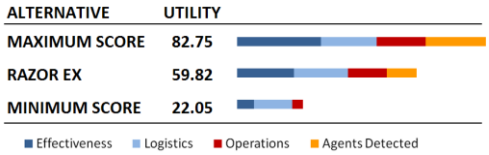
ANALYTICAL Laboratory Ranking

RAZOR EX BioThreat Detection System ranked in the top third of all evaluated products for analytical laboratories and earned 73% of the utility points of the best score.



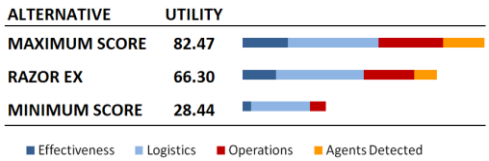
DIAGNOSTIC Laboratory Ranking

RAZOR EX BioThreat Detection System ranked in the top third of all evaluated products for diagnostic laboratories and earned 72% of the utility points of the best score.



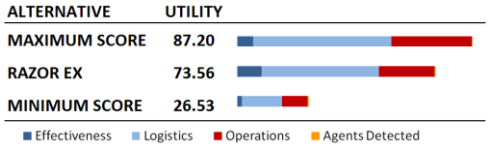
MOBILE Laboratory Ranking

RAZOR EX BioThreat Detection System ranked in the top third of all evaluated products for mobile laboratories and earned 80% of the utility points of the best score.



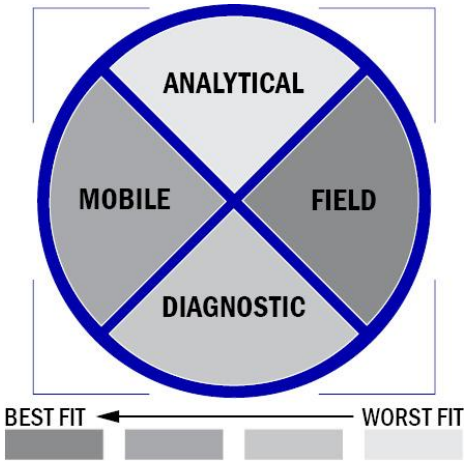
FIELD USE Ranking

RAZOR EX BioThreat Detection System ranked in the top third of all evaluated products for field use and earned 84% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Idaho Technology, Inc.
390 Wakara Way
Salt Lake City, UT 84108

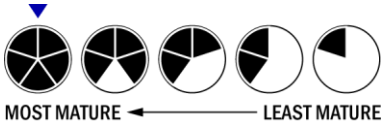
Point of Contact:
Lou Banks

COST

- $38,500.00/system or device
- $200.00/10-plex assay

SPECIFICITY

- False Positives: <1%
- False Negatives: <1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30-60 minutes for detection
- 1 sample, >10 tests/ sample per run
- Currently semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- < 5 minutes set up
- Almost instantaneous down time
- 3-5 steps are required
- DVD/ Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp
- Performance is not influenced by relative humidity
- Between 6 months to 1 year

Transportation:
- Approximately the size of a toaster
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- No service required
- Preventive maintenance by customer
- Maintenance is included
- Expected life 5-10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Batteries
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can not be processed while in progress
- No centrifugation steps required
- A single shaking or vortexing, mixing, degassing or filtering step required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 100 ul for a test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Not network capable
- Wireless and wired connections
- Autonomous system with some effort
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

REAL (Raman Shifted Eyesafe Aerosol Lidar)

by ITT Corporation

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

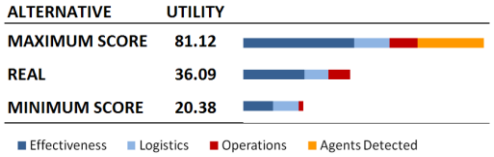
REAL is an eyesafe lidar system capable of detecting and tracking bio- and nonbio-aerosols and clouds at distances of several km with resolution of a few meters. It does not distinguish bio- from nonbio-aerosols. It is currently deployed as part of Pentagon Shield.

TECHNOLOGY:

REAL is an elastic backscatter lidar operating at an eyesafe wavelength of 1.54 microns.

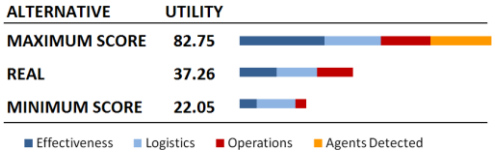
ANALYTICAL Laboratory Ranking

REAL ranked in the bottom third of all evaluated products for analytical laboratories and earned 44% of the utility points of the best score.



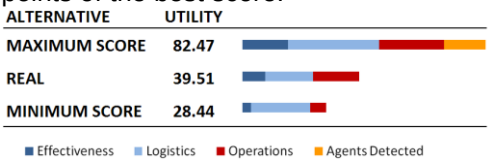
DIAGNOSTIC Laboratory Ranking

REAL ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 45% of the utility points of the best score.



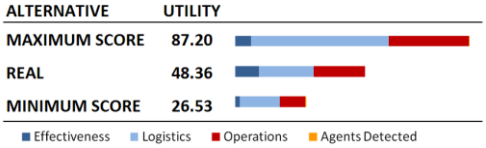
MOBILE Laboratory Ranking

REAL ranked in the bottom third of all evaluated products for mobile laboratories and earned 48% of the utility points of the best score.



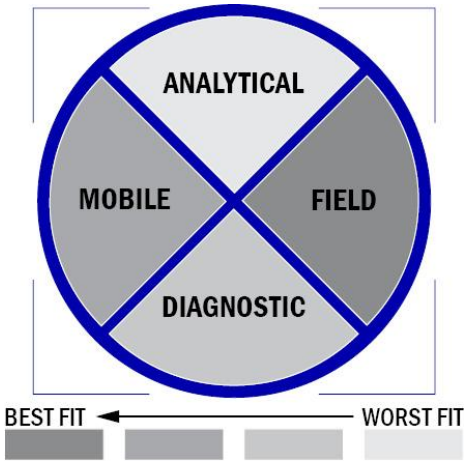
FIELD USE Ranking

REAL ranked in the bottom third of all evaluated products for field use and earned 55% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ITT Corporation
5901 Indian School Rd NE
Albuquerque NM 87110

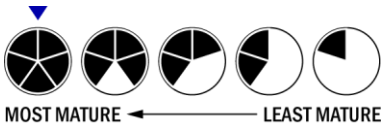
Point of Contact:
Patrick Ponsardin
505 889 7000
patrick.ponsardin@itt.com

COST

- $1,300,000.00/system or unit

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- >20 minutes set-up required
- Almost instant down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Peak performance at normal relative humidity conditions
- Greater than 3 years shelf life

Transportation:
- Larger than home dishwasher
- Via commercial carrier/ Tactical military wheeled and tracked vehicle/ Fixed wing military and rotary wing aircraft
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service more than twice a year
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 3-5 years
- <5 minutes daily QA
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 220V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System could call final result in the future

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquid

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB or single pos or neg response generated
- Network capable
- Wired connections
- Easily adapted to fully autonomous with some effort
- High end desktop computer
- Stores and archives data outputs and creates an electronic record
- Software closed, not available for modification
- Hardware closed, not available for modification

REBS (Resource Effective BioIdentification System)

by Battelle Memorial Institute

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria
Viruses
Toxins
Identification of specific isotopes

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

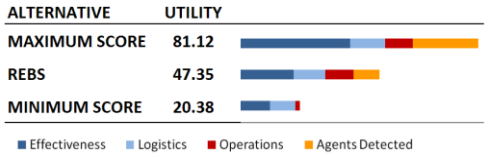
The Resource Effective BioIdentification System (REBS) is an autonomous bioaerosol identification system that is based on micro-Raman spectroscopy. The integrated system was developed by Battelle to meet the future biological and chemical point and tactical detection needs by reducing logistical burden and expense. REBS is reagentless and does not require consumables. REBS conducts a series of actions that include aerosol collection, sample analysis, results reporting, communications, and sample archival. The processes are accomplished automatically, operating hands-free for extended durations in excess of one month. Aerosol collection is accomplished with a low-volume yet high-efficiency electrostatic particulate collector that continuously samples the air. In parallel, the collected particulate materials are then rapidly scanned to discriminate potential chemical and biological particulates from the complex components within environmental airstreams. Rapid scanning of the complex particulate mixtures targets specific spectroscopic markers indicative of chemical and biological warfare agents. The resulting spectroscopic signatures are statistically correlated to a database of known chemical and biological warfare agents. Because REBS identifies warfare agents spectroscopically, the database of threat signatures can be quickly adapted to new or emerging threats. The REBS database is extensible and can be updated by wireless transmission of software updates to deployed systems. This feature enhances the system's identification capabilities without the need for major changes to the system hardware. Designed to lower the operational costs of chemical and biological warfare agent protection, without sacrificing accuracy, REBS enables rapid yet actionable threat identification in varied and complex environments.

TECHNOLOGY:

Battelle has developed an autonomous chemical and biological aerosol identification technique leveraging the proven strengths and advantages of micro-Raman technology. The REBS approach incorporates automated sampling of the environment, electrostatic sample collection with single particle Raman spectroscopy, and multivariate signature analysis methods to harvest and analyze the aerosol materials.

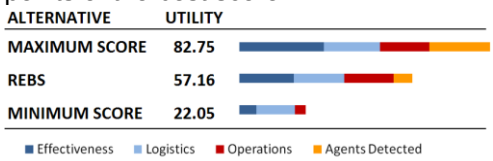
ANALYTICAL Laboratory Ranking

REBS ranked in the middle third of all evaluated products for analytical laboratories and earned 58% of the utility points of the best score.



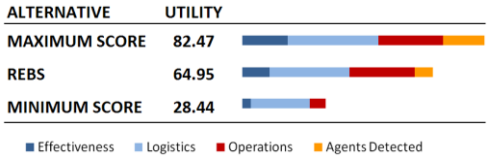
DIAGNOSTIC Laboratory Ranking

REBS ranked in the top third of all evaluated products for diagnostic laboratories and earned 69% of the utility points of the best score.



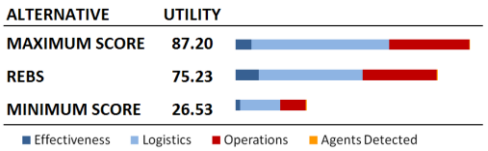
MOBILE Laboratory Ranking

REBS products for mobile laboratories and earned 79% of the utility points of the best score.



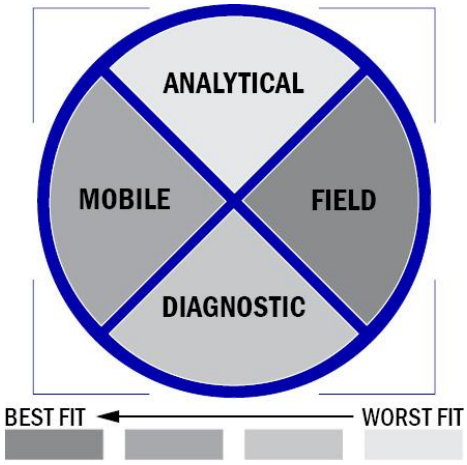
FIELD USE Ranking

REBS ranked in the top third of all evaluated products for field use and earned 86% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Battelle Memorial Institute
505 King Avenue
Columbus, Ohio 43201

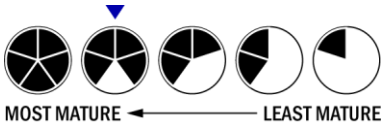
Point of Contact:
Andrew P. Bartko
bartkoa@Battelle.org

COST

- $48,000.00/system or device

SPECIFICITY

- False Positives: <0.05%
- False Negatives: <0.05%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, single test/ sample per run
- Fully automated

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from -21°C to 41°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of carry-on luggage
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life 3-5 years
- <5 minutes daily QA
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance pending
- FDA clearance pending
- Does not test liquids

System Maturity:
- Is commercially available
- Appearance in peer reviewed publication or independent evaluation information not available
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless and wired connections
- Fully autonomous
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software is open but modification requires licensing
- System hardware is open but modification requires licensing

REBS (Resource Effective BioIdentification System) - Laboratory Variant

by Battelle Memorial Institute

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (100-1,000 PFU/mL)
Toxins (1-100 ng/mL)
Aerosolized chemical agent
Liquid chemical agent (1ppb-1ppm)
Identification of specific isotopes

DETECTION MATRICES:

Demonstrated:
Nasal and throat swabs, Environmental air, Environmental water, Food, Powder

DESCRIPTION:

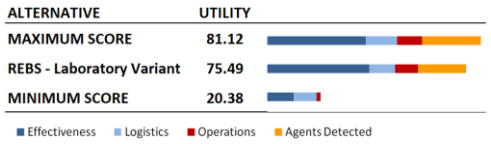
The Resource Effective BioIdentification System (REBS) -Laboratory Variant is a microbial identification technology that enumerates and identifies microbes using a combination of microscopic imaging and Raman microspectroscopy. The measurement process begins when the system collects particulate material on a solid substrate within a defined region. Next, using standard microscopy techniques, the collected material is imaged at a high magnification, and each field of view is recorded and indexed as the macroscopic collection region is scanned. This iterative process continues until the entire collected region has been scanned. From these images, all particles are located automatically by image processing algorithms, and their morphological properties are used as a first test to discriminate biological particles from non-biological particles. The collection substrate is then moved to bring each particle directly below the microscope objective in order to measure its Raman spectrum. This spectral signature provides accurate discrimination of biological particles from non-biological particles. Moreover, the particle can be identified by matching the measured spectrum to a database of spectra for known materials. Identification is supported only if spectral signatures of the material are available in the spectral database.

TECHNOLOGY:

Battelle has developed an autonomous micro-Raman spectroscopy technology that enables chemical and biological aerosol identification. The technology incorporates automated sample analysis, single particle Raman spectroscopy, and multivariate signature analysis methods to analyze the chemical and biological materials.

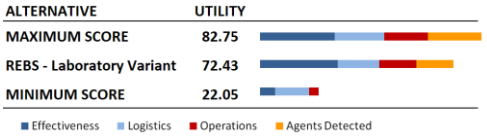
ANALYTICAL Laboratory Ranking

REBS - Laboratory Variant ranked in the top third of all evaluated products for analytical laboratories and earned 93% of the utility points of the best score.



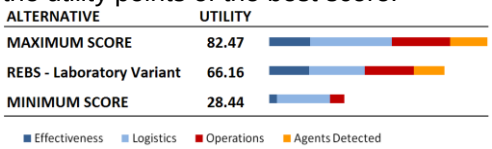
DIAGNOSTIC Laboratory Ranking

REBS - Laboratory Variant ranked in the top third of all evaluated products for diagnostic laboratories and earned 88% of the utility points of the best score.



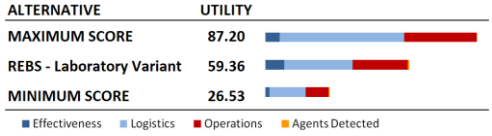
MOBILE Laboratory Ranking

REBS - Laboratory Variant ranked in the top third of all evaluated products for mobile laboratories and earned 80% of the utility points of the best score.



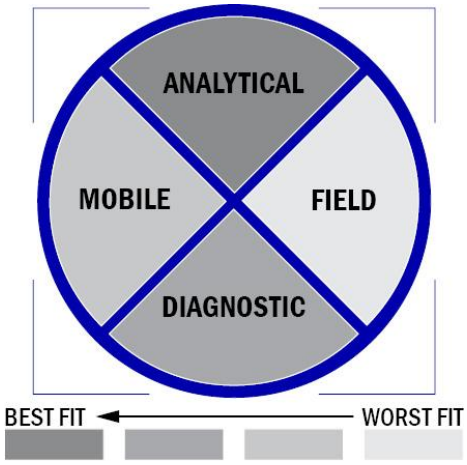
FIELD USE Ranking

REBS - Laboratory Variant ranked in the middle third of all evaluated products for field use and earned 68% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Battelle Memorial Institute
505 King Avenue
Columbus, Ohio 43201

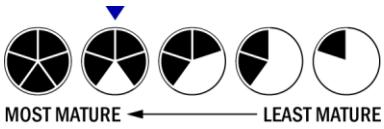
Point of Contact:
Andrew P. Bartko, Ph.D.
bartkoa@Battelle.org

COST

- Not Available
- $0.003/analysis

SPECIFICITY

- False Positives: 0.05%
- False Negatives: 0.05%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Currently semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- < 5 minutes set up
- < 1 minute down time
- 0-2 steps are required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 25°C to 37°C
- No consumables required
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Commercial carrier
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 3-5 years
- Less than 5 minutes QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- A single shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance pending
- FDA approval pending
- Less than 10 ul for a test

System Maturity:
- Is commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Autonomous system with easy adaptation
- Laptop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open but modification requires licensing
- The system hardware is open but modification requires licensing

Rotor-Gene Q Real-time PCR System

by QIAGEN, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)
Toxins (1-100 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swab, Stool, Urine, Environmental water, Soil, Food, Powder, Insect vectors

DESCRIPTION:

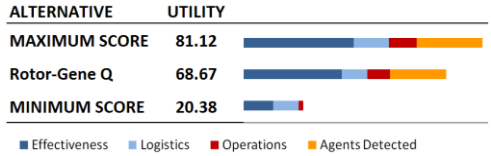
QIAGEN's Rotor-Gene Q real-time PCR system is designed to measure an increase of amplified DNA fragments for quantitative and qualitative analysis. Various chemistries are utilized to detect any nucleic acid sequence from multiple sources for a wide range of applications(i.e. pathogens, bacteria, viruses and spores from blood, environmental, soil and tissue samples). Assay targets include: Bacillus Anthracis Yersinia Pestis (Plague, Pest) Francisella Tularensis (Tularemia) Coxiella Burnetii (Q Fever) Filo Virus (Ebola/Marburg) Crimian Congo Haemorrhagic fever (CCHF) Orthopoxvirus Borrelia spec. Listeria monocytogenes Salmonella spec. Dengue virus Plasmodium spec. West Nile Virus SARS-Coronavirus Influenzavirus Influenzavirus/H5 Campylobacter spec. Chlamydia trachomatis Mycobacterium tuberculosis Mycobacterium Mycobacterium paratuberculosis Mycoplasma pneumoniae Herpes simplex virus-1/2 Hepatitis A virus Hepatitis B virus Parvovirus B19 Enterovirus Cytomegalovirus Epstein-Barr virus Varicella-Zoster virus.

TECHNOLOGY:

Real-time polymerase chain reaction amplification cycler. Each tube spins in a chamber of moving air, keeping all samples at precisely the same temperature during rapid thermal cycling. Analysis is based on intercalating dyes such as SYBR Green, probes such as hydrolysis (TaqMan) or hybridization (FRET) probes, or multiplex chemistries. Sample is illuminated and the fluorescent signal is rapidly collected by a fluorometer to determine quantities of starting templates of genetic markers. System uses multiple LED's for excitation and a PMT for detection. Multiplex up to six (6) dyes in a single tube spanning UV to infrared wavelengths (460-712 nm).

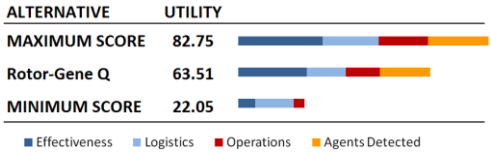
ANALYTICAL Laboratory Ranking

Rotor-Gene Q ranked in the top third of all evaluated products for analytical laboratories and earned 85% of the utility points of the best score.



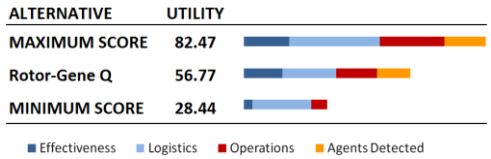
DIAGNOSTIC Laboratory Ranking

Rotor-Gene Q ranked in the top third of all evaluated products for diagnostic laboratories and earned 77% of the utility points of the best score.



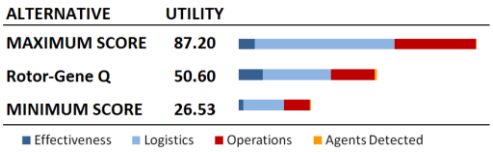
MOBILE Laboratory Ranking

Rotor-Gene Q ranked in the middle third of all evaluated products for mobile laboratories and earned 69% of the utility points of the best score.



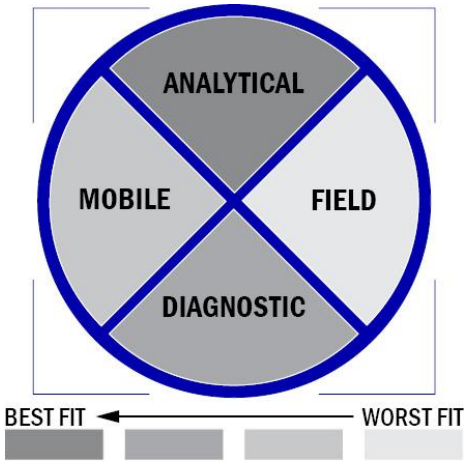
FIELD USE Ranking

Rotor-Gene Q ranked in the bottom third of all evaluated products for field use and earned 58% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

QIAGEN, Inc.
19300 Germantown Road
Germantown, MD 20874

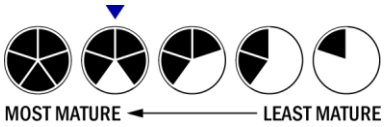
Point of Contact:
Keith Jolliff
1.240.686.7664
keith.jolliff@qiagen.com

COST

- $29,583.00 - 46,925.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30 - 60 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- No screen
- Between 200-500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- <5 minutes set-up
- <1 minute down time
- 3-5 steps required
- Web video/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours/ Must be frozen at temps at or below -20°C (cryo-storage)
- Peak performance at normal relative humidity conditions
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of carry-on luggage
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician only
- Maintenance included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Requires water aliquots
- External air or gas source required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wired connections
- Not autonomous
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software is closed and not available for modification
- System hardware is closed and not available for modification

RuggID System

by Nanosphere, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e3-10e4 CFU/mL)
Viruses (10e3-10e4 PFU/mL)
Toxins (<1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Environmental water, Food, Powder

DESCRIPTION:

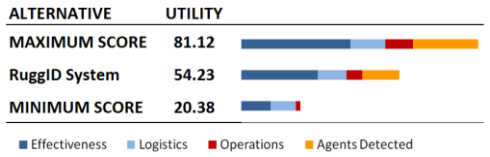
Nanosphere Inc.'s RuggID System is a universal molecular testing system that transcends limitations of existing technologies. The RuggID platform's superior performance is based on proprietary and patented gold nanoparticle probes to identify DNA, RNA and protein targets. The platform comprises self-contained, single-use, disposable test cartridges, the RuggID autoprocessing system (RuggID APS) that performs the assay, and the RuggID reader that controls the APS, performs image analysis, and provides results. The operator adds the sample to the disposable test cartridge, which is inserted into the RuggID APS. The APS, performs microfluidic manipulations and temperature adjustments required for the assay. The cartridge is subsequently analyzed by the reader and a definitive identification result is displayed. Key features of the RuggID system include: (1) Overall Simplicity. All assay steps after sample addition are automated. Minimal training needed owing to RuggID's intuitive user-interface. Objective data is provided eliminating user interpretation. (2) Field-Ready Device - system has been ruggedized to withstand various environmental and physical assaults. Together, with the stability of the assay components, the RuggID System offers high reliability testing for battlefield personnel and/or first responders. (3) Single Platform for Detecting Nucleic Acids and Proteins. Multiplex assays have been developed for the detection of bio-warfare agent DNA (or RNA) as well as for the multiplex detection of protein-based markers and bio-toxins. Current detection capability: Bacillus anthracis, Francisella tularensis, Yersinia pestis, Smallpox virus, MS2 phage, Bacillus thuringiensis (Commercially available.) Botulinum toxins A and B, Ricin toxin (Assay developed).

TECHNOLOGY:

Detection is based on the high scatter efficiency associated with gold nanoparticle probes. Bio-warfare agent DNA is directly detected by 'sandwiching' the target between DNA capture molecules attached to a solid substrate and DNA-functionalized gold nanoparticle probes. The gold probes impart exquisite specificity and sensitivity allowing direct detection of targets without amplification. Protein-based targets are detected by using antibodies as capture molecules and antibody-coated gold nanoparticles as labels. All assays are accomplished automatically in a single use microfluidic cartridge which is automatically processed by the RuggID System.

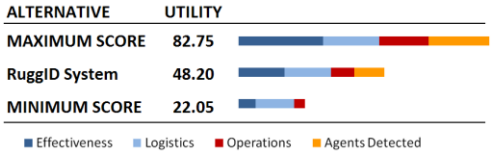
ANALYTICAL Laboratory Ranking

RuggID System ranked in the top third of all evaluated products for analytical laboratories and earned 67% of the utility points of the best score.



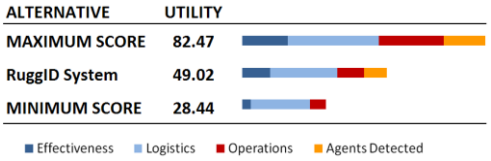
DIAGNOSTIC Laboratory Ranking

RuggID System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 58% of the utility points of the best score.



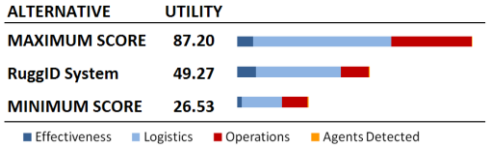
MOBILE Laboratory Ranking

RuggID System ranked in the bottom third of all evaluated products for mobile laboratories and earned 59% of the utility points of the best score.



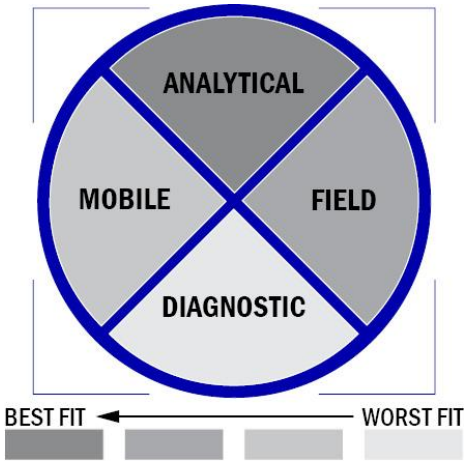
FIELD USE Ranking

RuggID System ranked in the bottom third of all evaluated products for field use and earned 56% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Nanosphere, Inc.
4088 Commercial Ave
Northbrook, IL 60062
www.nanosphere.us

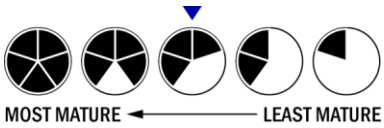
Point of Contact:
Sudhakar Marla
phone: (847) 400-9170
fax: (847) 400-9199
email: smarla@nanosphere.us

COST

- $85,000.00/system or device
- $50.00/sample

SPECIFICITY

- False Positives: <2%
- False Negatives: <2%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Currently semi- automated

Signature:
- No sounds or alarms
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes for set up
- 3-5 minutes down time
- 0-2 steps are required
- Customer site training

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at 4°C
- Unknown influence of relative humidity
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Commercial carrier/ Fixed and rotary wing aircraft/ Ship transport
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 4 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service less than once a year
- No preventive maintenance
- Maintenance not included
- Greater than 10 years
- < 5 minutes QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time not available
- Data cannot be processed while in progress
- No centrifugation steps required
- A single shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not available
- FDA approval not available
- Less than 100 ul for a test

System Maturity:
- Brass board
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Fully autonomous system with significant effort
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

SABT

by THALES Defense & Security

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria
Viruses
Toxins

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

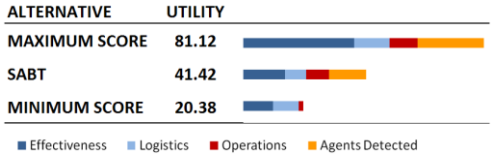
The SABT is a complete field system that, once deployed, is capable of detecting a Nuclear, Biological or Chemical (NBC) attack and identifying biological. The system is made of the following components: - a field laboratory (M3IB) - a network of CBRN detection beacons (CERBER) - a command and control center (NABOUCCO) The complete system is fully autonomous and able to communicate with military networks.

TECHNOLOGY:

The SABT integrates many detection and identification technologies: - biological identification: PCR, based on nucleic acids amplification, can identify viruses and bacteria's with a high sensitivity and ELISA, adapted for automated and rapid results, can identify all kind of biological threats, bacteria's, viruses or toxins - bioaerosol detection and chemical detection: flame spectrometry.

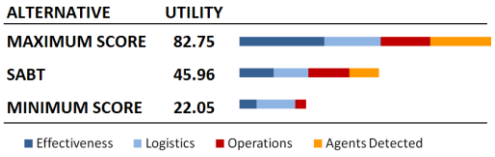
ANALYTICAL Laboratory Ranking

SABT System ranked in the bottom third of all evaluated products for analytical laboratories and earned 51% of the utility points of the best score.



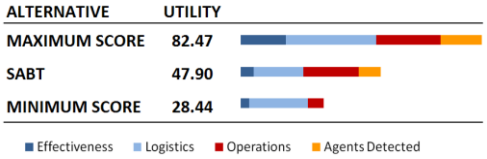
DIAGNOSTIC Laboratory Ranking

SABT System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 56% of the utility points of the best score.



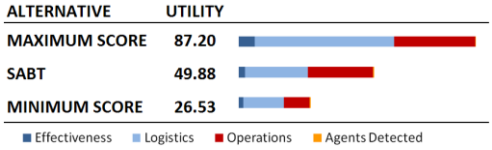
MOBILE Laboratory Ranking

SABT System ranked in the bottom third of all evaluated products for mobile laboratories and earned 58% of the utility points of the best score.



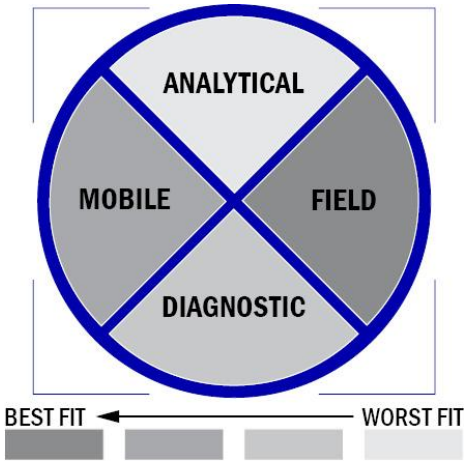
FIELD USE Ranking

SABT System ranked in the bottom third of all evaluated products for field use and earned 57% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

THALES Defense & Security
C4I systems Division
20-22 rue Grange Dame Rose
CS 90519 78141

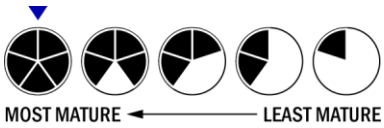
Point of Contact:
Jérôme LOUAT
jerome.louat@Thalesgroup.com

COST

- Not available

SPECIFICITY

- False positives: Not available
- False negatives: Not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms can be deactivated
- Screen cannot be dimmed
- Greater than 500 BTU/hour

Training and Speed:
- More than a day of training and significant skills are required
- >20 minutes set up required
- Minimal down time
- 0-2 steps are required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Components should be stored at room temp but can with stand temps > 45°C for <24 hours/ Must be stored at 4°C/ Must be frozen
- Performance is not influenced by relative humidity
- 1-3 years shelf life

Transportation:
- Larger than a home dishwasher
- Tactical military wheeled and tracked vehicle/ Fixed wing military aircraft/ Ship transport
- Weighs >50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions
- 5 or more components

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by technician only
- Maintenance is not included
- Expected life >10 years
- 10-20 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1 hr

Physical System Requirements:
- Requires multiple outlets or a dedicated circuit breaker
- Not intended for portable use
- Does not require water
- External air or gas source is required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- > 250 ul for a test

System Maturity:
- Is commercially available and meets mil specs
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB
- Network capable
- Wireless and wired connections
- Fully autonomous
- On board computer chip
- The system automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

SAFESITE MTX (Multi Threat Monitor)

by MSA

DETECTS THE FOLLOWING:

Demonstrated:
Aerosolized Chemical Agent (0.001-0.1 mg/mg3)
Identification of radioisotopes in tissue/ tissue damage

DETECTION MATRICES:

Demonstrated:
Environmental air, Soil

DESCRIPTION:

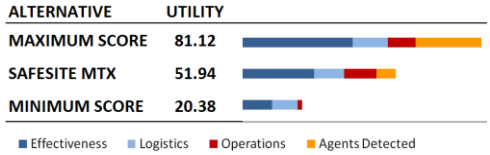
The SAFESITE® Multi-Threat Wireless Detection System monitors, detects and communicates the presence of up to six potential threats, including chemical warfare agents (CWA), gamma radiation, volatile organic compounds (VOC), toxic industrial chemicals (TIC), combustible gas and oxygen deficiency, and operates within a wireless network. • Toxic Industrial Chemicals – Detects for many (TICs) such as chlorine ammonia hydrogen cyanide and hydrogen chloride • Gamma Radiation – and µ to m REM levels • Volatile Organic Compounds - Uses a Photoionization detector 10.6 eV ionization source to detect chemicals • Chemical Warfare Agents – Uses a SAW array to detect both nerve and blister agents. Excellent false positive resistance and sub mg/m3 detection levels. • Integrated GPS for automatic sensor position on GIS charts • Compatible with ADASHI OptiMetrics 1st Responder Software – chemical plume modeling and weather integration. • SAFESITE MTX monitor is designed as a open architecture data communication platform.

TECHNOLOGY:

This sensor uses different technologies to meet the mission requirement, electrochemical sensor, catalytic, photionization, CZT, Geiger Muller and Surface Acoustic Wave (SAW) array.

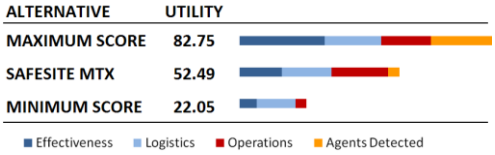
ANALYTICAL Laboratory Ranking

SAFESITE MTX System ranked in the middle third of all evaluated products for analytical laboratories and earned 64% of the utility points of the best score.



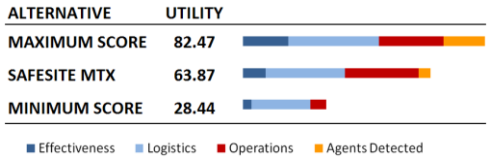
DIAGNOSTIC Laboratory Ranking

SAFESITE MTX System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 63% of the utility points of the best score.



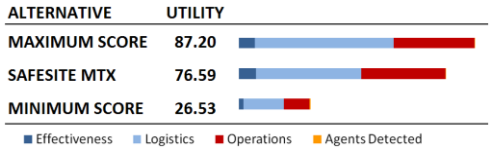
MOBILE Laboratory Ranking

SAFESITE MTX System ranked in the top third of all evaluated products for mobile laboratories and earned 77% of the utility points of the best score.



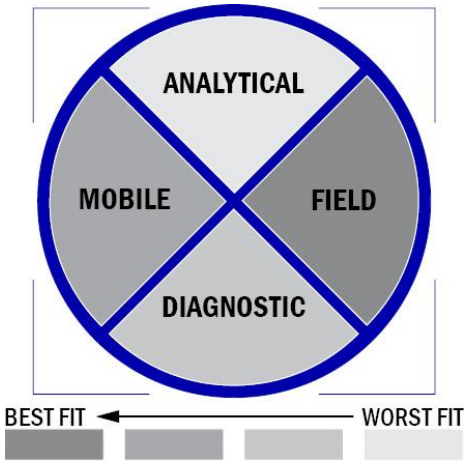
FIELD USE Ranking

SAFESITE MTX System ranked in the top third of all evaluated products for field use and earned 88% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

MSA
1000 Cranberry Woods Drive
Cranberry Township, PA 16066

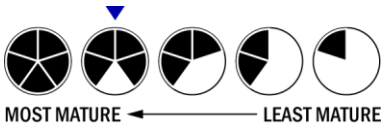
Point of Contact:
Norman Davis Jr.
norm.davis@MSAnet.com
724-776-8884

COST

- $40,000/system or device
- <$1.00/analysis

SPECIFICITY

- False positives: - <1%
- False negatives: - <0.01%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully-automated

Signature:
- Sounds or alarms cannot be deactivated
- Screen can be dimmed or turned off
- < 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 5-10 minute set up
- Minimal down time
- 0-2 steps are required
- DVD/ Web video/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Can be used from <-21°C to >42°C
- Does not require consumables
- Performance is not influenced by relative humidity
- >3 years shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transport
- Weighs 1-5 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 3-5 years
- <5 minutes daily QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Batteries
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps are required
- No shaking or vortexing, mixing, degassing or filtering steps are required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Does not test liquids

System Maturity:
- Commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- >250 GB
- Network capable
- Wired and wireless connections
- Fully autonomous
- Basic desktop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

SAM 940 (Radionuclide Isotope Identifier)

by Berkeley Nucleonics Corporation

DETECTS THE FOLLOWING:

Demonstrated:
Discrimination between radiation types
Identification of specific isotopes

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

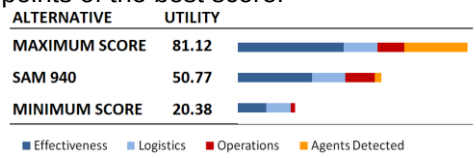
Identification of known and unknown radio-isotopes for environmental, security and anti-terrorism activities. Identify multiple nuclear isotopes, shielded nuclear isotopes, highly enriched uranium and weapons grade Pu.

TECHNOLOGY:

Scintillator or solid state detectors coupled with collector electronics and a multi-channel analyzer. Fast microprocessors (released in 2009) allow peak and template matching with full background and compton subtraction. Identification is then achievable at levels 100X below background radiation (ambient levels).

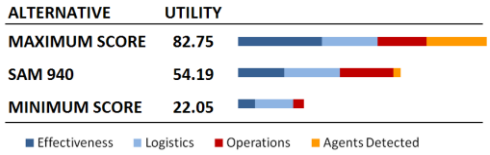
ANALYTICAL Laboratory Ranking

SAM 940 ranked in the middle third of all evaluated products for analytical laboratories and earned 63% of the utility points of the best score.



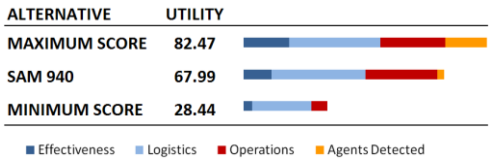
DIAGNOSTIC Laboratory Ranking

SAM 940 ranked in the middle third of all evaluated products for diagnostic laboratories and earned 66% of the utility points of the best score.



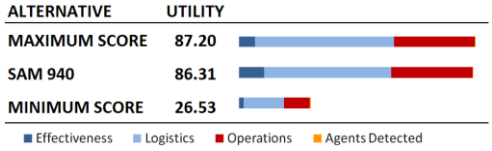
MOBILE Laboratory Ranking

SAM 940 ranked in the top third of all evaluated products for mobile laboratories and earned 82% of the utility points of the best score.



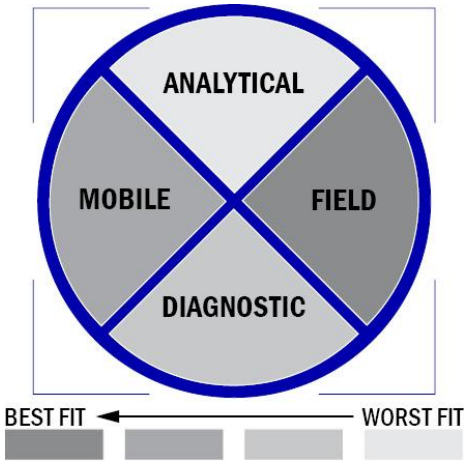
FIELD USE Ranking

SAM 940 ranked in the top third of all evaluated products for field use and earned 99% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

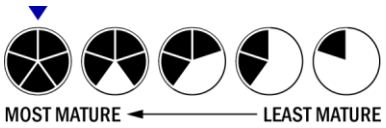
Berkeley Nucleonics Corporation
2955 Kerner Blvd.
San Rafael CA 94901

COST

- $10,000.00/system or device
- $1.00/analysis

SPECIFICITY

- False Positives:1%
- False Negatives: 1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- < 5 minutes set up
- Almost instantaneous down time
- 0-2 steps are required
- DVD/ Web video/ Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from <-21°C to >42°C
- No consumable required
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a toaster
- Commercial carrier
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- No service required
- Preventive maintenance serviceable by customer
- Maintenance is included
- Expected life greater than 10 years
- No QA required
- It likely that exposure to hazardous agent cannot be decontaminated

Physical System Requirements:
- Batteries
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Less than 10 ul for a test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Autonomous system
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open but modification requires licensing
- The system hardware is open but modification requires licensing

SAMPLE (Scanning Aerosol Micropulse LIDAR -Eyesafe)

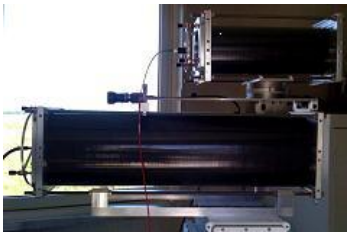
by ITT Information Systems

DETECTS THE FOLLOWING:

Demonstrated:
Aerosolized Chemical Agent

DETECTION MATRICES:

Nothing demonstrated.



DESCRIPTION:

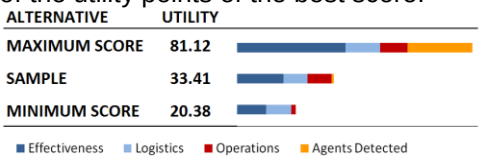
The Scanning Aerosol Micropulse LIDAR -Eyesafe (SAMPLE) is an eyesafe 1.5 micron aerosol backscatter lidar, capable of detecting monitoring and warning of CB aerosols up to a standoff range of 10km. It provides 3D maps of atmospheric particulates using cloud detection and aggregation algorithms.

TECHNOLOGY:

SAMPLE is highly robust due to its all fiber coupled design and leveraging of telecom fiber technologies. It uses digital detection via photon counting mode for exceedingly high sensitivity. It has very low SWaP.

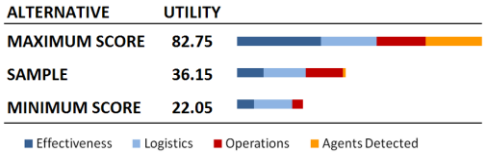
ANALYTICAL Laboratory Ranking

SAMPLE System ranked in the bottom third of all evaluated products for analytical laboratories and earned 41% of the utility points of the best score.



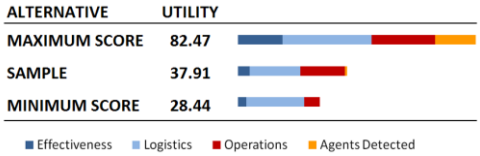
DIAGNOSTIC Laboratory Ranking

SAMPLE System ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 44% of the utility points of the best score.



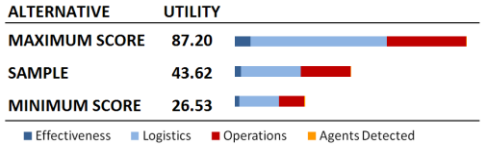
MOBILE Laboratory Ranking

SAMPLE System ranked in the bottom third of all evaluated products for mobile laboratories and earned 46% of the utility points of the best score.



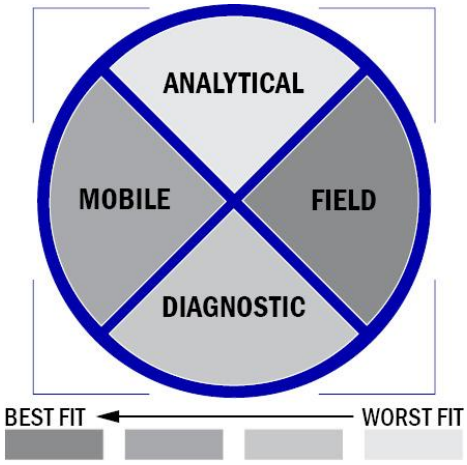
FIELD USE Ranking

SAMPLE System ranked in the bottom third of all evaluated products for field use and earned 50% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ITT Information Systems
127 Berry St Suite 400
Ft. Wayne, IN 46802

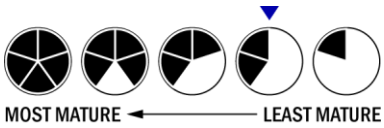
Point of Contact:
Jeff Pruitt
260-451-1374
jeff.pruitt@itt.com

COST

- $500,000.00/system or device
- $30,000.00/year operation cost

SPECIFICITY

- False positives: Not applicable
- False negatives: Not applicable



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Could be adapted to a fully automated system with some effort

Signature:
- Sounds or alarms cannot be deactivated
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- > 20 minutes set up
- Minimal down time
- 0-2 steps are required
- Manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at room temperature (27°C)
- Peak performance at normal relative humidity conditions
- Shelf life of reagents/test kits > 3 years

Transportation:
- Larger than a home dishwasher
- All modes of transport
- Weighs > 50 kg

Re-use:
- Multiple detection assays

Maintenance:
- Service more often than every 6 months
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 5-10 years
- 10-20 minutes daily QA required

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source is required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps are required
- No shaking or vortexing, mixing, degassing or filtering steps are required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Does not test liquids

System Maturity:
- Bread board
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB
- Network capable
- Wired connections
- Could be adapted to a fully autonomous system with some effort
- High end desktop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open but modification requires licensing
- The system hardware is open but modification requires licensing

SCIAB

by THALES Defense & Security

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria
Viruses
Toxins

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

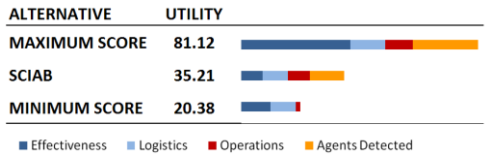
The SCIAB is a fully stand alone automated air monitoring system designed to provide quickly a reliable identification of pathogen bioaerosols through integration of two orthogonal identification technologies. The device is currently still in development phase.

TECHNOLOGY:

The SCIAB integrate a full range of innovative technologies to provide a significant evolution regarding existing solution. Those technologies include: - rapid reagentless immunological identification - rapid nucleic acid identification - high efficiency wet air sampling - various fluidic processing technology for sample concentration, lysis and regulation.

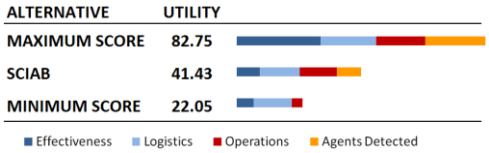
ANALYTICAL Laboratory Ranking

SCIAB System ranked in the bottom third of all evaluated products for analytical laboratories and earned 43% of the utility points of the best score.



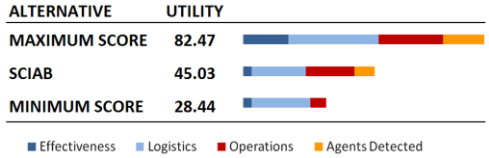
DIAGNOSTIC Laboratory Ranking

SCIAB System ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 50% of the utility points of the best score.



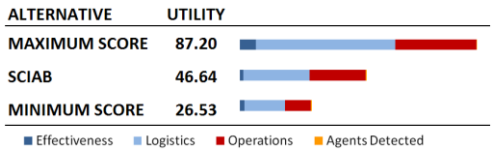
MOBILE Laboratory Ranking

SCIAB System ranked in the bottom third of all evaluated products for mobile laboratories and earned 55% of the utility points of the best score.



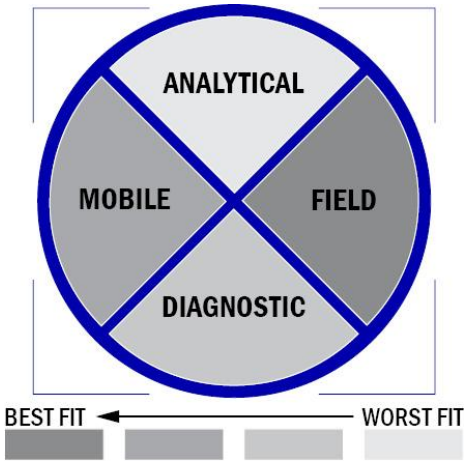
FIELD USE Ranking

SCIAB System ranked in the bottom third of all evaluated products for field use and earned 53% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

THALES Defense & Security
C4I systems Division
20-22 rue Grange Dame Rose
CS 90519 78141

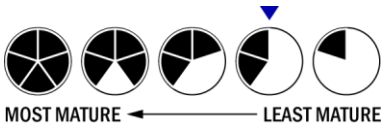
Point of Contact:
Jérôme LOUAT
jerome.louat@Thalesgroup.com

COST

- Not available

SPECIFICITY

- False positives: Not available
- False negatives: Not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- Fully automated

Signature:
- Sounds or alarms can be deactivated
- Screen cannot be dimmed or turned off

Training and Speed:
- Day of training and technical skills are required
- 5-10 set up required
- Minimal down time
- 0-2 steps are required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be stored at room temperature but can withstand temperatures in excess of 45°C for periods of less than 24 hours
- Performance is not influenced by relative humidity
- 1-3 years shelf life

Transportation:
- Approximately the size of a home dishwasher
- All modes of transportation
- Weighs >50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service > every 6 months
- Preventive maintenance serviceable by technician only
- Maintenance is not included
- Expected life 5-10 years
- < 5 minutes daily QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Batteries
- 4-8 hours
- Requires water aliquots
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps are required
- No shaking or vortexing, mixing, degassing or filtering steps are required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- > 250 ul for a test

System Maturity:
- Only one incomplete device or system exist (bread board)
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB
- Network capable
- Wireless and wired connections
- Fully autonomous
- Basic desktop computer
- The system automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

SensAlert Plus Gas Detection Equipment

by Sensidyne

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

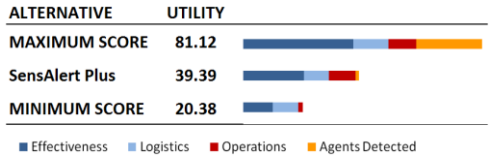
Gas Detection unit for employee safety monitoring. Designed for ambient air monitoring. Several gas sensors available ranging from combustible %LEL range to chlorine, ammonia, hydrogen sulfide, carbon monoxide and may more gases available. There is FM approval on the product. The product is designed to be permanently mounted in an area. It is industrial grade and is offered in Class I Division I housings as well as Division II and also general purpose. The sensor head assembly is intrinsically safe by design and the sensor can be mounted up to 100 feet away from the transmitter display. The sensor can be hot swapped even in a classified area with the transmitter under power.

TECHNOLOGY:

The FM and ATEX hazardous area approved SensAlert Plus transmitter has dual in-line conduit entries and an intrinsically safe sensor head. A large backlit LCD display and non-intrusive user interface enables easy configuration, maintenance, and complete sensor data retrieval. Configurable relays, analog or digital outputs, diagnostics, and Test-on-Demand™ deliver the highest reliability and functionality available from any point gas detector. The SensAlert Plus sensor head is certified intrinsically safe and can be mounted to the transmitter or remotely up to 100 feet (30m) away. Sensors are available for monitoring toxic, Oxygen, and combustible (Infrared and Catalytic Bead) gases in many ranges. Sensors have active continuous temperature compensation and nonvolatile memory for transportable calibration and stored application data including gas name or type, span, alarm values, and exposure history. All SensAlert Plus sensors are recognized by the transmitter which automatically configures to the onboard sensor data, while retaining custom configuration settings.

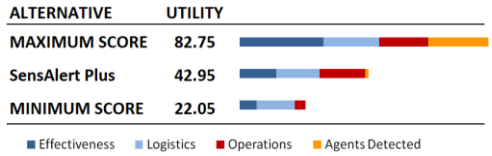
ANALYTICAL Laboratory Ranking

SensAlert Plus ranked in the bottom third of all evaluated products for analytical laboratories and earned 49% of the utility points of the best score.



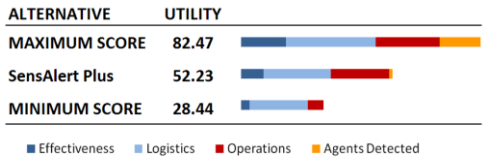
DIAGNOSTIC Laboratory Ranking

SensAlert Plus ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 52% of the utility points of the best score.



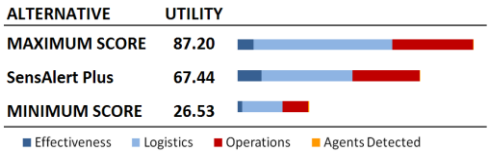
MOBILE Laboratory Ranking

SensAlert Plus ranked in the middle third of all evaluated products for mobile laboratories and earned 63% of the utility points of the best score.



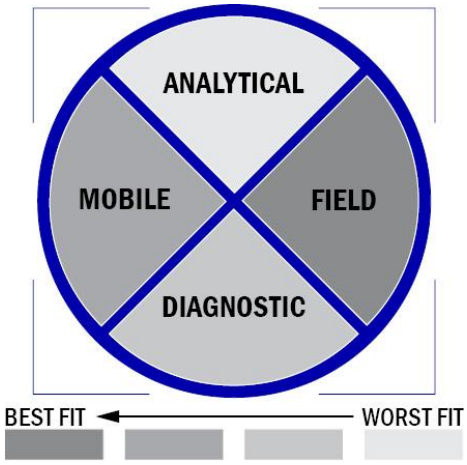
FIELD USE Ranking

SensAlert Plus ranked in the middle third of all evaluated products for field use and earned 77% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Sensidyne, LP
16333 Bay Vista Drive
Clearwater, FL 33760-3135

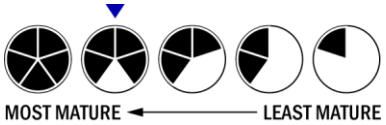
Point of Contact:
rupa@sensidyne.com
800-451-9444

COST

- $3,910.00/ transmitter, sensor and controller

SPECIFICITY

- False Positives: Available upon request from the manufacturer
- False Negatives: Available upon request from the manufacturer



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen contrast is adjustable
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- More than 20 minutes required for set-up
- 3-5 minutes down time
- 0-2 steps are required
- Customer and manufacturer site training/ Hard-copy and Web-based operators manual

Operational conditions:
- Can be used from -21°C to 41°C
- Components stored at 4°C
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a toaster
- Transport via commercial carrier or ship
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service more than twice a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life greater than 10 years
- No daily QA necessary
- Hazardous agent isolated to discrete elements and/or decontamination requires <1 hr

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering step required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 100 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connection
- Could be autonomous with some effort
- Laptop computer needed
- Stores and archives data outputs but does not create electronic records
- System software is closed and not available for modification
- System hardware is closed and not available for modification

Sensidyne/Kitagawa Gas Detector Tube

by Sensidyne

DETECTS THE FOLLOWING:
Nothing demonstrated.

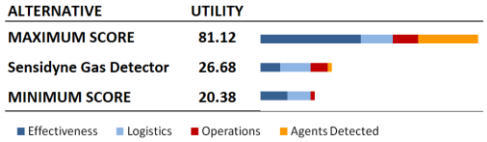
DETECTION MATRICES:
Nothing demonstrated.

DESCRIPTION:
Sealed glass colorimetric tubes are used with a hand operated piston pump to detect about 300 target gases by length-of-stain.

TECHNOLOGY:
Colorimetric length of stain.

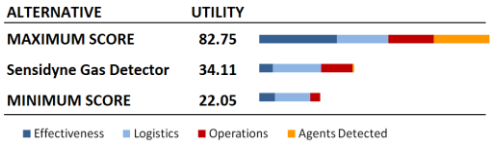
ANALYTICAL Laboratory Ranking

Sensidyne/Kitagawa Gas Detector Tube ranked in the bottom third of all evaluated products for analytical laboratories and earned 33% of the utility points of the best score.



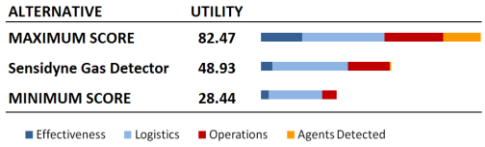
DIAGNOSTIC Laboratory Ranking

Sensidyne/Kitagawa Gas Detector Tube ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 41% of the utility points of the best score.



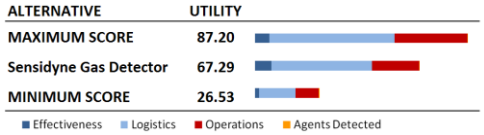
MOBILE Laboratory Ranking

Sensidyne/Kitagawa Gas Detector Tube ranked in the bottom third of all evaluated products for mobile laboratories and earned 59% of the utility points of the best score.



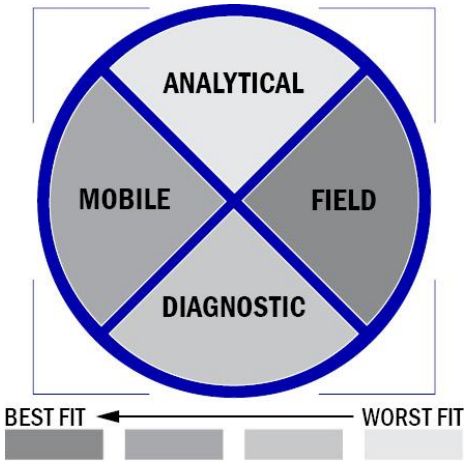
FIELD USE Ranking

Sensidyne/Kitagawa Gas Detector Tube ranked in the middle third of all evaluated products for field use and earned 77% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Sensidyne, LP
16333 Bay Vista Drive
Clearwater, FL 33760-3135

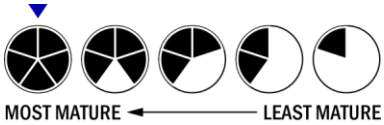
Point of Contact:
Ron Roberson
rroberson@sensidyne.com
800-451-9444, ext 684

COST

- $385.00/Pump kit
- $64.30/box of 10 tubes

SPECIFICITY

- False Positives: Unknown
- False Negatives: Unknown



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, single test/sample per run
- Not amenable to full or semi-automation

Signature:
- Sounds or alarms not present
- No screen
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 3-5 steps are required
- Compact disk or DVD

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a soda can
- All means of transportation
- Weighs less than 1 kg

Re-use:
- Designed for single use
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance is not applicable to this system
- Maintenance not included
- Expected life greater than 10 years
- QA less than 5 minutes
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- No electrical equipment
- Unit is hand operated
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering step required
- Does not interpret raw data or call positive/negative

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Not network capable
- Not autonomous
- No computational power needed
- No internal memory for data storage or electronic records
- System does not employ software
- System hardware is closed and not available for modification

SilverQuant Pathogen Detection System

by Gentel Biosciences

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Demonstrated:
Blood

DESCRIPTION:

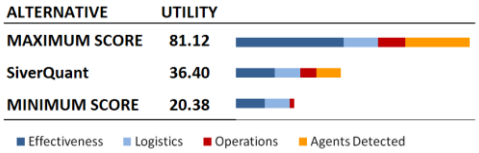
The system consists of a low cost scanning system (hardware, software and computer included) that is used to measure antibodies to pathogens (viral or bacterial) in patient (human, monkey, rodent, etc.) blood or sera. Pathogen panels for screening are available off-the-shelf or can be easily customized to meet customer needs.

TECHNOLOGY:

The ultra-sensitive detection system (2-10 times > fluorescence is based on gold nano-particles conjugated to species specific antibodies which direct the deposition of silver particles in order to visualize the pathogen spot and identify the infectious organism.

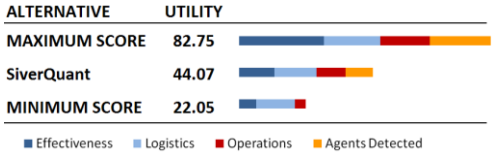
ANALYTICAL Laboratory Ranking

SilverQuant ranked in the bottom third of all evaluated products for analytical laboratories and earned 45% of the utility points of the best score.



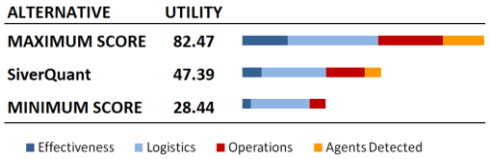
DIAGNOSTIC Laboratory Ranking

SilverQuant ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 53% of the utility points of the best score.



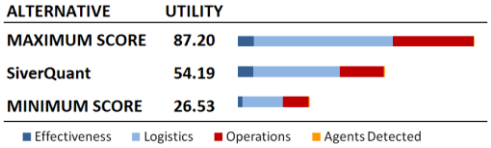
MOBILE Laboratory Ranking

SilverQuant ranked in the bottom third of all evaluated products for mobile laboratories and earned 57% of the utility points of the best score.



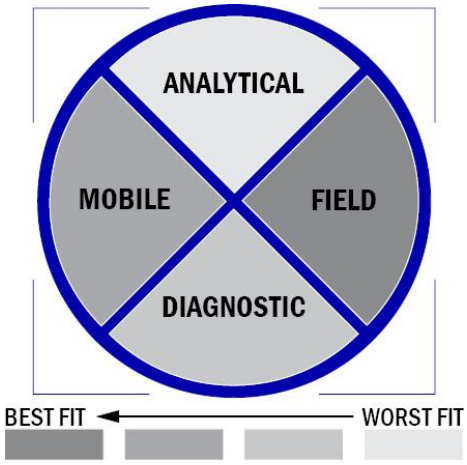
FIELD USE Ranking

SilverQuant ranked in the bottom third of all evaluated products for field use and earned 62% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Gentel Biosciences
5500 Nobel Drive
Suite #230
Madison, WI 53711

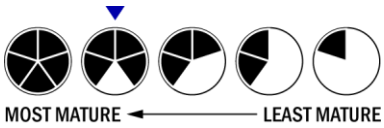
Point of Contact:
Dan Clutter
608-441-2904 x4029

COST

- $8,990.00/system or device

SPECIFICITY

- False Positives: 0-5%
- False Negatives: 0-5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1 - 8 hours for detection
- 1 sample, >10 tests/ sample per run
- Could be adapted to fully automated with some effort

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up required
- <1 minute down time
- 9-12 steps required
- DVD/ Web-based video/ Customer and manufacturer site training/ Hard-copy and web-based operators manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be frozen but can stand temps >4°C for <24 hours; must be at room temp (27°C)/ Must be at 4°C
- Performance is not influenced by relative humidity
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of carry-on luggage
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 4 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service less than once a year
- Preventive maintenance not applicable
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Decon not applicable

Physical System Requirements:
- 110V electrical requirement
- Not portable
- Requires water aliquots
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data processing while in progress information not available
- No centrifugation steps
- Multiple shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Satellite, wireless and wired connections
- Not autonomous
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software is open but modification requires licensing
- System hardware is open but modification requires licensing

SmartBio Sensor (SBS)

by Smiths Detection, Inc

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (90% probability of detection at 500 CFU/liter of air)
Viruses (90% probability of detection at 5000 CFU/liter of air)

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

SBS is a portable and ruggedized real-time bio-aerosol detector that detects and classifies bacteria, bacterial spores, virus and bio-toxins, including unanticipated or genetically modified organisms while maintaining little response to common environmental interferents. It furthermore collects particles on the sensor coupon which can be aqueously eluted and identified using PCR and toxin antibody screening technologies such as Bio-Seeq PLUS and Prime Alert Toxin Screens.

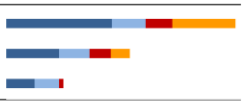
TECHNOLOGY:

SBS continuously samples the air and captures particles based on inertial impaction. SBS is comprised of 8 sensing films that interact with the target organism resulting in a change in fluorescence signal from those sensing films. Pattern recognition is used to detect and classify compounds, resulting in a user selectable visual and audio signal.

ANALYTICAL Laboratory Ranking

SmartBio Sensor (SBS) ranked in the middle third of all evaluated products for analytical laboratories and earned 54% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
SmartBio Sensor (SBS)	43.72
MINIMUM SCORE	20.38

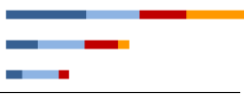


Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

SmartBio Sensor (SBS) ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 52% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
SmartBio Sensor (SBS)	42.99
MINIMUM SCORE	22.05

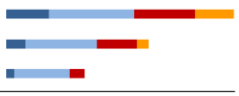


Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

SmartBio Sensor (SBS) ranked in the middle third of all evaluated products for mobile laboratories and earned 63% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
SmartBio Sensor (SBS)	51.55
MINIMUM SCORE	28.44

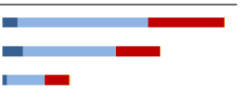


Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

SmartBio Sensor (SBS) ranked in the middle third of all evaluated products for field use and earned 71% of the utility points of the best score.

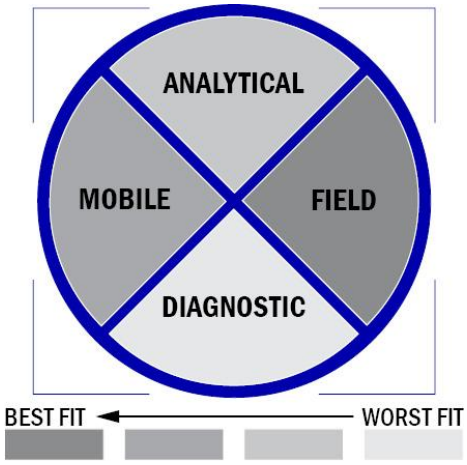
ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
SmartBio Sensor (SBS)	62.08
MINIMUM SCORE	26.53



Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

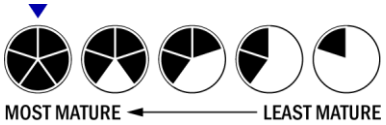
Smiths Detection. Inc.
60A Columbia Rd
Morristown, NJ 07960
973 496 9200

COST

- $29,500.00/system or device
- $25.00/ pair of sensors (8-12 hours detection)

SPECIFICITY

- False Positives: 1 false alarm per week (168 hours) of operation
- False Negatives: unknown



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, single tests/ sample per run
- System is semi-automated

Signature:
- Sounds or alarms not present
- Screen not present
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes set up
- Almost no down time
- 0-2 steps are required
- Customer and manufacturer site training/ Hard copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at 4°C
- peak performance at normal relative humidity conditions
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means of transportation
- Weighs between 5 and 25kg

Re-use:
- Multiple detection assays
- 0-1 or more solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service less than once a year
- Preventive maintenance is N/A
- Maintenance is not included
- Expected life 5-10 years
- No QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 220V electrical requirement
- 4-8 hours battery use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be analyzed during a run
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- System does not test liquids

System Maturity:
- Commercially available and meets milspecs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- System currently autonomous
- Onboard computer chip
- Store and archive data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

SmartCycler System

by Cepheid

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Viruses (100-1,000 PFU/mL)
Toxins (1-100 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Food

DESCRIPTION:

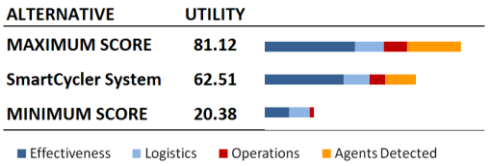
The Cepheid SmartSystem™ is potentially the most sensitive realtime PCR testing platform available on the market. With up to 96 individually programmable reaction sites, it is one of today's most flexible, easy-to-use systems. No other system is designed for complete portability in the field. The SmartCycler System is highly robust and compact, with no moving components—ideally suited for mobile use in field-testing applications. By automating the entire amplification and detection process, the SmartCycler System can deliver highly accurate and consistent test results from prepared biological samples in 20–40 minutes. Flexible and Expandable Cepheid's SmartCycler® instrument is the only random access, modular real-time PCR instrument on the market with up to 96 sites that can each run a different protocol. Installation of the SmartCycler System is plug-and-play, and system expansion only requires an additional USB connection. Fast With the SmartCycler System, you can optimize PCR denaturation, annealing and extension temperatures and times in a single run. The SmartCycler System can deliver results in less than half the time of a 96-well plate instrument. High Throughput Two SmartCycler instruments can process an equal or greater number of samples than a 96 well instrument in a single day. Assay Optimization Made Easy Increase Flexibility - random access accommodates varied cycling conditions, with variable amplicon lengths, cycling times, and assay design; Increasing Robustness, Decreasing time to results. Mobile Heavy-duty airline-safe transport case and laptop configuration is available for the SmartCycler System, making it ideal for field work.

TECHNOLOGY:

The Cepheid SmartSystem™ is potentially the most sensitive realtime PCR testing platform available on the market. With up to 96 individually programmable reaction sites, it is one of today's most flexible, easy-to-use systems. No other system is designed for complete portability in the field. The SmartCycler System is highly robust and compact, with no moving components—ideally suited for mobile use in field-testing applications. By automating the entire amplification and detection process, the SmartCycler System can deliver highly accurate and consistent test results from prepared biological samples in 20–40 minutes.

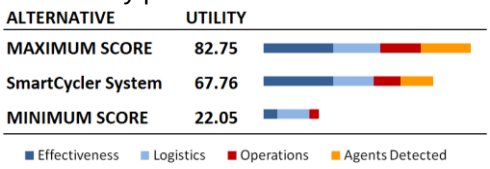
ANALYTICAL Laboratory Ranking

SmartCycler System ranked in the top third of all evaluated products for analytical laboratories and earned 77% of the utility points of the best score.



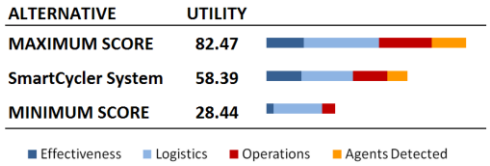
DIAGNOSTIC Laboratory Ranking

SmartCycler System ranked in the top third of all evaluated products for diagnostic laboratories and earned 82% of the utility points of the best score.



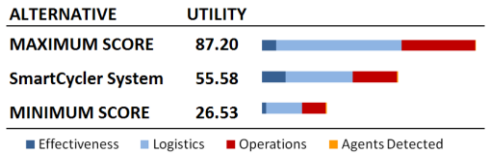
MOBILE Laboratory Ranking

SmartCycler System ranked in the middle third of all evaluated products for mobile laboratories and earned 71% of the utility points of the best score.



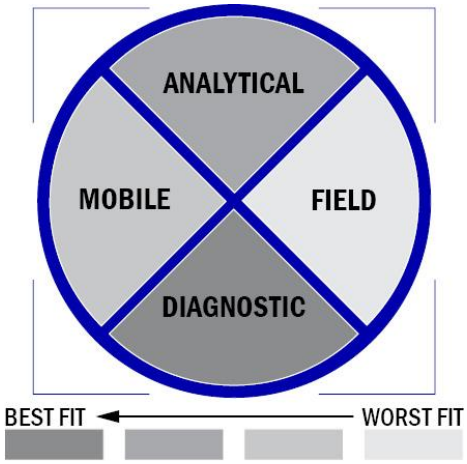
FIELD USE Ranking

SmartCycler System ranked in the bottom third of all evaluated products for field use and earned 64% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089

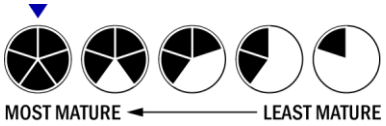
Point of Contact:
Chinmay Sheth

COST

- $34,995.00/system or device
- ~$3.00/assay

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30-60 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- No set up
- Almost instantaneous down time
- 0-2 steps are required
- DVD/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can withstand temperatures in excess of 45°C for periods of less than 24 hours/ Must be stored at room temp/ Must be stored at 4°C
- Performance is not influenced by relative humidity
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All modes of transportation
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 0-1solutions, buffer, and/or reagents
- 2 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician
- Maintenance is not included
- <5 minutes QA required

Physical System Requirements:
- 110V electrical requirement
- < 1 hour battery use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- A single centrifugation step required
- A single shaking or vortexing, mixing, degassing or filtering step
- Software will call final result

Sensitivity and Detection:
- 510K clearance shown
- FDA approval shown
- Less than 100 ul for a test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- No data transition
- Not capable of autonomy
- Basic desktop computer
- Store and archive data outputs but not create an electronic record
- The system software is open and available for modification
- The system hardware is closed and not available for modification

SPIR ID Handheld Detection & Identification

by Mirion Technologies (MGPI), Inc.

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

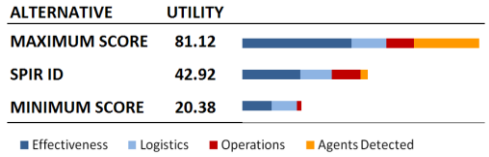
The SPIR-ID is a rugged handheld device designed to efficiently search for radioactive materials and "on the fly" discriminate threats such as illicit trafficking and Radiological Dispersal Devices (RDDs). the SPIR-ID quickly and reliably identifies and categorizes radionuclides for demanding scenarios including heavily shielded or masked threats due to a large volume detector associated with the Identpro/SIA algorithm specifically designed for homeland security. Detection and Identification performances exceeds all ANSI N42-34 requirements. Rugged construction and simple routine user mode are ideally suited for field use in harsh environments.

TECHNOLOGY:

The SPIR-ID 3" NaI(Tl) includes a 3*2" rugged NaI(Tl) detector, plus a GM tube and 2 ancillary LiI(Eu) Neutron detectors. Identification performance allow correct threat assessment for very demanding scenarios exceeding current standards such as mixed isotopes, heavily shielded isotopes, medical isotopes or background masked SNMs.

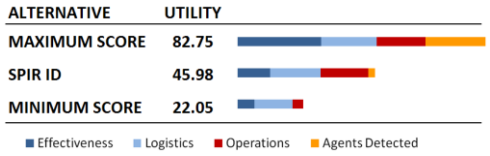
ANALYTICAL Laboratory Ranking

SPIR ID ranked in the middle third of all evaluated products for analytical laboratories and earned 53% of the utility points of the best score.



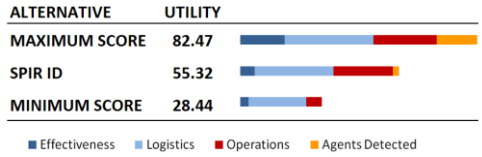
DIAGNOSTIC Laboratory Ranking

SPIR ID ranked in the middle third of all evaluated products for diagnostic laboratories and earned 56% of the utility points of the best score.



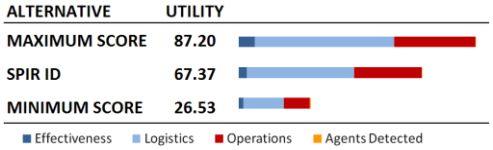
MOBILE Laboratory Ranking

SPIR ID ranked in the middle third of all evaluated products for mobile laboratories and earned 67% of the utility points of the best score.



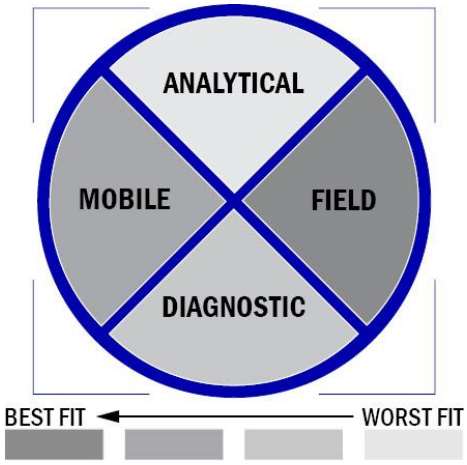
FIELD USE Ranking

SPIR ID ranked in the middle third of all evaluated products for field use and earned 77% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Mirion Technologies (MGPI), Inc.
5000 Highlands Parkway, Ste 150
Smyrna, GA 30082

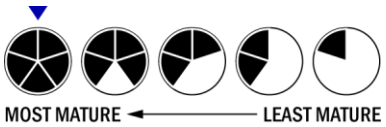
Point of Contact:
Keith Spero
770.432.2744 x163

COST

- $25,000/system or device

SPECIFICITY

- False positives: Less than 1/hr/week
- False negatives: Not applicable



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms can be deactivated
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- <5 minutes set up
- Minimal down time
- 0-2 steps are required
- Customer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Does not require consumables
- Performance is not influenced by relative humidity

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs 1-5 kg

Re-use:
- Multiple detection assays

Maintenance:
- Service once per year
- Maintenance is included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Batteries
- 4-8 hours of battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps are required
- No shaking or vortexing, mixing, degassing or filtering steps are required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Does not test liquids

System Maturity:
- Commercially available and meets military specifications
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB
- Network capable
- Wireless and wired connections
- Fully autonomous
- Internal PC
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open but modification requires licensing
- The system hardware is open but modification requires licensing

StepOne

by Applied Biosystems - Life Technologies

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

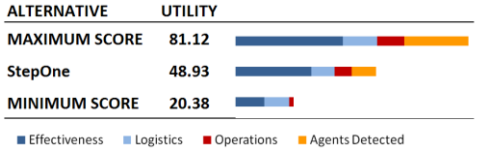
Applied Biosystems' 48-well low throughput real-time PCR instrument, the StepOne™ Real-Time PCR System, makes it simple and easy to get publication ready high quality data on day one. This remarkably simple real-time PCR system is designed with a user-friendly yet powerful interface for researchers new to real-time PCR. Bring total confidence to your research with the StepOne™ System that collects and saves data from all filters in every run without depending on a computer or plate setup. Key product features: * Intuitive, flexible software and wizards guide new users through their real-time PCR experiments in three easy-to follow steps * Data stored both on the instrument and computer for extra safety * Long-life LED-based optical system records fluorescence from FAM™/SYBR® Green, VIC®/JOE™, and ROX™ dyes for gene expression analysis, pathogen quantitation, SNP genotyping, and presence/absence assays * Fast system with plug and play assays and reagents for maximum time savings * Ultra-compact footprint fits any laboratory setting * LCD touchscreen and USB drive with the option of PC-free instrument operation * Remote monitoring and email notification with run file attached for immediate access to results--even remotely * Easily upgradeable to the StepOnePlus™ Real-Time PCR System

TECHNOLOGY:

The StepOne allows a real-time TaqMan ® polymerase chain reaction amplification of genes on a peltier-based thermocycling apparatus.

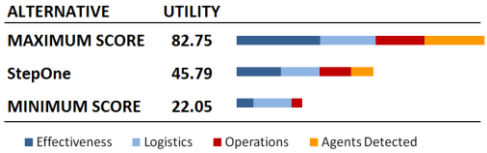
ANALYTICAL Laboratory Ranking

StepOne System ranked in the middle third of all evaluated products for analytical laboratories and earned 60% of the utility points of the best score.



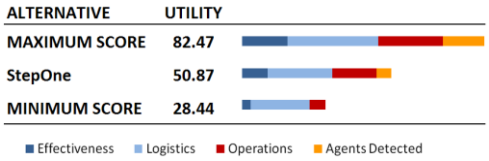
DIAGNOSTIC Laboratory Ranking

StepOne System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 55% of the utility points of the best score.



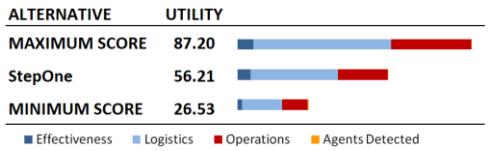
MOBILE Laboratory Ranking

StepOne System ranked in the bottom third of all evaluated products for mobile laboratories and earned 62% of the utility points of the best score.



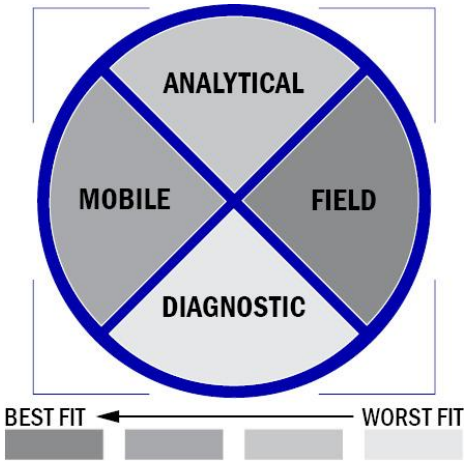
FIELD USE Ranking

StepOne System ranked in the bottom third of all evaluated products for field use and earned 64% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Applied Biosystems - Life Technologies
850 Lincoln Centre Drive
Foster City, CA 94404

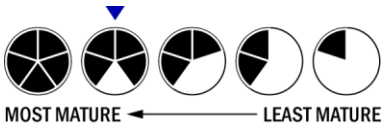
Point of Contact:
Giambattista Selvaggi
giambattista.selvaggi@lifetech.com

COST

- $16,000/system or device
- Cost per analysis is variable

SPECIFICITY

- False Positives: Not available
- False Negatives: Not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Currently semi-automated

Signature:
- Sounds or alarms can be deactivated
- Screen cannot be dimmed or turned off
- < 500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 5-10 minutes set up
- 1-3 minutes down time
- 6-8 steps are required
- Customer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components must be stored at 4°C
- Performance is not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 5-25 kg

Re-use:
- Multiple detection assays
- >5 solutions, buffer, and/or reagents
- 3 components

Maintenance:
- No service required
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life unknown
- No QA required
- Exposure to hazardous agent requires up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- Multiple centrifugation steps are required
- Multiple shaking or vortexing, mixing, or filtering steps are required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Less than 10 ul for a test

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Wired and wireless connections
- Fully autonomous system with some effort
- On-board computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

StepOne Plus real-time PCR system

by Applied Biosystems, Inc.

DETECTS THE FOLLOWING:
Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)

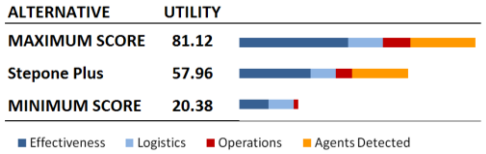
DETECTION MATRICES:
Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Environmental air, Environmental water, Soil, Food, Powder, Insect vector

DESCRIPTION:
Real-time PCR system for all qPCR applications.

TECHNOLOGY:
Real-time PCR system for all qPCR applications. Taqman, SYBR Green, HRM, etc...

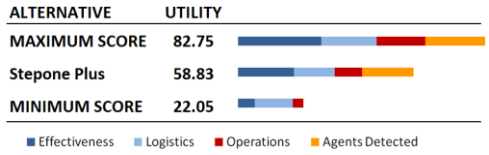
ANALYTICAL Laboratory Ranking

StepOne Plus ranked in the top third of all evaluated products for analytical laboratories and earned 71% of the utility points of the best score.



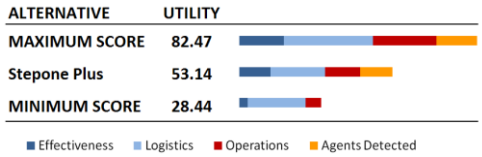
DIAGNOSTIC Laboratory Ranking

StepOne Plus ranked in the top third of all evaluated products for diagnostic laboratories and earned 71% of the utility points of the best score.



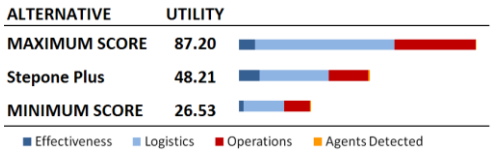
MOBILE Laboratory Ranking

StepOne Plus ranked in the middle third of all evaluated products for mobile laboratories and earned 64% of the utility points of the best score.



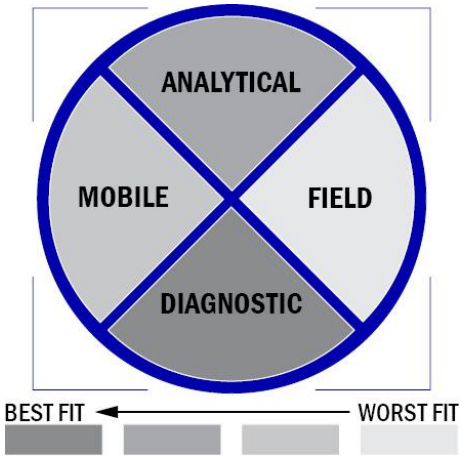
FIELD USE Ranking

StepOne Plus ranked in the bottom third of all evaluated products for field use and earned 55% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

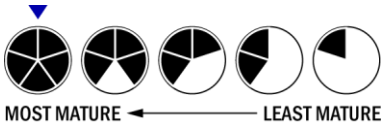
Applied Biosystems, Inc.
850 Lincoln Centre Drive
Foster City, CA 94404
650-554-3080

COST

- $33,000/system or device

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run

Signature:
- No sounds or alarms
- Screen cannot be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- Less than 5 minutes set up
- Less than 1 minute down time
- 6-8 steps are required
- Web video/ Customer and manufacturer site training

Operational conditions:
- Can be used from 4°C to 41°C
- Components must be frozen
- Influenced by relative humidity unknown
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means of transportation
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life >10 years
- 10-20 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be process while in progress
- No centrifugation steps required
- Multiple shaking or vortexing, mixing, degassing or filtering steps required
- Software could call final result in future

Sensitivity and Detection:
- FDA approval shown
- Less than 10 ul for a test

System Maturity:
- Is commercially available and meets milspecs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Not capable of autonomy
- Laptop computer
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

StreetLab Mobile Chemical/Biological Identification Instrument

by Morpho Detection

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (>100,000 CFU/mL)
Liquid chemical agent
(> 1 ppt)

DETECTION MATRICES:

Demonstrated:
Powder

DESCRIPTION:

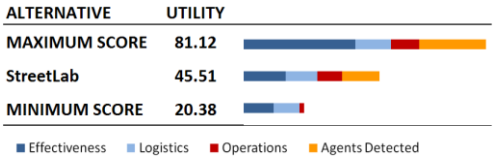
StreetLab Mobile is an easy to use, portable, ruggedized tool for rapid field identification of chemical and biological threats in one device. Designed with first responders in mind, StreetLab Mobile has a simple and intuitive user interface, large buttons for use by a gloved hand, and requires minimal user training prior to use. A diverse chemical library covering chemical warfare agents, explosives, precursors, narcotics, cutting agents, toxic industrial chemicals, pesticides, fertilizers, and household chemicals along with the ability to customize the library in the field provides flexibility to cover diverse identification needs. Sampling can be performed either as a substance is encountered on the ground, in a bottle/bag, or in sample vials. The non-contact testing allows for analysis through many glass or plastic containers to limit exposure to the unknown substance; non-destructive testing preserves samples for additional analysis. One hand or hands free analysis is possible due to the ergonomic design allowing a responder to put StreetLab Mobile down and perform other critical tasks while on scene. Remote wireless connectivity allows operation from a safe distance in potentially hazardous scenarios; results are wirelessly transmitted to a laptop where the included software allows further analysis of the chemical spectra. Dual-detection capable-screen for chemical and biological threats on the same instrument. Certified to IP 67 standards for ingress protection StreetLab Mobile is dunkable for easy post-incident decon.

TECHNOLOGY:

StreetLab Mobile uses Raman spectroscopy for chemical and biological analysis. For chemical identification the laser illuminates the chemical, inelastically scattered photons interact with molecular bonds contained in the substance to provide a unique fingerprint spectrum; this is a function of molecular geometry and environment of a chemical sample. Results are clear, repeatable and completed in one step. For biological identification, StreetLab Mobile is used as a reader for a sandwich assay containing antibody-modified magnetic beads to capture and concentrate target analytes in solution and surface-enhanced Raman spectroscopy (SERS) tags conjugated with these same antibodies for specific detection.

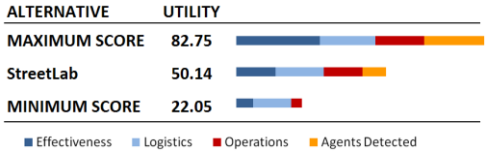
ANALYTICAL Laboratory Ranking

StreetLab Mobile ranked in the middle third of all evaluated products for analytical laboratories and earned 56% of the utility points of the best score.



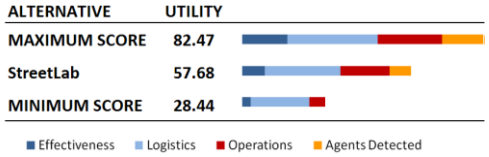
DIAGNOSTIC Laboratory Ranking

StreetLab Mobile ranked in the middle third of all evaluated products for diagnostic laboratories and earned 61% of the utility points of the best score.



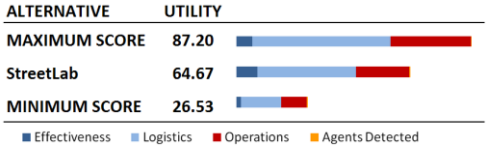
MOBILE Laboratory Ranking

StreetLab Mobile ranked in the middle third of all evaluated products for mobile laboratories and earned 70% of the utility points of the best score.



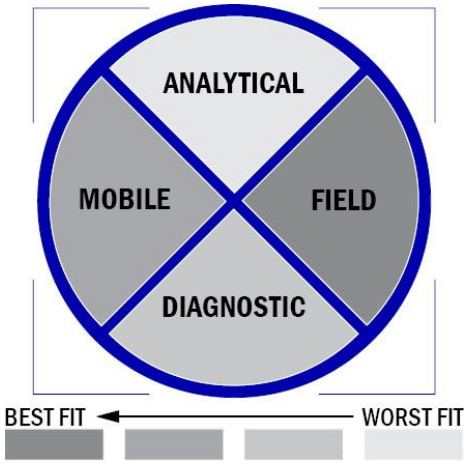
FIELD USE Ranking

StreetLab Mobile ranked in the middle third of all evaluated products for field use and earned 74% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Morpho Detection
205 Lowell Street
Wilmington, MA 01887

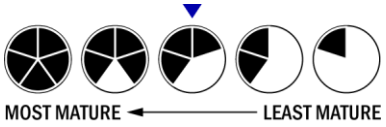
Point of Contact:
800 433 5346

COST

- $45,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15 - 30 minutes for detection
- 1 sample, <10 tests/ sample per run
- Could be adapted to semi-automated with some effort

Signature:
- Sounds or alarms present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- >5 minutes set-up
- Almost instantaneous down time
- 3-5 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components must be stored at room temperature (27°C)
- Performance is not influenced by relative humidity
- 1 to 6 months shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service not required
- Preventive maintenance not applicable
- Maintenance included
- Expected life 3-5 years
- No daily QA
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- Single shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance shown
- Less than 10 ul to test liquids

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 250 GB raw data generated
- Not network capable
- Wireless, wired connections
- Could be fully autonomous with some effort
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software open but modification requires licensing
- Hardware open and available for modification

T2Dx

by T2 Biosystems

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)
Liquid chemical (<1ppb)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Urine, Environmental water, Soil, Food, Powder

DESCRIPTION:

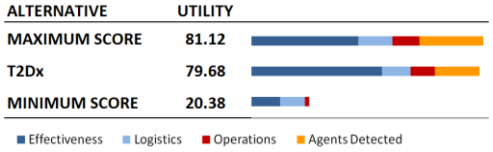
T2's revolutionary new technology is based on clinically-proven magnetic resonance MR technology, and uses nanoparticles coupled with reagents to quickly detect—within minutes—the presence of specific substances in solution using a miniaturized, portable MRI instrument. Detection of the high level magnetic resonance signal from the solution enables the detection of low concentrations of target agents or substances. Unlike most existing diagnostic detection techniques which are based on optical detection methods that require pure samples and multiple processing steps, T2's technology is not optical and therefore does not require purification of biological samples. This significant advantage allows the T2 system to perform single-step processing and rapid turnaround times without the need for trained technicians. Furthermore, the technology can accurately identify almost any specimen, including proteins, nucleic acids, or enzymes; bacterial, cancer or other cells; viruses; or small molecule drug compounds within almost any sample, including whole blood, plasma, serum and urine. T2's system is faster, more reliable, more portable and more readily accessible than any diagnostic testing system now on the market.

TECHNOLOGY:

Compact, rugged, non-optical detection of immunoassay and nucleic acid assay targets, directly in unprocessed samples.

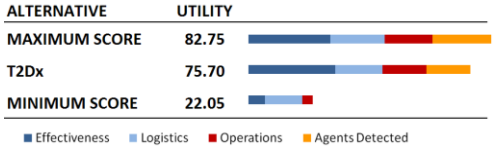
ANALYTICAL Laboratory Ranking

T2Dx ranked in the top third of all evaluated products for analytical laboratories and earned 98% of the utility points of the best score.



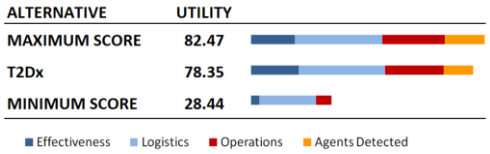
DIAGNOSTIC Laboratory Ranking

T2Dx ranked in the top third of all evaluated products for diagnostic laboratories and earned 91% of the utility points of the best score.



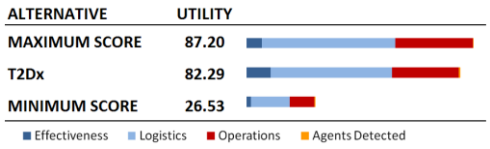
MOBILE Laboratory Ranking

T2Dx ranked in the top third of all evaluated products for mobile laboratories and earned 95% of the utility points of the best score.



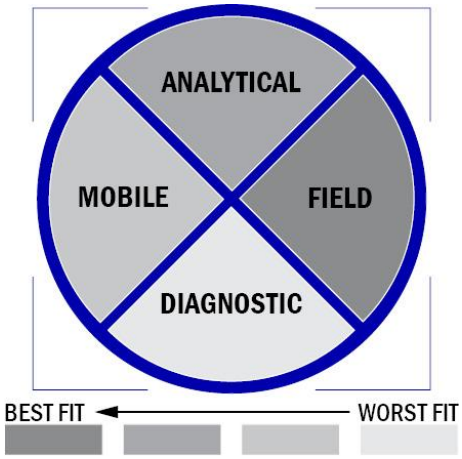
FIELD USE Ranking

T2Dx ranked in the top third of all evaluated products for field use and earned 94% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

T2 Biosystems
101 Hartwell Avenue
Lexington, MA 02421

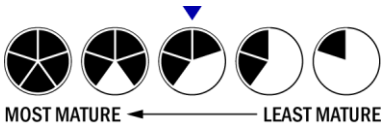
Point of Contact:
Rahul Dhanda
781-457-1225

COST

- $5,000.00-50,000.00/system or device depending on configuration
- <$5.00/analysis

SPECIFICITY

- False Positives: <1%
- False Negatives: <1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- Greater than 20 minutes set up
- < 1 minute down time
- 0-2 steps are required
- Customer and manufacturer site training

Operational conditions:
- Can be used from < -21°C to > 42°C (All temperatures)
- Components should be stored at room temp but can withstand temperatures >45°C for < 24 hours
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All means of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 4 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 1-3 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- 4-8 hours battery use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results not available
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 10 ul for a test

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Satellite, wireless and wired connections
- Autonomous system with some effort
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open but modification requires licensing
- The system hardware is open but modification requires licensing

TacBio

by Research International, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Viruses (10e3-10e4 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Environmental air, Environmental water, Soil, Food, Powder, Insect vectors

DESCRIPTION:

No information available.

TECHNOLOGY:

No information available.

ANALYTICAL Laboratory Ranking

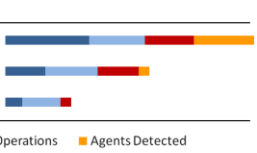
TacBio ranked in the middle third of all evaluated products for analytical laboratories and earned 60% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
TacBio	49.05
MINIMUM SCORE	20.38

DIAGNOSTIC Laboratory Ranking

TacBio ranked in the middle third of all evaluated products for diagnostic laboratories and earned 58% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
TacBio	48.03
MINIMUM SCORE	22.05



MOBILE Laboratory Ranking

TacBio ranked in the top third of all evaluated products for mobile laboratories and earned 73% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
TacBio	59.82
MINIMUM SCORE	28.44

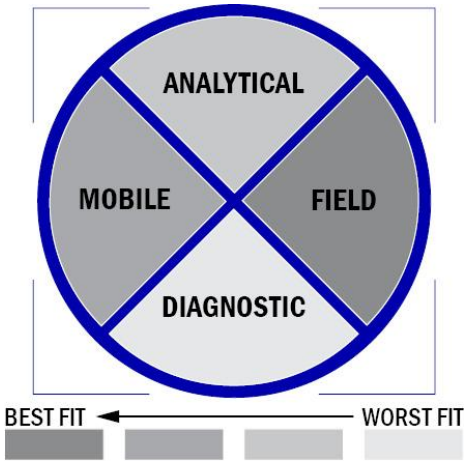
FIELD USE Ranking

TacBio ranked in the top third of all evaluated products for field use and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
TacBio	73.08
MINIMUM SCORE	26.53

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Idaho Technology, Inc.
390 Wakara Way
Salt Lake City, UT 84108

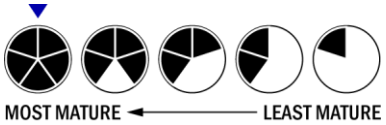
Point of Contact:
Lou Banks

COST

- $38,500.00/system or device
- $200.00/analysis

SPECIFICITY

- False Positives: Not Available
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 30-60 minutes for detection
- 1 sample, >10 tests/ sample per run
- Currently semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- < 5 minutes set up
- Almost instantaneous down time
- 3-5 steps are required
- DVD/ Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp
- Performance is not influenced by relative humidity
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of a toaster
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- No service required
- Preventive maintenance serviceable by customer
- Maintenance is included
- Expected life 5-10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- Batteries
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can not be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 100 ul for a test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Autonomous system with some effort
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

TAC-BIO / I-Collector

by General Dynamics Armament and Technical Products

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria
Viruses
Toxins

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

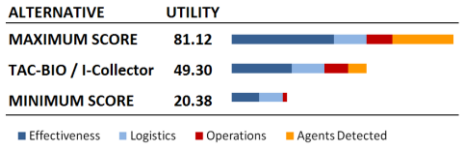
The Tactical Biological Detector (TAC-BIO) is a low-cost, low-power, lightweight sensor that utilizes semiconductor ultraviolet light emitting diodes for reagentless detection of biological aerosols. TAC-BIO continuously samples the air searching for the presence of biological warfare agents and provides a warning upon automatic detection of an event. It provides broad biological threat detection in a small size. When packaged with a dry collector and sensor management electronics, it is called an Intelligent Collector (I-Collector) and can be used as a stand-alone detection node or as a trigger in combination with networked sensing components. It has been included as a sensing component within GDATP's ATHINA Biological Security System (ABSS). The I Collector node is 1 cu-ft. and 27 pounds and has undergone significant testing with simulants, agents, and background interferents. TAC-BIO was developed by the U.S. Army Edgewood Chemical Biological Center (ECBC) to achieve a revolutionary new bio-detection device that maintained a credible core detection capability at a significantly reduced cost, size, weight and power compared to existing capabilities. The detector has been licensed to GDATP for production, and ECBC and GDATP are collaboratively developing enhanced detector capabilities through a Cooperative Research and Development Agreement (CRADA). Improvements in detection performance and product development have yielded increased sensitivity, improved small particle detection, and advanced algorithms while reducing the power requirements and creating a producible baseline design for cost, usability, and maintenance goals.

TECHNOLOGY:

TAC-BIO utilizes semiconductor ultraviolet light emitting diodes for reagentless detection of biological aerosols. In order to improve sensitivity and small particle detection, GDATP has added an aerosol concentrator, improved UV LED performance, and developed advanced algorithms. Improved designs for the electronics, optical path, and mechanical packaging have reduced the size, weight and power of the system. Improved detection algorithms on the TAC-BIO also reduce the number of false alarms and provide higher confidence in the sample collected. When used as an I-Collector/trigger, it minimizes the life cycle costs associated with consumables that are required for identification operations.

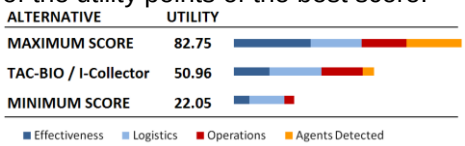
ANALYTICAL Laboratory Ranking

TAC-BIO / I-Collector ranked in the middle third of all evaluated products for analytical laboratories and earned 60% of the utility points of the best score.



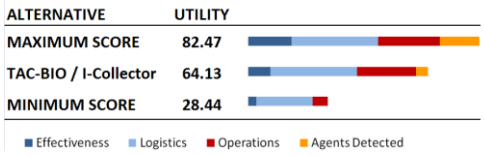
DIAGNOSTIC Laboratory Ranking

TAC-BIO / I-Collector ranked in the middle third of all evaluated products for diagnostic laboratories and earned 58% of the utility points of the best score.



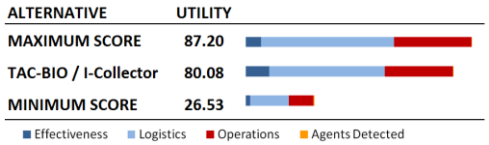
MOBILE Laboratory Ranking

TAC-BIO / I-Collector ranked in the top third of all evaluated products for mobile laboratories and earned 73% of the utility points of the best score.



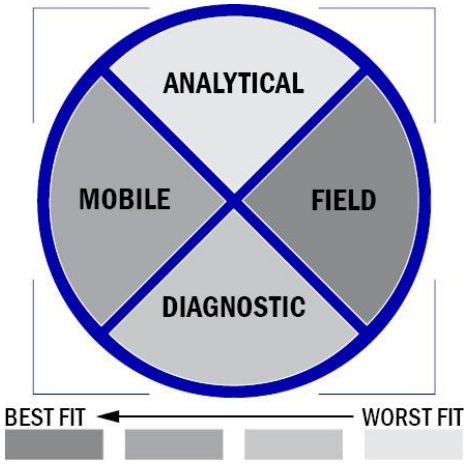
FIELD USE Ranking

TAC-BIO / I-Collector ranked in the top third of all evaluated products for field use and earned 84% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

General Dynamics Armament and Technical Products
4205 Westinghouse Commons Drive
Charlotte, NC 28273

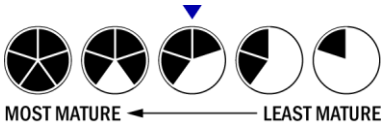
Point of Contact:
Doug Woody
980.235.2402
dwoody@gdatp.com

COST

- Information not available

SPECIFICITY

- False Positives: 2%
- False Negatives: 5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- <5 minutes set-up
- Almost instantaneous down time
- 0-2 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from -21°C to 41°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life not applicable
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless, wired connections
- Fully autonomous
- On board computer chip
- Stores and archives data outputs but does not create an electronic record
- System software open but modification requires licensing
- System hardware open and available for modification

T-COR 4 Handheld Real-Time PCR Thermocycler

by Tetracore, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Environmental air, Environmental water, Powder

DESCRIPTION:

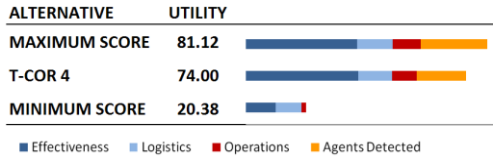
Tetracore's T-COR 4 Handheld Real-Time PCR Thermocycler can process four independent samples and is capable of analyzing two targets per sample. The T-COR 4 has a footprint of 9" x 7.5" x 3", weighs 6 pounds, and runs continuously off battery power for 8 hours. The system is capable of running both standard TaqMan® real-time PCR and Isothermal real-time fluorescence based amplification. Isothermal real-time fluorescence based amplification allows for confirmatory analysis in 10 minutes. The user can choose to run the device in either stand alone mode or connected to a PC. Intuitive software allows the user to set up, run, and analyze an experiment. Easy to learn and simple to use, the T-COR 4 is designed for use by both first responders in the field and biologists in the laboratory. We have demonstrated the identification of agents in powder samples, agents in environmental samples, bacteria, and viruses. Tetracore produces 18 dry real-time PCR and 4 dry Isothermal Assays for the T-COR 4. Dry assays developed for the system are subject to accelerated stability testing at 55 degrees Celsius and 45 degrees Celsius, and to real-time stability testing at room temperature. We have data supporting a shelf life of more than 18 months at room temperature. The T-COR 4 is an open system capable of running any customer's assay, in either a wet or dry formulation. A handheld, battery powered centrifuge is included with the system.

TECHNOLOGY:

A handheld, battery powered, peltier-based thermocycler designed for use with TaqMan® real-time PCR amplification and Isothermal real-time fluorescence based amplification. Isothermal real-time fluorescence based amplification allows for confirmatory analysis in 10 minutes. Tetracore has designed a proprietary, modular optical system such that the instrument can be modified to suit future end users requirements. The developed optical technology enables Tetracore to support the fields of biotechnology, such as nucleic acid detection, polypeptide detection, and environmental sensing.

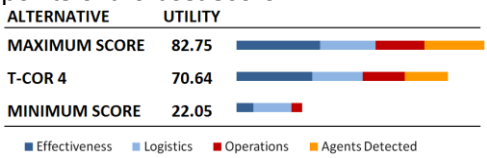
ANALYTICAL Laboratory Ranking

T-COR 4 ranked in the top third of all evaluated products for analytical laboratories and earned 91% of the utility points of the best score.



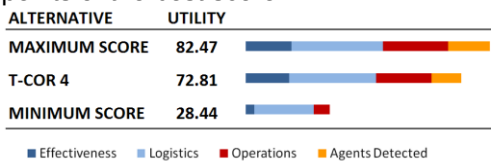
DIAGNOSTIC Laboratory Ranking

T-COR 4 ranked in the top third of all evaluated products for diagnostic laboratories and earned 85% of the utility points of the best score.



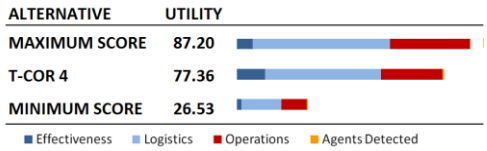
MOBILE Laboratory Ranking

T-COR 4 ranked in the top third of all evaluated products for mobile laboratories and earned 88% of the utility points of the best score.



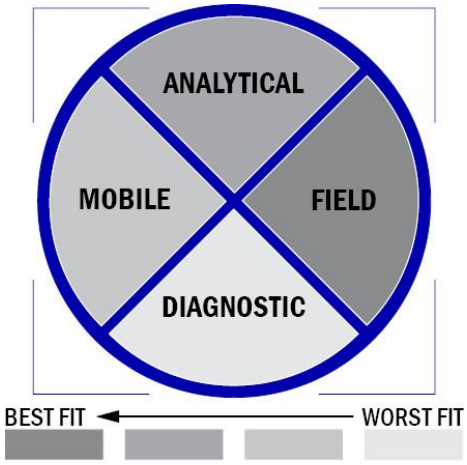
FIELD USE Ranking

T-COR 4 ranked in the top third of all evaluated products for field use and earned 89% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Tetracore, Inc.
9901 Belward Campus Drive
Suite 300
Rockville, MD, 20850

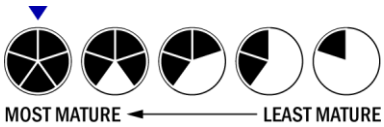
Point of Contacts:
William M. Nelson, M.D.
David Almassian

COST

- $16,000.00/system or device

SPECIFICITY

- False Positives: 1%
- False Negatives: FNR cannot be reported as a single number because it is sample type, sample prep, assay, and concentration specific.



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- Multiple samples, multiple tests/samples per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 3-5 steps required
- DVD/ Web video/ Customer and manufacturer site training/ Hard copy and web manual

Operational conditions:
- Can be used from 4°C - 41°C
- Components should be stored at room temp but can stand temps > 45°C for <24 hours
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service less than once a year
- Preventive maintenance not applicable
- Maintenance included
- Expected life 3-5 years
- No daily QA required
- Hazardous agent isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 4-8 hours battery life
- Requires water aliquots
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- Single centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering step
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 10 ul required for test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless and wired connections
- Not autonomous
- On board computer chip
- Stores and archives data outputs and creates electronic records
- System software is closed and not available for modification
- System hardware is closed and not available for modification

TechniCART

by Pajarito Scientific Corporation

DETECTS THE FOLLOWING:

Demonstrated:
Identification of specific isotopes

DETECTION MATRICES:

Nothing demonstrated.

DESCRIPTION:

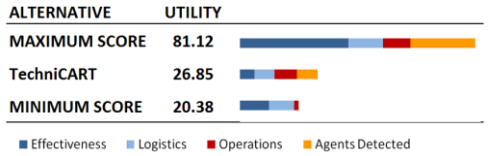
The TechniCART™ has been engineered to allow rapid and easy transportation of an entire portable non destructive assay (NDA) system, e.g. a High Purity Germanium (HPGe) detector, shield and collimator together with laptop and acquisition electronics. The flat-free large caster wheels permit movement through grass, dirt and gravel type terrain. The TechniCART™ also allows the detector to be positioned at different angles, from vertically downward to vertically upward. The design of the system results in a multi-use platform that is mobile, adaptable, rugged and ergonomically efficient. The TechniCART™ has a light-weight aluminum frame that accommodates 200 lbs of equipment. An extension arm can be supplied that allows a vertical reach of 96 inches. An outrigger arm provides additional stability for extended heights.

TECHNOLOGY:

One of the uses of the TechniCART™ is to allow first responders to rapidly deploy a non-destructive assay system at a selected location to identify and quantify radioactive material. The flat-free large caster wheels permit movement through grass, dirt and gravel type terrain. The TechniCART™ also allows the detector to be positioned at different angles, from vertically downward to vertically upward. The design of the system results in a multi-use platform that is mobile, adaptable, rugged and ergonomically efficient. The TechniCART™ has a light-weight aluminum frame that accommodates 200 lbs of equipment. An extension arm can be supplied that allows a vertical reach of 96 inches. An outrigger arm provides additional stability for extended heights.

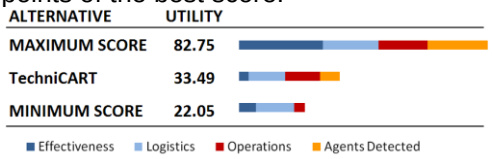
ANALYTICAL Laboratory Ranking

TechniCART ranked in the bottom third of all evaluated products for analytical laboratories and earned 33% of the utility points of the best score.



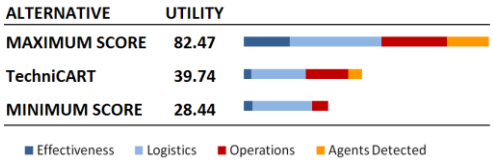
DIAGNOSTIC Laboratory Ranking

TechniCART ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 40% of the utility points of the best score.



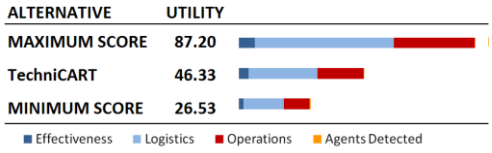
MOBILE Laboratory Ranking

TechniCART ranked in the bottom third of all evaluated products for mobile laboratories and earned 48% of the utility points of the best score.



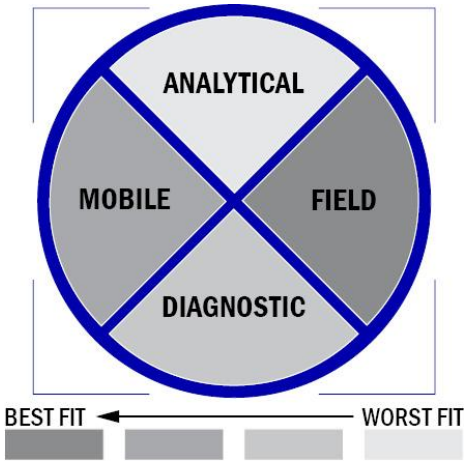
FIELD USE Ranking

TechniCART ranked in the bottom third of all evaluated products for field use and earned 53% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

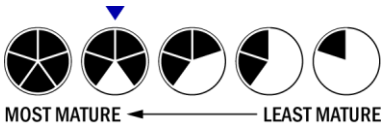
Pajarito Scientific Corporation
2532 Camino Entrada
Santa Fe, NM 87507 USA
Email: info@PajaritoScientific.com
Phone: +1.505.424.6660

COST

- $15,000.00 - 100,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15 - 30 minutes for detection
- 1 sample, single test/ sample per run
- Automation information not available

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- >20 minutes set-up
- 1-3 minutes down time
- 3-5 steps required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Temperature range information not available
- Does not require consumables
- Performance is not influenced by relative humidity
- Shelf life not applicable

Transportation:
- Larger than home dishwasher
- All modes of transportation
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life >10 years
- 5-10 minutes daily QA
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- 4-8 hours battery life
- Does not require water
- Germanium detector requires liquid nitrogen
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Greater than 250 ul to test liquids

System Maturity:
- Is commercially available
- Appearance in peer reviewed publication or independent evaluation information not available
- Technology ownership and intellectual property owned

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Wireless, wired connections
- Could easily be a fully autonomous system
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- Software closed and not available for modification
- Hardware closed and not available for modification

TessArray® RPM-Flu Respiratory Pathogen Assay

by TessArae, LLC

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Environmental air, Soil

DESCRIPTION:

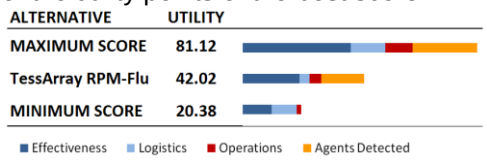
The TessArray® RPM-Flu assay simultaneously detects and definitively identifies more than 35 distinct classes of respiratory agents, both viral and bacterial, in a single assay in less than 24 hours. The assay generates agent-specific genomic sequence information as the output, and can easily discriminate between known, unknown, emerging, and deliberately altered pathogens to the subtype and/or strain level. The assay is designed for use by centralized testing laboratories to detect respiratory agents in throat swabs, nasal washes, bronchoalveolar lavages, and other clinical matrices.

TECHNOLOGY:

The TessArray RPM-Flu assay is based on resequencing microarray technology that runs on an Affymetrix® GeneChip® 3000 System. Genomic material (both RNA and DNA) extracted from the sample is amplified using locus-specific primers in highly multiplexed reactions (30-40 primer pairs/reaction) using a relaxed amplification strategy to maximize assay sensitivity. Amplified material is hybridized to the resequencing microarray under stringent conditions to maximize assay specificity. The TessArae Gene Cipher algorithm analyzes the resulting sequence data to detect and identify the agents present in the sample. RPM-Flu is the only assay that simultaneously maximizes both sensitivity and specificity.

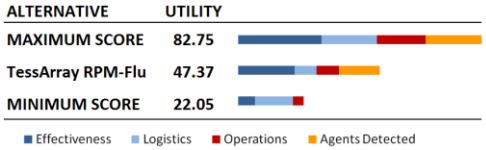
ANALYTICAL Laboratory Ranking

TessArray RPM-Flu ranked in the bottom third of all evaluated products for analytical laboratories and earned 52% of the utility points of the best score.



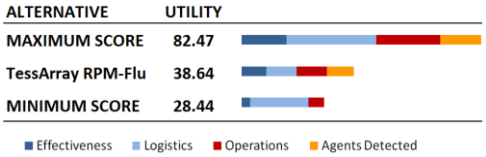
DIAGNOSTIC Laboratory Ranking

TessArray RPM-Flu ranked in the middle third of all evaluated products for diagnostic laboratories and earned 57% of the utility points of the best score.



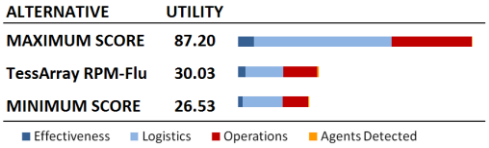
MOBILE Laboratory Ranking

TessArray RPM-Flu ranked in the bottom third of all evaluated products for mobile laboratories and earned 47% of the utility points of the best score.



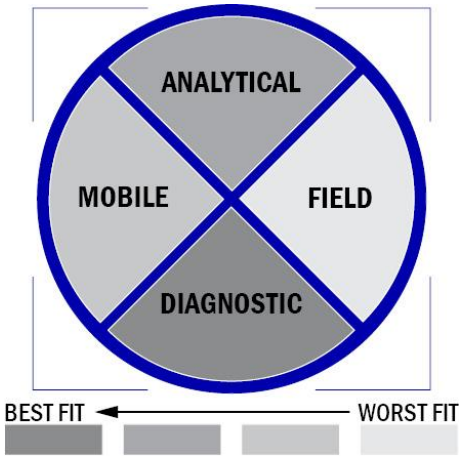
FIELD USE Ranking

TessArray RPM-Flu ranked in the bottom third of all evaluated products for field use and earned 34% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

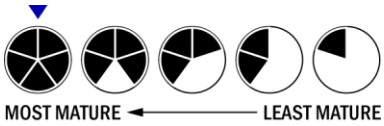
TessArae LLC
46090 Lake Center Plaza Suite 304
Potomac Falls, VA 20165
703-444-7188
info@tessarae.com

COST

- $219,000.00/system or device
- $300.00/analysis

SPECIFICITY

- False Positives: 0%
- False Negatives: <5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- Greater than 8 hours for detection
- Multiple samples, single tests/ sample per run
- Adapt to semi-automation with some effort

Signature:
- No sounds or alarms
- No screen present

Training and Speed:
- A day of training and technical skills are required
- 10-20 minutes set up
- Less than 5 minute down time
- Greater than 12 steps required
- Customer and manufacturer site training/ Hard-copy and Web manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at 4°C/ Components must be frozen
- Performance is not influenced by relative humidity
- 6 months - 1 year shelf life

Transportation:
- Larger than a dishwasher
- Commercial carrier
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician
- Maintenance is included
- Expected life 5-10 years
- No QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Water aliquots required
- External air or gas source not required
- External vacuum is required

Ease of Use:
- Real-time results not available
- Multiple centrifugation steps required
- Multiple shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance pending
- FDA approval shown
- Less than 50 ul for a test

System Maturity:
- Is commercially available and meets milspecs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Not network capable
- Wireless and wired connections
- Not capable of autonomy
- Basic desktop computer
- Automatically stores and archives data and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

TessArray® RPM-TEI Tropical and Emerging Infections Assay

by TessArae, LLC

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Environmental air, Soil

DESCRIPTION:

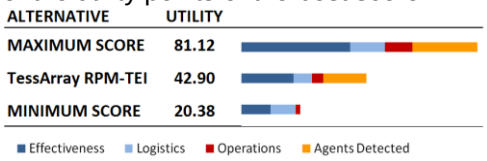
The TessArray® RPM-TEI (Tropical and Emerging Infections) assay simultaneously detects and definitively identifies more than 40 distinct classes of Category A, B, C and zoonotic biothreat agents, both viral and bacterial, as well as seven bacterial toxin genes, in a single assay in less than 24 hours. The assay generates agent-specific genomic sequence information as the output, and can easily discriminate between known, unknown, emerging, and deliberately altered pathogens to the subtype and/or strain level. The assay is designed for use by centralized testing laboratories to detect biothreat agents in clinical and environmental matrices, including whole blood, throat swabs, surfaces, air, and dirt.

TECHNOLOGY:

The TessArray RPM-TEI assay is based on resequencing microarray technology that runs on an Affymetrix® GeneChip® 3000 System. Genomic material (both RNA and DNA) extracted from the sample is amplified using locus-specific primers in highly multiplexed reactions (30-40 primer pairs/reaction) using a relaxed amplification strategy to maximize assay sensitivity. Amplified material is hybridized to the resequencing microarray under stringent conditions to maximize assay specificity. The TessArae Gene Cipher algorithm analyzes the resulting sequence data to detect and identify the agents present in the sample. RPM-TEI is the only assay that simultaneously maximizes both sensitivity and specificity.

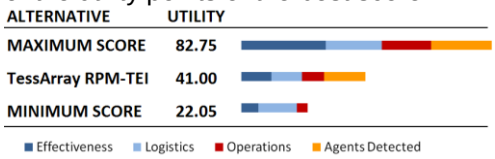
ANALYTICAL Laboratory Ranking

TessArray RPM-TEI ranked in the middle third of all evaluated products for analytical laboratories and earned 53% of the utility points of the best score.



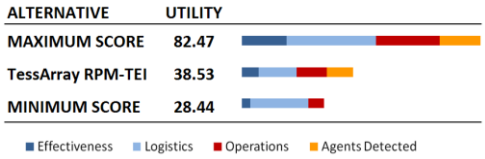
DIAGNOSTIC Laboratory Ranking

TessArray RPM-TEI ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 50% of the utility points of the best score.



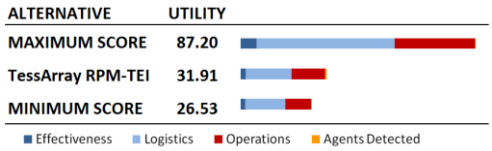
MOBILE Laboratory Ranking

TessArray RPM-TEI ranked in the bottom third of all evaluated products for mobile laboratories and earned 47% of the utility points of the best score.



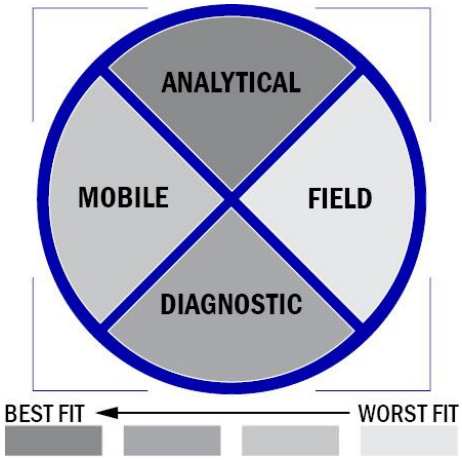
FIELD USE Ranking

TessArray RPM-TEI ranked in the bottom third of all evaluated products for field use and earned 37% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

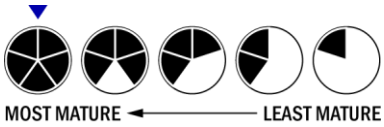
TessArae LLC
46090 Lake Center Plaza Suite 304
Potomac Falls, VA 20165
703-444-7188
info@tessarae.com

COST

- $219,000.00/system or device
- $300.00/analysis

SPECIFICITY

- False Positives: 0%
- False Negatives: <5%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- Greater than 8 hours for detection
- Multiple samples, single tests/ sample per run
- Adapt to semi-automation with some effort

Signature:
- No sounds or alarms
- No screen present

Training and Speed:
- A day of training and technical skills are required
- Less than 5 minutes set up
- Less than 1 minute down time
- Greater than 12 steps required
- Customer and manufacturer site training/ Hard-copy and Web manual

Operational conditions:
- Can be used from 25°C to 37°C
- Components must be stored at 4°C/ Components must be frozen
- Performance is not influenced by relative humidity
- 6 months - 1 year shelf life

Transportation:
- Larger than a dishwasher
- Commercial carrier
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician
- Maintenance is included
- Expected life 5-10 years
- No QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Water aliquots required
- External air or gas source not required
- External vacuum is required

Ease of Use:
- Real-time not available
- Multiple centrifugation steps required
- Multiple shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance incapable
- FDA approval incapable
- Less than 50 ul for a test

System Maturity:
- Is commercially available and meets milspecs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Not network capable
- Wireless and wired connections
- Not capable of autonomy
- Basic desktop computer
- Automatically stores and archives data but not create an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

ThreatShield-C®

by Hamilton Sundstrand Corp.

DETECTS THE FOLLOWING:

Demonstrated:
Aerosolized chemical agent (0.001-0.1 mg/mg3)

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

The ThreatShield-C™ is an automated chemical vapor detector designed to detect toxic industrial chemicals (TICs) and chemical warfare agents (CWAs) in fixed-site applications. Multiple ThreatShield-C™ detectors provide an integrated chemical warning system. The simple mounting characteristics, continuous operation, low maintenance requirements, and broad detection capabilities make the ThreatShield-C™ ideal for the protection of buildings, public venues and critical transportation hubs from chemical attack. High sensitivity and a low false alarm rate provide reliable Detect-to-Warn capability.

TECHNOLOGY:

The ThreatShield-C™ detects toxic vapors by sampling ambient air through a proprietary inlet system. This inlet system selectively transfers TICs and CWAs into an analyte gas flow that sweeps target vapors through an ionization region and into the Differential Mobility Spectrometer-Ion Mobility Spectrometer (DMS-IMS2) sensor. The DMS acts as a pre-filter for subsequent IMS analysis, greatly reducing chemical background noise and the associated false alarm responses. Two IMS drift tubes allow the simultaneous detection of both positive and negative ions, broadening the types of compounds detected and decreasing the time for alarm response.

ANALYTICAL Laboratory Ranking

ThreatShield-C® ranked in the bottom third of all evaluated products for analytical laboratories and earned 50% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
ThreatShield-C	40.58
MINIMUM SCORE	20.38

DIAGNOSTIC Laboratory Ranking

ThreatShield-C® ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 48% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
ThreatShield-C	39.92
MINIMUM SCORE	22.05

MOBILE Laboratory Ranking

ThreatShield-C® ranked in the bottom third of all evaluated products for mobile laboratories and earned 53% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
ThreatShield-C	43.69
MINIMUM SCORE	28.44

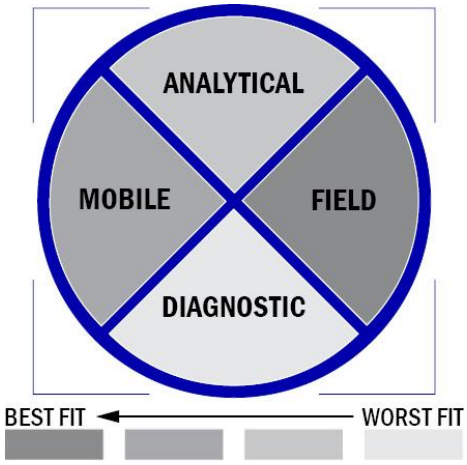
FIELD USE Ranking

ThreatShield-C® ranked in the bottom third of all evaluated products for field use and earned 59% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
ThreatShield-C	51.38
MINIMUM SCORE	26.53

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Hamilton Sundstrand Corp.
2771 N. Garey Ave.
Pomona, CA

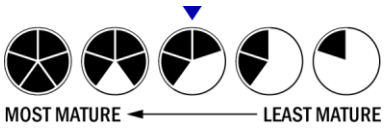
Point of Contact:
Dr. Andrew Szumlas
(909) 593-3581 Ext. 4787

COST

- Not Available

SPECIFICITY

- False Positives: Not Applicable
- False Negatives: Not Applicable



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Currently fully automated

Signature:
- Sounds or alarms not present
- No screen present
- Between 200-500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- Greater than 20 minutes set up
- Almost instantaneous down time
- 0-2 steps are required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- No consumable required
- Performance is not influenced by relative humidity
- No consumables required

Transportation:
- Approximately the size of a carry-on luggage suitcase
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 5-10 years
- No QA required
- Exposure to hazardous agent would require up to 1 day to decontaminate

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- System does not test liquids

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property licensing is pending

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Autonomous system
- Basic desktop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

TIRF FluoroGazer analytical grade TIRF-EC

by TIRF Technologies

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)
Toxins (less than 1 ng/mL)
Liquid chemical (1ppb-1ppm)

DETECTION MATRICES:

Demonstrated:
Blood

DESCRIPTION:

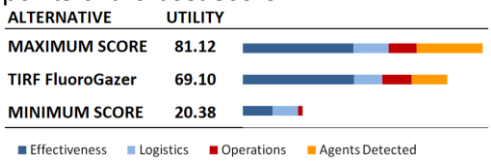
FluoroGazer is a multipurpose, supersensitive, highly multiplexed chem-bio sensor designed for use in analytical laboratory. FluoroGazer is capable of simultaneous detecting thousands of nucleic acid and protein markers, toxins, metabolites, as well as chemical agents in liquid and gaseous phase. Limit of detection is at the level of single molecules, rate of response –several seconds to a few minutes. FluoroGazer requires minimum or no sample preparation and is capable of detecting nucleic acid and protein markers in such complex biological fluids as whole blood. In conjunction with reagentless bioassays that contain DNA and antibody-based molecular recognition moieties equipped with embedded luminescence reporters, FluoroGazer is well-suited for clinical diagnostics, food & water safety, forensic, biodefense, and agricultural applications. In contrast to traditional DNA and protein microarrays that detect only end-point results, FluoroGazer TIRF-EC microarrays monitor the entire course of association and dissociation kinetics and its dependency on electrochemical polarization, which allows for rapidly discriminating between single nucleotide mismatches and distinguishing close homologs of proteins.

TECHNOLOGY:

FluoroGazer employs Total Internal Reflection Fluorescence (TIRF) combined with ElectroChemistry and Electric field Control (TIRF-EC). FluoroGazer supports evanescent wave fluorescence assays, Electro-Chemi-Luminescence (ECL), other luminescence assays, as well as assays immobilized in a submicron hydrogel layer deposited at the TIRF-EC surface. Depending on the application, TIRF-EC microarray contains from a few spots of assays in a single flow channel to thousands of chem-bio assays in four separate flow channels. TIRF-EC microarrays include internal positive and negative controls and standards for normalization and calibration, which provides high reliability and broad dynamic range to analyses. TIRF-EC sensor chips with microarrays are incorporated into reusable or disposable cartridges that can be equipped with user-defined sample preparation modules.

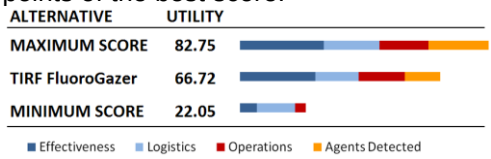
ANALYTICAL Laboratory Ranking

TIRF FluoroGazer in the top third of all evaluated products for analytical laboratories and earned 85% of the utility points of the best score.



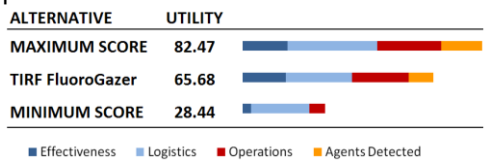
DIAGNOSTIC Laboratory Ranking

TIRF FluoroGazer ranked in the top third of all evaluated products for diagnostic laboratories and earned 81% of the utility points of the best score.



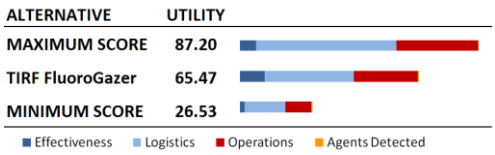
MOBILE Laboratory Ranking

TIRF FluoroGazer ranked in the top third of all evaluated products for mobile laboratories and earned 80% of the utility points of the best score.



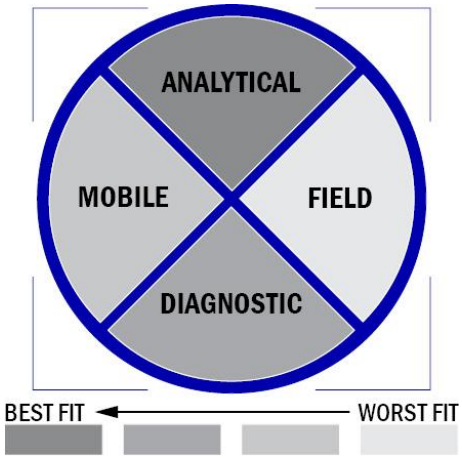
FIELD USE Ranking

TIRF FluoroGazer ranked in the middle third of all evaluated products for field use and earned 75% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

TIRF Technologies
951 Aviation Parkway, Suite 700
Morrisville, NC 27560
T: 919-463-9545.
F: 919-463-9574.
I: www.TIRFtechnologies.com.

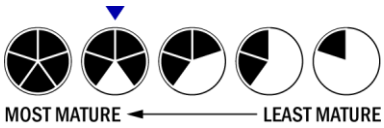
Point of Contact:
Alex Asanov, CEO
asn@tirftechnologies.com

COST

- $120,000.00/system or device
- $8.00-400.00/analysis based on user defined application

SPECIFICITY

- False Positives: 0.000001%
- False Negatives: 0.00001%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- 1 sample, >10 tests/ sample per run
- Easily adapted to automation

Signature:
- Sounds or alarms not present
- Screen can be dimmed
- Between 200-500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- Less than 5 minutes set up
- 1-3 minutes down time
- 0-2 steps are required
- DVD/ Customer and manufacturer site training/ Hard copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components stored at room temp can withstand >45°C for < 24 hours/ Components stored frozen can with stand >4°C for <24 hours
- Peak performance at normal relative humidity conditions
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Commercial carrier
- Weighs between 5 and 25kg

Re-use:
- Multiple detection assays
- 2 or more solutions
- 2 components

Maintenance:
- Service once a year
- Preventive maintenance is serviceable by customer
- Maintenance is included
- Expected life 5-10 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1hr

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Requires water aliquots
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be analyzed during a run
- No centrifugation steps
- No shaking or vortexing or filtering steps required
- Software could call final result in future

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 50 ul for a test

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired
- System fully autonomous with some effort
- Onboard computer chip
- Store and archive data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

TIRF Sense handheld sensor TIRF-EC

by TIRF Technologies

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Demonstrated:
Blood

DESCRIPTION:

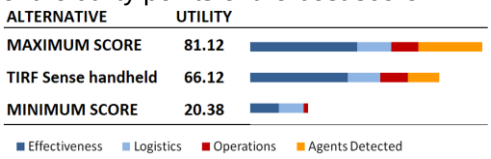
Handheld TIRF-EC sensor is designed for use in the field and is capable of simultaneous detecting up to a hundred of nucleic acid and protein markers, toxins, metabolites, as well as chemical agents in liquid and gaseous phase. The sensor is sensitive device with rate of response from several seconds to a few minutes. TIRF-EC sensor requires minimum or no sample preparation and is capable of detecting nucleic acid and protein markers in such complex biological fluids as whole blood. In conjunction with bioassays based on DNA and antibodies equipped with embedded luminescence reporters, the sensor is well-suited for first responder applications, point-of-care diagnostics, food & water safety, forensic, biodefense, and agricultural applications. In contrast to traditional DNA and protein microarrays that detect only end-point results, the TIRF-EC sensor monitors the kinetics of association and dissociation of biological and chemical analytes and the dependency of kinetics on electrochemical polarization, which allows for rapidly discriminating between single nucleotide mismatches and distinguishing close homologs of proteins.

TECHNOLOGY:

Handheld TIRF-EC sensor employs Total Internal Reflection Fluorescence (TIRF) combined with ElectroChemistry (TIRF-EC). The sensor supports evanescent wave fluorescence assays, Electro-Chemi-Luminescence (ECL), other luminescence assays, as well as assays immobilized in a submicron hydrogel layer deposited at the TIRF-EC surface. Depending on the application, TIRF-EC microarray contains from a few spots of assays in a single flow channel to hundreds of chem-bio assays in four separate flow channels. TIRF-EC microarrays include internal positive and negative controls and standards for normalization and calibration, which provides high reliability and broad dynamic range to analyses. TIRF-EC sensor chips with printed microarrays are incorporated into reusable or disposable cartridges that can be equipped with user-defined sample preparation modules.

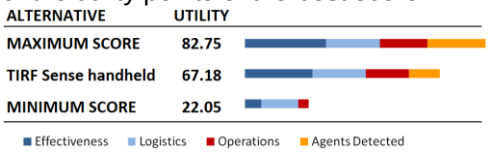
ANALYTICAL Laboratory Ranking

TIRF Sense handheld ranked in the top third of all evaluated products for analytical laboratories and earned 92% of the utility points of the best score.



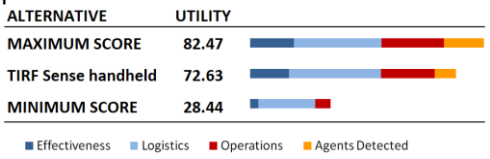
DIAGNOSTIC Laboratory Ranking

TIRF Sense handheld ranked in the top third of all evaluated products for diagnostic laboratories and earned 88% of the utility points of the best score.



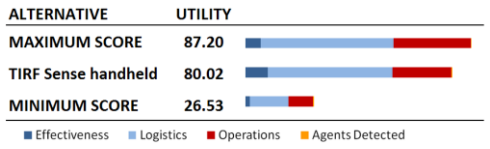
MOBILE Laboratory Ranking

TIRF Sense handheld ranked in the top third of all evaluated products for mobile laboratories and earned 81% of the utility points of the best score.



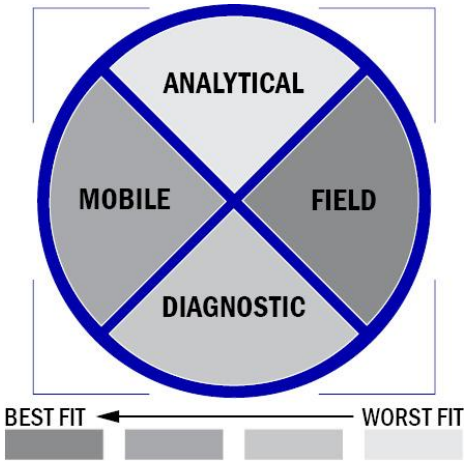
FIELD USE Ranking

TIRF Sense handheld ranked in the top third of all evaluated products for field use and earned 82% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

TIRF Technologies
951 Aviation Parkway, Suite 700
Morrisville, NC 27560
T: 919-463-9545.
F: 919-463-9574.
I: www.TIRFtechnologies.com.

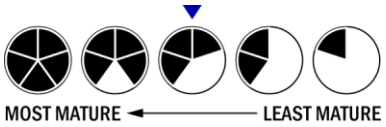
Point of Contact:
Alex Asanov, CEO
asn@tirftechnologies.com

COST

- $24,000.00/system or device
- $8.00-100.00/analysis, depending on the type of microarray and specific assays

SPECIFICITY

- False Positives: 0.000001%
- False Negatives: 0.00001%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- 1 sample, >10 tests/ sample per run
- Adapted to automation with some effort

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- Less than 5 minutes set up
- 1-3 minutes down time
- 0-2 steps are required
- Customer and manufacturer site training

Operational conditions:
- Can be used from 4°C to 41°C
- Components stored at room temp can withstand >45°C for < 24 hours/ Components stored frozen can with stand >4°C for <24 hours
- Peak performance at normal relative humidity conditions
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a soda can
- All means of transportation
- Weighs less than 1kg

Re-use:
- Multiple detection assays
- 2 or more solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service every 6 months
- Preventive maintenance is serviceable by customer
- Maintenance is included
- Expected life 3-5 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1hr

Physical System Requirements:
- Batteries
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be analyzed during a run
- No centrifugation steps
- No shaking or vortexing or filtering steps required
- Software could call final result in future

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 50 ul for a test

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- System fully autonomous with some effort
- Onboard computer chip
- Store and archive data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

TIRF Sense portable sensor TIRF-EC

by TIRF Technologies

DETECTS THE FOLLOWING:

Capable:
Bacteria (1-100 CFU/mL)
Viruses (100-1000 PFU/mL)
Toxins (less than 1 ng/mL)
Liquid chemical (1ppb-1ppm)

DETECTION MATRICES:

Demonstrated:
Blood

DESCRIPTION:

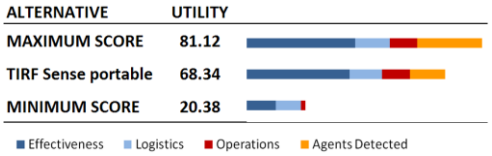
Portable TIRF-EC sensor is designed for use in the field and mobile labs and is capable of simultaneous detecting hundreds of nucleic acid and protein markers, toxins, metabolites, as well as chemical agents in liquid and gaseous phase. The sensor is supersensitive device with rate of response from several seconds to a few minutes. TIRF-EC sensor requires minimum or no sample preparation and is capable of detecting nucleic acid and protein markers in such complex biological fluids as whole blood. In conjunction with bioassays based on DNA and antibodies equipped with embedded luminescence reporters, the sensor is well-suited for first responder applications, point-of-care diagnostics, food & water safety, forensic, biodefense, and agricultural applications. In contrast to traditional DNA and protein microarrays that detect only end-point results, the TIRF-EC sensor monitors the kinetics of association and dissociation of biological and chemical analytes and dependency of the kinetics on electrochemical polarization, which allows for rapidly discriminating between single nucleotide mismatches and distinguishing close homologs of proteins.

TECHNOLOGY:

Portable TIRF-EC sensor employs Total Internal Reflection Fluorescence (TIRF) combined with ElectroChemistry and Electric field Control (TIRF-EC). The sensor supports evanescent wave fluorescence assays, Electro-Chemi-Luminescence (ECL), other luminescence assays, as well as assays immobilized in a submicron hydrogel layer deposited at the TIRF-EC surface. Depending on the application, TIRF-EC microarray contains from a few spots of assays in a single flow channel to hundreds of chem-bio assays in four separate flow channels. TIRF-EC microarrays include internal positive and negative controls and standards for normalization and calibration, which provides high reliability and broad dynamic range to analyses. TIRF-EC sensor chips with printed microarrays are incorporated into reusable or disposable cartridges that can be equipped with user-defined sample preparation modules.

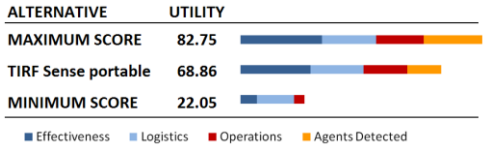
ANALYTICAL Laboratory Ranking

TIRF Sense portable ranked in the top third of all evaluated products for analytical laboratories and earned 84% of the utility points of the best score.



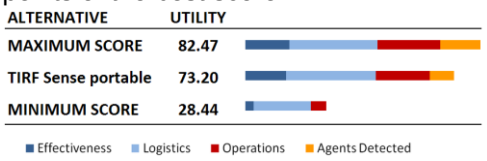
DIAGNOSTIC Laboratory Ranking

TIRF Sense portable ranked in the top third of all evaluated products for diagnostic laboratories and earned 83% of the utility points of the best score.



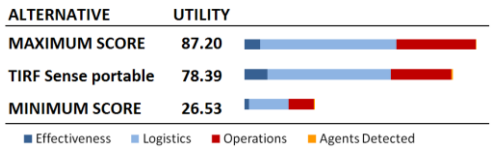
MOBILE Laboratory Ranking

TIRF Sense portable ranked in the top third of all evaluated products for mobile laboratories and earned 89% of the utility points of the best score.



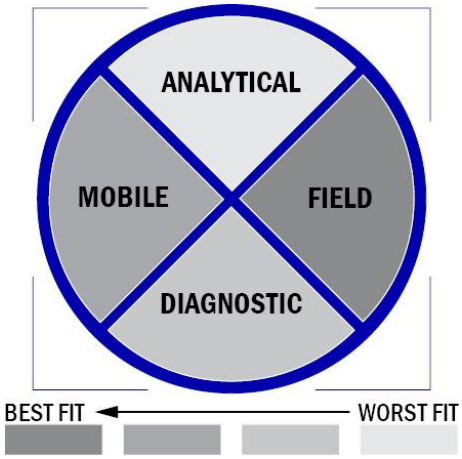
FIELD USE Ranking

TIRF Sense portable ranked in the top third of all evaluated products for field use and earned 90% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

TIRF Technologies
951 Aviation Parkway, Suite 700
Morrisville, NC 27560
T: 919-463-9545.
F: 919-463-9574.
I: www.TIRFtechnologies.com.

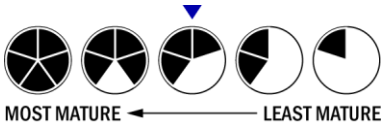
Point of Contact:
Alex Asanov, CEO
asn@tirftechnologies.com

COST

- $37,000.00/system or device
- $8.00-100.00/analysis, depending on the type of microarray and specific assays

SPECIFICITY

- False Positives: 0.000001%
- False Negatives: 0.00001%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- 1 sample, >10 tests/ sample per run
- Adapted to automation with some effort

Signature:
- Sounds or alarms not present
- Screen can be dimmed
- Less than 200 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- Less than 5 minutes set up
- 1-3 minutes down time
- 0-2 steps are required
- Customer and manufacturer site training

Operational conditions:
- Can be used from 4°C to 41°C
- Components stored at room temp can withstand >45°C for < 24 hours/ Components stored frozen can with stand >4°C for <24 hours
- Peak performance at normal relative humidity conditions
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All means of transportation
- Weighs between 1 and 5kg

Re-use:
- Multiple detection assays
- 2 buffer and/or reagents
- 2 components

Maintenance:
- Service every 6 months
- Preventive maintenance is serviceable by customer
- Maintenance is included
- Expected life 3-5 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1hr

Physical System Requirements:
- Batteries
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be analyzed during a run
- No centrifugation steps
- No shaking or vortexing or filtering steps required
- Software could call final result in future

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 50 ul for a test

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- System fully autonomous with some effort
- Onboard computer chip
- Store and archive data outputs and creates an electronic record
- The system software is open and available for modification
- The system hardware is open and available for modification

Tritium Monitor

by Technical Associates

DETECTS THE FOLLOWING:
Demonstrated:
Discrimination between radiation types
Identification of specific isotopes

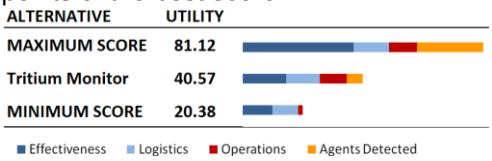
DETECTION MATRICES:
Demonstrated:
Environmental air

DESCRIPTION:
No information available.

TECHNOLOGY:
No information available.

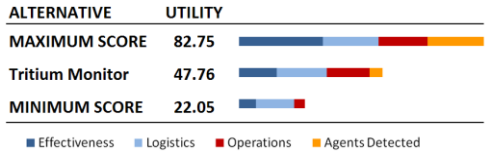
ANALYTICAL Laboratory Ranking

Tritium Monitor ranked in the bottom third of all evaluated products for analytical laboratories and earned 50% of the utility points of the best score.



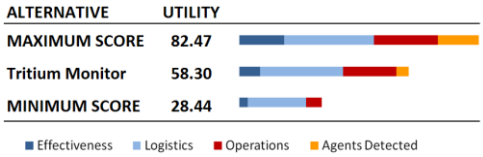
DIAGNOSTIC Laboratory Ranking

Tritium Monitor ranked in the middle third of all evaluated products for diagnostic laboratories and earned 58% of the utility points of the best score.



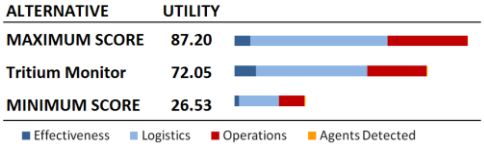
MOBILE Laboratory Ranking

Tritium Monitor ranked in the middle third of all evaluated products for mobile laboratories and earned 71% of the utility points of the best score.



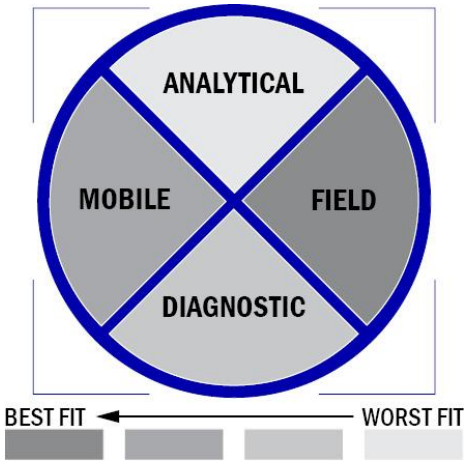
FIELD USE Ranking

Tritium Monitor ranked in the top third of all evaluated products for field use and earned 83% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Technical Associates
7051 Eton Ave.
Canoga Park, CA 91303

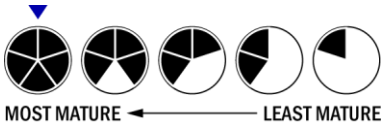
Point of Contact:
Robert Goldstein
818-883-7043

COST

- $5,800.00/system or device

SPECIFICITY

- False Positives: User makes determination
- False Negatives: User makes determination



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- Manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours
- Peak performance at normal relative humidity conditions
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Does not test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- > 250 GB raw data generated
- Network capable
- Wired connections
- Not autonomous
- On board computer chip
- Could be adapted to store and archive data outputs and create an electronic record
- System does not employ any software
- System hardware is closed and not available for modification

TruArray

by Akonni Biosystems Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Viruses (100-1000 PFU/mL)
Toxins (1-100 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Urine, Wound, Environmental air, Environmental water, Soil, Food, Powder

DESCRIPTION:

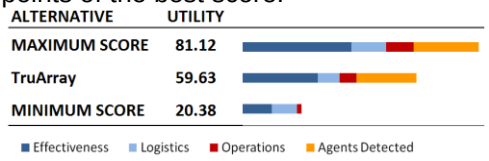
The Akonni TruArray is a portable microarray in vitro diagnostic device employing a dual nucleic acid and immunoassay test methodology to increase diagnostic confidence limits of rare and emerging infectious diseases. The platform includes sample preparation, reagents, microarray detection, and all hardware and software to run an end-to-end protocol. Because of the unique attributes of gel element arrays and the disposable fluidic cartridge, Akonni can offer a user the ability to analyze for hundreds of genetic- or immuno-based disease traits in one, rapid, simple to use platform. The state-of-the-art technology can easily be adapted to custom DHHS or DOD applications and can be quickly re-configured for new or emerging infectious disease targets. Military, EMT and medical personnel could use the portable device, with minimal training and expense, to identify the presence of pathogens.

TECHNOLOGY:

The platform employs a patented sample preparation technology (TruTip) for rapid (<4 mins) extraction, purification and concentration of nucleic acid from clinical and environmental samples. The core gel-drop microarray technology was exclusively licensed from Argonne National Laboratory whom led the development of the technology throughout the 1990s under funding from the Human Genome Program and from DOD's DARPA biodefense program. The biological assay (PCR and immunocapture) was developed by USAMRIID and ported over to Akonni's microarray chip under a DTRA program. Subsequently, Akonni obtained a license from USAMRIID and its affiliates, to the nucleic acid sequences, primers and probes.

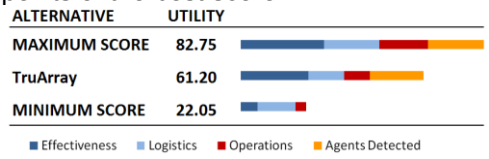
ANALYTICAL Laboratory Ranking

TruArray ranked in the top third of all evaluated products for analytical laboratories and earned 74% of the utility points of the best score.



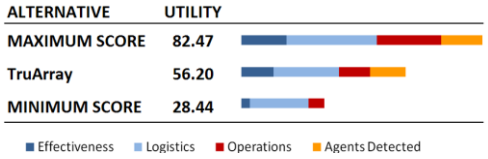
DIAGNOSTIC Laboratory Ranking

TruArray ranked in the top third of all evaluated products for diagnostic laboratories and earned 74% of the utility points of the best score.



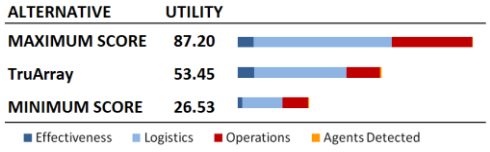
MOBILE Laboratory Ranking

TruArray ranked in the middle third of all evaluated products for mobile laboratories and earned 68% of the utility points of the best score.



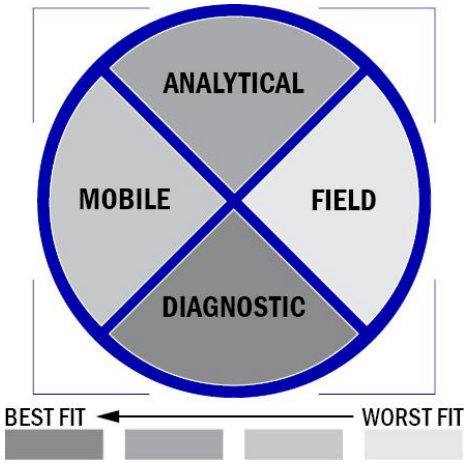
FIELD USE Ranking

TruArray ranked in the bottom third of all evaluated products for field use and earned 61% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Akonni Biosystems Inc.
400 Sagner Ave., Suite 300
Frederick, MD 21701

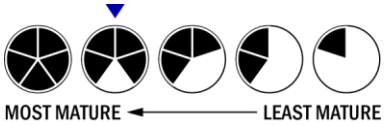
Point of Contact:
Charles Daitch
301-698-0101
info@akonni.com

COST

- $40,000.00/system or device
- $30.00/analysis

SPECIFICITY

- Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15-30 minutes for detection
- 1 sample, >10 tests/ sample per run
- Currently semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 5-10 minutes set up
- < 1 minute down time
- 9-12 steps are required
- DVD/ Web video/ Customer and manufacturer site training/ Hard-copy and Web manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components must be stored at 4°C
- Unknown influence of relative humidity
- 6 months - 1 year shelf life

Transportation:
- Approximately the size of a toaster
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 4 solutions, buffer, and/or reagents
- 3 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life unknown
- < 5 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- 1-2 hour battery use
- Does not require water
- External air or gas source not required
- External vacuum is required

Ease of Use:
- Real-time results not available
- No centrifugation steps required
- A single shaking or vortexing, mixing, degassing or filtering step required
- Software will call final result

Sensitivity and Detection:
- 510K clearance pending
- FDA approval shown
- Greater than 250 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is fully licensed

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Autonomous system with significant effort
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open but modification requires licensing
- The system hardware is open but modification requires licensing

TruDefender FT

by Thermo Scientific

DETECTS THE FOLLOWING:

Demonstrated:
Liquid chemical agent (<1 ppt)

DETECTION MATRICES:

Demonstrated:
Powder

DESCRIPTION:

Thermo Scientific TruDefender FT analyzer is a rugged, handheld FTIR system for rapid, in-the-field identification of unknown chemicals including explosives, narcotics, toxic industrial chemicals, precursors and more. The instrument brings the power of FTIR directly into the hazard zone, enabling the responder to analyze—and act—faster than ever before. Weighing less than three pounds (1.4kg), the TruDefender® FT device was built to meet the needs of first responders. It is ergonomically designed for easy use in Level A gear and rugged enough to withstand the rigors of field use. Key Benefits: • Fast, accurate identification. Returns results in seconds. Onboard hazard database provides full safety and treatment information, further speeding appropriate response. • Easy to use. Intuitive, menu-driven interface is consistent across instruments for fast training and proficiency. • Built for field use. Certified to MIL-STD 810F for ruggedness including drop, shock, vibration and operation in extreme temperatures. • Automatic mixture analysis. Enhances substance identification capability and eliminates the need for subtraction of spectra. • Easy maintenance. Self-contained and requires no scheduled maintenance, calibration, warm up time or mirror alignment, and uses no consumables.

TECHNOLOGY:

Fourier Transform Infrared (FTIR) Spectroscopy FTIR is an absorption spectroscopy technique where an infrared light is passed through the sample. Some wavelengths may be absorbed, while others merely pass through the sample unaffected. Specific molecular bonds absorb a specific amount of energy and these losses of energy correspond to the peaks returned in an analysis. FTIR absorptions are strong and provide outstanding and easily interpretable results for substances which contain polar covalent bonds. FTIR spectroscopy is best used as a primary analysis technique for identifying colored substances such as industrial dyes, pigments and oils, and fluorescent materials.

ANALYTICAL Laboratory Ranking

TruDefender FT ranked in the bottom third of all evaluated products for analytical laboratories and earned 51% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
TruDefender FT	41.07
MINIMUM SCORE	20.38

DIAGNOSTIC Laboratory Ranking

TruDefender FT ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 53% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
TruDefender FT	44.05
MINIMUM SCORE	22.05

MOBILE Laboratory Ranking

TruDefender FT ranked in the top third of all evaluated products for mobile laboratories and earned 73% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
TruDefender FT	59.84
MINIMUM SCORE	28.44

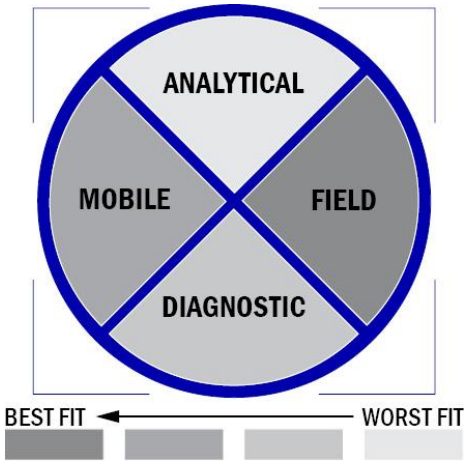
FIELD USE Ranking

TruDefender FT ranked in the top third of all evaluated products for field use and earned 88% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
TruDefender FT	76.92
MINIMUM SCORE	26.53

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Thermo Scientific Portable Optical Analysis
Part of Thermo Fisher Scientific
46 Jonspin Road
Wilmington, MA 01887

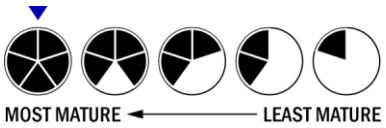
Point of Contact:
John Kenneweg
john.kenneweg@thermofisher.com
(301) 447-2331
www.thermoscientific.com/ahura

COST

- $45,000.00/system or device

SPECIFICITY

- False Positives: 1.1%
- False Negatives: 0%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- Almost instantaneous down time
- 0-2 steps required
- DVD/ Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays.
- 0-1 solutions, buffer, and/or reagents
- 0 components

Maintenance:
- Service not required
- Preventive maintenance not applicable
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Not network capable
- Wireless, wired connections
- Not autonomous
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software is closed and not available for modification
- System hardware is closed and not available for modification

TruDefender FTG

by Thermo Scientific

DETECTS THE FOLLOWING:

Demonstrated:
Liquid chemical agent (<1 ppt)

DETECTION MATRICES:

Demonstrated:
Powder

DESCRIPTION:

Thermo Scientific TruDefender FTG is a rugged, handheld FTIR system for tactical headspace gas identification directly in the field. Based on the award winning TruDefender FT™ unit, its easy-to-use interface and lightweight, rugged design help first responders provide a more rapid, comprehensive response to unknown security incidents. The TruDefender FTG™ unit uses field-proven FTIR technology to quickly and precisely identify gases in the headspace of barrels, drums, bottles and other chemical or solvent containers. Industrial chemicals, organic solvents and volatile organic compounds (VOCs) are easily identified using the TruDefender FTG unit. Key Benefits: High selectivity. Advanced software algorithms enable precise identification results which don't require user interpretation. Easy to use. One-button operation and an intuitive menu-driven interface enable even novice users to be proficient with minimal training. Background scans are never required before analysis. Handheld and rugged. The TruDefender FTG unit weighs less than three pounds (1.4 kg), is designed for field environments, and is fully decon-capable. Easy maintenance. The TruDefender FTG unit is a self-contained unit which requires no scheduled maintenance or calibration, and uses no consumables. Sensing tower is easily removed for cleaning and decontamination.

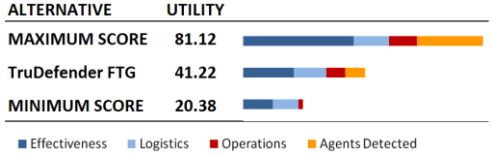
TECHNOLOGY:

FTIR Sensing Tower Technology FTIR spectroscopy, the underlying technology in the TruDefender product line, is a highly precise and selective optical technique used for unknown substance identification. For headspace gas identification, the instrument emits a beam of infrared light directly into the sample. The returning light then bounces off a mirror into the sensing tower and passes through the sensing devices within the tower. The result is a concentrated absorption of molecules by the instrument enabling FTIR analysis.

ANALYTICAL Laboratory Ranking

TruDefender FTG ranked in the bottom third of all evaluated products for analytical laboratories and earned 51% of the utility points of the best score.

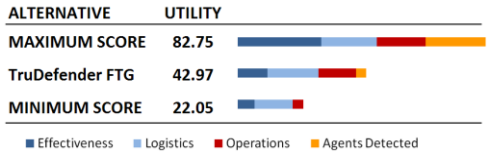
ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
TruDefender FTG	41.22
MINIMUM SCORE	20.38



DIAGNOSTIC Laboratory Ranking

TruDefender FTG ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 52% of the utility points of the best score.

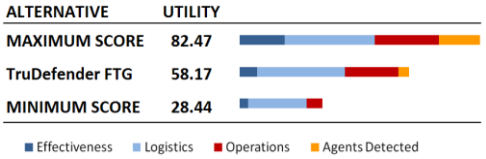
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
TruDefender FTG	42.97
MINIMUM SCORE	22.05



MOBILE Laboratory Ranking

TruDefender FTG ranked in the middle third of all evaluated products for mobile laboratories and earned 71% of the utility points of the best score.

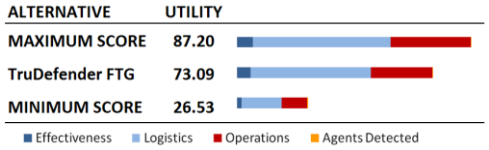
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
TruDefender FTG	58.17
MINIMUM SCORE	28.44



FIELD USE Ranking

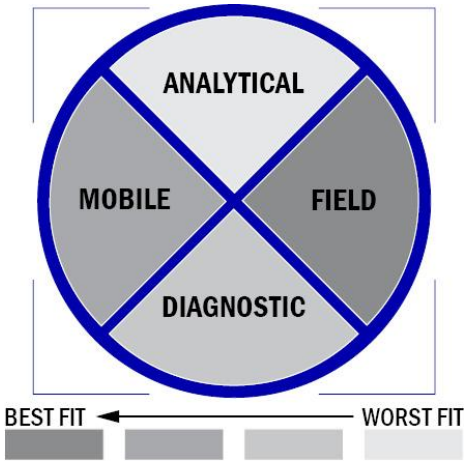
TruDefender FTG ranked in the top third of all evaluated products for field use and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
TruDefender FTG	73.09
MINIMUM SCORE	26.53



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Thermo Scientific Portable Optical Analysis
Part of Thermo Fisher Scientific
46 Jonspin Road
Wilmington, MA 01887

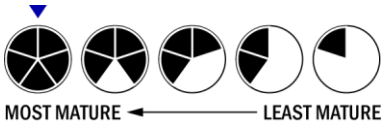
Point of Contact:
John Kenneweg
john.kenneweg@thermofisher.com
(301) 447-2331
www.thermoscientific.com/ahura

COST

- $40,000.00/system or device

SPECIFICITY

- False Positives: 1.1%
- False Negatives: 0%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/ sample per run
- Semi-automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- No set-up required
- <1 minute down time
- 3-5 steps required
- DVD/ Customer and manufacturer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from < -21°C to > 42°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a soda can
- All modes of transportation
- Weighs less than 1 kg

Re-use:
- Multiple detection assays.
- 0-1 solutions, buffer, and/or reagents
- 0 components

Maintenance:
- Service not required
- Preventive maintenance not applicable
- Maintenance not included
- Expected life 5-10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- No electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results not available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Not network capable
- Wired connections
- Not autonomous
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- System software closed, not available for modification
- System hardware is closed and not available for modification

UGV-Based Mountable and Dismountable Standoff Chemical Sensor

by ITT Corporation

DETECTS THE FOLLOWING:

Demonstrated:
Liquid chemical agent
(> 1 ppt)

DETECTION MATRICES:

Demonstrated:
Environmental water, Soil

DESCRIPTION:

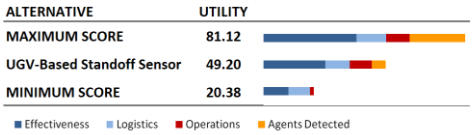
This is an ITT LISA Manportable sensor mounted on a Qinetiq Talon robot. It provides rapid scanning and short range standoff (0.5 m to 3 m) detection and identification of chemicals, agents, advanced threats and explosive materials. The user remotely controls the robot, views the interrogated spot and is provided detection and ID results in real time.

TECHNOLOGY:

The sensor is based upon 10 years of UV Raman standoff spectroscopic sensor development by ITT. It is a robot compatible version of the ITT LISA Manportable sensor.

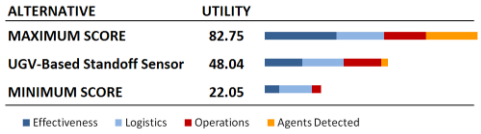
ANALYTICAL Laboratory Ranking

UGV Standoff Chemical Sensor ranked in the middle third of all evaluated products for analytical laboratories and earned 61% of the utility points of the best score.



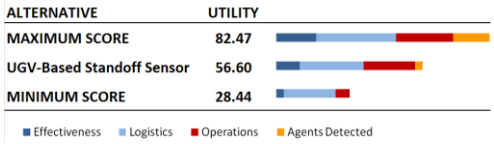
DIAGNOSTIC Laboratory Ranking

UGV Standoff Chemical Sensor ranked in the middle third of all evaluated products for diagnostic laboratories and earned 58% of the utility points of the best score.



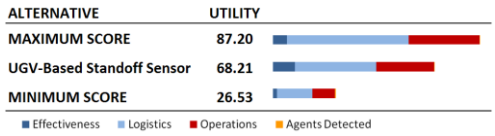
MOBILE Laboratory Ranking

UGV Standoff Chemical Sensor ranked in the middle third of all evaluated products for mobile laboratories and earned 69% of the utility points of the best score.



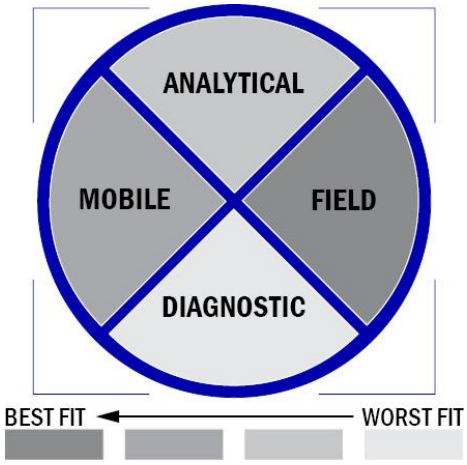
FIELD USE Ranking

UGV Standoff Chemical Sensor ranked in the middle third of all evaluated products for field use and earned 78% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

ITT Corporation
5901 Indian School Rd NE
Albuquerque NM 87110

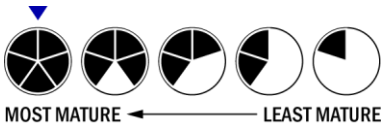
Point of Contact:
Ted Lobb
505 889 7038
ted.lobb@itt.com

COST

- $575,000.00/system or device

SPECIFICITY

- False Positives: Not Available
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Currently semi-automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- A day of training and technical skills are required
- 5-10 minutes set up
- Almost instantaneous down time
- 0-2 steps are required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temperature but can withstand temperatures in excess of 45°C for periods of less than 24 hours
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a home dishwasher
- All means of transportation
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 5-10 years
- 5-10 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1hr

Physical System Requirements:
- Batteries
- 2-4 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Less than 10 ul for a test

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wireless and wired connections
- Autonomous system with significant effort
- No computational power
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

UMSS (Universal Mass Spectrometer Sensor)

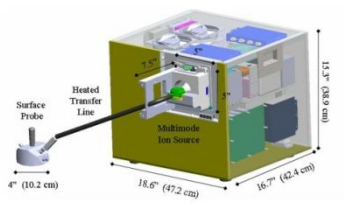
by Science & Engineering Services, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e3-10e4CFU/mL)
Viruses (1oe3-10e4 PFU/mL)
Toxins (1-100 ng/ml)
Liquid chemical agent
(1 ppb-1 ppm)

DETECTION MATRICES:

Demonstrated:
Powder



DESCRIPTION:

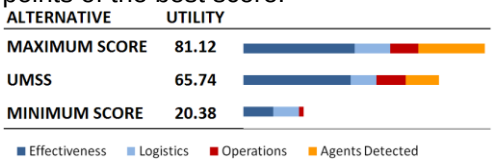
The Universal Mass Spec Sensor (UMSS) is sized and designed to deliver a next generation portable Mass Spec capability for both biological and chemical (Explosives, Narcotics, CWA and TIC) materials. Sample inlet is via heated probe and/or direct injection. A key attribute of UMSS is rapid sample processing in clutter and the ability to enable (create/transfer) library updates of new hazards and/or unknowns within a few hours. In terms of logistics, the consumables cost per sample is less than one dollar and train-up for non-technical users is two days.

TECHNOLOGY:

The Universal Mass Spec Sensor (UMSS) uses a hexapole ion-trap mass spectrometer in which MS/MS is conducted either via secondary electro-spray ionization (SESI) of chemical samples or via supplemental AP-MALDI module for biological samples. Sample materials undergo rapid ionization and MS/MS of targeted markers to sift rapidly thru clutter against specialized-onboard and/or commercial internet-accessible databases.

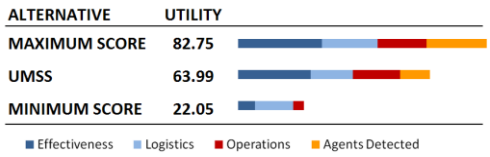
ANALYTICAL Laboratory Ranking

UMSS ranked in the top third of all evaluated products for analytical laboratories and earned 81% of the utility points of the best score.



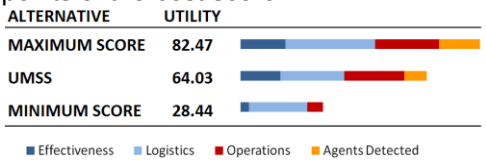
DIAGNOSTIC Laboratory Ranking

UMSS ranked in the top third of all evaluated products for diagnostic laboratories and earned 77% of the utility points of the best score.



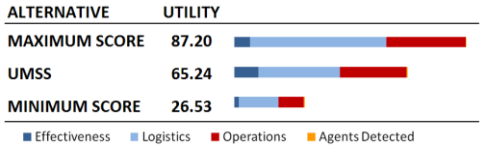
MOBILE Laboratory Ranking

UMSS ranked in the top third of all evaluated products for mobile laboratories and earned 78% of the utility points of the best score.



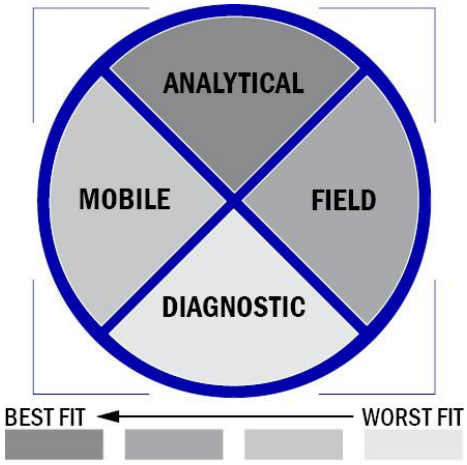
FIELD USE Ranking

UMSS ranked in the middle third of all evaluated products for field use and earned 75% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Science & Engineering Services, Inc.
6992 Columbia Gateway Drive
Columbia, Maryland 21046

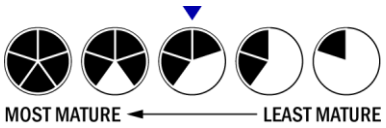
Point of Contact:
Robert M. Serino, Ph.D.
443.539.0139

COST

- $250,000.00/system or device

SPECIFICITY

- False Positives: 1%
- False Negatives: 1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Semi-automated

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- 10-20 minutes set-up
- 1-3 minutes down time
- 0-2 steps required
- Customer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components must be stored at 4°C
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of carry-on luggage
- Transport via commercial carrier/ Tactical military wheeled and tracked vehicle/ Fixed wing military aircraft
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- 3 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by customer
- Maintenance included
- Expected life >10 years
- No daily QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance capable
- FDA clearance capable
- Less than 10 ul to test liquids

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Wireless and wired connections
- Fully autonomous
- Laptop computer
- Stores and archives data outputs and creates an electronic record
- System software open and available for modification
- System hardware open and available for modification

uScope MX - POC Diagnostics

by Microscopes International

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (1-100 CFU/mL)
Viruses (1-100 PFU/mL)
Toxins (<1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Environmental water, Soil, Food, Powder, Insect vectors

DESCRIPTION:

Microscopes International(MI) builds portable digital slide microscopes for brightfield and fluorescence microscopy. In a transportable form factor these USB attachable devices are small, light weight and easy to use. The uScope MX is small enough for field work and powerful enough for laboratory use. When used with Microscopes International multi-test slides and diagnostic software the uScope MX can automatically perform a large variety of biological tests with a single sample. Digital automation enables remote control and diagnostics to be performed by experts anywhere in the world. The uScope MX is USB connected to a computing device (PC, Laptop, Tablet) and can be used to automate any test that a microscope can detect. Software API's can be used to attach the uScope MX to existing biological detection software or to create specialized tests.

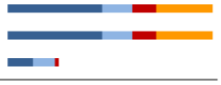
TECHNOLOGY:

Microscopes International has created the first portable low cost wavelength limited Digital Microscope (uScope MX). A full array of morphological (e.g., cell count, hematology, white cell differential, bacteria, fluorescent markers, tissue sample, etc.) and diagnostic tests (e.g., immunological, protein, hormonal, chemical, genetic, etc.) can be performed on the same drop of blood (or body fluid) at wavelength limited resolution and is fully automated. The system is mobile, can be powered by USB, battery or wall plug, is the size of an external hard drive and has an overnight Fedex shipping weight of less than 4 lbs.

ANALYTICAL Laboratory Ranking

uScope MX - POC Diagnostics ranked in the top third of all evaluated products for analytical laboratories and earned 100% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
uScope MX - POC Diagnostics	81.12
MINIMUM SCORE	20.38

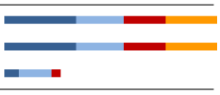


Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

uScope MX - POC Diagnostics ranked in the top third of all evaluated products for diagnostic laboratories and earned 100% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
uScope MX - POC Diagnostics	82.75
MINIMUM SCORE	22.05

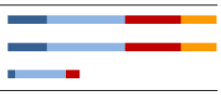


Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

uScope MX - POC Diagnostics ranked in the top third of all evaluated products for mobile laboratories and earned 100% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
uScope MX - POC Diagnostics	82.47
MINIMUM SCORE	28.44

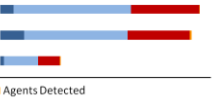


Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

uScope MX - POC Diagnostics ranked in the top third of all evaluated products for field use and earned 96% of the utility points of the best score.

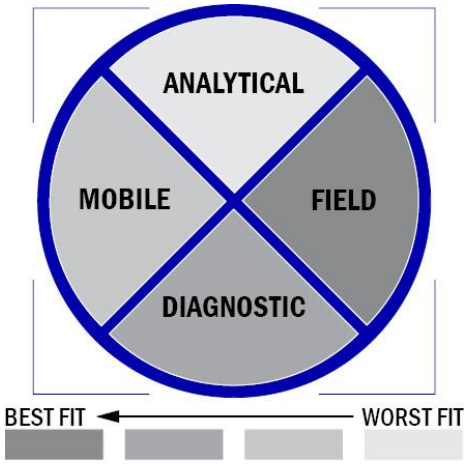
ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
uScope MX - POC Diagnostics	83.78
MINIMUM SCORE	26.53



Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Microscopes International
555 Republic Drive, Suite 105
Plano, TX 75074-5469

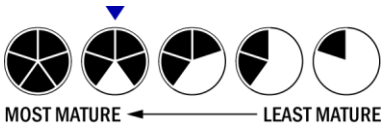
Point of Contact:
Scott Byker
scott.byker@uscopes.com
888.726.7350 x712

COST

- $12,500.00/system or device
- $20.00/analysis

SPECIFICITY

- False Positives: Not Available
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Easily adapted to full automation

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- < 5 minutes set up
- < 1 minute down time
- 0-2 steps are required
- Customer and manufacturer site training

Operational conditions:
- Can be used from < -21°C to > 42°C
- Components should be stored at room temp but can with stand temps > 45°C for periods < 24 hours
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of a toaster
- All means of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Less than once a year service
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 3-5 years
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1 hr

Physical System Requirements:
- Batteries
- 1-2 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval shown
- Less than 10 ul for a test

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Satellite, wireless and wired connections
- Autonomous system with easy adaptation
- Laptop computer
- The system could be adapted to store and archive data outputs and create an electronic record
- The system software is open but modification requires licensing
- The system hardware is open but modification requires licensing

VDSC-2M

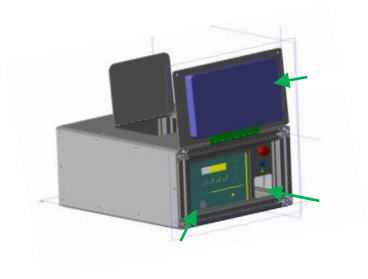
by Virus Detection Systems

DETECTS THE FOLLOWING:

Demonstrated:
Viruses (1-100 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Environmental air, Environmental water, Soil, Food, Powder, Insect vectors



DESCRIPTION:

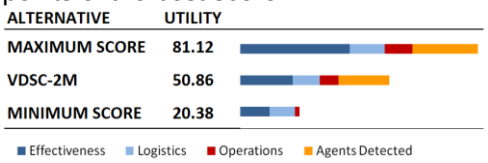
The system will separate, detect and provide preliminary identification of all viruses in a sample. The technology is based on the fact that viruses have a unique size and that there is almost nothing else in this same size range. This has several advantages over antibody or genetic detection systems as the size cannot be artificially manipulated to avoid detection. Also, the cost per sample is very low and is independent to the number of virus types in the sample.

TECHNOLOGY:

Viruses have a very unique size and can be thought of as small particles. The system can separate and detect the virus particles using proven particle technology.

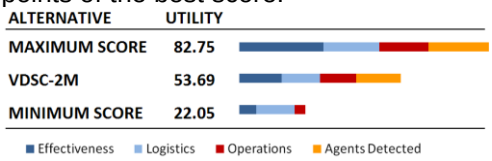
ANALYTICAL Laboratory Ranking

VDSC-2M ranked in the middle third of all evaluated products for analytical laboratories and earned 63% of the utility points of the best score.



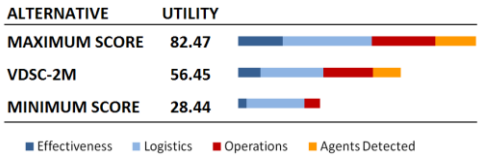
DIAGNOSTIC Laboratory Ranking

VDSC-2M ranked in the middle third of all evaluated products for diagnostic laboratories and earned 65% of the utility points of the best score.



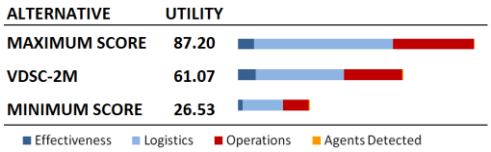
MOBILE Laboratory Ranking

VDSC-2M ranked in the middle third of all evaluated products for mobile laboratories and earned 68% of the utility points of the best score.



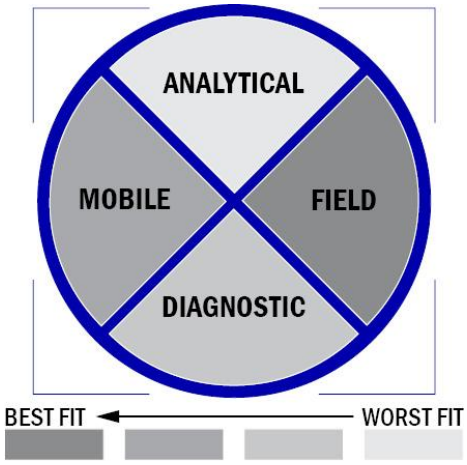
FIELD USE Ranking

VDSC-2M ranked in the middle third of all evaluated products for field use and earned 70% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Virus Detection Systems Corporation
7117 North Ridge Dr
Raleigh, NC 27615

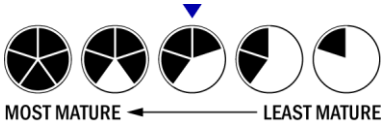
Point of Contact:
Dennis Phillips

COST

- $95,0 00.00/system or device
- $5.00/analysis

SPECIFICITY

- False Positives: Not Applicable
- False Negatives: Not Applicable



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15-30 minutes for detection
- Multiple samples, single tests/ sample per run
- Fully automated with some effort

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief training and minimal technical skills
- < 5 minutes set up
- Almost no down time
- 3-5 steps are required
- Customer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be at room temp but can withstand >45°C for periods <24 hours
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Military wheeled and tracked vehicles/ Fixed wing aircraft/ Ship transport
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 2 solutions, buffer, and/or reagents
- 3 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 5-10 years
- 5-10 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires <1 hr

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Requires water aliquots
- External air or gas source required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can not be processed while in progress
- No centrifugation steps required
- Multiple shaking or vortexing, mixing, degassing or filtering steps required
- Software could call final results in future

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Greater than 250 ul for a test

System Maturity:
- Brass board
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Satellite, wireless and wired connections
- Not capable of autonomy
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is open but modification requires licensing
- The system hardware is open but modification requires licensing

VereID Biosystem and VereChip

by Veredus Laboratories Pte Ltd

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria
Viruses

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine, Wound, Environmental air, Environmental water, Soil, Food, Powder

DESCRIPTION:

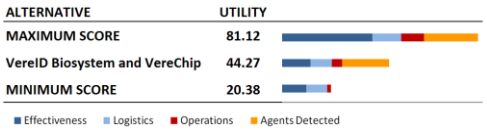
VereID Biosystem combines molecular biology, microfluidics and microelectronics to bring the future of diagnostics and surveillance to you today. The VereID Biosystem is designed as a Point-of-Care system, but it also allows for laboratory analysis due to its scalability. This system consists of a Temperature Control System, as well as an Optical Reader, which powers the VereChip. The VereChip technology is a breakthrough in innovation, integrating two powerful molecular biological technologies: PCR and Microarray to allow simultaneous detection of multiple targets with high sensitivity and specificity. Our products include VereFlu (influenza detection), VereThreat (biothreat detection), VereFood (food pathogen detection), VereTrop (tropical disease detection). Customized chips are also available.

TECHNOLOGY:

The VereChip technology is a breakthrough in innovation, integrating two powerful molecular biological technologies: PCR and Microarray to allow simultaneous detection of multiple targets with high sensitivity and specificity.

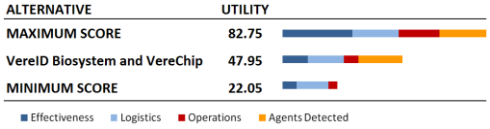
ANALYTICAL Laboratory Ranking

VereID Biosystem and VereChip System ranked in the middle third of all evaluated products for analytical laboratories and earned 55% of the utility points of the best score.



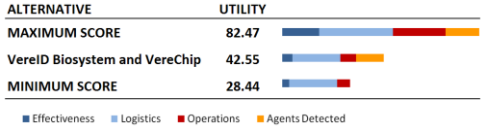
DIAGNOSTIC Laboratory Ranking

VereID Biosystem and VereChip System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 58% of the utility points of the best score.



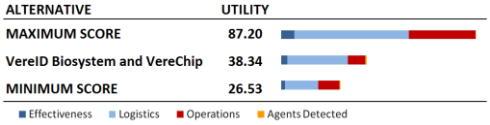
MOBILE Laboratory Ranking

VereID Biosystem and VereChip System ranked in the bottom third of all evaluated products for mobile laboratories and earned 52% of the utility points of the best score.



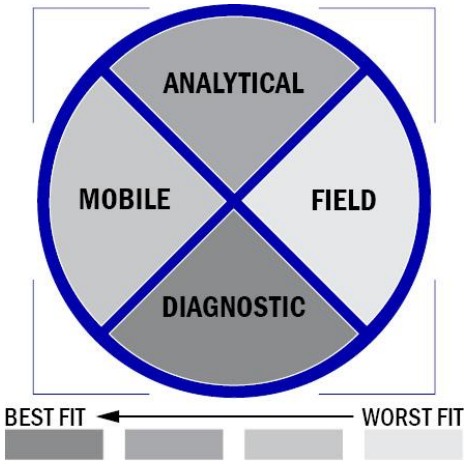
FIELD USE Ranking

VereID Biosystem and VereChip System ranked in the bottom third of all evaluated products for field use and earned 44% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Veredus Laboratories Pte Ltd
83 Science Park Drive
#04-02 The Curie Singapore Science Park
1 Singapore 118258

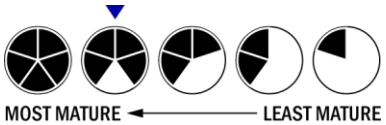
Point of Contact:
65 6496 8600

COST

- Not available

SPECIFICITY

- False positives: Not available
- False negatives: Not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, multiple tests/ sample per run
- Could be adapted to fully autonomous system with some effort

Signature:
- Sounds or alarms can be deactivated
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- Less than 5 minutes set up
- Minimal down time
- 6-8 steps are required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Components must be stored at room temperature (27°C)/ Must be stored at 4°C/ Must be frozen/ Must be frozen at temperatures at or below -20°C (cryo-storage)
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of carry on suitcase
- Transport via commercial carrier/ Tactical military wheeled and tracked vehicle/ Ship transport
- Weighs 5-25 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 4 components

Maintenance:
- Service once per year
- Preventive maintenance serviceable by technician only
- Maintenance is not included
- Expected life 3-5 years

Physical System Requirements:
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- Some centrifugation steps may be required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Depends on extraction kit

System Maturity:
- Commercially available
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB
- Not capable of autonomy
- Laptop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

Verigene System

by Nanosphere, Inc.

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria
Viruses
Toxins (<1 ng/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Nasal and throat swabs, Stool, Urine

DESCRIPTION:

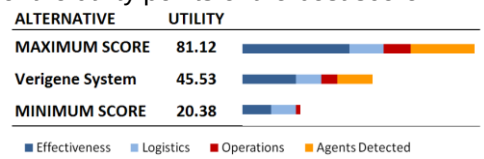
Nanosphere (Northbrook, IL) has developed the FDA-cleared Verigene® System, which is comprised of instrumentation and single use Verigene® Test Cartridges (IVDs) based on proprietary gold nanoparticle technology. With the Verigene System, users can accomplish sensitive, accurate, and rapid multiplex detection of nucleic acid and protein targets using enhanced signal-amplification techniques.

TECHNOLOGY:

We have developed a generically applicable, microarray based nano-probe test. The assay uses a multi-step robotic process, which relies on nonisotropically oriented antibodies on functionalized glass as multiplexed microarrays to capture targets from an assay sample. Functionalized, 130 angstrom diameter gold nano-probes (measured by static light scattering, 5 nm S.D.) also bind to the target through a molecular-scale complex containing antibodies. The target-bound molecular complex is then quantified through silver enhancement of the functionalized gold. Assays in this format can be rapidly configured and implemented for a wide array of potential biomarkers. For example we have demonstrated a robust and ultra-sensitive assay for cardiac troponin with an LOD of less than 500 femtograms per mL serum, and an overall CV of less than 20%. The assay also shows very low background, a broad dynamic range and over 3 logs of linear dose response.

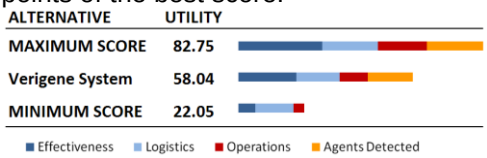
ANALYTICAL Laboratory Ranking

Verigene System ranked in the middle third of all evaluated products for analytical laboratories and earned 56% of the utility points of the best score.



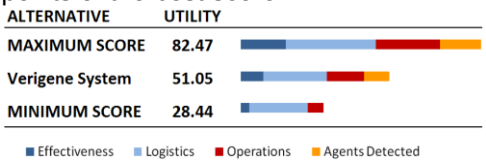
DIAGNOSTIC Laboratory Ranking

Verigene System ranked in the top third of all evaluated products for diagnostic laboratories and earned 70% of the utility points of the best score.



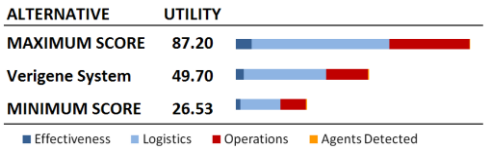
MOBILE Laboratory Ranking

Verigene System ranked in the middle third of all evaluated products for mobile laboratories and earned 62% of the utility points of the best score.



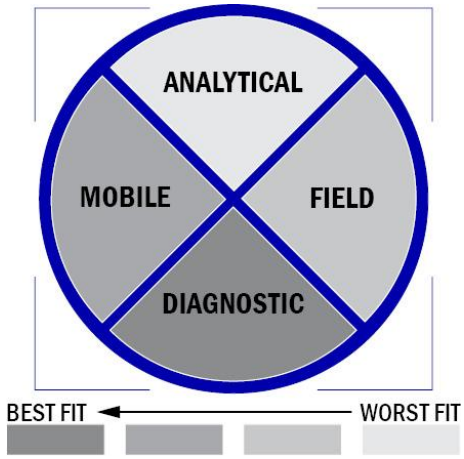
FIELD USE Ranking

Verigene System ranked in the bottom third of all evaluated products for field use and earned 57% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

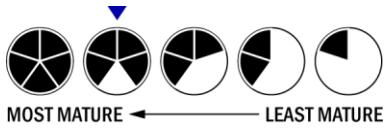
Nanosphere, Inc.
4088 Commercial Ave
Northbrook, IL 60062
www.nanosphere.us
847-400-9000

COST

- $40,000.00/system or device
- $35.00-85.00/test

SPECIFICITY

- False Positives: <1%
- False Negatives: <1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- 1 sample, >10 tests/ sample per run
- Currently fully automated

Signature:
- No sounds or alarms
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- Less than 5 minutes for set up
- 3-5 minutes down time
- 3-5 steps are required
- Customer site training/ Hard copy manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components must be stored at 4°C/ Components must be frozen at temperatures at or below -20°C (cryo-storage)
- Performance is not influenced by relative humidity
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Commercial carrier/ Tactical vehicle/ Fixed and rotary wing aircraft/ Ship transport
- Weighs between 25 and 50 kg

Re-use:
- Multiple detection assays
- >5 solutions, buffer, and/or reagents

Maintenance:
- Service less than once a year
- Preventive maintenance N/A
- Maintenance not included
- Unknown system life
- No QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time not available
- No centrifugation steps required
- A single shaking or vortexing, mixing, degassing or filtering steps required
- Software will call final result

Sensitivity and Detection:
- 510K clearance shown
- FDA approval shown
- Less than 250 ul for a test

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connections
- Fully autonomous system with significant effort
- Onboard computer chip
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

Veriti Thermal Cycler

by Applied Biosystems/ Life Technologies

DETECTS THE FOLLOWING:
Nothing demonstrated.

DETECTION MATRICES:
Nothing demonstrated.

DESCRIPTION:
This device is for laboratory research use only. The device is used to heat and cool liquid scientific samples.

TECHNOLOGY:
This device is a peltier-based system used for the polymerase chain reaction of genes.

ANALYTICAL Laboratory Ranking

Veriti Thermal Cycler ranked in the bottom third of all evaluated products for analytical laboratories and earned 25% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
Veriti Thermal Cycler	20.38
MINIMUM SCORE	20.38

DIAGNOSTIC Laboratory Ranking

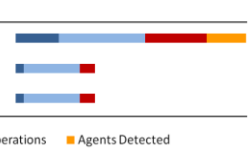
Veriti Thermal Cycler ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 27% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
Veriti Thermal Cycler	22.05
MINIMUM SCORE	22.05

MOBILE Laboratory Ranking

Veriti Thermal Cycler ranked in the bottom third of all evaluated products for mobile laboratories and earned 34% of the utility points of the best score.

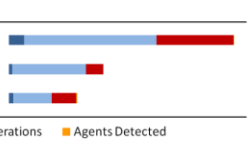
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
Veriti Thermal Cycler	28.44
MINIMUM SCORE	28.44



FIELD USE Ranking

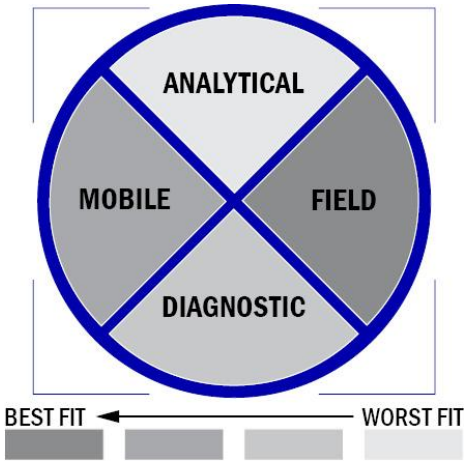
Veriti Thermal Cycler ranked in the bottom third of all evaluated products for field use and earned 42% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
Veriti Thermal Cycler	36.59
MINIMUM SCORE	26.53



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Applied Biosystems/Life Technologies
5791 Van Allen Way
Carlsbad, California 92008 USA
(760) 603-7200

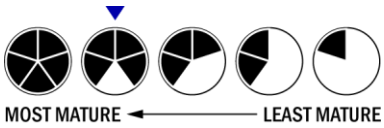
Point of Contact:
Judith Acaba
650-638-6736

COST

- $8,000.00/system or device
- $100.00/analysis

SPECIFICITY

- False Positives: Not Available
- False Negatives: Not Available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 1-8 hours for detection
- Multiple samples, single tests/ sample per run
- Semi-automated with some effort

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Greater than 500 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- <5-10 minutes set up
- Less than 1 minute down time
- 3-5 steps are required
- DVD/ Web-based manual

Operational conditions:
- Can be used from 4°C to 37°C
- Components should be stored frozen but can with stand temperatures > 4°C for periods < 24 hours / Components must be stored at 4°C
- Peak performance at normal relative humidity conditions
- 6 months to 1 year shelf life

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Commercial carrier/ Rotary wing aircraft/ Ship transport
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 5 or more solutions, buffer, and/or reagents
- 5 or more components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by technician
- Maintenance is not included
- Expected life 5-10 years
- > 20 minutes QA required
- Exposure to hazardous agent would require up to 4 hours to decontaminate

Physical System Requirements:
- 220V electrical requirement
- Not intended for portable use
- Does not require water
- External vacuum not required

Ease of Use:
- Real-time results not available
- Data can not be processed while in progress
- Multiple centrifugation steps required
- Multiple shaking or vortexing, mixing, degassing or filtering steps required
- Software will not call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA approval not applicable
- Less than 100 ul for a test

System Maturity:
- Is commercially available
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- Not network capable
- Wired connections
- Autonomous system with some effort
- Onboard computer chip
- The system does not contain internal memory for data storage or electronic record keeping
- The system does not employ software
- The system hardware is closed and not available for modification

Veritide Ceeker

by Veritide Ltd

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria

DETECTION MATRICES:

Demonstrated:
Powder

DESCRIPTION:

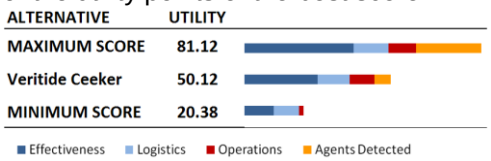
The Veritide Ceeker is an instrument designed to quickly and easily screen for the presence of Anthrax spores. It can be used when there is only a tiny quantity of sample available and testing takes only 7 minutes. Packaged in a tough protective waterproof case. Fully decontaminable by immersion in bleach solution. Non-destructive testing: sample is not destroyed or consumed. Designed for use by operator in a full Level A ChemBio suit.

TECHNOLOGY:

The Veritide™ Ceeker™ uses exposure to an intense UV-A source to modify the fluorescent properties of the sample undergoing analysis. Between exposure doses the sample is excited by UV at 365 nm and the resulting sample fluorescence is measured at 3 different wavelengths. These measurements enable a spore-containing substance to be detected and differentiated from other materials such as hoax substances.

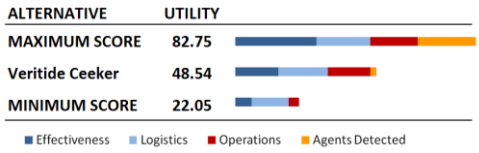
ANALYTICAL Laboratory Ranking

Veritide Ceeker ranked in the middle third of all evaluated products for analytical laboratories and earned 62% of the utility points of the best score.



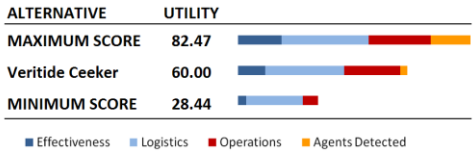
DIAGNOSTIC Laboratory Ranking

Veritide Ceeker ranked in the middle third of all evaluated products for diagnostic laboratories and earned 59% of the utility points of the best score.



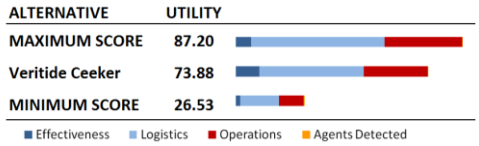
MOBILE Laboratory Ranking

Veritide Ceeker ranked in the top third of all evaluated products for mobile laboratories and earned 73% of the utility points of the best score.



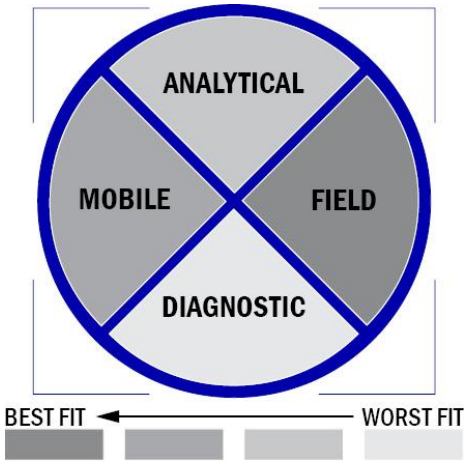
FIELD USE Ranking

Veritide Ceeker ranked in the top third of all evaluated products for field use and earned 85% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

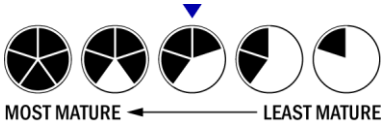
Veritide Ltd
P.O. Box 13768
Christchurch 8141
New Zealand

COST

- $ 25,000.00/system or device

SPECIFICITY

- False Positives: 0
- False Negatives: 0



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, single test/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen cannot be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- 5-10 minutes required for set-up
- Almost instantaneous down time
- 0-2 steps are required
- Customer site training

Operational conditions:
- Can be used from -10°C to 40°C
- Consumables not required
- Performance is not influenced by relative humidity
- Greater than 3 years shelf life

Transportation:
- Approximately the size of a toaster
- Transport via tactical military wheeled and tracked vehicle
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 1 component

Maintenance:
- Service once/year
- No preventive maintenance
- Maintenance not included
- Expected life greater than 10 years
- No daily QA necessary
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 1-2 hours battery life
- Portable
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering step required
- Software calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Does not test liquids

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Not network capable
- Not autonomous
- No computational power needed
- Stores and archives data outputs and creates electronic records
- System software is closed and not available for modification
- System hardware is closed and not available for modification

VIBP

by THALES Defense & Security

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria
Viruses
Toxins
Aerosolized Chemical Agent
Liquid Chemical Agent

DETECTION MATRICES:

Demonstrated:
Environmental air,
Environmental water, Powder

DESCRIPTION:

The VIBP is a complete system designed for first responders and law enforcement agencies. It provides a full field capability to identify biological and chemical agents from field samples. The analytical solution is integrated in an air transportable vehicle with data analysis and transfer capabilities.

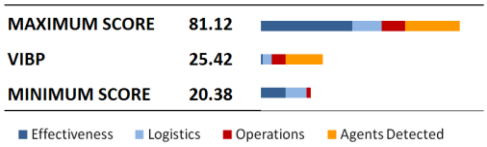
TECHNOLOGY:

The VIBP integrate proven detection and identification technologies, specifically: - PCR for nucleic acid amplification and detection - Immunological tickets - Mass spectrometry - Infrared spectrometry analysis.

ANALYTICAL Laboratory Ranking

VIBP System ranked in the bottom third of all evaluated products for analytical laboratories and earned 31% of the utility points of the best score.

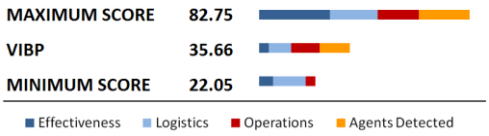
ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
VIBP	25.42
MINIMUM SCORE	20.38



DIAGNOSTIC Laboratory Ranking

VIBP System ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 43% of the utility points of the best score.

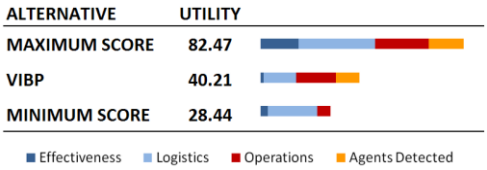
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
VIBP	35.66
MINIMUM SCORE	22.05



MOBILE Laboratory Ranking

VIBP System ranked in the bottom third of all evaluated products for mobile laboratories and earned 49% of the utility points of the best score.

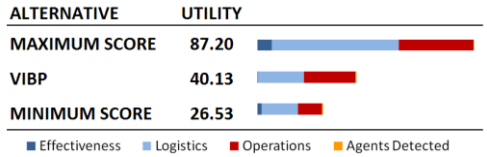
ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
VIBP	40.21
MINIMUM SCORE	28.44



FIELD USE Ranking

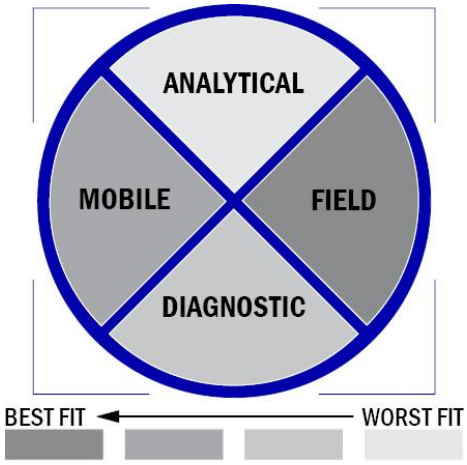
VIBP System ranked in the bottom third of all evaluated products for field use and earned 46% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
VIBP	40.13
MINIMUM SCORE	26.53



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

THALES Defense & Security
C4I systems Division
20-22 rue Grange Dame Rose
CS 90519 78141

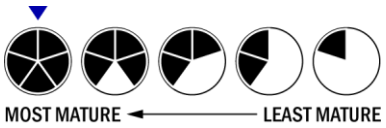
Point of Contact:
Jérôme LOUAT
jerome.louat@Thalesgroup.com

COST

- Not available

SPECIFICITY

- False positives: Not available
- False negatives: Not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- Not amenable to full or semi-automation

Signature:
- Sounds or alarms can be deactivated
- Screen can be dimmed or turned off

Training and Speed:
- More than a day of training and significant technical skills are required
- >20 minutes set up required
- <5 minutes down time
- Customer and manufacturer site training/ Hard-copy operators manual manuscript

Operational conditions:
- Can be used from < -21°C to > 42°C
- Components should be stored at room temp but can with stand temps > 45°C for < 24 hours/ Must be stored at 4°C/ Must be frozen
- Performance is not influenced by relative humidity
- 1-3 years shelf life

Transportation:
- Larger than a home dishwasher
- Transport via tactical military wheeled and tracked vehicle/ Fixed wing military aircraft/ Ship transport
- Weighs >50 kg

Re-use:
- Multiple detection assays

Maintenance:
- Service > every 6 months
- Preventive maintenance serviceable by technician only
- Maintenance is not included
- Expected life >10 years
- >20 minutes daily QA required
- Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour

Physical System Requirements:
- 220V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source is required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data cannot be processed while in progress
- Single centrifugation step required
- Single shaking or vortexing, mixing, degassing or filtering step required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- > 250 ul for a test

System Maturity:
- Is commercially available and meets military specifications
- Has not appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property is owned

Interoperability and System Complexity:
- <100 GB
- Network capable
- Wireless and wired connections
- Not capable of autonomy
- Laptop computer
- The system automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

Vides Bioassay System

by Resonant Sensors Incorporated

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (100-1,000 CFU/mL)
Toxins (100-1,000 ng/ml)
Aerosolized Chemical Agent (0.00003-0.0001 mg/m3)
Liquid Chemical Agent (1 ppb-1ppm)

DETECTION MATRICES:

Demonstrated:
Blood, Environmental air, Environmental water, Food

DESCRIPTION:

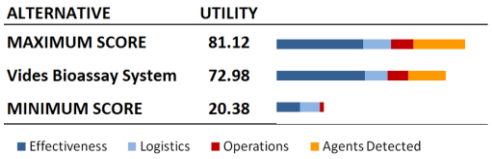
Resonant Sensors Incorporated (RSI) has developed a new class of photonic label-free biosensor systems for rapid biochemical detection. Our products include disposable sensor plates and associated benchtop reader systems that quantify biochemical reactions in real time with outstanding accuracy and repeatability. This differentiating technology provides new assay tools for laboratories that will dramatically reduce the labor time and cost of biochemical tests. The system is fully controlled through advanced software, which includes data analysis features to provide either kinetic or end-point information. Our sensor platform can be applied to monitor virtually any bio- or chemical reaction in a variety of matrices (including serum, environmental water samples, and food). Selectivity is imparted on the sensor element using conventional surface chemistries (such as silane) to covalently attach commercially available antibody, aptamer, or DNA selective layers. As a test begins, the analyte binds to the detection-layer target, and the system monitors instantaneous changes at the sensor surface. Test time is limited only by chemical binding dynamics, and is typically less than 15 minutes. Qualitative data is available immediately after sample introduction. The RSI sensor plates are readily adaptable to standard immunoassay, cell-based, DNA, or microbial testing methods. The sensors are integrated into standard microwell formats so that laboratories may still use existing automated sample handling equipment. RSI sensor plates are available in a variety of reactive surfaces (silane or custom). They may also be purchased pre-sensitized for specific assays, such as S. aureus, S. enterotoxin A and B, and others.

TECHNOLOGY:

RSI's products are based upon guided-mode resonance (GMR) sensor technology that occurs in sub-wavelength waveguide-gratings. When these sensors are illuminated with a broadband light source, a specific wavelength of light is reflected. Interaction of a target analyte with a biochemical layer on the sensor surface yields measurable spectral shifts that directly identify the binding event without additional processing or foreign tags. The GMR sensor surface may be optimized with an array of capture molecules, allowing rapid detection of multiple analytes in a variety of matrices.

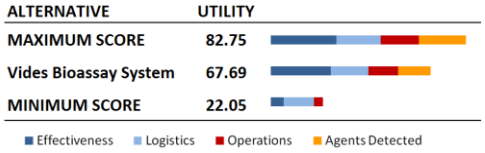
ANALYTICAL Laboratory Ranking

Vides Bioassay System ranked in the top third of all evaluated products for analytical laboratories and earned 90% of the utility points of the best score.



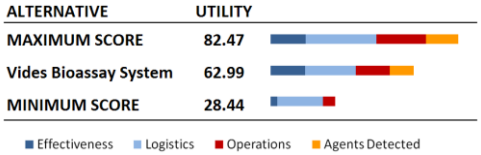
DIAGNOSTIC Laboratory Ranking

Vides Bioassay System ranked in the top third of all evaluated products for diagnostic laboratories and earned 82% of the utility points of the best score.



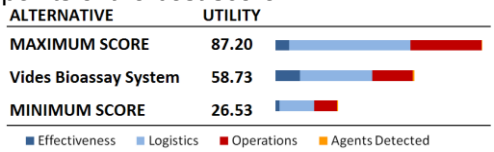
MOBILE Laboratory Ranking

Vides Bioassay System ranked in the top third of all evaluated products for mobile laboratories and earned 76% of the utility points of the best score.



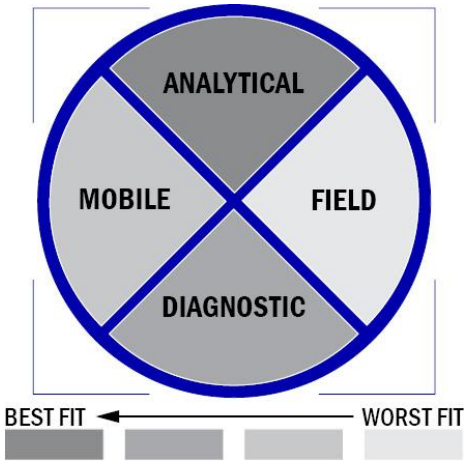
FIELD USE Ranking

Vides Bioassay System ranked in the middle third of all evaluated products for field use and earned 67% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Resonant Sensors Incorporated
416 Yates Street
NH518, Box 19016
Arlington, TX 76010

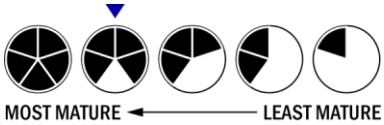
Point of Contact:
Phone: (817) 272-3450

COST

- $75,000/system or device
- Cost of analysis depends on targeted assay

SPECIFICITY

- False positive and negative rates are typically less than 5% depending on specific assay



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2-15 minutes for detection
- Multiple samples, multiple tests/ sample per run
- Could easily be adapted into a fully autonomous system

Signature:
- Sounds can be deactivated
- Screen can be dimmed
- < 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- < 5 minutes set up
- 1-3 minutes down time
- 0-2 steps are required
- Customer and manufacturer site training/ Hard-copy manual

Operational conditions:
- Can be used from 4°C to 41°C
- Components stored at room temp but can withstand > 45°C for < 24 hours/ Stored frozen but can withstand > 4°C for < 24 hours/ Must be stored at room temp/ Must be stored at 4°C/ Must be frozen
- Performance at normal relative humidity is unknown
- Between 1-6 months shelf life

Transportation:
- Approximately the size of a carry on suitcase
- All modes of transportation
- Weighs between 25-50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions and/or reagents
- 1 component

Maintenance:
- Service < once per year
- Preventive maintenance serviceable by customer
- Maintenance is not included
- Expected life 5-10 years
- No QA required
- Exposure to hazardous agent is isolated to discrete elements and/or decon requires <1 hr

Physical System Requirements:
- 110V electrical requirement
- Not intended for portable use
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps are required
- No shaking or vortexing, mixing, degassing or filtering steps are required
- Software will call final result

Sensitivity and Detection:
- 510K clearance capable
- FDA approval capable
- Less than 50 ul for a test

System Maturity:
- Commercially available
- Has appeared in peer reviewed publication or independent evaluation
- The technology ownership and intellectual property fully licensed

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Wired and wireless connections
- Could be adapted to fully autonomous system with some effort
- Laptop computer
- Automatically stores and archives data outputs and creates an electronic record
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

ViriChip System

by BioForce Nanosciences

DETECTS THE FOLLOWING:

Demonstrated:
Viruses (10e3-10e4 PFU/mL)

DETECTION MATRICES:

Demonstrated:
Blood, Stool, Urine, Environmental water, Food

DESCRIPTION:

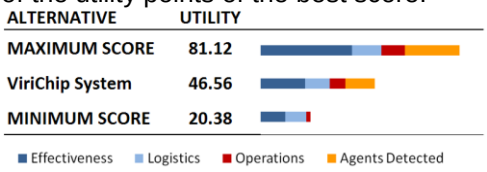
The ViriChip System (VS) is intended to be a rapid, rugged virus capture and identification system based on capture of the intact virus particle rather than components (proteins, nucleic acid, etc.) that may be found and detected in environmental samples. The use is primarily for rapid (20-40 minute) detection and identification of viruses found in environmental samples, foods and water, and in biodefense situations. As such it is intended for use by first responders in situations requiring rapid decision making. A laboratory version is planned for armed forces and medical clinics and hospitals.

TECHNOLOGY:

The VS employs atomic force microscopy to measure height and morphology of virus particles captured by qualified ligands (immunoglobins, aptomers, etc.). Qualified ligands include those having the ability to bind to intact virus particles and with little or no binding to disrupted virus subcomponents or peptides. Microfluidics and micron-sized multiplexed capture domains arrayed in specific patterns by a NanoEnabler permit specificity and sensitivity. Readouts will be by a hand-held atomic force microscope with data management by internal computer software.

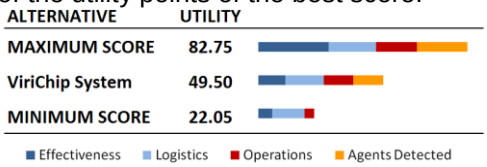
ANALYTICAL Laboratory Ranking

ViriChip System ranked in the middle third of all evaluated products for analytical laboratories and earned 57% of the utility points of the best score.



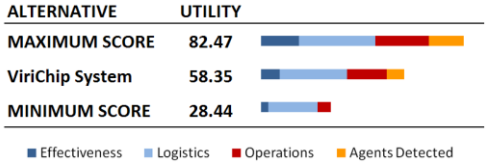
DIAGNOSTIC Laboratory Ranking

ViriChip System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 60% of the utility points of the best score.



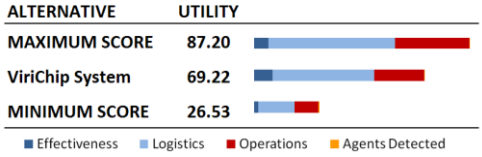
MOBILE Laboratory Ranking

ViriChip System ranked in the middle third of all evaluated products for mobile laboratories and earned 71% of the utility points of the best score.



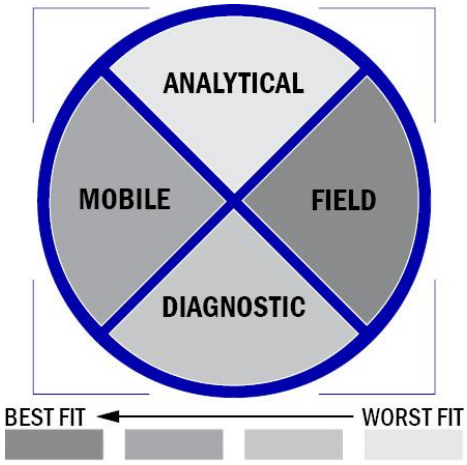
FIELD USE Ranking

ViriChip System ranked in the middle third of all evaluated products for field use and earned 79% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

BioForce Nanosciences
609 East Lincoln Way
Ames, Iowa 50010
515-233-8333
info@bioforcenano.com

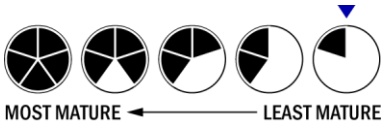
Point of Contact:
Dr. Johnson
515-233-3257

COST

- $35,000.00 - 45,000.00/system or device

SPECIFICITY

- False Positives: Less than 2%
- False Negatives: Less than 1%



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 15 - 30 minutes for detection
- 1 sample, <10 tests/ sample per run
- Could easily be adapted into a fully automated system

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- An afternoon of training and some technical skills required
- <5 minutes set-up required
- Almost instantaneous down time
- 0-2 steps required
- Web-based video

Operational conditions:
- Can be used from 4°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for <24 hours/ Must be stored at 4°C
- Performance is not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 1 and 5 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service less than once a year
- Preventive maintenance serviceable by customer
- Maintenance inclusion TBD
- Expected life 5-10 years
- 5-10 minutes QA required
- Hazardous agent is isolated to discrete elements and/or decon requires up to one hour

Physical System Requirements:
- No electrical requirement
- 2-4 hours battery life
- Requires water aliquots
- External air or gas source required
- External vacuum source not required

Ease of Use:
- Real-time results not available
- Data processing while in progress not applicable
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 10 ul to test liquids

System Maturity:
- White board
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property owned

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Wireless and wired connections
- Not autonomous
- On board computer chip
- Could be adapted to store and archive data outputs and create electronic record
- Software closed , not available for modification
- Hardware closed not available for modification

Voice200

by Syft Technologies, Inc.

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Demonstrated:
Urine, Environmental air

DESCRIPTION:

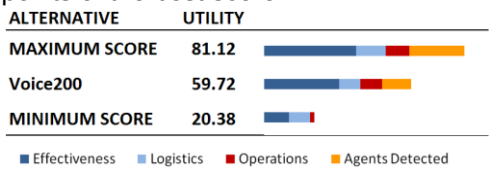
The Voice200 is a Selected Ion Flow Tube Mass Spectrometer designed for both lab use and first responder use. It can measure TICs, TIMs, Explosives, CWAs, as whole air, breath and head space analysis down to parts per trillion ranges with little or no sample prep and in Real Time.

TECHNOLOGY:

Voice200 takes ionized air through upstream quadrupole and filters all but H3O+, NO+ and O2+ ions which are sequentially mounted to flow tube every 20 milliseconds where the ions react with the analyte in a soft chemical first order reaction. The reaction products enter a downstream quadrupole where they are filtered again before being detected by a particle counter. The results are quantified in Real Time. The system can differentiate all isobars and some isomers, based on the use of the three precursor ions. Both SIM and Scan modes are possible and system can be operated by non-scientific operator.

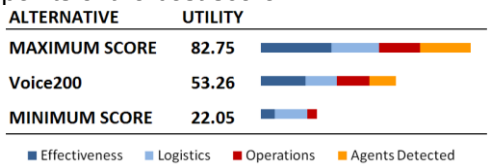
ANALYTICAL Laboratory Ranking

Voice200 ranked in the top third of all evaluated products for analytical laboratories and earned 74% of the utility points of the best score.



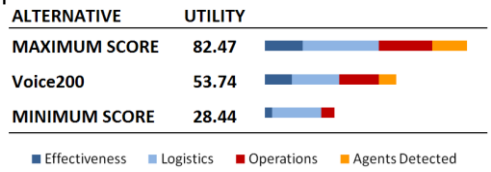
DIAGNOSTIC Laboratory Ranking

Voice200 ranked in the middle third of all evaluated products for diagnostic laboratories and earned 65% of the utility points of the best score.



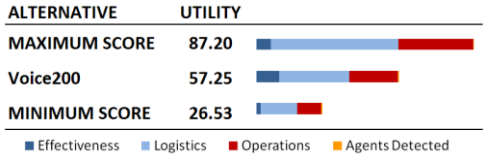
MOBILE Laboratory Ranking

Voice200 ranked in the middle third of all evaluated products for mobile laboratories and earned 64% of the utility points of the best score.



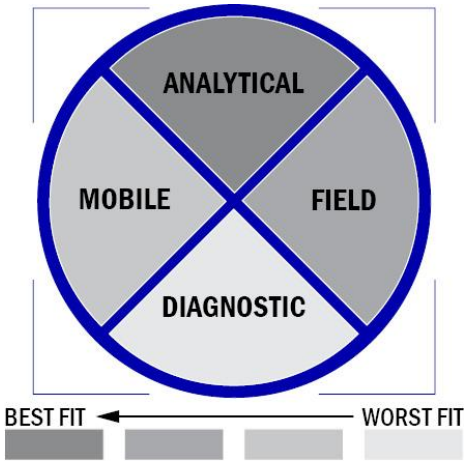
FIELD USE Ranking

Voice200 ranked in the middle third of all evaluated products for field use and earned 66% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Syft Technologies, Inc.
1525 Park Manor Blvd, Suite 272
Pittsburgh, PA 15205

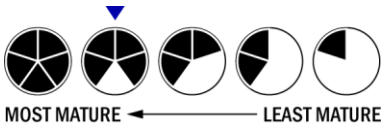
Point of Contact:
Wesley Kenneweg
412-996-5915

COST

- $225,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/ sample per run
- Fully automated

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- Very brief (minutes-hours) training and minimal technical skills
- 10-20 minutes set-up
- Almost instantaneous down time
- 0-2 steps required
- Customer site training

Operational conditions:
- Can be used from 4°C to 37°C
- Does not require consumables
- Performance is not influenced by relative humidity
- No consumables required

Transportation:
- Approximately the size of a home dishwasher
- All modes of transportation
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- 2 components

Maintenance:
- Service every 6 months
- Preventive maintenance serviceable by technician only
- Maintenance not included
- Expected life 5-10 years
- <5 minutes daily QA
- Exposure to hazardous agent would require up to 1 day to decontaminate

Physical System Requirements:
- 220V electrical requirement
- Not portable
- Requires water aliquots
- External air or gas source required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 250 ul to test liquids

System Maturity:
- Is commercially available
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single positive or negative response generated
- Network capable
- Satellite, wireless and wired connections
- Fully autonomous
- No computer required
- Stores and archives data outputs and creates an electronic record
- System software is open but modification requires licensing
- System hardware is open but modification requires licensing

Warlock

by Pacific Advanced Technology

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Demonstrated:
Environmental air

DESCRIPTION:

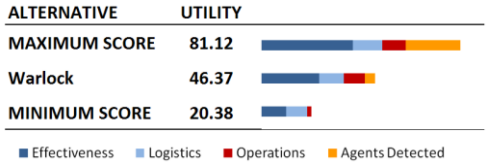
The Warlock was designed to detect contaminated surfaces with chemical agents as well as remotely detecting chemical agent and biological agents that have been aerosolized and dispersed in the atmosphere. The Warlock can be used both in the field and in a laboratory environment to analysis chemical and biological warfare agents. The system is versatile and adaptive for many applications within the Chemical and Biological agent warfare. The Warlock is an imaging spectrometer that operates in the short, mid and long-wave infrared to give the operator an image of the chemical or biological agent on a surface or in a cloud that has been dispersed at an extended range up to many kilometers.

TECHNOLOGY:

The Warlock is based on an embedded diffractive optical assembly that images in many spectral bands creating an hyper-spectral data cube. Using any number of software tools, some provided with the Warlock and other typical used by the Hyper-spectral community, allows for analysis of the spectral of any object in the field of view of the camera. Various algorithms can be implemented in real-time in an embedded processor in the Warlock or in post processing using PC computers.

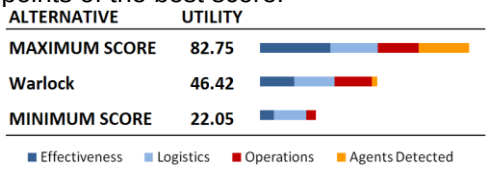
ANALYTICAL Laboratory Ranking

Warlock ranked in the middle third of all evaluated products for analytical laboratories and earned 57% of the utility points of the best score.



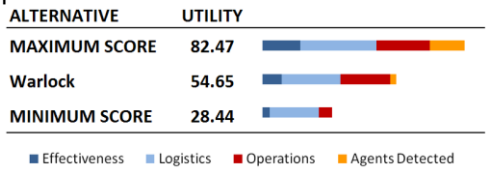
DIAGNOSTIC Laboratory Ranking

Warlock ranked in the middle third of all evaluated products for diagnostic laboratories and earned 56% of the utility points of the best score.



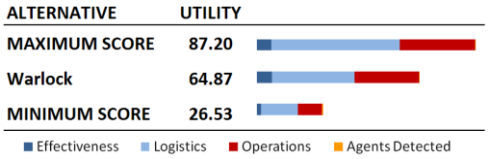
MOBILE Laboratory Ranking

Warlock ranked in the middle third of all evaluated products for mobile laboratories and earned 66% of the utility points of the best score.



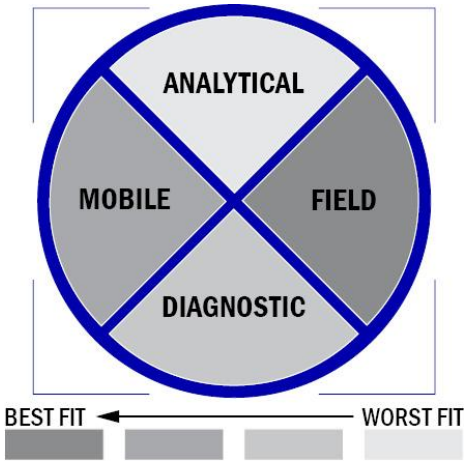
FIELD USE Ranking

Warlock ranked in the middle third of all evaluated products for field use and earned 74% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Pacific Advanced Technology
2029 Village Lane, Suite 202
PO Box 140
Solvang, CA 93464-0140

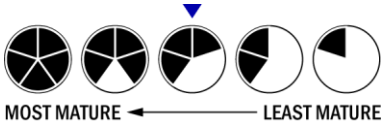
Point of Contact:
Michele Hinnrichs
805-688-2688

COST

- $ 150,000.00/system or device

SPECIFICITY

- False Positives: Unknown
- False Negatives: Unknown



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- Multiple samples, multiple tests/sample per run
- Adaptable into a fully automated system

Signature:
- Sounds or alarms present
- Screen can be dimmed or turned off
- Between 200-500 BTU/hour

Training and Speed:
- Day of training and technical skills required
- 5-10 minutes required for set-up
- Almost instantaneous down time
- 0-2 steps are required
- Manufacturer site training

Operational conditions:
- Can be used from -21°C to 41°C
- Components should be stored at room temp but can withstand temps in excess of 45°C for less than 24 hours
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life

Transportation:
- Approximately the size of carry-on suitcase
- All means of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0-1 solutions, buffer, and/or reagents
- No additional consumables

Maintenance:
- No service required
- No preventive maintenance
- Maintenance not included
- Expected life 5- 10 years
- No daily QA necessary
- Device decontamination methods unknown

Physical System Requirements:
- 4-8 hours battery life
- Portable
- Does not require water
- External air or gas source not required
- External vacuum not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps required
- No shaking or vortexing, mixing, degassing or filtering step required
- Software could call final result in future

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Less than 10 ul for a test

System Maturity:
- Brass board
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property is owned

Interoperability and System Complexity:
- < 100 GB or single response generated
- Network capable
- Wired connection
- Could be autonomous with some effort
- Laptop computer needed
- Stores and archives data outputs and creates electronic records
- System software open but mods require licensing
- System hardware open but mods require licensing

Water Testing Kit NBC Defense

by Sigma-Aldrich GmbH

DETECTS THE FOLLOWING:

Nothing demonstrated.

DETECTION MATRICES:

Demonstrated:
Environmental water

DESCRIPTION:

The German Armed Forces searched for a possibility to analyze potable water under field conditions and we had the opportunity to develop a kit for this purpose. The result of our development was a set of three cases, which can be handled by a single person. Two cases are dedicated to check standard parameters of potable water like pH, conductivity, Nitrate, Nitrite, Chlorine, etc. The third case contains tests to analyze water on different Chemical Warfare Agents. With this test kit it is possible to check raw water and potable water according to the limits of the German Drinking Water Ordinance and STANAG 2136 med. Since 2006 the German Armed Forces uses this kit to check the quality of raw water and potable water together with their water purifications systems. The features of this kit are: - Robustness of all materials (Technical robustness) - The test kit can be used in any environment (cold or hot; day or night). - Robustness of the tests (Analytical robustness) - Tests can be performed by anyone after short instructions - Tests can be performed with protective gear.

TECHNOLOGY:

We use simple and robust test which allow to analyze water in any environment. No need to cool reagents or any other special measure. Most test are photometric tests. The analyte reacts with a reagent which results in a color change which can be quantified by a photometer. The test on Nerve Agents is done by inhibition of Acetyl Choline esterease by nerve agents or other ACE inhibitors. The enzyme is stable at room temp and for a few days even at elevated temp.

ANALYTICAL Laboratory Ranking

Water Testing Kit NBC Defence ranked in the bottom third of all evaluated products for analytical laboratories and earned 48% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	81.12
Water Testing Kit NBC Defence	38.80
MINIMUM SCORE	20.38

Effectiveness Logistics Operations Agents Detected

DIAGNOSTIC Laboratory Ranking

Water Testing Kit NBC Defence ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 53% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.75
Water Testing Kit NBC Defence	43.45
MINIMUM SCORE	22.05

Effectiveness Logistics Operations Agents Detected

MOBILE Laboratory Ranking

Water Testing Kit NBC Defence ranked in the middle third of all evaluated products for mobile laboratories and earned 63% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	82.47
Water Testing Kit NBC Defence	51.89
MINIMUM SCORE	28.44

Effectiveness Logistics Operations Agents Detected

FIELD USE Ranking

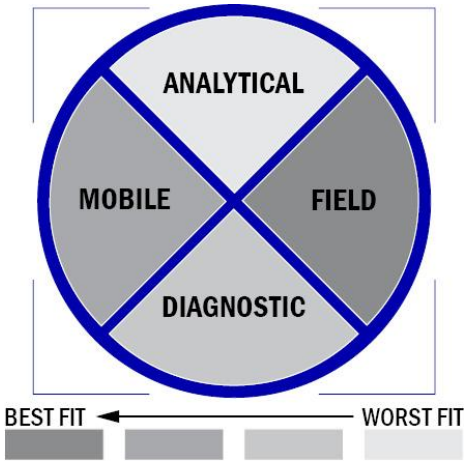
Water Testing Kit NBC Defence ranked in the middle third of all evaluated products for field use and earned 69% of the utility points of the best score.

ALTERNATIVE	UTILITY
MAXIMUM SCORE	87.20
Water Testing Kit NBC Defence	59.94
MINIMUM SCORE	26.53

Effectiveness Logistics Operations Agents Detected

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Sigma-Aldrich GmbH
Industriestrasse 25
CH-9470 Buchs (SG), Switzerland

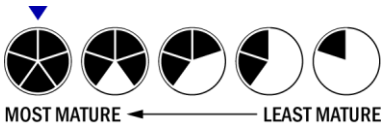
Point of Contact:
Gerd Hayenga
gerd.hayenga@sial.com

COST

- $35,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 - 15 minutes for detection
- 1 sample, >10 tests/ sample per run
- Not amenable to full or semi-automation

Signature:
- Sounds or alarms not present
- No screen
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- No set-up required
- Almost instant down time
- 3-5 steps required
- Customer site training/ Hard-copy operators manual

Operational conditions:
- Can be used from -21°C to 41°C
- Components should be stored at room temp but can stand temps >45°C for < 24 hours
- Performance not influenced by relative humidity
- Between 1-3 years shelf life

Transportation:
- Approximately the size of dishwasher
- Transport via tactical military wheeled and tracked vehicle/ Fixed wing military and rotary wing aircraft/ Ship transport
- Weighs more than 50 kg

Re-use:
- Multiple detection assays
- 5 or more solutions
- All components included

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Preventive maintenance not included
- Expected life 5-10 years
- No daily QA required
- Hazardous agent would require up to 4 hours to decon

Physical System Requirements:
- 4-8 hours battery life
- Does not require water
- External air or gas source not required
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering step
- System does not call final result

Sensitivity and Detection:
- 510K clearance not applicable
- FDA clearance not applicable
- Greater than 250 ul required for test

System Maturity:
- Is commercially available and meets mil specs
- Has not appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property licensing not involved

Interoperability and System Complexity:
- Raw data size information not available
- Not network capable
- Fully autonomous
- No computer required
- Stores and archives data outputs and creates electronic records
- System software is open and available for modification
- System hardware is open and available for modification

zNose

by Electronic Sensor Technology

DETECTS THE FOLLOWING:

Demonstrated:
Bacteria (10e3-10e4 CFU/mL)
Aerosolized chemical agent (< 0.000001 mg/m3)
Liquid chemical agent (100 ppm – 1 ppt)

DETECTION MATRICES:

Demonstrated:
Environmental air, Environmental water, Soil, Food, Powder, Insect vectors

DESCRIPTION:

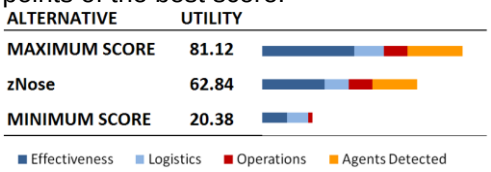
The zNose is an ultra fast portable GC with part-per-trillion, pico gram mass sensitivity which can be networked into any reporting system. Tests including vapor sample, data analysis and instrument reset are less than one minute as well as operated remotely. A handheld pocket accessory provides the ability to collect samples anywhere. Rapid detection of chemical and biological threats include but are not limited to TATP, C-4 taggant, DMNB taggant, 3-MNT taggant, 4-MNT taggant, HMX,ANFO,DETA SHEET, TNT,DNT,RDX, PETN, Tetryl, NG, Sarin, Tabun, Soman,VX, Sulphur Mustard, Methyl Salicylate and Chloroacetophenone and more.

TECHNOLOGY:

The instrument utilizes an ultra fast GC system with a hydrocarbon spectrum analyzer C4-C22, an integrated vapor preconcentrator, a solid state detector with electronically variable sensitivity and long term stability. The detector head is 5.7 pounds.

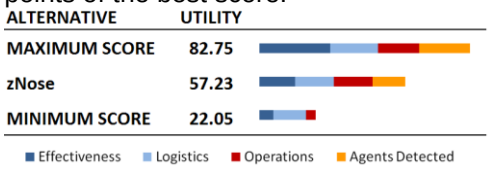
ANALYTICAL Laboratory Ranking

zNose ranked in the top third of all evaluated products for analytical laboratories and earned 77% of the utility points of the best score.



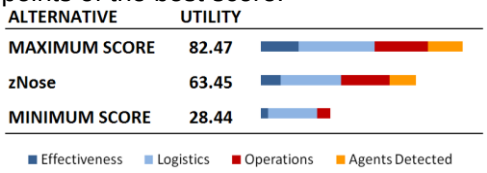
DIAGNOSTIC Laboratory Ranking

zNose ranked in the top third of all evaluated products for diagnostic laboratories and earned 69% of the utility points of the best score.



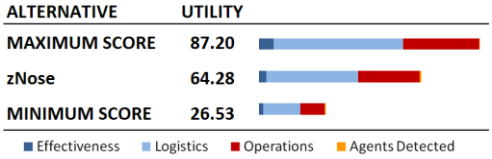
MOBILE Laboratory Ranking

zNose ranked in the top third of all evaluated products for mobile laboratories and earned 77% of the utility points of the best score.



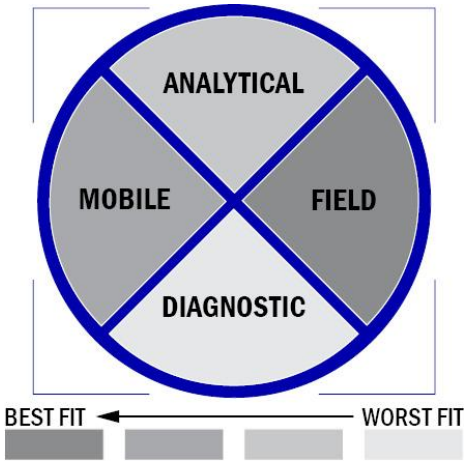
FIELD USE Ranking

zNose ranked in the middle third of all evaluated products for field use and earned 74% of the utility points of the best score.



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Summary of Analysis



CONTACT INFORMATION

Electronic Sensor Technology
1125-B Business Center Circle
Newbury Park, CA 91320

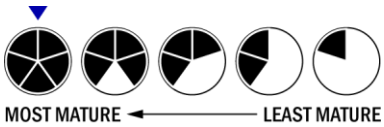
Point of Contact:
Marlene Stewart
805-214-6091
mstewart@estcal.com

COST

- $30,000.00/system or device

SPECIFICITY

- False Positives: Information not available
- False Negatives: Information not available



Evaluation Criteria Provided by Vendor

Throughput of Product:
- 2 minutes or less for detection
- 1 sample, single test/sample per run
- Could easily be adapted into a fully automated system

Signature:
- Sounds or alarms not present
- Screen can be dimmed or turned off
- Less than 200 BTU/hour

Training and Speed:
- Very brief (mins-hours) training and minimal technical skills
- 10-20 minutes set-up
- Almost instantaneous down time
- 0-2 steps required
- DVD/ Web video/ Customer and manufacturer site training/ Hard-copy and web manual

Operational conditions:
- Used from < -21°C to > 42°C
- Does not require consumables
- Performance is not influenced by relative humidity
- Shelf life not applicable

Transportation:
- Approximately the size of a toaster
- All modes of transportation
- Weighs between 5 and 25 kg

Re-use:
- Multiple detection assays
- 0 solutions, buffers, and/or reagents
- 0 components

Maintenance:
- Service once a year
- Preventive maintenance serviceable by customer
- Maintenance not included
- Expected life >10 years
- >5 minutes QA required
- Decon would take less than one hour

Physical System Requirements:
- No electrical requirement
- 6-8 hours battery life
- Does not require water
- Uses helium canister in unit or can be external supply
- External vacuum source not required

Ease of Use:
- Real-time results available
- Data can be processed while in progress
- No centrifugation steps
- No shaking or vortexing, mixing, degassing or filtering steps
- System calls final result

Sensitivity and Detection:
- 510K clearance information not available
- FDA clearance information not available
- Less than 10 ul to test liquids

System Maturity:
- Is commercially available and meets mil specs
- Has appeared in peer reviewed publication or independent evaluation
- Technology ownership and intellectual property owned

Interoperability and System Complexity:
- < 100 GB or single pos or neg response generated
- Network capable
- Wireless, wired connections
- Could easily be fully autonomous system
- On board computer chip
- Stores and archives data outputs and creates an electronic record
- Software open, available for modification
- Hardware open, available for modification

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Appendix I:
Weighted Questions

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Weighted Survey Questions

1. Throughput of Product

1.1. Given a test sample that has not undergone refinement or unique sample preparation, how many minutes would it take to perform a detection assay from start to finish on that sample?

100 2 minutes or less
80 Between 2 and 15 minutes
60 Between 15 and 30 minutes
40 Between 30 and 60 minutes
20 Between 60 minutes and 8 hours
0 Greater than 8 hours

1.2. What best describes the maximum number of detection assays or individual tests the system or device can analyze per run with a single operator?

100 Multiple samples, multiple tests/ sample per run
75 Multiple samples, single tests/ sample per run
50 1 sample, >10 tests/ sample per run
25 1 sample, <10 tests/ sample per run
0 1 sample, single test/ sample per run

1.3. Given a collected sample that has not undergone any sample preparation, what is the most appropriate statement concerning the level of automation of the system or the potential for automation? (Full automation assumes no human interface once the sample run has been initiated while semi-automated assumes that a limited amount human interface is necessary during the sample testing.)

100 The system or device is currently fully automated
80 The system or device is currently semi-automated
60 The system could easily be adapted into a fully automated system
40 The system could be adapted to a fully automated system with some effort
20 The system could be adapted to a semi-automated system with some effort
0 The system or approach is not amenable to full or semi-automation

2. Signature

2.1. Are there sounds, alert tones, or alarms that the detection device or system produces that cannot be deactivated?

100 No
0 Yes

2.2. Is the visualization screen able to be dimmed or turned off?

100 Yes
0 No
- There is no screen on this device

2.3. What is the thermal output of the system in British Thermal Units (BTU)/hour?

100	Less than 200 BTU/hour
50	Between 200-500 BTU/hour
0	Greater than 500 BTU/hour

3. Training

3.1. What best describes the training necessary for operation of the detection device or system?

100	Very brief (minutes-hours) training and minimal technical skills
70	An afternoon of training and some technical skills required
40	A day of training and technical skills are required
0	More than a day of training and significant technical skills are required

3.2. Please indicate which methods are currently available for training users on the operation of this device: (Answers not scored because this question did not factor into the analysis.)

Compact disk or DVD
Web-based video
Customer site training
Manufacturer site training
Hard-copy operators manual manuscript
Web-based operators manual manuscript

4. Speed

4.1. What is the average time to set-up, perform instrument warm-up, or allow the system to auto-calibrate (*if required*) before the device or system is ready to begin testing?

100	No set-up of the system is required
75	Less than 5 minutes is required
50	5-10 minutes is required
25	10-20 minutes is required
0	Greater than 20 minutes is required

4.2. During system operation, what is the down time (clear and reboot time) between the end of an analytical run and the beginning of the next analytical run?

100	Almost instantaneously
90	< 1 minute
75	1-3 minutes
50	3-5 minutes
0	< 5 minutes

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

4.3. Given a sample, which of the following is an appropriate statement regarding the number of manual steps required to perform a single detection assay of one sample (e.g., air sampling, vortexing, heating, washing, degassing etc.)?

100 0-2 steps are required
75 3-5 steps are required
50 6-8 steps are required
25 9-12 steps are required
0 Greater than 12 steps are required

5. Operational Conditions

5.1. What is the suggested temperature range that the detection device or system be operated within?

100 Can be used from < -21°C to > 42°C (All temperatures)
75 Can be used from -21°C to 41°C
50 Can be used from 4°C to 41°C
25 Can be used from 4°C to 37°C
0 Can be used from 25°C to 37°C

5.2. What are the temperature storage requirements of the consumable components? (More than one box can be selected in response to this question). (Answers not scored because this question did not factor into the analysis.)

Components should be stored at room temperature but can withstand temperatures in excess of 45°C for periods of less than 24 hours
Components should be stored frozen but can with stand temperatures in excess of 4°C for periods of less than 24 hours
Components must be stored at room temperature (27°C)
Components must be stored at 4°C
Components must be frozen
Components must be frozen at temperatures at or below -20°C (cryo-storage)
This system does not require consumables

5.3. Assuming that the average relative humidity of an indoor laboratory is between 35 to 40 percent, would deviations outside of that range impact the performance of the detection device or system?

100 No, performance is not influenced by relative humidity
30 Yes, device or system has peak performance at normal relative humidity conditions
0 Device must be used in a temperature stable, dry environment for optimum performance
0 Unknown

5.4. When stored at the recommended storage conditions, what is the shelf life of the system reagents or test kits?

100 Greater than 3 years
75 Between 1 to 3 years
30 Between 6 months and 1 year
15 Between 1 to 6 months
0 Less than 1 month

6. Mobility

6.1. What are the dimensions (footprint) of the detection device or system? This includes associated computers or other devices required to enable the system to function.

100 Approximately the size of a soda can
80 Approximately the size of a toaster
40 Approximately the size of a carry-on luggage suitcase
0 Approximately the size of a home dishwasher
0 Larger than a home dishwasher

6.2. Please choose the best response(s) in regards to the ability of the system to withstand transportation when properly packaged according to manufacturer's instructions? If desired feel free to identify transportation (shock, vibration, dust, water resistance) compliance testing in the Additional Comments section (below). (Answers not scored because this question did not factor into the analysis.)

Suitable for transport via commercial carrier such as tractor trailer on paved roads
Suitable for transport via tactical military wheeled and tracked vehicle
Suitable for transport via fixed wing military aircraft
Suitable for transport via rotary wing aircraft
Suitable for transport via ship transport

6.3. What is the weight of the detection device or system? (Including any necessary equipment such as adapters, computers, controllers, cables and carrying cases required for transportation.)

100 Less than 1 kg
90 Between 1 and 5 kg
50 Between 5 and 25 kg
25 Between 25 and 50 kg
0 More than 50 kg

6.4. Choose the answer that best represents the system's ability to connect with and transmit data to DoD data networks.

100 Satellite, wireless and wired connections are available
75 Satellite and wired connections are available
50 Wireless and wired connections are available
25 Wired connections are available
0 This system is not capable of transmitting data

6.5. Please describe the computing power necessary to operate and return a response for the system:

0 High end desktop computer
0 Basic desktop computer
20 Laptop computer
80 On board computer chip in the system
100 No computational power needed

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

7. Re-Use

7.1. Is the detection device or system disposable or designed for single use? (Answers not scored because this question did not factor into the analysis.)
Device or system is designed for a single use.
Device or system is intended for multiple detection assays.

7.2. What is the total number of solutions or buffers (NOT INCLUDING WATER) that are used in the detection device or system? If the system currently has freeze-dried assays or can combine master mixes then score your system as though it has been done in that manner, that each master mix constitutes one solution or buffer.

100	0-1 solutions or buffer
80	2 solutions or buffers
60	3 solutions or buffers
30	4 solutions or buffers
0	More than 4 solutions or buffers

7.3. Not including the buffers or solutions, what is the total number of additional consumables (such as tubes, lids, gases etc.) required per assay in your device or system? This includes all the consumables required for sample preparation and analysis.

100	1 component
80	2 components
60	3 components
30	4 components
0	5 or more components

8. Maintenance

8.1. How often does the device or system need to be serviced?

100	Never
75	Less than once a year
50	Once a year
25	Every 6 months
0	More often than every 6 months

8.2. Please choose the most appropriate response in regards to preventative maintenance:

100	Preventive maintenance serviceable by customer
0	Preventive maintenance serviceable by service technician only
-	Not applicable to this system

8.3. Is preventive maintenance included in the warranty by the manufacturer or is a service agreement required?

100	Yes it is included
0	No it is not included

8.4. If not disposable or single use, what is the expected life of the device or system? (Assuming the regular manufacturer suggested maintenance is performed.)

100 Greater than 10 years
90 5-10 years
60 3-5 years
30 1-3 years
0 Less than 1 year
- Unknown
- Not applicable

8.5. What is the average time for performing daily quality assurance procedures on the device or system?

100 No daily quality assurance procedures necessary
75 Less than 5 minutes required
50 5 to 10 minutes required
25 10 to 20 minutes required
0 Greater than 20 minutes required

8.6. Consider a situation in which during analysis of a test sample an accident occurs resulting in minor contamination of the area where sample is introduced into the device. Choose the best response in regards to the ability to decontaminate the device following that exposure to hazardous agent?

100 Hazardous agent is isolated to discrete elements and/or decontamination requires up to one hour
80 Exposure to hazardous agent would require up to 4 hours to decontaminate
60 Exposure to hazardous agent would require up to 1 day to decontaminate
40 Exposure to hazardous agent would require greater than 2 days to decontaminate
0 It likely that exposure to hazardous agent cannot be decontaminated
- The device is single use and disposable so no decontamination is needed

9. Physical System Requirements

9.1. What is the electrical requirement for the detection device or system NOT including other equipment needed (e.g., centrifuge, shaker, laptop)?

100 There is no electrical requirement
90 System or device uses batteries
40 System or device has 110V electrical requirement
30 System or device has 220V electrical requirement
10 System or device has a greater than 220V electrical requirement
0 System or device requires multiple outlets or a dedicated circuit breaker

9.2. If the system is designed for portable use, how long can it operate on battery power while performing analyses?

50 <1 Hour
70 1 – 2 Hours
90 2 – 4 Hours
100 4 – 8 Hours
- Not intended for portable use

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

9.3. Are there water requirements for the device or system?
100 The device or system does not require water
30 The device or system requires water aliquots
0 The device or system requires a continual supply of water

9.4. Are there air or gas requirements of the device or system?
100 The device or system does not require an external air or gas source
25 The device or system requires an external air source
15 The device or system requires an external gas source
0 The device or system requires both an external air and gas source

9.5. Is an external vacuum source required for the operation of the device or system?
100 No
0 Yes

10. Ease of Use

10.1. Can the operator view results during a run in "real-time"?
100 Yes
0 No

10.2. If the answer to the above is "yes", can the operator process data from an analysis that is currently in progress?
100 Yes
0 No

10.3. Given a raw sample, are there any centrifugation steps during sample preparation which are required for detection?
100 There are no centrifugation steps required
40 There is a single centrifugation step required
0 There are multiple centrifugation steps required

10.4. Given a sample, are there any shaking or vortexing, mixing, degassing, or filtering steps required in sample preparation?
100 There are no shaking or vortexing, mixing, degassing or filtering steps required
40 There is a single shaking or vortexing, mixing, degassing or filtering step required
0 There are multiple shaking or vortexing, mixing, degassing or filtering steps required

10.5. Will the system interpret raw data or call a positive or a negative result through internal software?
100 This capability is currently available
40 This capability could be developed in the future
0 This system is not amenable to his capability

11. Sensitivity and Detection

11.1. Have any of the system assays sought or received 510K clearance?
100 Shown
80 Pending
40 Capable
0 Incapable
- Not Applicable to this system

11.2. Have any of the system assays received FDA approval?
100 Shown
80 Pending
40 Capable
0 Incapable
- Not Applicable to this system

11.3. Given a collected liquid sample that has not undergone any sample preparation, what is the volume of the sample required to run an individual test for the detection device or system?
100 Less than 10 ul
80 Less than 50 ul
60 Less than 100 ul
30 Less than 250 ul
0 Greater than 250 ul
- This system does not test liquids

11.4. When the system is being employed as optimally designed what is the percentage (%) of false positives and false negative test events? (Answers not scored because this question did not factor into the analysis.)
False Positives
False Negatives
Comments

11.5. Given a sample of bacterial agent in phosphate buffered saline, please choose the approximate sensitivity or limit of detection of your system.
100 1-100 colony forming units (CFU) per ml of original sample
80 100-1,000 CFU per ml of original sample
60 1,000-10,000 CFU per ml of original sample
30 10,000-100,000 CFU per ml of original sample
0 Greater than 100,000 CFU per ml of original sample
- Not applicable to this system

11.6. Given a sample of viral agent in phosphate buffered saline, please choose the approximate sensitivity or limit of detection of your system.
100 1-100 plaque forming units (PFU) per ml of original sample
80 100-1,000 PFU per ml of original sample
60 1,000-10,000 PFU per ml of original sample
30 10,000-100,000 PFU per ml of original sample
0 Greater than 100,000 PFU per ml of original sample
- Not applicable to this system

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

11.7. Given a sample of toxin in phosphate buffered saline, please choose the approximate sensitivity or limit of detection of your system.

100	less than 1 nanogram (ng) per ml
90	1-100 nanograms (ng) per ml
80	100-1,000 ng per ml
60	1,000-10,000 ng per ml
30	10,000-100,000 ng per ml
0	Greater than 100,000 ng per ml
-	Not applicable to this system

11.8. Given a sample of vaporous chemical agent in air, please choose the approximate sensitivity or limit of detection of your system.

100	< 0.000001 mg/m3
80	0.000001-0.00003 mg/m3
60	0.00003-0.0001 mg/m3
30	0.0001 – 0.001 mg/m3
0	0.001 – 0.1 mg/mg3
-	Not applicable to this system or device

11.9. Given a liquid sample of chemical agent, please choose the approximate sensitivity or limit of detection of your system.

100	< 1 part per billion (ppb)
80	1 ppb – 1 part per million (ppm)
60	1 ppm – 100 ppm
30	100 ppm – 1 part per thousand (ppt)
0	> 1 ppt
-	Not applicable to this system or device

12. Versatility Of Sample Input

12.1. Can the system identify agents in blood samples?

100	Demonstrated
80	Pending
40	Capable
0	Incapable
-	Not Applicable to this system

12.2. Can the system identify agents in nasal and throat swab samples?

100	Demonstrated
80	Pending
40	Capable
0	Incapable
-	Not Applicable to this system

12.3. Can the system identify agents in stool samples?

100	Demonstrated
80	Pending
40	Capable
0	Incapable
-	Not Applicable to this system

12.4. Can the system identify agents in urine samples?

100	Demonstrated
80	Pending
40	Capable
0	Incapable
-	Not Applicable to this system

12.5. Can the system identify agents in patient wound samples?

100	Demonstrated
80	Pending
40	Capable
0	Incapable
-	Not Applicable to this system

12.6. Can the system identify agents in environmental air matrices?

100	Demonstrated
80	Pending
40	Capable
0	Incapable
-	Not Applicable to this system

12.7. Can the system identify agents in environmental water samples?

100	Demonstrated
80	Pending
40	Capable
0	Incapable
-	Not Applicable to this system

12.8. Can the system identify agents in environmental soil samples?

100	Demonstrated
80	Pending
40	Capable
0	Incapable
-	Not Applicable to this system

12.9. Can the system identify agents in food samples?

100	Demonstrated
80	Pending
40	Capable
0	Incapable
-	Not Applicable to this system

12.10. Can the system identify agents in powder samples?
- 100 Demonstrated
- 80 Pending
- 40 Capable
- 0 Incapable
- - Not Applicable to this system

12.11. Please choose the best response in regards to the lysis of spores by the device or system?
- 100 Spore lysis not necessary for detection by system
- 90 Fully automated spore lysis
- 70 Semi-automated spore lysis
- 50 Add on capability that is full or semi-automated for spore lysis
- 25 Manual kit not integrated with the system handles spore lysis
- - System does not detect spores

12.12. Can the system identify agents in insect, and other arthropod vector samples?
- 100 Demonstrated
- 80 Pending
- 40 Capable
- 0 Incapable
- - Not Applicable to this system

12.13. Can the system identify bacteria?
- 100 Demonstrated
- 70 Capable
- 0 Incapable
- - Not Applicable to this system

12.14. Can the system identify viruses?
- 100 Demonstrated
- 70 Capable
- 0 Incapable
- - Not Applicable to this system

12.15. Can the system identify toxins?
- 100 Demonstrated
- 70 Capable
- 0 Incapable
- - Not Applicable to this system

12.16. Can the system identify aerosolized nerve agent?
- 100 Demonstrated
- 70 Capable
- 0 Incapable
- - Not Applicable to this system

12.17. Can the system identify liquid nerve agent?
- 100 Demonstrated
- 70 Capable
- 0 Incapable
- - Not Applicable to this system

12.18. Can the system identify radioisotopes in tissue or biological damage caused by radioisotopes?
100 Demonstrated
70 Capable
0 Incapable
- Not Applicable to this system

12.19. Does the system discriminate between radiation types (e.g. alpha, beta, gamma, neutron, etc)?
100 Yes
0 No

12.20. Does the system identify specific isotopes?
100 Yes
0 No

13. System Maturity

13.1. What best describes the maturity of the detection device or system?
100 Is commercially available and meets military specifications
75 Is commercially available
50 A few devices or systems exist (brass board)
25 Only one incomplete device or system exist (bread board)
0 Only a concept on paper exists (white board)

13.2. If you answered question 68 with c, d, or e, please estimate the detection system's timeframe to commercialization (release to the commercial market)?
100 Is expected to be ready for commercialization within one calendar year
50 Is expected to be ready for commercialization within two calendar years
0 Is expected to be ready for commercialization within three or more calendar years

13.3. If you answered question 68 with c, d, or e, please estimate the level of further investment required to advance the system or device to the point where it is ready for commercialization.
100 None – it is ready for commercialization
75 < $1,000,000
50 $1,000,000 - $2,000,000
0 > $2,000,000

13.4. Has your detection system or device been featured in any peer reviewed scientific publication or independent evaluation?
100 Yes
0 No

13.5. Please choose the best response in regards to the technology ownership and intellectual property of the device or system?
100 The technology ownership and intellectual property is owned
75 The technology ownership and intellectual property is fully licensed
40 The technology ownership and intellectual property licensing is pending
0 The technology ownership and intellectual property licensing is not possible
- There is no technology ownership and intellectual property involved

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

14. Interoperability and System Complexity

14.1. Please choose the appropriate response in the amount of raw data generated from a single analytical run when fully loaded to capacity:
100 > 250 GB
75 200-249 GB
50 150-199 GB
25 100-149 GB
0 < 100 GB or single positive or negative response generated

14.2. Network readiness: is the system designed to be a part of a network and share data among other systems?
100 Yes
0 No

14.3. Can the system be autonomous, run remotely with no direct contact?
100 The system or device is currently fully autonomous
75 The system could easily be adapted into a fully autonomous system
50 The system could be adapted to a fully autonomous system with some effort
25 The system could be adapted to a fully autonomous system with significant effort
0 The system is not capable of autonomy

14.4. Can the system store and record data output from the device or system?
100 The system automatically stores and archives data outputs and creates an electronic record
75 The system will store and archive data outputs but not create an electronic record
50 The system will not store and archive data outputs but will create an electronic record
25 The system could be adapted to store and archive data outputs and create an electronic record
0 The system does not contain internal memory for data storage or electronic record keeping.

14.5. Please choose the most appropriate response in regards to whether your system software is open or closed:
100 The system software is open and available for modification
50 The system software is open but modification requires licensing
0 The system software is closed and not available for modification
- The system does not employ any software

14.6. Please choose the most appropriate response in regards to whether your system hardware is open or closed:
100 The system hardware is open and available for modification
50 The system hardware is open but modification requires licensing
0 The system hardware is closed and not available for modification
- The system is single use or this question does not apply to this device

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Appendix II:
Full System Rankings

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Biological Specific Systems – Field Use

Home Healthcare Diagnostics	85.05
NIDS Medical Reader System	84.27
uScope MX - POC Diagnostics	83.78
Mobile Laboratory	83.60
T2Dx	82.29
AIDA	80.20
TAC-BIO / I-Collector	80.08
TIRF Sense Handheld	80.02
CDS-100	79.15
Intelliprobe TM	79.06
MULTIPLEXED PATHOGEN DETECTION	78.83
Nanosecond X-Ray Detector	78.82
TIRF Sense Portable	78.39
MSA Biosensor 2200R	78.27
MSA BIOSENSOR 4000	78.06
LP-CBRSS	77.83
MICT	77.55
T-COR 4	77.36
QTL Biosensor 2200R	77.29
QTL BIOSENSOR 4000	77.22
QFlu - Flu and Drug	76.83
Rapid BioAlert Reader	76.44
Liat Analyzer	76.16
QFlu - Rapid Flu and Drug	76.00
Prime Alert Biodetection System	75.99
REBS	75.23
BEADS	74.67
Defender TSR System	74.11
BioTM-FD	73.93
Veritide Ceeker	73.88
RAZOR EX	73.56
Capsenze analyzer	73.27
Envi Assay and ChemPro Reader	73.14
TacBio	73.08
ALPHA SENTRY ONE	72.73
PanNAT system	72.53
METRO SENTRY ONE	72.48
BUILDING SENTRY ONE	72.46
Proteus Asklepios	72.34
Genedrive	72.11
NIDS Auto-Reader	71.68
Morphix ChemBio Detector	71.11
BioThreat Integrated System	71.02
Envi BioScout	70.95
Firefly2	70.59
AIROCOLLECT-DETECT-288	70.35
Advanced Liquid Logic	70.27
BioAdvise	70.15
MSD Cartridge Reader	69.83
Diagnostic Biosensors System	69.76
RAMP	69.34
Portable Air Monitor	69.29
Raptor	69.23

ViriChip System	69.22
BioCheck	68.91
MBio MQ	68.77
NetBio Rapid DNA Analysis System	68.42
Bio-Seeq PLUS	68.30
IBTIS	67.96
Lightning MVP	67.50
EC Lab Analyzer	67.20
InnoScan	67.00
BioHawk	66.92
Guardian Reader System	66.86
ABSS	66.78
ARETE TRAP	65.61
TIRF FluoroGazer	65.47
UMSS	65.24
Rapid Portable Biosensor	64.82
StreetLab	64.67
Biocode-1000	64.58
Radio Frequency Phase Shift	64.54
BIOWARD	64.45
zNose	64.28
3M Integrated Cycler	64.22
MENTOR-100	63.74
FilmArray	63.39
Biosignatures for Pesticide Exposure	62.89
Palladium Diagnostic System	62.55
SmartBio Sensor (SBS)	62.08
Enigma-ML	61.96
LightCycler 2.0	61.83
qNano	61.65
Enigma-FL	61.63
MSD SECTOR PR2 Model 1500	61.24
VDSC-2M	61.07
MSD SECTOR PR2 Model 1900	61.05
Informant 15-Min Mold Test	60.68
Clinical Bio-Seeq	60.35
CBRN Water Purity Monitor	60.35
KIM	60.33
Pro-Strips Multi-Agent Test	60.25
BADD Anth-Kit-10	60.05
BADD Bot-Kit-10	60.05
AIR	59.98
REBS - Laboratory Variant	59.36
Liat WorkStation	59.21
CBDS	58.99
Vides Bioassay System	58.73
Biological alarm monitor (MAB)	58.56
M-BAND	58.55
MSD SECTOR PR2 Model 1800	58.50
Exicycler 96	58.34
AbleSentry	57.80
JBPDS	57.67
CBMS/CBDS	57.36

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

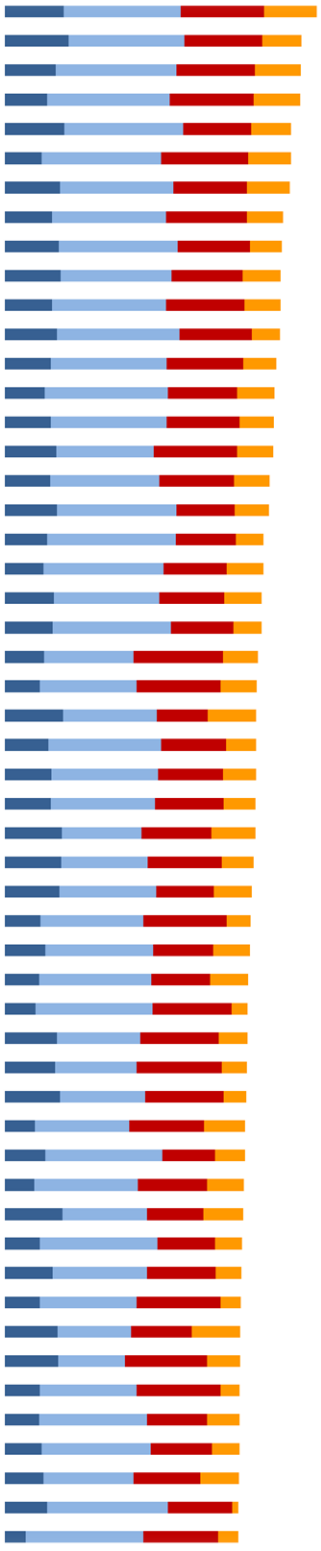
BADD Tul-Kit-10	56.80
BADD Pla-Kit-10	56.52
StepOne	56.21
IVDS	56.20
JBSDS, Increment 1	56.00
GeneXpert	55.90
InSyte	55.73
Low-Cost Biological Standoff	55.70
BioFlash-E	55.67
SmartCycler System	55.58
Rapid Detection of Pathogens	55.53
EpiSENSE	55.08
C-FLAPS	55.03
ID-24	55.00
LightCycler 480	54.82
BADD SEB-Kit-10	54.52
LuBEA	54.36
ABI ViiA 7	54.25
SiverQuant	54.19
Eco Real-Time PCR System	53.99
EAGLE	53.97
Luminex MAGPIX System	53.64
FABS	53.63
TruArray	53.45
EC BAND	53.44
JBSDS, Increment 2	53.05
FLAPS III Model 3317	52.80
eSensor XT-8	52.59
ABI 7500 Fast	52.43
Apollo 200	52.13
BioFlash - Dx	52.12
Luminex 100/200 System	52.09
ABI 7500 Fast Dx	52.01
Falcon II	51.69
BioSentryPlus	50.85
BADD Ric-Kit-10	50.63
Rotor-Gene Q	50.60
ABI 2720	50.27
ProteOn(TM) XPR36	50.04
SABT	49.88
BD MAX	49.76
Verigene System	49.70
RuggID System	49.27
RapidPlex	49.13
NucliSens easyQ	49.07
Octet	48.95
ABI 9700	48.94
DCI-I	48.85
MS-200 Microarray Scanner	48.72
CARD Device	48.61
ASAP II	48.40
Caliper LabChip GXII	48.38
REAL	48.36

Stepone Plus	48.21
JBAIDS	48.18
Immulite 2000	48.03
Food Safety Security Module	47.74
MX300	47.55
ExiStation	47.32
Experion Automated System	46.97
SCIAB	46.64
pTD	46.53
BoTest	46.30
R.A.P.I.D.	45.83
Mx3000P Mx3005P	43.43
M3IB	42.34
CFX Real-Time PCR	41.74
DNA PROfiler	41.19
C1000TM Thermal Cycler	40.65
PLEX-ID System	40.53
ABI 7900HT	40.52
ABI 7900HT	40.52
VIBP	40.13
MiSeq System	39.97
BioPlex 2200	39.24
VereID Biosystem and VereChip	38.34
LLMDA	36.63
Veriti Thermal Cycler	36.59
BioMark System	34.81
Bio-Plex 200	34.30
iScan System	32.71
BeadXpress Reader	32.16
TessArray RPM-TEI	31.91
BioThreat Alert ELISA Kit(s)	31.35
Ion Torrent Genome Machine	30.86
Mass Spec-Based Detection	30.19
TessArray RPM-Flu	30.03
HiSeq 2000 Sequencing System	27.66
Genome Analyzer IIx	27.48
HiSeq 1000 Sequencing System	27.46
HiScanSQ Systems	26.53

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Biological Specific Systems – Mobile Laboratory

uScope MX - POC Diagnostics	82.47
T2Dx	78.35
Mobile Laboratory	78.16
NIDS Medical Reader System	77.96
CDS-100	75.68
Home Healthcare Diagnostics	75.60
MICT	75.33
MSA BIOSENSOR 4000	73.52
TIRF Sense Portable	73.20
T-COR 4	72.81
QTL BIOSENSOR 4000	72.80
TIRF Sense Handheld	72.63
MSA Biosensor 2200R	71.64
Intelliprobe TM	71.27
QTL Biosensor 2200R	70.98
Proteus Asklepios	70.88
BEADS	69.99
Liat Analyzer	69.77
AIDA	68.35
Rapid BioAlert Reader	68.26
Advanced Liquid Logic	67.90
MULTIPLEXED PATHOGEN DETECTION	67.81
NIDS Auto-Reader	66.82
ALPHA SENTRY ONE	66.53
LightCycler 2.0	66.37
RAZOR EX	66.30
Capsenze analyzer	66.30
BioThreat Integrated System	66.19
REBS - Laboratory Variant	66.16
TIRF FluoroGazer	65.68
3M Integrated Cycler	65.17
REBS	64.95
MSD Cartridge Reader	64.74
Raptor	64.26
TAC-BIO / I-Collector	64.13
UMSS	64.03
Biocode-1000	63.97
InnoScan	63.69
zNose	63.45
Genedrive	63.40
BioAdvise	63.05
Vides Bioassay System	62.99
PanNAT system	62.57
EC Lab Analyzer	62.45
METRO SENTRY ONE	62.28
LightCycler 480	62.17
CBDS	62.10
BUILDING SENTRY ONE	62.07
RAMP	61.95
NetBio Rapid DNA Analysis System	61.92
FilmArray	61.90
QFlu - Flu and Drug	61.69
Prime Alert Biodetection System	61.60



Defender TSR System	61.53
Envi Assay and ChemPro Reader	61.35
QFlu - Rapid Flu and Drug	61.11
MSD SECTOR PR2 Model 1900	61.08
Liat WorkStation	60.84
MSD SECTOR PR2 Model 1500	60.55
LP-CBRSS	60.41
BioHawk	60.40
Luminex 100/200 System	60.24
MENTOR-100	60.21
MBio MQ	60.08
Veritide Ceeker	60.00
TacBio	59.82
Luminex MAGPIX System	59.69
Portable Air Monitor	59.68
Palladium Diagnostic System	59.63
Exicycler 96	59.63
Nanosecond X-Ray Detector	59.59
Diagnostic Biosensors System	59.58
MSD SECTOR PR2 Model 1800	59.16
ABI ViiA 7	59.04
Rapid Portable Biosensor	58.98
ABSS	58.86
BioTM-FD	58.73
AIROCOLLECT-DETECT-288	58.62
Enigma-ML	58.60
SmartCycler System	58.39
ViriChip System	58.35
Enigma-FL	58.08
Guardian Reader System	58.00
StreetLab	57.68
IBTIS	57.58
Rotor-Gene Q	56.77
ABI 7500 Fast Dx	56.73
Clinical Bio-Seeq	56.68
VDSC-2M	56.45
TruArray	56.20
Bio-Seeq PLUS	55.87
eSensor XT-8	55.60
ABI 7500 Fast	55.49
M-BAND	55.48
KIM	55.45
LuBEA	55.26
GeneXpert	55.00
Morphix ChemBio Detector	54.76
Falcon II	54.63
EpiSENSE	54.61
Firefly2	54.41
Envi BioScout	54.36
CBRN Water Purity Monitor	54.29
Lightning MVP	54.26
JBAIDS	53.75
EAGLE	53.75

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

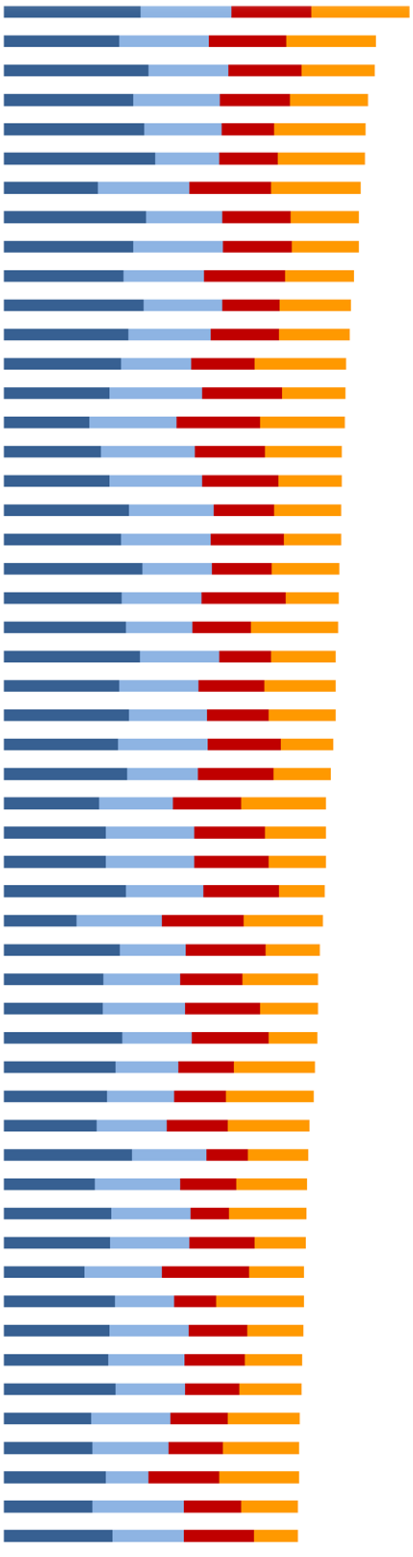
AIR	53.74
ARETE TRAP	53.36
IVDS	53.33
BioCheck	53.25
Stepone Plus	53.14
BioFlash-E	52.34
Radio Frequency Phase Shift	52.17
NucliSens easyQ	52.13
qNano	52.00
ExiStation	51.98
Caliper LabChip GXII	51.82
BD MAX	51.73
Rapid Detection of Pathogens	51.72
SmartBio Sensor (SBS)	51.55
Biological alarm monitor (MAB)	51.37
DCI-I	51.16
Food Safety Security Module	51.10
Verigene System	51.05
RapidPlex	51.03
EC BAND	51.01
MX300	50.99
Biosignatures for Pesticide Exposure	50.96
InSyte	50.93
CBMS/CBDS	50.90
StepOne	50.87
R.A.P.I.D.	50.85
ID-24	50.68
ASAP II	50.32
CARD Device	49.65
Eco Real-Time PCR System	49.56
RuggID System	49.02
PLEX-ID System	48.85
Pro-Strips Multi-Agent Test	48.66
JBPDS	48.51
BADD Anth-Kit-10	48.46
BADD Bot-Kit-10	48.46
Octet	48.33
SABT	47.90
AbleSentry	47.76
SiverQuant	47.39
C-FLAPS	47.34
ABI 2720	47.21
pTD	47.13
FABS	46.84
JBSDS, Increment 1	46.63
Low-Cost Biological Standoff	46.37
BioSentryPlus	46.17
ABI 9700	45.90
BoTest	45.74
Informant 15-Min Mold Test	45.44
BIOWARD	45.28
BioFlash - Dx	45.26
SCIAB	45.03

BADD Tul-Kit-10	45.01
JBSDS, Increment 2	44.28
FLAPS III Model 3317	43.71
DNA PROfiler	43.07
Mx3000P Mx3005P	42.90
BADD Pla-Kit-10	42.82
LLMDA	42.81
Experion Automated System	42.80
VereID Biosystem and VereChip	42.55
ABI 7900HT	41.88
ABI 7900HT	41.88
ProteOn(TM) XPR36	41.82
Immulite 2000	41.67
M3IB	41.58
BADD SEB-Kit-10	41.49
Apollo 200	41.41
MS-200 Microarray Scanner	40.48
BioMark System	40.46
BADD Ric-Kit-10	40.27
VIBP	40.21
CFX Real-Time PCR	39.92
REAL	39.51
TessArray RPM-Flu	38.64
TessArray RPM-TEI	38.53
MiSeq System	37.24
BioPlex 2200	36.10
BeadXpress Reader	36.04
C1000TM Thermal Cycler	35.97
Ion Torrent Genome Machine	35.05
BioThreat Alert ELISA Kit(s)	34.82
Mass Spec-Based Detection	34.06
Bio-Plex 200	32.27
iScan System	32.07
HiSeq 2000 Sequencing System	30.97
HiSeq 1000 Sequencing System	30.64
Genome Analyzer IIx	30.32
HiScanSQ Systems	29.57
Veriti Thermal Cycler	28.44

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Biological Specific Systems – Diagnostic Laboratory

uScope MX - POC Diagnostics	82.75
Mobile Laboratory	75.98
T2Dx	75.70
MICT	74.34
LightCycler 2.0	73.84
Luminex 100/200 System	73.70
NIDS Medical Reader System	72.79
REBS - Laboratory Variant	72.43
CDS-100	72.39
Proteus Asklepios	71.50
3M Integrated Cycler	70.90
T-COR 4	70.64
LightCycler 480	69.86
MSA BIOSENSOR 4000	69.66
Home Healthcare Diagnostics	69.60
Intelliprobe TM	68.99
QTL BIOSENSOR 4000	68.94
Liat Analyzer	68.88
TIRF Sense Portable	68.86
Liat WorkStation	68.48
Biocode-1000	68.31
Luminex MAGPIX System	68.26
SmartCycler System	67.76
Advanced Liquid Logic	67.70
Vides Bioassay System	67.69
TIRF Sense Handheld	67.18
TIRF FluoroGazer	66.72
ABI ViiA 7	65.76
QTL Biosensor 2200R	65.76
MSA Biosensor 2200R	65.71
InnoScan	65.44
ALPHA SENTRY ONE	65.09
CBDS	64.51
FilmArray	64.15
BEADS	64.06
UMSS	63.99
Rotor-Gene Q	63.51
ABI 7500 Fast Dx	63.21
Exicycler 96	62.37
eSensor XT-8	62.13
MSD Cartridge Reader	61.88
Caliper LabChip GXII	61.73
BioThreat Integrated System	61.61
NIDS Auto-Reader	61.23
TruArray	61.20
MULTIPLEXED PATHOGEN DETECTION	61.17
Capsenze analyzer	60.91
BD MAX	60.71
GeneXpert	60.37
MSD SECTOR PR2 Model 1900	60.26
JBAIDS	60.25
Rapid BioAlert Reader	60.06
EC Lab Analyzer	60.01



RAZOR EX	59.82
AIDA	59.65
Raptor	59.65
MSD SECTOR PR2 Model 1500	59.30
NetBio Rapid DNA Analysis System	59.23
Stepone Plus	58.83
NucliSens easyQ	58.80
LuBEA	58.69
Enigma-ML	58.56
PLEX-ID System	58.42
MSD SECTOR PR2 Model 1800	58.06
Verigene System	58.04
ExiStation	57.95
MBio MQ	57.65
Palladium Diagnostic System	57.26
zNose	57.23
REBS	57.16
PanNAT system	57.06
ABI 7500 Fast	56.96
Genedrive	56.95
MENTOR-100	56.69
Food Safety Security Module	56.54
Clinical Bio-Seeq	56.27
BioAdvise	56.12
Rapid Portable Biosensor	55.96
QFlu - Flu and Drug	55.92
Falcon II	55.48
QFlu - Rapid Flu and Drug	55.12
EpiSENSE	55.03
IBTIS	54.92
MX300	54.43
BioHawk	54.37
R.A.P.I.D.	54.17
METRO SENTRY ONE	54.09
BUILDING SENTRY ONE	53.91
Diagnostic Biosensors System	53.90
Portable Air Monitor	53.79
VDSC-2M	53.69
Enigma-FL	52.96
M-BAND	51.25
CARD Device	51.14
TAC-BIO / I-Collector	50.96
IVDS	50.83
RapidPlex	50.65
AIR	50.54
ABSS	50.28
ID-24	50.02
DCI-I	49.91
BioFlash-E	49.53
Octet	49.51
ViriChip System	49.50
EAGLE	49.44
Envi Assay and ChemPro Reader	49.36

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

ASAP II	49.17
LLMDA	49.11
RAMP	49.07
KIM	48.99
Radio Frequency Phase Shift	48.82
AIROCOLLECT-DETECT-288	48.75
InSyte	48.62
Veritide Ceeker	48.54
RuggID System	48.20
TacBio	48.03
BioMark System	47.96
VereID Biosystem and VereChip	47.95
CBRN Water Purity Monitor	47.66
Nanosecond X-Ray Detector	47.63
BioSentryPlus	47.38
TessArray RPM-Flu	47.37
Rapid Detection of Pathogens	47.36
BioTM-FD	47.28
LP-CBRSS	47.11
Eco Real-Time PCR System	46.88
DNA PROfiler	46.83
Guardian Reader System	46.63
Biological alarm monitor (MAB)	46.49
Immulite 2000	46.33
Defender TSR System	46.16
ABI 2720	45.97
SABT	45.96
qNano	45.83
StepOne	45.79
Biosignatures for Pesticide Exposure	45.76
Prime Alert Biodetection System	45.58
BoTest	45.51
CBMS/CBDS	45.21
ABI 9700	44.90
pTD	44.66
EC BAND	44.37
ABI 7900HT	44.14
ABI 7900HT	44.14
BeadXpress Reader	44.08
SiverQuant	44.07
BioFlash - Dx	43.67
Experion Automated System	43.62
ARETE TRAP	43.12
Bio-Seeq PLUS	42.99
SmartBio Sensor (SBS)	42.99
FABS	42.95
BioPlex 2200	42.68
JBSDS, Increment 1	42.57
Firefly2	42.44
Low-Cost Biological Standoff	42.36
C-FLAPS	41.65
Morphix ChemBio Detector	41.59
Envi BioScout	41.55

SCIAB	41.43
AbleSentry	41.01
TessArray RPM-TEI	41.00
JBSDS, Increment 2	40.75
JBPDS	40.74
MS-200 Microarray Scanner	40.69
M3IB	40.65
Ion Torrent Genome Machine	40.47
Mx3000P Mx3005P	40.13
CFX Real-Time PCR	39.57
Lightning MVP	39.40
FLAPS III Model 3317	38.39
ProteOn(TM) XPR36	38.08
REAL	37.26
BioCheck	37.24
Mass Spec-Based Detection	37.19
Pro-Strips Multi-Agent Test	36.73
Apollo 200	36.63
MiSeq System	36.58
BADD Anth-Kit-10	36.53
BADD Bot-Kit-10	36.53
BioThreat Alert ELISA Kit(s)	35.78
VIBP	35.66
iScan System	35.29
HiSeq 2000 Sequencing System	35.01
HiSeq 1000 Sequencing System	34.28
Genome Analyzer IIx	34.14
HiScanSQ Systems	33.68
BADD Tul-Kit-10	33.58
Bio-Plex 200	33.07
Informant 15-Min Mold Test	32.60
C1000TM Thermal Cycler	30.96
BADD Ric-Kit-10	30.82
BADD Pla-Kit-10	30.37
BIOWARD	29.59
BADD SEB-Kit-10	29.37
Veriti Thermal Cycler	22.05

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Biological Specific Systems – Analytical Laboratory

uScope MX - POC Diagnostics	81.12
T2Dx	79.68
CDS-100	76.17
REBS - Laboratory Variant	75.49
LightCycler 480	74.63
Mobile Laboratory	74.18
T-COR 4	74.00
Proteus Asklepios	73.38
Vides Bioassay System	72.98
LightCycler 2.0	72.84
Luminex 100/200 System	72.65
Luminex MAGPIX System	72.01
MICT	70.51
CBDS	69.55
Advanced Liquid Logic	69.42
MSA BIOSENSOR 4000	69.16
NIDS Medical Reader System	69.12
TIRF FluoroGazer	69.10
Rotor-Gene Q	68.67
QTL BIOSENSOR 4000	68.56
TIRF Sense Portable	68.34
3M Integrated Cycler	68.11
Liat WorkStation	66.87
MSD SECTOR PR2 Model 1900	66.60
Biocode-1000	66.48
TIRF Sense Handheld	66.12
NIDS Auto-Reader	65.80
UMSS	65.74
MSD SECTOR PR2 Model 1500	65.00
BioThreat Integrated System	64.77
MSA Biosensor 2200R	64.48
InnoScan	64.47
QTL Biosensor 2200R	64.38
Home Healthcare Diagnostics	64.28
ABI ViiA 7	63.94
MSD SECTOR PR2 Model 1800	63.89
Liat Analyzer	63.35
BEADS	63.32
zNose	62.84
SmartCycler System	62.51
LuBEA	61.40
EC Lab Analyzer	61.14
Food Safety Security Module	61.11
ABI 7500 Fast Dx	60.94
Exicycler 96	60.58
Rapid BioAlert Reader	60.41
ABI 7500 Fast	60.11
TruArray	59.63
MULTIPLEXED PATHOGEN DETECTION	59.27
ALPHA SENTRY ONE	59.16
RAZOR EX	59.14
MSD Cartridge Reader	58.43
BioFlash-E	58.37

DCI-I	58.36
MENTOR-100	58.32
Intelliprobe TM	58.17
Capsenze analyzer	58.17
Stepone Plus	57.96
eSensor XT-8	57.89
FilmArray	57.76
Caliper LabChip GXII	57.70
NetBio Rapid DNA Analysis System	57.47
Falcon II	57.14
BioAdvise	57.11
M-BAND	57.11
PLEX-ID System	56.84
RAMP	56.74
NucliSens easyQ	56.50
Raptor	56.44
ExiStation	56.23
AIDA	56.00
Rapid Portable Biosensor	56.00
Palladium Diagnostic System	55.97
Genedrive	55.97
RapidPlex	55.73
CARD Device	55.55
Enigma-ML	55.33
EpiSENSE	54.74
RuggID System	54.23
METRO SENTRY ONE	54.16
BUILDING SENTRY ONE	53.66
MBio MQ	53.64
Clinical Bio-Seeq	53.08
MX300	53.02
Enigma-FL	52.82
AIROCOLLECT-DETECT-288	52.12
JBAIDS	52.06
ID-24	51.89
IVDS	51.78
Octet	51.67
R.A.P.I.D.	51.61
KIM	51.39
ASAP II	51.33
Guardian Reader System	51.21
BioTM-FD	51.01
BD MAX	50.97
VDSC-2M	50.86
BioHawk	50.49
InSyte	50.34
PanNAT system	49.68
pTD	49.55
EAGLE	49.52
EC BAND	49.47
Portable Air Monitor	49.35
TAC-BIO / I-Collector	49.30
TacBio	49.05

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Defender TSR System	48.99
StepOne	48.93
IBTIS	48.91
Biological alarm monitor (MAB)	48.45
ABI 7900HT	48.37
ABI 7900HT	48.37
BioSentryPlus	48.25
CBMS/CBDS	47.43
ABSS	47.39
REBS	47.35
Mx3000P Mx3005P	47.31
ViriChip System	46.56
Eco Real-Time PCR System	46.51
AIR	46.44
GeneXpert	46.41
QFlu - Rapid Flu and Drug	46.18
BioMark System	46.17
LP-CBRSS	46.04
LLMDA	45.82
CBRN Water Purity Monitor	45.76
ABI 2720	45.60
BoTest	45.58
Verigene System	45.53
FABS	45.52
StreetLab	45.51
QFlu - Flu and Drug	45.47
C-FLAPS	45.07
DNA PROfiler	44.98
VereID Biosystem and VereChip	44.27
ABI 9700	44.27
Envi Assay and ChemPro Reader	43.88
SmartBio Sensor (SBS)	43.72
Bio-Seeq PLUS	43.37
TessArray RPM-TEI	42.90
Firefly2	42.73
Radio Frequency Phase Shift	42.66
ARETE TRAP	42.62
CFX Real-Time PCR	42.33
Prime Alert Biodetection System	42.32
Ion Torrent Genome Machine	42.25
Rapid Detection of Pathogens	42.23
JBSDS, Increment 1	42.16
Low-Cost Biological Standoff	41.98
Experion Automated System	41.63
JBSDS, Increment 2	41.48
SABT	41.42
AbleSentry	40.72
Lightning MVP	40.46
Morphix ChemBio Detector	39.53
qNano	39.41
BioFlash - Dx	38.87
Nanosecond X-Ray Detector	38.18
M3IB	37.98

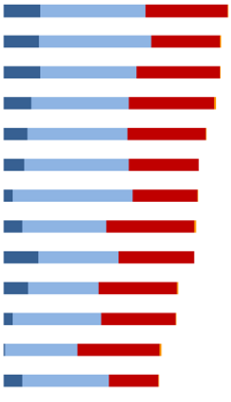
BioThreat Alert ELISA Kit(s)	37.78
Immulite 2000	37.67
Mass Spec-Based Detection	37.35
Envi BioScout	37.33
Pro-Strips Multi-Agent Test	37.26
BADD Anth-Kit-10	37.06
BADD Bot-Kit-10	37.06
JBPDS	36.88
MS-200 Microarray Scanner	36.56
SiverQuant	36.40
ProteOn(TM) XPR36	36.16
REAL	36.09
Apollo 200	35.91
BeadXpress Reader	35.74
FLAPS III Model 3317	35.67
BADD Tul-Kit-10	35.26
SCIAB	35.21
BioPlex 2200	35.12
Biosignatures for Pesticide Exposure	34.31
HiSeq 2000 Sequencing System	33.70
Bio-Plex 200	33.03
BioCheck	32.66
HiSeq 1000 Sequencing System	32.36
Genome Analyzer IIx	31.64
MiSeq System	31.61
HiScanSQ Systems	31.46
BADD Ric-Kit-10	30.85
iScan System	29.86
C1000TM Thermal Cycler	29.85
BADD Pla-Kit-10	29.85
BADD SEB-Kit-10	29.51
Informant 15-Min Mold Test	28.28
VIBP	25.42
BIOWARD	21.44
Veriti Thermal Cycler	20.38

APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Chemical Specific Systems – Field Use

ChemPro PD	84.93
ChemPro 100i	83.91
T2Dx	82.29
Blacklight (D1000)	81.74
NIDS Biothreat Detection Kit	81.08
AIDA	80.20
TIRF Sense Handheld	80.02
HAZMATCAD	79.29
PASS	79.29
CDS-100	79.15
CRITICAL	78.63
TIRF Sense portable	78.39
LP-CBRSS	77.83
MICT	77.55
JUNO	77.41
TruDefender FT	76.92
JSLSCAD	76.57
DISe	76.24
REBS	75.23
FirstDefender RM/RMX	73.25
TruDefender FTG	73.09
ALPHA SENTRY ONE	72.73
METRO SENTRY ONE	72.48
BUILDING SENTRY ONE	72.46
HazMatID 360	72.28
LaserScan Analyzer	72.28
Morphix ChemBio Detector	71.11
Chameleon	70.88
MultiRAE Plus	70.82
HMT	70.43
RAMP	69.34
Portable Air Monitor	69.29
ChemSight	68.77
UGV-Based Standoff Sensor	68.21
HAPSITE ER	67.83
SensAlert Plus	67.44
Sensidyne Gas Detector	67.29
TIRF FluoroGazer	65.47
UMSS	65.24
Warlock	64.87
StreetLab	64.67
BIOWARD	64.45
zNose	64.28
CALS	63.83
CBRN Water Purity Monitor	60.35
Water Testing Kit NBC Defence	59.94
REBS - Laboratory Variant	59.36
Low-cost Sagnac LWIR	59.22
CBDS	58.99
Vides Bioassay System	58.73
AbleSentry	57.80
CBMS/CBDS	57.36
Voice200	57.25

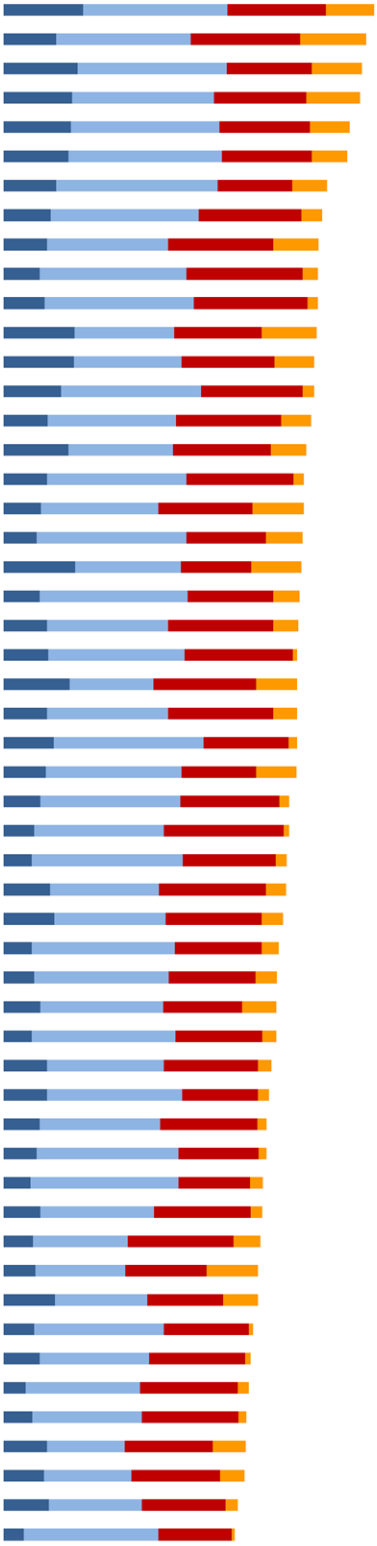
Laser Photo-Acoustic	56.94
Quant NQAD QT-500 Detector	55.17
JCSD	54.95
EAGLE	53.97
ThreatShield-C	51.38
LISA	49.45
DX-4030 Portable FTIR	49.22
DCI-I	48.85
REAL	48.36
ICS-5000	44.32
SAMPLE	43.62
VIBP	40.13
High-Speed Resonant FTIR	39.23

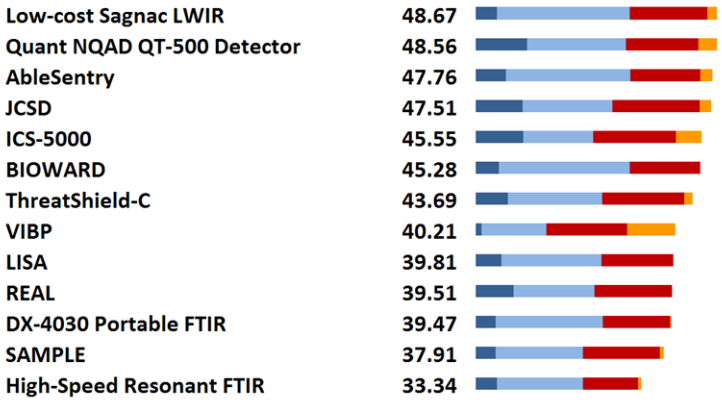


APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Chemical Specific Systems – Mobile Laboratory

T2Dx	78.35
NIDS Biothreat Detection Kit	76.60
CDS-100	75.68
MICT	75.33
TIRF Sense portable	73.20
TIRF Sense Handheld	72.63
AIDA	68.35
ChemPro 100i	67.36
ALPHA SENTRY ONE	66.53
Blacklight (D1000)	66.47
ChemPro PD	66.39
REBS - Laboratory Variant	66.16
TIRF FluoroGazer	65.68
PASS	65.64
REBS	64.95
UMSS	64.03
HAZMATCAD	63.45
zNose	63.45
LaserScan Analyzer	63.16
Vides Bioassay System	62.99
JUNO	62.59
METRO SENTRY ONE	62.28
DISe	62.10
CBDS	62.10
BUILDING SENTRY ONE	62.07
CRITICAL	62.06
RAMP	61.95
LP-CBRSS	60.41
JSLSCAD	60.38
TruDefender FT	59.84
Portable Air Monitor	59.68
HAPSITE ER	59.08
TruDefender FTG	58.17
HazMatID 360	57.81
StreetLab	57.68
FirstDefender RM/RMX	57.60
UGV-Based Standoff Sensor	56.60
Chameleon	56.16
HMT	55.63
MultiRAE Plus	55.53
Morphix ChemBio Detector	54.76
Warlock	54.65
CBRN Water Purity Monitor	54.29
EAGLE	53.75
Voice200	53.74
ChemSight	52.76
SensAlert Plus	52.23
Water Testing Kit NBC Defence	51.89
CALS	51.29
DCI-I	51.16
CBMS/CBDS	50.90
Laser Photo-Acoustic	49.54
Sensidyne Gas Detector	48.93

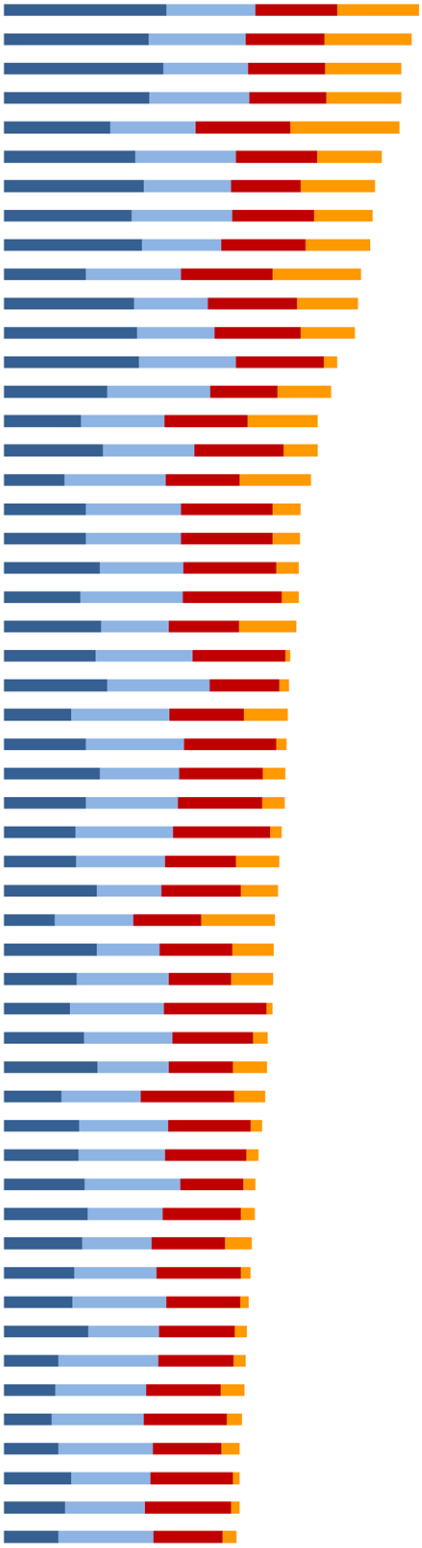




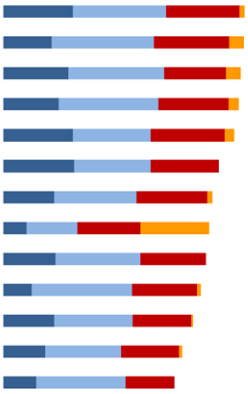
APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Chemical Specific Systems – Diagnostic Laboratory

T2Dx	75.70
MICT	74.34
REBS - Laboratory Variant	72.43
CDS-100	72.39
NIDS Biothreat Detection Kit	72.13
TIRF Sense portable	68.86
Vides Bioassay System	67.69
TIRF Sense Handheld	67.18
TIRF FluoroGazer	66.72
ALPHA SENTRY ONE	65.09
CBDS	64.51
UMSS	63.99
PASS	60.71
AIDA	59.65
zNose	57.23
REBS	57.16
LaserScan Analyzer	55.94
METRO SENTRY ONE	54.09
BUILDING SENTRY ONE	53.91
Portable Air Monitor	53.79
Blacklight (D1000)	53.75
Voice200	53.26
DISe	52.16
CRITICAL	51.97
JUNO	51.75
HAZMATCAD	51.51
HAPSITE ER	51.34
ChemPro 100i	51.22
ChemPro PD	50.59
StreetLab	50.14
DCI-I	49.91
EAGLE	49.44
ICS-5000	49.23
RAMP	49.07
JSLSCAD	48.98
UGV-Based Standoff Sensor	48.04
Quant NQAD QT-500 Detector	47.90
CBRN Water Purity Monitor	47.66
LP-CBRSS	47.11
Warlock	46.42
Chameleon	45.82
Laser Photo-Acoustic	45.69
CBMS/CBDS	45.21
HMT	44.95
MultiRAE Plus	44.57
JCSD	44.26
TruDefender FT	44.05
HazMatID 360	43.82
Water Testing Kit NBC Defence	43.45
TruDefender FTG	42.97
SensAlert Plus	42.95
CALS	42.93
FirstDefender RM/RMX	42.41

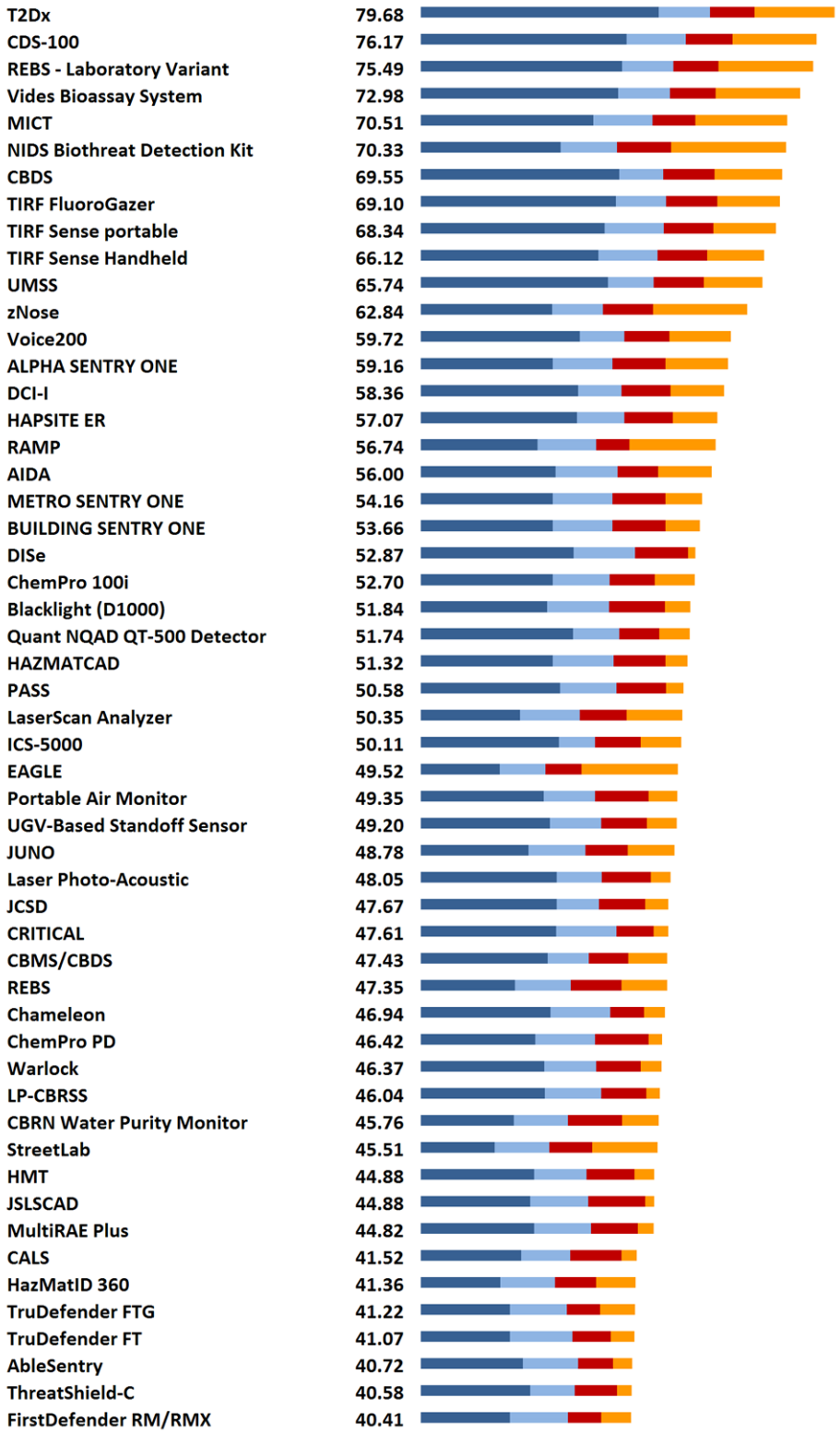


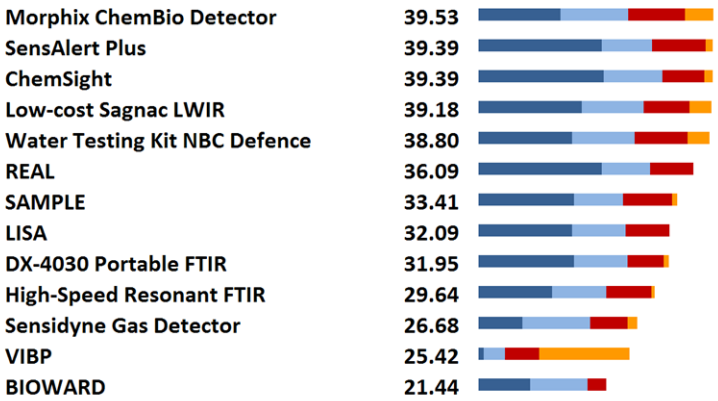
ChemSight	41.71
Morphix ChemBio Detector	41.59
AbleSentry	41.01
Low-cost Sagnac LWIR	40.77
ThreatShield-C	39.92
REAL	37.26
SAMPLE	36.15
VIBP	35.66
LISA	35.05
Sensidyne Gas Detector	34.11
DX-4030 Portable FTIR	32.80
High-Speed Resonant FTIR	30.96
BIOWARD	29.59



APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED

Chemical Specific Systems – Analytical Laboratory





APPROVED FOR UNLIMITED DISTRIBUTION
UNCLASSIFIED