Biological Detectors

Market Survey

2007 Edition

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EDGEWOOD BIODEFENSE

EDGEWOOD CHEMICAL BIOLOGICAL CENTER
A U.S. Army RDECOM Laboratory

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

Authors' Letter

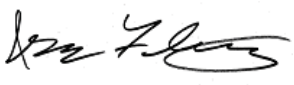
Dear Reader:

We revised our 2005 market survey on biological detectors to help inform and update the research and scientific community on current and future detectors for biological threat agents. Many of the detection devices and systems evaluated in this survey use PCR and/or immunoassay technology, but other technologies were also included. We evaluated products that are commercially available and some emerging technologies of interest. There are four different scenarios considered within this document and each has a customized weighting mechanism which reflects the needs of detection systems for that situation. We gathered the product information by sending out a questionnaire to manufacturers and then ranking each answer.

We would like to suggest the following methodology for using this guide. First, review the scenarios in Section 7; choose one of interest to you and note how the devices or systems ranked for that scenario. Second, take note of the portion the product ranked within and then look at the raw score. 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. Next, go to Appendix II and look up the product name for detailed information on the product. Finally, contact the manufacturer for more information or visit their website.

Appendix I is a quick reference guide to each product in the survey. The name of each product is color coded by technology to make it easier to find a product that may interest you. Appendix II, which includes the product information, is alphabetized to make it easier to find a product of interest. Appendix I also includes a maturity gauge so you can quickly tell if the product is commercially available or not. We hope that you find this survey both helpful and interesting. If you have any comments or suggestions, please contact us.

Sincerely,



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Executive Summary

Detection of biological warfare agents currently relies upon PCR and immunoassay-based methods or the combination of both. There is a wide array of PCR and immunoassay technologies available to today's scientist. Products are typically designed for a specific application, whether it is for environmental detection or diagnosis. In this report, information pertaining to the use and performance of several leading PCR and immunoassay technologies was collected and evaluated. Several new or alternative methods were also evaluated. The effectiveness of these detection devices was evaluated for four different scenarios: field use, mobile laboratory use, diagnostic laboratory use, and analytical laboratory use. The evaluation criteria for each of these scenarios was based upon expert opinion.

Detection devices intended for field use were evaluated based upon the total agents that can be detected, their maturity, size, set up time, time to detect, and the maintainability of the device or system. Technologies that evaluated well in this scenario include small, versatile detection cartridges, as well as several handheld PCR devices. Devices or systems that did not fare as well in the evaluation often required several additional pieces of equipment for use (e.g., centrifuges, water baths, vortexes), which decreased the ease of use and increased the number of manual steps required for operation. Also the larger sized devices or systems did not fare well in this scenario.

Detection devices intended for mobile laboratory use were evaluated based upon their ability to detect bacteria, toxins, and total agents; operational conditions; size; and re-use ability. Technologies that evaluated well in this scenario included reasonably sized, sensitive detection devices that can detect many agents. Devices that did not fare as well in the evaluation often required several manual steps and manpower requirements, while reducing the ease of use.

Detection devices intended for diagnostic laboratory use were evaluated based upon their utility, total agents that can be detected, time to detect, ease of use, and sensitivity. Technologies that evaluated well in this scenario included fast and effective detection devices based upon PCR technology for clinical samples. Systems and devices that did not fare as well in the evaluation often took a long time to detect, did not have a high level of sensitivity, or had to use many consumables.

Detection devices intended for analytical laboratory use were evaluated based upon their ability to obtain a high sensitivity, utility, volume of sample needed, total agents that can be detected, and ability to multiplex. Detection devices or systems that did well in this scenario include PCR focused technologies and those systems that used automated technologies that combined PCR and immunoassay. Systems and devices that did not fare as well in this evaluation were generally those that did not have a high sensitivity or were unable to multiplex.

Instructions for the Use of This Guide

This report is most useful in the selection of a PCR or immunoassay based technology for detection of biological, viral, and toxin targets. For the purpose of this report, evaluation models were created to generate the ordered lists of technologies. These evaluation models are useful in assessing emerging technologies and new products for the four scenarios discussed.

This report should be used as a guide and the information of each product was provided by the manufacturer and assumed to be correct. **When evaluating products based on the scenario, observe the score in generalized blocks.** Scoring summaries have been used to break analyzed technologies into sections to help.

Appendix I is a quick guide to the products that were evaluated in this survey. The names of the products are color coded according to the technology they utilize. There also is a maturity gauge that indicates that (1) the device or system is commercially available and meets military specification, (2) the device or system is commercially available, (3) a few devices exist, or (4) only one incomplete device exists or only a concept on paper exists.

Appendix II is an alphabetized product information sheet with detailed information on each product evaluated in the survey. Further information on a product of interest can be obtained by contacting the manufacturer or visiting their website, if provided.

Foreword

The Department of Defense (DoD) is concerned about the proliferation of biological warfare agents and the nation's ability to detect and diagnose the potential exposure of US troops or an attack on the homeland. Therefore, periodic technology reviews and evaluations are coordinated by the Edgewood Chemical Biological Center (ECBC) to assist the biological defense community.

Presented here are assessments of the technologies available for biological agent detection, including PCR- and immunoassay-based technologies as well as a few emerging technologies. This market survey assesses these technologies within a variety of settings, including analytical laboratories, medical diagnostic laboratories, mobile laboratories, and field use. It is the aim of this guide to assist technology managers and research scientists in the field of biological agent detection.

This guide includes information to assist research scientists and the scientific and technology community to select or track detection technologies that meet their varied applications. It includes a thorough market survey of detection devices or systems available, current through September 2007. Brief technical discussions that consider the principles of operation and technological basis of several pieces of equipment are presented.

Although Appendix II contains technical information provided by the vendor for each product, it is considered supplementary. Readers that find this information too lengthy may bypass the Appendix with no effect on their overall understanding of the evaluation. For readers who desire more technical information, points of contact from the manufacturer as well as company websites are listed with each product.

This guide describes devices or systems for detecting biological warfare agents important to the biodefense community. It mainly focuses on PCR and immunoassay based technologies, but does include other technologies in various stages of development. Please refer to Appendix I for an overview of the detection devices and systems evaluated, the technologies available, and the maturity of each device or system presented.

Reference herein to any specific commercial products, processes, or services by trade name, trademark, manufacturer, or otherwise does not necessarily constitute or imply its endorsement or recommendation by the United States Government. The information and statements contained in this guide shall not be used for the purpose of advertising, or to imply the endorsement or recommendation of the United States Government. With respect to the information provided in this guide, neither the United States Government nor any of its employees make any warranty, expressed or implied, including but not limited to the warranties of merchantability and fitness for a particular purpose. Further, neither the United States Government nor any of its employees assume any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed.

The information in this guide on specific equipment and technologies was obtained through literature, web searches, and other market surveys. Technical comments, suggestions, and product updates are encouraged from interested parties. They may be addressed to the Edgewood Chemical Biological Center, 5183 Blackhawk Road, E3150 Suite A118, Aberdeen Proving Ground, MD 21010. It is anticipated that this guide will be updated every two years. Questions pertaining to the specific products included in this document should be directed to the manufacturer. Contact information for each evaluated equipment item is included in this report.

Preface

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Market Survey: Biological Detectors

Guide for Selection of Detection Devices and Systems

by Isaac Fruchey, M.S. and Peter Emanuel, Ph.D.

1. Introduction

The purpose of this document is to provide the science and technology community and the research and development scientist with information to aid in the pursuit of biological assay and detection technology development. This report reviews vendor-supplied information about detection devices or systems that are currently used in biological research and in biodetection assays. Also included in the report are several immature devices or systems that have potential use in biological research and in biodetection assays.

This document is divided into eight sections and includes two appendices. *Section 2* presents a description of the four scenarios that address detection devices or systems needs. *Section 3* provides an overview of PCR based detection technologies. *Section 4* provides an overview of immunoassay based detection technologies. *Section 5* is a brief introduction to the decision analysis process used in the evaluation. *Section 6* discusses the selection factors that were used to compare and evaluate the different detection devices or systems. *Section 7* presents an evaluation of detection devices or systems and general recommendations pertaining to the four different scenarios. *Section 8* concludes with a concise summary of the current state of biological agent detection devices or systems. *Appendix I* is a quick reference table that divides the products by technology and also indicates the maturity level of the product. *Appendix II* describes individual products that were evaluated in this guide.

2. Four Different Scenarios Where Detection Devices or Systems Are Needed

Several fundamentally different methods for detecting biological agents have been or are being developed. However, in different operational environments, one device or system may be preferred over others based on situational circumstances. In the following scenarios, four distinctly different environments demonstrate how different situations can require different devices or systems for biological agent detection.

FIELD SCENARIO

Field use detection devices or systems are typically used by the soldiers or researchers conducting research outside of a typical laboratory setting. 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 to operate. 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 re-use. 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 detection of agents range, (e.g., can be specific for one particular target) because several different devices may be deployed on a mission.

MOBILE LABORATORY SCENARIO

Mobile laboratory detection devices or systems are located in deployable laboratories. They would likely be semi-automated or integrated into a system that is capable of a higher throughput of samples (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 as space is limited and because 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, indicating that 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 every biological warfare agent of concern.

ANALYTICAL LABORATORY SCENARIO

The forensic analytical laboratory scenario is typically a fixed site location that processes samples with the highest scrutiny and validates previous assays. Analytical laboratory detection devices or systems would be concerned with looking for the greatest amount of recovery possible. This would be very important when trying to detect biological agents from small dilute samples. There are no real concerns with logistical or operational concerns, such as size, weight, signature, transportation, additional equipment, and consumables. Ideally, the analytical laboratory detection device or system must be able to detect biological agents from all encountered samples with a consistently high level of effectiveness and sensitivity. The ideal system or device would also be able to multiplex.

DIAGNOSTIC LABORATORY SCENARIO

Diagnostic laboratory detection devices or systems are typically located in a hospital or a similar medical setting. They would be fully automated devices capable of high throughput of samples. The device or system must be able to detect agents from blood, tissue, cultured cells, and other typical samples. An ideal detection device would detect agents very quickly, detect a large variety of agents, have a high level of sensitivity, and be easy to operate. This type of device would be used in a hospital setting where size, signature, additional equipment, and electrical requirements are of less concern. Calibration and accuracy are critical factors in a medical environment. The device should be easily maintained with regularly scheduled maintenance, and be relatively easy for a medical staff to operate.

3. Overview of PCR Techniques

Polymerase chain reaction (PCR) refers to a highly sensitive technique by which minute quantities of specific DNA or RNA sequences can be enzymatically amplified to the extent that a sufficient quantity of material is available to reach a threshold "signal" for detection. The impetus for development of this technology grew out of basic research carried out by Kary Mullis, who was awarded the 1993 Nobel Prize for chemistry for PCR, and co-workers and other scientists working at the Cetus Corporation and Department of Human Genetics in Emerysville, California.

The starting material for PCR, the target sequence, is a gene or segment of DNA. The target sequence can be amplified a million fold in a short amount of time. The complementary strands of a double-stranded molecule of DNA are separated by heating. Two small pieces of synthetic DNA, each complementing a specific sequence at one end of the target sequence, serve as primers. Each primer binds to its complementary sequence. Polymerase, a naturally occurring enzyme, starts at each primer and copies the sequence of that strand. Exact replicas of the target sequence have now been produced. In subsequent cycles, double-stranded molecules of both the original DNA and the copies are separated by heating and the primers again bind to the complementary sequences and the polymerase replicates them.

After many cycles, there are a great number of small pieces of DNA of the target sequence and this unlimited quantity is then available for further analysis.

The versatility of PCR has been astounding, and it has opened new avenues of research. Applications for PCR include molecular cloning, DNA sequencing, archeology, forensics, amplification of unknown sequences, clinical pathology, genetic diagnosis, characterizing unknown mutations, fingerprinting/population analysis, genome analysis, and quantitative PCR of RNA or DNA. It has become a constantly changing tool with further potential in the future. For further information on PCR, please see the University of California, Berkeley PCR Project website at http://sunsite.berkeley.edu/biotech/pcr/whatisPCR.html or contact Edgewood BioDefense at 410-436-5562.

4. Overview of Immunoassay Techniques

Immunoassays were first described in the 1950s, although they were not readily applied outside of clinical laboratories until the advent of economical automated plate-reading systems and personal computers to analyze the data. Immunoassays are quick and accurate tests that can be used on-site and in the laboratory to detect specific molecules. Immunoassays rely on the inherent ability of an antibody to bind to the specific structure of a molecule.

Antibodies are proteins generated by animals in response to the invasion of a foreign molecule (antigen) into the body. Because antibodies are developed based on the specific three-dimensional structure of an antigen, or analyte, they are highly specific and will bind only to that structure. There are four typical immunoassay formats: monoclonal-polyclonal sandwich, antigen-down, competitive inhibition, and rapid.

In a typical microtiter plate sandwich immunoassay, such as the E. coli 0157 Visual Immunoassay (VIA™), a monoclonal antibody is absorbed onto a plastic microtiter plate. The test sample is added to the plate, the antibody on the plate will bind the target antigen, if present, and retain it in the plate. Next, a polyclonal antibody is added and will also bind to the antigen, which is now 'sandwiched' between the two antibodies. This binding reaction can be measured by radio-isotopes or by enzymes. The radio-isotope or enzyme generates a color signal proportional to the amount of target antigen present. The degree of color can be detected and measured with the naked eye, a scintillation counter, or spectrophotometer depending on the immunoassay format.

In an antigen-down or direct immunoassay, the analyte is coated onto a 96-well microtiter plate and used to bind antibodies found in a sample. When the sample is added, the antigen on the plate it is bound by antibodies from the sample, which are then retained in the well. A species-specific labeled antibody is added which binds to the antibody bound to the antigen on the plate. The higher the signal, the more antibodies there are in the sample.

Competitive inhibition assays are often used to measure small analytes because competitive inhibition assays only require the binding of one antibody. In a sequential competitive inhibition assay format, such as the AflaCup™ Test Kit, a monoclonal antibody is coated onto a 96-well microtiter plate. When the sample is added, the antibody captures free analyte out of the sample. Next, a known amount of labeled analyte is added. The labeled analyte will then also attempt to bind to the monoclonal antibody absorbed onto the plate; however, the labeled analyte is inhibited from binding to the monoclonal by the presence of previously bound analyte from the sample. The amount of unlabeled analyte in the sample is inversely proportional to the signal generated by the labeled analyte. The classic competitive inhibition assay format required the simultaneous addition of labeled and unlabeled analyte. Both analytes will then compete for the binding site on the

monoclonal capture antibody on the plate. Like the sequential competitive inhibition format, the colored signal is inversely proportional to the concentration of unlabeled target analyte in the sample.

Rapid immunoassay tests use antibodies to react with antigens and can be developed as monoclonal-polyclonal sandwich formats, competitive inhibition formats and antigen-down formats. With a rapid test, the antibody and antigen reagents are bound to porous membranes, which react with positive samples while channeling excess fluids to a nonreactive part of the membrane. There are two common configurations: a lateral flow test, such as the Bio Threat Alert test strips, where the sample is simply placed in a well and the results are read immediately; and a flow through system, which requires placing the sample in a well, washing the well, adding an analyte-colloidal gold conjugate, and reading the results after a few minutes. One sample is tested per strip or cassette.

For further information on immunoassay technology, please refer to http://www.immunochemistry.com, contact the Critical Reagents Program at (410) 436-9111, or contact Edgewood BioDefense at 410-436-5562.

5. Evaluation Process

Four scenarios of use were selected for the analysis. These scenarios represent distinctly different uses of detection technologies; in essence, each scenario involves different objectives and requirements. 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.

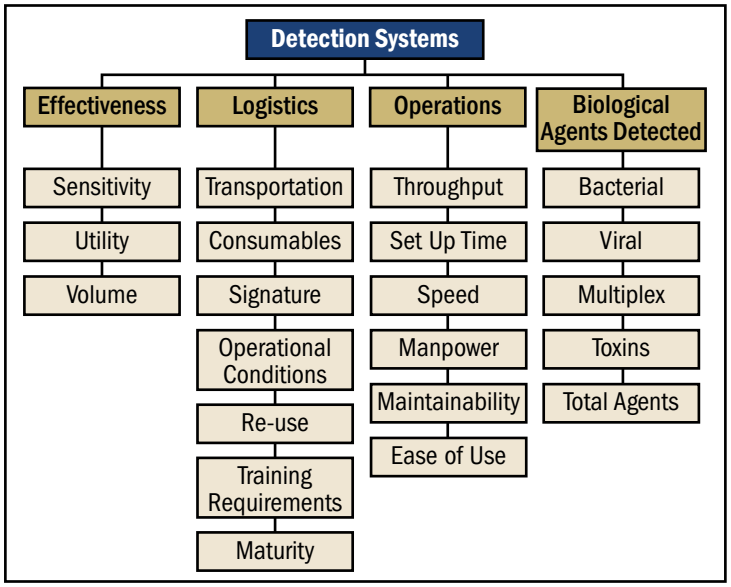


Figure 1. Hierarchical representation of criteria for detection devices or systems product evaluation.

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 0 for the lowest expected performance, to 100 for the highest level of expected performance. Intermediate levels of performance were assigned values between 0 and 100. For this study, products were assessed at discrete scale levels, as opposed to continuous scales. The definitions and performance scales for the evaluation criteria are shown in Section 6 of this report.

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 lowest level criteria for each of the three legs of the hierarchy. 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 LAB	DIAGNOSTIC LAB	ANALYTICAL LAB
Sensitivity	2.5	5.0	24.0	30.0
Utility	2.0	5.0	12.0	5.0
Volume	0.5	5.0	4.0	15.0
Transportation	13.5	10.0	2.2	1.0
Consumables	4.5	5.0	2.2	1.0
Signature	2.3	1.0	0.0	1.0
Operational Conditions	4.5	8.0	1.5	1.0
Re-Use	4.5	8.0	1.5	1.0
Training Requirements	2.3	4.0	4.5	2.0
Maturity	13.5	4.0	3.0	3.0
Throughput	4.5	0.7	2.5	2.0
Set Up Time	9.0	0.4	2.5	1.0
Speed	9.0	1.5	10.0	2.0
Manpower	4.5	2.2	1.2	1.0
Maintainability	13.5	5.2	1.2	1.0
Ease of Use	4.5	4.9	7.5	3.0
Bacterial	1.0	6.0	3.0	3.0
Viral	1.0	4.5	3.0	3.0
Multiplex	1.0	1.5	3.0	9.0
Toxins	1.0	6.0	3.0	3.0
Total Agents	1.0	1.2	8.0	12.0

Table 1. Weighted Performance Criteria Used in the Evaluation Model Determined by Subject Matter Experts

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 also obtained information from subject matter experts working in these particular fields concerning the performance of detection products with which they were familiar. The authors evaluated every product that submitted a completed questionnaire.

Each product was scored relative to each criterion for each scenario. Overall scores and rankings were generated by the decision analysis software Logical Decisions® for Windows (LDW), using a linear additive approach where each criterion score is multiplied by the criterion weight and summed over all the criteria.

The results were analyzed to determine each product's overall effectiveness (utility) for each scenario. These scores were used to identify the best-fit scenario for each technology, as well as determine its potential effectiveness in all four scenarios.

6. Selection Factors

1.0 EFFECTIVENESS GOAL

Ability of the detection system to effectively detect the biological agent from the target source. Taking into consideration the concentration of the biological agent being detected and the amount of sample needed for testing.

1.1 Sensitivity Measure. Ability of detection system to detect the lowest concentration of target agent possible.

100 Detects 1-100 colony forming units (CFUs) per ml
90 Detects 100-1,000 CFUs per ml
75 Detects 1,000-10,000 CFUs per ml
50 Detects 10,000-100,000 CFUs per ml
0 Detects greater than 100,000 CFUs per ml unknown

1.2 Utility Measure. The best setting in which to use the detection device or system.

- Small, lightweight, easy to carry, and/or for field use*
- Small, lightweight, easy to carry, and/or for field use; and small, little, or no additional equipment and/or suitable for a mobile or deployable lab*
- Small, little, or no additional equipment and suitable for a mobile or deployable lab*
- Large, relatively easy to use but best suited for a hospital or other diagnostic setting*
- Large, relatively easy to use but best suited for a hospital or other diagnostic setting and large, very sensitive, and intended for an analytical lab*
- Large, very sensitive, and intended for an analytical lab*

**Varies according to the scenario utilized*

1.3 Volume Measure. The volume of sample needed to effectively detect the target agent with the detection system or device.

100 Less than 10 ul
75 Less than 50 ul
50 Less than 100 ul
25 Less than 250 ul
0 Greater than 250 ul

2.0 LOGISTICS GOAL

Effect of the detection system or device on support and logistical systems.

2.1 Transportation Measure. Ability to transport the detection system or device. Takes into consideration the portability of the system, as well as the weight and volume of the device or system.

- Approximately the size of a soda can*
- Approximately the size of a toaster*
- Approximately the size of a carry-on luggage suitcase*
- Approximately the size of a home dishwasher*
- Larger than a home dishwasher*

**Varies according to the scenario utilized*

2.2 Component Measure. Requirement of consumables (items that would need to be re-supplied, such as water, fuel, batteries, chemical, power, etc.) that have to be transported to the site for detection.

100 0-1 consumable or expendable
80 2 consumables or expendables
60 3 consumables or expendables
30 4 consumables or expendables
0 5 or more consumables or expendables or unknown

2.3 Signature Measure. Effect of the detection system or device on the signature of covert operations.

100 Less than 200 British Thermal Units (BTUs) generated
50 Between 200-500 BTUs generated
0 Greater than 500 BTUs generated or unknown

2.4 Operational Conditions Measure. Temperature ranges at which the detection device or system can operate with little or no loss of efficacy.

100 Can be used from 4°C to 45°C
95 Can be used from 4°C to 37°C
80 Can be used from 15°C to 37°C
50 Can be used from 25°C to 37°C
0 Can only be used at 25°C or unknown

2.5 Re-use Measure. Ability of device or system to be cleaned and returned to service, or designed for single use only.

- Device or system is designed for a single use*
- Device or system is intended for multiple detection assays*

**Varies according to the scenario utilized*

2.6 Training Requirements Measure. The amount of training required before being able to utilize the detection device or system.

100 Very brief training
80 An afternoon of training
50 A day of training
0 More than a day of training

2.7 Maturity Measure. The availability of the detection device or system commercially.

100 Is commercially available and meets military specifications
90 Is commercially available
30 A few devices or systems exist (brass board)
15 Only one incomplete device or system exist (bread board)
0 Only a concept on paper exist (white board)

3.0 OPERATIONS GOAL

Effect of the detection device or system on detection efforts and operations during usage.

3.1 Throughput Measure. The throughput of the detection system or device, measured in samples/run and also related to batch size.

100 Can run 384 samples/batch or higher
80 Can run 96 samples/batch or higher
60 Can run 32 samples/batch or higher
20 Can run 2 samples/batch or higher
0 Can only run 1 sample/batch

3.2 Set-up Measure. The amount of time need to start up the detection device or system, including quality assurance procedures.

100 No set-up required
80 Less than 5 minutes
60 5-10 minutes
40 10-20 minutes
0 Greater than 20 minutes

3.3 Speed Measure. Total time required to detect a single target agent from a single surface wipe in liquid.

100 20 minutes or less
90 Between 20 and 30 minutes
75 Between 30 and 40 minutes
50 Between 40 and 50 minutes
25 Between 50 and 60 minutes
0 Greater than 60 minutes

3.4 Manpower Measure. The potential for automation of the device or system.

100 The system or device is currently fully automated
90 The system or device could easily be adapted into a fully automated system
60 The system or device could be adapted to a fully automated system with some effort
30 The system or device could be adapted to a semi-automated system with some effort
0 The system or approach is not amendable to automation

3.5 Maintainability Measure. The amount of times the detection device or system needs to be serviced.

100 Never needs serviced
90 Needs service less than once a year
60 Needs service once a year
30 Needs service every 6 months
0 Needs service more often than every 6 months or known

3.6 Ease of Use Measure. The complexity and number of steps required to operate the detection device or system.

100	0-2 steps required
80	3-5 steps required
50	6-8 steps required
20	9-12 steps required
0	Greater than 12 steps required or unknown

4.0 BIOLOGICAL AGENTS DETECTED GOAL

Ability of the detection device or system to detect biological agents, such as bacteria or viruses, detect toxins, or multiple agents at the same time.

4.1 Bacterial Measure. Number of assays that have been developed to detect bacteria that are important to biodefense.

100	Can detect 4 or more bacterial agents
75	Can detect 3 bacterial agents
50	Can detect 2 bacterial agents
25	Can detect 1 bacterial agent
0	Can not detect any bacterial agents

4.2 Viral Measure. Number of assays that have been developed to detect viruses that are important to biodefense.

100	Can detect 4 or more viral agents
75	Can detect 3 viral agents
50	Can detect 2 viral agents
25	Can detect 1 viral agent
0	Can not detect any viral agents

4.3 Multiplex Measure. Ability to detect multiple biodefense agents or toxins at the same time.

100	Assay available and capable of detecting 4 or more agents or toxins
50	Assay not available, but capable of detecting 4 or more agents or toxins
75	Assay available and capable of detecting 2 or more agents or toxins
50	Assay not available, but capable of detecting 2 or more agents or toxins
0	Not capable of detecting multiple agents or toxins

4.4 Toxins Measure. Number of assays that have been developed to detect toxins that are important to biodefense.

100	Can detect 4 or more toxins
75	Can detect 3 toxins
50	Can detect 2 toxins
25	Can detect 1 toxin
0	Cannot detect any toxins

4.5 Total Agents Measure. Total number of biological warfare agents that assays have been developed for and can be detected.

100	Can detect more than 20 total agents
83.3	Can detect 20-16 total agents
66.7	Can detect 15-11 total agents
50	Can detect 10-6 total agents
33.3	Can detect 5-2 total agents
16.7	Can detect only 1 agent
0	Cannot detect any agents

7. Evaluation of Detection Devices or Systems

FIELD USE

In the evaluation of detection equipment for field use, factors pertaining to the simplicity of transportation of the device or system, time for set up, detection speed, maintainability, maturity, and total agents detectable were considered as the most important criteria. An ideal field use device would be small and easily transportable, require few manual steps to operate, easy to maintain, and be able to operate at a variety of environmental conditions. Small, easy to use, and versatile detection devices topped the evaluation for field use detection products. The SMART Tickets Bio Threat Alert Test Strips and the RAMP Tickets scored well as field devices for immunoassay technologies and represent the best fit for this scenario.

The RAZOR scored well as field devices for the handheld PCR technologies. This PCR device ranges in size from 1 kg to 5 kg and would likely be transportable via backpack for field use. Systems and devices that did not fare as well in the evaluation often require several additional pieces of equipment (e.g., centrifuges, shaker, vortex) for use, which decreased the ease of use and increased the number of manual steps. Figure 2 highlights the criteria specific to the evaluation of products and technologies for field use.

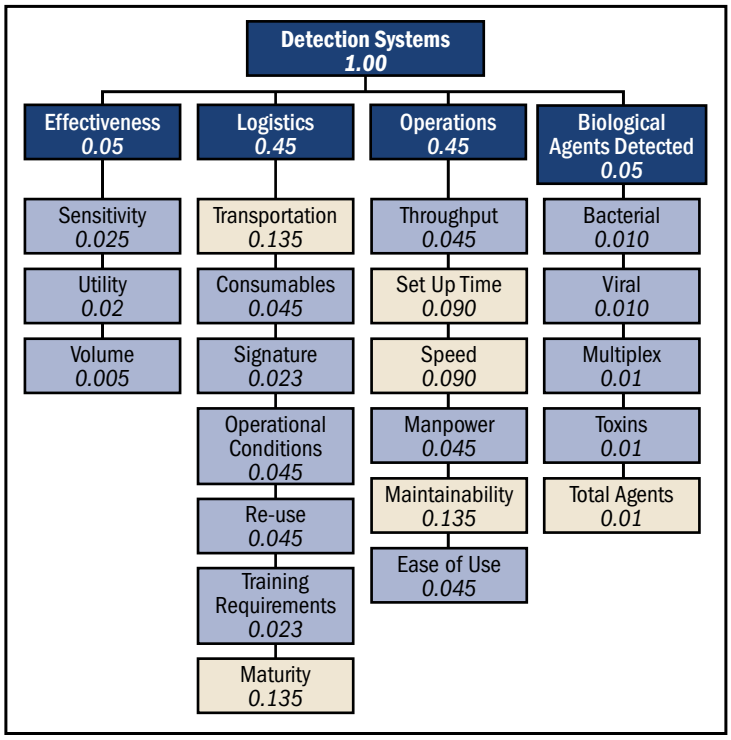
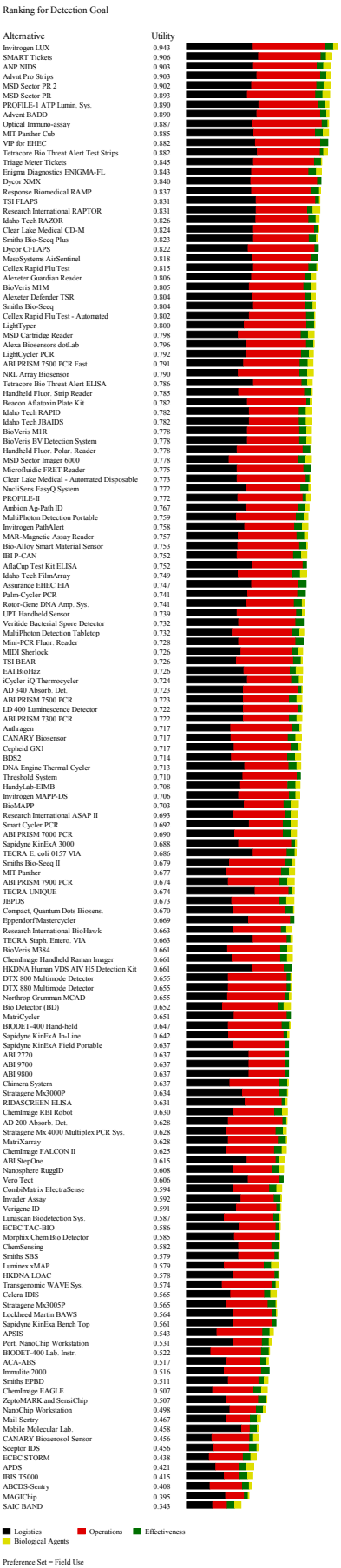


Figure 2. Hierarchical representation of criteria for Evaluation of Detection Products for Field Use



MOBILE LABORATORY

In the evaluation of detection equipment for mobile laboratories, factors pertaining to the bacterial, total agents, and toxins detectable; transportation; operational conditions; and re-use ability were considered as the most important criteria. 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.

Easy transportation and the ability of a device to detect many agents topped the evaluation for mobile laboratory detection products. The ABI PRISM 7900 Sequence Detection System was the highest ranked PCR device. Combining a less than once a year service requirement and ability to detect 25 agents, this system represents the best fit for this scenario. The SMART Tickets were the highest ranked immunoassay devices with no service required and ability to detect 14 agents currently, with others in development. Systems and devices that did not fare as well in the evaluation often required several manual steps for detection, which increased the process time and manpower requirements and reduced the ease of use. Figure 3 highlights the criteria specific to the evaluation of products and technologies for mobile laboratory use.

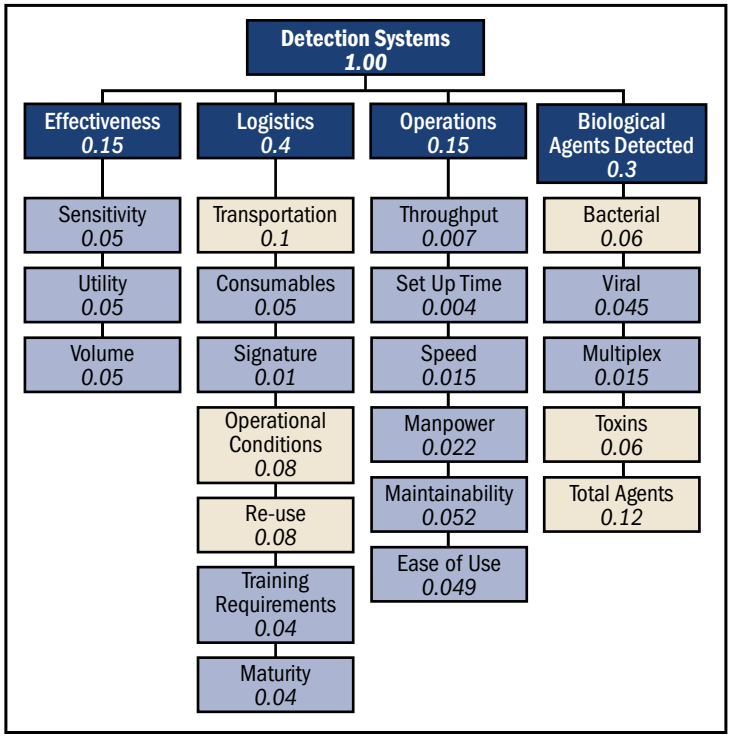
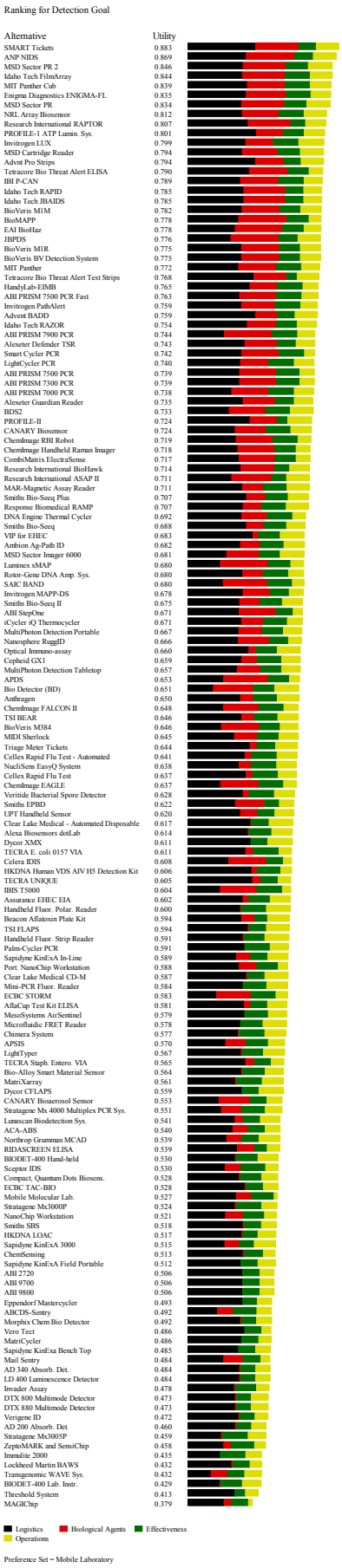


Figure 3. Hierarchical representation of criteria for Evaluation of Detection Products for Mobile Laboratories



DIAGNOSTIC LABORATORY

In the evaluation of detection equipment for diagnostic laboratories, factors pertaining to the sensitivity, utility, time to detect, ease of use, and total agents detectable were considered as the most important criteria. An ideal diagnostic laboratory device would require relatively quick performance and would have high sensitivity requirements.

Effective, fast, and efficient detection devices topped the evaluation for diagnostic laboratory detection devices or systems. The ABI Prism 7900 Detection System was the highest ranked PCR device. Combining high sensitivity and few consumables, this system represents the best fit for this scenario. The Sector Images 6000 and the Sector PR100 scored the highest among the immunoassay detection devices. Systems and devices that did not fare as well in the evaluation were often not sensitive, used many consumables, were slow to detect, and did not detect many agents.

Figure 4 highlights the criteria specific to the evaluation of products and technologies for diagnostic laboratory use.

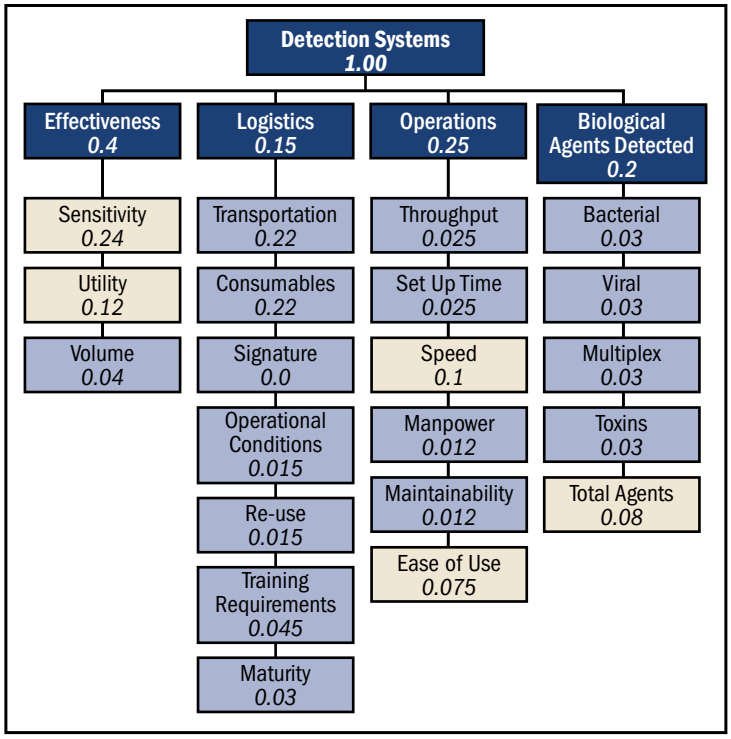
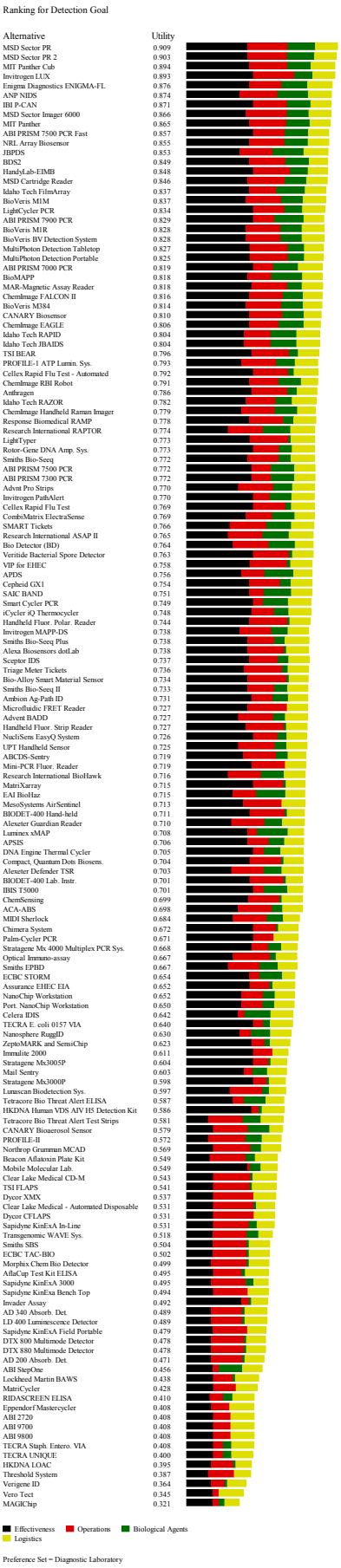


Figure 4. Hierarchical representation of criteria for Evaluation of Detection Products for Diagnostic Laboratories



ANALYTICAL LABORATORY

In the evaluation of detection equipment for analytical laboratories, factors pertaining to sensitivity, utility, volume, total agents detected, and ability to multiplex were considered to be the most important criteria. An ideal analytical laboratory device would require the generation of a nearly perfect sensitivity, as well as ability to detect many agents in the same sample. The ABI PRISM 7900 and 7000 detection systems scored particularly well in the evaluation for analytical laboratory PCR detection products. The ABI PRISM 7900 was the highest ranked device, combining high sensitivity and the ability to detect many agents and multiple agents in the same sample, and represents the best fit for this scenario. Other devices, such as the BioMAPP and APDS systems, use both PCR and immunoassay technologies and scored well in this category due to their high sensitivity and ability to detect multiple agents in a single sample. Most of the immunoassay devices did not fare well for this category due to lack of sensitivity and lack of multiplex capabilities with the exception of the Sector Images 6000. Systems and devices that did not fare as well in the evaluation often had poor sensitivity. Figure 5 highlights the criteria specific to the evaluation of products and technologies for analytical laboratory use.

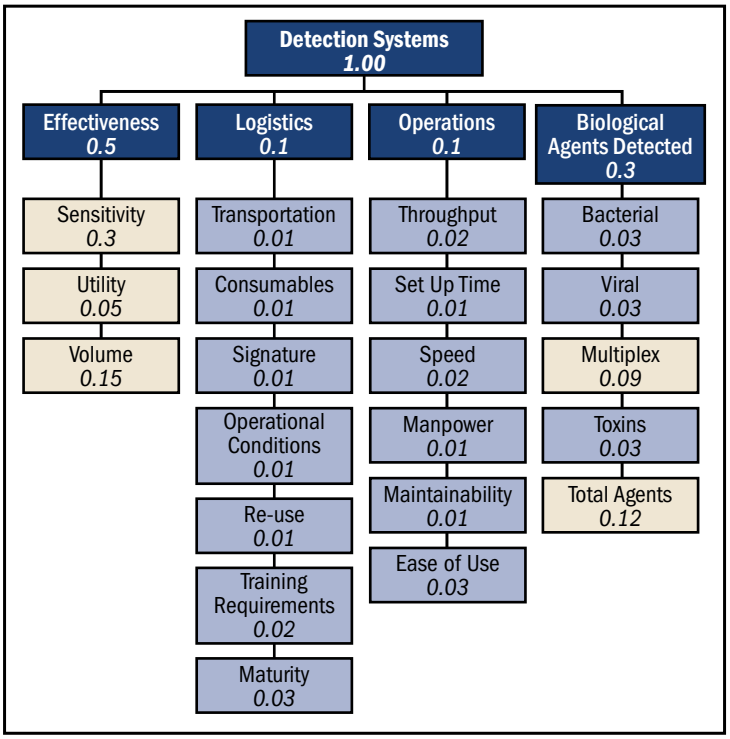
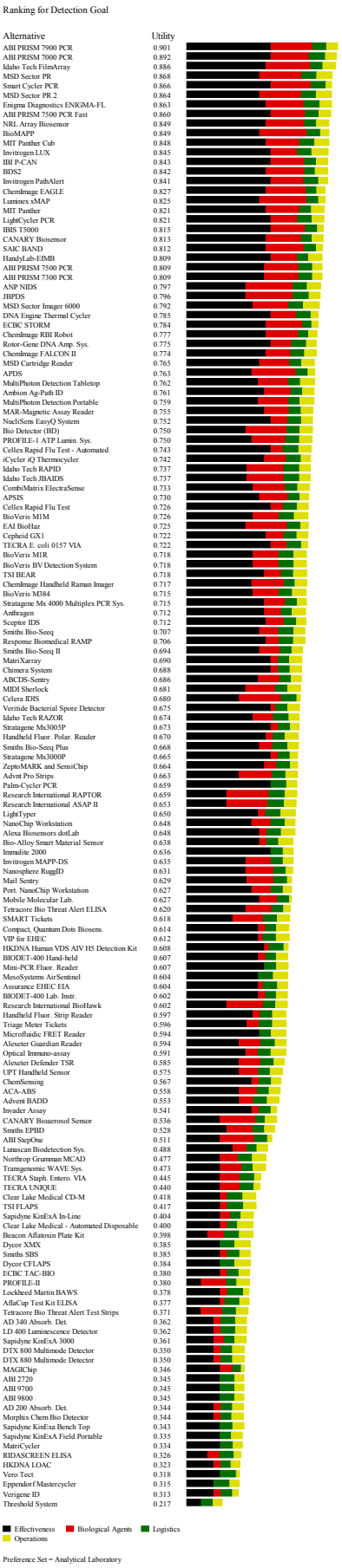


Figure 5. Hierarchical representation of criteria for Evaluation of Detection Products for Analytical Laboratories



8. Summary

The process of comparison and contrast among competing scientific technologies is a useful exercise to assist the research community in deciding which product best fits their particular needs. As a variety of fundamentally different technologies now exist for the task of detection, a method for comparison is particularly useful at this time. Product information was collected from interested vendors and compared with a model, as well as a handful of traditional protocols. A set of important and discriminating criteria was established to differentiate between competing technologies and used to generate overall rankings for four different usage scenarios. The overall ranking weights were based upon the authors' experiences and opinions, and would likely vary slightly from person to person, although they tend to represent the general opinions of the research community at large. The model generated during this report permits sensitivity analysis that could be used to consider other views.

A potentially useful way to use this guide would be to review the research scenario that most relates to an area of interest, identify which products scored well in the evaluation for each technology, and then closely examine these products using the product information contained within Appendix II. When looking at the product score, do not judge the product base solely on the raw score. Look at the product score in blocks (top, middle, bottom); the products were evaluated in blocks of thirds. Information for product representatives is included for each product so that additional information can be obtained. Appendix II is intended as an independent document that can be used as a general guide to present information on several options for detection products.

Appendix I: Technology Quick Reference

	PCR Based Technology	Immunoassay Technology	Both PCR & Immunoassay Technologies	Other Technology: Specify	Maturity Gauge
ABCDS-Sentry		✓			
ABI 2720	✓				
ABI 9700	✓				
ABI 9800	✓				
ABI PRISM 7000 PCR	✓				
ABI PRISM 7300 PCR	✓				
ABI PRISM 7500 PCR	✓				
ABI PRISM 7500 PCR Fast	✓				
ABI PRISM 7900 PCR	✓				
ABI StepOne	✓				
ACA-ABS		✓			
AD 200 Absorb. Det.		✓			
AD 340 Absorb. Det.		✓			
Advent BADD		✓			
Advnt Pro Strips		✓			
AflaCup Test Kit ELISA		✓			
Alexa Biosensors dotLab		✓			
Alexeter Defender TSR		✓			
Alexeter Guardian Reader		✓			
Ambion Ag-Path ID	✓				
ANP NIDS		✓			
Anthragen		✓			

	PCR Based Technology	Immunoassay Technology	Both PCR & Immunoassay Technologies	Other Technology: Specify	Maturity Gauge
APDS			✓		
APSIS	✓			PCR and Microarray	
Assurance EHEC EIA		✓			
BDS2				Optical Sensor	
Beacon Aflatoxin Plate Kit		✓			
Bio-Alloy Smart Material Sensor		✓			
BIODET-400 Lab. Instr.		✓			
BIODET-400 Hand-held		✓			
Bio Detector (BD)		✓			
BioMAPP			✓		
BioVeris BV Detection System		✓			
BioVeris M1M	✓				
BioVeris M1R		✓			
BioVeris M384		✓			
CANARY Bioaerosol Sensor		✓		B cell based	
CANARY Biosensor		✓		B cell based	
Celera IDIS	✓				
Cellex Rapid Flu Test				Enzymatic	
Cellex Rapid Flu Test - Automated				Enzymatic	
Cepheid GX1	✓				
ChemImage EAGLE				Raman spectroscopy	
ChemImage FALCON II				Raman spectroscopy	

	PCR Based Technology	Immunoassay Technology	Both PCR & Immunoassay Technologies	Other Technology: Specify	Maturity Gauge
ChemImage Handheld Raman Imager				Raman spectroscopy	
ChemImage RBI Robot				Raman spectroscopy	
ChemSensing				Colorimetric	
Chimera System	✓				
Clear Lake Medical - Automated Disposable			✓		
Clear Lake Medical CD-M				Imaging system	
CombiMatrix ElectraSense				Microarray	
Compact, Quantum Dots Biosensor		✓			
DNA Engine Thermal Cycler	✓				
DTX 800 Multimode Detector		✓			
DTX 880 Multimode Detector		✓			
Dycor CFLAPS				Non-specific biological particle detector	
Dycor XMX				Non-specific biological particle detector	
EAI BioHaz				Non-specific test for DNA and protein	
ECBC STORM			✓		
ECBC TAC-BIO				Non-specific biological particle detector	
Enigma Diagnostics ENIGMA-FL	✓				
Eppendorf Mastercycler	✓				
Handheld Fluor. Polar. Reader		✓			
Handheld Fluor. Strip Reader		✓			
HandyLab-EIMB	✓				
HKDNA Human VDS AIV H5 Detection Kit	✓				

	PCR Based Technology	Immunoassay Technology	Both PCR & Immunoassay Technologies	Other Technology: Specify	Maturity Gauge
HKDNA LOAC				Microarray	
IBI P-CAN				B cell based	
IBIS T5000	✓			PCR and mass spectrometry	
iCycler iQ Thermocycler	✓				
Idaho Tech FilmArray	✓			Microarray	
Idaho Tech JBAIDS	✓				
Idaho Tech RAPID	✓				
Idaho Tech RAZOR	✓				
Immulite 2000		✓			
Invader Assay				Enzymatic	
Invitrogen LUX	✓				
Invitrogen MAPP-DS				Resonance light scattering	
Invitrogen PathAlert	✓				
JBPDS		✓			
LD 400 Luminescence Detector				Photometric	
LightCycler PCR	✓				
LightTyper	✓				
Lockheed Martin BAWS				Non-specific biological particle detector	
Luminex xMAP		✓			
Lunascan Biodetection Sys.		✓		Optical Fiber with Fluorescence	
MAGIChip			✓	Microarray	
Mail Sentry	✓				

	PCR Based Technology	Immunoassay Technology	Both PCR & Immunoassay Technologies	Other Technology: Specify	Maturity Gauge
MAR-Magnetic Assay Reader		✓		Mutual Induction	
MatriCycler	✓				
MatriXarray	✓				
MesoSystems AirSentinel				Non-specific biological particle detector	
Mini-PCR Fluor. Reader	✓				
Microfluidic FRET Reader		✓			
MIDI Sherlock				Gas chromatography	
MIT Panther				B cell based	
MIT Panther Cub				B cell based	
Mobile Molecular Lab.	✓				
Morphix Chem Bio Detector				Non-specific biological particle detector	
MSD Cartridge Reader		✓			
MSD Sector Imager 6000		✓			
MSD Sector PR		✓			
MultiPhoton Detection Portable		✓			
MultiPhoton Detection Tabletop		✓			
NanoChip Workstation				Microarray	
Nanosphere RuggID			✓		
Northrop Grumman MCAD				Non-specific biological particle detector	
NRL Array Biosensor		✓			
NucliSens EasyQ System	✓				
Optical Immuno-assay		✓			

	PCR Based Technology	Immunoassay Technology	Both PCR & Immunoassay Technologies	Other Technology: Specify	Maturity Gauge
Palm-Cycler PCR	✓				
Port. NanoChip Workstation	✓			Microarray	
PROFILE-1 ATP Lumin. Sys.				Luminescence	
PROFILE-II		✓			
Research International BioHawk		✓			
Research International RAPTOR		✓			
Research International ASAP II		✓			
Response Biomedical RAMP		✓			
RIDASCREEN ELISA		✓			
Rotor-Gene DNA Amp. Sys.	✓				
SAIC BAND			✓		
Sapidyne KinExA 3000		✓			
Sapidyne KinExA Bench Top		✓			
Sapidyne KinExA Field Portable		✓			
Sapidyne KinExA In-Line		✓			
Sceptor IDS	✓				
Smart Cycler PCR	✓				
SMART Tickets		✓			
Smiths Bio-Seeq	✓				
Smiths Bio-Seeq II	✓				
Smiths Bio-Seeq Plus	✓				
Smiths EPBD		✓			

	PCR Based Technology	Immunoassay Technology	Both PCR & Immunoassay Technologies	Other Technology: Specify	Maturity Gauge
Smiths SBS				Non-specific biological particle detector	
Stratagene Mx3000P	✓				
Stratagene Mx3005P	✓				
Stratagene Mx 4000 Multiplex PCR Sys.	✓				
TECRA E. coli 0157 VIA		✓			
TECRA Staph. Entero. VIA		✓			
TECRA UNIQUE		✓			
Tetracore Bio Threat Alert ELISA		✓			
Tetracore Bio Threat Alert Test Strips		✓			
Threshold System	✓				
Transgenomic WAVE Sys.	✓			Liquid Chromatography	
Triage Meter Tickets		✓			
TSI BEAR				DNA hybridization	
TSI FLAPS				Non-specific biological particle detector	
UPT Handheld Sensor		✓			
Verigene ID		✓		Nanoparticle Probes	
Veritide Bacterial Spore Detector				Optical detection	
Vero Tect				Non-specific biological particle detector	
VIP for EHEC		✓			
ZeptoMARK and SensiChip				Microarray	

Maturity Gauge Key:

 Commercially available & meets military specs

 Commercially available

 A few devices exist

 Only one incomplete device exists

 Only a concept on paper

Appendix II: Evaluation of Detection Products

ABI 2720

by Applied Biosystems

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, E. coli 0157:H7, Francisella tularensis, Vibrio cholera, Corynebacterium diptheria, Burkholderia mallei, Burkholderia pseudomallei, Yersinia pestis, Coxiella burnetti, Rickettsia prowazekii, Brucella species, Marburg virus, Rift Valley fever virus, VEE virus, Hanta virus, Yellow fever virus, Dengue fever virus, Ebola viruses, Orthopox virus, MS-2 bacteriophage *(Assays developed)*

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 uses peltier-based elements to enable the PCR amplification process. PCR is composed of three segments, which can be programmed on the thermal cycler. In the pre-PCR segment, you define an incubation temperature and hold time sufficient to denature double-stranded DNA. The PCR segment is the actual cycling segment that generates the amplified product. The key parameters are used for template denaturation, primer annealing, and primer extension. The post-PCR incubation temperature defines how to soak your samples at a specified temperature until you are ready to analyze them.

ANALYTICAL Laboratory Ranking

ABI 2720 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
Best Score	0.901
ABI 2720	0.345
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

ABI 2720 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
Best Score	0.909
ABI 2720	0.408
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

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.

ALTERNATIVE	UTILITY
Best Score	0.883
ABI 2720	0.506
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

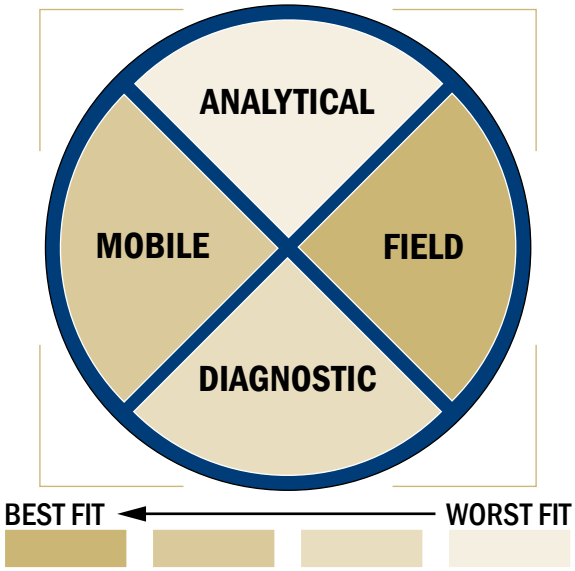
ABI 2720 ranked in the middle third of all evaluated products for field use and earned 68% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
ABI 2720	0.637
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

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850 Lincoln Center Drive
Foster City, CA 94494
www.Appliedbiosystems.com

Point of Contact:
Andy Felton
(800) 248-0281
(650) 638-6045 fax
feltonac@appliedbiosystems.com

COST

- $4,395.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- 384 sample/batch or higher
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:
- Very brief (minutes-hours) training and minimal technical skills
- 10-20 minutes is required for system set-up
- 3-5 manual steps required for detection

Re-use:
- 4 step cleaning procedure

Maintenance:
- Once a year service required
- Expected life is between 3-5 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 5 and 25 kg

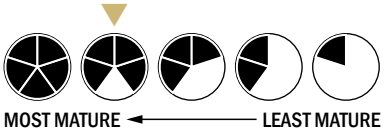
Ease of use/Utility::
- Can not view results “in real time”
- Multiple shaking or vortexing steps
- System can not interpret raw data or call a positive through internal software
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- Unknown

Maturity gauge:
- Is commercially available
- Has been featured in peer reviewed scientific publications or independent evaluation



ABI PRISM 7000 Sequence Detection System

by Applied Biosystems

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, E. coli 0157: H7, Francisella tularensis, Vibrio cholera, Corynebacterium diptheria, Burkholderia mallei, Burkholderia pseudomallei, Yersinia pestis, Coxiella burnetti, Rickettsia prowazekii, Brucella species, Marburg virus, Rift Valley fever virus, VEE virus, Hanta virus, Yellow fever virus, Dengue fever virus, Ebola viruses, Orthopox virus, MS-2 bacteriophage *(Assays developed)*

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 a four position emission filter wheel, 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 no crosstalk.

ANALYTICAL Laboratory Ranking

ABI PRISM 7000 Sequence Detection System ranked in the top third of all evaluated products for analytical laboratories and earned 99% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
ABI PRISM 7000 PCR	0.892
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

ABI PRISM 7000 ranked in the top third of all evaluated products for diagnostic laboratories and earned 90% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
ABI PRISM 7000 PCR	0.819
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

ABI PRISM 7000 ranked in the top third of all evaluated products for mobile laboratories and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
ABI PRISM 7000 PCR	0.738
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

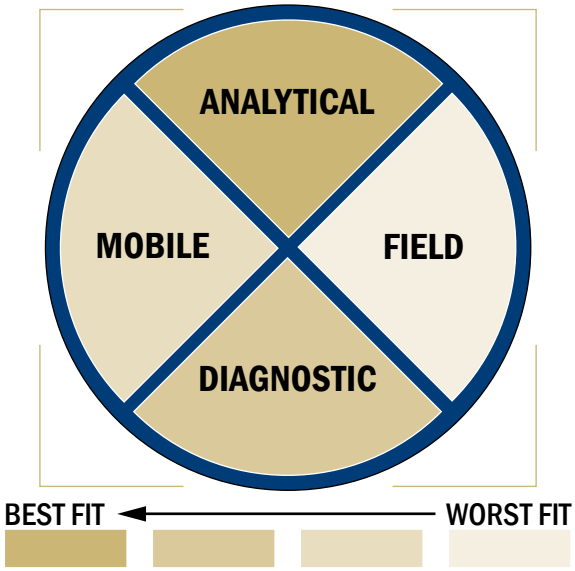
ABI PRISM 7000 ranked in the middle third of all evaluated products for field use and earned 73% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
ABI PRISM 7000 PCR	0.690
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

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www.Appliedbiosystems.com

Point of Contact:
Andy Felton
(800) 248-0281
(650) 638-6045 fax
feltonac@appliedbiosystems.com

COST

- $0.50/ sample plus Taq enzyme
- $42,761 GSA price/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection greater than 60 minutes
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:

- Very brief training
- Less than 5 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 3 components
- No cleaning required

Maintenance:

- 2 consumables or expendables needed
- Less than once a year service required
- Expected life is 5-10 years
- Less than 5 minutes required for daily assurance procedures

Transportation:

- Approximately the size of a home dishwasher
- Between 5 and 25 kg
- Shelf life between 1 and 3 years

Ease of use/Utility:

- Cannot view results “in real time”
- No centrifugation steps
- Single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting two or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

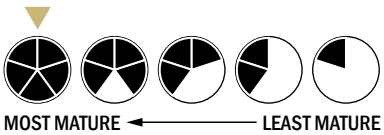
- Operated from 4 °C to 37 °C
- Components must be stored at 4 °C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- Is commercially available and meets military specifications



ABI 7300 Real Time PCR System

by Applied Biosystems

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Corynebacterium diphtheria, Burkholderia pseudomallei, Coxiella burnetti, Brucella species, E.coli O157:H7, Vibrio cholera, Burkholderia mallei, Yersinia pestis, Rickettsia prowazekii, Marburg virus, Influenza virus, Dengue fever virus, Orthopox virus, Rift valley fever virus, Venezuelan equine encephalitis virus, Yellow fever virus, Ebola virus, MS-2 bacteriophage *(Assay developed)*

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 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 7300 System ranked in the top third of all evaluated products for analytical laboratories and earned 90% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
ABI PRISM 7300 PCR	0.809
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

ABI 7300 System ranked in the top third of all evaluated products for diagnostic laboratories and earned 85% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
ABI PRISM 7300 PCR	0.772
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

ABI 7300 System ranked in the top third of all evaluated products for mobile laboratories and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
ABI PRISM 7300 PCR	0.739
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

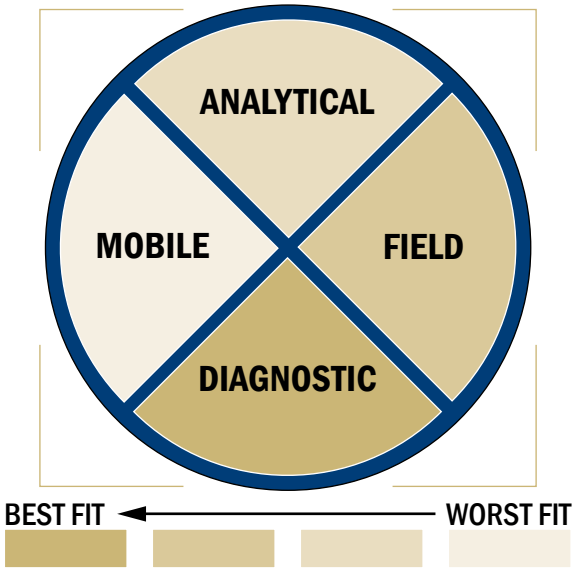
ABI 7300 System ranked in the middle third of all evaluated products for field use and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
ABI PRISM 7300 PCR	0.722
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Applied Biosystems
850 Lincoln Center Drive
Foster City, CA 94494
www.Appliedbiosystems.com

Point of Contact:
Andy Felton
(800) 248-0281
(650) 638-6045 fax
feltonac@appliedbiosystems.com

COST

- $0.50/sample plus Taq enzyme
- $34,900/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection greater than 60 minutes
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:

- A day of training
- No set-up required
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 3 components
- No cleaning required

Maintenance:

- 4 consumables or expendables needed
- Once a year service required
- Expected life is between 5-10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 25 and 50 kg
- Shelf life measure not applicable

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available but capable of detecting four or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:

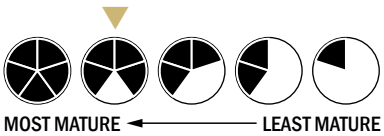
- Operated from 4 °C to 37 °C
- Components must be stored at 4 °C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

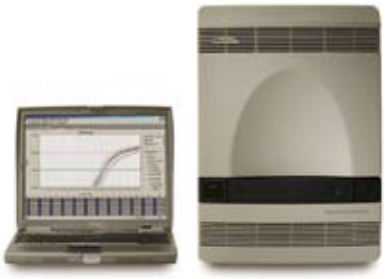
- Is commercially available



ABI PRISM 7500 PCR Fast Analysis

by Applied Biosystems

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Corynebacterium diphtheria, Burkholderia pseudomallei, Coxiella burnetti, Brucella species, E.coli O157:H7, Vibrio cholera, Burkholderia mallei, Yersinia pestis, Rickettsia prowazekii, Marburg virus, Influenza virus, Dengue fever virus, Orthopox virus, Rift valley fever virus, Venezuelan equine encephalitis virus, Yellow fever virus, Ebola virus, MS-2 bacteriophage *(Assay developed)*



DESCRIPTION:
The Applied Biosystems 7500 Fast Real-Time PCR System is an integrated system designed to perform both real-time PCR and post-PCR analysis. This instrument is capable of analyzing 96 samples simultaneously in a 96-well plate format.

The 7500 Fast provides specialized application specific software that collects and analyzes the fluorescence data for the application of absolute quantitation, gene expression, genotyping and pathogen detection.

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 PRISM 7500 Sequence Detection System ranked in the top third of all evaluated products for analytical laboratories and earned 95% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
ABI PRISM 7500 PCR Fast	0.860
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

ABI PRISM 7500 ranked in the top third of all evaluated products for diagnostic laboratories and earned 94% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
ABI PRISM 7500 PCR Fast	0.857
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

ABI PRISM 7500 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
Best Score	0.883
ABI PRISM 7500 PCR Fast	0.763
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

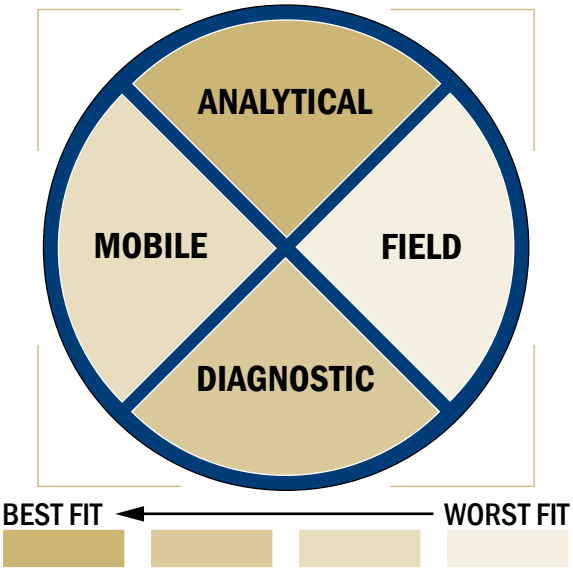
ABI PRISM 7500 ranked in the top third of all evaluated products for field use and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
ABI PRISM 7500 PCR Fast	0.791
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

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Andy Felton
(800) 248-0281
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feltonac@appliedbiosystems.com

COST

- $0.50/sample plus cost of Taq enzyme
- $49,900/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection between 30 and 40 minutes
- 96 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:

- A day of training and technical skills required
- No set-up required
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 3 components

Maintenance:

- Once a year service required
- Expected life is between 5-10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 25 and 50 kg
- Reagent shelf life between 6 months and 1 year

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:

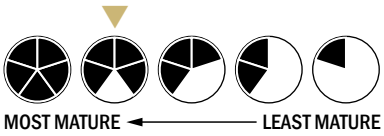
- Operated from 4 °C to 37 °C
- Components must be stored at 4 °C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- Is commercially available
- Has been featured in peer reviewed scientific publications or independent evaluation



ABI 7500 Real Time PCR System

by Applied Biosystems

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Corynebacterium diphtheria, Burkholderia pseudomallei, Coxiella burnetti, Brucella species, E.coli O157:H7, Vibrio cholera, Burkholderia mallei, Yersinia pestis, Rickettsia prowazekii, Marburg virus, Influenza virus, Dengue fever virus, Orthopox virus, Rift valley fever virus, Venezuelan equine encephalitis virus, Yellow fever virus, Ebola virus, MS-2 bacteriophage *(Assay developed)*

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 Sequence Detection System ranked in the top third of all evaluated products for analytical laboratories and earned 90% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
ABI PRISM 7500 PCR	0.809
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

ABI 7500 ranked in the top third of all evaluated products for diagnostic laboratories and earned 85% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
ABI PRISM 7500 PCR	0.772
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

ABI 7500 ranked in the top third of all evaluated products for mobile laboratories and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
ABI PRISM 7500 PCR	0.739
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

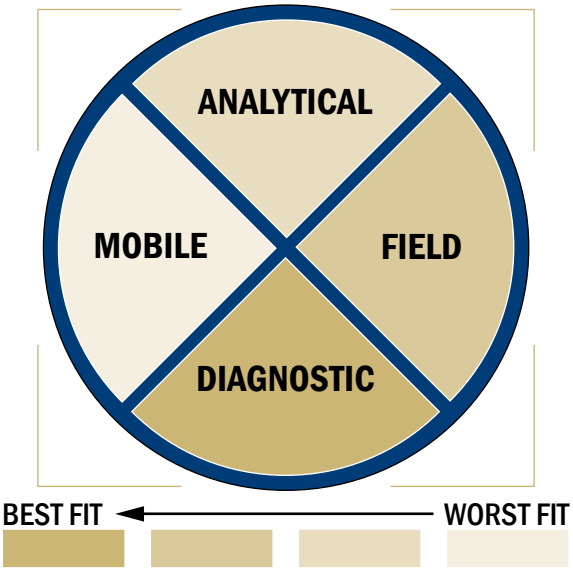
ABI 7500 ranked in the middle third of all evaluated products for field use and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
ABI PRISM 7500 PCR	0.723
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

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www.Appliedbiosystems.com

Point of Contact:
Andy Felton
(800) 248-0281
(650) 638-6045 fax
feltonac@appliedbiosystems.com

COST

- $0.50/sample plus cost of Taq enzyme
- $42,500.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection greater than 60 minutes
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:

- A day of training
- No set-up required
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 3 components
- No cleaning required

Maintenance:

- 5 or more consumables or expendables needed
- Once a year service required
- Expected life is between 5-10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 25 and 50 kg
- Shelf life measure not applicable

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available but capable of detecting four or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:

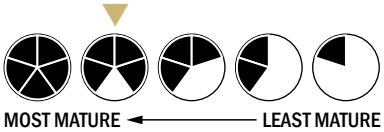
- Operated from 4 °C to 37 °C
- Components must be stored at 4 °C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- Is commercially available



ABI PRISM 7900HT Sequence Detection System

by Applied Biosystems

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, E. coli 0157: H7, Francisella tularensis, Vibrio cholera, Corynebacterium diptheria, Burkholderia mallei, Burkholderia pseudomallei, Yersinia pestis, Coxiella burnetti, Rickettsia prowazekii, Brucella species, Marburg virus, Rift Valley fever virus, VEE virus, Hanta virus, Yellow fever virus, Dengue fever virus, Ebola viruses, Orthopox virus, MS-2 bacteriophage, Botulinum toxins A, B, E, SEB, Ricin *(Assays developed)*

DESCRIPTION:

The instrument is an integrated system designed to perform both real-time PCR and post-PCR analysis. The instrument is capable of analyzing 384 samples simultaneously in a 384-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 can 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 has an argon ion laser excitation source (488 nm), and utilizes a spectrograph and charge coupled device (CCD) camera to enable continuous wavelength detection from 500-660 nm. Instrument software should utilize a multicomponenting algorithm to provide precise deconvolution of multiple dye signals to enable the simultaneous detection of multiple fluorophores. The instrument can process at least 5,000 real-time quantitative PCR sample wells per day (24 hour period), and at least 30,000 SNP genotyping samples every 2.5 hours.

ANALYTICAL Laboratory Ranking

ABI PRISM 7900HT Sequence Detection System 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
Best Score	0.901
ABI PRISM 7900 PCR	0.901
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

ABI PRISM 7900HT ranked in the top third of all evaluated products for diagnostic laboratories and earned 91% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
ABI PRISM 7900 PCR	0.829
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

ABI PRISM 7900HT ranked in the top third of all evaluated products for mobile laboratories and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
ABI PRISM 7900 PCR	0.744
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

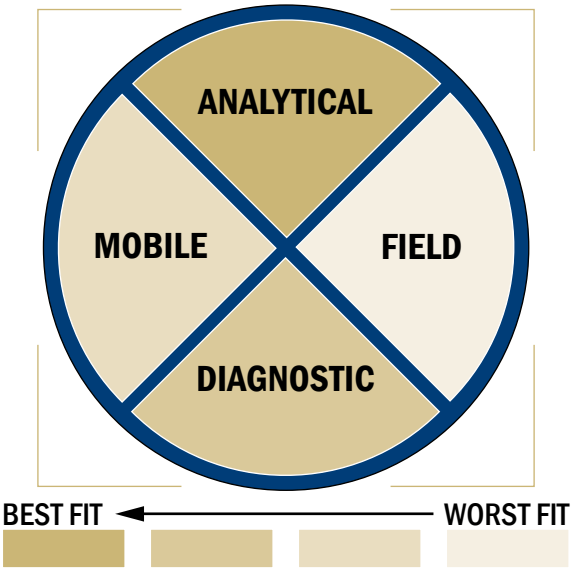
ABI PRISM 7900HT ranked in the middle third of all evaluated products for field use and earned 71% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
ABI PRISM 7900 PCR	0.674
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

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Point of Contact:
Andy Felton
(800) 248-0281
(650) 638-6045 fax
feltonac@appliedbiosystems.com

COST

- $0.50/sample plus cost of Taq enzyme
- $90,000.00 GSA price/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection greater than 60 minutes
- 384 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:

- A day of training
- No set-up required
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 3 components
- No cleaning required

Maintenance:

- 0-1 consumable or expendable needed
- Less than once a year service required
- Expected life greater than 10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a home dishwasher
- Between 5 and 25 kg
- Shelf life between 1 and 3 years

Ease of use/Utility:

- Cannot view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

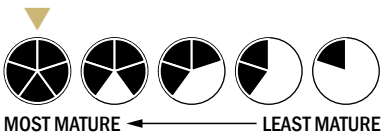
- Operated from 4 °C to 37 °C
- Components must be stored at 4 °C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- Is commercially available and meets military specifications



ABI 9700

by Applied Biosystems

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, E. coli 0157:H7, Francisella tularensis, Vibrio cholera, Corynebacterium diptheria, Burkholderia mallei, Burkholderia pseudomallei, Yersinia pestis, Coxiella burnetti, Rickettsia prowazekii, Brucella species, Marburg virus, Rift Valley fever virus, VEE virus, Hanta virus, Yellow fever virus, Dengue fever virus, Ebola viruses, Orthopox virus, MS-2 bacteriophage, Botulinum toxins A, B, E, SEB, Ricin *(Assays developed)*

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 uses peltier-based elements to enable the PCR amplification process. PCR is composed of three segments, which can be programmed on the thermal cycler. In the pre-PCR segment, you define an incubation temperature and hold time sufficient to denature double-stranded DNA. The PCR segment is the actual cycling segment that generates the amplified product. The key parameters are used for template denaturation, primer annealing, and primer extension. The post-PCR incubation temperature defines how to soak your samples at a specified temperature until you are ready to analyze them.

ANALYTICAL Laboratory Ranking

ABI 9700 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
Best Score	0.901
ABI 9700	0.345
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

ABI 9700 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
Best Score	0.909
ABI 9700	0.408
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

ABI 9700 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
Best Score	0.883
ABI 9700	0.506
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

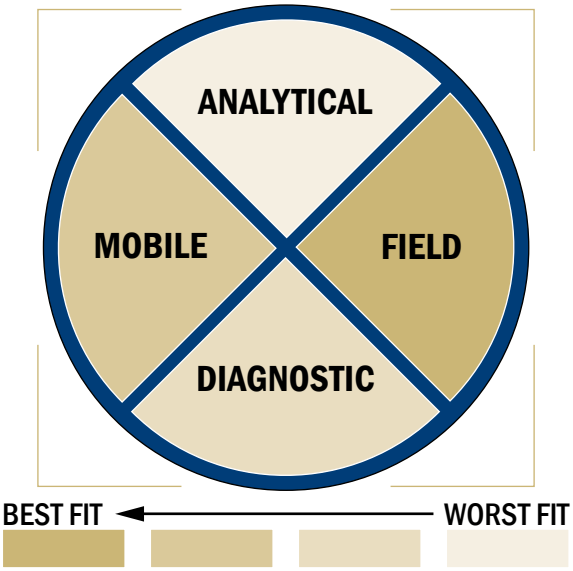
ABI 9700 ranked in the middle third of all evaluated products for field use and earned 68% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
ABI 9700	0.637
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



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Point of Contact:
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feltonac@appliedbiosystems.com

COST

- $0.50/sample plus cost of Taq enzyme
- $7,745.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- 384 samples/batch or higher
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:
- Very brief (minutes-hours) training with minimal technical skills
- 10-20 minutes is required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 3 components

Maintenance:
- Once a year service required
- Expected life is between 3-5 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 5 and 25 kg

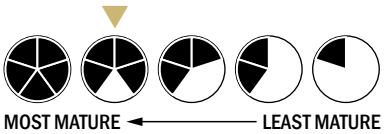
Ease of use/Utility:
- Can not view results in "real time"
- There are multiple shaking and vortexing steps required
- System can not interpret raw data or call a positive through internal software
- One additional piece of equipment needed

Signature:
- There are sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

Maturity gauge:
- Is commercially available
- Has been featured in peer reviewed scientific publications or independent evaluation



ABI 9800

by Applied Biosystems

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, E. coli 0157:H7, Francisella tularensis, Vibrio cholera, Corynebacterium diptheria, Burkholderia mallei, Burkholderia pseudomallei, Yersinia pestis, Coxiella burnetti, Rickettsia prowazekii, Brucella species, Marburg virus, Rift Valley fever virus, VEE virus, Hanta virus, Yellow fever virus, Dengue fever virus, Ebola viruses, Orthopox virus, MS-2 bacteriophage, Botulinum toxins A, B, E, SEB, Ricin *(Assays developed)*

DESCRIPTION:

The Applied Biosystems 9800 Fast Thermal Cycler 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 instrument control panel consists of a display screen and 22 keys. The display screen shows a graphical representation of PCR events, including pre-PCR holds, PCR cycling, and post-PCR holds. You use the keys to enter information into fields on the display screen.

TECHNOLOGY:

The Applied Biosystems 9800 Thermal Cycler uses peltier-based elements to enable the PCR amplification process. PCR is composed of three Segments, which can be programmed on the thermal cycler. In the pre-PCR segment, you define an incubation temperature and hold time sufficient to denature double-stranded DNA. The PCR segment is the actual cycling segment that generates the amplified product. The key parameters are used for template denaturation, primer annealing, and primer extension. The post-PCR incubation temperature defines how to soak your samples at a specified temperature until you are ready to analyze them.

ANALYTICAL Laboratory Ranking

ABI 9800 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
Best Score	0.901
ABI 9800	0.345
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

ABI 9800 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
Best Score	0.909
ABI 9800	0.408
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

ABI 9800 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
Best Score	0.883
ABI 9800	0.506
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

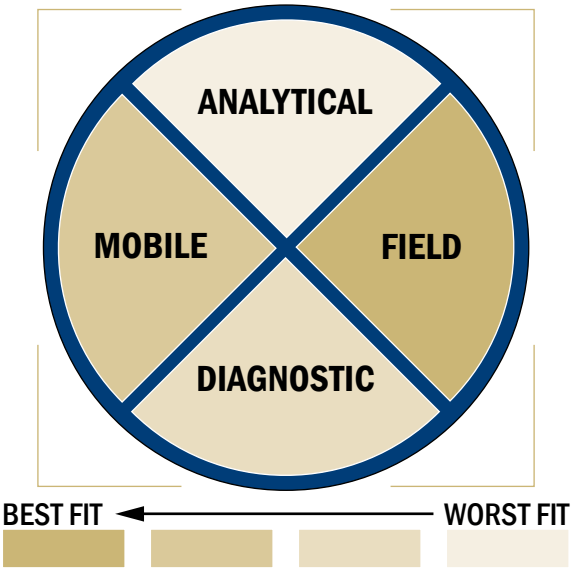
ABI 9800 ranked in the middle third of all evaluated products for field use and earned 68% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
ABI 9800	0.637
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Applied Biosystems
850 Lincoln Center Drive
Foster City, CA 94494
www.Appliedbiosystems.com

Point of Contact:
Andy Felton
(800) 248-0281
(650) 638-6045 fax
feltonac@appliedbiosystems.com

COST

- $0.50/sample plus cost of Taq enzyme
- $8,995.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- 384 samples/batch or higher
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:
- Very brief (minutes-hours) training and minimal technical skills
- 10-20 minutes is required for set-up
- 3-5 manual steps required for detection

Re-use:
- 4 step cleaning process

Maintenance:
- Once a year service required
- Expected life is between 3-5 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 5 and 25 kg

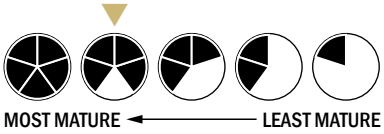
Ease of use/Utility:
- Can view results “in real time”
- There are multiple shaking and vortexing steps required
- System can not interpret raw data or call a positive through internal software
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

Maturity gauge:
- Is commercially available
- Has been featured in peer reviewed scientific publications or independent evaluation



ABI StepOne™ Real-Time PCR System

by Applied Biosystems

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Corynebacterium diphtheria, Burkholderia pseudomallei, Coxiella burnetti, Brucella species, E.coli O157:H7, Vibrio cholera, Burkholderia mallei, Yersinia pestis, Rickettsia prowazekii, Marburg virus, Smallpox virus, Influenza virus, Dengue fever virus, Orthopox virus, Rift valley fever virus, Venezuelan equine encephalitis virus, Yellow fever virus, Ebola virus, MS-2 bacteriophage *(Assays developed)*

DESCRIPTION:
The Applied Biosystems StepOne™ Real-Time PCR System is a remarkably powerful real-time PCR instrument designed with a user-friendly interface. Flexible and easy to use, the StepOne system can be set up and operated with total confidence, even by researchers with little or no previous real-time PCR experience. Highly affordable and cost-effective, this new low-throughput system adapts to every level of experience.

TECHNOLOGY:
The StepOne System is a real-time TaqMan polymerase chain reaction amplification of genes on a peltier-based thermocycling apparatus.

ANALYTICAL Laboratory Ranking

ABI StepOne 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
Best Score	0.901
ABI StepOne	0.511
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations
Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

ABI StepOne ranked in the middle third of all evaluated products for diagnostic laboratories and earned 50% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
ABI StepOne	0.456
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics
Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.883
ABI StepOne	0.671
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations
Preference Set: *Mobile Laboratory*

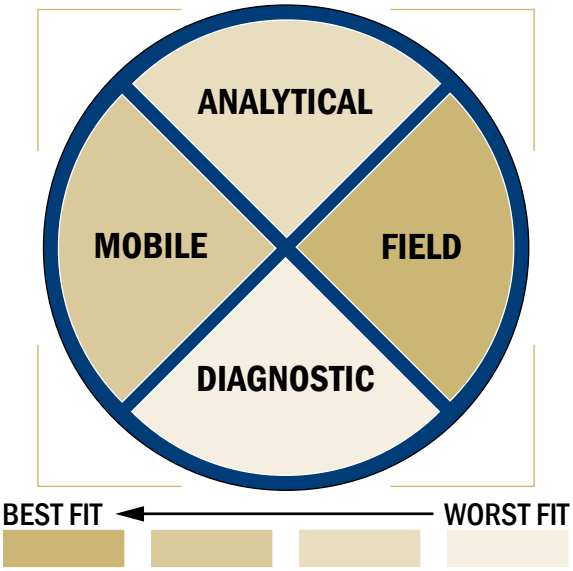
FIELD USE Ranking

ABI StepOne 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
Best Score	0.943
ABI StepOne	0.615
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents
Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Applied Biosystems
850 Lincoln Center Drive
Foster City, CA 94494
www.Appliedbiosystems.com

Point of Contact:
Andy Felton
(800) 248-0281
(650) 638-6045 fax
feltonac@appliedbiosystems.com

COST

- $0.50/sample plus cost of Taq enzyme
- $22,900.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V or 220V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- 48-96 samples/batch or higher
- 10-30 ul volume needed per test for detection
- The system or device is not amenable to automation

Training/Speed/Manpower:

- A day of training
- Greater than 20 minutes is required for set-up

Re-use:

- Device or system is intended for multiple use
- 2 components
- Clean thermal cycling block with 10% bleach

Maintenance:

- Once a year service required
- Expected life is greater than 10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a toaster
- Between 5 and 25 kg
- Reagent shelf life between 1 to 3 years

Ease of use/Utility:

- Can view results “in real time” with additional PC
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting four or more biological agents or toxins within the same test
- One additional piece is required

Signature:

- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:

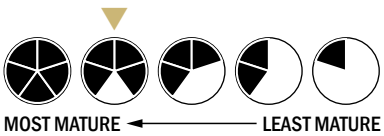
- Operated from 15°C to 30°C
- Components must be frozen
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- Is commercially available
- Has not been featured in peer reviewed scientific publications or independent evaluations



AD 200 Absorbance Detector

by Beckman Coulter

CAPABLE OF DETECTING THE FOLLOWING:
None reported

DESCRIPTION:
The AD 200 Absorbance Detector is intended to be used for research applications including colorimetric immunoassays, such as ELISAs, reporter assays, and protein quantification assays. The AD 200 is capable of measuring assays in 6-384 well plates and cuvettes. The AD 200 can perform measurements in multiple modes including single wavelength, dual wavelength, kinetic, linear scan, area scan and spectral scan. Full programming and data analysis are available either through powerful on-board software or via the use of a remote PC and software. Preprogrammed cuvette applications make nucleic acid and protein quantitation quick and easy.

TECHNOLOGY:
The AD 200 Absorbance Detector employs a controlled tungsten halogen lamp and a deuterium lamp as light sources and a single silicon photodiode as the detector for measuring light (absorbance) in the 190 – 1000nm wavelength range. It employs the use a grating monochromator to select specific wavelengths to measure, and has a dynamic range to 4.0 OD. In addition, the AD 200 features programmable shaking and temperature control options for microplate measurements.

ANALYTICAL Laboratory Ranking

AD 200 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
Best Score	0.901
AD 200 Absorb. Det.	0.344
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

AD 200 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
Best Score	0.909
AD 200 Absorb. Det.	0.471
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

AD 200 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
Best Score	0.883
AD 200 Absorb. Det.	0.460
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

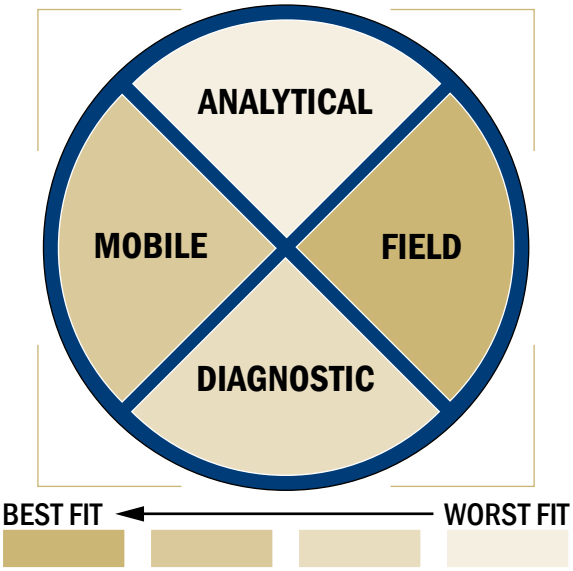
AD 200 ranked in the middle third of all evaluated products for field use and earned 67% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
AD 200 Absorb. Det.	0.628
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Beckman Coulter
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Fullerton, CA 92834
www.beckmancoulter.com

Point of Contact:
Matt Maloney, Margaret Kelly
(317) 808-4217, (714) 773-8022
(714) 773-6690 fax
MJMaloney@beckman.com,
mmkelly@beckman.com

COST

- Unknown/sample
- $15,950.00-$18,950.00/device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection in 20 min or less
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:

- An afternoon of training
- Less than 5 min required for set-up
- 6-8 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- Number of solutions or buffers used is assay dependent
- 1 component
- No cleaning required

Maintenance:

- 2 consumables or expendables needed
- Needs service once a year
- Expected system or device life of 5-10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life measure is not applicable

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System is able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting 4 or more targets in a single well
- 2 additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:

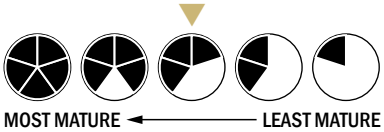
- Operated from 15 °C to 37 °C
- Components storage conditions are not applicable
- Device or system has peak performance at normal relative humidity conditions only

Sensitivity:

- Unknown CFU per ml

Maturity gauge:

- Expected to be ready for commercialization within one calendar year
- A few systems or devices exist (brass board)



AD 340 Absorbance Detector

by Beckman Coulter

CAPABLE OF DETECTING THE FOLLOWING:
None reported

DESCRIPTION:
The AD 340 Absorbance Detector is intended to be used for research applications including colorimetric immunoassays, such as ELISAs, reporter assays, and protein quantification assays. The AD 340 is capable of measuring assays in 6-384 well plates. The AD 340 can perform measurements in multiple modes including single wavelength, dual wavelength, kinetic, linear scan and area scan. Full programming and data analysis are available either through powerful on-board software or via the use of a remote PC and software.

TECHNOLOGY:
The AD 340 Absorbance Detector employs a controlled tungsten halogen lamp as a light source and a single silicon photodiode as the detector for measuring light (absorbance) in the 340–750nm wavelength range. It employs the use of filters to select specific wavelengths to measure, and has a dynamic range to 4.0 OD. In addition, the AD 340 features programmable shaking and temperature control options.

ANALYTICAL Laboratory Ranking

AD 340 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
Best Score	0.901
AD 340 Absorb. Det.	0.362
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

AD 340 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 54% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
AD 340 Absorb. Det.	0.489
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

AD 340 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
Best Score	0.883
AD 340 Absorb. Det.	0.484
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

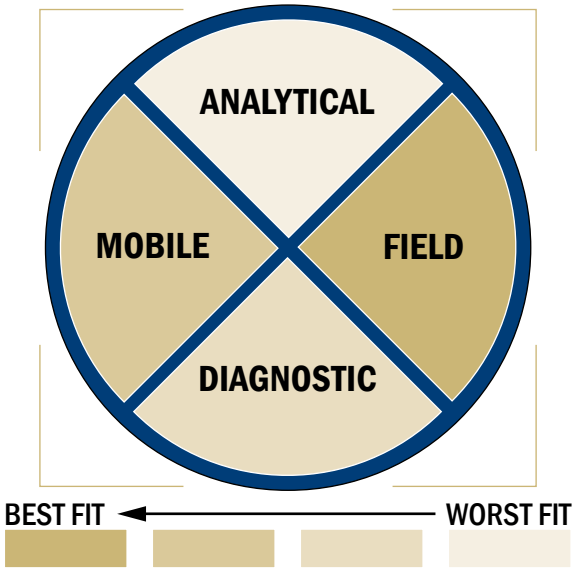
AD 340 ranked in the middle third of all evaluated products for field use and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
AD 340 Absorb. Det.	0.723
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Beckman Coulter
4300 N. Harbor Blvd. Box 3100
Fullerton, CA 92834
www.beckmancoulter.com

Point of Contact:
Matt Maloney, Margaret Kelly
(317) 808-4217, (714) 773-8022
(714) 773-6690 fax
MJMaloney@beckman.com,
mmkelly@beckman.com

COST

- Unknown/sample
- $7,995.00-8,995.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 min or less
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a semi-automated system with some effort

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 minutes required for set-up
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- NA solutions or buffers used
- 1 component
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Once a year service required
- Expected life is 5-10 years
- No daily quality assurance procedures required

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life measure is not applicable

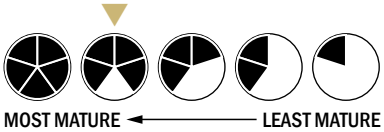
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System sometimes able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- Components storage conditions are not applicable
- Device or system has peak performance at normal relative humidity conditions only

Sensitivity:
- Unknown CFU per ml

Maturity gauge:
- Is commercially available



Automated Bioaerosol Collection and Detection System (ABCDS)

by Constellation Technology

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, MS-2 bacteriophage, SEB
(Assays developed)

DESCRIPTION:

The Automated Bioaerosol Collection and Detection System (ABCDS) is a fully automated bio-warning system. This system can detect bacteria and identify the genus and species as well as detect and identify viruses and toxins. The goal of the technology is to provide remote point detection of multiple biological agents in ambient air. The system integrates an aerosol collector, a sensor and a processor which provide the ability to collect air samples, load samples on the sensor, collect and analyze data and determine a positive signal without manual intervention. All components of the sensing element, the waveguide and reagents are reusable therefore operating costs are minimal, approximately $0.57 per assay for four agents in duplicate (ROM estimate, not sale price). Low operating costs, reusable tests and quick analysis make it feasible for the ABCDS to continuously monitor ambient air, obviating the need for a trigger. This would allow the ABCDS to be used in the role of the traditional trigger as well as a collector/identifier. Additional cost and weight benefits would also be realized.

TECHNOLOGY:

The technology utilizes sandwich fluorescence immunoassays to detect and identify target analytes. The assays are performed on the surface of a planar waveguide using a patterned array of immobilized antibodies to provide a means of capturing a target analyte from the sample. Processing on the planar waveguide with a cocktail of fluorescent tracer antibodies results in the formation of fluorescent immunocomplexes, or "sandwiches." Upon evanescent excitation of the fluorescent immunocomplexes by a small diode laser, a CCD camera detects the pattern of fluorescent tracer spots on the sensor surface, and image analysis software correlates the position and intensity of the fluorescent signals with a signal that an agent has been detected and the identity of that agent. Current laboratory testing has consistently achieved test times of approximately 10 minutes in both manual and automated testing modes. In the continuous assay configuration, each of the 14 lanes of the flow cell intersects 12 separate tests on the waveguide. Each lane on the flow cell has the ability to run a complete, independent automated assay. The outer two lanes of the flow cell are used for positive controls, leaving the inner 12 lanes for assaying individual samples. The 12 lanes are used to accomplish batch analysis in continuous succession of sample fluid from an air collector. An aliquot of fluid sample from the collector is introduced into the first lane and an assay of that sample is initiated. This assay will take approximately 10 minutes to complete. During this time, subsequent aliquots are introduced into subsequent lanes and assays are initiated in each lane respectively. When the assay in the last lane is completed, the next aliquot is introduced into the first lane and the sequence is repeated. When a positive is detected in a particular lane, an alarm is indicated. It should be pointed out that reconfiguration of the automated analysis to accommodate other test situations, such as simultaneous analysis of different samples or other types of batch analyses that do not require continuous succession, is easily accommodated.

ANALYTICAL Laboratory Ranking

ABCDS 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
Best Score	0.901
ABCDS-Sentry	0.686
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

ABCDS 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
Best Score	0.909
ABCDS-Sentry	0.719
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

ABCDS 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
Best Score	0.883
ABCDS-Sentry	0.492
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

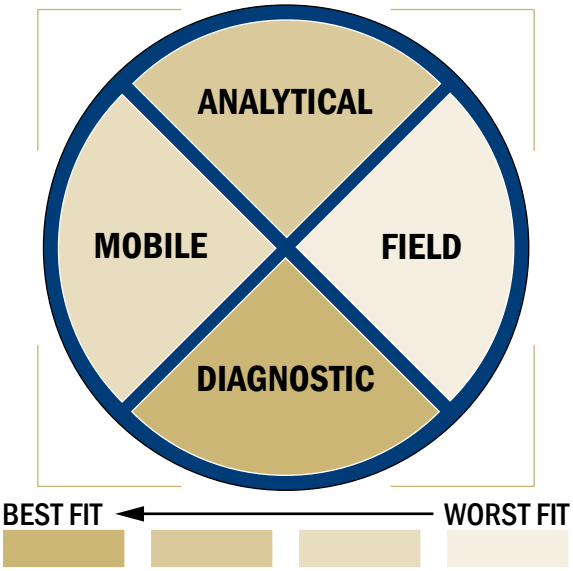
ABCDS ranked in the bottom third of all evaluated products for field use and earned 43% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
ABCDS-Sentry	0.408
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
7887 Bryan Dairy Road, Suite 100
Largo, FL 33777
www.contech.com

Point of Contact:
Tammy Santana
727-547-0600 x6400
727-545-6150 fax
santana@contech.com

COST
- $0.57/sample
- $80,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 min or less
- 1 samples/batch
- Greater than 250 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- An afternoon of training
- 10-20 min required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 3 solutions or buffer used
- 5 or more components
- No cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- Service needs are unknown
- Expected life measure unknown
- 10-20 minutes required for daily quality assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- More than 50 kg
- Shelf life between 6 months - 1 year

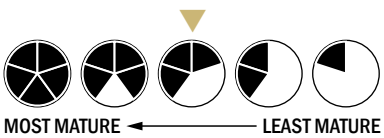
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay available, and capable of detecting two or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- BTUS generated unknown

Operational conditions:
- Operated from 25 °C to 37 °C
- Components must be stored at 4 °C
- The influence on performance of the device or system by relative humidity is unknown

Sensitivity:
- 1,000-10,000 CFU per ml

Maturity gauge:
- Expected to be ready for commercialization within one calendar year
- A few systems or devices exist (brass board)



Automated Continuous Analysis Array Biosensor (ACA-ABS)

by Constellation Technology

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, MS-2 bacteriophage, SEB *(Assays developed)*

DESCRIPTION:

The Automated, Continuous Analysis – Array Bio-Sensor (ACA-ABS) is a fully automated bio-warning system. This system can detect bacteria and identify the genus and species as well as detect and identify viruses and toxins. The goal of the technology is the simultaneous automatic analysis of up to 12 samples or a continuous sampling stream for multiple biological agents in about 10 minutes. All components of the sensing element, the waveguide and reagents are reusable therefore operating costs are minimal; approximately $0.57 per assay for four agents in duplicate (ROM estimate, not sale price). Low operating costs, reusable tests and quick analysis make it feasible for the ACA-ABS to continuously monitor a sample stream, obviating the need for a trigger. This would allow the ACA-ABS to be used in the role of the traditional trigger as well as an identifier. Additional cost and weight benefits would also be realized.

TECHNOLOGY:

The technology utilizes sandwich fluorescence immunoassays to detect and identify target analytes. The assays are performed on the surface of a planar waveguide using a patterned array of immobilized antibodies to provide a means of capturing a target analyte from the sample. Processing on the planar waveguide with a cocktail of fluorescent tracer antibodies results in the formation of fluorescent immunocomplexes, or "sandwiches." Upon evanescent excitation of the fluorescent immunocomplexes by a small diode laser, a CCD camera detects the pattern of fluorescent tracer spots on the sensor surface, and image analysis software correlates the position and intensity of the fluorescent signals with a signal that an agent has been detected and the identity of that agent. Current laboratory testing has consistently achieved test times of approximately 10 minutes in both manual and automated testing modes. In the continuous assay configuration, each of the 14 lanes of the flow cell intersects 12 separate tests on the waveguide. Each lane on the flow cell has the ability to run a complete, independent automated assay. The outer two lanes of the flow cell are used for positive controls, leaving the inner 12 lanes for assaying individual samples. The 12 lanes are used to accomplish batch analysis in continuous succession of sample fluid from an air collector. An aliquot of fluid sample from the collector is introduced into the first lane and an assay of that sample is initiated. This assay will take approximately 10 minutes to complete. During this time, subsequent aliquots are introduced into subsequent lanes and assays are initiated in each lane respectively. When the assay in the last lane is completed, the next aliquot is introduced into the first lane and the sequence is repeated. When a positive is detected in a particular lane, an alarm is indicated. It should be pointed out that reconfiguration of the automated analysis to accommodate other test situations, such as simultaneous analysis of different samples or other types of batch analyses that do not require continuous succession, is easily accommodated.

ANALYTICAL Laboratory Ranking

ACA-ABS ranked in the middle third of all evaluated products for analytical laboratories and earned 62% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
ACA-ABS	0.558
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

ACA-ABS ranked in the middle third of all evaluated products for diagnostic laboratories and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
ACA-ABS	0.698
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

ACA-ABS 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
Best Score	0.883
ACA-ABS	0.540
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

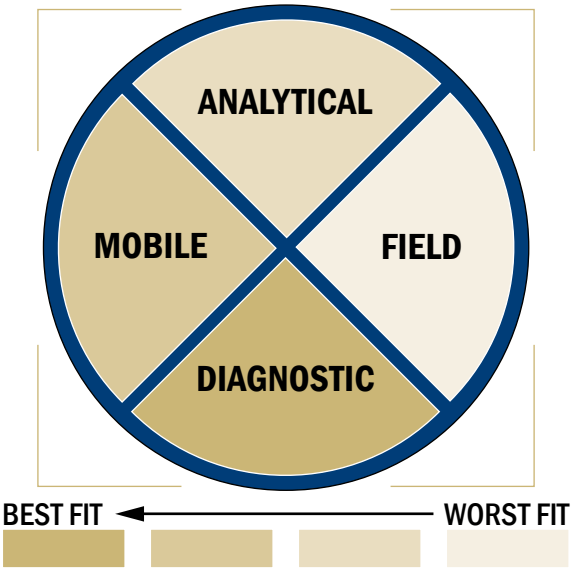
ACA-ABS ranked in the bottom third of all evaluated products for field use and earned 55% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
ACA-ABS	0.517
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Constellation Technology
7887 Bryan Dairy Road, Suite 100
Largo, FL 33777
www.contech.com

Point of Contact:
Tammy Santana
727-547-0600 x6400
727-545-6150 fax
santana@contech.com

COST

- $0.57/sample
- $40,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection in 20 min or less
- 2 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:

- Very brief training
- 10-20 min required for set-up
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple detections
- 2 solution or buffer used
- 5 or more components
- No cleaning required

Maintenance:

- 0-1 consumable or expendable needed
- Service needs are unknown
- Expected life measure unknown
- 10-20 minutes required for daily quality assurance procedures

Transportation:

- Approximately the size of a home dishwasher
- Between 25-50 kg
- Shelf life between 6 months - 1 year

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- One additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- BTUS generated unknown

Operational conditions:

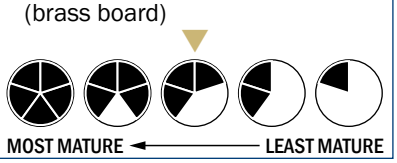
- Operated from 25 °C to 37 °C
- Components must be stored at 4 °C
- The influence on performance of the device or system by relative humidity is unknown

Sensitivity:

- 1,000-10,000 CFU per ml

Maturity gauge:

- Expected to be ready for commercialization within one calendar year
- A few systems or devices exist (brass board)



AflaCup Test Kit

by International Diagnostic Systems

CAPABLE OF DETECTING THE FOLLOWING:
Aflatoxins

DESCRIPTION:
The AflaCup provides a fast, easy to use and reliable means to test for total aflatoxins. The result is easily interpreted by a simple color change: a blue dot denotes a negative result, a white cup means the sample contains aflatoxin above the detection limit. To comply with various accuracy needs, test kits are available for a 10 to 20 ppb detection limit. Dilution schemes allow for further detection limits.

TECHNOLOGY:
The AflaCup is a qualitative test based on solid phase immunoassay technology in which an antibody binds specifically with aflatoxin. This rapid qualitative screen has been specifically developed for grain elevator operators, cottonseed dealers, tree nut handlers and pet food companies.

This technology could be adapted for other threats and is shown as an example of current technology.

ANALYTICAL Laboratory Ranking

AflaCup Test Kit ranked in the bottom third of all evaluated products for analytical laboratories and earned 42% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
AflaCup Test Kit ELISA	0.377
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

AflaCup Test Kit ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 54% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
AflaCup Test Kit ELISA	0.495
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

AflaCup Test Kit 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
Best Score	0.883
AflaCup Test Kit ELISA	0.581
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

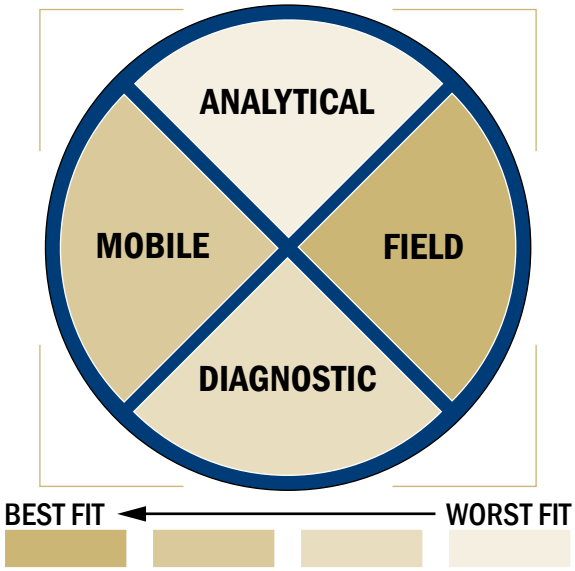
AflaCup Test Kit ranked in the top third of all evaluated products for field use and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
AflaCup Test Kit ELISA	0.752
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Romer Labs, Inc.
1301 Stylemaster Drive
Union, MO 63084-1156
www.romerlabs.com

Point of Contact:
Sales Department
(636) 583-8600
(636) 583-6553 fax
sales@romerlabs.com

COST

- Approx. $5.00-7.00/sample
- $130.00-185.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- No electrical requirement
- The system or device does require water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 1 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device is not amendable to automation

Training/Speed/Manpower:
- Very brief training
- 10-20 minutes required for set-up
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 4 solutions or buffers used
- 4 components
- No cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- No service required
- Expected life is not applicable
- No daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life between 6 months and 1 year

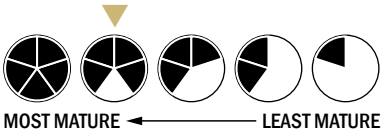
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- There is a single shaking or vortexing step
- System never able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- NA CFU per ml

Maturity gauge:
- Is commercially available



AgPath-ID™ One-Step RT-PCR Kit

by Ambion

CAPABLE OF DETECTING THE FOLLOWING:
Marburg virus, Influenza virus, Dengue fever virus, Rift valley fever virus, Venezuelan equine encephalitis virus, Yellow fever virus, Ebola virus *(Assays developed); (Can be used on multiple real time thermocyclers)*

DESCRIPTION:
AgPath-ID™ One-Step RT-PCR Kit obtains results in about 1 hour, consistently detects RNA pathogens with high specificity and sensitivity, contains ROX for quantitative fluorescent signal normalization and has a simplified setup due to fewer components.

The AgPath-ID One-Step RT-PCR Kit is designed for sensitive, robust amplification and detection of RNA pathogens and targets using a rapid single-tube real-time reverse transcription PCR (RT-PCR) strategy. The kit was developed using real-time detection of reaction products via TaqMan® chemistry, but is fully compatible with both SYBR® Green real-time detection and end-point RT-PCR.

TECHNOLOGY:
The reactions are assembled in a single tube, minimizing sample handling errors and reducing setup time. The RT-PCR Enzyme Mix included in the kit is composed of Ambion's highly efficient ArrayScript™ Reverse Transcriptase, a mutant MMLV RT capable of producing high cDNA yields, and AmpliTaq® Gold, the preferred hot-start DNA polymerase for specific target amplification. The included RT-PCR Buffer contains the passive reference dye, ROX, for quantitative fluorescent signal normalization. A Detection Enhancer is also provided as an optional reagent for amplification of templates with a high GC content or persistent secondary structure.

ANALYTICAL Laboratory Ranking

AgPath ID ranked in the top third of all evaluated products for analytical laboratories and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Ambion Ag-Path ID	0.761
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

AgPath ID ranked in the top third of all evaluated products for diagnostic laboratories and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Ambion Ag-Path ID	0.731
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

AgPath ID ranked in the middle third of all evaluated products for mobile laboratories and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Ambion Ag-Path ID	0.682
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

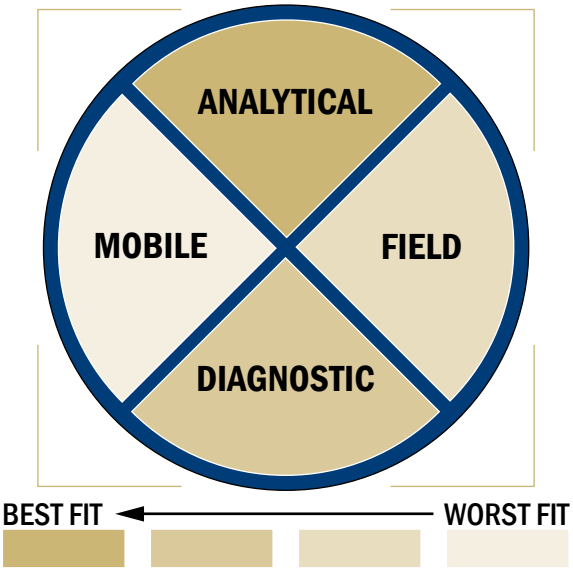
AgPath ID ranked in the top third of all evaluated products for field use and earned 81% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Ambion Ag-Path ID	0.767
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Applied Biosystems
850 Lincoln Center Drive
Foster City, CA 94494
www.Appliedbiosystems.com

Point of Contact:
Andy Felton
(800) 248-0281
(650) 638-6045 fax
feltonac@appliedbiosystems.com

COST

- $1.35/sample
- $135.00/100 reactions

Evaluation Criteria Provided by Vendor

System requirements:

- There is no electrical requirement
- The system or device does require water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection greater than 60 minutes
- 384 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be easily adapted into a fully automated system

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes is required for set-up
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for a single use
- 2 solutions or buffers used
- 2 components

Maintenance:

- No service required
- Expected life is not applicable
- No daily quality assurance procedures

Transportation:

- Reagent shelf life is between 6 months and 1 year

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System may be able to interpret raw data or call a positive through internal software in the future
- Capable of detecting two or more biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:

- No sounds produced that cannot be deactivated

Operational conditions:

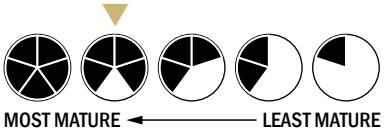
- Components must be frozen
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- Is commercially available
- Has not been featured in any peer reviewed scientific publications or independent evaluation



AirSentinel 1000B

by MesoSystems

CAPABLE OF DETECTING THE FOLLOWING:

None reported *(Generic detector)*

DESCRIPTION:

The AirSentinel 1000B is a lightweight, continuously-operating monitor that may be used to detect potentially harmful airborne biological threats. It was designed specifically to detect aerosolized biological material in indoor environments, such as buildings and other critical infrastructures. The AirSentinel facilitates the process of identifying possible bio-terror agents to allow timely containment, treatment and remediation. AirSentinel works by monitoring the amount of particles in the air and examining their fluorescence properties when illuminated by UV light. A particle counter and an optional air prefilter are used for low concentration threats and prefiltering particles respectively. AirSentinel runs continuously, analyzing a new aerosol sample approximately every 30 seconds to 10 minutes, depending on user-set parameters. If a sample emits sufficient fluorescence a second air sampler located inside the AirSentinel operating at a higher flow rate is activated to capture a second sample for further analysis. A separate system, not manufactured by MesoSystems or a laboratory is required to perform agent identification analysis.

TECHNOLOGY:

The AirSentinel 1000B uses a combination of particle count information, ultraviolet (UV) particle fluorescence and MesoSystems' algorithm to determine whether an increased aerosol event is a suspect biological release. Upon alert, a secondary aerosol sample is collected for use in identification tests. Sensitivity varies for each biological agent. The AirSentinel detects biological particles in the 1-10 micron diameter range including bacteria, viral particles and toxins (production impurities).

ANALYTICAL Laboratory Ranking

AirSentinel 1000B ranked in the middle third of all evaluated products for analytical laboratories and earned 67% of the utility points of the best score

ALTERNATIVE	UTILITY
Best Score	0.901
MesoSystems AirSentinel	0.604
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

AirSentinel 1000B ranked in the middle third of all evaluated products for diagnostic laboratories and earned 78% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
MesoSystems AirSentinel	0.713
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

AirSentinel 1000B 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
Best Score	0.883
MesoSystems AirSentinel	0.579
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

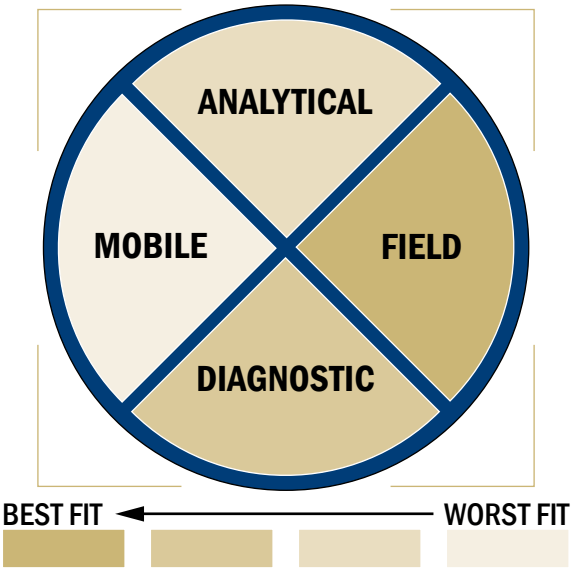
AirSentinel 1000B ranked in the top third of all evaluated products for field use and earned 87% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
MesoSystems AirSentinel	0.818
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Mesosystems
1001 Menaul Blvd. NE, Ste. A
Albuquerque, NM 87107
www.mesosystems.com

Point of Contact:
Kenny Yeh
(801) 706-6141
kyeh@mesosystems.com

COST

- $25.00/sample
- $4,500.00-6,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 24 VDC electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection less than 20 minutes
- 384 samples/batch or higher
- The system or device could is currently fully automated

Training/Speed/Manpower:
- Very brief (minutes-hours) training and minimal technical skills
- 5-10 minutes is required for set-up
- 0-2 manual steps required for detection

Re-use:
- 1 component
- Periodic cleaning for maintenance

Maintenance:
- Every 6 months service required
- Expected life is between 3-5 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg

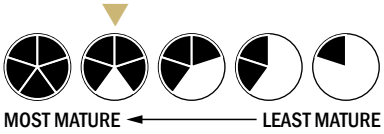
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at room temperature
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- Can be set by the user

Maturity gauge:
- Is commercially available
- Has been featured in peer reviewed scientific publications or independent evaluations



Anthragen

by Collaborative Genetics

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Botulinum toxin A *(Assays developed)*

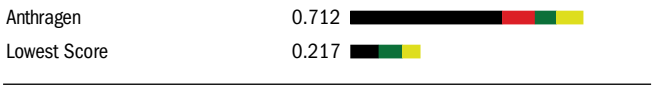
DESCRIPTION:
We are currently developing our first product. The product will be a qualitative device that can detect anthrax spores in an environmental sample and the LF and PA in whole blood within five minutes.

TECHNOLOGY:
The device will be an antibody/antigen-based product that is a sandwich assay. The device will contain a filter that is treated with biologics that will lyse the blood cells to extract the toxins and will capture red blood cells and allow only plasma further down the lateral flow device.

ANALYTICAL Laboratory Ranking

Anthragen ranked in the middle third of all evaluated products for analytical laboratories and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Anthragen	0.712
Lowest Score	0.217

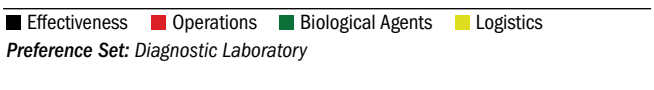


Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Anthragen ranked in the top third of all evaluated products for diagnostic laboratories and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Anthragen	0.786
Lowest Score	0.321

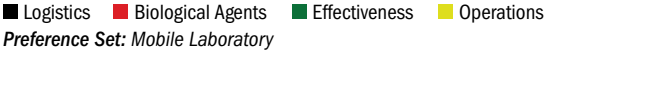


Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Anthragen ranked in the middle third of all evaluated products for mobile laboratories and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Anthragen	0.650
Lowest Score	0.379

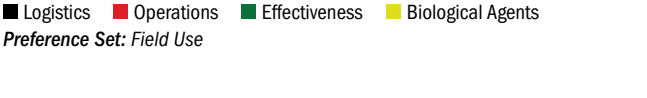


Preference Set: *Mobile Laboratory*

FIELD USE Ranking

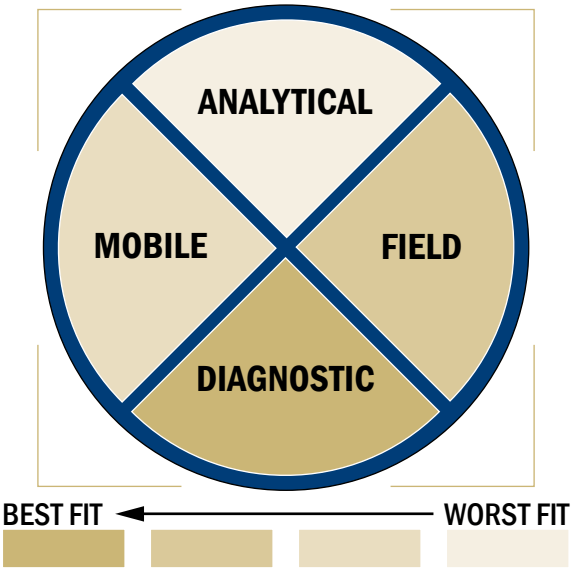
Anthragen ranked in the top third of all evaluated products for field use and earned 81% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Anthragen	0.717
Lowest Score	0.343



Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Collaborative Genetics
1152 Bond Ave
Rexburg, ID 83440
www.collaborativegenetics.com

Point of Contact:
Bruce J. Tedeschi
(208) 359-2446
btedeschi@collaborativegenetics.com

COST

- Approximately $3.00/sample
- $40.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 32 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or approach could easily be adapted to a fully automated system

Training/Speed/Manpower:
- Very brief training
- Less than 5 min set-up required
- 3-5 manual steps required for detection

Re-use:
- Device or system is designed for multiple detection assays
- 0-1 solution or buffer used
- 3 components
- Cleaning with 70% isopropanol required

Maintenance:
- 0-1 consumable or expendable needed
- Needs service less than once a year
- Expected life measure is greater than 10 years
- Less than 5 min required for daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life between 1 to 3 years

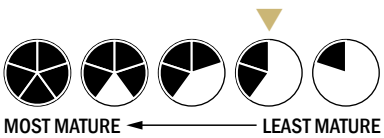
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System is able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two or more agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- Sounds are produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 4 °C to 45 °C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

Maturity gauge:
- Expected to be ready for commercialization within one calendar year
- Only one incomplete device or system exist (bread board)



APSIS (Assay Processing and Specific Identification System)

by Bruker Daltonik GmbH

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, E. coli O157:H7, Orthopox virus, Smallpox virus, MS-2 bacteriophage

DESCRIPTION:

Bruker Daltonics -20 years of tradition, flexibility and performance in chemical, biological and nuclear detection. The newly developed APSIS is an identifier for harmful pathogens, like bacteria, spores and viruses, based on their genomic fingerprint stored in their DNA or RNA. The system is intended for the on site analysis of microorganisms (bacteria, spores and viruses) in mobile labs and onboard vehicles. The performance is not limited to harmful pathogens used as BWA but also covers pathogens for clinical diagnostic purposes.

TECHNOLOGY:

APSIS cartridge combines two current technologies for detection: In the first step the target DNA/RNA is amplified by PCR to achieve a detectable amount of DNA/RNA. The second step is the hybridization against sample sequences on the glass substrate within the presence of the same buffer and the same volume where PCR was performed. The fluorescence pattern is readout by fluorescence detection giving a characteristic pattern. The pattern is evaluated by a dedicated software tool. The design of the processing cartridge is optimized for minimal user interaction. An integrated EPROM gives a complete process control and enables the cartridge to be completely self describing for protocol purposes. The APSIS System has a modular design consisting of a process station with eight parallel but independently operating processing slots for thermal and fluid processing and a reader unit. Inside the reader unit the fluorescence readout is performed using microscope optics.

ANALYTICAL Laboratory Ranking

APSIS ranked in the middle third of all evaluated products for analytical laboratories and earned 81% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
APSIS	0.730
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.909
APSIS	0.706
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

APSIS 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
Best Score	0.883
APSIS	0.570
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

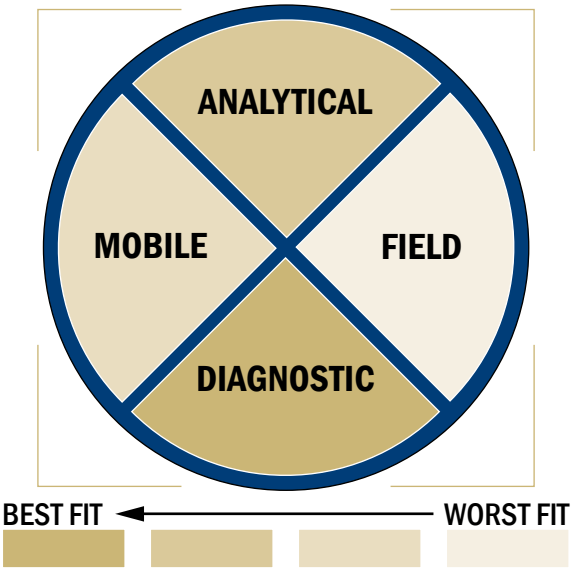
APSIS ranked in the bottom third of all evaluated products for field use and earned 58% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
APSIS	0.543
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Bruker Daltonik GmbH
Permoserstr. 15
Leipzig, D-04318 Germany
www.bdal.de

Point of Contact:
Dr. Norbert Klöpper
+493412431448
+493412431404 fax
nkl@bdal.de

COST

- $50.00/sample
- $115,000/device or system

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 220V electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 50-60 min
- 2 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 min required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 3 solutions or buffers used
- 3 components
- No cleaning required

Maintenance:
- 3 consumables or expendables needed
- Needs service once a year
- Expected life measure of 5-10 years
- Less than 5 minutes required for daily quality assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- More than 50 kg
- Shelf life between 1-3 years

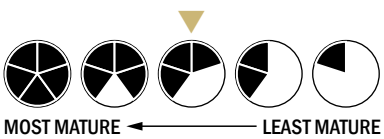
Ease of use/Utility:
- Cannot view results “in real time”
- No centrifugation steps
- A single shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay available, and capable of detecting four or more biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4 °C to 37 °C
- Components can be stored at 25 °C to 37 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1,000 CFU per ml

Maturity gauge:
- Expected to be ready for commercialization within one calendar year
- A few systems or devices exist (brass board)



ASAP II

by Research International

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Yersinia pestis Coxiella burnetti, Brucella species, E.coli O157: H7, Smallpox virus, Venezuelan equine encephalitis virus, Botulinum toxin A, Botulinum toxin B, Staphylococcal toxin B *(Assay developed);* MS-2 bacteriophage, Ricin toxin *(Commercially available as a freeze-dried reagent)*

DESCRIPTION:

The ASAP II collection/detection system continuously monitors for the presence of aerosol biohazards and will identify biological agents ranging from protein toxins to whole cells and spores as frequently as every 20 minutes. It is an integration at the hardware and software levels, of Research International's proven SASS™ 2000 Plus multiple-effect air sampler technology and its RAPTOR™ four-channel bioassay system. ASAP II is provided with a small fixed-installation environmental enclosure that maximizes reagent life and unattended monitoring time. In operation, the SASS™ 2000 Plus collector samples air continuously and transfers particulates in the air to a secondary water phase of about 4-5 ml volume. Aerosol sampling is performed using aerodynamically sound methods certified by fluid dynamic software models. Water samples of 1-2 cc are periodically transferred from the SASS 2000 to the RAPTOR. The RAPTOR then automatically performs a multi-step bioassay for up to four bio-targets on the liquid sample using a disposable assay coupon. Each of these 4-channel assay coupons may be reused from 20 to 50 times over a 36-hour unattended operating period before replacement of the coupon and related reagents is necessary. This provides extremely competitive per-assay costs and allows operation by minimally trained personnel.

TECHNOLOGY:

The aerosol collector is a highly efficient, multiple-effect, wetted-wall cyclone that extracts and transfers pathogens from sampled air to a small fixed water volume for subsequent assay. A unique and patented feature is the ability to perform this function continuously for an extended time period without fluid sample loss. The biosensor is based on monolayer receptor-ligand reactions taking place on the surface of injection molded polystyrene waveguides. All fluidic and optoelectronic steps associated with the assay are performed automatically. The baseline protocol used to identify specific pathogens is the 'sandwich format' fluoroimmunoassay. In a typical waveguide-based sandwich immunoassay, the cylindrical waveguide has a monolayer of capture antibody immobilized on its surface. Following incubation with sample and then with a fluorophore-labeled antibody, the signal is measured and results displayed within 15 minutes.

ANALYTICAL Laboratory Ranking

ASAP II ranked in the middle third of all evaluated products for analytical laboratories and earned 72% of the utility points of the best score

ALTERNATIVE	UTILITY
Best Score	0.901
Research International ASAP II	0.653
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

ASAP II ranked in the top third of all evaluated products for diagnostic laboratories and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Research International ASAP II	0.765
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.883
Research International ASAP II	0.711
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

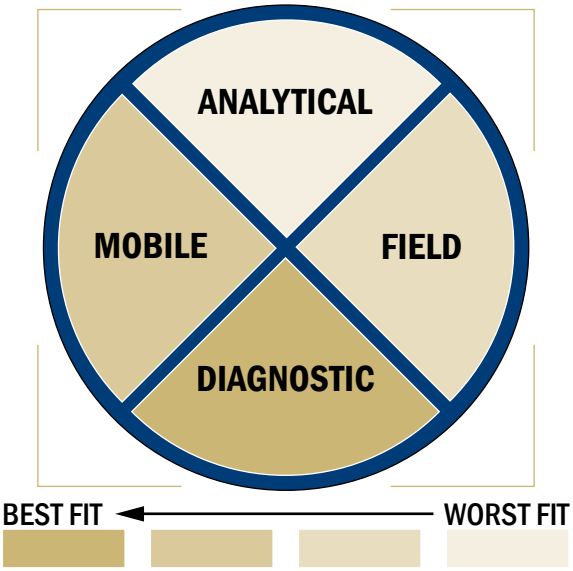
ASAP II ranked in the top third of all evaluated products for field use and earned 73% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Research International ASAP II	0.693
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Research International
17161 Beaton Road SE
Monroe, WA 98272
www.resrchintl.com

Point of Contact:
Elric Saaski
(360) 805-4930
elricsaaski@resrchintl.com

COST

- $2.00/sample
- $75,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device requires a continual water supply
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection less than 20 minutes
- 2 samples/batch or higher; 4 different assays on a single sample simultaneously
- Less than 250 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- Greater than 20 minutes set-up required
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 3 solutions or buffers used
- 0 component
- Cleaning with buffer when dirty

Maintenance:

- Less than once a year service required
- Expected life is greater than 10 years
- 10-20 minutes required for daily quality assurance procedures

Transportation:

- Approximately the size of a home dishwasher
- Between 25 and 50 kg
- Reagent shelf life between 6 months and 1 year

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting four biological agents or toxins within the same test
- No additional piece of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:

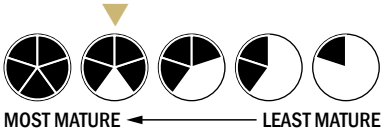
- Operated from 4°C to 45°C
- Components must be stored at room temperature
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1,000-50,000 CFU per ml

Maturity gauge:

- Is commercially available
- Has been featured in peer reviewed scientific publications or independent evaluations



Assurance EHEC EIA

by BioControl Systems, Inc.

CAPABLE OF DETECTING THE FOLLOWING:
E. coli 0157:H7 *(Assay validated)*

DESCRIPTION:
Assurance EIAs are enzyme immunoassays (EIAs) for food and environmental testing. These tests have been extensively validated through the AOAC Official Method process. Assurance EIAs are used in industry and independent and government laboratories. Results are read as a standard microplate reader printout.

Assurance EIAs are available for the detection of Salmonella (AOAC Official Method 992.11), Listeria (AOAC Official Method 996.14), and E. coli 0157:H7 (AOAC Official Method 996.10). Also available is the Assurance Gold EIA format, a visually or instrumentally read EIA, for Salmonella (AOAC Official Method 999.08), and Campylobacteria.

TECHNOLOGY:
Proprietary antibodies with high specificity to EHEC antigens are bound to microwell plates. Appropriately enriched test samples and positive controls are added to plates. Any EHEC antigens present will bind to microwells, forming antibody-antigen complex. Nonreactive material is washed away. Alkaline phosphatase antibody conjugate is added and, after incubation, unbound conjugate is washed away. The substrate p-nitrophenylphosphate, is added and absorbance of resulting colored product is read spectrophotometrically at 405-410 nm.

ANALYTICAL Laboratory Ranking

Assurance EHEC EIA ranked in the middle third of all evaluated products for analytical laboratories and earned 67% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Assurance EHEC EIA	0.604
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Assurance EHEC EIA ranked in the middle third of all evaluated products for diagnostic laboratories and earned 72% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Assurance EHEC EIA	0.652
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Assurance EHEC EIA 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
Best Score	0.883
Assurance EHEC EIA	0.602
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

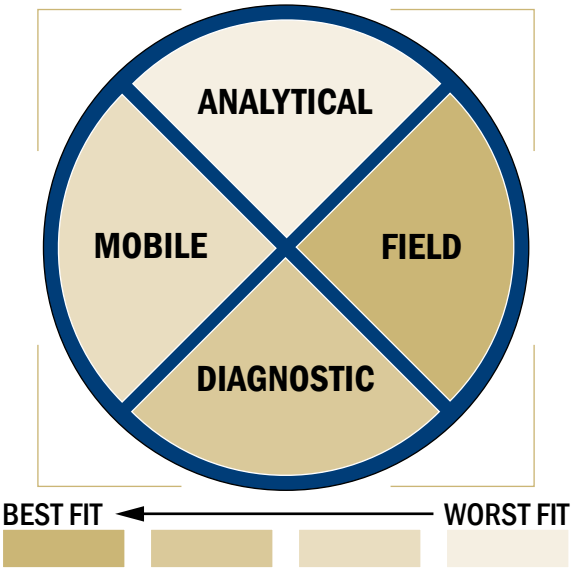
Assurance EHEC EIA ranked in the top third of all evaluated products for field use and earned 79% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Assurance EHEC EIA	0.747
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

BioControl Systems, Inc.
12822 SE 32nd St.
Bellevue, WA 98055
www.biocontrolsys.com

Point of Contact:
Maritta Ko
(425) 603-1123 x105
(425) 603-0070 fax
mko@biocontrolsys.com

COST

- $4.00-7.00/sample
- $2.50-4.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System has a 110V electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 96 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- 5-10 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is designed for multiple detection
- 3 solutions or buffers used
- 3 components
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- No service required
- NA expected life
- 5-10 minutes daily assurance procedures required

Transportation:
- Approximately the size of a toaster
- Less than 1 kg
- Shelf life between 1 and 3 years

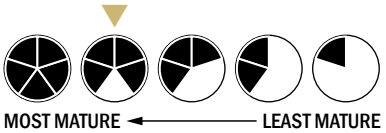
Ease of use/Utility:
- Cannot view results “in real time”
- No centrifugation steps
- A single shaking or vortexing step
- System never able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generate

Operational conditions:
- Operated from 15 °C to 37 °C
- Components must be stored at 4 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

Maturity gauge:
- Is commercially available



Autonomous Pathogen Detection System (APDS)

by Lawrence Livermore National Lab (LLNL)

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Yersinia pestis, Vibrio cholera, Coxiella burnetti, Marburg virus, VEE virus, Orthopox virus, MS-2 bacteriophage, Botulinum toxins A, B, E, SEB, Ricin *(Assays developed)*

DESCRIPTION:

A stand-alone system for rapid, continuous monitoring of multiple airborne biological threat agents in the environment has been developed. This system, the autonomous pathogen detection system (APDS), acts as a "biosmoke alarm" and is targeted for protection of domestic applications such as the Olympics, mass transit systems, and other high profile targets in which the public is at high risk to bioterrorist attacks. The APDS is completely automated, offering aerosol sampling, in-line sample preparation fluidics, and orthogonal immunoassay and nucleic acid detection device. This system has flexibility, cost, and system performance and should be compared to competing technologies.

TECHNOLOGY:

The objective of this research project is to develop a stand-alone pathogen detection system capable of rapid, continuous, low cost environmental monitoring of multiple airborne biological threat agents. The final APDS will be completely automated, offering aerosol sampling, in-line sample preparation fluidics, multiplex detection and identification immunoassays, and orthogonal, multiplexed PCR (nucleic acid) amplification and detection. While the primary focus has been on protection of civilians from terrorist attacks, the same system could also have a role in protecting military personnel from biological warfare attacks. APDS instruments can be used at high profile events such as the Olympics for short-term, intensive monitoring or more permanent installation in major public buildings or transportation nodes. All of these units can be networked to a single command center so that a small group of technical experts could maintain and respond to alarms at any of the sensors. The APDS has several key advantages over competing technologies: (1) the ability to measure up to 100 different agents and controls in a single sample, (2) the flexibility and ease with which new bead-based assays can be developed and integrated into the system, (3) the presence of an orthogonal, real-time detection module for highly sensitive and selective nucleic acid amplification and detection, (4) the ability to use the same basic system components for multiple deployment architectures, and (5) the relatively low cost per assay (<$1 per 10-plex or $0.10 per assay) and minimal consumables. The object of this two year proposal is to complete development and testing of the APDS-II (multiplexed immunoassay screen followed by nucleic acid confirmation) and APDS-III (multiplexed immunoassays and multiplexed nucleic acid detection) platforms.

ANALYTICAL Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.901
APDS	0.763
Lowest Score	0.217

Effectiveness, Biological Agents, Logistics, Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.909
APDS	0.756
Lowest Score	0.321

Effectiveness, Operations, Biological Agents, Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

APDS ranked in the middle third of all evaluated products for mobile laboratories and earned 74% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
APDS	0.653
Lowest Score	0.379

Logistics, Biological Agents, Effectiveness, Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

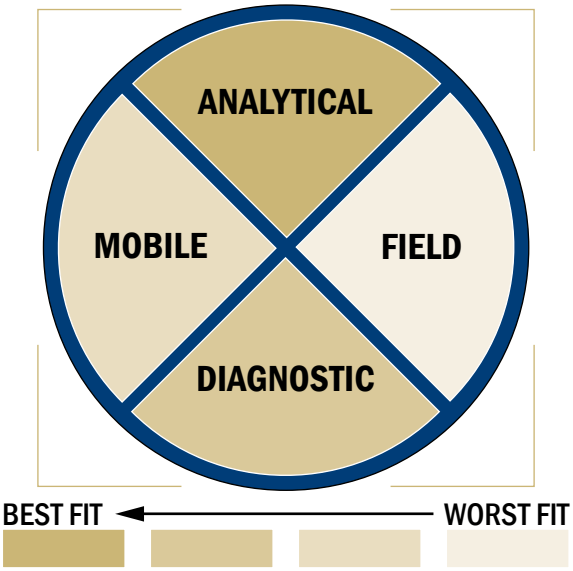
APDS ranked in the bottom third of all evaluated products for field use and earned 45% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
APDS	0.421
Lowest Score	0.343

Logistics, Operations, Effectiveness, Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
Lawrence Livermore National Lab
7000 East Ave, L-174
Livermore, CA 94550

Point of Contact:
Bill Colston
(925) 423-0375
(925) 424-2778 fax
colston@llnl.gov

COST
- $1.00/sample
- $150,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 20 and 30 minutes
- 1 sample/batch
- Less than 50 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- An afternoon of training
- Greater than 20 minutes required for set-up
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:
- 3 consumables or expendables needed
- More often than every 6 months service required
- NA expected life
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Larger than a home dishwasher
- Between 25 and 50 kg
- Shelf life less than 1 month

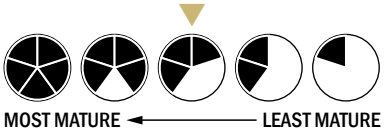
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at room temperature
- Unknown performance of the device or system in relative humidity

Sensitivity:
- 1,000-10,000 CFU per ml

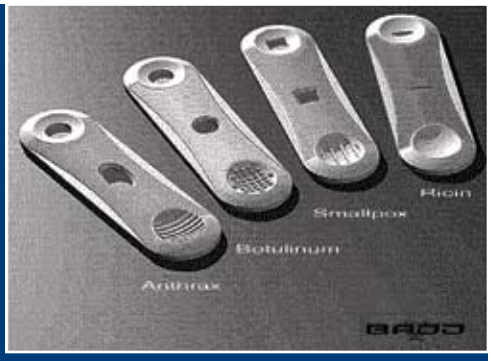
Maturity gauge:
- A few devices or systems exist (brass board)



BADD

by Sigma-Aldrich Fine Chemicals

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Botulinum toxins A, B, E, Ricin, Smallpox, SEB *(Commercially available as wet/ frozen reagent)*



DESCRIPTION:
The BADD Anthrax Rapid Detection Device is a test available that detects minute, yet high amounts of Anthrax on environmental surfaces or in solutions. The BADD Device works without the need for extensive sample preparation steps or additional expensive equipment. Each kit contains everything necessary to take a sample and perform an immediate evaluation, anywhere in the world, with results in 15 minutes or less. Accuracy, ease of use, a capacity to detect credible threat levels, and no cross reactivity with Bacillus globigii or Bacillus thuringiensis makes the BADD Anthrax Rapid Detection Device the perfect test for field detection. In addition to anthrax detection, BADD devices are also available for ricin toxin and botulinum toxin. A test for First Responders evaluating threat credibility.

TECHNOLOGY:
Antigen and antibody rapid screening based on lateral flow technology.

ANALYTICAL Laboratory Ranking

BADD 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
Best Score	0.901
Advent BADD	0.553
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

BADD ranked in the top third of all evaluated products for diagnostic laboratories and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Advent BADD	0.727
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

BADD 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
Best Score	0.883
Advent BADD	0.759
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

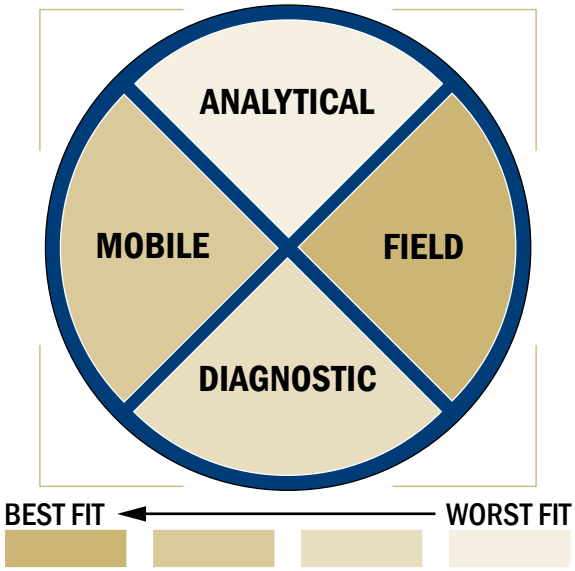
BADD ranked in the top third of all evaluated products for field use and earned 94% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Advent BADD	0.890
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Sigma-Aldrich Fine Chemicals
3050 Spruce Street
Saint Louis, MO 63103
www.SigmaAldrich.com

Point of Contact:
Dean Lyon
(314) 286-7786 x7156
(314) 652-0000 fax
dlyon@sial.com

COST

- $50.00/sample
- $50.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- No electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 20 and 30 minutes
- 1 samples/batch
- Less than 10 ul volume needed per test for detection
- The system or device could be adapted into a semi-automated system with some effort

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 3-5 manual steps required for detection

Re-use:
- Device or system is designed for single use
- 0-1 solution or buffer used
- 3 components
- No cleaning required

Maintenance:
- 3 consumables or expendables needed
- No service required
- NA expected life
- No daily quality assurance procedures

Transportation:
- Approximately the size of a soda can
- Less than 1 kg
- Shelf life between 1 and 3 years

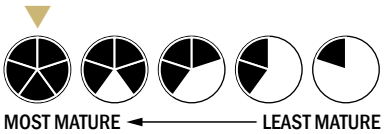
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- There is a single shaking or vortexing step
- System never able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generate

Operational conditions:
- Operated from 4 °C to 45 °C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 10,000-100,000 CFU per ml

Maturity gauge:
- Is commercially available and meets military specifications



Beacon Aflatoxin Plate Kit

by Beacon Analytical Systems, Inc.

CAPABLE OF DETECTING THE FOLLOWING:
Aflatoxin, T-2 Mycotoxin *(Assays developed)*

DESCRIPTION:
The Beacon Aflatoxin Plate Kit is a competitive immunoassay for the quantification of Aflatoxin residues in grains and grain-based products. The limit of detection is two parts per billion. A ground sample is extracted by shaking with a 70% methanol solution. This extract is filtered and then analyzed in the immunoassay along with calibrator solutions of known Aflatoxin concentration and the Aflatoxin content of the sample is derived. The total assay time is less than 20 minutes.

TECHNOLOGY:
The Beacon Aflatoxin Plate Kit is based on the well-established technique of enzyme-labeled competitive immunoassays. This technique has been utilized in clinical laboratories for well over 20 years. The antibodies utilized will detect Aflatoxin B1, B2, G1 and G2 but have minimal reactivity with M1. The kit requires minimal operator training and dedicated equipment and is capable of yielding quantitative results in the range of 2-50 ppb in less than 20 minutes.

ANALYTICAL Laboratory Ranking

Beacon Aflatoxin Plate kit 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
Best Score	0.901
Beacon Aflatoxin Plate Kit	0.398
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Beacon Aflatoxin Plate kit 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
Best Score	0.909
Beacon Aflatoxin Plate Kit	0.549
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Beacon Aflatoxin Plate kit ranked in the middle third of all evaluated products for mobile laboratories and earned 67% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Beacon Aflatoxin Plate Kit	0.594
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

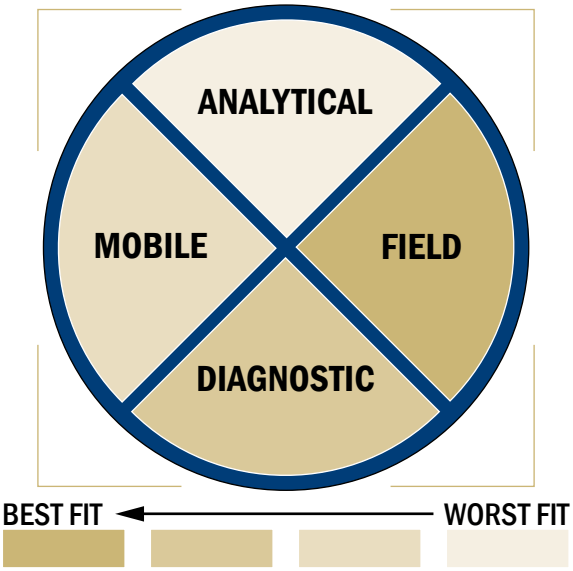
Beacon Aflatoxin Plate kit ranked in the top third of all evaluated products for field use and earned 83% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Beacon Aflatoxin Plate Kit	0.782
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Beacon Analytical Systems, Inc.
383 Presumpscot St.
Portland, ME 04103
www.beaconkits.com

Point of Contact:
Brian Skoczenski
(207) 761-2199
(207) 761-9238 fax
brians@beaconkits.com

COST

- Approx. $3.00/sample
- $240.00/96 test system or device

Evaluation Criteria Provided by Vendor

System requirements:

- No electrical requirement
- The system or device does require water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection 20 minutes or less
- 96 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:

- An afternoon of training
- 5-10 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 4 solutions or buffers used
- 1 component
- No cleaning required

Maintenance:

- 3 consumables or expendables needed
- Less than once a year service required
- Expected life is 3-5 years
- 10-20 minutes required for daily assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 1 and 5 kg
- Shelf life between 1 and 3 years

Ease of use/Utility:

- Cannot view results “in real time”
- No centrifugation steps
- Single shaking or vortexing step
- System able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

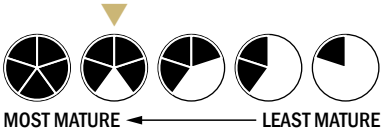
- Operated from 15 °C to 37 °C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- NA CFU per ml

Maturity gauge:

- Is commercially available



BEAR™

by TSI

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Smallpox virus *(Assay developed)*

DESCRIPTION:

TSI's CPATH system is an identification system based on the Bridged Element Analyte Recognition (BEAR™) technology. The system currently (1/2007) exists as a laboratory prototype. The BEAR™ approach entails rapid (<15 seconds) multiplexed detection of unique bioagent DNA through hybridization to specific permanently affixed DNA molecules bridging MEMS micro-circuits. Hybridization events result in an increase of conductivity across specific circuits at a magnitude that is directly related to the degree of match between the two molecules. Thus, the sensor is uniquely capable of accurate identification of known pathogens (100% match) and unknown pathogen variants (<100% match). Once detection is confirmed, the bioagent DNA can be expelled from the bridged circuit, and the sensor is reset for multiple (100's) subsequent detection events. The system requires minimal consumables, infrastructure and support requirements. A fieldable system for a broad array of applications including field and laboratory use is scheduled for release in early 2008. The primary benefits are minimal sample preparation, robustness with regards to sample contamination, high sensitivity, and fast speed of detection making it an ideal candidate for point of use detection. Initial product development requires manual sample introduction with parallel development efforts incorporating continuous monitoring capability: Detection capability has been developed for simulants of Bacillus anthracis and Small Pox (Variola). Development of additional markers for Yersinia pestis (plague), Francisella tularensis (tularemia), and Clostridium botulinum toxin (botulism) are scheduled for 2007.

TECHNOLOGY:

Bioagents within the collected samples are disrupted through chemical lysis and pumped across the surface of a MEMS chip containing individual single-stranded DNA elements bridged across electrical circuit gaps. If the sample contains DNA fragments matching those bridged DNA elements, DNA-DNA hybridization occurs. Hybridization of the sample DNA to the permanently bridged receptor DNA (bridging elements) results in significant and reproducible changes in the electrical characteristics of the MEMS circuit. Current increase beyond a threshold indicates the presence of a specific bioagent, and the magnitude of increase indicates the degree of match between the bridging element and the bioagent DNA.

ANALYTICAL Laboratory Ranking

BEAR 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
Best Score	0.901
TSI BEAR	0.718
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

BEAR ranked in the top third of all evaluated products for diagnostic laboratories and earned 88% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
TSI BEAR	0.796
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

BEAR ranked in the middle third of all evaluated products for mobile laboratories and earned 73% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
TSI BEAR	0.646
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

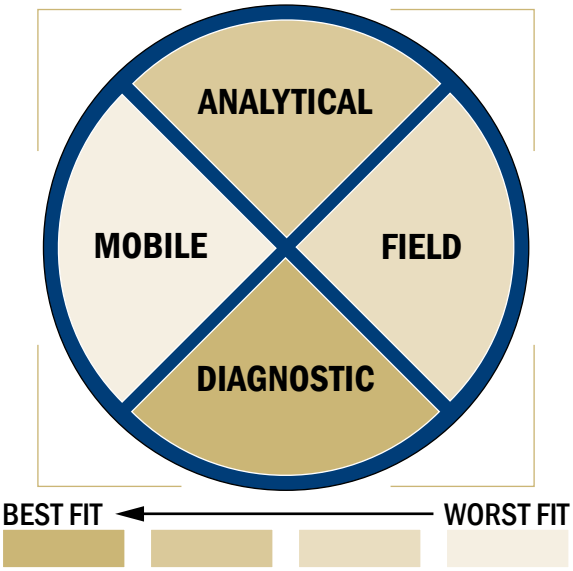
BEAR ranked in the middle third of all evaluated products for field use and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
TSI BEAR	0.726
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

TSI
500 Cardigan Road
Shoreview, MN 55126
www.tsi.com

Point of Contact:
Darrick Niccum
(651) 490-3834
dniccum@tsi.com

COST

- <$10.00/sample
- ~$50,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection greater in 20 minutes or less
- 32 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- 5-10 minutes set-up required
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 2 solutions or buffers used
- 1 component
- Flush system with buffer

Maintenance:

- Once a year service required
- Expected life is between 5-10 years
- 5-10 minutes daily quality assurance procedures

Transportation:

- Approximately the size of a toaster
- Between 5 and 25 kg
- Reagent shelf life greater than 3 years

Ease of use/Utility:

- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System may be able to interpret raw data or call a positive through internal software in the future
- Capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:

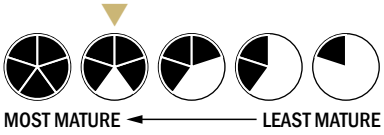
- Operated from 4°C to 37°C
- Components must be stored at 25°C to 45°C
- The effect of relative humidity is unknown

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- A few devices or systems exist (brass board)
- Is expected to be ready for commercialization within one calendar year
- $1,000,000-$2,000,000 required for device or system to advance to commercialization
- Has not been featured in any peer reviewed scientific publications or independent evaluations



Bio-Alloy 'Smart' Material Sensor

by IatroQuest Corporation

CAPABLE OF DETECTING THE FOLLOWING:
MS-2 bacteriophage
(Assays developed)

DESCRIPTION:
IatroQuest Corporation's breakthrough, patented platform technology called Bio-Alloy, supports the development of a new and cost-effective approach to biosensing. Bio-Alloy technology converges biotechnology, nanotechnology, advanced semiconductor materials and photonics to create "smart materials." Unique attributes enable these materials to detect and identify, in a label-free and real-time manner, a wide range of biological agents as well as specific toxic chemical agents, with a high degree of sensitivity and selectivity. Applications in point and stand-off detection for biodefense are the primary focus with follow-on applications in medical diagnostics, environmental and life science sectors.

TECHNOLOGY:
The Bio-Alloy sensing technology platform combines elements of nanotechnology, advanced semiconductor materials, biotechnology and photonics to generate 'smart materials' with unique biosensing attributes. These advanced materials are produced in four steps: 1) Silicon chip preparation: dicing silicon chips to provide the basic material for Bio- Alloy, 2) Nanostructuring: chemically treating silicon chips to produce nanostructured, photoluminescent, materials (feature size 2–3 nanometers), 3) Surface chemistry: attachment of linker molecules (required to attach biorecognition moieties), and 4) Bioprocessing: immobilizing specific recognition elements (e.g. antibody fragments, enzymes, sDNA) to produce specific biosensing capability. The underlying detection principle, based on a unique photoluminescence (green light emission) response generated directly by the Bio-Alloy material, relies on quantum confinement and changes in the surface energy when the surface is excited with low-power blue light (micro-Watt LED; one second integration time). Affinity binding of target agents to recognition elements linked to the Bio-Alloy surface causes perturbations in the surface energy states/photoluminescence response detected as an increase in light intensity.

ANALYTICAL Laboratory Ranking

Bio-Alloy ranked in the middle third of all evaluated products for analytical laboratories and earned 71% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Bio-Alloy Smart Material Sensor	0.638
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Bio-Alloy ranked in the top third of all evaluated products for diagnostic laboratories and earned 81% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Bio-Alloy Smart Material Sensor	0.734
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Bio-Alloy ranked in the middle third of all evaluated products for mobile laboratories and earned 64% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Bio-Alloy Smart Material Sensor	0.564
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

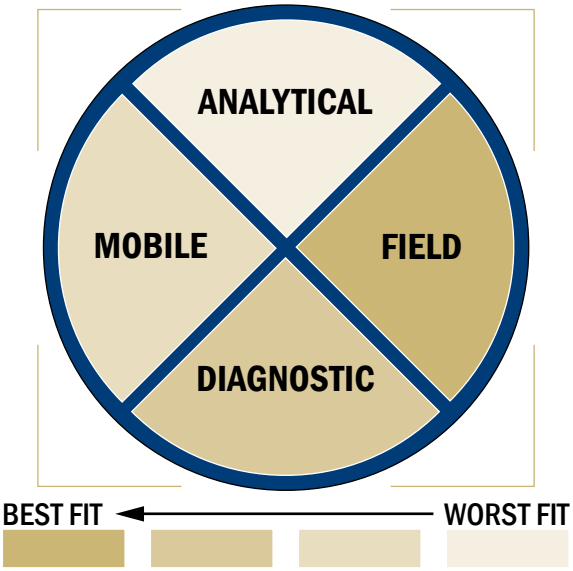
Bio-Alloy ranked in the top third of all evaluated products for field use and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Bio-Alloy Smart Material Sensor	0.753
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

IatroQuest Corporation
309-2183 Ogilvie Rd
Ottawa, Ontario K1J 1C8
www.IatroQuest.com

Point of Contact:
David Armstrong
(613) 990-0864
(613) 991-3843 fax
darmstrong@iatroquest.com

COST

- $0.50-$1.00/sample
- $10,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:

- System or device uses batteries
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection in 20 min or less
- 384 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:

- An afternoon of training
- Less than 5 min required for set-up
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple detections
- 0-1 solution or buffer used
- 1 components
- No cleaning required

Maintenance:

- 2 consumables or expendables needed
- Needs service every 6 months
- Expected life measure unknown
- No daily quality assurance procedures required

Transportation:

- Approximately the size of a toaster
- Less than 1 kg
- Shelf life between 6 months-1 year

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System may be capable of interpreting raw data or call a positive through internal software in the future
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

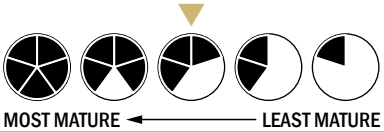
- Operated from 4 °C to 45 °C
- Components must be stored at 4 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- 100-1,000 CFU per ml

Maturity gauge:

- Expected to be ready for commercialization within two calendar years
- A few systems or devices exist (brass board)



Bio Detector (BD)

by Smiths Detection

CAPABLE OF DETECTING THE FOLLOWING:
Burkholderia mallei, MS-2 bacteriophage, SEB, Ricin *(Assays developed);*
Bacillus anthracis, Francisella tularensis, Burkholderia pseudomallei, Coxiella burnetti, Brucella species, VEE virus, Smallpox virus, Botulinum toxin A *(Assays validated)*

DESCRIPTION:
The Biological Detector (BD) was jointly developed and field-tested by Smiths Detection – Edgewood (formerly Environmental Technologies Group, Inc.) and the U.S. Army for use in the U.S. Army's BIDS. The BD simultaneously detects up to eight different biological agents. Additional assays have been developed and validated for use for the BD and can be easily "swapped" depending on the intelligence. The BD is an on-demand, portable, system, or can run continuously for 14 hours. This is a mature product that has been in production for seven years. The BD has also been selected by the UK MoD for use in the IBDS. A total of 110 units have been fielded to date, and 42 more units will be manufactured for the UK.

TECHNOLOGY:
The BD uses the principles of Immuno-ligand Assay (ILA) chemistries and the light-addressable potentiometric sensor (LAPS), licensed to Smiths by Molecular Devices Corporation, to specifically identify biological agents. The BD draws a one-milliliter liquid sample, which is segmented and specifically analyzed for eight different biological agents. The BD uses biotin and fluorescein labeled antibodies, and a tape cassette using biotin coated nitrocellulose membrane as the capture surface.

ANALYTICAL Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.901
Bio Detector (BD)	0.750
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

BD ranked in the top third of all evaluated products for diagnostic laboratories and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Bio Detector (BD)	0.764
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

BD ranked in the middle third of all evaluated products for mobile laboratories and earned 74% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Bio Detector (BD)	0.651
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

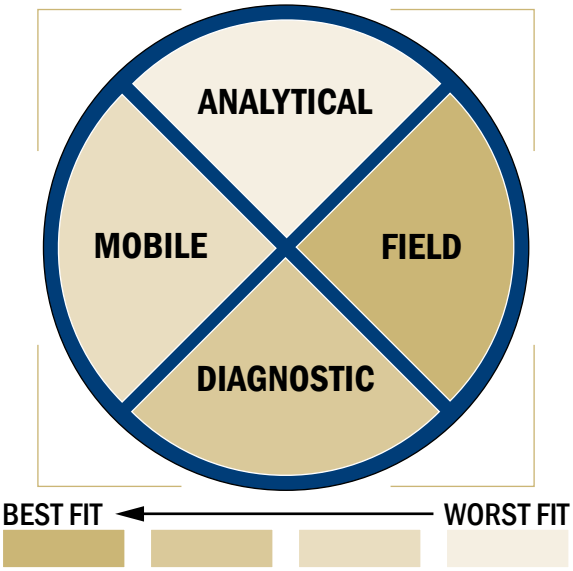
BD ranked in the middle third of all evaluated products for field use and earned 69% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Bio Detector (BD)	0.652
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Smiths Detection-Edgewood
2202 Lakeside Blvd.
Edgewood, MD 21040
www.smithsdetection.com

Point of Contact:
Keith Uithoven
(410) 510-9263 x263
(410) 510-9496 fax
keith.uithoven@smithsdetection.com

COST

- $4.78/sample
- $225,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection 20 minutes or less
- 2 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:

- A day of training
- 10-20 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 3 components
- Unit comes with a cleaning kit

Maintenance:

- 0-1 consumable or expendable needed
- No service required
- Expected life is 5-10 years
- 10-20 min required for daily quality assurance procedures

Transportation:

- Approximately the size of a home dishwasher
- More than 50 kg
- Shelf life between 1 and 3 years

Ease of use/Utility:

- Cannot view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- Sounds are produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:

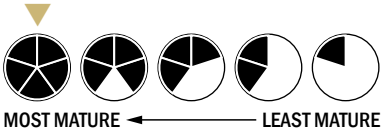
- Can only be operated at 25°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- 10,000-100,000 CFU per ml

Maturity gauge:

- Is commercially available and meets military specifications



BioHAZ™ Kit

by EAI

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Corynebacterium diphtheria, Burkholderia pseudomallei, Coxiella burnetti, Brucella species, E.coli O157:H7, Vibrio cholera, Burkholderia mallei, Yersinia pestis, Rickettsia prowazekii, Marburg virus, Smallpox virus, Influenza virus, Dengue fever virus, Orthopox virus, Rift valley fever virus, Venezuelan equine encephalitis virus, Yellow fever virus, Ebola virus, MS-2 bacteriophage, Botulinum toxin B, Staphylococcal toxin B, Ricin toxin *(Assay developed)*

DESCRIPTION:
The BioHAZ is a portable field system designed for use by emergency response personnel at incidents where biological materials may be present, and sample collection, screening and analysis are performed. This system contains all materials necessary to collect liquid and solid samples for on-site biological screening and off-site positive analysis, and prescribes detailed instructions to ensure sample integrity. The system is designed to allow the user to select the proper sampling package which includes sample sponges, sterile swabs, syringes, spatulas, bags, and culture tubes; chain-of-custody forms, markers, and custody seals. Sample screening and possible identification is conducted through fluorometry, luminometry, colorimetry and sample specific analyses is performed through the use of sensitive membrane antigen rapid tests. Step-by-step instructions from preparation for entry into the hot zone through sample collection, screening, identification, and transfer are included. The system is packaged in rugged portable water-tight containers with each sample collection kit and sample processing kit marked for easy locating and use. All sampling/processing kits and other individual components are designed to be disposable and replaceable.

TECHNOLOGY:
The BioHAZ is a dual instrument that performs two independent tests with a luminometer and fluorometer. The luminometer determines whether bacteria or spores are present and the fluorometer determines whether DNA is present in the sample. Protein Test strips are used to indicate the presence of a protein and the pH test strip indicates the degree of acidity or alkalinity of the sample. The Assay tests check for the presence of specific bacterial, toxin or viral biological agent.

ANALYTICAL Laboratory Ranking

BioHAZ 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
Best Score	0.901
EAI BioHaz	0.725
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

BioHAZ 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
Best Score	0.909
EAI BioHaz	0.715
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

BioHAZ ranked in the top third of all evaluated products for mobile laboratories and earned 88% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
EAI BioHaz	0.778
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

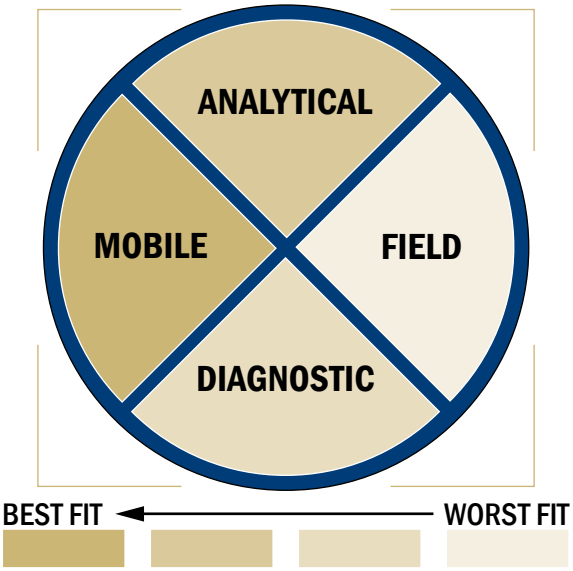
BioHAZ ranked in the top third of all evaluated products for field use and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
EAI BioHaz	0.726
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

EAI Corporation
1308 Continental Drive
Abingdon, MD 21009
www.eaicorp.com

Point of Contact:
Dan Decker
Phone: 410-671-9375
(443) 372-1264
(410) 671-9374 fax
ddecker@eaicorp.com

COST

- $100.00-150.00/sample
- $19,995.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection between 20 and 30 minutes
- 1 sample/batch
- Greater than 250 ul volume needed per test for detection
- The system or device is not amenable to automation

Training/Speed/Manpower:

- A day of training
- 10-20 minutes of set-up required
- 9-12 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:

- No service required
- Expected life is greater than 10 years
- 10-20 minutes of daily quality assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Reagent shelf life between 1 to 3 years

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System cannot interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

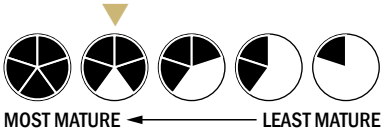
- Operated from 25°C to 37°C
- Components must be stored at 4°C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 10,000-100,000 CFU per ml

Maturity gauge:

- Is commercially available
- Has been featured in peer reviewed scientific publications or independent evaluations



Biological Aerosol Warning System (BAWS)

by Lockheed Martin

CAPABLE OF DETECTING THE FOLLOWING:
None reported *(Generic detector)*

DESCRIPTION:
Lockheed Martin has developed a ruggedized, deployable Biological Aerosol Warning System (BAWS) which uses an array of nonspecific detectors to provide an operational "detect-to-warn" capability. The BAWS provides early warning of biological attack though deployment of Remote Sensor Units (RSUs) in and around field sites and fixed facilities. Information from the RSUs is evaluated at the Base Station and appropriate alerts and alarms are issued for proper response. BAWS detects medium-to-large releases of aerosolized biological material, and is powered by rechargeable lithium ion batteries provided as part of the system, vehicle power, or other available power sources. The BAWS system is autonomous, small, lightweight, and requires minimal consumables and training to operate.

TECHNOLOGY:
The Lockheed Martin Biological Aerosol Warning System (BAWS) is typically defined as a complete biological sensor network comprised of 10 Remote Sensor Units (RSUs) and one Base Station. The principle technology utilized in BAWS is Airborne Particle Counting (APC)- utilizing proven light scattering techniques for individual particles; and Ultraviolet Light-Induced Fluorescence (UV-LIF)-utilizing mass integrated total particle fluorescence. BAWS also has a dry filter and/or centrifugal impaction sample collection capability for integration with other customer defined biological identifiers.

ANALYTICAL Laboratory Ranking

BAWS ranked in the bottom third of all evaluated products for analytical laboratories and earned 42% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Lockheed Martin BAWS	0.378
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

BAWS 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
Best Score	0.909
Lockheed Martin BAWS	0.438
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

BAWS 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
Best Score	0.883
Lockheed Martin BAWS	0.432
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

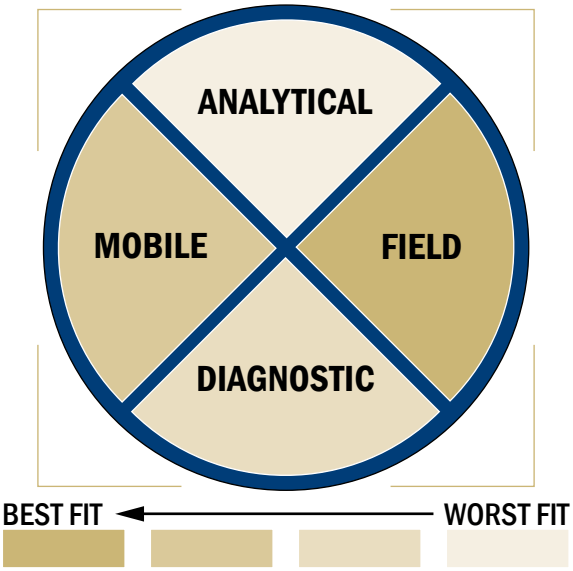
BAWS ranked in the middle third of all evaluated products for field use and earned 60% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Lockheed Martin BAWS	0.564
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Lockheed Martin MS2 Homeland Security Systems
9500 Godwin Drive
Manassas, VA 20110-4157
www.lockheedmartin.com

Point of Contact:
Rick Read
(703) 367-1546
richard.read@lmco.com

COST

- $800,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device can use batteries, 110V or 220V electricity
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- 1 sample/batch
- The system or device is currently fully automated

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- Greater than 20 minutes set-up required

Re-use:

- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 1 component
- No cleaning required

Maintenance:

- Once a year service required
- Expected life is greater than 10 years
- No daily quality assurance procedures

Transportation:

- Larger than a home dishwasher
- More than 50 kg
- No reagents

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

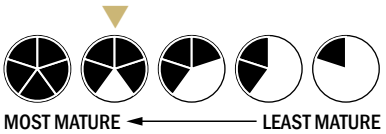
Operational conditions:

- Operated from -10°C to 50°C
- Components must be stored from -20°C to 60°C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- Approx. 3000 CFU per L of air

Maturity gauge:



BIODET-400 Handheld

by Ciencia Inc.

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis

DESCRIPTION:
The BIODET-400 system provides the capability for rapid, highly multiplexed detection of biological pathogens and toxins. It uses on-chip immunoassay technology with a novel evanescent wave sensing method that enables label-free detection with high sensitivity. The evanescent wave is created either via grating-coupled surface waveguides or via grating-coupled surface plasmon resonance (GCSPR). The chip (1 cm^2) is plastic, has an impressed grating, and surface chemistry for immobilizing antibodies (up to 400 spots per chip). The sample to be analyzed (in liquid form) is caused to flow over the chip, either with microchannels and a manifold for multiple inputs, or uniformly for a single input. Readout is accomplished with a beam of NIR light produced by an LED and imaging detection is performed with CCD camera, whereby changes in the index of refraction at all antibody sites are simultaneously measured. Since no labels are required (fluorescent, enzymatic, chemiluminescent, etc.) samples can be processed directly with minimal or no preparation. The system can potentially be configured as an on-line, real-time continuous monitor, a laboratory instrument, or a hand-held portable device.

TECHNOLOGY:
Appropriate antibodies are immobilized in array format on the chip, either at manufacture or in the field using unique self-assembly methods. A manifold assembly houses necessary buffers. Sample is introduced to manifold and pumped across sensor chip. Manifold, chip, and pump parts are disposable. Microarray includes up to 400 spots, for simultaneous detection of up to 100 or more analytes (in duplicate or triplicate plus reference spots). Sensitivity is ~ 1 pg/mm^2. We estimate that sensitivity is sufficient for detection of single spores of Bacillus anthracis.

The technology and instrument described have been developed for proteomics and high throughput screening applications. Target proteins are fixed on the chip surface, and liquid is caused to flow over this surface. In this manner, data on binding kinetics is rapidly collected for protein arrays of sizes of 400 spots. The detection method does not require the use of labels (such as fluorescent, enzymatic or chemiluminescent), which results in very simple protocols and rapid detection.

In the past year, this instrument has been evaluated for on-chip immunoassay purposes, and found to be of great value in terms of sensitivity, array format, speed, and versatility. A number of applications are being developed at Ciencia for NASA and National Institutes of Health. These include bioreactor product monitoring in space, phenotyping of animal models and other proteomics applications. Ciencia recently received a grant from the National Science Foundation to explore the use of this system for detection of environmental pathogens. Our results thus far indicate that this system would provide powerful technology for rapid detection of biological agents, both in the laboratory and the field. Based on the results of this year's work, Ciencia intends to produce and market the instrument for bio-agent detection as well as pathogen detection, in general. Development is required to design apparatus to insert collected samples in the chip buffer compartments, the channels themselves, and the specific assays. A summary of position might show that an immunoassay system was 85% developed with 15% remaining.

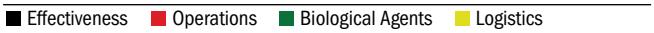
ANALYTICAL Laboratory Ranking
BioDET-400 handheld ranked in the middle third of all evaluated products for analytical laboratories and earned 42% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
BIODET-400 Hand-held	0.607
Lowest Score	0.217

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking
BioDET-400 handheld ranked in the middle third of all evaluated products for diagnostic laboratories and earned 48% of the utility points of the best score.

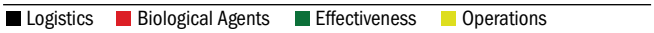
ALTERNATIVE	UTILITY
Best Score	0.909
BIODET-400 Hand-held	0.711
Lowest Score	0.321



Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking
BioDET-400 handheld ranked in the bottom third of all evaluated products for mobile laboratories and earned 49% of the utility points of the best score.

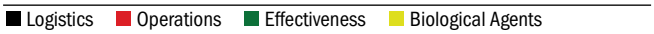
ALTERNATIVE	UTILITY
Best Score	0.883
BIODET-400 Hand-held	0.530
Lowest Score	0.379



Preference Set: *Mobile Laboratory*

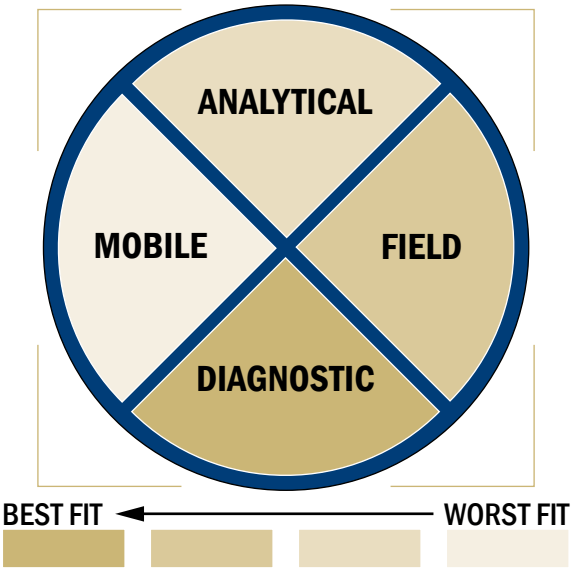
FIELD USE Ranking
BioDET-400 handheld ranked in the middle third of all evaluated products for field use and earned 60% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
BIODET-400 Hand-held	0.647
Lowest Score	0.343



Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Ciencia Inc.
111 Roberts St., Suite K
East Hartford, CT 06108
www.ciencia.com

Point of Contact:
S. Fernandez, Ph.D
(860) 528-9737
(860) 528-5658 fax
Fernandez@ciencia.com

COST

- $50.00/sample
- $40,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 1 sample/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device is not amendable to automation

Training/Speed/Manpower:
- A day of training
- 5-10 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 1 components
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- Estimated once a year service required
- Expected life is 5-10 years
- 5-10 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 1 and 5 kg
- Shelf life between 6 months and 1 year

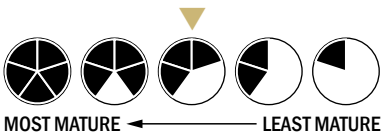
Ease of use/Utility:
- Cannot view results “in real time”
- No centrifugation steps
- There is a single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 4 °C to 37 °C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

Maturity gauge:
- A few devices or systems exist (brass board)



BIODET-400 Laboratory Instrument

by Ciencia Inc.

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis

DESCRIPTION:
The BIODET-400 system provides the capability for rapid, highly multiplexed detection of biological pathogens and toxins. It uses on-chip immunoassay technology with a novel evanescent wave sensing method that enables label-free detection with high sensitivity. The evanescent wave is created either via grating-coupled surface waveguides or via grating-coupled surface plasmon resonance (GCSPR). The chip (1 cm^2) is plastic, has an impressed grating, and surface chemistry for immobilizing antibodies (up to 400 spots per chip). The sample to be analyzed (in liquid form) is caused to flow over the chip, either with microchannels and a manifold for multiple inputs, or uniformly for a single input. Readout is accomplished with a beam of NIR light produced by an LED and imaging detection is performed with CCD camera, whereby changes in the index of refraction at all antibody sites are simultaneously measured. Since no labels are required (fluorescent, enzymatic, chemiluminescent, etc.) samples can be processed directly with minimal or no preparation. The system can potentially be configured as an on-line, real-time continuous monitor, a laboratory instrument, or a hand-held portable device.

TECHNOLOGY:
Appropriate antibodies are immobilized in array format on the chip, either at manufacture or in the field using unique self-assembly methods. A manifold assembly houses necessary buffers. Sample is introduced to manifold and pumped across sensor chip. Manifold, chip, and pump parts are disposable. Microarray includes up to 400 spots, for simultaneous detection of up to 100 or more analytes (in duplicate or triplicate plus reference spots). Sensitivity is ~ 1 pg/mm^2. We estimate that sensitivity is sufficient for detection of single spores of Bacillus anthracis.

ANALYTICAL Laboratory Ranking

BioDET-400 laboratory instrument ranked in the middle third of all evaluated products for analytical laboratories and earned 67% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
BIODET-400 Lab. Instr.	0.602
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

BioDET-400 laboratory instrument ranked in the middle third of all evaluated products for diagnostic laboratories and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
BIODET-400 Lab. Instr.	0.701
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

BioDET-400 laboratory instrument 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
Best Score	0.883
BIODET-400 Lab. Instr.	0.429
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

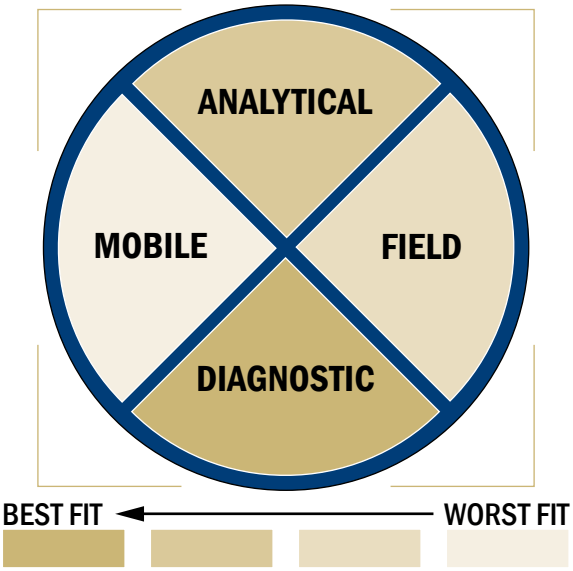
BioDET-400 laboratory instrument ranked in the bottom third of all evaluated products for field use and earned 55% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
BIODET-400 Lab. Instr.	0.522
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Ciencia Inc.
111 Roberts St., Suite K
East Hartford, CT 06108
www.ciencia.com

Point of Contact:
S. Fernandez, Ph.D.
(860) 528-9737
(860) 528-5658 fax
Fernandez@ciencia.com

COST

- $50.00/sample
- $40,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection 20 minutes or less
- 1 sample/batch
- Less than 100 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:

- A day of training
- 5-10 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 1 component
- No cleaning required

Maintenance:

- 0-1 consumable or expendable needed
- Needs service once a year
- Expected life is 5-10 years
- 5-10 minutes required for daily assurance procedures

Transportation:

- Approximately the size of a home dishwasher
- Between 5 and 25 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility:

- Cannot view results “in real time”
- No centrifugation steps
- There is a single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:

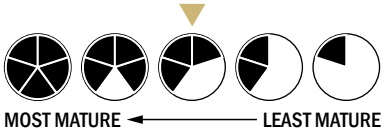
- Operated from 15 °C to 37 °C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- A few devices or systems exist (brass board)



BioHawk

by Research International

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Coxiella burnetti, Brucella species, Yersinia pestis, Smallpox virus, Venezuelan equine encephalitis virus, MS-2 bacteriophage, Botulinum toxin A, Botulinum toxin B *(Assay developed)*

DESCRIPTION:

The BioHawk assay system consists of a wetted-wall cyclone collector tightly integrated with a rapid, automatic fluorometric detector. The BioHawk is portable (11.8 kg) and can test a single sample for eight different toxins, viruses, bacteria, spores, fungi and other diverse targets. Based on two proven technologies (the extremely reliable third-generation SASS collector and RAPTOR detector), users can anticipate this device will operate for two years or more with no breakdowns or leaks, and that it will tolerate debris-laden samples (such as are produced in mailrooms and food processing facilities) - impressive feats for a fully automated wet assay system. Originally developed for the Marine Corps, the instrument can be operated by minimally trained personnel such as mail room operators and first responders or by trained technical personnel such as laboratory technicians. The completely self-contained instrument is the culmination of a careful integration of optics, fluidics, electronics, and software into one compact system for both laboratory and field assays. It performs user-defined, multi-step, assay protocols for collecting aerosols and monitoring fluorescently-labeled immunoassays occurring on the surface of 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.

TECHNOLOGY:

The aerosol collector is a highly efficient, multiple-effect, wetted-wall cyclone that extracts and transfers pathogens from sampled air to a small fixed water volume for subsequent assay. A unique and patented feature is the ability to perform this function continuously for an extended time period without fluid sample loss. The biosensor is based on monolayer receptor-ligand reactions taking place on the surface of injection molded polystyrene waveguides. All fluidic and optoelectronic steps associated with the assay are performed automatically. The baseline protocol used to identify specific pathogens is the 'sandwich format' fluoroimmunoassay. In a typical waveguide-based sandwich immunoassay, the cylindrical waveguide has a monolayer of capture antibody immobilized on its surface. Following incubation with sample and then with a fluorophore-labeled antibody, the signal is measured and results displayed within 15 minutes.

ANALYTICAL Laboratory Ranking

BioHawk ranked in the middle third of all evaluated products for analytical laboratories and earned 67% of the utility points of the best score

ALTERNATIVE	UTILITY
Best Score	0.901
Research International BioHawk	0.602
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

BioHawk 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
Best Score	0.909
Research International BioHawk	0.716
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.883
Research International BioHawk	0.714
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

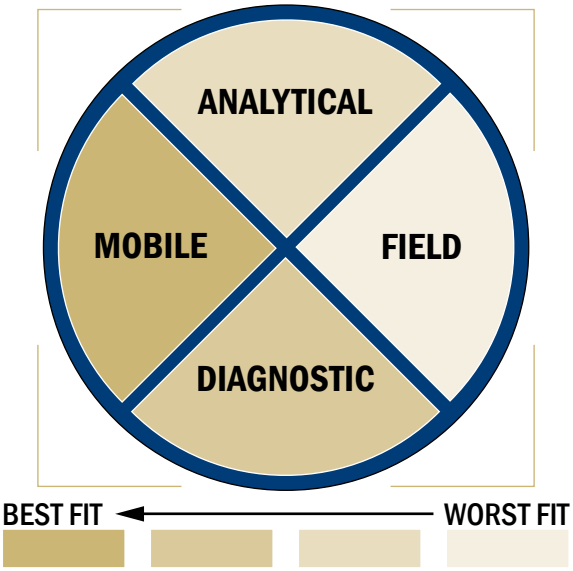
BioHawk ranked in the middle third of all evaluated products for field use and earned 70% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Research International BioHawk	0.663
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
Research International
17161 Beaton Road SE
Monroe, WA 98272
www.resrchintl.com

Point of Contact:
Elric Saaski
(360) 805-4930
elricsaaski@resrchintl.com

COST
- $1.00/sample
- $50,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device uses BA-5590/U batteries or 110V electricity
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection less than 20 minutes
- 2 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- Very brief (minutes-hours) training and minimal technical skills
- 10-20 minutes of set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 2 solutions or buffers used
- 0 components
- Automatic cleaning with water and buffer

Maintenance:
- Once a year service required
- Expected life is between 5-10 years
- 10-20 minutes required for daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Reagent shelf life between 6 months and 1 year

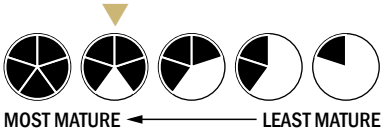
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4 °C to 37 °C
- Components must be stored at room temperature
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1,000-50,000 CFU per ml

Maturity gauge:
- A few devices or systems exist (brass board)
- Is expected to be ready for commercialization within one calendar year
- <$1,000,000 to be ready for commercialization
- Has not been featured in peer reviewed scientific publication or independent evaluations



Biological Detection System – Generation 2 (BDS2)

by Echo Technologies, Inc.

CAPABLE OF DETECTING THE FOLLOWING:
None reported
(Generic detector)

DESCRIPTION:
Echo Technologies, Inc. (ETI) has developed an optical sensor array designed to detect and classify biological agents and toxins, and to discriminate these materials from typical non-biological interferents. The sensor array will generically detect BW threat agents including bacteria, bacterial spores, toxins and viruses. The system was designed to be used in two primary configurations: as a handheld, or stand-alone point detector; or as a "smart trigger" when integrated with a larger instrumentation suite.

TECHNOLOGY:
The sensors are optical transducers that use optical substrates and fluorescent reporter molecules to detect broad classes of microorganisms. Using a multi-sensor array the nature of the threat can be assessed and distinguished from non-biological material, and from the naturally occurring biological background (e.g., airborne dead bacteria, fungi, molds and humic matter). Detection of broad classes of chemical and biological threats is particularly well suited to situations where the nature of the contaminants is unknown. The information from multiple sensors in an array is analyzed as an ensemble using chemometric algorithms, thereby providing more information than an individual sensor for a single analyte. This presumptive determination can then be used to trigger an array of identification sensors or signal the need for a more sophisticated confirmatory analysis.

ANALYTICAL Laboratory Ranking

BDS2 ranked in the top third of all evaluated products for analytical laboratories and earned 93% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
BDS2	0.842
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

BDS2 ranked in the top third of all evaluated products for diagnostic laboratories and earned 93% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
BDS2	0.849
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

BDS2 ranked in the top third of all evaluated products for mobile laboratories and earned 83% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
BDS2	0.733
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

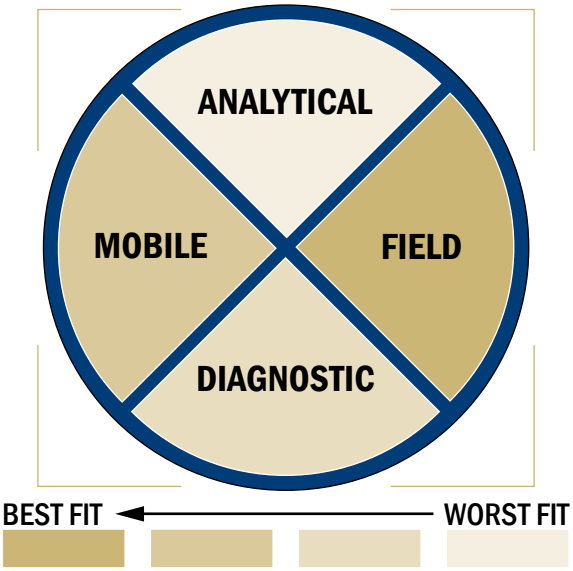
BDS2 ranked in the middle third of all evaluated products for field use and earned 76% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
BDS2	0.714
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
Echo Technologies, Inc.
5250 Cherokee Avenue
Alexandria, VA 22312
www.echotech.net

Point of Contact:
Marilyn Ripin; Mary Beth Tabacco
703-658-7692; 617-443-0066
703-941-8172; 617-204-3080 fax
mripin@erols.com; mtabacco@erols.com

COST
- $5.00/sample
- $10,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:
- System or device uses batteries
- The system or device does not requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 min or less
- 2 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief training required
- 5-10 min required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 0-1 solution or buffer used
- 2 components
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- Needs service less than once a year
- Expected life measure of 3-5 years
- Less than 5 minutes required for daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life between 1-6 months

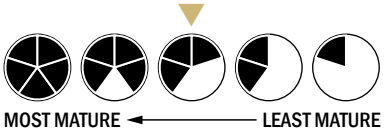
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay available, and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generate

Operational conditions:
- Can be operated from 4 °C to 45 °C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1,000 CFU per ml

Maturity gauge:
- Expected to be ready for commercialization within one calendar year
- A few systems or devices exist (brass board)



BioMAPP

by BAE Systems

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, E. coli 0157:H7, Francisella tularensis, Vibrio cholera, Burkholderia mallei, Brucella species, Rift Valley fever virus, Venezuelan Equine Encephalitis virus, Hanta virus, Yellow fever virus, Dengue fever virus, Orthopox virus, MS-2 bacteriophage, Botulinum toxins A, B, E, Ricin *(Assays developed)*

DESCRIPTION:

The BioMAPP (Biological Multi-Analyte Pathogen Profiler) Detection System has the ability to perform a wide range of assays, including nucleic acid assays for both DNA and RNA and immunoassays. It also allows assays for antibodies in clinical samples that indicate prior exposure to a BW agent, even if that agent is no longer present in the sample. This is a capability absent in systems that rely solely on nucleic acid detection assays. The BioMAPP system can interrogate a single 10-20 uL sample for up to 100 different analytes/agents and controls, simultaneously. This large capacity not only allows testing for multiple targets at once, it also allows rejection of near neighbors, permits differentiation of target strains, and supports inclusion of controls. In addition, the system allows for the identification of multiple targets for each agent. This redundant identification of each agent essentially eliminates false positive and false negative samples. To help reduce logistic support requirements, the BioMAPP uses clinical or environmental sample sizes as small as 10-20 uL. Once a processed sample has been added to the device, detection and agent identification are completed in a matter of seconds. An optional separate device (XY Platform) allows automated assays of 96 different samples (again, with up to 100 assays performed on each sample). A high-throughput version also exists, that can perform nearly one-half million assays per day. Thus, a great many sample assays can be performed without needing a large number of analyzers; one device can do the work of many.

TECHNOLOGY:

With xMAP technology, molecular reactions take place on the surface of microscopic beads called microspheres. For each reaction in a xMAP profile, thousands of molecules are attached to the surface of internally color-coded microspheres. The assigned color-code identifies the reaction throughout the test. The magnitude of the biomolecular reaction is measured using a second molecule called a reporter. The reporter molecule signals the extent of the reaction by attaching to the molecules on the microspheres. Because the reporter's signal is also a color, there are two sources of color, the color-code inside the microsphere and the reporter color on the surface of the microsphere. To perform a test, the color-coded microspheres, reporter molecules, and sample are combined. This mixture is then injected into an instrument that uses microfluidics to align the microspheres in single file where lasers illuminate the colors inside and on the surface of each microsphere. Next, advanced optics capture the color signals. Finally, digital signal processing translates the signals into real-time, quantitative data for each reaction. The BioMAPP utilizes xMAP technology which enables simultaneously assay detection up to 100 analytes in a single well of a microtiter plate, using very small sample volumes. The system delivers fast and cost-effective bioassay results on many assay formats including nucelic acid assays, receptor-ligand assays, immunoassays and enzymatic assays.

ANALYTICAL Laboratory Ranking

BioMAPP ranked in the top third of all evaluated products for analytical laboratories and earned 94% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
BioMAPP	0.849
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

BioMAPP ranked in the top third of all evaluated products for diagnostic laboratories and earned 90% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
BioMAPP	0.818
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

BioMAPP ranked in the top third of all evaluated products for mobile laboratories and earned 88% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
BioMAPP	0.778
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

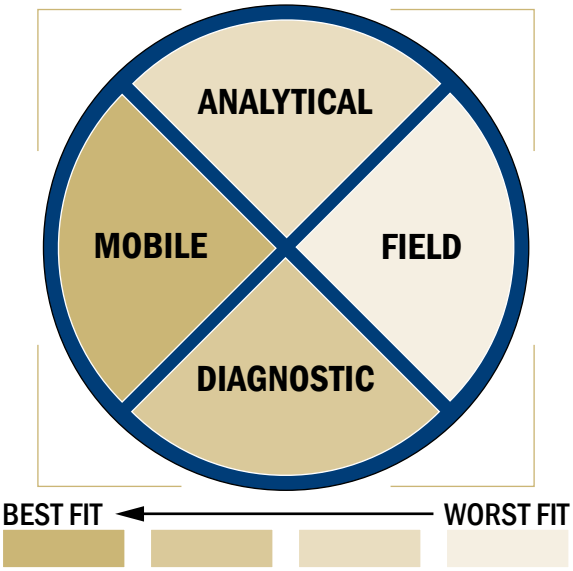
BioMAPP ranked in the middle third of all evaluated products for field use and earned 75% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
BioMAPP	0.703
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

BAE Systems, Inc.
Integrated Defense Solutions
Austin, TX 78725
Woodinville, WA 98072
www.baesystems.com

Point of Contact:
Gary Morris
(512) 926-2800
(512) 929-4774 fax
gary.k.morris@baesystems.com

COST

- $1.84/sample
- $70,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has a 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection between 30 and 40 minutes
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted to a fully automated system with some effort

Training/Speed/Manpower:

- A day of training
- Greater than 20 minutes required for set-up
- 6-8 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 1 component
- Daily washing with water required

Maintenance:

- 3 consumables or expendables needed
- Every 6 months service required
- Expected life is greater than 10 years
- Less than 5 minutes of daily quality assurance procedures required

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 25 and 50 kg
- Shelf life between 1 and 3 years

Ease of use/Utility:

- Can view results “in real time”
- Multiple centrifugation steps
- A single shaking or vortexing step
- System is sometimes able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- Four additional pieces of equipment needed

Signature:

- Sounds are produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:

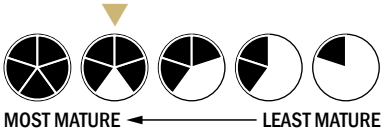
- Operated from 15 °C to 37 °C
- Components can be stored at 25 °C to 37 °C
- Device or system has peak performance at normal relative humidity conditions only

Sensitivity:

- 100-1,000 CFU per ml

Maturity gauge:

- Is commercially available



Bio-Seeq

by Smiths Detection

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis *(Commercially available as a freeze-dried reagent),* Yersinia pestis *(Assay validated),* Smallpox virus *(Assay developed)*

DESCRIPTION:

There is a growing need for portable, battery-powered instruments capable of detecting and identifying biological agents that may be used against military and civilian targets. The Bio-Seeq detection system, developed by Smiths Detection, is designed to address this need. The instrument weighs 6.5lbs, processes up to six samples at one time, and will operate for up to 2.5 hours with a rechargeable battery. Two independent optical channels allow the simultaneous detection of an agent of interest along with an internal positive control to verify that the sample was correctly processed. The ease of sample preparation and reagent handling is a key component in reliably performing PCR assays. The consumable developed by Smiths Detection is complete and self-contained with all necessary reagents, filtering, and reconstitution fluids. Processing of the assay involves a simple wipe of the target powder followed by a simple rotating action and then shaking on the part of the operator. No pipetting or other fluid transfer is required to complete a test. The amplification of the sample is performed by the instrument and results in an indication of positive, negative, or indeterminate is displayed for samples that have been inhibited by an environmental substance. Positive samples have cycle time or CT number that indicate the approximate concentration. Test results and data are stored in non-volatile EEPROM for later retrieval using PC based software. Processing time for most reagents is less than 40 minutes. Tests with anthrax samples have shown that detection limits as low as 125 CFU's per test were reliably detected. The instrument is currently available with a menu of Anthrax and Tularemia. Plague and Smallpox will be planned.

TECHNOLOGY:

Polymerase Chain Reaction technology is a well known and researched technology used to rapidly identify a potential threat agent by its unique DNA. Six independently controlled thermocyclers are used to process real time Taqman assays. Detection of amplification products uses fluorescent-labeled probes designed for a specific agent of interest. Dual light paths allow the simultaneous detection of two different fluorescent probes during the amplification process. The speed, small size, and low power of the thermocycler is what makes the Bio-Seeq unique in the field of portable DNA detection.

ANALYTICAL Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.901
Smiths Bio-Seeq	0.707
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Bio-Seeq ranked in the top third of all evaluated products for diagnostic laboratories and earned 85% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Smiths Bio-Seeq	0.772
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Bio-Seeq ranked in the middle third of all evaluated products for mobile laboratories and earned 78% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Smiths Bio-Seeq	0.688
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

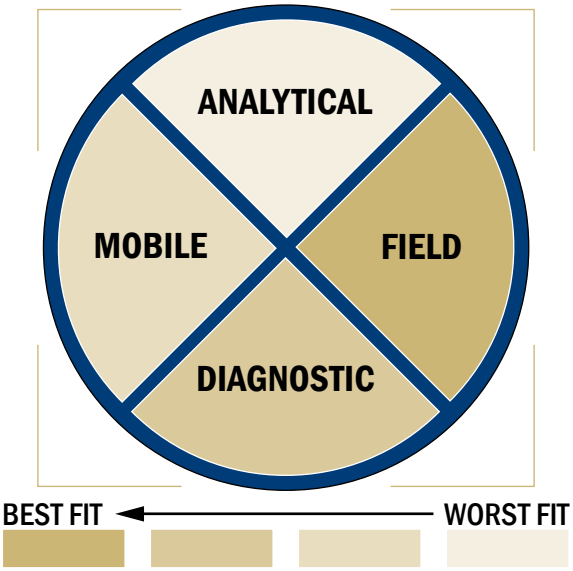
Bio-Seeq ranked in the top third of all evaluated products for field use and earned 85% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Smiths Bio-Seeq	0.804
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Smiths Detection
2202 Lakeside Blvd.
Edgewood, MD 21040
www.smithsdetection.com

Point of Contact:
Doug Green
(410) 510-9209
(410) 510-9496 fax
doug.green@smithsdetection.com

COST

- $30.00/sample
- Approximately $30,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection between 30 and 40 minutes
- 2 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted to a fully automated system with some effort

Training/Speed/Manpower:

- Very brief training
- Less than 5 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 2 components
- No cleaning required

Maintenance:

- 2 consumables or expendables needed
- Once a year service required
- Expected life is 5-10 years
- No daily quality assurance procedures required

Transportation:

- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life between 1 and 3 years

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- A single shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

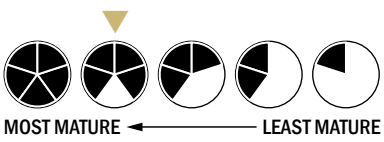
- Operated from 4 °C to 37 °C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- 100-1,000 CFU per ml

Maturity gauge:

- Is commercially available



Bio-Seeq II

by Smiths Detection

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Yersinia pestis, Orthopox virus *(Commercially available as a freeze-dried reagent)*; Ricin toxin *(Assay developed)*

DESCRIPTION:
The Bio-Seeq™ II is a new PCR thermocycler instrument from Smiths Detection. A number of key features differentiate it from other portable PCR instrumentation systems. The Bio-Seeq™ II uses Thermoelectric-Cooling for rapid and reliable thermocycling in high ambient temperatures and it contains four independent optical channels allowing four simultaneous measurements from a single sample. The sealed operation utilizing fiber optics allows full immersion for decontamination. The machine employs a 5.4" Windows CE LCD Touch screen and contains integral GPS to identify both where and when sample are taken. The Bio-Seeq™ II supports up to six thermocyclers in a reliable redundant configuration, can be operated while wearing PPE and is rechargeable during operation. All this is ruggedly packaged in an integral case. Assays currently available for the Bio-Seeq™ II are Anthrax pX01 and pX02, Tularemia, Plague, Orthopox and Training consumable. The Bio-seeq II is under development with a projected ready date of November 2007.

TECHNOLOGY:
The Bio-Seeq™ II is a robust field deployable PCR instrument designed to be used by field based personnel. The Bio-Seeq™ II uses both PCR and non-PCR based chemistries to detect a range of Biological Warfare Agents including bacterial and viral pathogens, as well as toxins on the same instrument. The Bio-Seeq™ II comprises six independent thermocycler modules each with four independent optical allowing up to four different tests of six separate samples. The novel chemistry used by the Bio-Seeq™ II improves the reliability of the detection assays. These combined features allow the field deployment of a rapid and reliable detection capability.

ANALYTICAL Laboratory Ranking

Bio-Seeq II ranked in the top third of all evaluated products for analytical laboratories and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Smiths Bio-Seeq II	0.694
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Bio-Seeq II ranked in the top third of all evaluated products for diagnostic laboratories and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Smiths Bio-Seeq II	0.733
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Bio-Seeq II ranked in the middle third of all evaluated products for mobile laboratories and earned 76% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Smiths Bio-Seeq II	0.675
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

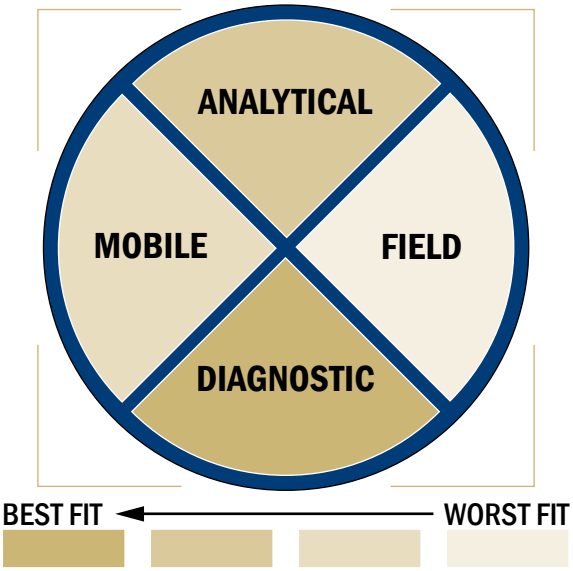
Bio-Seeq II ranked in the middle third of all evaluated products for field use and earned 72% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Smiths Bio-Seeq II	0.679
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Smiths Detection
2202 Lakeside Blvd.
Edgewood, MD 21040
www.smithsdetection.com

Point of Contact:
Doug Green
(410) 510-9209
(410) 510-9496 fax
doug.green@smithsdetection.com

COST

- $30.00/sample
- $33,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:

- System or device uses batteries or 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection between 40 and 50 minutes
- 2 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 1 component
- No cleaning required

Maintenance:

- Less than once a year service required
- Expected life is greater than 10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Reagent shelf life between 1 to 3 years

Ease of use/Utility:

- Cannot view results “in real time”
- No centrifugation steps
- There is a single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

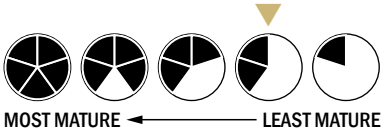
- Operated from 4 °C to 37 °C
- Components must be stored at room temperature
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 100-1,000 CFU per ml

Maturity gauge:

- Only one incomplete device or system exists (bread board)
- Is expected to be ready for commercialization within one calendar year
- Less than $1,000,000 required to advance the device or system to commercialization
- Has not been featured in any peer reviewed scientific publications or independent evaluations



Bio-Seeq Mail Sentry System

by Smiths Detection – Edgewood

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis *(Commercially available as a freeze-dried reagent);* Yersinia pestis *(Assay validated);* Smallpox virus *(Assay developed)*

DESCRIPTION:
The Bio-Seeq Mail Sentry is a Bio Detection system for screening mail and small parcels and is designed to provide reliable on-site mail screening capabilities. The Mail Sentry provides consistent performance and maximum reliability through it's automated, simple user-interface. All mail and parcels are processed through a sealed cabinet which minimizes exposure to the user and helps to contain the threat. Utilizing Polymerase Chain Reaction (PCR) technology, the same technology used in the U.S. Postal Service biological detection screening system, the Mail Sentry provides rapid, extremely accurate results.

TECHNOLOGY:
Utilizing Polymerase Chain Reaction (PCR) technology, the same technology used in the U.S. Postal Service biological detection screening system, the Mail Sentry provides rapid, extremely accurate results. The mail and packages are contained within a protective cabinet maintained under negative pressure designed to minimize agent exposure and prevent the spread of contamination. The exhaust is filtered through HEPA filters to capture aerosolized bio-agents, maximizing the safety of the mail handler operating environment.

ANALYTICAL Laboratory Ranking

Bio-Seeq Mail Sentry ranked in the middle third of all evaluated products for analytical laboratories and earned 70% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Mail Sentry	0.629
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Bio-Seeq Mail Sentry ranked in the middle third of all evaluated products for diagnostic laboratories and earned 66% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Mail Sentry	0.603
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Bio-Seeq Mail Sentry 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
Best Score	0.883
Mail Sentry	0.484
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

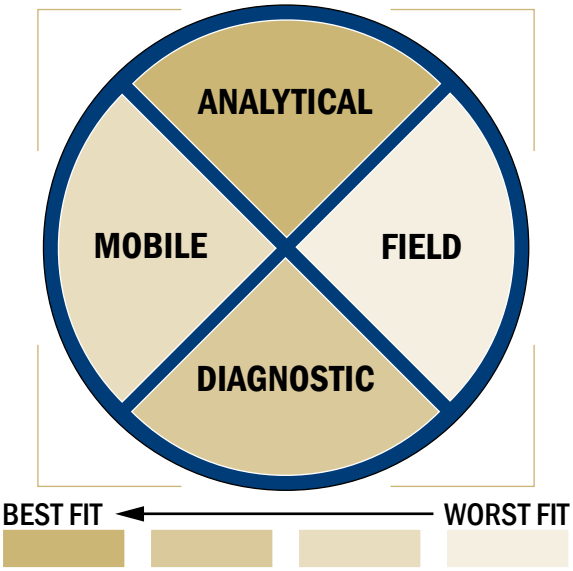
Bio-Seeq Mail Sentry ranked in the bottom third of all evaluated products for field use and earned 50% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Mail Sentry	0.467
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Smiths Detection – Edgewood
2202 Lakeside Blvd.
Edgewood, MD 21040
www.smithsdetection.com

Point of Contact:
David Karmel
(410) 510-9163
(410) 510-9497 fax
David.Karmel@smithsdetection.com

COST

- $35.00/sample
- $150,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection in greater than 60 min
- 2 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:

- An day of training
- Greater than 20 min required for set-up
- 6-8 manual steps required for detection

Re-use:

- Device or system is intended for multiple detections
- 0-1 solution or buffer used
- 2 components
- Cleaning involves periodic rinse cycles

Maintenance:

- 0-1 consumable or expendable needed
- Needs service every six months
- Expected life measure of 5-10 years
- Less than 5 minutes required for daily quality assurance procedures

Transportation:

- Larger than a home dishwasher
- More than 50 kg
- Shelf life between 1-3 years

Ease of use/Utility:

- Cannot view results “in real time”
- No centrifugation steps
- A single shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay available, and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:

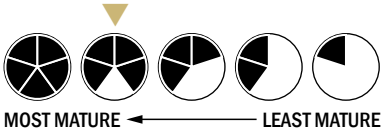
- Operated from 15 °C to 37 °C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- 100-1,000 CFU per ml

Maturity gauge:

- Is commercially available



Bio-Seeq Plus

by Smiths Detection

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Yersinia pestis, Orthopox virus *(Commercially available as a freeze-dried reagent)*; Ricin toxin *(Assay developed)*

DESCRIPTION:
The Bio-Seeq™ PLUS is an improved version of the original Bio-Seeq™ product from Smiths Detection. It is capable of detecting bacterial and viral pathogens using an improved 'Smiths Enhanced PCR' system. It is a battery-operated hand-held PCR detector, which addresses critical military and civilian requirements. A key feature of the Bio-Seeq™ PLUS is its ease of use by first responders at an incident. Operation of the unit is simple, even for an inexperienced operator wearing full IPE. The new restyled design also benefits from improved thermocycler and battery reliability, and improves the ease of use of the original product. The instrument is of robust, reliable construction.

The handheld is a fully field portable PCR identifier with results in less than 40 minutes. It supports up to six independent simultaneous assays with a wide range of BW threat assays available. Bio-seeq Plus can run up to 20 assays on a single charge and a novel Ricin assay can be run alongside other BW assays. Ergonomic design allows operation while wearing IPE. The handheld unit can be recharged while operating, has a low power indicator and is CE approved. The Bio-seeq PLUS will be available from April 2007.

TECHNOLOGY:
The Bio-Seeq PLUS is a robust handheld field deployable PCR instrument designed to be used by field based personnel. The Bio-Seeq PLUS uses both PCR and non-PCR based chemistries to detect a range of Biological Warfare Agents including bacterial and viral pathogens, as well as toxins on the same instrument. The Bio-Seeq PLUS comprises six independent thermocycler modules allowing six different identification runs to be carried out if necessary. The novel chemistry used by the Bio-Seeq PLUS improves the reliability of the detection assays. These combined features allow the field deployment of a rapid and reliable detection capability.

ANALYTICAL Laboratory Ranking

Bio-Seeq Plus ranked in the middle third of all evaluated products for analytical laboratories and earned 74% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Smiths Bio-Seeq Plus	0.668
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Bio-Seeq Plus ranked in the top third of all evaluated products for diagnostic laboratories and earned 81% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Smiths Bio-Seeq Plus	0.738
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Bio-Seeq Plus ranked in the middle third of all evaluated products for mobile laboratories and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Smiths Bio-Seeq Plus	0.707
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

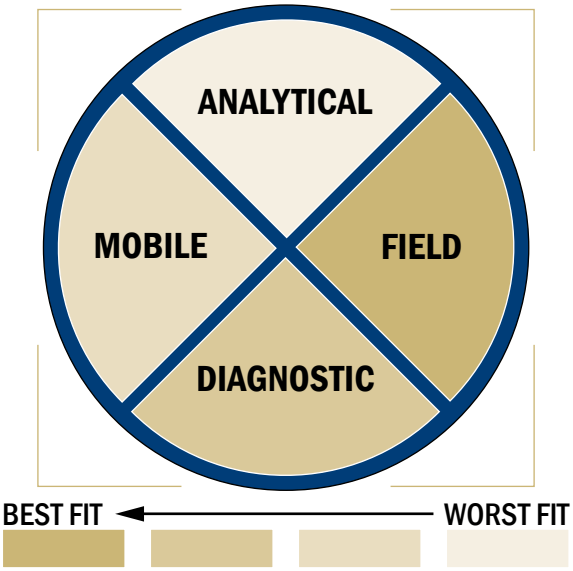
Bio-Seeq Plus ranked in the top third of all evaluated products for field use and earned 87% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Smiths Bio-Seeq Plus	0.823
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Smiths Detection
2202 Lakeside Blvd.
Edgewood, MD 21040
www.smithsdetection.com

Point of Contact:
Doug Green
(410) 510-9209
(410) 510-9496 fax
doug.green@smithsdetection.com

COST

- $30.00/sample
- $33,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection between 40-50 minutes
- 6 samples/batch
- Less than 50 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 1 component
- No cleaning required

Maintenance:

- Less than once a year service required
- Expected life is greater than 10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a toaster
- Between 1 and 5 kg
- Reagent shelf life is 1 to 3 years

Ease of use/Utility:

- Cannot view results “in real time”
- No centrifugation steps
- 1 shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

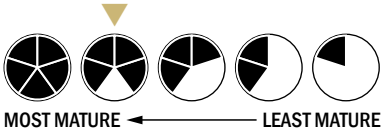
- Operated from 4 °C to 37 °C
- Components must be stored at room temperature
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 100-1,000 CFU per ml

Maturity gauge:

- Is commercially available
- Has not been featured in peer reviewed scientific publications or independent evaluations



BioThreat Alert Tests Strips & Optional Reader

by Tetracore Inc. and Alexeter Technologies

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Brucella species, Yersinia pestis, Orthopox virus, Botulinum toxin A, Botulinum toxin B, Staphylococcal toxin B, Ricin toxin, Abrin toxin *(Commercially available as a freeze-dried reagent)*

DESCRIPTION:
The BioThreat Alert Test Strip is an antibody-based assay intended for biological agent screening in environmental samples. It is designed for both field and laboratory use but is not intended for use on clinical samples. Although results can be read by eye, an optical reader is available for use with the strips to analyze, quantify, and record the result, but usage of this reader is optional.

TECHNOLOGY:
The BioThreat Alert Test Strip from Tetracore, Inc is a lateral flow immunochromatographic assay that uses two antibodies in combination to specifically detect a biological agent in solution. One of the specific antibodies is labeled with a colloidal gold derivative and when sufficient target material is present, the colloidal gold label provides a red line that is visualized after accumulating in the test sample region of the strip. When a sample is added to the BioThreat Alert Test Strip, the sample begins to mix with the colloidal gold-labeled antibody and simultaneously moves along the strip membrane by capillary action. If the target is present, the second specific antibody captures the colloidal gold-labeled antibody and bound target, forming a colored band in the sample or "S" window of the strip. As an internal control, a second band visualized in the control or "C" window of the strip is an indication that the test strip functioned properly. Two colored bands (in the "S" and "C" windows) are required to determine a positive result. (Also featured on page 122-123.)

ANALYTICAL Laboratory Ranking

Bio Threat Alert Tests Strips 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
Best Score	0.901
Tetracore Bio Threat Alert Test Strips	0.371
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Bio Threat Alert Tests Strips ranked in the middle third of all evaluated products for diagnostic laboratories and earned 64% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Tetracore Bio Threat Alert Test Strips	0.581
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Bio Threat Alert Tests Strips ranked in the top third of all evaluated products for mobile laboratories and earned 87% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Tetracore Bio Threat Alert Test Strips	0.768
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

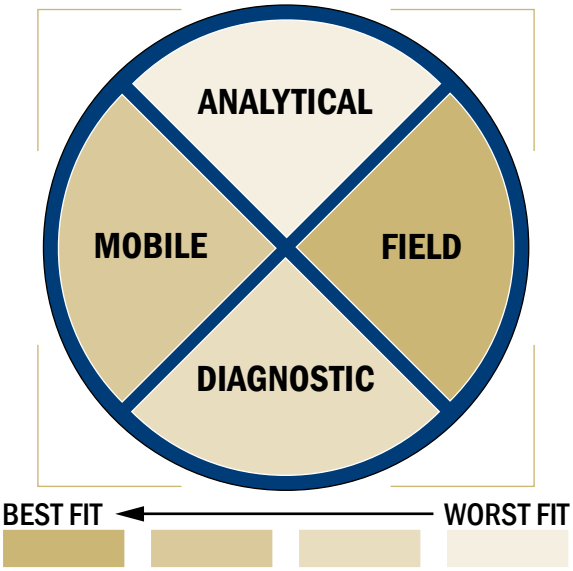
Bio Threat Alert Tests Strips ranked in the top third of all evaluated products for field use and earned 94% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Tetracore Bio Threat Alert Test Strips	0.882
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Tetracore, Inc.
11 Firstfield Road
Gaithersburg, MD
20878
www.tetracore.com

Point of Contact:
Tom O'Brien
(301) 258-7553
(301) 258-9740 fax
tobrien@tetracore.com

Alexeter Technologies
830 Seton Court,
Suite 6
Wheeling, IL 60090
www.alexeter.com

Jim Whelan
(847) 419-1507
(847) 419-1648 fax
jwhelan@alexeter.com

COST

- $24.20/test
- $5,500.00/reader

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has no electrical requirement; optional reader has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 minutes or less
- 1 sample/batch
- Less than 250 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief (minutes-hours) training and minimal technical skills
- No set-up required; optional reader requires 2 minutes set up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for single use; optional reader is designed for multiple use
- 0-1 solution or buffer used
- 2 components
- No cleaning required

Maintenance:
- No service required; optional reader needs once a year service
- Optional reader expected life is between 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a soda can; optional reader is the size of a toaster
- Less than 1 kg; optional reader is between 1 and 5 kg
- Reagent shelf life between 1 and 3 years

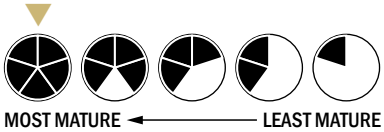
Ease of use/Utility:
- Can view results "in real time"
- No centrifugation steps
- There is a single shaking or vortexing step
- Optional reader is able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at room temperature
- The performance of the device or system is influenced by relative humidity

Sensitivity:
- 10,000- >100,000 CFU per ml

Maturity gauge:
- Is commercially available and meets military specifications
- Has been featured in peer reviewed scientific publications or independent evaluations



BioVeris (BV) Detection System

by BioVeris Corp.

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, SEB, E. coli 0157:H7, Botulinum toxins A, B, E *(Commercially available as wet/ frozen reagent)* Francisella tularensis, Yersinia pestis, Smallpox virus, Orthopox virus, Ricin *(Commercially available as a freeze-dried reagent)*

DESCRIPTION:

The BV Detection System is an automated analyzer designed for use with BV reagents. This system provides sample handling, detection based upon BioVeris (BV) Technology, electrochemiluminescence, and analysis in a 50 tube carousel-based format. This system is designed for the detection of multiple analytes, from small molecules, to proteins, to microorganisms, in a wide variety of matrices. The system processes a single sample in about one minute and an entire carousel in less than an hour. It can also run a partial or an entire carousel in a single or multi-test mode. The instrument automatically performs a system check to ensure proper system operation on start-up. The system allows for use of pre-set protocols or user determined protocols, and real-time updates of system output and data review.

TECHNOLOGY:

BV Technology uses a paramagnetic microparticle as the solid support for formation of a reaction. Multiple compounds can be labeled with BV-TAG, the product name for ruthenium (II) tris-bipyridine. Using a variety of linking chemistries, the ruthenium molecule can be directly bound to proteins, thiols, oligonucleotides, carbohydrates, and carboxyl groups using a simple labeling and purification procedure. For BV technology, ruthenium serves as the detector molecule for the system. At the core of the instrument system is a flow cell designed to measure the amount of ruthenium bound to the paramagnetic microparticles through a chemical reaction known as electrochemiluminescence. When the reaction mixture enters the flow cell, a magnet captures the microparticles on the surface of an electrode. Any components of the assay or sample that are not bound specifically to the microparticles through the assay component interactions continue past the electrode and exit the system as part of the waste stream. BV-TAG labeled species on the microparticles are detected by introducing tripropylamine (TPA) to the flow cell, applying an oxidizing potential at the electrode and measuring the integrated intensity of the emitted light. The flow cell is then washed with a cleaning solution and prepared for the next sample. For the electrochemiluminescent reaction, the system uses two bulk reagent solutions that enter the flow cell via bulk solution containers attached directly to the instrument system. The first bulk reagent, known as BV Assay Buffer contains TPA that is used in the electrochemiluminescent reaction process. The second bulk reagent is BV Cell Cleaner that is used by the system to remove the previous reaction from the flow cell in preparation for receipt of the next sample.

ANALYTICAL Laboratory Ranking

BV 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.

ALTERNATIVE	UTILITY
Best Score	0.901
BioVeris BV Detection System	0.718
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

BV Detection System ranked in the top third of all evaluated products for diagnostic laboratories and earned 91% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
BioVeris BV Detection System	0.828
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

BV Detection System ranked in the top third of all evaluated products for mobile laboratories and earned 88% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
BioVeris BV Detection System	0.775
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

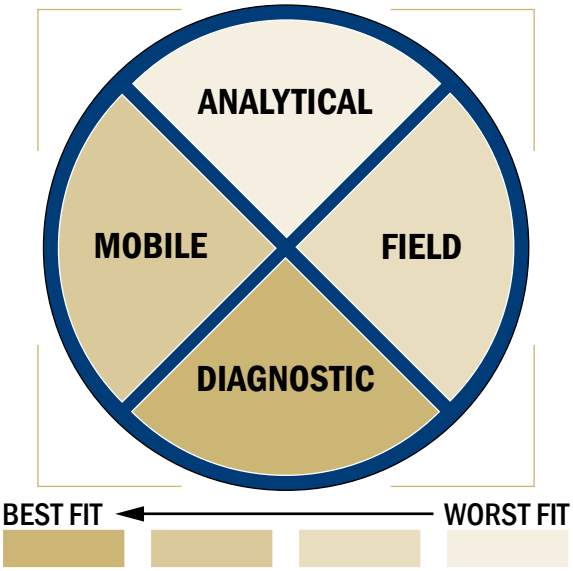
BV Detection System ranked in the top third of all evaluated products for field use and earned 83% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
BioVeris BV Detection System	0.778
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

BioVeris Corporation
16020 Industrial Drive
Gaithersburg, MD 20877
www.bioveris.com

Point of Contact:
Jill White
(301) 869-9800 x1054
(240) 632-2206 fax
jwhite@bioveris.com

COST

- $<10.00/sample
- $42,604.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 20 and 30 minutes
- 32 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- 10-20 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 3 solutions or buffers used
- 1 component
- A decontamination protocol is required for use one time per week

Maintenance:
- 0-1 consumable or expendable needed
- Once a year service required
- Expected life is 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 1 and 3 years

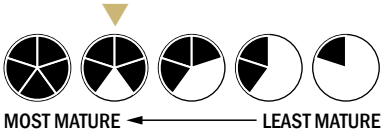
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1,000 CFU per ml

Maturity gauge:
- Is commercially available



CANARY BioAerosol Sensor

by MIT Lincoln Laboratory

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, E. coli O157: H7, Francisella tularensis, Vibrio cholera, Yersinia pestis, Brucella species, Smallpox virus, VEE virus, Dengue fever virus, Orthopox virus
(Assays developed)

DESCRIPTION:
CANARY is a cell-based biosensor technology that has demonstrated a unique combination of speed and sensitivity for pathogen identification in a wide range of sample types including bioaerosol samples, clinical samples, surface wipes, and food. CANARY tests are simple, use few consumables, and can be performed in small, lightweight equipment that is compatible with battery power for field use. CANARY tests can be as simple as adding a drop of cells to a sample (e.g., dry-impacted bioaerosol samples) and placing the mixture in a luminometer to detect antigen-specific light generation in less than one minute. For maximum sensitivity in complex liquid samples, brief spins are incorporated into a procedure that can provide identification in three minutes after sample collection.

TECHNOLOGY:
CANARY utilizes B cells that have been genetically engineered to produce aequorin, a calcium-sensitive bioluminescent protein originally found in the Aequorea victoria jellyfish. The sensor works as follows: (1) The B cells can be exposed to suspected bioagents or other pathogens from an air sample or other source. (2) The B cells produce antibodies specific for certain bioagents. If one of those agents is present in the sample, it will bind to the antibodies on the surface of the B cell. (3) Crosslinking of a B cell's antibodies by a bioagent triggers an intracellular enzymatic cascade that releases calcium inside the cell. (4) In the presence of calcium, the aequorin emits blue-green light at 469 nm within seconds of antigen-specific crosslinking. (5) Light from stimulated B cells can be detected using a photomultiplier tube or other photodetector. CANARY can currently identify 13 different bacterial and viral agents including Bacillus anthracis spores, Yersinia pestis, Francisella tularensis, and vaccinia, and development is underway to enable toxin identification.

ANALYTICAL Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.901
CANARY Bioaerosol Sensor	0.536
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

CANARY ranked in the middle third of all evaluated products for diagnostic laboratories and earned 64% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
CANARY Bioaerosol Sensor	0.579
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

CANARY 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
Best Score	0.883
CANARY Bioaerosol Sensor	0.553
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

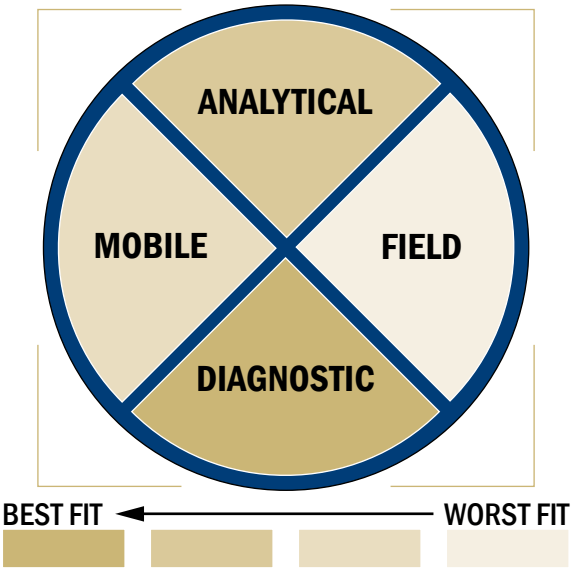
CANARY ranked in the bottom third of all evaluated products for field use and earned 48% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
CANARY Bioaerosol Sensor	0.456
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
MIT Lincoln Laboratory
244 Wood St.
Lexington, MA 02420

Point of Contact:
Mark A. Hollis
(781) 981-7840
(781) 981-3867 fax
hollis@ll.mit.edu

COST
- Approximately $0.50/sample
- >$100,000/device or system

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device requires no water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 min or less
- 2 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- More than a day of training
- 5-10 min required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 0-1 solution or buffer used
- 2 components
- No cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- Needs service more often than every 6 months
- Expected life measure of greater than 10 years
- 5-10 minutes required for daily quality assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- More than 50 kg
- Shelf life between 1-3 years

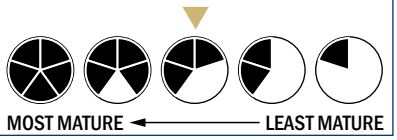
Ease of use/Utility:
- Can view results “in real time”
- A single centrifugation step
- No shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay available, and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- Sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:
- Operated from 4 °C to 37 °C
- Components can be stored at 4 °C to 37 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- CFU per ml is not applicable

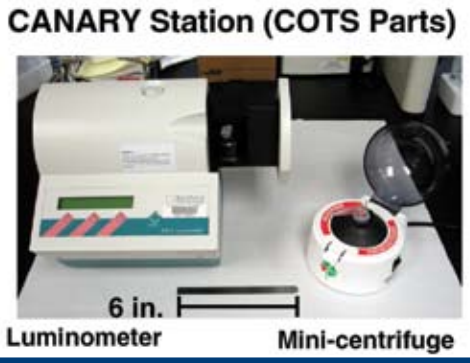
Maturity gauge:
- Expected to be ready for commercialization within three or more calendar year
- A few systems or devices exist (brass board)



CANARY Biosensor

by MIT Lincoln Laboratory

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, E. coli O157:H7, Francisella tularensis, Vibrio cholera, Yersinia pestis, Brucella species, Smallpox virus, VEE virus, Dengue fever virus, Orthopox virus *(Assays developed)*



DESCRIPTION:

CANARY is a cell-based biosensor technology that has demonstrated a unique combination of speed and sensitivity for pathogen identification in a wide range of sample types including bioaerosol samples, clinical samples, surface wipes, and food. CANARY tests are simple, use few consumables, and can be performed in small, lightweight equipment that is compatible with battery power for field use. CANARY tests can be as simple as adding a drop of cells to a sample (e.g., dry-impacted bioaerosol samples) and placing the mixture in a luminometer to detect antigen-specific light generation in less than a minute. For maximum sensitivity in complex liquid samples, brief spins are incorporated into a procedure that can provide identification in three minutes after the sample is collected.

TECHNOLOGY:

CANARY utilizes B cells that have been genetically engineered to produce aequorin, a calcium-sensitive bioluminescent protein originally found in the Aequorea victoria jellyfish. The sensor works as follows: (1) The B cells can be exposed to suspected bioagents or other pathogens from an air sample or other source. (2) The B cells produce antibodies specific for certain bioagents. If one of those agents is present in the sample, it will bind to the antibodies on the surface of the B cell. (3) Crosslinking of a B cell's antibodies by a bioagent triggers an intracellular enzymatic cascade that releases calcium inside the cell. (4) In the presence of calcium, the aequorin emits blue-green light at 469 nm within seconds of antigen-specific crosslinking. (5) Light from stimulated B cells can be detected using a photomultiplier tube or other photodetector. CANARY can currently identify 13 different bacterial and viral agents including Bacillus anthracis spores, Yersinia pestis, Francisella tularensis, and vaccinia, and development is underway to enable toxin identification.

ANALYTICAL Laboratory Ranking

CANARY Biosensor ranked in the top third of all evaluated products for analytical laboratories and earned 90% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
CANARY Biosensor	0.813
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

CANARY Biosensor ranked in the top third of all evaluated products for diagnostic laboratories and earned 89% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
CANARY Biosensor	0.810
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.883
CANARY Biosensor	0.724
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

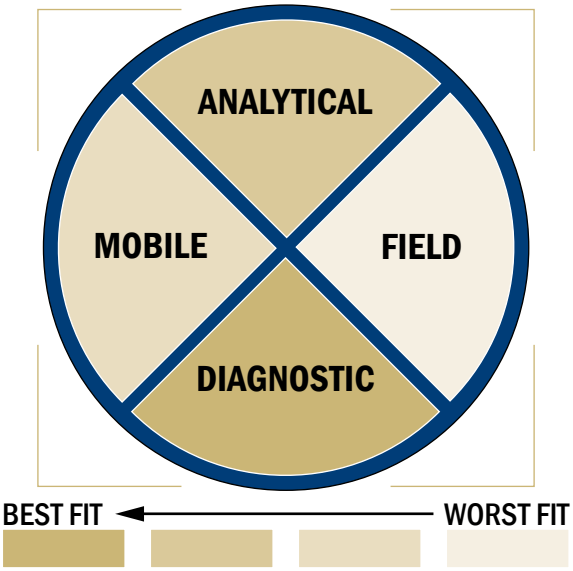
CANARY Biosensor ranked in the top third of all evaluated products for field use and earned 76% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
CANARY Biosensor	0.717
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
MIT Lincoln Laboratory
244 Wood St.
Lexington, MA 02420

Point of Contact:
Mark A. Hollis
(781) 981-7840
(781) 981-3867 fax
hollis@ll.mit.edu

COST
- Approximately $0.50/sample
- $6,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:
- System or device uses batteries
- The system or device requires no water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 min or less
- 2 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could be adapted to a fully automated system with some effort

Training/Speed/Manpower:
- A day of training required
- Less than 5 min required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 2 solutions or buffers used
- 4 components
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Never needs service
- Expected life measure of greater than 10 years
- 5-10 minutes required for daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage
- Between 1-5 kg
- Shelf life between 1-3 years

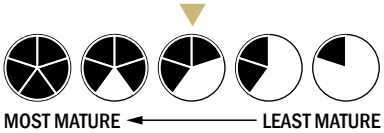
Ease of use/Utility:
- Can view results “in real time”
- Multiple centrifugation steps
- No shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay available, and capable of detecting four or more biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1,000 CFU per ml

Maturity gauge:
- Expected to be ready for commercialization within one calendar year
- A few systems or devices exist (brass board)



CFLAPS

by Dycor

CAPABLE OF DETECTING THE FOLLOWING:
None reported *(Generic detector)*

DESCRIPTION:
Our core technology, CFLAPS, is a biological detection system which functions on the principle that biological agents will fluoresce when subjected to certain wavelengths of ultraviolet laser light. Our detection system has at its core a Fluorescent Laser Aerodynamic Particle Sizer model 3317 (FLAPS3). Dycor's purpose-built XMX high-volume aerosol concentrator draws in large volumes of air, concentrates the constituent particles and passes them through the FLAPS to determine the size and concentration of biological agents which may be present. Samples can also be collected for identification of such agents in the laboratory or in the field. Dycor developed the highly accurate alarming algorithms for the system, a critical factor in minimizing false alarms and maintaining the highest standards of reliability and accuracy in detecting and tracking biological agents in the air. Through our extensive experience in the test and evaluation of a wide range of configurations and operational capability of biological detection equipment, we have also developed control software for biological systems, as well as systems architecture that allows for rapid integration of our detection capability with nuclear, radiological and chemical detection and identification capability as desired, and which supplies valid samples and collection data for biological identification systems. Combined with our CBNET biodetection alarm algorithm, control and analysis software, this fully integrated system is sold as the C-FLAPS Biological Detection System.

TECHNOLOGY:
The CFLAPS System provides three key real-time measurements of individual airborne particles in the concentrated airstream: the scattered-light intensity and the fluorescence emissions in two wavelength regions measured using two highly-sensitive photomultiplier tubes. These simultaneous single particle measurements provide a robust data set for the rapid detection of airborne biological threat agents under various background environments and when processed using appropriate alarm algorithm techniques, deliver exceptional agent discrimination and interference rejection response for biological threat detection applications. Fluorescence and scattered-light signals are excited using one reliable, stable, and commercially available laser diode.

ANALYTICAL Laboratory Ranking

CFLAPS ranked in the bottom third of all evaluated products for analytical laboratories and earned 42% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Dycor CFLAPS	0.384
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

CFLAPS 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
Best Score	0.909
Dycor CFLAPS	0.531
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

CFLAPS 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
Best Score	0.883
Dycor CFLAPS	0.559
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

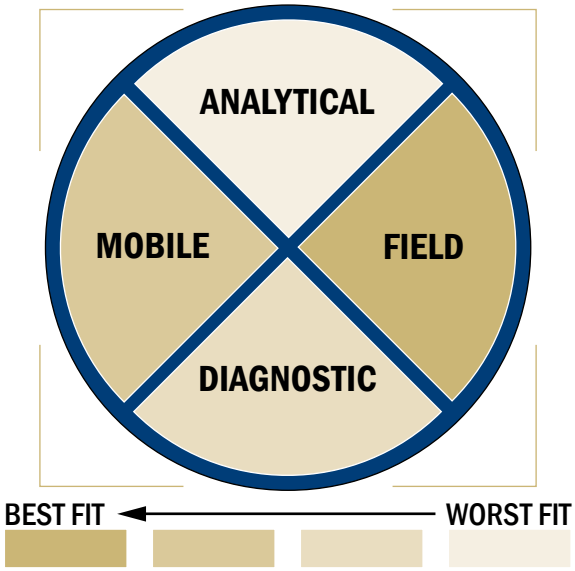
CFLAPS ranked in the top third of all evaluated products for field use and earned 87% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Dycor CFLAPS	0.822
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
Dycor Technologies Ltd.
1851 - 94 Street
Edmonton, Alberta
T6N 1E6, Canada
www.dycor.com

Point of Contact:
Antony Roth
(780) 486-0091 x2326
(780) 486-3535 fax
apr@dycor.com

COST
- Unreported cost per sample

Evaluation Criteria Provided by Vendor

System requirements:
- System or device uses batteries or has a 110V or 220V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 minutes or less
- 384 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- As little as an afternoon and as much as multiple days
- Less than 5 minutes set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- Infrequent cleaning required

Maintenance:
- More often than every 6 months service is required
- Expected life is greater than 10 years
- Less than 5 minutes daily quality assurance procedure

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 25 and 50 kg

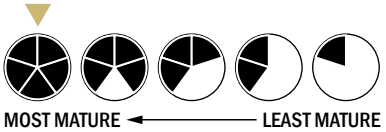
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200-500 BTUS generated

Operational conditions:
- Operated from 4 °C to 45 °C
- Components must be stored at 25 °C to 45 °C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 15 ACPLA (Agent Containing Particles per Liter of Air)

Maturity gauge:
- Is commercially available and meets military requirements
- Based on technology (FLAPS2) that has been featured in peer reviewed scientific publications or independent evaluations



ChemSensing Colorimetric Sensor

by ChemSensing, Inc.

CAPABLE OF DETECTING THE FOLLOWING:

Able to Detect any Organisms for Which Volatile Metabolites Are Known

DESCRIPTION:

ChemSensing, Inc. (CSI) possesses a unique chemical detection technology in which colorimetric changes in an array of dyes constitute a signal much like that generated by the mammalian olfaction system; each dye is a cross-responsive sensor. This technology uses a disposable two-dimensional array of chemoresponsive dyes as the primary sensor elements, making it particularly suitable for detecting many of the odiferous compounds produced by microbiological agents. Striking visual identification of a wide range of volatile organic compounds (VOCs), including carboxylic acids, alcohols, amines, ethers, thioethers, and thiols, are easily made at part per billion (ppb) levels (i.e., sensitivities comparable to or better than gas chromatographic flame ionization (GC-FID) or mass spectrometric (GC-MS) detection). Our strategy toward detection of biological agents involves recognition and differentiation based on the volatile metabolites generated by a microorganism. Each species of organism emits a distinct profile of enzymatic reaction products in the form of VOCs, e.g., amines, sulfides or fatty acids. Based on cross-responsive sensor elements, this array records the composite responses unique to each microorganism. We envision this technology as having applications for real-time, portable, easy-to-use, commercial sensors for detection of pathogens and hazardous substances having applications in medicine, biotechnology, food safety, environmental monitoring, in addition to detection of chemical and biological warfare agents.

TECHNOLOGY:

Metalloporphyrins are a natural choice for the detection of metal-ligating vapors because of their open coordination sites for axial ligation, their large spectral shifts upon ligand binding, and their intense coloration. CSI's technology takes advantage of the large color changes induced in metalloporphyrins upon ligand binding to create a simple colorimetric technique that minimizes the need for extensive signal transduction hardware. The large spectral changes (and readily observable color changes) that occur in solution during ligand binding to metalloporphyrins have been well documented. Furthermore, the periphery of the metalloporphyrin can be easily modified, thereby adjusting the accessibility of the metal ion to the ligand and inducing shape-selective ligation. Using metal centers that span a range of chemical hardness and ligand binding affinity and substituents that allow varying access to the metal, a wide range of volatile analytes are differentiable. Porphyrins also show significant solvochromic effects, so even weakly interacting vapors (e.g., arenes, halocarbons, or ketones) show distinguishable colorimetric effects. Estimates of our sensitivity based on initial experiments and the known growth rates for E. coli are ~50 cells/mL after one hour of growth and ~103 cell/mL for a 10 minute analysis time for a one mL culture volume with 0.25 mL headspace gas volume (based on demonstrated ChemSensing array limit of recognition for acetic acid (~50 ppb) and the production rate of acetic acid by E. coli in glucose rich liquid media (1.5 x 10-16 moles/bacteria/min at 37°C, pH 7, doubling time 55 min).

ANALYTICAL Laboratory Ranking

ChemSensing Colorimetric Sensor 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
Best Score	0.901
ChemSensing	0.567
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

ChemSensing Colorimetric Sensor ranked in the middle third of all evaluated products for diagnostic laboratories and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
ChemSensing	0.699
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.883
ChemSensing	0.513
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

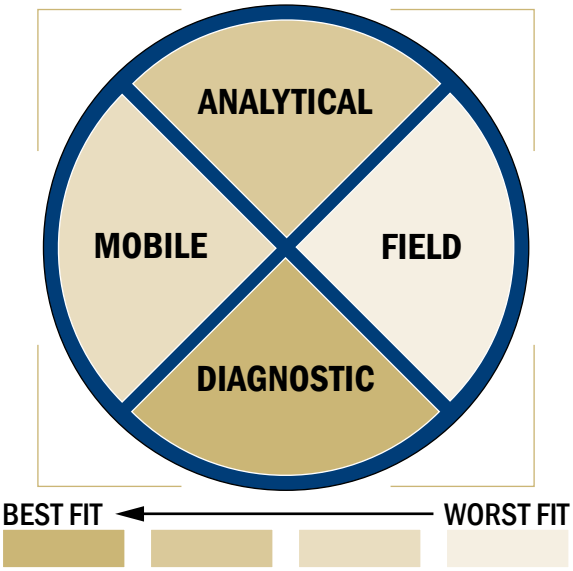
ChemSensing Colorimetric Sensor ranked in the middle third of all evaluated products for field use and earned 62% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
ChemSensing	0.582
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

ChemSensing, Inc.
60 Hazelwood Drive
Champaign, IL 61820
www.chemsensing.com

Point of Contact:
Joel Dryer
(847) 412-0010
(847) 412-0008 fax
joel@chemsensing.com

COST

- Approximately $0.25/sample
- $6,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:

- System or device uses batteries
- The system or device does not require water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection in less than 20 min
- 1 sample/batch
- Less than 50 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:

- Very brief training
- No set-up required
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple detections
- 0-1 solution or buffer used
- 1 component
- No cleaning required

Maintenance:

- 0-1 consumable or expendable needed
- Needs service less than once a year
- Expected life measure of 5-10 years
- No daily quality assurance procedures necessary

Transportation:

- Approximately the size of a toaster
- Between 1-5 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

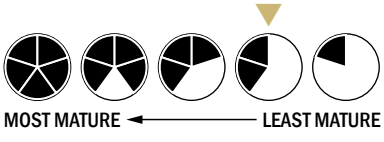
- Operated from 4 °C to 37 °C
- Components can be stored at 25 °C to 37 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- 100-1,000 CFU per ml

Maturity gauge:

- Expected to be ready for commercialization within two calendar years
- Only one incomplete device or system exist (bread board)



Chimera System

by Thermo Hybaid

CAPABLE OF DETECTING THE FOLLOWING:
Various biological agents

DESCRIPTION:
The Thermo Hybaid Chimera System is a dedicated real time PCR machine capable of performing fast and precise thermal cycling combined with sensitive and accurate fluorescent readings. This combination, along with intuitive software, enables quantitative PCR, end-point analysis and SNP scoring on the one instrument.

The unit is intended for use by both academic and industrial users for the low level detection of both DNA and RNA in real time and its subsequent quantitation.

TECHNOLOGY:
The Thermo Hybaid Chimera System uses a halogen lamp as excitation source and a PMT as the detection method. By using up to eight filters per reaction it is possible to have an excitation and emission range of 340 to 720nm. The Chimera uses a standard 96 well microplate format (with a gradient block for ease of optimization) and is totally robot-compatible due to the CD drawer mechanism employed. Detection of one copy up to 108 copies is possible with a read speed of under 10 sec. per filter set.

ANALYTICAL Laboratory Ranking

Chimera System 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
Best Score	0.901
Chimera System	0.688
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Chimera System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 74% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Chimera System	0.672
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Chimera System 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
Best Score	0.883
Chimera System	0.577
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

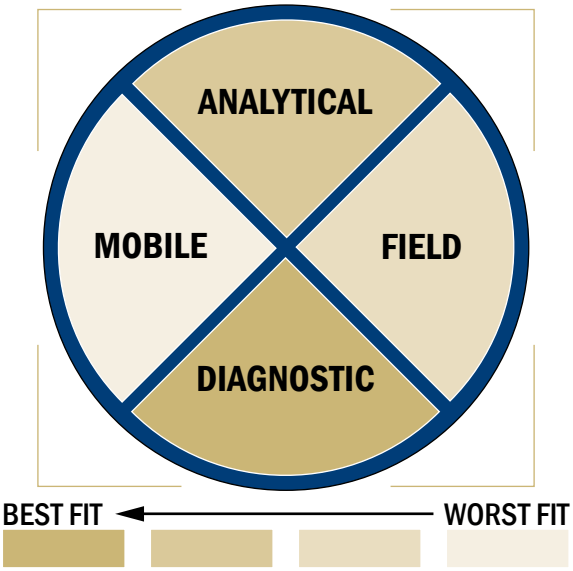
Chimera System ranked in the middle third of all evaluated products for field use and earned 68% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Chimera System	0.637
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
Action Court
2 Ashford Road
Ashford, Middlesex TW15 1XB, UK
www.thermo.com

Point of Contact:
Dr. Miles Schofield
+44 1784 425033
+44 1784 248085 fax
miles.schofield@thermo.com

COST
- Dependent on assay/sample
- Approx. $50,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 96 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 3 solutions or buffers used
- 2 components
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Less than once a year service required
- Expected life is 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 25 and 50 kg
- Shelf life between 1 and 3 year

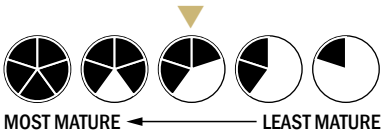
Ease of use/Utility:
- Can view results “in real time”
- Single centrifugation step
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 4 °C to 45 °C
- Components must be stored at room temperature
- Performance of the device or system is unknown at relative humidity

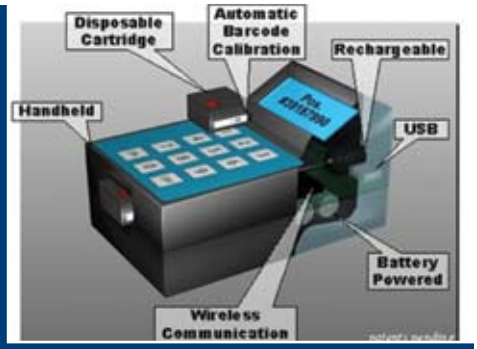
Sensitivity:
- 1-100 CFU per ml

Maturity gauge:
- A few devices or systems exist (brass board)



Clear Lake Medical Automated Disposable Assays

by Clear Lake Medical Foundation Inc.



CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Corynebacterium diphtheria, Burkholderia pseudomallei, Coxiella burnetti, Brucella species, E.coli O157:H7, Vibrio cholera, Burkholderia mallei, Yersinia pestis, Rickettsia prowazekii, Marburg virus, Smallpox virus, Influenza virus, Dengue fever virus, Orthopox virus, Rift valley fever virus, Venezuelan equine encephalitis virus, Yellow fever virus, Ebola virus, MS-2 bacteriophage, Botulinum toxin A, Botulinum toxin B, Saxitoxin, Conotoxin, Alfatoxin, Staphylococcal toxin B, Ricin toxin, Abrin toxin, T-2 mycotoxin *(Assay developed)*

DESCRIPTION:

The Clear Lake Medical Foundation Inc. is developing technologies for at home healthcare diagnosis and management. Those tests range from microscopic imaging for home testing, colorimetric based testing, immunochemical testing, to DNA/PCR testing. A generic processing and analysis platform has been built to accommodate a large panel of mixed mode tests. Testing is designed to be fully automated and disposable; without any skill or training requirements.

TECHNOLOGY:

The platform technology provides a disposable cartridge that supports the automation of DNA, PCR, ELISA, and similar tests. Processing is fully automated; including washing, mixing, thermal cycling, and analysis, and takes place within a disposable cartridge that also serves as one level of biocontainment. Up to a hundred different analyses can be grafted to one disposable cartridge. A handheld battery operated instrument is used for control, data acquisition, storage and communications. The patent pending technology is being developed for home care testing.

ANALYTICAL Laboratory Ranking

Clear Lake Medical Automated Disposable Assays 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
Best Score	0.901
Clear Lake Medical - Automated Disposable	0.400
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Clear Lake Medical Automated Disposable Assays 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
Best Score	0.909
Clear Lake Medical - Automated Disposable	0.531
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Clear Lake Medical Automated Disposable Assays 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
Best Score	0.883
Clear Lake Medical - Automated Disposable	0.617
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

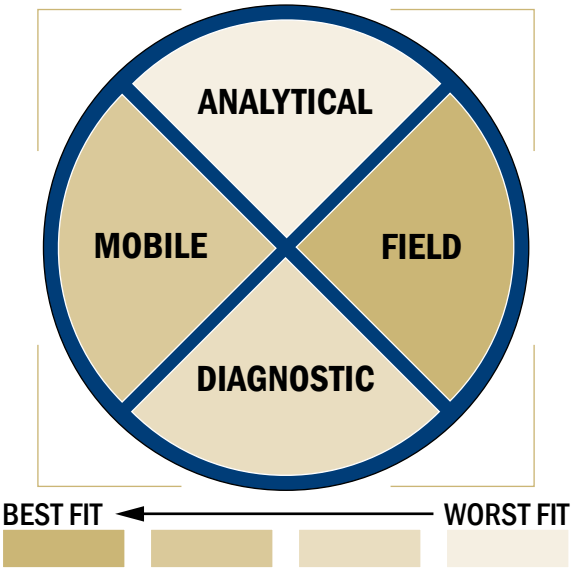
Clear Lake Medical Automated Disposable Assays ranked in the top third of all evaluated products for field use and earned 82% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Clear Lake Medical - Automated Disposable	0.773
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Clear Lake Medical Foundation Inc.
2437 Bay Area Blvd., MS448
Houston, TX 77058
www.clearlakemedicalfoundation.com

Point of Contact:
Glenn Spaulding
(281) 827-4707
(281) 488-1878 fax
gspaulding@clearlakemedicalfoundation.com

COST

- Unknown cost

Evaluation Criteria Provided by Vendor

System requirements:

- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection in 20 minutes or less
- 96 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for single use
- 1 component
- No cleaning required

Maintenance:

- Less than once a year service required
- Expected life is greater than 10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a soda can
- Less than 1k

Ease of use/Utility:

- Can view results “in real time”
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

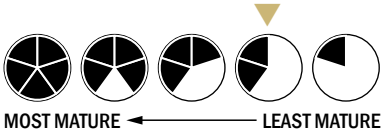
- Operated from 4 °C to 45 °C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- Unknown sensitivity

Maturity gauge:

- Only one incomplete device or system exists (bread board)
- Is expected to be ready for commercialization within one calendar year
- Less than $1,000,000 required to advance system or device to commercialization



Clear Lake Medical CD-M™

by Clear Lake Medical Foundation Inc.

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Corynebacterium diphtheria, Burkholderia pseudomallei, Coxiella burnetti, Brucella species, E.coli O157:H7, Vibrio cholera, Burkholderia mallei, Yersinia pestis, Rickettsia prowazekii, Marburg virus, Smallpox virus, Influenza virus, Dengue fever virus, Orthopox virus, Rift valley fever virus, Venezuelan equine encephalitis virus, Yellow fever virus, Ebola virus, MS-2 bacteriophage, Botulinum toxin A, Botulinum toxin B, Saxitoxin, Conotoxin, Alfatoxin, Staphylococcal toxin B, Ricin toxin, Abrin toxin, T-2 mycotoxin *(Assay developed)*

DESCRIPTION:
The Clear Lake Medical Foundation Inc. has developed a compact digital microscope for brightfield and fluorescent microscopy (CD-M™, patents pending). It is useful for microarray analysis such as gene arrays, protein arrays, tissue arrays, and comparative genomic hybridization arrays; and other areas of microscopy including blood, urine and other analyses for bacteria. The digital microscope if fully automated has supporting slide scanning and analysis as well as remote operation. A four-slide analysis system operates within the enclosure of a "Shuttle PC" – a personal computer (PC) that is approximately the size of a shoebox. All the capabilities of a standard PC are available. A smaller version digital brightfield and fluorescent microscope in development has a generic form factor and interface optimized to fit in the compact disk bay (CD bay) of a PC, supporting single slide analyses. Both units can operate as field units for various threat analyses and treatment.

TECHNOLOGY:
The compact digital microscope platform enables automated imaging of slide based assays for bacteria and viruses; and additionally supports rapid field assessment of body fluids such as blood, urine, saliva, sputum, and nasopharyngeal samples. Since slide scanning is automated, no operating skill is necessary; a point-and-click interface. Images can be evaluated by PC software or uplinked to a remote site for evaluation by medical personnel.

ANALYTICAL Laboratory Ranking

Clear Lake Medical CD-M 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
Best Score	0.901
Clear Lake Medical CD-M	0.418
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Clear Lake Medical CD-M 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
Best Score	0.909
Clear Lake Medical CD-M	0.543
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Clear Lake Medical CD-M 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
Best Score	0.883
Clear Lake Medical CD-M	0.587
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

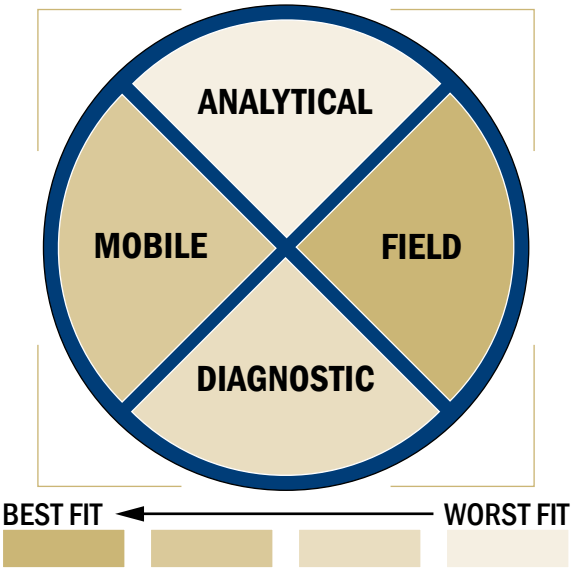
Clear Lake Medical CD-M ranked in the top third of all evaluated products for field use and earned 87% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Clear Lake Medical CD-M	0.824
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Clear Lake Medical Foundation Inc.
2437 Bay Area Blvd., MS448
Houston, TX 77058
www.clearlakemedicalfoundation.com

Point of Contact:
Glenn Spaulding
(281) 827-4707
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gspaulding@clearlakemedicalfoundation.com

COST

- Unknown cost/sample
- $3,000.00-10,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device uses batteries or has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection in 20 minutes or less
- 2 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes set-up required
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 2 components

Maintenance:

- Less than once a year service required
- Expected life is greater than 10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life measure not applicable

Ease of use/Utility:

- Can view results “in real time”
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

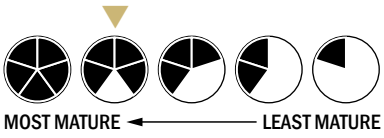
- Operated from 4 °C to 37 °C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- Unknown sensitivity

Maturity gauge:

- Is expected to be commercially available with one calendar year
- Less than $1,000,000 required to advance system or device to commercialization



Compact, Quantum Dots Based Biosensor

by The Aerospace Corporation

CAPABLE OF DETECTING THE FOLLOWING:

Able to detect any organisms for which an antibody based assay is available

DESCRIPTION:

The Aerospace Corporation has been carrying out work toward the development of a miniaturized, immunoassay-based, optical biosensor that has the ability to detect multiple pathogens and/or biological toxins on a single sensing element (e.g., optical fiber or waveguide). This biosensor is based upon the use of a new class of fluorescent labels for antibodies: semiconductor quantum dots. Fluorescent quantum dots are nanocrystals that can readily be tailored to emit different visible and infrared wavelengths of light. An undesirable feature of fluorescent dyes used in the conventional immunoassay sensors is that emission efficiencies of the dyes often degrade with time due to photo bleaching, which could cause the detection signal to drift with time and require frequent calibrations. Quantum dots, on the other hand, are much less sensitive to photobleaching and are thus ideal for field applications that require long-life and reliable service-free operation. Aerospace has demonstrated that, upon being properly bound to antibodies, the quantum dots can be used as optical taggant labels to "color code" different antibodies that are selective for a variety of pathogens and biological toxins. Despite their different color emissions, quantum dots can be all excited by the same UV wavelength. A single diode laser can thus be used to excite a mixture of optical labels producing emission from each quantum dot. The use of quantum dots as antibody taggants will thus allow the use of a very compact device to detect multiple pathogens and biological toxins. The use of quantum dots as optical labels for antibodies will also have applications in a variety of compact biosensors, including array-based immunoassay detectors. Such biosensors will be well-suited for use by the counterproliferation, force protection, and homeland defense communities for detecting the clandestine manufacture, battlefield, or terrorist use of biological weapons.

TECHNOLOGY:

In order for quantum dots to be successfully used for biosensor applications, they must first be chemically bound to antibodies in such a way that the quantum dots retain their fluorescence under biologically compatible conditions while the selectivities and affinities of antibodies to their antigens are not degraded. Aerospace has developed methods for synthesizing water-soluble ZnS-capped, CdSe quantum dots as well as methods to chemically bind these quantum dots directly to antibodies. This has enabled the production of a new class of fluorescent-tagged antibody molecules. Aerospace has carried out studies to characterize the antibody-quantum dot complexes spectroscopically, and also studied the stability of these complexes. Aerospace was the first group to report the covalent bonding of an antibody to a quantum dot surface as well as to demonstrate that the quantum dot-labeled antibodies retain specificity to their antigens. Aerospace has developed improved approaches for synthesizing quantum dots of varying sizes and with different emission wavelengths as well as has carried out studies to help understand and control the stability and quantum yield of the water-soluble quantum dots.

ANALYTICAL Laboratory Ranking

Compact, Quantum Dots Based Sensor ranked in the middle third of all evaluated products for analytical laboratories and earned 68% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Compact, Quantum Dots Biosens.	0.614
Lowest Score	0.217

Effectiveness, Biological Agents, Logistics, Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Compact, Quantum Dots Based Sensor ranked in the middle third of all evaluated products for diagnostic laboratories and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Compact, Quantum Dots Biosens.	0.704
Lowest Score	0.321

Effectiveness, Operations, Biological Agents, Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Compact, Quantum Dots Based Sensor ranked in the bottom third of all evaluated products for mobile laboratories and earned 60% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Compact, Quantum Dots Biosens.	0.528
Lowest Score	0.379

Logistics, Biological Agents, Effectiveness, Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

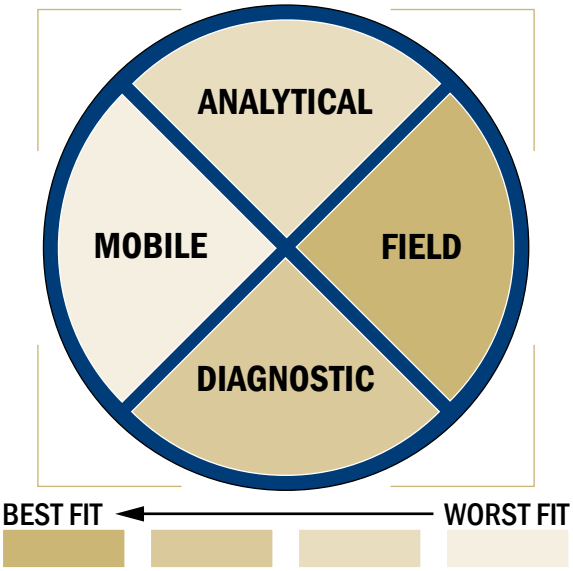
Compact, Quantum Dots Based Sensor ranked in the middle third of all evaluated products for field use and earned 71% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Compact, Quantum Dots Biosens.	0.670
Lowest Score	0.343

Logistics, Operations, Effectiveness, Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
The Aerospace Corporation
P.O. Box 92957
Los Angeles, CA 90009

Point of Contact:
Yat Chan
(310) 336-5073
(310) 336-6801 fax
yat.c.chan@aero.org

COST
- Unknown/sample
- Unknown price/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device uses batteries
- The system or device does require water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 30 and 40 minutes
- 384 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief training
- 5-10 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 3 components
- No cleaning required

Maintenance:
- 3 consumables or expendables needed
- Every 6 months service required
- Expected life is 3-5 years
- 5-10 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Less than 1 kg
- Shelf life between 1 and 3 years

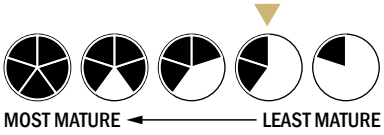
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

Maturity gauge:
- Only one incomplete device or system exist (bread board)



DNA Engine Thermal Cycler

by MJ Research, Inc.

CAPABLE OF DETECTING THE FOLLOWING:

E. coli 0157:H7 *(Assay developed);* Bacillus anthracis, Francisella tularensis, Yersinia pestis, Brucella species, Smallpox virus, Orthopox virus *(Commercially available as a freeze-dried reagent)*

DESCRIPTION:

With DNA assays that are either PCR-based, or sequence-based -- thermal cyclers are the primary instrument platform required. MJ Research offers a modular design of Peltier-effect thermal cyclers that have become the worldwide "industry standard" instrument since introduction of this third-generation technology in 1994. Today, there are three platforms: the one-block "DNA Engine"; the two-block "DNA Engine Dyad"; and the four-block "DNA Engine Tetrad II". Each of these can be fit with modular "Alpha Unit" interchangeable sample-block/heat-pump assemblies. Standard Alpha Units are available to fit 96x0.2ml tubes (or one 96-well plate); 2x48x0.2ml tubes; 60x0.5ml tubes; 2x30x0.5ml tubes, 384-well plate, 2x eight glass slides (15mmx30mm); or a flat surface for large microarrays or biochips. With the 96-well blocks, all instrument platforms are capable of "gradient" operation, where the block can incubate with a 1°-24°C thermal gradient across its surface, to assist in optimizing protocols. These instruments could readily serve as part of a larger system being designed for the detection/diagnosis/analysis of BW/BT pathogens, where end-product analysis was conducted through gel-electrophoresis or a plate reader or a fluorescence-detection thermal cycler (when using end-point analysis, as with melt curves, 3-4 blocks can "feed" a single fluorescence-detection unit). Within the past year, MJ Research has introduced two major new accessories. The first is the "MotoAlpha", which is a sophisticated motorized heated lid that allows reactions down to one microliter volumes in 96- or 384-well plates. The second is the "Chromo4" Alpha Unit, which is a unique four-color fluorescence-detection unit that allows real-time reactions on these platforms (or end-point analysis of plates through melt-curve analysis).

TECHNOLOGY:

The thermal cyclers are microprocessor-controlled precision incubators that operate using the Peltier Effect, which is a fundamental physical phenomenon that pumps heat electronically without any moving parts other than a fan to disperse excess heat. It also allows for a precision and speed of control unrivaled by any other technology with instrumentation working at the scale of laboratory devices. MJ Research was the first company to develop such instrumentation and introduce it commercially (although according to the inventor of PCR and Nobel-laurate, Kary Mullis, the very first "PCR machine" was a Peltier-effect instrument, custom-built circa 1984). MJ introduced its first commercial unit in 1988, and since that time, the technology has virtually supplanted the four other technologies of thermal control used in this molecular-biology application. The DNA Engine line was MJ's third generation of instrument offered. MJ builds its thermal cyclers starting with extremely pure bismuth & tellurium, from which semiconductor crystals are grown in furnaces using a proprietary process. These crystals are then sliced, diced, treated, QC'd and assembled into working "thermoelectric modules," which are then incorporated into increasingly larger assemblies that eventually compose the entire instrument. The result is the best performing, most reliable, and most precise thermoelectric technology in any thermal cycler currently offered. Among the many features the instrument incorporates includes, 1) modularity, where individual "Alpha Unit" sample-block/heat-pump assemblies can be swapped in seconds, 2) speed of ramping that is quite rapid, to allow shorter protocols, 3) precision of control that is NIST-traceable and highly reproducible well-to-well, run-to-run, and instrument-to-instrument, 4) robust and time-proven circuit designs and software, 5) a gradient-block function with the 96-well Alpha that allows a range of temperatures of 1°-24° across the block during any incubation with no loss of NIST-traceable accuracy, 6) a worldwide distribution (and repair) network, such that authorized distributors exist in over forty nations with familiarity with the instrument and an ability to service them, 7) competitive pricing and commercial availability.

ANALYTICAL Laboratory Ranking

DNA Engine Thermal Cycler ranked in the top third of all evaluated products for analytical laboratories and earned 87% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
DNA Engine Thermal Cycler	0.785
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

DNA Engine Thermal Cycler ranked in the middle third of all evaluated products for diagnostic laboratories and earned 78% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
DNA Engine Thermal Cycler	0.705
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

DNA Engine Thermal Cycler ranked in the middle third of all evaluated products for mobile laboratories and earned 78% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
DNA Engine Thermal Cycler	0.692
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

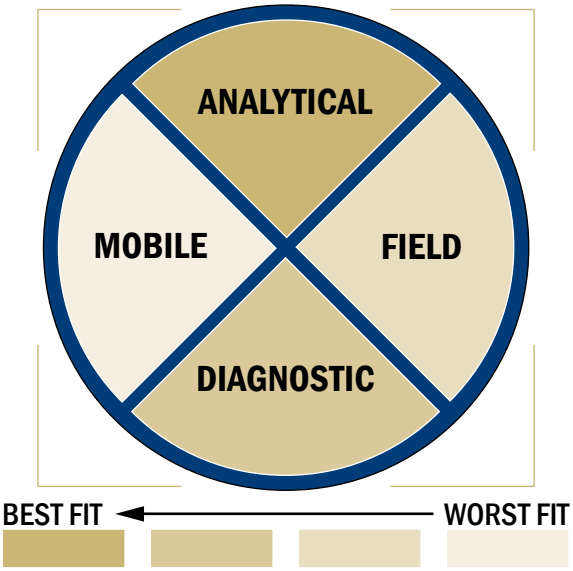
DNA Engine Thermal Cycler ranked in the middle third of all evaluated products for field use and earned 76% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
DNA Engine Thermal Cycler	0.713
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

MJ Research, Inc.
590 Lincoln Street
Waltham, MA 02451
www.mjr.com

Point of Contact:
John Hansen
(617) 972-8157 x8157
(617) 923-8080 fax
johnh@mjr.com

COST

- $0.50/sample plus cost of Taq enzyme
- A one-block DNA Engine costs about $7000.00, a two-block Dyad costs about $13,500.00, and a four-block Tetrad II costs about $24,000.00

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirements
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection greater than 60 minutes
- 384 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:

- An afternoon of training
- Less than 5 min required for set-up
- Manual steps required for detection NA

Re-use:

- Device or system is intended for multiple use
- Unknown solution or buffer used
- Unknown components
- No cleaning required

Maintenance:

- 5 or more consumables or expendables needed
- Needs service less than once a year
- Expected life is 5-10 years
- No daily assurance procedures needed

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Greater than 3 year shelf life

Ease of use/Utility:

- Cannot view results “in real time”
- Unknown centrifugation steps
- Unknown shaking or vortexing step
- System may be able to interpret raw data or call a positive through internal software in the future
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Unknown additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:

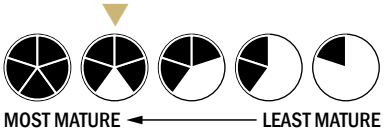
- Operated from 4 °C to 37 °C
- Unknown components storage
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- Is commercially available



dotLab

by Alexa Biosensors

CAPABLE OF DETECTING THE FOLLOWING:
None reported

DESCRIPTION:
The dotLab System is an automated bench-top instrument designed for sensitive detection of proteins, viruses, cells and DNA fragments. The technology behind the dot™ approach is user friendly: Highly selective receptor molecules (e.g. antibodies) specific to the target substance are deposited onto the dotLab Sensor in specific line patterns known to generate diffractive images. Upon binding of target molecules, illumination by a laser results in a readily detectable light diffraction image that is analyzed quantitatively by the optical reader. The small number of moving parts and the simplicity of the optical system ensure a high level of system reliability and precision. The commercially available dotLab system is designed to allow rapid assay development and validation in a laboratory environment. These assays can then be deployed on companion systems for point of care diagnostics under development that feature the same basic technology but offer reduced complexity and fixed assay menus in both a bench top and cartridge format. A wide range of affinity reagents are suitable for use in the disposable sensors including antibodies, peptides, aptamers, DNA and others. Combined with the range of assay formats possible, this provides a rapid and sensitive method for detection of biological species across wide concentration ranges. The optical design provides direct compatibility with most biological samples such as serum, plasma, urine, tissue lysates etc. with minimal sample preparation.

TECHNOLOGY:
The dotLab System brings together two mature, well-understood technologies: grating-based light diffraction and immobilized capture surfaces. This combination produces a sensitive and very simple technique for the detection of molecular binding events without the use of fluorescent labels. Protein-specific capture molecules are immobilized on the dotLab Sensor surface in distinct locations, or assay spots. The capture molecules within each spot are not randomly distributed, but are immobilized in a series of parallel lines that produces a specific diffraction pattern when illuminated with a laser. When a flowing stream of sample is introduced into the flow cell, target molecules bind to the assay spots, resulting in an increased diffraction signal. The dotLab System uses the intensity of the diffraction signal to generate real-time binding curves. The illumination and detection beams never pass through the sample, which makes the dotLab System ideal for the detection of proteins in complex biological samples such as serum, plasma, and crude cell lysates.

ANALYTICAL Laboratory Ranking

dotLAB Biosensor ranked in the middle third of all evaluated products for analytical laboratories and earned 72% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Alexa Biosensors dotLab	0.648
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.909
Alexa Biosensors dotLab	0.738
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

dotLAB Biosensor 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
Best Score	0.883
Alexa Biosensors dotLab	0.614
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

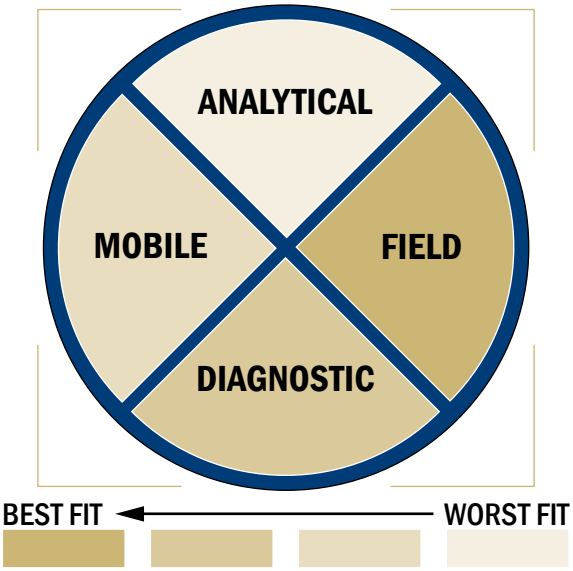
dotLAB Biosensor ranked in the top third of all evaluated products for field use and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Alexa Biosensors dotLab	0.796
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Axela Biosensors Inc.
480 University Avenue, Suite 910
Toronto, Ontario
M5G 1V2, Canada
www.axelabiosensors.com

Point of Contact:
Paul Smith, VP Sales & Business Development
(416) 260-9050 x2291
(416) 260-9255
dotlabinfo@axelabiosensors.com

COST

- $10.00-20.00/sample
- $59,300.00/system or device; Sensor kit $180.00/12 sensors

Evaluation Criteria Provided by Vendor

System requirements:

- System or device is 100-240 VAC self-regulating
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection between 20 and 30 minutes
- 32 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes set-up required
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for single use
- 0-1 solution or buffer used
- 3 components
- Optional cleaning with acid buffer and neutralizing buffer

Maintenance:

- Once a year service required
- Expected life is between 3-5 years
- Less than 5 minutes daily quality assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- More than 50 kg
- Reagent shelf life between 6 months and 1 year

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- There is one shaking or vortexing step
- System may be able to interpret raw data or call a positive through internal software in the future
- Capable of detecting multiple biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:

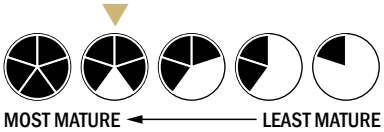
- Operated from 15°C to 30°C
- Components must be stored at 4°C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 100-1000 CFU per ml

Maturity gauge:

- Is commercially available
- Has been featured in a peer reviewed scientific publication or independent evaluation



DTX 800 Multimode Detector

by Beckman Coulter

CAPABLE OF DETECTING THE FOLLOWING:
None reported

DESCRIPTION:
The DTX 800 Multimode detector allows detection via fluorescence, luminescence and absorbance modes. It can operate as standalone instrument or can be integrated seamlessly with automated systems. The DTX 800 is ideal for a broad range of systems biology applications including drug discovery, genomics, proteomics and cell-based research. The DTX 800 unique optics design (patents pending) ensures precise performance and sensitivity across all detection modes. The DTX 800 features fluorescence intensity (top reading), absorbance (visible) and glow luminescence for 96- to 384-well plates. The DTX 800 intuitive software platform provides instrument control and easy protocol development.

TECHNOLOGY:
The DTX 800 Multimode Detector employs high powered LEDs as light sources. A single silicon photodiode and photon counting PMT are used for detection in the 340-650nm range. Filters are used to select specific wavelengths to measure.

ANALYTICAL Laboratory Ranking

DTX800 ranked in the bottom third of all evaluated products for analytical laboratories and earned 71% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
DTX 800 Multimode Detector	0.350
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

DTX800 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 81% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
DTX 800 Multimode Detector	0.478
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

DTX800 ranked in the bottom third of all evaluated products for mobile laboratories and earned 64% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
DTX 800 Multimode Detector	0.473
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

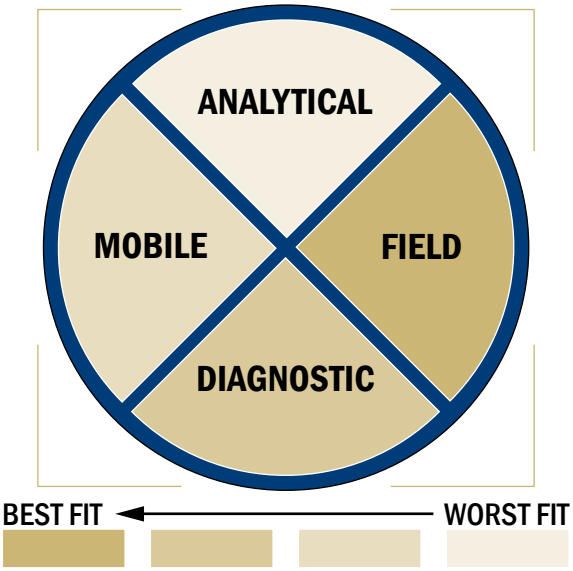
DTX800 ranked in the middle third of all evaluated products for field use and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
DTX 800 Multimode Detector	0.655
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
Beckman Coulter
4300 N. Harbor Blvd. Box 3100
Fullerton, CA 92834
www.beckmancoulter.com

Point of Contact:
Matt Maloney, Margaret Kelly
(317) 808-4217, (714) 773-8022
(714) 773-6690 fax
MJMaloney@beckman.com
mmkelly@beckman.com

COST
- Unknown/sample
- $11,000.00/device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 min or less
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 min required for set-up
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- Number of solutions or buffers used is assay dependent
- 1 component
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Needs service once a year
- Expected system or device life of 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life measure is not applicable

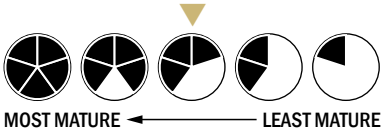
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System may be able to interpret raw data or call a positive through internal software in the future
- Assay not available, but capable of detecting 4 or more targets in a single well
- 2 additional pieces of equipment needed

Signature:
- No sounds are produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- Components storage conditions are not applicable
- Device or system has peak performance at normal relative humidity conditions only

Sensitivity:
- Unknown CFU per ml

Maturity gauge:
- Will be ready for commercialization within one calendar year
- A few devices or systems exist (brass board)



DTX 880 Multimode Detector

by Beckman Coulter

CAPABLE OF DETECTING THE FOLLOWING:
None reported

DESCRIPTION:
The DTX 880 Multimode detector allows detection via fluorescence, luminescence and absorbance modes. It can operate as standalone instrument or can be integrated seamlessly with automated systems. The DTX 880 is ideal for a broad range of systems biology applications including drug discovery, genomics, proteomics and cell-based research. The DTX 880 unique optics design (patents pending) ensures precise performance and sensitivity across all detection modes. The DTX 880 features fluorescence intensity (top and bottom reading), time-resolved fluorescence, fluorescence polarization, absorbance (UV and visible), glow luminescence and temperature control for 6- to 1536-well plates. The DTX 880 intuitive software platform provides instrument control and easy protocol development.

TECHNOLOGY:
The DTX 880 Multimode Detector employs high powered LEDs and a deuterium lamp for light sources. A single silicon photodiode and photon counting PMT are used for detection in the 230-750nm range. Filters are used to select specific wavelengths to measure.

ANALYTICAL Laboratory Ranking

DTX880 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
Best Score	0.901
DTX 880 Multimode Detector	0.350
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

DTX880 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
Best Score	0.909
DTX 880 Multimode Detector	0.478
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

DTX880 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
Best Score	0.883
DTX 880 Multimode Detector	0.473
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

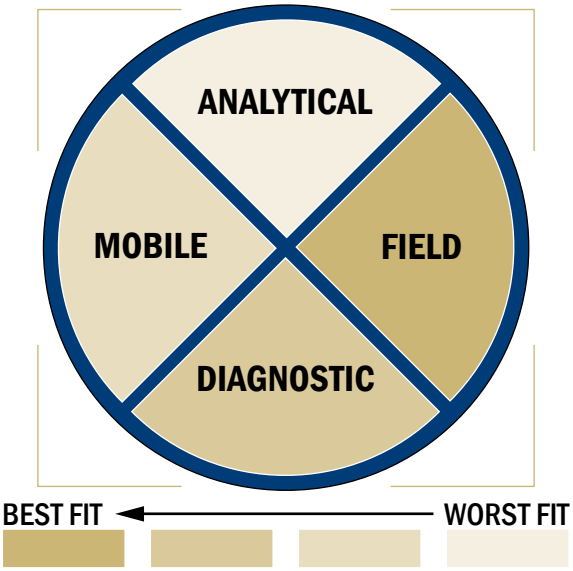
DTX880 ranked in the middle third of all evaluated products for field use and earned 69% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
DTX 880 Multimode Detector	0.655
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
Beckman Coulter
4300 N. Harbor Blvd. Box 3100
Fullerton, CA 92834
www.beckmancoulter.com

Point of Contact:
Matt Maloney, Margaret Kelly
(317) 808-4217, (714) 773-8022
(714) 773-6690 fax
MJMaloney@beckman.com
mmkelly@beckman.com

COST
- Unknown/sample
- $19,950.00/device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 min or less
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 min required for set-up
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- Number of solutions or buffers used is assay dependent
- 1 component
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Needs service once a year
- Expected system or device life of 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life measure is not applicable

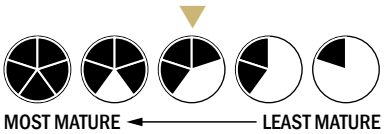
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System may be able to interpret raw data or call a positive through internal software in the future
- Assay not available, but capable of detecting 4 or more targets in a single well
- 2 additional pieces of equipment needed

Signature:
- No sounds are produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- Components storage conditions are not applicable
- Device or system has peak performance at normal relative humidity conditions only

Sensitivity:
- Unknown CFU per ml

Maturity gauge:
- Will be ready for commercialization within one calendar year
- A few devices or systems exist (brass board)



EAGLE

by ChemImage

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Burkholderia pseudomallei, Brucella species, E.coli O157:H7, Vibrio cholera, Burkholderia mallei, Yersinia pestis, Influenza virus, MS-2 bacteriophage, Botulinum toxin A, Staphylococcal toxin B, Ricin toxin *(Assay validated)*

DESCRIPTION:
The EAGLE transportable chemical/biological threat detection system can rapidly identify organic and inorganic industrial chemicals, reveal the presence of chemical or biological weapons of mass destruction, 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 biological threats. 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 top third of all evaluated products for analytical laboratories and earned 92% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
ChemImage EAGLE	0.827
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Eagle ranked in the top third of all evaluated products for diagnostic laboratories and earned 89% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
ChemImage EAGLE	0.806
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Eagle 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
Best Score	0.883
ChemImage EAGLE	0.637
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

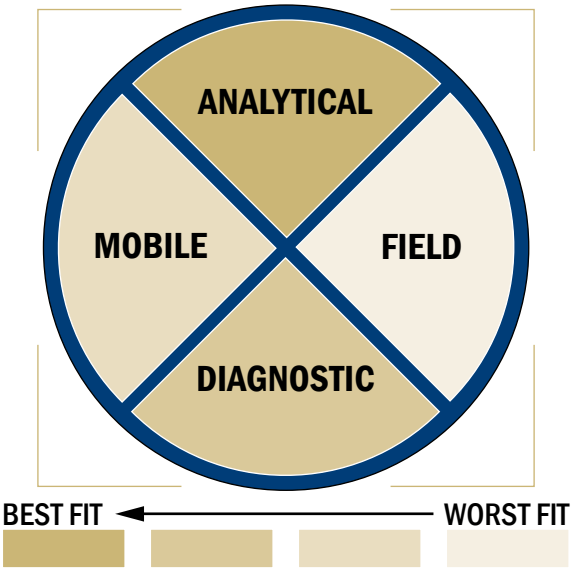
Eagle ranked in the bottom third of all evaluated products for field use and earned 54% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
ChemImage EAGLE	0.507
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
ChemImage
7301 Penn Ave
Pittsburgh, PA 15208
www.chemimage.com

Point of Contact:
Charles W. Gardner. PhD
(412) 241-7335 x212
(412) 241-7311
cgardner@chemimage.com

COST
- $0.54/sample
- $184,000.00/system or device

Evaluation Criteria Provided by Vendor

System Requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 minutes or less
- 1 sample/batch
- Less than 10 ul volume needed per test for detection
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:
- A day of training and technical skills are required
- 10-20 minutes set-up required
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 2 components
- Cleaning required with 5% bleach wipe

Maintenance:
- Every 6 month service required
- Expected life is greater than 10 years
- 10 to 20 minutes daily quality assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- More than 50 kg
- Reagent shelf life greater than 3 years

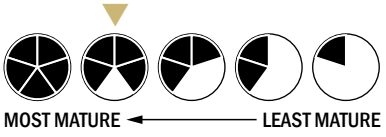
Ease of use/Utility:
- Can view results “in real time”
- There is a single centrifugation step
- There is a single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 25°C to 45°C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1000 CFU per ml

Maturity gauge:
- Is commercially available



E. coli 0157 Visual Immunoassay (VIA)

by TECRA International Pty Ltd

CAPABLE OF DETECTING THE FOLLOWING:
E. coli 0157:H7
(Commercially available as a freeze-dried reagent)

DESCRIPTION:
A rapid and specific screening test for detection of E. coli O157 (including E. coli 0157:H7 and other enterohaemorrhagic E. coli O157 strains) in food and environmental samples. After an overnight enrichment, results can be obtained within two hours.

The ELISA can be used manually and the results read by eye. However, it can also be semi-automated with the use of microtitre plate readers and washers or fully automated for large scale testing. The kit is available in a 96 and 48 well format.

TECHNOLOGY:
The TECRA E. coli O157 VIA is an Enzyme-linked Immunoassay (ELISA) performed in a sandwich configuration.

ANALYTICAL Laboratory Ranking

E.coli 0157 Visual Immunoassay 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
Best Score	0.901
TECRA E. coli 0157 VIA	0.722
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations
Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

E.coli 0157 Visual Immunoassay ranked in the middle third of all evaluated products for diagnostic laboratories and earned 70% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
TECRA E. coli 0157 VIA	0.640
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics
Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

E.coli 0157 Visual Immunoassay 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
Best Score	0.883
TECRA E. coli 0157 VIA	0.611
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations
Preference Set: *Mobile Laboratory*

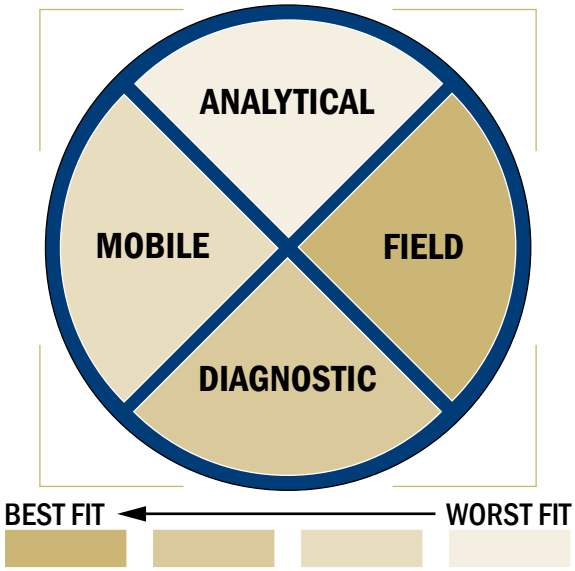
FIELD USE Ranking

E.coli 0157 Visual Immunoassay ranked in the middle third of all evaluated products for field use and earned 72% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
TECRA E. coli 0157 VIA	0.686
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents
Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
TECRA International Pty Ltd
13 Rodborough Rd.
Frenchs Forest, NSW 2086 Australia
www.tecra.net

Point of Contact:
Nick Vale
+61 2 8977011
+61 2 9453 3422 fax
nick.vale@tecra.net

COST
- $7.00/sample
- $306.00 for 48 wells, $557.00 for 96 wells/ system or device

Evaluation Criteria Provided by Vendor

System requirements:
- No electrical requirement
- The system or device does require water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 384 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 min required for set-up
- 9-12 manual steps required for detection

Re-use:
- Device or system is designed for single use
- More than 4 solutions or buffers used
- 5 or more components
- NA cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- No service required
- Expected life is not applicable
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Less than 1 kg
- Shelf life between 1-3 years

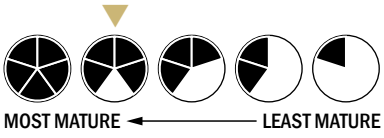
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System never able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- Two additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4 °C to 45 °C
- Components must be stored at 4 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

Maturity gauge:
- Is commercially available



ElectraSense™ Automated Microarray Hybridizer Reader

by CombiMatrix

CAPABLE OF DETECTING THE FOLLOWING:

Corynebacterium diphtheria, Burkholderia pseudomallei, Coxiella burnetti, Vibrio cholera, Burkholderia mallei, Rickettsia prowazekii, Ebola virus, Staphylococcal toxin B, Ricin toxin *(Assay developed);* Bacillus anthracis, Francisella tularensis, Brucella species, Yersinia pestis, Influenza virus, Venezuelan equine encephalitis virus *(Assay validated)*

DESCRIPTION:

The ElectraSense™ Automated Microarray Hybridizer Reader is a small instrument that greatly simplifies use of the CombiMatrix ElectraSense™ microarray for biothreat agent detection. Because this array uses electrochemical detection (ECD) to measure macromolecular interactions on each of >12,000 electrodes (spots), the instrument does not use complex optical components. Rather, it takes electrical measurements directly off each electrode on the array in less than a minute. Eliminating optics significantly reduces the size and complexity of the hybridizer reader and permits integrated automation through the use of an XY stage and a sampling robot to support liquid handling steps. The instrument occupies about one cubic foot and has space for expansion to include sample preparation, amplification, and other assay processes that are required to achieve the desired capability of detecting up to 50 different biothreats or pathogens. This instrument also includes options that allow the user to tailor how electrical measurements are made on the microarray along with reagent combinations that are required for new assays and methods of detection.

TECHNOLOGY:

The CombiMatrix ElectraSense™ microarray is a silicon chip with >12,000 individually addressable electrodes. Using proprietary electrochemistry, unique oligonucleotide probes can be synthesized at each electrode. Microarray synthesis is totally automated, takes about 24 hours, and is totally customizable. This gives the user an extremely versatile platform upon which to develop new microarray content and assays. While the array can be used with fluorescence detection, CombiMatrix has developed electrochemical detection (ECD) as an alternative with comparable sensitivity and performance to fluorescence. CombiMatrix has also developed methods for binding antibodies to specific electrodes on the microarray to support serological assays and has demonstrated the feasibility of creating other binding ligands that may be useful for biothreat agent detection. While still in development, serological assays performed array demonstrate comparable sensitivity to ELISA plate assays.

ANALYTICAL Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.901
CombiMatrix ElectraSense	0.733
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.909
CombiMatrix ElectraSense	0.769
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.883
CombiMatrix ElectraSense	0.717
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

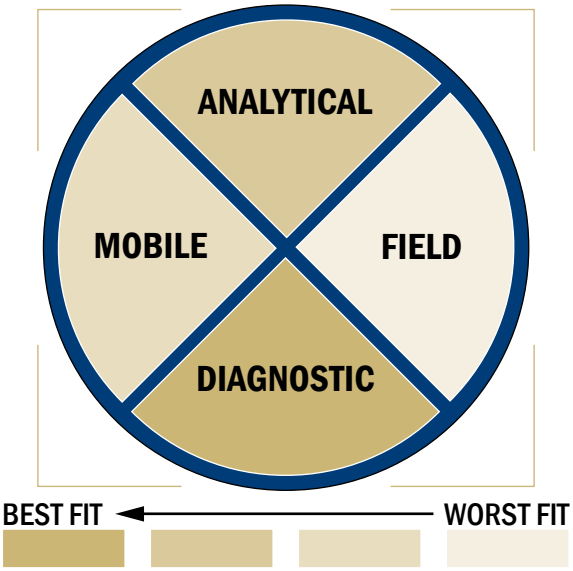
ElectraSense ranked in the middle third of all evaluated products for field use and earned 63% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
CombiMatrix ElectraSense	0.594
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

CombiMatrix Corporation
6500 Harbour Heights Pkwy., Suite #303
Mukilteo, WA 98275
http://www.combimatrix.com/aboutus_contact.htm

Point of Contact:
(425) 493-2000
(425) 493-2010 fax
sales@combimatrix.com

COST

- $150.00-450.00/sample
- $50,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection between 50 and 60 minutes
- 384 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:

- An afternoon of training and some technical skills required
- Less than 5 minutes set-up required
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 4 solutions or buffers used
- 2 components
- Cleaning required

Maintenance:

- Expected life is between 3-5 years
- Quality assurance procedures have not been developed

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Reagent shelf life between 6 months to 1 year

Ease of use/Utility:

- Cannot view results “in real time”
- No centrifugation steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

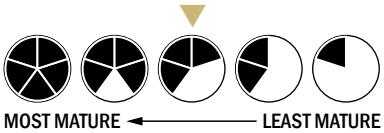
- Operated from 4 °C to 37 °C
- Components must be stored at 4 °C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 100-1000 CFU per ml

Maturity gauge:

- A few devices or systems exist (brass board)
- Is expected to be ready for commercialization within one calendar year
- Less than $1,000,000 is required to advance the device or system to commercialization
- Has been featured in peer reviewed scientific publications or independent evaluations



Enhanced Plasmon Bio-Detector (EPBD)

by Smiths Detection

CAPABLE OF DETECTING THE FOLLOWING:
Francisella tularensis, Coxiella burnetti, Brucella species, Yersinia pestis, MS-2 bacteriophage, Staphylococcal toxin B, Ricin toxin *(Assay developed)*

DESCRIPTION:
The EPBD instrument is designed as a fully automated instrument to perform identification of biological agents using continuous flow-through sample analysis. All classes of biological agents can be simultaneously identified with the sensor chips having multiplex capability, currently up to six agents can be simultaneously monitored with a planned increase in capacity to greater than twenty agents. The EPBD instrument is a continuous monitoring device and, due to its rapid time to result, is intended as an early warning of bio-agent release. The instrument is designed to receive sample directly from a sample collection system (SCS) that captures airborne samples into an aqueous buffer. The sample capture is a continuous process and the EPBD continuously draws this sample buffer across the sensor chip. The instrument is intended for installation within vehicles, for facilities protection or within an enclosure, e.g., for perimeter protection. The instrument will require the SCS to capture sample material for the EPBD to monitor. If required, an associated forensic sampling system for retaining sample in the event of a threat release can be incorporated.

TECHNOLOGY:
The EPBD is a single instrument that uses two detection technologies, one based on Surface Plasmon Resonance for proteins/toxins and small biological particles (e.g., viruses), and the second based on light scattering for all other biological particles (e.g., larger viruses and bacteria/spores). In both detector units an immunoassay method utilizes direct binding of the particles from environmental capture samples. For both detectors a range of antibodies are coated at known positions thus allowing multiple threat agents to be simultaneously monitored. The instrument is currently in development.

ANALYTICAL Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.901
Smiths EPBD	0.528
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.909
Smiths EPBD	0.667
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

EPBD 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
Best Score	0.883
Smiths EPBD	0.622
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

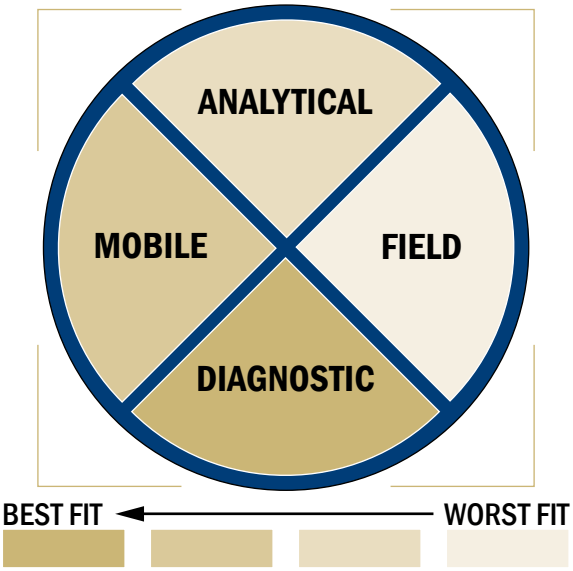
EPBD ranked in the bottom third of all evaluated products for field use and earned 54% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Smiths EPBD	0.511
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Smiths Detection
549 Park Avenue
Bushey, Hertfordshire WD23 2BW
England
www.SmithsDetection.com

Point of Contact:
Paul Pashby
+44 (0) 1923 658213
+44 (0) 1923 236407
Paul.Pashby@SmithsDetection.com

COST

- $75.00/sample
- $80,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V or 220V electrical requirement
- The system or device has an installed solution tank (filled weekly) or requires a water source
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 minutes or less
- 20 simultaneous threats monitored for with continuous monitoring
- Greater than 250 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- Very brief (minutes-hours) or an afternoon of training with varying degrees of technical skills required
- Greater than 20 minutes set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 2 components
- No cleaning required

Maintenance:
- Once a year service required
- Expected life is greater than 10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 25 and 50 kg
- Reagents shelf life between 1 to 3 years

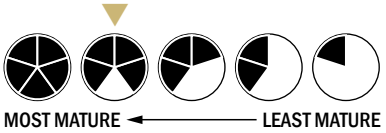
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- Components must be stored at 4 °C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 10,000-100,000 CFU per ml

Maturity gauge:
- A few devices or systems exist (brass board)
- Is expected to be ready for commercialization within two calendar years
- $1,000,000-$2,000,000 requires for device or system to advance to commercialization
- Has been featured in peer reviewed scientific publications or independent evaluations



ENIGMA-FL

by Enigma Diagnostics

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Corynebacterium diphtheria, Burkholderia pseudomallei, Coxiella burnetti, Brucella species, E.coli O157:H7, Vibrio cholera, Burkholderia mallei, Yersinia pestis, Rickettsia prowazekii, Marburg virus, Smallpox virus, Influenza virus, Dengue fever virus, Orthopox virus, Rift valley fever virus, Venezuelan equine encephalitis virus, Yellow fever virus, Ebola virus, MS-2 bacteriophage *(Assay developed)*

DESCRIPTION:

The Enigma-FL rapid biological agent detection system combines the speed and sensitivity of PCR with the simplicity and ruggedness needed for field-based operation. 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 the end result can take less than 40 minutes. Field hardened and rapidly deployable, it operates with ambient stored reagents in a single disposable cartridge. This eliminates the logistics and training burden associated with traditional PCR instruments that require refrigerated reagents and manual sample processing. Enigma's products are specifically designed to deliver on-site results to first responders, security personnel and veterinary professionals after minimal training. The instrument can process a range of sample types including environmental samples, cyclone aerosol collection fluid, blood and swabs. Analyzing the sample is a simple 40 minute, three-step process that minimizes hands-on time: dispense sample into a single-use cartridge; load cartridge, select test and walk away; and the result is conveyed via a simple traffic light system.

TECHNOLOGY:

The Enigma-FL automates all steps in the PCR process from sample processing to results calling. Automated sample processing is based on robust magnetic bead DNA & RNA purification technology which includes chemical extraction and sonication. Sample processing is fully integrated with real-time PCR analysis using multiplexed fluorescent detection technologies such as Taqman & LUX. Rapid thermal cycling is achieved using unique Electrically Conducting Polymer (ECP) technology which directly heats the reaction mix. This significantly benefits thermal transfer rates and produces ultra-rapid thermal equilibration. Reagent stabilization (lyophilisation) delivers ambient storage of the test consumable. The test result is automatically determined using a proprietary numerical fit for specific and control target amplification combined with simple logic and displayed by a traffic light system.

ANALYTICAL Laboratory Ranking

ENIGMA-FL ranked in the top third of all evaluated products for analytical laboratories and earned 96% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Enigma Diagnostics ENIGMA-FL	0.863
Lowest Score	0.217

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

DIAGNOSTIC Laboratory Ranking

ENIGMA-FL ranked in the top third of all evaluated products for diagnostic laboratories and earned 96% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Enigma Diagnostics ENIGMA-F	0.876
Lowest Score	0.321

Effectiveness Biological Agents Logistics Operations

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

ENIGMA-FL ranked in the top third of all evaluated products for mobile laboratories and earned 95% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Enigma Diagnostics ENIGMA-FL	0.835
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

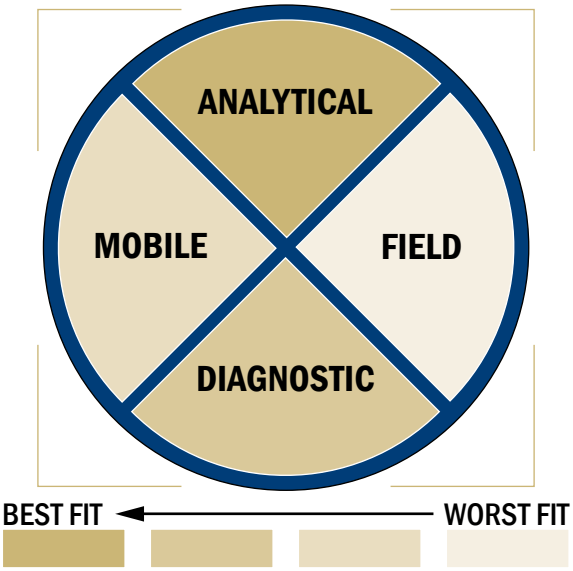
ENIGMA-FL ranked in the top third of all evaluated products for field use and earned 89% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Enigma Diagnostics ENIGMA-FL	0.843
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Enigma Diagnostics Ltd
Building 224, Tetricus Science Park,
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Salisbury, Wiltshire SP4 0JQ
United Kingdom
www.enigmadiagnostics.com

Point of Contact:
Dr. Ian George
+44 1980 590 131
+44 1980 590 132
ian.george@enigmadiagnostics.com

COST

- $30.00/sample
- $70,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device uses batteries or has 220V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection between 30 and 40 minutes
- 1 sample/batch
- Greater than 250 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 3 solutions or buffers used
- 1 component
- Internal UV light decontaminates, further cleaning with alcohol, hypochlotite and DNAse solutions if required.

Maintenance:

- Once a year service required
- Expected life is between 5-10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Reagent shelf life between 6 months and 1 year

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- There are sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

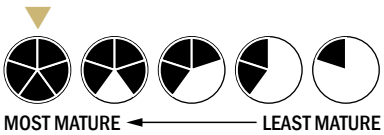
- Operated from 4 °C to 45 °C
- Components must be stored at room temperature
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 10-1000 CFU per ml

Maturity gauge:

- Is commercially available and meets military specifications
- Has been featured in peer reviewed scientific publications or independent evaluations



Eppendorf Mastercycler

by Eppendorf

CAPABLE OF DETECTING THE FOLLOWING:
Able to detect any organisms/ toxins for which assays can be developed

DESCRIPTION:
The Eppendorf Mastercycler gradient thermal cycler is a relatively small-sized instrument designed to quickly multiply DNA and RNA by rapidly heating and cooling samples. Samples should be placed in tubes or PCR plates along with a Mastermix and run on the instrument for 30 to 40 cycles.

TECHNOLOGY:
The Eppendorf Mastercycler gradient thermal cycler uses Peltier heating and cooling technology. The instrument is designed to perform temperature and time holding combinations from 4 degrees Celsius to 99 degrees Celsius and from one second to 99 hours 99 minutes and 99 seconds. The instrument is also equipped with Triple Circuit Technology (TCT) which allows for an almost linear 1 to 20 degree Celsius gradient function. This function can be used to minimize assay optimization. Mastercyclers come equipped with a removable Personal Card on which the user can store up to 10 protocols. It is relatively small and lightweight and does not take up much bench space.

ANALYTICAL Laboratory Ranking

Eppendorf Mastercycler 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
Best Score	0.901
Eppendorf Mastercycler	0.315
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Eppendorf Mastercycler 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
Best Score	0.909
Eppendorf Mastercycler	0.408
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Eppendorf Mastercycler 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
Best Score	0.883
Eppendorf Mastercycler	0.493
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

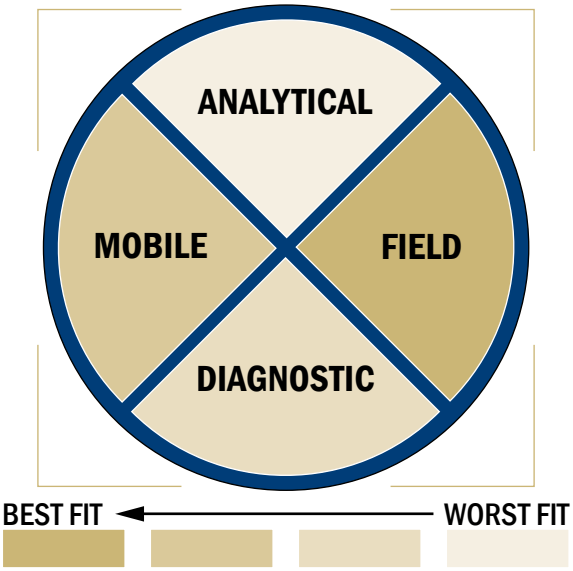
Eppendorf Mastercycler ranked in the middle third of all evaluated products for field use and earned 71% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Eppendorf Mastercycler	0.669
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Brinkmann
One Cantiague Rd.
Westbury, NY 11590
www.brinkmann.com

Point of Contact:
Stefanie Ellis
(516) 515-2337
(516) 334-7521 fax
sellis@brinkmann.com

COST

- $0.50 plus cost of Taq enzyme
- $7,885.00 GSA price/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection greater than 60 minutes
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a semi-automated system with some effort

Training/Speed/Manpower:

- Very brief training
- Less than 5 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 3 components
- No cleaning required

Maintenance:

- 3 consumables or expendables needed
- Once a year service required
- Expected life is 3-5 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 1 and 3 years

Ease of use/Utility:

- Cannot view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System never able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:

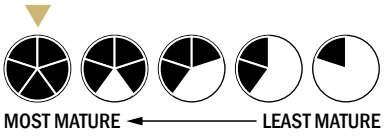
- Operated from 15 °C to 37 °C
- Components must be frozen
- Performance of the device or system is unknown in humidity

Sensitivity:

- Unknown CFU per ml

Maturity gauge:

- Is commercially available and meets military specifications



FALCON II

by ChemImage

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Burkholderia pseudomallei, Brucella species, E.coli O157:H7, Vibrio cholera, Burkholderia mallei, Yersinia pestis, Influenza virus, MS-2 bacteriophage, Botulinum toxin A, Staphylococcal toxin B, Ricin toxin *(Assay validated)*

DESCRIPTION:

The FALCON II Wide-field Raman imaging system combines the 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 the 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. The FALCON II produces two-dimensional and three-dimensional 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. The ChemImage proprietary use of a liquid crystal imaging spectrometer provides unparalleled image fidelity, spatial and spectral resolution for high throughput hyperspectral screening of materials. The FALCON II also performs dispersive Raman spectroscopy at high spectral resolution for microscopy applications. Limited or no sample preparation is 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 or 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. The Falcon II system can be configured to operate in visible as well as Raman with optional fluorescence or Near Infrared (NIR) absorbance/reflectance capabilities. The Falcon II system consists of three major subsystems all packaged in one convenient unit. The subsystems are an excitement source to provoke material response, imaging optics to acquire sample response information and an optical detection system with optical filters and cameras 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 86% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
ChemImage FALCON II	0.774
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

FALCON II ranked in the top third of all evaluated products for diagnostic laboratories and earned 90% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
ChemImage FALCON II	0.816
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

FALCON II 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
Best Score	0.883
ChemImage FALCON II	0.648
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

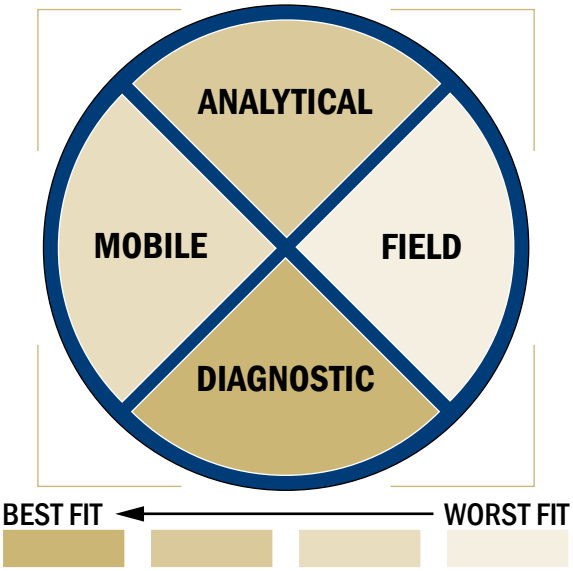
FALCON II ranked in the middle third of all evaluated products for field use and earned 66% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
ChemImage FALCON II	0.625
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

ChemImage
7301 Penn Ave
Pittsburgh, PA 15208
www.chemimage.com

Point of Contact:
Matthew P. Nelson. PhD
(412) 241-7335 x209
(412) 241-7311
nelson@chemimage.com

COST

- $0.54/sample
- $204,347.00/system or device

Evaluation Criteria Provided by Vendor

System Requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 minutes or less
- 384 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:
- A day of training and technical skills are required
- 10-20 minutes set-up required
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 2 components
- Cleaning consist of wiping with 5% bleach

Maintenance:
- Every 6 months service required
- Expected life is greater than 10 years
- 10-20 minutes daily quality assurance procedures

Transportation:
- Larger than a home dishwasher
- More than 50 kg
- Reagent shelf life greater than 3 years

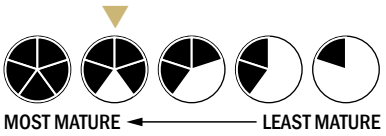
Ease of use/Utility:
- Can view results “in real time”
- There is a single centrifugation step
- There is a single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 25°C to 45°C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1000 CFU per ml

Maturity gauge:
- Is commercially available
- Has been featured in peer reviewed scientific publications or independent evaluations



FilmArray System

by Idaho Technology

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Burkholderia pseudomallei, Coxiella burnetti, Brucella species, E.coli O157:H7, Vibrio cholera, Burkholderia mallei, Yersinia pestis, Rickettsia prowazekii, Marburg virus, Smallpox virus, Influenza virus, Dengue fever virus, Orthopox virus, Rift valley fever virus, Venezuelan equine encephalitis virus, Ebola virus, Botulinum toxin A, Ricin toxin *(Assay developed)*

DESCRIPTION:
The FilmArray system is an automated system to identify dozens of biological agents with very high sensitivity and specificity. The FilmArray platform is evolved from the Razor - Idaho tech's battery-operated, plastic-pouch-based real-time PCR instrument. The FilmArray system adds automated sample preparation and the ability to analyze both bacteria and DNA. The result is a revolution in diagnostic capability capable of automatically preparing a sample and analyzing it for 100 agents simultaneously.

TECHNOLOGY:
The FilmArray system is an automated sample preparation and biologic agent analysis system. It has the capability of automated sample preparation, reverse transcription for RNA viruses, and a two-stage nested multiplex PCR process. It has the diagnostic capability capable of automatically preparing a sample and analyzing it for 100 agents simultaneously.

ANALYTICAL Laboratory Ranking

FilmArray System ranked in the top third of all evaluated products for analytical laboratories and earned 98% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Idaho Tech FilmArray	0.886
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

FilmArray System ranked in the top third of all evaluated products for diagnostic laboratories and earned 92% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Idaho Tech FilmArray	0.837
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

FilmArray System ranked in the middle third of all evaluated products for mobile laboratories and earned 96% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Idaho Tech FilmArray	0.844
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

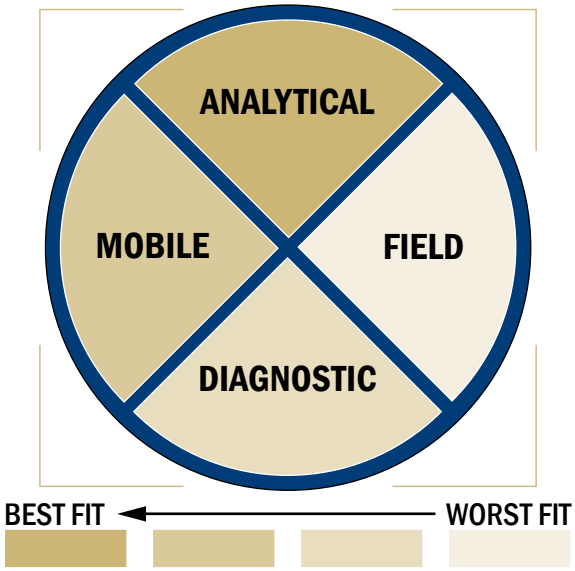
FilmArray System ranked in the top third of all evaluated products for field use and earned 79% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Idaho Tech FilmArray	0.749
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
Idaho Technology
390 Wakara Way
Salt Lake City, UT 84108
www.idahotech.com

Point of Contact:
Matt Scullion, Marketing Manager Applied Science
(801) 736-6354 x327
(801) 588-0507
matt.scullion@idahotech.com

COST
- less than $185.00/sample

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 50 and 60 minutes
- 96 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 2 components
- Remove previous reagent pouch

Maintenance:
- Less than once a year service required
- Expected life is between 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 5 and 25 kg
- Reagent shelf life between 6 months to 1 year

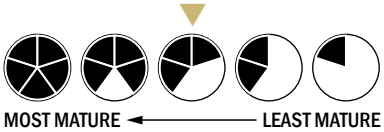
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4 °C to 37 °C
- Components must be stored at room temperature
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1,000 CFU per ml

Maturity gauge:
- A few devices or system exist (brass board)
- Is expected to be ready for commercialization within two calendar years
- Greater than $2,000,000 is required to advance the device or system to commercialization
- Has not been featured in any peer reviewed scientific publications or independent evaluations



Fluorescence Aerosol Particle Sensor (FLAPS III™) Model 3317

by TSI

CAPABLE OF DETECTING THE FOLLOWING:
None reported
(Generic detector)

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 stimulants for bio-threat agents (spore & vegetative bacteria, viruses and toxins), and has undergone significant field testing to verify its performance. The 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 Defence.

TECHNOLOGY:
The 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 of 10,000 hours of continuous operation). An opposed nozzle design, consisting of an inlet nozzle and an 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 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
Best Score	0.901
TSI FLAPS	0.417
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

TSI FLAPS III 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
Best Score	0.909
TSI FLAPS	0.541
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

TSI FLAPS III ranked in the middle third of all evaluated products for mobile laboratories and earned 67% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
TSI FLAPS	0.594
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

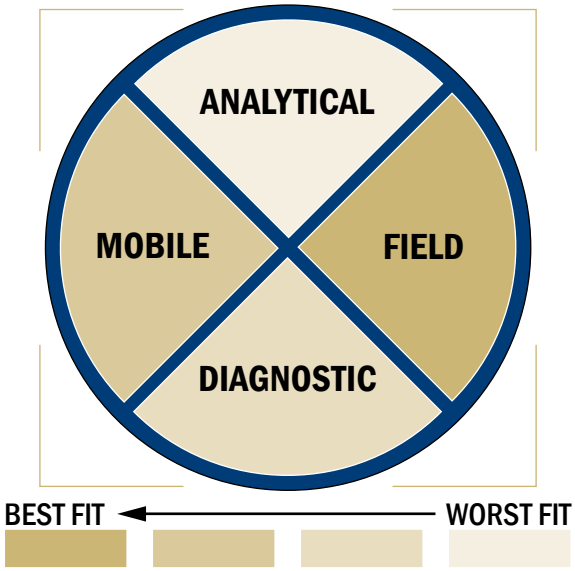
TSI FLAPS III ranked in the top third of all evaluated products for field use and earned 88% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
TSI FLAPS	0.831
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

TSI Incorporated
500 Cardigan Road
Shoreview, MN 55126

Point of Contact:
Richard Remiarz
(651) 490-2773
(651) 490-3824 fax
rremiarz@tsi.com
www.tsi.com

COST

- $100,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- No liquid sample is required
- No reaction or assay is performed
- The system or device is currently fully automated

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes set-up required
- 0-2 manual steps required for detection

Re-use:

- Continuous use
- 0-1 solution or buffer used
- No components
- Occasional cleaning with compressed air

Maintenance:

- Less than once a year service required
- Expected life is greater than 10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a toaster
- Between 5 and 25 kg

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

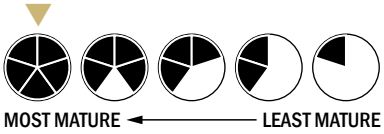
- Operated from 0°C to 45°C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- Less than 25 ACPLA (Agent Containing Particles per Liter Air)

Maturity gauge:

- Is commercially available and meets military specifications
- Has been featured in peer reviewed scientific publications or independent evaluations



Guardian Defender TSR (Test Strip Reader) Reader System™

by Alexeter Technologies

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Brucella species, Yersinia pestis, Smallpox virus, Orthopox virus, Botulinum toxin A, Botulinum toxin B, Abrin toxin *(Assay validated)*

DESCRIPTION:

The first comprehensive solution for the detection and identification of biological warfare agents was introduced by Alexeter Technologies in the fall of 2000: The Guardian Reader System™. Developed specifically for first responders, the Guardian Reader System has since then become the first choice for biological detection and identification among first responders and security agencies around the world. The hand-held Defender TSR (Test Strip Reader) offers 15-minute results in the field for the detection of anthrax, ricin , botulinum toxin, staphylococcal enterotoxin B (SEB), plague, tularemia, brucella, abrin toxin and orthopox. Other biological agents can be detected using the BioCheck Powder Screening test. Designed with the first responder in mind, all tests can be run in parallel, yielding answers for all eight tests in 40 minutes. Alexeter also provides on-site training and 24/7 worldwide technical support to our customers.

TECHNOLOGY:

The Defender Reader is a precision optical device which interprets the results of our test strips (monoclonal and polyclonal immunoassays). Hand-held, it features full wireless communication capabilities (802.11b, Bluetooth) and network connectivity.

ANALYTICAL Laboratory Ranking

Guardian Defender TSR ranked in the middle third of all evaluated products for analytical laboratories and earned 70% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Alexeter Defender TSR	0.585
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Guardian Defender TSR ranked in the middle third of all evaluated products for diagnostic laboratories and earned 66% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Alexeter Defender TSR	0.703
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Guardian Defender TSR 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
Best Score	0.883
Alexeter Defender TSR	0.743
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

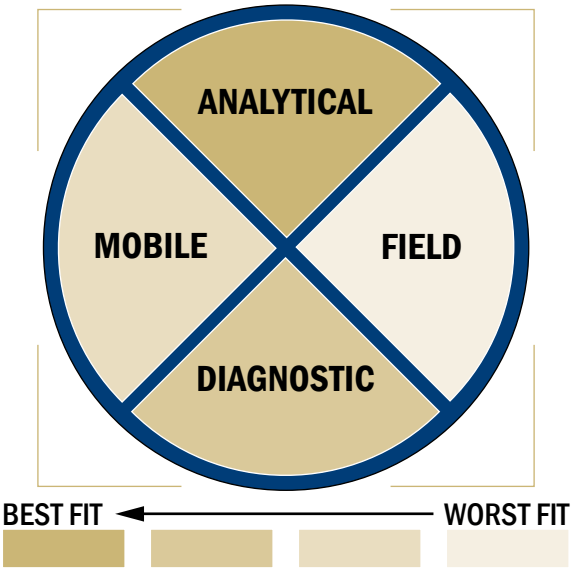
Guardian Defender TSR ranked in the top third of all evaluated products for field use and earned 50% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Alexeter Defender TSR	0.804
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

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11 Firstfield Road
Gaithersburg, MD
20878
www.tetracore.com

Point of Contact:
Tom O'Brien
(301) 258-7553
(301) 258-9740 fax
tobrien@tetracore.com

Alexeter Technologies
830 Seton Court,
Suite 6
Wheeling, IL 60090
www.alexeter.com

Tom Fryzel
(847) 419-1507 x13
(847) 419-1648 fax
service@alexeter.com

COST

- $24.20/sample
- $5500.00/Guardian Reader
- $9995.00/Defender TSR

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has battery power, 110V or 220V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection less than 20 minutes
- 9 different pathogen tests simultaneously
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:
- An afternoon of training and some technical skill
- Less than 5 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for single use
- 0-1 solution or buffer used
- 2 components
- No cleaning required

Maintenance:
- Every 3 years service required
- Expected life is greater than 10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a soda can
- Between 1 and 5 kg
- Reagent shelf life is between 1 to 3 years

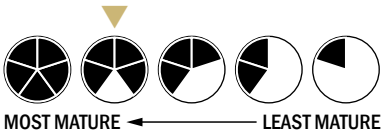
Ease of use/Utility:
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Not capable of detecting two or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 25°C to 37°C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 10,000-100,000 CFU per ml

Maturity gauge:
- Is commercially available
- Has been featured in peer reviewed scientific publications or independent evaluations



Guardian Reader

by Tetracore Inc. and Alexeter Technologies

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Yersinia pestis, Brucella species, Orthopox virus, Botulinum toxins A, B, SEB, Ricin *(Commercially available as wet/frozen reagent)*

DESCRIPTION:
The Bio Threat Alert is intended for biological agent screening in environmental samples. The Bio Threat Alert Test Strip is designed for both field and laboratory use but is not intended for use on clinical samples.

TECHNOLOGY:
The Guardian Reader is designed to accept and analyze only Bio Threat Alert Test Strips and will automatically identify the type of Bio Threat Alert Test Strip (i.e., anthrax, botulinum, etc.) prior to analysis. The operator is automatically navigated through the test procedure via LCD displayed instructions. The Guardian Reader provides an objective evaluation of the test result relative to the assigned Bio Threat Alert Test Strip batch threshold, displays the result, prints a report and records the full test result in non-volatile memory. The operator has the option in selecting either MANUAL or AUTO reading modes. MANUAL mode is selected for immediate analysis of Bio Threat Alert Test Strips that have already completed the test incubation outside the Reader. The AUTO mode is selected when the operator desires the Reader to precisely time the Bio Threat Alert Test Strip incubation before analysis.

ANALYTICAL Laboratory Ranking

Guardian Reader ranked in the middle third of all evaluated products for analytical laboratories and earned 66% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Alexeter Guardian Reader	0.594
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Guardian Reader ranked in the middle third of all evaluated products for diagnostic laboratories and earned 78% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Alexeter Guardian Reader	0.710
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.883
Alexeter Guardian Reader	0.735
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

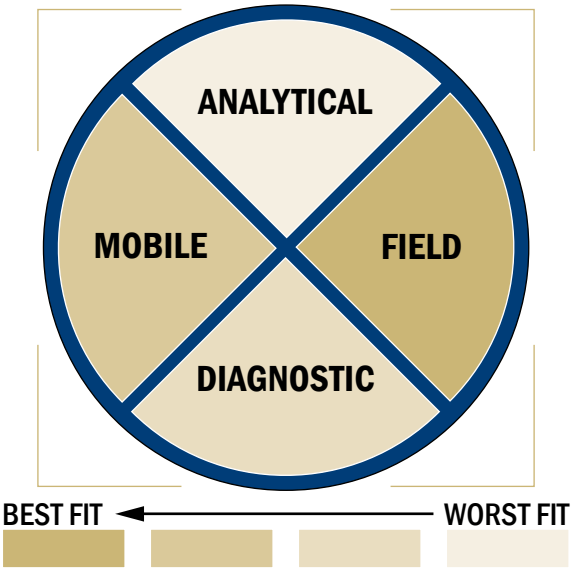
Guardian Reader ranked in the top third of all evaluated products for field use and earned 85% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Alexeter Guardian Reader	0.806
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

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Alexeter Technologies
830 Seton Court,
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www.alexeter.com

Tom Fryzel
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(847) 419-1648 fax
service@alexeter.com

COST

- $24.20/sample
- $7,885.00 GSA price/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 2 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or device could be adapted into a semi-automated system with some effort

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system intended for multiple use
- 0-1 solution or buffer used
- 5 components
- No cleaning required

Maintenance:
- 4 consumables or expendables needed
- No service required
- Expected life is 5-10 years
- No daily quality assurance procedures necessary

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 1 and 5 kg
- Shelf life between 1 and 3 years

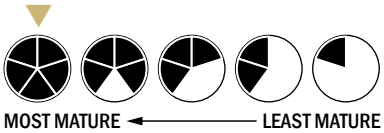
Ease of use/Utility:
- Can view results "in real time"
- No centrifugation steps
- Single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- Components can be stored at room temperature
- Peak performance at normal relative humidity conditions only

Sensitivity:
- Greater than 100,000 CFU per ml

Maturity gauge:
- Is commercially available



GX1 Integrated Thermocycler

by Cepheid

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Yersinia pestis *(Commercially available as a freeze-dried reagent)*

DESCRIPTION:
The GX1 combines a closed cartridge-based sample preparation with amplification and detection functions performed by I-CORE modules in an integrated automated nucleic acid analysis instrument. The GX1 can purify, concentrate, detect, and identify targeted nucleic acid sequences, taking unprocessed samples to results in less than 40 minutes. Current techniques for accomplishing the same complex series of procedures require extensive manual labor by skilled technicians taking anywhere from six hours to three days. The GX1's onboard computer, software and barcode scanner easily manages data and results. The GX1 has a small footprint and low power requirement making it suitable for applications requiring portability. GX1 is a portable, single site instrument with an on-board user interface display designed to cater to lower throughput areas such as Physician Offices, ICU, ED, etc. for clinical applications as well as Industrial, and Biothreat applications. The GX1 instrument will perform amplification and detection without user intervention.

TECHNOLOGY:
The one site, nucleic acid analysis instrument integrates real-time amplification and detection with automated sample preparation, delivering real-time PCR results from unprocessed samples in less than 40 minutes. The I-CORE (Intelligent Cooling/Heating Optical Reaction) module incorporates state-of-the art microelectronic optical design. The GX1 accommodates microfluidic cartridges that automatically perform the complex steps of nucleic acid extraction. After the automated extraction is complete, the nucleic acid concentrate is moved into the cartridge reaction chamber where amplification and detection takes place. The GX1 has a small footprint and low power requirement making it suitable for applications requiring portability.

ANALYTICAL Laboratory Ranking

GX1 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
Best Score	0.901
Cepheid GX1	0.722
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

GX1 ranked in the top third of all evaluated products for diagnostic laboratories and earned 83% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Cepheid GX1	0.754
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

GX1 ranked in the middle third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Cepheid GX1	0.659
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

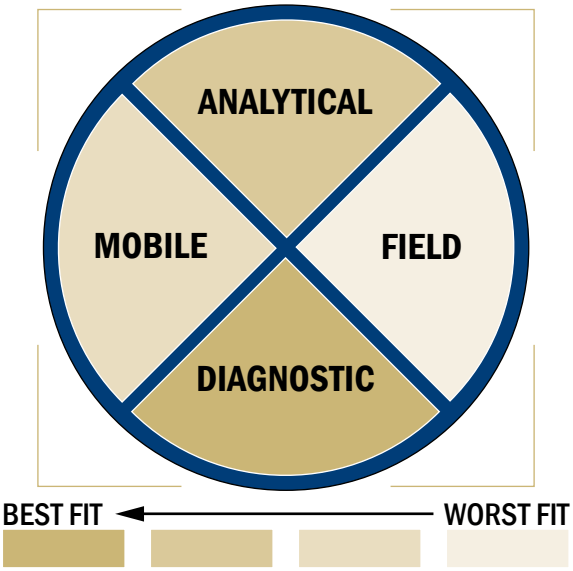
GX1 ranked in the middle third of all evaluated products for field use and earned 76% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Cepheid GX1	0.717
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Cepheid
904 Caribbean Dr.
Sunnyvale, CA 94089
www.cepheid.com

Point of Contact:
Francisco Dias Lourenco
(408) 400-8240
Francisco.Diaslourenco@cepheid.com

COST

- $21.67/sample
- $25,000.00/system or device

Evaluation Criteria Provided by Vendor

System Requirements:

- System or device has 110V or 220V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection between 30 and 40 minutes
- 3 samples/batch
- Greater than 250 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 2 solutions or buffers used
- 1 component
- Cleaning required

Maintenance:

- Once a year service required
- Expected life is between 5-10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Reagent shelf life between 1 to 3 years

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

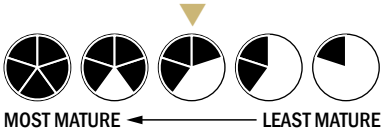
- Operated from 4 °C to 45 °C
- Components must be stored at room temperature
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 100-1000 CFU per ml

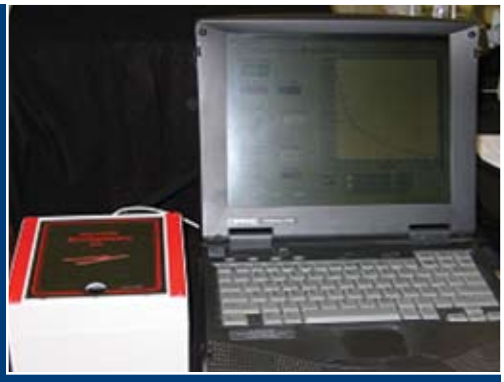
Maturity gauge:

- A few devices or systems exist (brass board)
- It is expected to be ready for commercialization within one calendar year
- Less than $1,000,000 required to advance system or device to commercialization
- Has been featured in peer reviewed scientific publications or independent evaluations



Handheld Fluorescence Strip Reader

by OmniSite BioDiagnostics, Inc.



CAPABLE OF DETECTING THE FOLLOWING:

Able to detect any organisms/ toxins for which handheld assays are developed.

DESCRIPTION:

The Handheld Fluorescence Strip Reader detects biological warfare agents on immunochromatographic test strips (similar to pregnancy test strips). In practice, three to four different agents can be detected on a single strip at low levels. The unit also contains a wireless data link to transfer detection data to a central location such as a website.

TECHNOLOGY:

A scanning epifluorescent head scans across the immunochromatographic test strip antibody capture lines and reads the fluorescence intensity along each capture line. These intensities are automatically compared with the intensity of control lines to determine if a biowarfare agent is present or not.

ANALYTICAL Laboratory Ranking

Handheld Fluorescence Strip Reader ranked in the middle third of all evaluated products for analytical laboratories and earned 66% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Handheld Fluor. Strip Reader	0.597
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Handheld Fluorescence Strip Reader ranked in the top third of all evaluated products for diagnostic laboratories and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Handheld Fluor. Strip Reader	0.727
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Handheld Fluorescence Strip Reader ranked in the middle third of all evaluated products for mobile laboratories and earned 67% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Handheld Fluor. Strip Reader	0.591
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

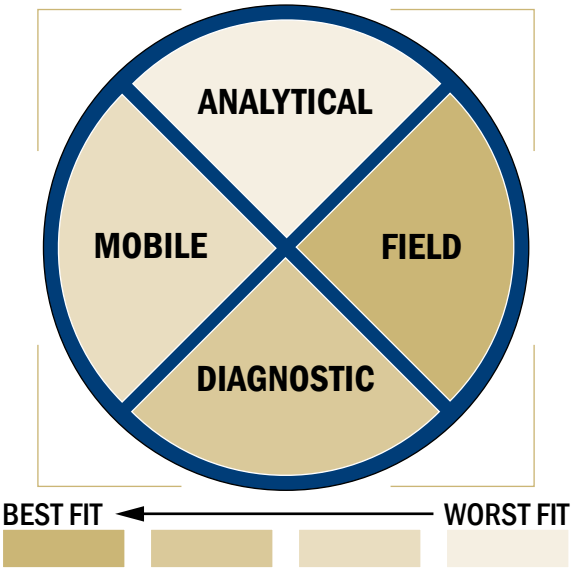
Handheld Fluorescence Strip Reader ranked in the top third of all evaluated products for field use and earned 83% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Handheld Fluor. Strip Reader	0.785
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

OmniSite BioDiagnostics, Inc.
101 West 6th Street, Suite 200
Austin, TX 78701

Point of Contact:
John G. Bruno
(512) 479-7732 x2202
(512) 494-0756 fax
bruno@spec.com

COST

- $0.10/sample plus cost of handheld assay
- Approx. $3,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection 20 minutes or less
- 2 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:

- Very brief training
- No set-up required
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 1 component
- No cleaning required

Maintenance:

- 0-1 consumable or expendable needed
- No service required
- Expected life is greater than 10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a toaster
- Less than 1 kg
- Shelf life greater than 3 years

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Not available, but capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

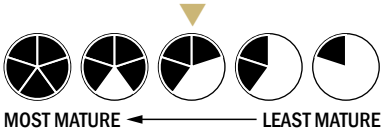
- Operated from 4°C to 45°C
- Components stored at 25°C to 45°C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- 100-1,000 CFU per ml

Maturity gauge:

- A few devices or system exist (brass board)



Handheld Fluorescence Polarization (FP) Reader

by OmniSite BioDiagnostics, Inc.

CAPABLE OF DETECTING THE FOLLOWING:
Able to detect any organisms/toxins for which assays are developed.

DESCRIPTION:
This instrument is a miniaturized (16 x 16 x 9 cm) fluorescence polarization (FP) device (excluding the laptop controller and data logger), capable of rapid one-step immunoassays (without wash steps). Although assays are currently performed in two mL of fluid in a cuvette, OmniSite is developing microfluidic cartridges that will contain freeze-dried reagents that can be rehydrated by the sample and assessed within minutes.

TECHNOLOGY:
FP is popular technique in the research and clinical diagnostic arenas, because it allows "homogenous" one-step assays (without wash steps) that are especially well suited to small molecule targets. However, FP measures rotational or tumbling speed of fluorophores before and after a molecular complex (e.g., antibody-antigen or aptamer-target complex) and is adaptable to a variety of targets such as proteins and even whole bacteria or other microbes. In the clinical diagnostic world, Abbott Laboratories has dominated with its industry standard table top FP device called the "TDx" for therapeutic drug monitoring and assessing drugs of abuse in serum samples. The OmniSite FP handheld instrument has demonstrated comparable sensitivity to the much larger and heavier table top Abbott TDx unit.

ANALYTICAL Laboratory Ranking

Handheld Fluorescence Polarization Reader ranked in the middle third of all evaluated products for analytical laboratories and earned 74% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Handheld Fluor. Polar. Reader	0.670
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.909
Handheld Fluor. Polar. Reader	0.744
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Handheld Fluorescence Polarization Reader 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
Best Score	0.883
Handheld Fluor. Polar. Reader	0.600
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

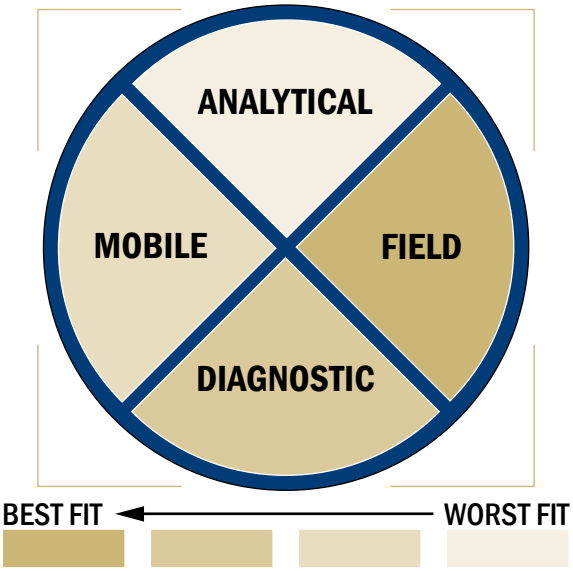
Handheld Fluorescence Polarization Reader ranked in the top third of all evaluated products for field use and earned 83% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Handheld Fluor. Polar. Reader	0.778
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
OmniSite BioDiagnostics, Inc.
101 West 6th Street, Suite 200
Austin, TX 78701

Point of Contact:
John G. Bruno
(512) 479-7732 x2202
(512) 494-0756 fax
bruno@spec.com

COST
- $0.10/sample plus cost of immunoassay
- $3,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V or battery requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 2 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 3 solutions or buffers used
- 1 component
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- No service required
- Expected life is greater than 10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Less than 1 kg
- Shelf life between 1 and 3 years

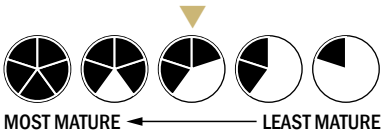
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- A single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at 25°C to 45°C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1,000 CFU per ml

Maturity gauge:
- A few devices or system exist (brass board)



Handheld Raman Imager

by ChemImage

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Burkholderia pseudomallei, Brucella species, E.coli O157:H7, Vibrio cholera, Burkholderia mallei, Yersinia pestis, Influenza virus, MS-2 bacteriophage, Botulinum toxin A, Staphylococcal toxin B, Ricin toxin *(Assay validated)*

DESCRIPTION:
The Handheld Raman Imager is primarily designed for use by military and municipal first responder organizations to detect the presence of hazardous bacterial spores, hazardous bacteria or toxins. While it is designed for powder measurement, with additional sample treatment, it can be used to analyze liquid suspensions. By the use of a suitable surface sampler, the Handheld Raman Imager can be used in the determination of surface contamination. The system can simultaneously identify the presence of over 1,000 biological and chemical materials, both threat and non-threat.

TECHNOLOGY:
The Handheld Raman Imager design utilizes Raman Chemical Imaging (RCI) to provide better identification of materials in mixtures when compared to instruments that rely on a single spectroscopic measurement. Raman chemical imaging combines molecular spectroscopy and digital imaging to provide rapid, non-contact, non-invasive characterization of materials.

ANALYTICAL Laboratory Ranking

Handheld Raman Imager 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
Best Score	0.901
ChemImage Handheld Raman Imager	0.717
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Handheld Raman Imager ranked in the top third of all evaluated products for diagnostic laboratories and earned 86% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
ChemImage Handheld Raman Imager	0.779
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.883
ChemImage Handheld Raman Imager	0.718
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

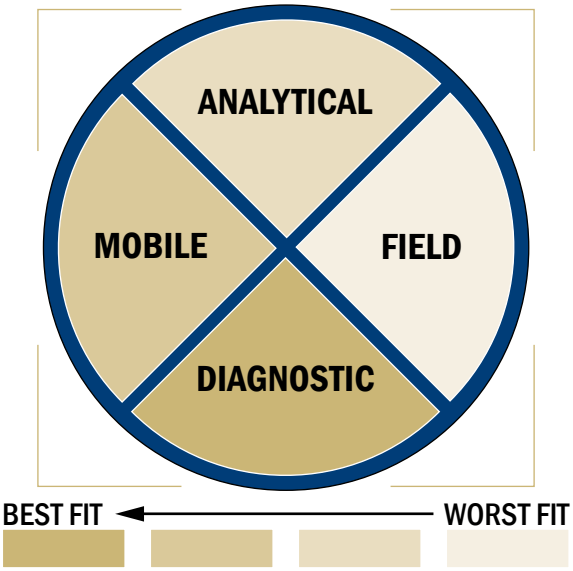
Handheld Raman Imager ranked in the middle third of all evaluated products for field use and earned 70% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
ChemImage Handheld Raman Imager	0.661
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
ChemImage
7301 Penn Ave
Pittsburgh, PA 15208
www.chemimage.com

Point of Contact:
Charles W. Gardner. PhD
(412) 241-7335 x212
(412) 241-7311
cgardner@chemimage.com

COST
- $0.54/sample
- $35,000.00/device or system

Evaluation Criteria Provided by Vendor

System Requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 minutes or less
- 384 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:
- An afternoon of training and some technical skills required
- 10-20 minutes set-up required
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 2 components
- Wipe exterior with 5% bleach solution

Maintenance:
- Every 6 months service required
- Expected life is greater than 10 years
- 10-20 minutes of daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 5 and 25 kg
- Reagent shelf life greater than 3 years

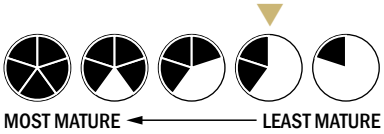
Ease of use/Utility:
- Can view results “in real time”
- There is a single centrifugation step
- There is a single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 25°C to 45°C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1,000-10,000 CFU per ml

Maturity gauge:
- Only one incomplete device or system exists (bread board)
- Is expected to be ready for commercialization within one calendar year
- $1,000,000-$2,000,000 required to advance device or system to commercialization
- Has not been featured in any peer reviewed scientific publications or independent evaluations



HandyLab-EIMB

by HandyLab Inc.

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Yersinia pestis, Brucella species, E. coli 0157:H7, Marburg virus, Orthopox virus, VEE virus, Latrotoxin *(Assay developed)*

DESCRIPTION:
The components of the HandyLab-EIMB system have undergone extensive development and are being integrated into a portable, low-cost, rapid, user-friendly DNA analysis system for commercial medical applications. We can easily adapt our state-of-the-art technology to custom DOD applications. Military personnel could use the handheld device, with minimal training and expense, to perform multiplexed PCR testing for the presence of pathogens and have definitive results within 30 minutes or less.

TECHNOLOGY:
The HandyLab device is a microfluidic-based sensing system that offers several key advantages: All wet chemistry, optical scans, and DNA assays performed on HandyLab's chips are proven analysis techniques that represent the gold standards in genetic BW identification (PCR). The HandyLab™ solution provides an almost "hands-free" technology, other than the loading and unloading of the cartridge, reducing the risk of human error. The sensitivity equals or exceeds that of existing PCR technology. The technology utilizes nano-volume samples and reagent plugs to perform analyses in less than 30 minutes. All operations are performed on a single chip using a proprietary design with minimal unused volume and reduced transport distances. Tests for different pathogens will be performed in parallel on EIMB's chip array. HandyLab chips have been designed to operate with independent series and parallel analysis paths for multi-step biochemical analysis. Accordingly, each lab-on-a-chip system can be custom designed to perform only those biochemical analysis functions essential to assess specified samples. The technology allows the user to carry what is currently "bench-top" equipment in the palm of their hand. Every test will be accompanied by on-board positive and negative controls to ensure the accuracy of a result. The chips will be produced using inexpensive microfabrication and injection molding techniques.

ANALYTICAL Laboratory Ranking

HandyLab-EIMB ranked in the top third of all evaluated products for analytical laboratories and earned 90% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
HandyLab-EIMB	0.809
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

HandyLab-EIMB ranked in the top third of all evaluated products for diagnostic laboratories and earned 93% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
HandyLab-EIMB	0.848
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

HandyLab-EIMB ranked in the top third of all evaluated products for mobile laboratories and earned 87% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
HandyLab-EIMB	0.765
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

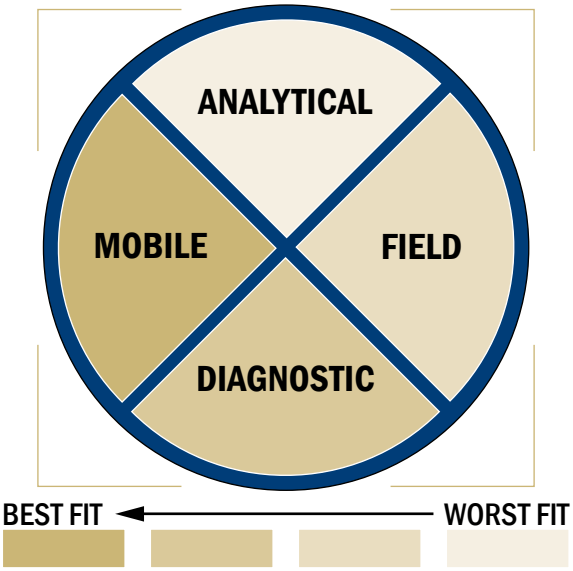
HandyLab-EIMB ranked in the middle third of all evaluated products for field use and earned 75% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
HandyLab-EIMB	0.708
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
HandyLab Inc.
3985 Research Park Dr.
Ann Arbor, MI 48108
www.handylab.com

Point of Contact:
Dr. Charles Daitch
(734) 663-4719 x240
(734) 663-7437 fax
cdaitch@handylab.com

COST
- $1.00-10.00/sample test cartridge
- $100.00-200.00 PDA reader/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 20 and 30 minutes
- 96 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is designed for single use
- 2 solutions or buffers used
- 2 components
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- Unknown service required
- Expected life is not applicable
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Less than 1 kg
- Shelf life greater than 3 years

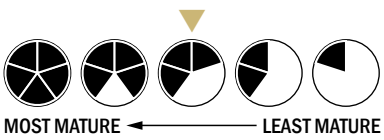
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components must be stored at 25°C to 45°C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

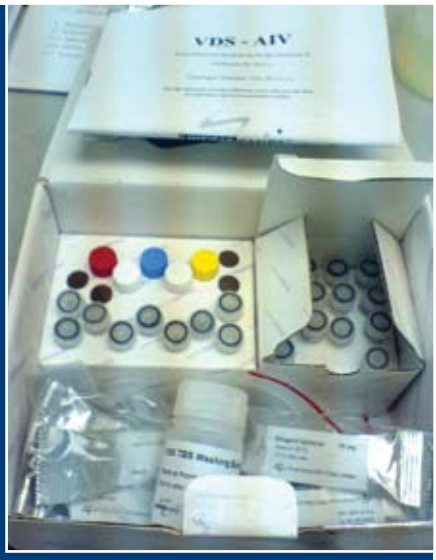
Maturity gauge:
- A few devices or system exist (brass board)



HKDNA Human VDS AIV H5 Detection Kit

by Hai Kang Life Corporation Limited

CAPABLE OF DETECTING THE FOLLOWING:
Influenza virus
(Commercially available as a wet/frozen reagent)



DESCRIPTION:
Human VDS AIV H5 Detection Kits were first launched in Hong Kong in 2001 and were the first commercially available nucleic acid-based test kits for the human avian influenza virus (AIV). The kits combine advanced RNA amplification technology and a proprietary detection system, making them far more sensitive than existing testing methodologies. The MP (microplate) version of the product has undergone stringent evaluations with data published in peer-reviewed scientific journals. Besides Human VDS AIV H5 which specifically detects nucleic acid of human AIV subtype H5, there are currently two other versions of kits available for AIV. Human VDS AIV H7 detects specifically nucleic acid of human AIV subtype H7 and Human VDS AIV H1-16 detects specifically nucleic acid of human AIV subtypes H1-16. Human VDS is an accurate, sensitive and specific testing tool for developing comprehensive and routine surveillance programs in hospitals, government health-related, inspection and quarantine departments, the food and catering industry, commercial and academic research laboratories, environmental care and protection agencies. The kits can utilize virtually any kind of sample for AIV testing—biological and environmental samples such as blood, cerebrospinal fluid, spleen and liver tissues, cervical smears, pus, saliva, sputum, urine, feces, and pharyngeal swabs. Results are available in as short as four hours. Together with its extremely high sensitivity and specificity, these properties make the diagnostic kit especially suitable for use in the Army where accurate and rapid result or confirmation is often required.

TECHNOLOGY:
Human VDS AIV H5 Detection Kits utilize the NASBA (nucleic acid sequence-based amplification) technology, a continuous, isothermal, enzyme-based method for the amplification of nucleic acid (Compton, 1991; Romano et al., 1996). Amplification is most suitable for RNA analytes and employs a mixture of reverse transcriptase, ribonuclease-H, RNA polymerase and two specially designed DNA oligonucleotide primers. Under optimum conditions a 10^12-fold level of amplification is possible. For detection, colorimetric signal is generated and measured in a standard 96-well microtitre plate spectrophotometer at 405nm. The system is highly sensitive and specific and can be used to detect a wide range of samples.

ANALYTICAL Laboratory Ranking

Human VDS AIV H5 Detection Kits ranked in the middle third of all evaluated products for analytical laboratories and earned 67% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
HKDNA Human VDS AIV H5 Detection Kit	0.608
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Human VDS AIV H5 Detection Kits ranked in the middle third of all evaluated products for diagnostic laboratories and earned 62% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
HKDNA Human VDS AIV H5 Detection Kit	0.586
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Human VDS AIV H5 Detection Kits 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
Best Score	0.883
HKDNA Human VDS AIV H5 Detection Kit	0.606
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

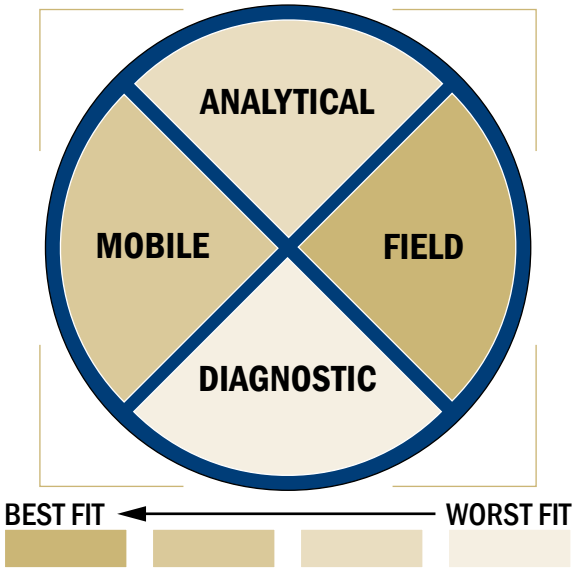
Human VDS AIV H5 Detection Kits ranked in the middle third of all evaluated products for field use and earned 70% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
HKDNA Human VDS AIV H5 Detection Kit	0.661
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Hai Kang Life Corporation Limited
8/F Hang Tung Resources Center
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Hong Kong
www.hkdnachips.com

Point of Contact:
Terence Lok Ting LAU, Ph.D.
(852) 2111-2123
(852) 2111-9762
terence.lau@hkdnachips.com

COST

- $30.00/sample
- $1,200.00/device or system (50 tests)

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 220V electrical requirement
- The system or device requires a continual supply of water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 32 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:
- An afternoon of training and some technical skills required
- 10-20 minutes set-up required
- Greater than 12 manual steps required for detection

Re-use:
- Device or system is intended for single use
- More than 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:
- No service required
- Expected life is between 1-3 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Reagent shelf life between 1 year to 3 years

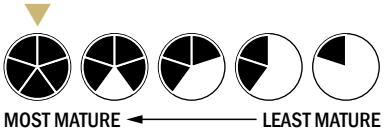
Ease of use/Utility:
- Cannot view results “in real time”
- There are multiple centrifugation steps
- There are multiple shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4 °C to 45 °C
- Components must be stored at room temperature or frozen
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

Maturity gauge:
- Is commercially available and meets military specifications
- Has been featured in peer reviewed scientific publications or independent evaluations



HKDNA LOAC

by Hai Kang Life Corporation Limited

CAPABLE OF DETECTING THE FOLLOWING:
None reported

DESCRIPTION:
DNA chips have revolutionized genomics and proteomics analysis, allowing large scale diagnostic testing and screening. This technology can be categorized into two classes, conventional DNA microarray and Lab-on-a-chip. The DNA microarray format is relatively more mature in terms of marketing, and has been adopted for drug discovery, genomics research, etc. Typically, a microarray contains nucleic acid fragments arranged in a predetermined pattern on a substrate, which can 'capture' complementary target nucleic acid sequences present in a sample. The resulting binding pattern can be detected by optical or electronic means by the appropriate detection mechanism (e.g., a fluorescently labeled detection probe complementary to a different region of the target nucleic acid). Thus potentially a large number of biological reactions and detections can be performed simultaneously on the same platform using only minute amounts of reagents and analytes (pico- to nano-liter). However, the microarray has many disadvantages. It is 1) expensive, 2) difficult to use – during both experimentation and data analysis, and therefore requires operation by skilled personnel 3) time consuming – around 10 or more hours for hybridization. These concerns make the microarray an unsuitable tool for routine diagnostic uses. HKDNA aims to develop a non-microfluidic system encompassing these disadvantages, making it suitable for routine use or on-site diagnosis e.g., differential diagnosis and rapid, sensitive detection of biological agents as for military uses, and for public purpose, to achieve routine clinical diagnosis of various pathogens, rare diseases, and for utilization in biochemical research.

TECHNOLOGY:
The HKDNA Lab-on-a-chip (LOAC) technology is a non-microfluidic system where more than one step of a procedure can be carried out by technology incorporated into the chip. The research involves development of DNA chip into a multiple pathogen detection cartridge that can simultaneously detect up to 300 DNA and/or RNA targets for specified pathogens, development of peripheral equipment to be used in conjunction with the chip cartridge, development of reaction protocols, validation of system performance and manufacture of the actual system.

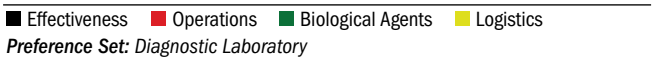
ANALYTICAL Laboratory Ranking
HKDNA LOAC ranked in the bottom third of all evaluated products for analytical laboratories and earned 76% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
HKDNA LOAC	0.323
Lowest Score	0.217

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking
HKDNA LOAC ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 74% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
HKDNA LOAC	0.395
Lowest Score	0.321



Preference Set: *Diagnostic Laboratory*

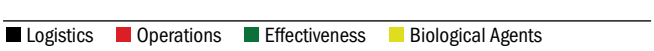
MOBILE Laboratory Ranking
HKDNA LOAC ranked in the bottom third of all evaluated products for mobile laboratories and earned 65% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
HKDNA LOAC	0.517
Lowest Score	0.379

Preference Set: *Mobile Laboratory*

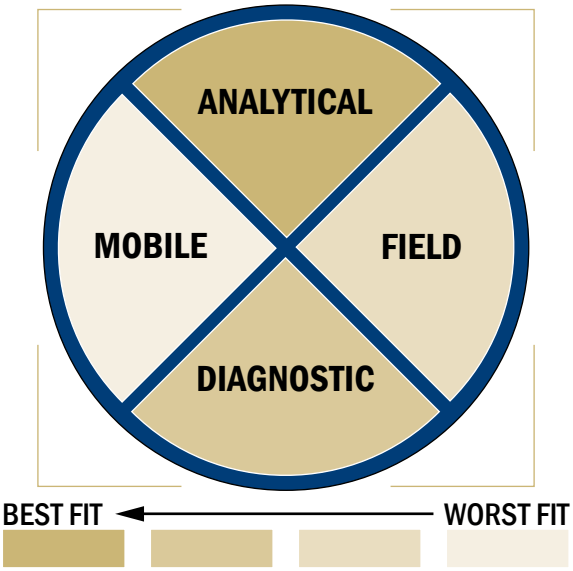
FIELD USE Ranking
HKDNA LOAC ranked in the middle third of all evaluated products for field use and earned 68% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
HKDNA LOAC	0.578
Lowest Score	0.343



Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
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18 A-Kung Ngam Village Road, Shau Kei Wan
Hong Kong
www.hkdnachips.com

Point of Contact:
Prof. Albert Cheung Hoi YU, Ph.D.
(852) 2111-2123
(852) 2111-9762
achy@hkdnachips.com

COST
- $30.00/sample
- $1,200.00/device or system (50 tests)

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V or 220V electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 50 and 60 minutes
- 2 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- A day of training and technical skills required
- 5-10 minutes set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for single use
- 4 solutions or buffers used
- 1 component
- No cleaning required

Maintenance:
- Once a year service required
- Expected life is between 3-5 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 1 and 5 kg
- Reagent shelf life between 1 to 6 months

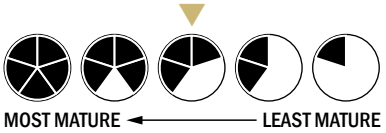
Ease of use/Utility:
- Cannot view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System may be able to interpret raw data or call a positive through internal software in the future
- Capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- Components must be stored at room temperature
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

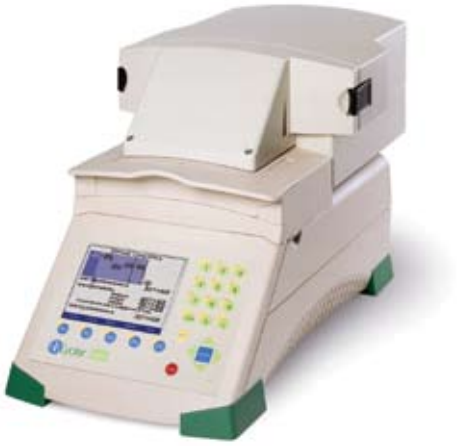
Maturity gauge:
- A few devices or systems exist (brass board)
- Is expected to be ready for commercialization within one calendar year
- More than $2,000,000 required to advance device or system to commercialization
- Has not been featured in any peer reviewed scientific publications or independent evaluations



iCycler iQ Thermocycler

by Bio-Rad Laboratories

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Yersinia pestis, Brucella species, Orthopox virus, Smallpox virus *(Commercially available as a freeze-dried reagent)*



DESCRIPTION:

The iCycler iQ Real-Time Detection System is, in essence a system that allows for the monitoring of up to four distinct fluorophores (used as markers for individual polymerase chain reactions–PCRs) from a sample at one time. PCR allows a researcher to study different pieces of DNA or genes from specific organisms. The iCycler iQ allows a researcher to look for the presence of up to four targets in each sample being tested. And because this test is based on the polymerase chain reaction—a way of amplifying the amount of starting material a researcher has—it is a very sensitive and quantitative method. A sample, e.g., a piece of tissue or a soil sample, can be tested for the presence or absence of up to four different pieces of DNA from specific pathogens at one time, increasing the amount of information that can be gathered from each sample. Real-time PCR is quickly becoming the accepted method for accurate qualitative and quantitative measurements of viral load, pathogen detection and gene expression.

TECHNOLOGY:

The iCycler iQ uses a halogen lamp for broad excitation, then employs both excitation and emission narrow band pass filters for discrimination between the many fluorescent reporter molecules that can be employed in real-time PCR. The system uses a proprietary intensifier technology (like used in the U.S. military's night vision technology) and a 10-bit CCD. Our illumination and detection strategy allows for the simultaneous capture of an image of a 96-well PCR plate – in this way up to 96 samples, can be read at one time. The thermal cycler that the detection system is mounted on is a Peltier-based cycler, with the best all-around market specifications for thermal cyclers (gradient capable, heating 3.3 C/sec.; cooling 2.0 C/sec.). A full description of the technical specifications for the detector and the thermal cycler can be found at: www.bio-rad.com/amplification.

ANALYTICAL Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.901
iCycler iQ Thermocycler	0.742
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.909
iCycler iQ Thermocycler	0.748
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.883
iCycler iQ Thermocycler	0.671
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

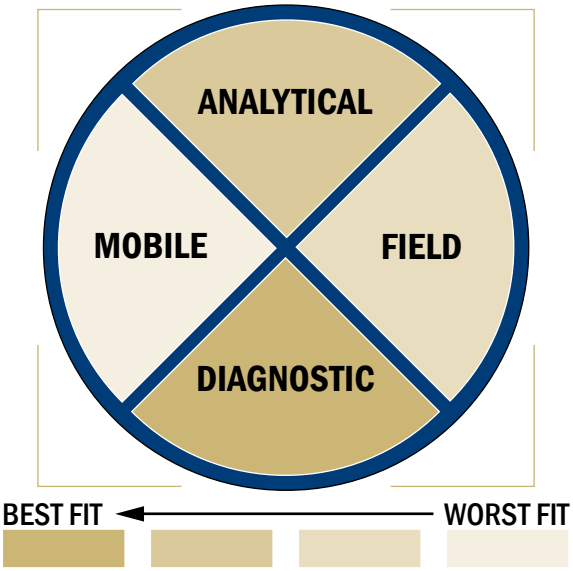
iCycler iQ ranked in the middle third of all evaluated products for field use and earned 78% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
iCycler iQ Thermocycler	0.724
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Bio-Rad Laboratories
2000 Alfred Nobel Drive
Hercules, CA 94547
www.bio-rad.com/iCycler

Point of Contact:
Hilary Srere
(510) 741-6940
(510) 741-5811 fax
hilary_srere@bio-rad.com

COST

- $0.50/sample plus Taq enzyme
- $40,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does require water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection between 40 and 50 minutes
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:

- An afternoon of training
- 10-20 minutes required for set-up
- 6-8 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 2 components
- No cleaning required

Maintenance:

- 4 consumables or expendables needed
- Once a year service required
- Expected life is 5-10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life greater than 3 years

Ease of use/Utility:

- Can view results “in real time”
- Single centrifugation step
- Single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

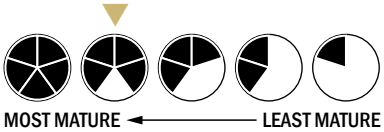
- Operated from 15 °C to 37 °C
- Components must be stored at 4 °C and room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- Is commercially available



Immulite 2000

by DPC

CAPABLE OF DETECTING THE FOLLOWING:
None reported

DESCRIPTION:
The IMMULITE 2000 system utilizes specific antibody-coated polystyrene beads as a solid phase. A bead is dispensed into a specially designed Reaction Tube, which serves as the vessel for the incubation, wash and signal development process.

TECHNOLOGY:
After the sample is incubated with alkaline phosphatase-labeled reagent, the reaction mixture is separated from the bead by spinning the Reaction Tube at a high-speed along its vertical axis. The fluid is transferred to a coaxial sump chamber, which is integral to the Bead/Tube Wash Station. Four discrete washes occur within seconds, allowing the Reaction Tubes to be processed sequentially, with uniform timing. The bead is left with no residual unbound label. The bound label is then quantified using the dioxetane substrate to produce light. Light is emitted when the chemiluminescent substrate reacts with the alkaline phosphatase label bound to the bead. The amount of light emitted is proportional to the amount of analyte originally present in the sample. The light emission is detected by the photomultiplier tube (PMT) and results are calculated for each sample.

ANALYTICAL Laboratory Ranking

Immulite 2000 ranked in the middle third of all evaluated products for analytical laboratories and earned 71% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Immulite 2000	0.636
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Immulite 2000 ranked in the middle third of all evaluated products for diagnostic laboratories and earned 67% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Immulite 2000	0.611
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Immulite 2000 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
Best Score	0.883
Immulite 2000	0.435
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

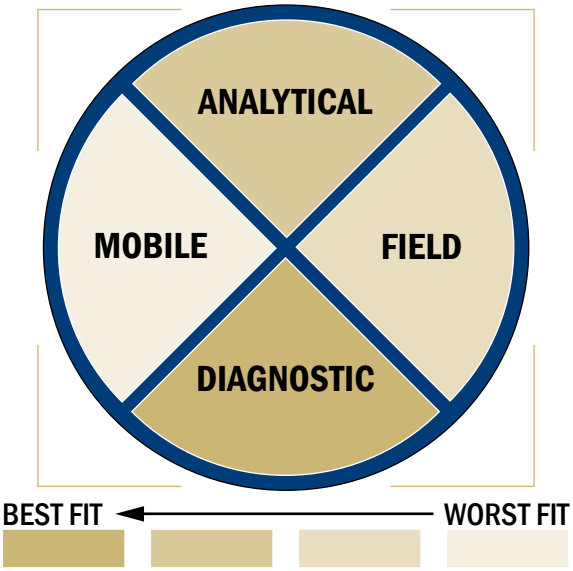
Immulite 2000 ranked in the bottom third of all evaluated products for field use and earned 55% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Immulite 2000	0.516
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

DPC
5700 W 96th Street
Los Angeles, CA 90045-5597
www.dpcweb.com

Point of Contact:
Mark Smith
(310) 642-5180 x7031
(310) 642-0192 fax
msmith@dpconline.com

COST

- $2.00-13.00/sample
- $124,500.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has greater than 220V electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection in greater than 60 min
- 384 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:

- More than a day of training
- Greater than 20 min required for set-up
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple detections
- 4 solutions or buffers used
- 2 components
- 5 minutes/day cleaning required

Maintenance:

- 0-1 consumable or expendable needed
- Needs service every 6 months
- Expected life measure of 5-10 years
- Greater than 20 minutes required for daily quality assurance procedures

Transportation:

- Larger than the size of a home dishwasher
- More than 50 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility:

- Can view results “in real time”
- A single centrifugation steps
- No shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:

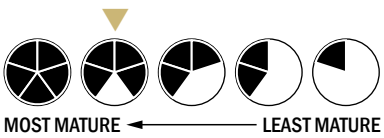
- Operated from 15°C to 37°C
- Components must be stored at 4°C
- Device or system has peak performance at normal relative humidity conditions only

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- Is commercially available



Infectious Disease Identification System (IDIS)

by Applied Biosystems

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Corynebacterium diphtheria, Burkholderia pseudomallei, Coxiella burnetti, Brucella species, E.coli O157: H7, Vibrio cholera, Burkholderia mallei, Yersinia pestis, Rickettsia prowazekii, Marburg virus, Influenza virus, Dengue fever virus, Rift valley fever virus, Yellow fever virus, Ebola virus, MS-2 bacteriophage *(Assay developed)*

DESCRIPTION:

The Infectious Disease Identification System (IDIS) is a standardized system for identification and detection of a broad range of infectious agents for epidemiological use. The system includes: ABIPRISM™ 6100 Nucleic Acid PrepStation, the Applied Biosystems 7900HT Real-Time PCR System with TaqMan® Low Density Array Capability, the IDIS TaqMan® Low Density Array preloaded with primers and TaqMan probes, and reagents for sample preparation and assays. The IDIS platform is capable of running 48 individual reactions per sample, up to eight samples, for a total of 384 individual reactions. All in less than four hours from sample collection to result. The ABI PRISM™ 6100 Nucleic Acid PrepStation isolates and purifies nucleic acids (DNA, RNA) from a variety of biological sample types, including cultured cells, animal and plant tissue, primary cell isolates, and whole blood. During the sample preparation process, nucleic acids from bacteria and viruses are lysed, then combined before analysis.

The IDIS TaqMan® Low Density Array functions as an array of reaction vessels for PCR/sequence detection. The wells of the Low Density Array contain Applied Biosystems TaqMan® primers and probes that detect the real-time amplification of nucleic acids from specific bacterial and viral targets. The Applied Biosystems 7900HT Sequence Detection System is designed for high-throughput detection of fluorescent PCR-related chemistries. The instrument performs real-time analysis of the TaqMan® Low Density Array and generates data files containing results that reflect presence or absence of the pathogens. IDIS received DHS's SAFETY Act Designation and Certification.

TECHNOLOGY:

Real-time Polymerase Chain Reaction (PCR) is the ability to monitor the progress of the PCR as it occurs (in real time). Data is collected throughout the PCR process, rather than at the end. This completely revolutionizes the way one approaches PCR-based quantitation of DNA and RNA. In real-time PCR, reactions are characterized by the point in time during cycling when amplification of a target is first detected rather than the amount of target accumulated after a fixed number of cycles. The higher the starting copy number of the nucleic acid target, the sooner an increase in fluorescence is observed.

ANALYTICAL Laboratory Ranking

Infectious Disease Identification System ranked in the top third of all evaluated products for analytical laboratories and earned 75% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Celera IDIS	0.680
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Infectious Disease Identification System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 71% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Celera IDIS	0.642
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Infectious Disease Identification System 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
Best Score	0.883
Celera IDIS	0.608
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

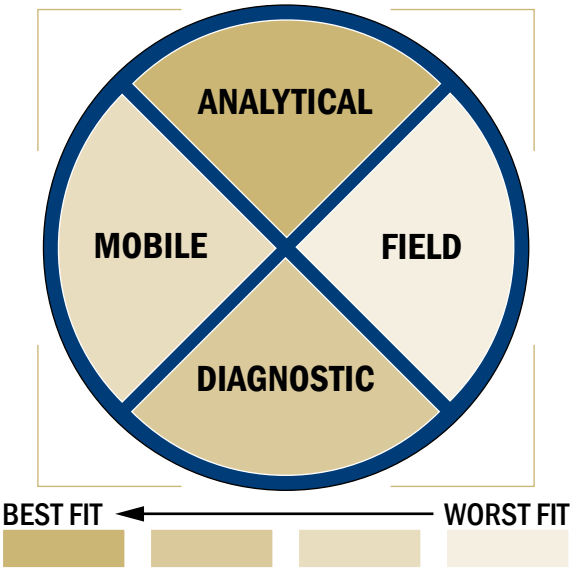
Infectious Disease Identification System ranked in the middle third of all evaluated products for field use and earned 60% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Celera IDIS	0.565
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Applied Biosystems
850 Lincoln Centre Drive
Foster City, CA 94404
www.appliedbiosystems.com

Point of Contact:
Brian Plew
(650) 554-2995
(650) 638-5787
plewbp@appliedbiosystems.com

COST

- $3.25/sample
- $113,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 220V electrical requirement and a twist lock plug
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection greater than 60 minutes
- 96 samples/batch or higher; 48 reactions per sample
- Less than 250 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:

- An afternoon of training and some technical skills required
- Less than 5 minutes set-up required
- Greater than 12 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:

- Once a year service required
- Expected life is between 5-10 years
- Less than 5 minutes daily quality assurance procedures

Transportation:

- Larger than a home dishwasher
- More than 50 kg
- Reagent shelf life between 6 months to 1 year

Ease of use/Utility:

- Can view results “in real time”
- There is a single centrifugation step
- There are multiple shaking or vortexing steps
- System may be able to interpret raw data or call a positive through internal software in the future
- Capable of detecting multiple biological agents or toxins within the same test
- Four or more additional pieces of general lab equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:

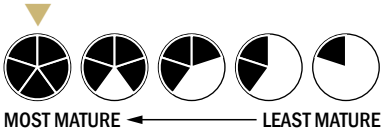
- Operated from 4 °C to 37 °C; optimal at 15 °C to 37 °C
- Components must be stored at 4 °C or frozen
- The performance of the device or system has peak performance at normal relative humidity conditions

Sensitivity:

- 1,000-10,000 CFU per ml

Maturity gauge:

- Is commercially available and meets military specifications
- Has not been featured in any peer reviewed scientific publications or independent evaluations



Integrated Detection System (IDS)

by Sceptor

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Yersinia pestis
(Commercially available as a freeze-dried reagent)

DESCRIPTION:

The Integrated Detection System (IDS) is a semi-automated system for sampling and detecting the presence of aerosolized biological threat materials in indoor environments. Incorporating the SpinCon Air Sampler and Cepheid GeneXpert real-time PCR analysis, the IDS provides a simple, cost effective method for protecting public buildings, transportation facilities and postal operations from potential biological threats such as anthrax. The IDS protects personnel and facilities by collecting and concentrating biological particulates from the surrounding air. At the end of the user defined sampling cycle, the IDS automatically injects the aerosol sample into a GeneXpert sample cartridge. The sample is then analyzed using the easy-to-use, automated and highly accurate real-time PCR instrument. Following sample collection, the analytical method purifies, concentrates, detects, and identifies targeted nucleic acid sequences, delivering answers from a collected sample in less than 30 minutes. Current techniques for accomplishing the same complex series of procedures require extensive manual labor by skilled technicians and can take anywhere from six hours to three days. The IDS incorporates proven sample collection, the GeneXpert cartridge-based sample preparation with amplification and detection functions in a fully integrated and automated nucleic acid analysis instrument. The system includes a simple, user-friendly graphical display allowing use and operation for virtually any skill level. The IDS components are rack-mounted and powered by 120VAC.

TECHNOLOGY:

The IDS uses the Cepheid GeneXpert® System to perform biological detection, which utilizes real-time polymerase chain reaction (PCR) to amplify and detect target DNA. Utilizing the unique sample/reagent cartridges, the system fully automates and integrates all the steps required for PCR-based DNA testing: sample preparation including cell lysis, DNA purification and amplification, and detection. Designed to simplify hands-on preparation, the system detects and identifies targeted nucleic acid sequences, delivering answers from unprocessed samples in 30 minutes or less, enabling time-critical DNA tests at the point of use.

ANALYTICAL Laboratory Ranking

Integrated Detection System 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
Best Score	0.901
Sceptor IDS	0.712
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Integrated Detection System ranked in the top third of all evaluated products for diagnostic laboratories and earned 81% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Sceptor IDS	0.737
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Integrated Detection System ranked in the bottom third of all evaluated products for mobile laboratories and earned 60% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Sceptor IDS	0.530
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

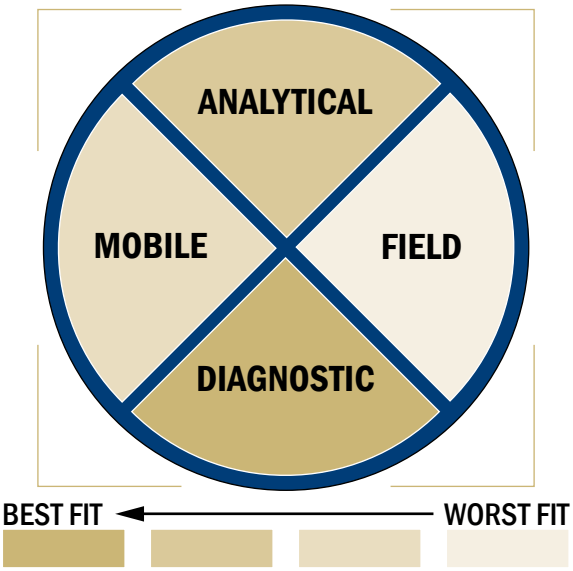
Integrated Detection System ranked in the bottom third of all evaluated products for field use and earned 48% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Sceptor IDS	0.456
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Sceptor
8301 State Line Road
Suite 101
Kansas City, MO 64114
www.sceptorindustries.com

Point of Contact:
Freeman Swank
(816) 360-3898
(816) 931-2451
fswank@sceptorindustries.com

COST

- $75.00/sample
- $80,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection between 30 and 40 minutes
- 2 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes set-up required
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 3 solutions or buffers used
- 2 components
- Cleaning required

Maintenance:

- More often than every 6 months service required
- Expected life is between 5-10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a home dishwasher
- More than 50 kg
- Reagent shelf life between 6 months to 1 year

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:

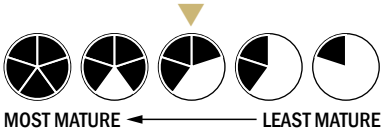
- Operated from 4 °C to 37 °C
- Components must be stored at room temperature
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 100-1,000 CFU per ml

Maturity gauge:

- A few devices or systems exist (brass board)
- Is expected to be commercially available within one calendar year
- Less than $1,000,000 required to advance device or system to commercialization
- Has not been featured in any peer reviewed scientific publications or independent evaluations



Invader Assay

by The Third Wave (TWT)

CAPABLE OF DETECTING THE FOLLOWING:
Able to detect any organisms of known specific DNA or RNA sequences.

DESCRIPTION:
The Invader Assay is an easy to use molecular analysis test. It can detect specific DNA or RNA sequences without the need for Polymerase Chain Reaction (PCR).

TECHNOLOGY:
The Third Wave™ Invader® DNA Assays use Cleavase® enzymes to recognize and cleave specific structures formed by the addition of two oligonucleotides to a nucleic acid target. In the Invader® DNA Assay, two oligonucleotides (a discriminatory Primary Probe and an Invader® Oligo) hybridize in tandem to the target DNA to form an overlapping structure. The 5'-end of the Primary Probe includes a 5'-flap that does not hybridize to the target DNA. The 3'-nucleotide of the bound Invader® Oligo overlaps the Primary Probe, but need not hybridize to the target DNA. The Cleavase® enzyme recognizes this overlapping structure and cleaves off the unpaired 5'-flap of the Primary Probe, releasing it as a target-specific product. The Primary Probe is designed to have a melting temperature close to the reaction temperature. Thus, under the assay conditions, the Primary Probe cycles on the target DNA isothermally. This allows for multiple rounds of Primary Probe cleavage for each target DNA, and amplification of the number of released 5'-flaps. In the secondary reaction, each released 5'-flap can serve as an Invader® Oligo on a fluorescence resonance energy transfer (FRET™) cassette to create another overlapping structure that is recognized and cleaved by the Cleavase® enzyme. When the FRET™ cassette is cleaved, the fluorophore (F) and quencher (Q) on the FRET™ cassette are separated, generating detectable fluorescence signal. Similar to the initial reaction, the released 5'-flap and the FRET™ cassette cycle, resulting in amplified fluorescence signal. The initial and secondary reactions run concurrently in the same well. The biplex format of the Invader® DNA Assay enables simultaneous detection of two DNA sequences in a single well. Most often, this involves detection of two variants of a particular polymorphism. The biplex format uses two different discriminatory Primary Probes, each with a unique 5'-flap, and two different FRET™ cassettes, each with a spectrally distinct fluorophore. By design, the released 5'-flaps will bind only to their respective FRET™ cassettes to generate a target-specific signal.

ANALYTICAL Laboratory Ranking

Invader Assay 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
Best Score	0.901
Invader Assay	0.541
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Invader Assay ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 54% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Invader Assay	0.492
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Invader Assay 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
Best Score	0.883
Invader Assay	0.478
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

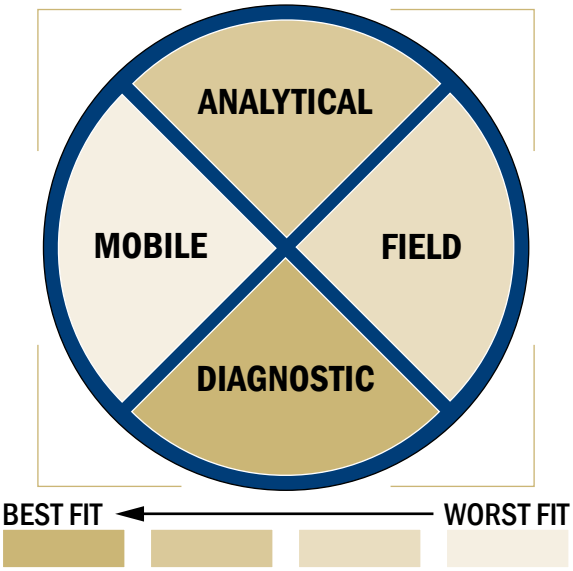
Invader Assay ranked in the bottom third of all evaluated products for field use and earned 62% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Invader Assay	0.592
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Third Wave Tech.
502 South Rosa Rd.
Madison, Wisconsin 53719
www.twt.com

Point of Contact:
Bruce Neri
(608) 663-7030
bneri@twt.com

COST

- $0.50/sample
- $42,761.00 GSA price/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection greater than 60 minutes
- 384 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:

- More than a day of training
- Greater than 20 minutes required for set-up
- Greater than 12 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 3 components
- No cleaning required

Maintenance:

- 5 or more consumables or expendables needed
- Less than once a year service required
- Expected life is 5-10 years
- No daily quality assurance procedures required

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 25 and 50 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility:

- Cannot view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System is never able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- Four or more additional pieces of equipment needed

Signature:

- Sounds produced that cannot be deactivated
- Unknown BTUS generate

Operational conditions:

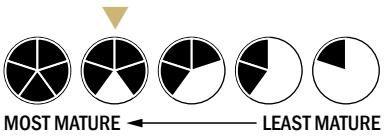
- Operated from 15 °C to 37 °C
- Components must be frozen
- Unknown performance of the device or system in humidity

Sensitivity:

- 1,000-10,000 CFU per ml

Maturity gauge:

- Is commercially available



JBAIDS Analysis

by Idaho Technology

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Burkholderia pseudomallei, Coxiella burnetti, Brucella species, E.coli O157:H7, Burkholderia mallei, Yersinia pestis, Rickettsia prowazekii, Marburg virus, Smallpox virus, Influenza virus, Dengue fever virus, Orthopox virus, Venezuelan equine encephalitis virus, Ebola virus, Botulinum toxin A, Ricin toxin *(Commercially available as a freeze-dried reagent);* Vibrio cholera *(Assay developed)*

DESCRIPTION:
The Joint Biologic Agent Identification and Diagnostic System (JBAIDS) is a portable real-time PCR system designed to identify biological agents. Because of its rugged design, reliability, and accuracy it has become the standard for the U.S. DoD. The JBAIDS system is the ideal choice for mobile analytical labs and field hospitals and is only available to the US Department of Defense. This instrument integrates Idaho Technology's LightCycler® Instrument technology into a portable, impact resistant package. Distinctive software allows simple "push-button" use of the JBAIDS System by field personnel with minimal training. This allows for field identification of pathogens quickly, safely, and accurately. The system is FDA 510K approved, is capable of running both environmental and clinical samples with over 16 validated matricies and 17 validated freeze dried target assays.

TECHNOLOGY:
The JBAIDS utilizes air driven real time PCR. Reactions are performed in glass capillaries to accomplish high-speed thermocycling in less than 30 minutes. It is a three-color instrument capable of using both Taqman™ and FRET™ based assays. It can perform qualitative detection, quantitative detection, melting curve analysis with additional laboratory capabilities embedded within the advanced software.

ANALYTICAL Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.901
Idaho Tech JBAIDS	0.737
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

JBAIDS Analysis ranked in the top third of all evaluated products for diagnostic laboratories and earned 88% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Idaho Tech JBAIDS	0.804
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

JBAIDS Analysis ranked in the top third of all evaluated products for mobile laboratories and earned 89% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Idaho Tech JBAIDS	0.785
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

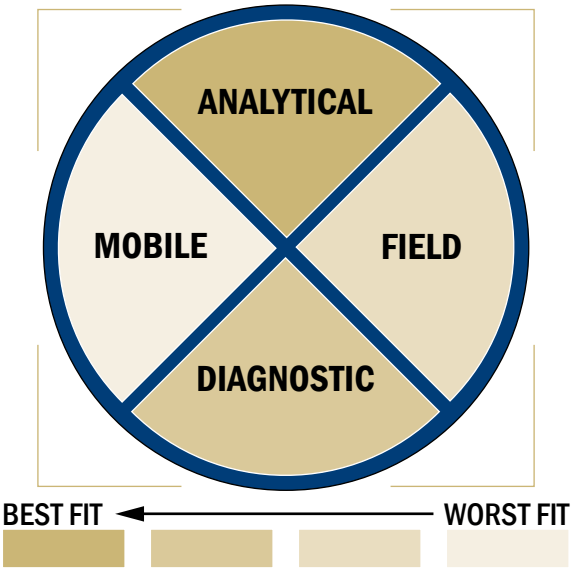
JBAIDS Analysis ranked in the top third of all evaluated products for field use and earned 83% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Idaho Tech JBAIDS	0.782
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
Idaho Technology
390 Wakara Way
Salt Lake City, UT 84108
www.idahotech.com

Point of Contact:
Matt Scullion, Marketing Manager Applied Science
(801) 736-6354 x327
(801) 588-0507
matt.scullion@idahotech.com

COST
- $30.00/sample

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V or 220V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 40 and 50 minutes
- 32 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:
- More than a day of training and significant technical skills required
- Less than 5 minutes set-up required
- Greater than 12 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 5 or more components
- Previous samples must be removed before next operation

Maintenance:
- Less than once a year service required
- Expected life is between 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Reagent shelf life 6 months to 1 year

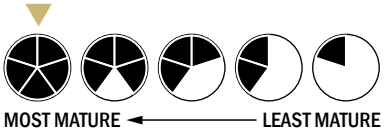
Ease of use/Utility:
- Can view results “in real time”
- There are multiple centrifugation steps
- There is a single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- Four or more additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from 4 °C to 37 °C
- Components must be stored at room temperature
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1000 CFU per ml

Maturity gauge:
- Is commercially available and meets military specifications
- Has not been featured in any peer reviewed scientific publications or independent evaluations



Joint Biological Point Detection System (JBPDS)

by General Dynamics-ATP

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Yersinia pestis and various other biological threat agents.

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 (similar to a pregnancy test strip) 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/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 colloidal gold based immunochromatographic assays 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 top third of all evaluated products for analytical laboratories and earned 88% of the utility points of the best score.

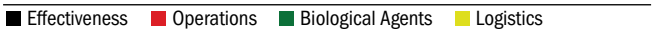
ALTERNATIVE	UTILITY
Best Score	0.901
JBPDS	0.796
Lowest Score	0.217

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

JBPDS ranked in the top third of all evaluated products for diagnostic laboratories and earned 94% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
JBPDS	0.853
Lowest Score	0.321



Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

JBPDS ranked in the top third of all evaluated products for mobile laboratories and earned 89% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
JBPDS	0.776
Lowest Score	0.379

Preference Set: *Mobile Laboratory*

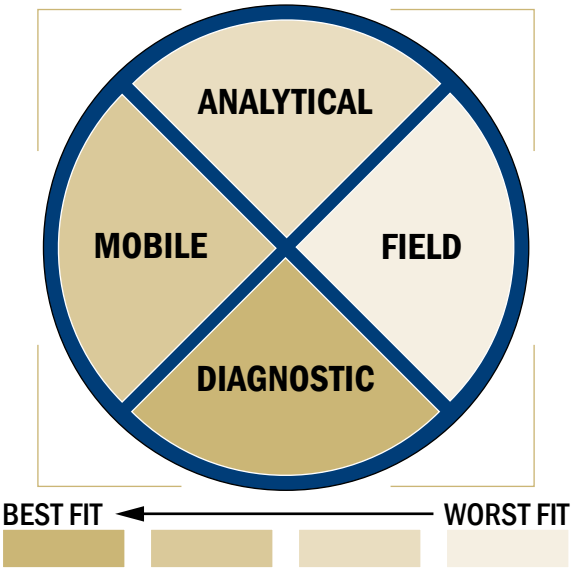
FIELD USE Ranking

JBPDS 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
Best Score	0.943
JBPDS	0.673
Lowest Score	0.343

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

General Dynamics-ATP
4205 Westinghouse Commons Dr.
Charlotte, NC 28273
www.gdatp.com

Point of Contact:
Mike Bryce
(980) 235-2214
(980) 235-2393
mbryce@gdatp.com

COST

- $52.00/sample
- $359,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection in 20 minutes or less
- Less than 100 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- Greater than 20 minutes set-up required
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 2 solutions or buffers used
- 2 components
- System is self cleaning

Maintenance:

- Less than once a year service required
- Expected life is greater than 10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a home dishwasher
- More than 50 kg
- Reagent shelf life 1 to 3 years

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:

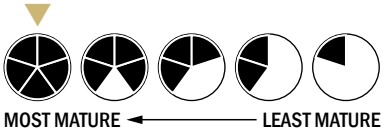
- Operated from -28°C to 50°C
- Components must be stored at 4°C to 45°C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- IAW Critical Reagents Program Limit of Detection (call 410-436-9111)

Maturity gauge:

- Is commercially available and meets military specifications
- Has been featured in peer reviewed scientific publications or independent evaluations



KinExA 3000

by Sapidyne Instruments Inc.

CAPABLE OF DETECTING THE FOLLOWING:

Able to detect any organisms/toxins for which assays can be developed.

DESCRIPTION:

The KinExA (Kinetic Exclusion Assay) 3000 is designed to measure molecular interaction in solution phase. The KinExA is distinct from both competition and sandwich assays, in that it measures directly from a solution the amount of free receptor or antibody. The KinExA 3000 was specifically designed to measure the interaction, equilibrium binding and kinetics, of biomolecule binding partners (most commonly antibody and antigen) without the need to modify either partner. The KinExA has been used for the characterization of antibody/antigen pairs numerous times. The KinExA 3000 has also been used to measure environmental estrogens, organophosphates, and as a biosensor for heavy metal ions in solution. Operation of the KinExA is simple, routine and easily handled by a semi-skilled operator.

TECHNOLOGY:

The KinExA is a general purpose flow fluorometer capable of detecting low concentrations of free antibody or receptor in solution phase. The detection technology is based on capture of the free antibody or receptor on an immobilized ligand column. The immobilized capture reagent is held in a capillary flow cell embedded in a lens and backed by a reflective surface. Excitation and emission collection is via a conventional epi-illumination filter design. As the sample is passed over the capture reagent, free receptor or antibody is captured and subsequently detected with a fluorescently labeled secondary antibody. When functioning to measure equilibrium constants, the equilibrated sample is rapidly passed over the column, limiting the contact time between sample and immobilized ligand. This ensures that the sample equilibrium is not disrupted during measurements. Larger volumes can be accommodated allowing concentration of proteins in dilute samples. This enables the KinExA to have sensitivities in the low pico-molar range for some antibodies. The ability to handle large volumes (more than five mL) could conceivably allow the user to measure extremely dilute samples and still obtain reliable measurements. We routinely measure samples in the low-picomolar concentration range with larger volumes. This could apply to analysis of most any molecule if the proper bio-detection protein could be engineered.

ANALYTICAL Laboratory Ranking

KinExA 3000 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
Best Score	0.901
Sapidyne KinExA 3000	0.361
Lowest Score	0.217

Effectiveness, Biological Agents, Logistics, Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

KinExA 3000 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 54% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Sapidyne KinExA 3000	0.495
Lowest Score	0.321

Effectiveness, Operations, Biological Agents, Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

KinExA 3000 ranked in the bottom third of all evaluated products for mobile laboratories and earned 58% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Sapidyne KinExA 3000	0.515
Lowest Score	0.379

Logistics, Biological Agents, Effectiveness, Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

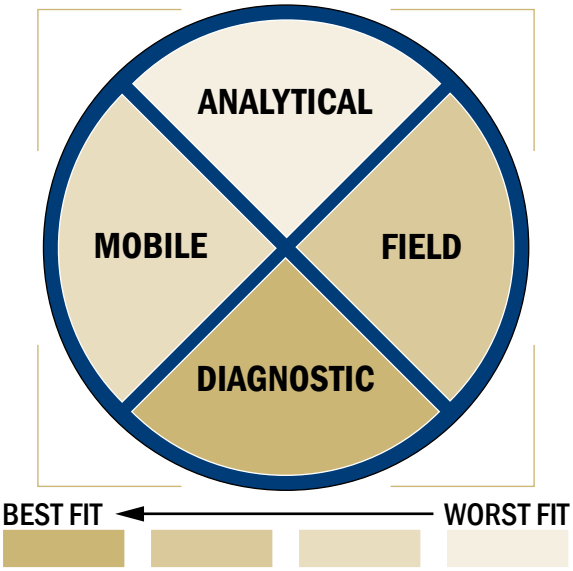
KinExA 3000 ranked in the middle third of all evaluated products for field use and earned 73% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Sapidyne KinExA 3000	0.688
Lowest Score	0.343

Logistics, Operations, Effectiveness, Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

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Point of Contact:
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(208) 345-5251 fax
steve@sapidyne.com, rmark@sapidyne.com

COST

- Unknown/sample
- $78,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection 20 minutes or less
- 2 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:

- A day of training
- Greater than 20 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 3 solutions or buffers used
- 5 or more components
- Requires a buffer rinse between similar samples on the same line, weekly rinse and monthly rinse

Maintenance:

- 5 or more consumables or expendables needed
- Less than once a year service required
- Expected life is greater than 10 years
- No daily quality assurance procedures required

Transportation:

- Approximately the size of a home dishwasher
- Between 25 and 50 kg
- Shelf life unknown

Ease of use/Utility:

- Cannot view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- Not capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

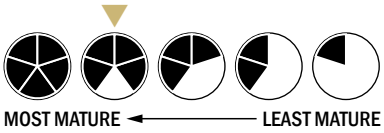
- Operated from 15°C to 37°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- Unknown

Maturity gauge:

- Is commercially available



KinExA Bench Top

by Sapidyne Instruments Inc.

CAPABLE OF DETECTING THE FOLLOWING:

Able to detect any organisms/toxins for which assays can be developed.

DESCRIPTION:

The KinExA (Kinetic Exclusion Assay) technology is a superior method of measuring biological binding interactions. The KinExA is distinct from both competition and sandwich assays, in that it measures directly the free portion of antibody in a sample, while ignoring the complexed portion. This is done without perturbing the mixture, as competition assays do, and will work with small antigens, unlike sandwich assays. The KinExA benchtop instrument was specifically designed to measure the concentration of a ligand in a liquid sample. The focus of the benchtop instrument is to automate the assay steps, thus reducing the skill level needed to perform the assay.

The KinExA technology (using the KinExA 3000 instrument) has been used for the characterization of antibody/antigen pairs numerous times. The KinExA 3000 has also been used to prove the principle of using KinExA technology to measure environmental estrogens, organophosphates, and as a biosensor for heavy metal ions in solution. While the specific assays are not yet developed for the benchtop instrument, proof of principle was completed using the larger and more expensive laboratory version of the KinExA instrument.

TECHNOLOGY:

The KinExA is a method capable of rapidly detecting low concentrations of free antibody or receptor in solution phase. The detection technology is based on capture of the free antibody or receptor on an immobilized ligand column. The immobilized capture reagent is held in a capillary flow cell, embedded in a lens, and backed by a reflective surface. Excitation and emission collection is via a conventional epi-illumination filter design. The high local concentration of ligand in the capture column allows efficient and rapid capture of solution antibody. The concentration of the solution antibody in the small volume of the flow cell, coupled with the extremely efficient optical system design, results in very sensitive detection capabilities. Finally, the kinetic exclusion assay principle avoids the competition inherent in typical small ligand immunoassays. These features combine to create a system with much better performance than current technologies. In a direct comparison to ELISA assays, using the same reagents, an independent researcher found the KinExA technology to be 10 to 1000 times more sensitive, with faster time to results (see Blake, DA et. al (2001) Analytica Chimica Acta; 444, 3-11).

ANALYTICAL Laboratory Ranking

KinExA Benchtop 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
Best Score	0.901
Sapidyne KinExa Bench Top	0.343
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

KinExA Benchtop ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 54% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Sapidyne KinExa Bench Top	0.494
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

KinExA Benchtop 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
Best Score	0.883
Sapidyne KinExa Bench Top	0.485
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

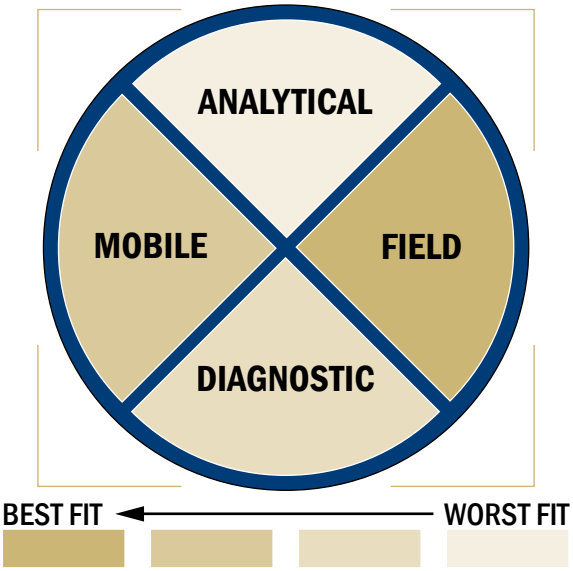
KinExA Benchtop ranked in the middle third of all evaluated products for field use and earned 59% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Sapidyne KinExa Bench Top	0.561
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



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steve@sapidyne.com, rmark@sapidyne.com

COST
- Unknown/sample
- $20,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 1 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- Very brief training
- Less than 5 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 2 solutions or buffers used
- 3 components
- Requires a buffer rinse between similar samples on the same line, weekly rinse and monthly rinse

Maintenance:
- 2 consumables or expendables needed
- More often than every 6 months service required
- Expected life is greater than 10 years
- No daily quality assurance procedures required

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life unknown

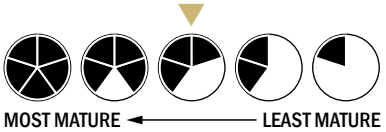
Ease of use/Utility:
- Cannot view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- NA
- Not capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- Components can be stored at 25 °C to 45 °C
- Components must be stored at 4 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- Unknown CFU per ml

Maturity gauge:
- A few devices or systems exist (brass board)



KinExA Handheld

by Sapidyne Instruments Inc.

CAPABLE OF DETECTING THE FOLLOWING:
Able to detect any organisms/toxins for which assays can be developed.

DESCRIPTION:
The KinExA (Kinetic Exclusion Assay) Handheld instrument is currently in development in collaboration with Dr. Diane A. Blake at Tulane University School of Medicine. The handheld is based on the same technology as the KinExA 3000, but in a lightweight, portable format. Developmental experiments using the Handheld are investigating its application for the detection of heavy metals in solution utilizing antibodies developed by Dr. Blake. The beta unit of the handheld is controlled by a hand held computer for ease of transport, field operation, and data transfer.

TECHNOLOGY:
The KinExA handheld is a portable, general-purpose flow fluorometer. The detection technology is based on capture of the free antibody or receptor on an immobilized ligand column. Excitation and emission collection is via a conventional epi-illumination filter design. As the sample is passed over the capture reagent, free receptor or antibody is captured and subsequently detected with a fluorescently labeled secondary antibody.

ANALYTICAL Laboratory Ranking

KinExA Handheld 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
Best Score	0.901
Sapidyne KinExA Field Portable	0.335
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

KinExA Handheld 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
Best Score	0.909
Sapidyne KinExA Field Portable	0.479
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.883
Sapidyne KinExA Field Portable	0.512
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

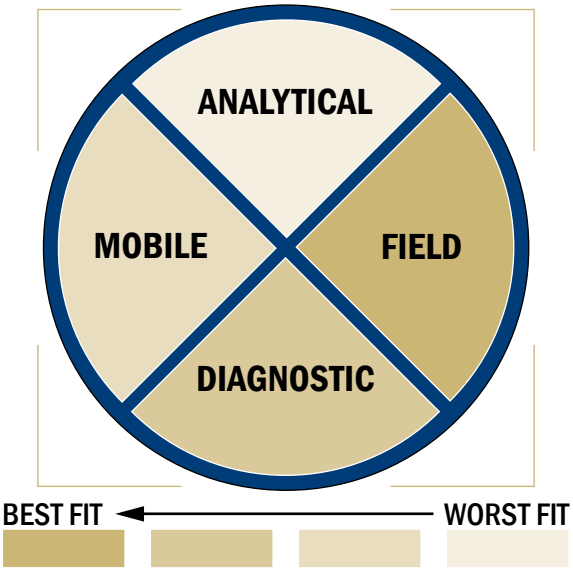
KinExA Handheld ranked in the middle third of all evaluated products for field use and earned 68% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Sapidyne KinExA Field Portable	0.637
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

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COST

- Unknown/sample
- Projected $5,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection 20 minutes or less
- 1 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or approach is not amendable to automation

Training/Speed/Manpower:

- An afternoon of training
- Greater than 20 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 2 solutions or buffers used
- 4 components
- May requires a buffer rinse between similar samples on the same line, weekly rinse and monthly rinse

Maintenance:

- 4 consumables or expendables needed
- Unknown service required
- Expected life unknown
- Unknown daily quality assurance procedures required

Transportation:

- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life unknown

Ease of use/Utility:

- Cannot view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- NA to interpret raw data or call a positive through internal software
- Unknown if assay is capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

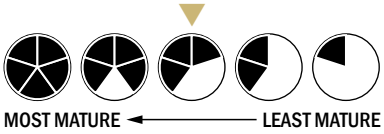
- Operated temperature unknown
- Components must be stored at 4 °C
- Unknown if performance of the device or system is influenced by relative humidity

Sensitivity:

- Unknown CFU per ml

Maturity gauge:

- A few devices or systems exist (brass board)



KinExA In-Line

by Sapidyne Instruments Inc.

CAPABLE OF DETECTING THE FOLLOWING:

Botulinum toxin A, Aflatoxin, Staphylococcal enterotoxin B; Assays could be developed for any pathogen for which an antibody exists.

DESCRIPTION:

The KinExA® In-Line Biosensor is an automated competitive exclusion immunoassay system applicable to a wide variety of matrices. KinExA In-Line technology provides an excellent general purpose platform to exploit the measurement of true binding affinity using unmodified molecules in solution phase to determine the concentration of a sample. This laboratory based fluorescence detector system is used for the measurement of concentration using solution phase binding affinity on unmodified molecules. The sensor can be regenerated in eight min and allows a minimum of 40 repeated readings before human interaction is needed. The fluidics and software allow samples to be obtained from up to eight different sources.

TECHNOLOGY:

The KinExA In-Line Biosensor offers a platform that exploits the measurement of true binding affinity using unmodified molecules in solution phase to determine concentration of the sample. This is accomplished by using a solid phase immobilized molecule to probe for free concentration of one interaction component.

ANALYTICAL Laboratory Ranking

KinExA In-line ranked in the bottom third of all evaluated products for analytical laboratories and earned 45% of the utility points of the best score.

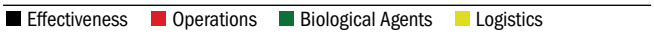
ALTERNATIVE	UTILITY
Best Score	0.901
Sapidyne KinExA In-Line	0.404
Lowest Score	0.217

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

KinExA In-line 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
Best Score	0.909
Sapidyne KinExA In-Line	0.531
Lowest Score	0.321

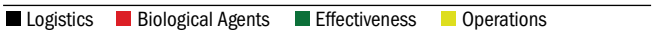


Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

KinExA In-line ranked in the middle third of all evaluated products for mobile laboratories and earned 67% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Sapidyne KinExA In-Line	0.589
Lowest Score	0.379

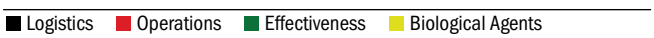


Preference Set: *Mobile Laboratory*

FIELD USE Ranking

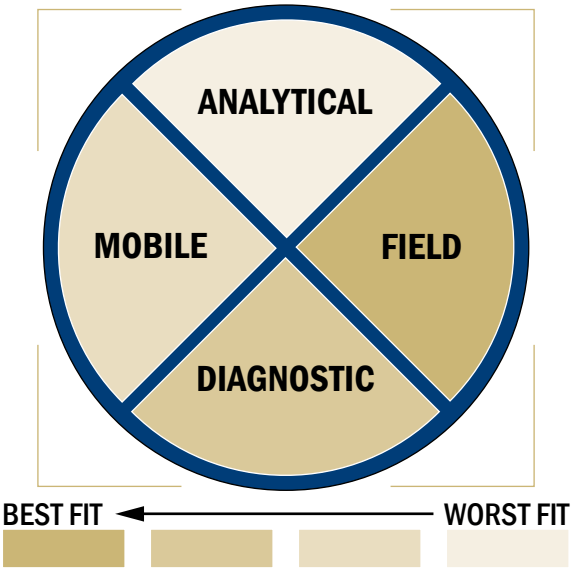
KinExA In-line ranked in the middle third of all evaluated products for field use and earned 68% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Sapidyne KinExA In-Line	0.642
Lowest Score	0.343



Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

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david@sapidyne.com

COST

- $72,000.00

Evaluation Criteria Provided by Vendor

System requirements:

- The system uses both 110V and 220V
- The system does not require water
- The system does not require an external air or gas source
- The system does not require an external vacuum source

Throughput of product:

- Single sample detection 20 minutes or less
- 2 samples/batch or higher
- Greater than 250ul volume needed per test for detection
- The system is fully automated

Training/Speed/Manpower:

- A day of training and technical skills are required
- 5-10 minutes of required for set-up
- 0-2 steps required for detection

Re-use:

- System is intended for multiple use
- 3 solutions or buffers are used
- 1 component
- Self-cleans with buffer

Maintenance:

- The system needs to be serviced once a year
- Expected life of the system is 5-10 years
- 5-10 minutes of daily quality procedures required

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg

Ease of use/Utility:

- Can view “real time” results
- No centrifugation steps are necessary
- There is a single shaking or vortexing step required
- The system can interpret raw data or call a positive through internal software
- The system detects a single agent per reaction
- No additional pieces of equipment are necessary

Signature:

- No sounds produced that cannot be deactivated

Operational conditions:

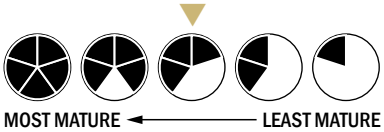
- Can be used from 4° to 45°
- Components must be stored at 4°C
- Performance of system is not influenced by relative humidity

Sensitivity:

- Unknown CFU per ml

Maturity gauge:

- A few devices or systems exist (brass board)



LD 400 Luminescence Detector

by Beckman Coulter, Inc.

CAPABLE OF DETECTING THE FOLLOWING:
Able to detect any organisms/ toxins with any luminescent or colormetric assay with appropriate wavelength range.

DESCRIPTION:
The LD 400 Luminescence Detector is intended to be used primarily for luminescent research applications, but it can also perform photometric measurements as well. Typical assays that can be performed include flash and glow assays, dual luciferase assays, reporter gene and toxicity assays, ATP and biomass assays, DNA assays, cellular function assays and colorimetric immunoassays, such as ELISAs and protein quantification assays. The LD 400 is capable of measuring assays in 96 well plates. The LD 400 can perform measurements in multiple modes including single wavelength, dual wavelength, photometric and luminescent kinetic, and linear scan. Full programming and data analysis are available either through powerful on-board software or via the use of a remote PC and software.

TECHNOLOGY:
The LD 400 Luminescence Detector employs a controlled tungsten halogen lamp as a light source and a photon counting PMT as the detector for measuring light in the 300-700nm (luminescence) and 405–690nm (absorbance) wavelength range. It employs the use of filters to select specific wavelengths to measure, and has a luminescent dynamic range >8 decades. In addition, the LD 400 features programmable shaking and two built-in dispensers for accommodating various types of reactions.

ANALYTICAL Laboratory Ranking

LD 400 Luminescence Detector 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
Best Score	0.901
LD 400 Luminescence Detector	0.362
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

LD 400 Luminescence Detector ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 54% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
LD 400 Luminescence Detector	0.489
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

LD 400 Luminescence Detector 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
Best Score	0.883
LD 400 Luminescence Detector	0.484
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

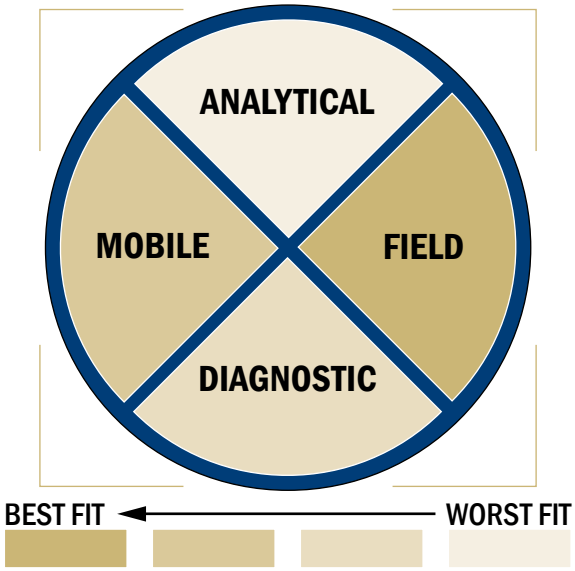
LD 400 Luminescence Detector ranked in the middle third of all evaluated products for field use and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
LD 400 Luminescence Detector	0.722
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Beckman Coulter, Inc.
4300 N. Harbor Blvd. Box 3100
Fullerton, CA 92834
www.beckmancoulter.com

Point of Contact:
Matt Maloney or Margaret Kelly
(317) 808-4217, (714) 773-8022
(714) 773-6690 fax
MJMaloney@beckman.com, mmkelly@beckman.com

COST

- Unknown/sample
- $13,995.00-17,995.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection 20 minutes or less
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a semi-automated system with some effort

Training/Speed/Manpower:

- An afternoon of training
- Less than 5 minutes required for set-up
- 6-8 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- NA solutions or buffers used
- 3 components
- Tubing cleaning required once a week

Maintenance:

- 2 consumables or expendables needed
- Once a year service required
- Expected life is 5-10 years
- No daily quality assurance procedures required

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- NA shelf life

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:

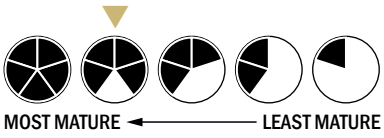
- Operated from 15 °C to 37 °C
- NA storage of components
- Device or system has peak performance at normal relative humidity conditions only

Sensitivity:

- Unknown CFU per ml

Maturity gauge:

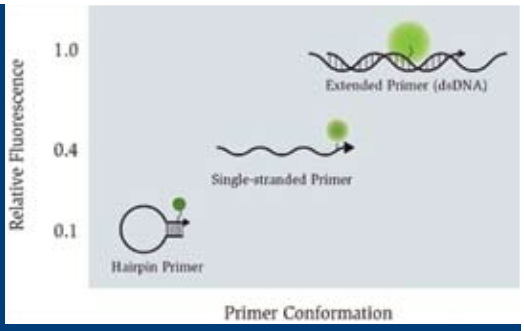
- Is commercially available



Light Upon Extension (LUX™)

by Invitrogen

CAPABLE OF DETECTING THE FOLLOWING:



Bacillus anthracis, Francisella tularensis, Yersinia pestis, Smallpox virus, Orthopox virus, Botulinum toxin B *(Commercially available as a wet/frozen reagent);* Influenza virus *(Assay developed); (Works on any real time PCR thermocycler)*

DESCRIPTION:

Light Upon Extension (LUX™) married with Platinum™ Taq DNA polymerase or Platinum Tfi DNA polymerase (LUX™ assays) represent a low cost, sensitive, specific, probe-less real time PCR solution for the detection of biothreat agents. Key advantages are performance (sensitivity/specificity); cost (significantly reduced cost compared to current assays due to the favorable freedom to operate position for these technologies as owned by Invitrogen), and flexibility (assays can be run on any real time PCR instruments). Unlike many other real-time detection technologies, LUX™ Fluorogenic Primers enable post-amplification melt curve analysis (without any additional manipulation) to confirm amplification of infectious agents. A rapid post-amplification ramping protocol provides melting curve data between two temperature points and the melting curve output provides visual analysis of the amplified PCR product to verify correct sequence amplifications and to discriminate against nonspecific amplification. These LUX™ Fluorogenic Primers provide, with little extra time investment, post-amplification confirmation that the correct pathogen target was amplified – thus eliminating false positive results from non-specific amplification or from external control contamination. There is a considerable amount of data regarding the LUX™ assays and their use in the detection of biothreat agents. Data from one government trial (TRA-04 at Dugway Proving Grounds) and two independent trials (performed by Midwest Research Institute and Battelle Memorial Institute) is available to show the robustness of the approach, as well as excellent sensitivity and reliability of the LUX™ assay system.

TECHNOLOGY:

Each LUX™ primer set includes a single-labeled fluorogenic primer and corresponding unlabeled primer. LUX™ fluorogenic primers are oligonucleotides labeled with a single fluorophore, close to the 3' end in a hairpin structure. The LUX™ Fluorogenic Primer is designed so that the hairpin secondary structure quenches the attached fluorophore. The corresponding unlabeled primer is designed to facilitate sequence-specific amplification of pathogen domains. Upon incorporation into a double-stranded PCR product, the primer releases this secondary structure and the fluorophore is dequenched. The fluorescent signal can be detected by all existing real-time quantitative PCR instrumentation.

ANALYTICAL Laboratory Ranking

Light Upon Extension ranked in the top third of all evaluated products for analytical laboratories and earned 93% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Invitrogen LUX	0.845
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Light Upon Extension ranked in the top third of all evaluated products for diagnostic laboratories and earned 98% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Invitrogen LUX	0.893
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Light Upon Extension ranked in the top third of all evaluated products for mobile laboratories and earned 90% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Invitrogen LUX	0.799
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

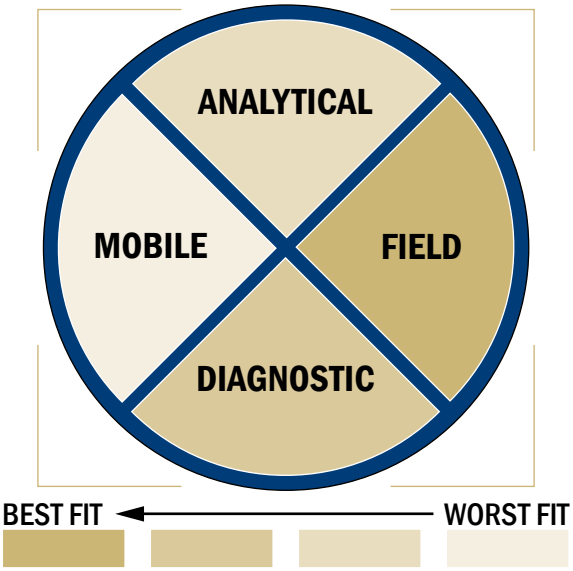
Light Upon Extension ranked in the top third of all evaluated products for field use and earned 100% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Invitrogen LUX	0.943
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Invitrogen Federal Systems
7335 Executive Way
Frederick, MD 21704
http://www.invitrogen.com/content.cfm?pageid=10275

Point of Contact:
Willem Folkerts, Business Director
(240) 379-4209
(240) 379-4750
willem.folkerts@invitrogen.com

COST

- $0.50-3.00/sample

Evaluation Criteria Provided by Vendor

System requirements:
- Dependent on the instrument being used; LUX assay only

Throughput of product:
- Dependent on the instrument being used; LUX assay only

Training/Speed/Manpower:
- Dependent on the instrument being used; LUX assay only

Re-use:
- Device or system is intended for multiple use
- 3 solutions or buffers used
- 3 components
- Dependent on the instrument being used; LUX assay only

Maintenance:
- Dependent on the instrument being used; LUX assay only

Transportation:
- Dependent on the instrument being used; LUX assay only
- Reagents shelf life between 6 months to 1 year

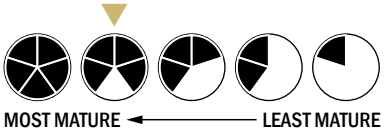
Ease of use/Utility:
- Can view results "in real time"
- Dependent on the instrument being used; LUX assay only

Signature:
- Dependent on the instrument being used; LUX assay only

Operational conditions:
- Dependent on the instrument being used; LUX assay only
- Components must be stored at room temperature or frozen
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

Maturity gauge:
- Is commercially available
- Has been featured in peer reviewed scientific publications or independent evaluations



LightCycler

by Roche Applied Science

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Yersinia pestis, Smallpox virus, Orthopox virus, Botulinum toxin A *(Commercially available as a freeze-dried reagent)*

DESCRIPTION:

The LightCycler is a Real-Time PCR machine used for rapid detection and analysis of DNA and RNA targets. Targets are both detected and quantified within 35 to 40 minutes using the system in a real-time manner without additional down stream analysis. Running gels for confirmatory testing is eliminated due to Melting Curve Analysis which makes it possible to analyze the quality and type of Nucleic acid being detected as compared to controls. PCR detection is very specific using the LightCycler with FRET Probe chemistries. The LightCycler is a flexible instrument with the ability to detect nucleic acids using SYBR Green, Hybridization Probe Chemistry and TaqMan Chemistry. Target detection sensitivity levels are down to 10 starting copies. The LightCycler is used for the detection of Anthrax with the Roche LightCycler-Bacillus anthracis Detection kit or with other anthrax assays. Other uses include the detection of DNA and RNA viruses and the detection of bacteria nucleic acid.

TECHNOLOGY:

The LightCycler uses air for rapid PCR temperature cycling. A heating coil controlled by thermocouples in a single well thermal chamber is used for heating. Cooling is accomplished by using a fan system to eject hot air and bring ambient air into the thermal chamber. The design ensures a programmed temperature accuracy of 0.3°C with temperature ramping rates of 20°C per second. Amplification cycles take a little as 30 seconds per cycle. PCR reactions take place in specially designed borosilicate glass capillaries, which hold up to 20ul of sample. The capillaries have a high surface to volume ratio for rapid sample heating and cooling. Detection of specific Nucleic Acid sequences is achieved using FRET Probe chemistry, either Hybridization Probe chemistry or TaqMan chemistry. The PCR products are detected using an optical system with three filters. All three filter channels are recorded during each run. The Excitation of the chemical dyes is achieved by using a Blue Light LED. Qualitative analysis of PCR products is possible using a unique feature called Melting Curve Analysis (MCA). All PCR products have a specific Tm (melting point) by which they can be identified. Small differences in Tm are easily determined using MCA. This allows a sample to be analyzed for small genetic variations such as point mutations, for a more specific genetic analysis of the target sample. Results are available on a computer and analysis takes as little as one minute. Positive results can be achieved from samples with as little as 10 copies of target nucleic acid.

ANALYTICAL Laboratory Ranking

LightCycler ranked in the highest third of all evaluated products for analytical laboratories and earned 91% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
LightCycler PCR	0.821
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

LightCycler ranked in the highest third of all evaluated products for diagnostic laboratories and earned 92% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
LightCycler PCR	0.834
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

LightCycler ranked in the highest third of all evaluated products for mobile laboratories and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
LightCycler PCR	0.740
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

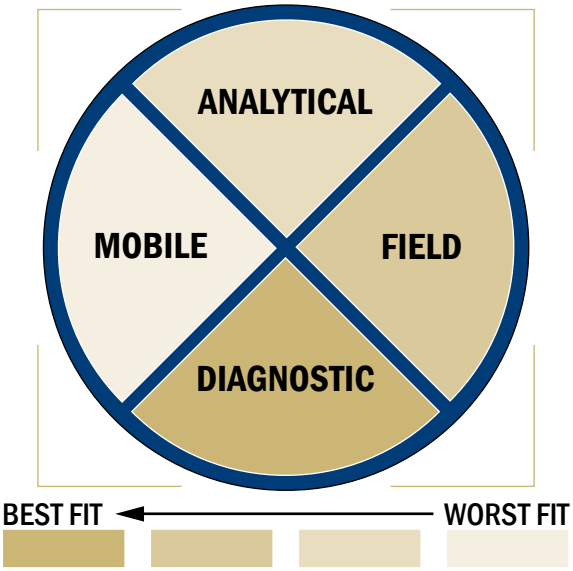
LightCycler ranked in the highest third of all evaluated products for field use and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
LightCycler PCR	0.792
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Roche Applied Science
9115 Hague Rd., P.O. Box 50414
Indianapolis, IN 46250-0141
www.roche-applied-science.com

Point of Contact:
Mary Pingitore
(800) 845-7355 x8015
(301) 482-1315 fax
mary.pingitore@roche.com

COST

- $2.38/sample
- $53,500.00 GSA, $57,500.00 non-GSA price/ system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection between 30 and 40 minutes
- 32 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could be adapted to a fully automated system with some effort

Training/Speed/Manpower:

- An afternoon of training
- Less than 5 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 3 solutions or buffers used
- 3 components
- No cleaning required

Maintenance:

- 2 consumables or expendables needed
- Less than once a year service required
- Expected life is 5-10 years
- Less than 5 minutes required for daily assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility:

- Can view results “in real time”
- Single centrifugation step required
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:

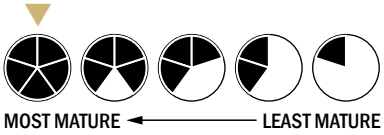
- Operated from 15 °C to 37 °C
- Components must be frozen
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- Is commercially available and meets military specifications



LightTyper Thermocycler

by Roche Applied Science

CAPABLE OF DETECTING THE FOLLOWING:

Able to detect any organisms/toxins for which assays can be developed.

DESCRIPTION:

The LightTyper is a high through-put Genetic Analysis System which uses Melting Curve Analysis to identify and genotype Genetic Sequences in PCR reactions. PCR reactions are preformed on a traditional block style thermal cycler in either a 96 or 384 well format. Fluorescent probes are included in the PCR reaction. After PCR is completed, the PCR sample trays are placed into the LightTyper. In eight minutes the samples are melted and fluorescent data collected from all samples. Data analysis can be conducted on the computer or data can be down loaded to a LIMS system. Data Analysis using the Call-It software will make allele calls for each sample. Samples are identified by their Melting Temperature (Tm).

TECHNOLOGY:

The LightTyper uses a CCD camera and an LED light source of 470nm which makes this a robust system. There are two long filters of 510nm and 600nm. The Temperature dynamic range is 40 to 98°C. The temperature ramp rate is 0.5 – 0.20°C. Run times range from six to 15 minutes. Images are acquired at 0.4 to 10 acquisitions/second. Thermal uniformity is 0.4°C. Two fluorescent chemistries can be used on the LightTyper; the Hybridization Probe chemistry and the Single Probe chemistry. Software is included with the system for Probe and PCR primer design for both chemistries. The Hybridization Probe chemistry is a well known FRET chemistry which uses two fluorescent dyes and two oligo probes which must hybridize on the DNA sequence of interest for detection. The Single Probe chemistry uses a probe, which consists of one oligo with a linker and attached fluorescent dye. When the probe is bound to the DNA target sequence it will fluoresce. When unbound (melted) the probe does not fluoresce. The change in fluorescence in a sample is the basis of the identification of the PCR sample for both chemistries.

Melting Curve fluorescent profiles are collected for all samples and converted to melting peaks using the Analysis Software. The Tm for the peaks is used to make sample identification calls. The calls can be made automatically by the software. Autodetection of probe Tm shifts can be done for shifts of 2.0°C or greater. Applications for the system include Sequence Identification, SNP (Single Nucleotide Polymorphisms) Analysis, small deletion and insertion mutation analysis. For sample tracking a bar-code reader is included. Other items included are a Pentium 4 computer with 1.8 GHZ, 512 MB DDR, 40GB HD, CDRW and 17 inch flat screen monitor. Color Printer also included. The system is LIMS ready.

ANALYTICAL Laboratory Ranking

LightTyper ranked in the highest third of all evaluated products for analytical laboratories and earned 72% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
LightTyper	0.650
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

LightTyper ranked in the highest third of all evaluated products for diagnostic laboratories and earned 85% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
LightTyper	0.773
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

LightTyper ranked in the middle third of all evaluated products for mobile laboratories and earned 64% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
LightTyper	0.567
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

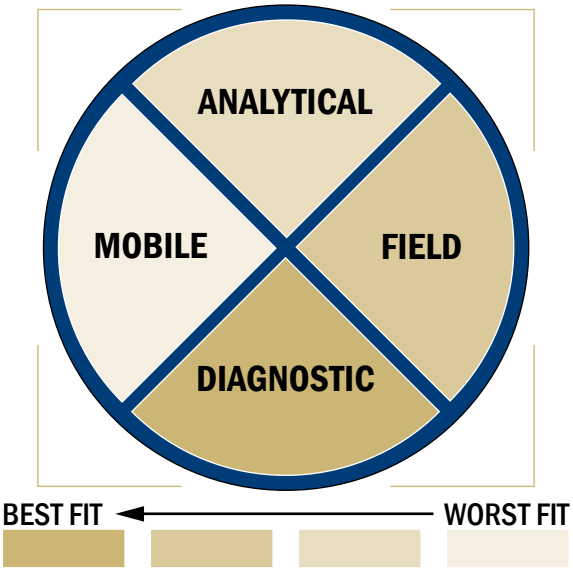
LightTyper ranked in the highest third of all evaluated products for field use and earned 85% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
LightTyper	0.800
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Roche Applied Science
9115 Hague Rd., P.O. Box 50414
Indianapolis, IN 46250-0141
www.roche-applied-science.com

Point of Contact:
Mary Pingitore or Dawn Coster
(800) 845-7355 x8015 or x8047
(301) 482-1315 fax
mary.pingitore@roche.com, dawn.coster@roche.com

COST

- less than $0.50/sample plus cost of Taq enzyme
- $45,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection 20 minutes or less
- 96 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted to a fully automated system

Training/Speed/Manpower:

- Very brief training
- Less than 5 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 3 solutions or buffers used
- 2 components
- No cleaning required

Maintenance:

- 2 consumables or expendables needed
- Once a year service required
- Expected life is 5-10 years
- Less than 5 minutes required for daily assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 1 and 3 years

Ease of use/Utility:

- Cannot view results “in real time”
- Single centrifugation step required
- No shaking or vortexing steps
- System is sometimes able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:

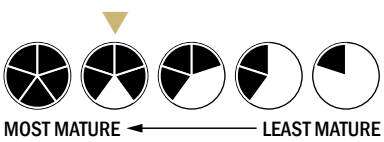
- Operated from 15 °C to 37 °C
- Components can be stored at 4 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- Is commercially available

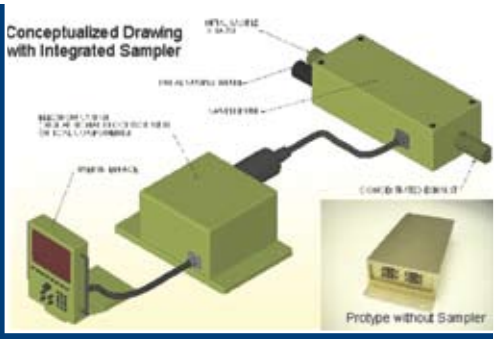


Lunascan Biodetection System

by Luna Innovations

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus globigii, MS-2 bacteriophage, Ovalbumin *(Assays developed)*



DESCRIPTION:

The Lunascan Biodetection system is a multi-platform measurement device that will reduce false-positives through independent, confirmation of binding events. Requiring multiple platforms to simultaneously return a positive response before triggering a detection warning will address background interference effects that may be more prevalent for a particular detection technique. The Lunascan Biodetection system is based upon optical fiber technology licensed from Lucent Technologies and patented by Luna Innovations. The detection system has been designed to integrate with field portable instrumentation and be capable of detecting multiple agents in soil, water, biological fluids, or air. Tests are currently performed in a semi-automated process with results available in less than ten minutes. Results have been recorded for simulants including BG, ovalbumin, and MS2.

TECHNOLOGY:

The Lunascan platform utilizes direct detection optical fiber technology coupled with fluorescence detection to determine the presence of biological warfare agents. Optical fiber sensors are ideal for field portable applications because they are small, lightweight, and rugged. Specifically, the system works by binding a target to an affinity film that has been coated to the fiber surface. Luna systems have been flight qualified and initial performance demonstrated using biological simulants such as BG, MS2, and ovalbumin. For direct detection, patented long-period grating (LPG) technology is used. The LPG is a spectral loss element that scatters light out of an optical fiber at a particular wavelength based in part on the refractive index of the surrounding environment. Therefore, the technique is not based on spectroscopy or absorption and is immune to background fluorescent effects. LPG-based biological sensors operate with specially designed affinity films that cause selective, quantitative changes in the refractive index 'seen' by the LPG in the presence of target molecules. As the coating absorbs target molecules the refractive index changes, causing a shift in the wavelength of the scattered light. This wavelength change is demodulated to determine target concentration enabling real-time monitoring of environmental conditions. The LPG sensor can be packaged with fluorescent probes to demonstrate orthogonal detection. The fluorescent probe is also based on optical fibers and uses a tag coupled to a target captured on an affinity film on the fiber surface. Light from the optical fiber excites the tag, which fluoresces. The resulting light is then captured and the intensity measured to determine concentration. Results of detection will be produced within 10 minutes for multiple targets. Audio and visual alarms can be provided.

ANALYTICAL Laboratory Ranking

Lunascan Biodetection 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
Best Score	0.901
Lunascan Biodetection Sys.	0.488
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Lunascan Biodetection System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 66% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Lunascan Biodetection Sys.	0.597
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Lunascan Biodetection System ranked in the middle third of all evaluated products for mobile laboratories and earned 61% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Lunascan Biodetection Sys.	0.541
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

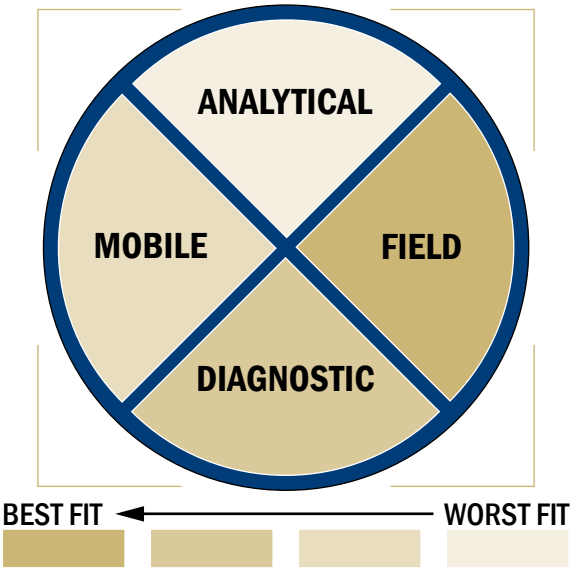
Lunascan Biodetection System ranked in the middle third of all evaluated products for field use and earned 62% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Lunascan Biodetection Sys.	0.587
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Luna Innovations
2851 Commerce Street
Blacksburg, VA 24060
www.lunainnovations.com

Point of Contact:
Ben Plowman
(770) 315-3115
(540) 961-0760 fax
plowmanb@lunainnovations.com

COST

- Approx. $3.00/sample
- $60,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 2 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- A day of training
- 10-20 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 3 solutions or buffers used
- 3 components
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Less than once a year service required
- NA expected life
- 5-10 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 1 and 3 years

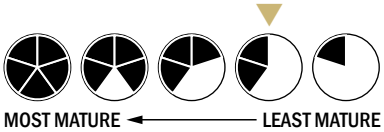
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- Sounds are produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 4 °C to 45 °C
- Components must be stored at 4 °C and at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 10,000-100,000 CFU per ml

Maturity gauge:
- Only one incomplete device or system exists (bread board)



M Series M1M

by BioVeris Corp.

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Yersinia pestis, Smallpox virus, Orthopox virus, Botulinum toxins A, B, E, Ricin, SEB *(Commercially available as a freeze-dried reagent)*; E. coli O157:H7 *(Commercially available as wet/frozen reagent and through the DoD's Critical Reagents Program)*

DESCRIPTION:

The M1M is an automated analyzer designed for use with BV™ reagents. This system provides sample handling, detection based upon BioVeris™ (BV) Technology, electrochemiluminescence, and analysis in a 96-well microplate or minitube format. This system is designed for the detection of multiple analytes, from small molecules, to proteins, to microorganisms, in a wide variety of matrices. The system processes a single sample in about one minute and an entire plate in approximately 90 minutes. It can also run a partial or an entire microplate in a single or multi-test mode. The instrument automatically performs a system check to ensure proper system operation on start-up. The system also checks for reagent type and reagent usage to ensure adequate supply and proper system function. The system also has the capability to dispense reagents into sample tubes or wells. An intuitive graphical software interface provides wizards to assist with plate set-up, allows for use of pre-set protocols or user determined protocols, and real-time updates of system output and data review. This system has been designed to meet applicable requirements of MIL-STD 810F.

TECHNOLOGY:

BV Technology uses a paramagnetic microparticle as the solid support for formation of a reaction. Multiple compounds can be labeled with BV-TAG™, the product name for ruthenium (II) tris-bipyridine. Using a variety of linking chemistries, the ruthenium molecule can be directly bound to proteins, thiols, oligonucleotides, carbohydrates, and carboxyl groups using a simple labeling and purification procedure. For BV technology, ruthenium serves as the detector molecule for the system. At the core of the instrument system is a flow cell designed to measure the amount of ruthenium bound to the paramagenetic microparticles through a chemical reaction known as electrochemiluminescence. When the reaction mixture enters the flow cell, a magnet captures the microparticles on the surface of an electrode. Any components of the assay or sample that are not bound specifically to the microparticles through the assay component interactions continue past the electrode and exit the system as part of the waste stream. BV-TAG labeled species on the microparticles are detected by introducing tripropylamine (TPA) to the flow cell, applying an oxidizing potential at the electrode and measuring the integrated intensity of the emitted light. The flow cell is then washed with a cleaning solution and prepared for the next sample. For the electrochemiluminescent reaction, the system uses two bulk reagent solutions that enter the flow cell via bulk solution containers attached directly to the instrument system. The first bulk reagent, known as BV Assay Buffer contains TPA that is used in the electrochemiluminescent reaction process. The second bulk reagent is BV Cell Cleaner that is used by the system to remove the previous reaction from the flow cell in preparation for receipt of the next sample.

ANALYTICAL Laboratory Ranking

M Series M1M ranked in the highest third of all evaluated products for analytical laboratories and earned 81% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
BioVeris M1M	0.726
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

M Series M1M ranked in the highest third of all evaluated products for diagnostic laboratories and earned 92% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
BioVeris M1M	0.837
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

M Series M1M ranked in the highest third of all evaluated products for mobile laboratories and earned 89% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
BioVeris M1M	0.782
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

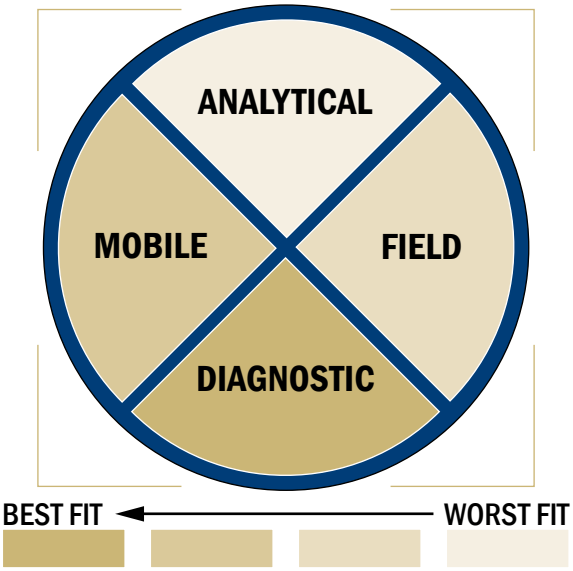
M Series M1M ranked in the highest third of all evaluated products for field use and earned 85% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
BioVeris M1M	0.805
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

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www.bioveris.com

Point of Contact:
Jill White
(301) 869-9800
(240) 632-2206 fax
jwhite@bioveris.com

COST

- $5.63/sample
- $2,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in between 20-30 min
- 32 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 min required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 3 solutions or buffers used
- 1 component
- A decontamination protocol is required for use one time per week

Maintenance:
- 0-1 consumable or expendable needed
- Needs service once a year
- Expected system or device life of 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 1-3 years

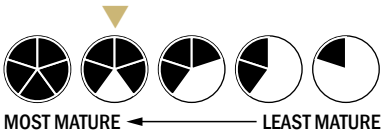
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System is able to interpret raw data or call a positive through internal software
- Multiplex assay not available
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4 °C to 37 °C
- Components can be stored at room temperature
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1,000 CFU per ml

Maturity gauge:
- Is commercially available



M SERIES M1R

by BioVeris Corp.

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, E. coli 0157: H7, Botulinum toxins A, B, E, SEB, Ricin *(Commercially available as wet/frozen reagent)*; Francisella tularensis, Yersinia pestis, Orthopox virus, Smallpox virus *(Commercially available as a freeze-dried reagent)*

DESCRIPTION:

The M1R is an automated analyzer designed for use with BV™ reagents. This system provides sample handling, detection based upon BioVeris™ (BV) Technology, electrochemiluminescence, and analysis in a 96-well microplate format. This system is designed for the detection of multiple analytes, from small molecules, to proteins, to microorganisms, in a wide variety of matrices. The system processes a single sample in about one minute and an entire plate in approximately 90 minutes. It can also run a partial or an entire microplate in a single or multi-test mode. The instrument automatically performs a system check to ensure proper system operation on start-up. The system also checks for reagent type and reagent usage to ensure adequate supply and proper system function. An intuitive graphical software interface provides wizards to assist with plate set-up, allows for use of pre-set protocols or user determined protocols, and real-time updates of system output and data review.

TECHNOLOGY:

BV Technology uses a paramagnetic microparticle as the solid support for formation of a reaction. Multiple compounds can be labeled with BV-TAG™, the product name for ruthenium (II) tris-bipyridine. Using a variety of linking chemistries, the ruthenium molecule can be directly bound to proteins, thiols, oligonucleotides, carbohydrates, and carboxyl groups using a simple labeling and purification procedure. For BV technology, ruthenium serves as the detector molecule for the system. At the core of the instrument system is a flow cell designed to measure the amount of ruthenium bound to the paramagenetic microparticles through a chemical reaction known as electrochemiluminescence. When the reaction mixture enters the flow cell, a magnet captures the microparticles on the surface of an electrode. Any components of the assay or sample that are not bound specifically to the microparticles through the assay component interactions continue past the electrode and exit the system as part of the waste stream. BV-TAG labeled species on the microparticles are detected by introducing tripropylamine (TPA) to the flow cell, applying an oxidizing potential at the electrode and measuring the integrated intensity of the emitted light. The flow cell is then washed with a cleaning solution and prepared for the next sample. For the electrochemiluminescent reaction, the system uses two bulk reagent solutions that enter the flow cell via bulk solution containers attached directly to the instrument system. The first bulk reagent, known as BV Assay Buffer contains TPA that is used in the electrochemiluminescent reaction process. The second bulk reagent is BV Cell Cleaner that is used by the system to remove the previous reaction from the flow cell in preparation for receipt of the next sample.

ANALYTICAL Laboratory Ranking

M Series M1R ranked in the highest third of all evaluated products for analytical laboratories and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
BioVeris M1R	0.718
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

M Series M1R ranked in the highest third of all evaluated products for diagnostic laboratories and earned 91% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
BioVeris M1R	0.828
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

M Series M1R ranked in the highest third of all evaluated products for mobile laboratories and earned 88% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
BioVeris M1R	0.775
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

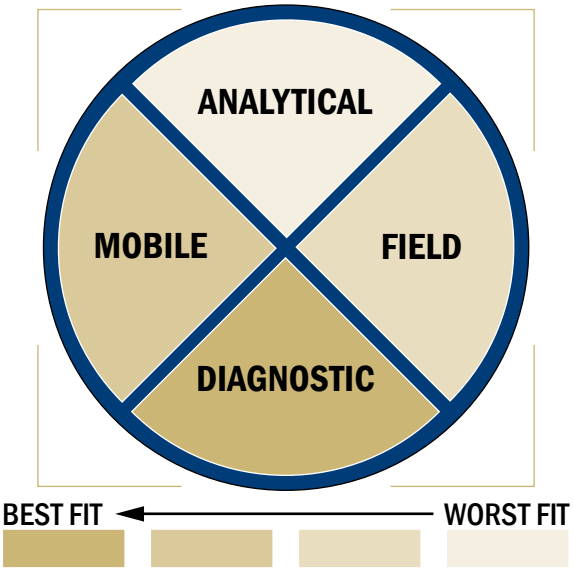
M Series M1R ranked in the highest third of all evaluated products for field use and earned 83% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
BioVeris M1R	0.778
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

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Gaithersburg, MD 20877
www.bioveris.com

Point of Contact:
Jill White
(301) 869-9800
(240) 632-2206 fax
jwhite@bioveris.com

COST

- $5.63/sample
- $<50,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection between 20 and 30 minutes
- 32 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:

- An afternoon of training
- 10-20 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 3 solutions or buffers used
- 1 component
- A decontamination protocol is required for use one time per week

Maintenance:

- 0-1 consumable or expendable needed
- Once a year service required
- Expected life is 5-10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 1 and 3 years

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

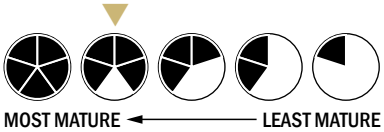
- Operated from 15 °C to 37 °C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- 100-1,000 CFU per ml

Maturity gauge:

- Is commercially available



M SERIES M384

by BioVeris Corp.

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, E. coli 0157:H7, Botulinum toxins A, B, E, SEB, Ricin *(Commercially available as wet/frozen reagent)*; Francisella tularensis, Yersinia pestis, Orthopox virus, Smallpox virus *(Commercially available as a freeze-dried reagent)*

DESCRIPTION:

The M384 is an automated analyzer designed for use with BV™ reagents. This system provides sample handling, detection based upon BioVeris™ (BV) Technology, electrochemiluminescence, and analysis in a 96- or 384-well microplate format. This system is designed for the detection of multiple analytes, from small molecules, to proteins, to microorganisms, in a wide variety of matrices. The system processes a single sample in about one minute and an entire plate in approximately 12 minutes. It can also run a partial or an entire microplate in a single or multi-test mode. The instrument automatically performs a system check to ensure proper system operation on start-up. The system also checks for reagent type and reagent usage to ensure adequate supply and proper system function. An intuitive graphical software interface provides wizards to assist with plate set-up, allows for use of pre-set protocols or user determined protocols, and real-time updates of system output and data review.

TECHNOLOGY:

BV Technology uses a paramagnetic microparticle as the solid support for formation of a reaction. Multiple compounds can be labeled with BV-TAG™, the product name for ruthenium (II) tris-bipyridine. Using a variety of linking chemistries, the ruthenium molecule can be directly bound to proteins, thiols, oligonucleotides, carbohydrates, and carboxyl groups using a simple labeling and purification procedure. For BV technology, ruthenium serves as the detector molecule for the system. At the core of the instrument system is a flow cell designed to measure the amount of ruthenium bound to the paramagenetic microparticles through a chemical reaction known as electrochemiluminescence. When the reaction mixture enters the flow cell, a magnet captures the microparticles on the surface of an electrode. Any components of the assay or sample that are not bound specifically to the microparticles through the assay component interactions continue past the electrode and exit the system as part of the waste stream. BV-TAG labeled species on the microparticles are detected by introducing tripropylamine (TPA) to the flow cell, applying an oxidizing potential at the electrode and measuring the integrated intensity of the emitted light. The flow cell is then washed with a cleaning solution and prepared for the next sample. For the electrochemiluminescent reaction, the system uses two bulk reagent solutions that enter the flow cell via bulk solution containers attached directly to the instrument system. The first bulk reagent, known as BV Assay Buffer contains TPA that is used in the electrochemiluminescent reaction process. The second bulk reagent is BV Cell Cleaner that is used by the system to remove the previous reaction from the flow cell in preparation for receipt of the next sample.

ANALYTICAL Laboratory Ranking

M Series M384 ranked in the highest third of all evaluated products for analytical laboratories and earned 79% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
BioVeris M384	0.715
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

M Series M384 ranked in the highest third of all evaluated products for diagnostic laboratories and earned 90% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
BioVeris M384	0.814
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

M Series M384 ranked in the highest third of all evaluated products for mobile laboratories and earned 73% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
BioVeris M384	0.646
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

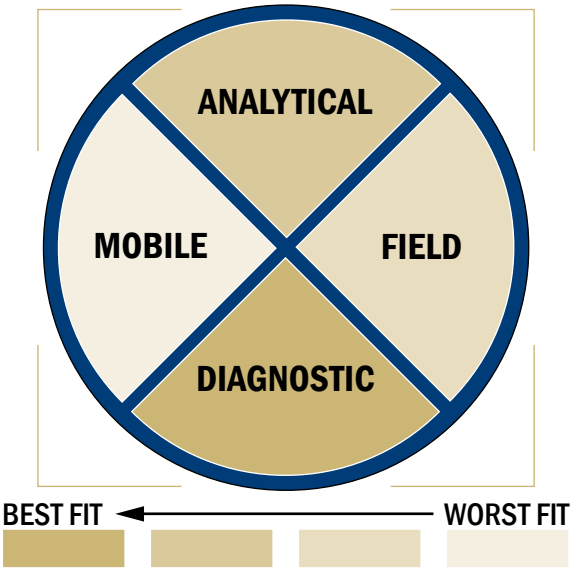
M Series M384 ranked in the middle third of all evaluated products for field use and earned 70% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
BioVeris M384	0.661
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

BioVeris Corporation
16020 Industrial Drive
Gaithersburg, MD 20877
www.bioveris.com

Point of Contact:
Jill White
(301) 869-9800
(240) 632-2206 fax
jwhite@bioveris.com

COST

- $4.75/sample wet frozen assay
- $<95,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 20 and 30 minutes
- 384 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- A day of training
- 10-20 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 3 solutions or buffers used
- 1 component
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- Every 6 months service required
- Expected life is 5-10 years
- 5-10 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- More than 50 kg
- Shelf life between 1 and 3 years

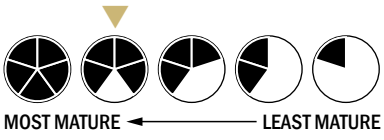
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- Single shaking or vortexing step
- System is able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 25 °C to 37 °C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1,000 CFU per ml

Maturity gauge:
- Is commercially available



MAGIChip

by Johns Hopkins University Applied Physics Laboratory

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Yersinia pestis, E. coli 0157: H7, Vibrio cholera, Corynebacterium diptheria, Burkholderia mallei, Burkholderia pseudomallei, Coxiella burnetti, Rickettsia prowazekii, Brucella species *(Assays developed)*

DESCRIPTION:

The technology described here is not a PCR system but an alternative approach to multiplexed bacterial identification. A bacterial biochip prototype has been developed to address these issues. The prototype consists of a microarray based on ribosomal sequences. Multiple probes are developed for unique areas of both 16S and 23S ribosomal sequences in order to discriminate bacteria not only at the genus and species level, but using all levels of the phylogenetic tree. This redundancy provides a greater degree of confidence in the identification as the correct pathway to an identification must be consistent throughout the analysis. For example, if an unknown and unculturable microorganism presented to the biochip has a low G/C content or is not gram positive, it is not possible to be misidentified as Bacillus anthracis even though the unknown may have some sequence similarity to specific Bacillus anthracis probes. In addition, the assay described herein is rapid and has a low possibility of artifactual results due to sample manipulations following extraction. Since ribosomal RNA is present in many copies per bacterial cell, PCR is not necessary to amplify the signal output. As all live cells and spores have ribosomal RNA, there is always a detectable signal. This is unlike PCR where identifications are often made by absence of signal. If the sequence is not present in the genome of the bacteria undergoing PCR, the signal is negative, leaving the investigator to determine whether matrix effects could have interfered with the reaction or whether the sample is a true negative. Finally, and perhaps most important in any new technology, the biochip format is extremely amenable to integration with current gold standard methods such as PCR or immunological assays. The current biochip has been developed for the identification of Bacillus species.

TECHNOLOGY:

MAGIChip microarray technology discriminates microorganisms from Kingdom to the species level based on single polymorphism nucleotide detection using ribosomal RNA. An adaptation of this approach also discriminates live versus dead bacterial and fungal agents. MAGIChip technology encompasses all steps from colony to signal readout and interpretation. This approach is rapid (under 1-2 hours), robust (portable, enzyme independent) and reusable (20-50 times, thus lowering costs). The current portable reader is small, lightweight and relatively inexpensive. Each reader is composed of a laser light source for illumination of the target molecules and a computer-controlled CCD camera for recording signal output. After the initial step, all the steps in the isolation, purification and labeling of material are performed in a single column. The preparation of sample is chemically based, not enzymatically based. User confidence measures have been added and additional measures are under advanced development for individual sample quality control. This technology has been developed for identification of Bacillus anthracis and can be developed for additional microbial targets including viruses (orthopox family completed). MAGIChip technology will enhance and harmonize with existing PCR based identification technology. A centralized secure database and collating tools are under advanced development as part of this effort.

ANALYTICAL Laboratory Ranking

MAGIChip ranked in the lowest third of all evaluated products for analytical laboratories and earned 38% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
MAGIChip	0.346
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

MAGIChip ranked in the lowest third of all evaluated products for diagnostic laboratories and earned 35% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
MAGIChip	0.321
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

MAGIChip ranked in the lowest third of all evaluated products for mobile laboratories and earned 43% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
MAGIChip	0.379
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

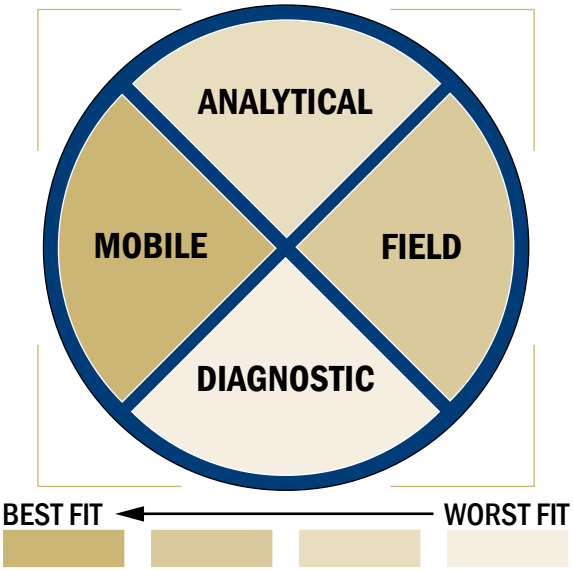
MAGIChip ranked in the lowest third of all evaluated products for field use and earned 42% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
MAGIChip	0.395
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
Johns Hopkins University Applied Physics Laboratory
11100 Johns Hopkins Rd., MS 2-217
Laurel, MD 20723

Point of Contact:
Joany Jackman
(443) 778-8501
(443) 778-6904 fax
Joany5@aol.com

COST
- $1.00-1.50/sample based on reuse of chips
- $20,000.00-25,000.00/portable reader
- Approx. $50.00/chip in batches of 1000

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement or can use batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 2 samples/batch or higher
- NA volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- A day of training
- Less than 5 minutes required for set-up
- Greater than 12 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 4 solutions or buffers used
- 3 components
- No cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- Unknown service required
- Expected life is 3-5 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Unknown shelf life

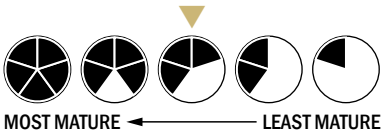
Ease of use/Utility:
- Cannot view results “in real time”
- Multiple centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- Sounds are produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Unknown operational conditions
- Unknown components storage
- Performance of the device or system is unknown at relative humidity

Sensitivity:
- Unknown CFU per ml

Maturity gauge:
- A few devices or systems exist (brass board)



MAPP-DS

by Invitrogen

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Yersinia pestis, Botulinum toxin A, Botulinum toxin B, Staphylococcal toxin B, Ricin toxin *(Assay developed)*

DESCRIPTION:
Under contract to the Defense Threat Reduction Agency (DTRA), Invitrogen Federal Systems has developed a multiplex array-based portable detector utilizing novel microfluidics and Resonance Light Scattering (RLS) based detection chemistry. RLS is an ultra-sensitive signal generation and detection technology based on nanometer-sized colloidal metal particles (RLS Particles) that can be used as labels for a wide variety of analytical bioassays. This MAPP-DS can multiplex six agents currently with the ability to increase to 50+ targets, in multiple matrices - clinical and environmental samples. It is fast – currently 20 to 40 minutes, less than 20 minutes expected in commercial product, blending high specificity and high sensitivity (based on RLS and antibody optimization). The MAPP-DS is easy to use, small (< 20lbs – portable) and ruggedized with on board software and minimal logistics. The workflow is simple and includes the following steps: filtration of the sample (note - future development will include integrated sample preparation); insertion of the array based microfluidic flow cell into the instrument; insertion of self contained reagent pack; injection of the sample; read the results in real time. Ten prototype units have been manufactured and are in the process of being validated. Commercialization of the system is planned in 2007/2008.

TECHNOLOGY:
Resonance Light Scattering (RLS) is an ultra-sensitive signal generation technology based on nanometer-sized colloidal metal particles. When illuminated with simple white light, RLS particles of uniform dimension generate an intense scattered light signal, the color and intensity of which are predictable from particle size, shape, and composition. Signal intensity is up to one million times greater than fluorescent dyes. The advantages of RLS based assays are (1) Sensitivity (> than fluorescence); (2) Stability (no photobleaching); (3) Archiving (permanent record); (4) Flexibility (conjugation to multiple molecules); (5) Simplicity (simple low cost, low power, white light illumination); (6) Manufacturability (established history).

ANALYTICAL Laboratory Ranking

MAPP-DS ranked in the highest third of all evaluated products for analytical laboratories and earned 70% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Invitrogen MAPP-DS	0.635
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations
Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

MAPP-DS ranked in the highest third of all evaluated products for diagnostic laboratories and earned 81% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Invitrogen MAPP-DS	0.738
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics
Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

MAPP-DS ranked in the highest third of all evaluated products for mobile laboratories and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Invitrogen MAPP-DS	0.678
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations
Preference Set: *Mobile Laboratory*

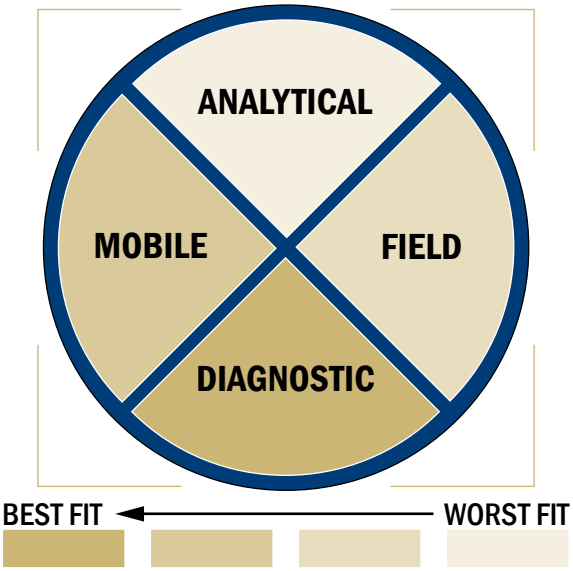
FIELD USE Ranking

MAPP-DS ranked in the highest third of all evaluated products for field use and earned 75% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Invitrogen MAPP-DS	0.706
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents
Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Invitrogen Federal Systems
7335 Executive Way
Frederick, MD 21704
http://www.invitrogen.com

Point of Contact:
Willem Folkerts, Business Director
(240) 379-4209
(240) 379-4750
willem.folkerts@invitrogen.com

COST

- $0.50-3.00/sample

Evaluation Criteria Provided by Vendor

System requirements:

- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection in 20 minutes or less
- 1 sample/batch
- Less than 100 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes set-up required
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 1 component
- Simple cleaning cycle using a single reagent pack is recommended after five assays.

Maintenance:

- Every 6 months service required
- Expected life is between 5-10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a toaster
- Between 5 and 25 kg
- Reagent shelf life between 6 months and 1 year

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

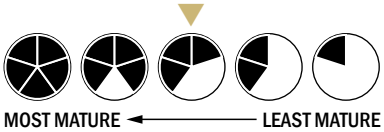
- Operated from 4°C to 45°C
- Components must be stored at 4°C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1,000-10,000 CFU per ml

Maturity gauge:

- A few devices or systems exist (brass board)
- Is expected to be ready for commercialization within one calendar year
- Less than $1,000,000 required to advance device or system to commercialization
- Has not been featured in any peer reviewed scientific publications or independent evaluations



MAR-Magnetic Assay Reader

by Quantum Design

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, E. coli 0157:H7, Orthopox virus, SEB *(assays developed)*

DESCRIPTION:
The Magnetic Assay Reader (MAR) is an innovative, patented platform capable of performing a wide range of biochemical assays in the fields of medical diagnostics, chemical and biological warfare agents, and research. The MAR provides quantitative results via the detection of superparamagnetic particles (used as labels) which are bound to the analyte. Used in this manner, magnetic particle detection offers the benefits of sensitivity, speed and low cost. Additionally, its' portability opens the avenues to convenient field and point of care testing.

TECHNOLOGY:
The MAR measures the amount of magnetic material bound to the analyte and localized in the analytical region. Three basic subsystems are employed in this detection system. A ferrite core electromagnet drives the oscillating magnetic field used to excite the paramagnetic particles to saturation, thereby ensuring maximum signal. Detection is performed by way of a mutual induction technique. The detector measures the local magnetic field expressed by the total mass of iron (as Fe3O4) in the sample. Then by way of an empirically established calibration curve, this value may be corrected to the number of molecules of analyte. Consisting of electronics, hardware and software, this subsystem provides a user-friendly interface and digital readout of data in standard ASCII files. The MAR is uniquely suited to a wide range of point-of-care applications in the fields of medical diagnostics, food and environmental monitoring, and battlefield detection of chemical and biological agents. The flexibility of the instrument built around the fundamental MAR detection principle, gives rise to many instrument configurations as may be required by the application.

ANALYTICAL Laboratory Ranking

MAR ranked in the highest third of all evaluated products for analytical laboratories and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
MAR-Magnetic Assay Reader	0.755
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

MAR ranked in the highest third of all evaluated products for diagnostic laboratories and earned 90% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
MAR-Magnetic Assay Reader	0.818
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.883
MAR-Magnetic Assay Reader	0.711
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

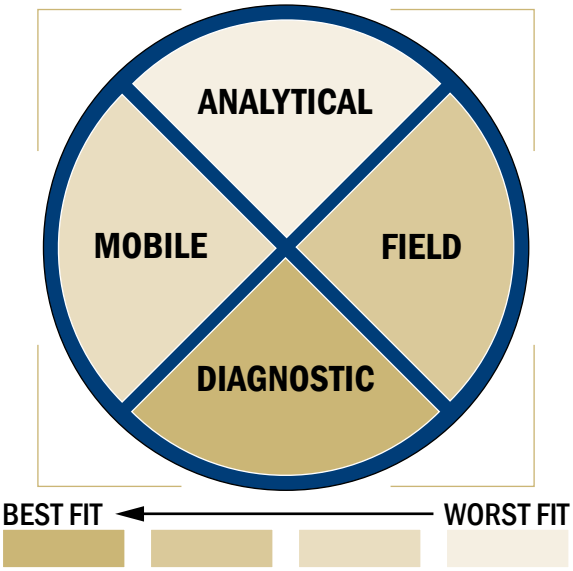
MAR ranked in the highest third of all evaluated products for field use and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
MAR-Magnetic Assay Reader	0.757
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Quantum Design
6325 Lusk Boulevard
San Diego,CA 92121
www.qdusa.com

Point of Contact:
Ron Laborde
(858) 481-4400
(858) 481-7410 fax
laborde@qdusa.com

COST

- $5.00/sample
- Less than $2000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 1 samples/batch or higher, adaptable for more samples/batch
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- Very brief training
- Less than 5 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 2 components
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- No service required
- Expected life is greater than 10 years
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Less than 1 kg
- Shelf life between 1 and 3 years

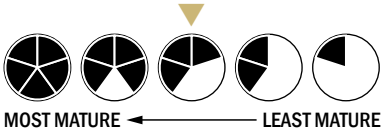
Ease of use/Utility:
- Can not view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting two or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4 °C to 37 °C
- Components must be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

Maturity gauge:
- A few devices or systems exist (brass board)



MatriCycler Thermocycler

by Quantum Design

CAPABLE OF DETECTING THE FOLLOWING:
Able to amplify any organisms/ toxins DNA

DESCRIPTION:
The MatriCycler is a high speed high throughput thermal cycler for use in amplifying DNA, DNA sequencing, and other applications requiring rapid changes in temperature. The system is based on a new patented technology that allows for both high speed thermal cycling and high density work. The system is the only thermal cycler currently available that will work with both 384 well plates and 1536 well plates with sample volumes as low as one microliter.

TECHNOLOGY:
The MatriCycler is not a detector. It is a high throughput thermocycler for amplifying DNA samples.

ANALYTICAL Laboratory Ranking

MatriCycler ranked in the lowest third of all evaluated products for analytical laboratories and earned 37% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
MatriCycler	0.334
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

MatriCycler ranked in the lowest third of all evaluated products for diagnostic laboratories and earned 47% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
MatriCycler	0.428
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.883
MatriCycler	0.486
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

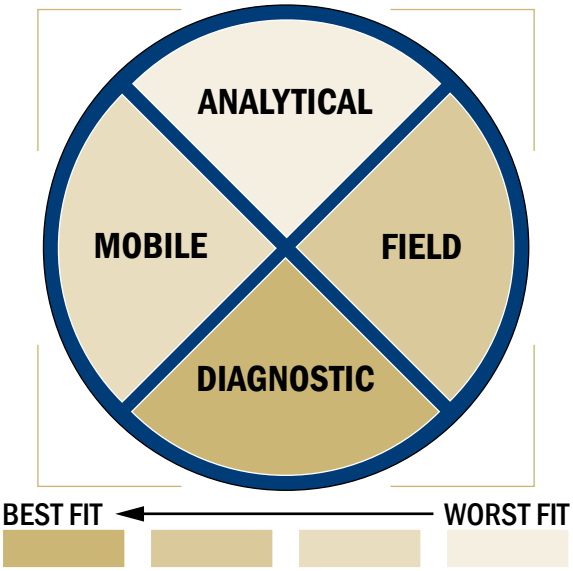
MatriCycler ranked in the middle third of all evaluated products for field use and earned 69% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
MatriCycler	0.651
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

MatriCal, Inc.
665 N. Riverpoint Blvd.
Spokane, WA 99202
www.matrical.com

Point of Contact:
Kevin R. Oldenburg
(509) 343-6222
(509) 343-6220 fax
Kevin.Oldenburg@matrical.com

COST

- $0.50/sample plus cost of Taq enzyme
- $34,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 30 and 40 minutes
- 384 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief training
- Less than 5 minutes required for set-up
- NA steps required for detection

Re-use:
- Device or system is intended for single use
- NA solution or buffer used
- NA components
- NA cleaning

Maintenance:
- 0-1 consumable or expendable needed
- Once a year service required
- Expected life is 3-5 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- NA shelf life

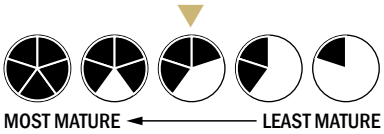
Ease of use/Utility:
- Cannot view results “in real time”
- NA centrifugation steps
- NA vortexing steps
- NA to interpret raw data or call a positive through internal software
- NA detecting multiple biological agents or toxins within the same test
- NA additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4 °C to 45 °C
- NA components storage
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1000 CFU per ml

Maturity gauge:
- A few devices or systems exist (brass board)



MatriXarray

by Roche Applied Science

CAPABLE OF DETECTING THE FOLLOWING:

Able to detect any organisms for which assay are developed.

DESCRIPTION:

MatriXarray is an integrated system for making Microarrays of oligonucleotides that includes software for designing Microarrays, a semi-conductor chip on which the microarray of oligonucleotides is made by in situ synthesis, a microarray synthesizer that can fit on a benchtop, and software for data acquisition and recording. With this system custom oligonucleotides microarrays can be produced within 48 hours, and users can customize the content of the chip, optimize microarray performance, and make immediate changes to microarray designs as revisions or new data appear in genomic databases. CombiMatrix oligonucleotides microarrays can be used for both gene expression and DNA sequence identification for pathogen detection and for SNP analysis. This system allows for a large number of DNA sequences to be detected with a very small amount of sample.

TECHNOLOGY:

DNA sequence Detection for Pathogen Analysis starts with design of oligonucleotides arrays. Roche has a client-server based software system to manage the entire process. The microarray starts with the design of an appropriate set of capture probes. The user begins by using a target specifier software module which checks genomic databases for cross hybridization. After probes are designed the user then uses software for arranging the oligos on a microarray. The layout data is sent to the synthesizer hardware to produce the microarrays. Each microarray has up to 1000 oligo targets. Oligos are synthesized on a silicone semiconductor chip using. A highly porous three-dimensional layer is applied to the surface of the chip that greatly increases the effective surface area of an assay site. Oligo capture probes are then synthesized in the porous layer by growing DNA sequences off on an initial nucleotide base that is covalently linked to the porous layer. Using this semiconductor technology for synthesis eliminates the need for moving parts on the chip production instrumentation. The Reader Hybridizer is bench top sized and can process up to six chips at one time. Fluorescent labels are attached to the sample of interest for detection purposes before hybridization.

ANALYTICAL Laboratory Ranking

MatriXarray ranked in the highest third of all evaluated products for analytical laboratories and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
MatriXarray	0.690
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.909
MatriXarray	0.715
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

MatriXarray ranked in the middle third of all evaluated products for mobile laboratories and earned 64% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
MatriXarray	0.561
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

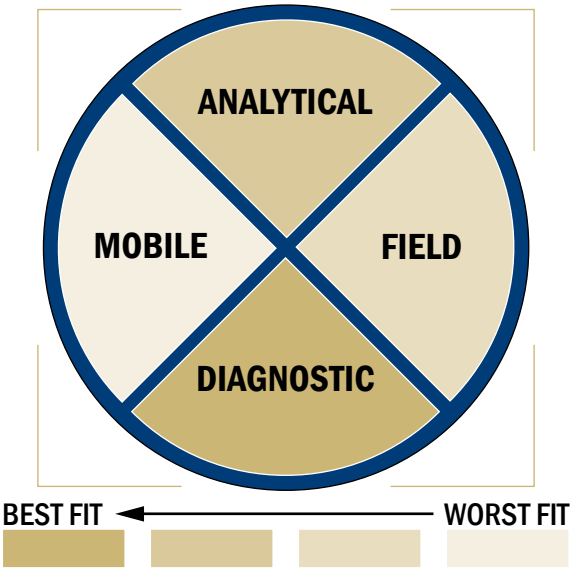
MatriXarray ranked in the middle third of all evaluated products for field use and earned 67% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
MatriXarray	0.628
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Roche Applied Science
9115 Hague Rd., P.O. Box 50414
Indianapolis, IN 46250-0141
www.roche-applied-science.com

Point of Contact:
Mary Pingitore
(800) 845-7355 x8015
(301) 482-1315 fax
mary.pingitore@roche.com

COST

- Unknown/sample
- Approx. $95,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection between 30 and 40 minutes
- 384 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:

- An afternoon of training
- Greater than 20 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- Unknown solution or buffer used
- 2 components
- No cleaning required

Maintenance:

- 2 consumables or expendables needed
- Less than once a year service required
- Expected life is 5-10 years
- Less than 5 minutes required for daily assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 1 and 3 years

Ease of use/Utility:

- Can not view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- Unknown if system is able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:

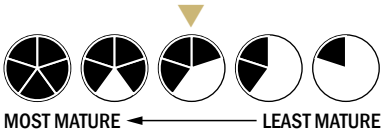
- Operated from 15 °C to 37 °C
- Components must be frozen
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- A few devices or systems exist (brass board), will be commercially available spring of 2003



MCAD

by Northrop Grumman

CAPABLE OF DETECTING THE FOLLOWING:
None reported *(Generic detector)*

DESCRIPTION:
The MCAD is a passive infrared standoff detector. The MCAD was designed specifically for use in the field for fixed-site and/or mobile (on-the-move) applications. The MCAD would be used to provide real-time warning of the presence of an airborne biological agent, and can be used to monitor the location of an airborne agent by using more than one MCAD to triangulate the position of the threat, permitting the user to track the position of the agent cloud(s) with time. The MCAD detects materials of interest both at the sensor, and at some distance from the sensor. It has been used for several years to detect chemicals in the air at multi-kilometer ranges. It monitors an area for the presence or absence of specific materials. Over the past few years the infrared spectral features of biological organisms have been better quantified. Evidence indicates distinct, identifiable infrared characteristics for a number of the biological materials. Preliminary detection algorithms have been developed and were used in a government field test in 2005, and have been further refined since then.

TECHNOLOGY:
The MCAD operates in the 8-12 µm region of the electromagnetic spectrum. It uses passive infrared spectroscopy to determine the presence or absence of specific materials of interest. The MCAD contains a Fourier Transform Infrared (FT-IR) spectrometer with a cryogenically cooled Mercury Cadmium Telluride (MCT) detector.

ANALYTICAL Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.901
Northrop Grumman MCAD	0.477
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

MCAD 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
Best Score	0.909
Northrop Grumman MCAD	0.569
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.883
Northrop Grumman MCAD	0.539
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

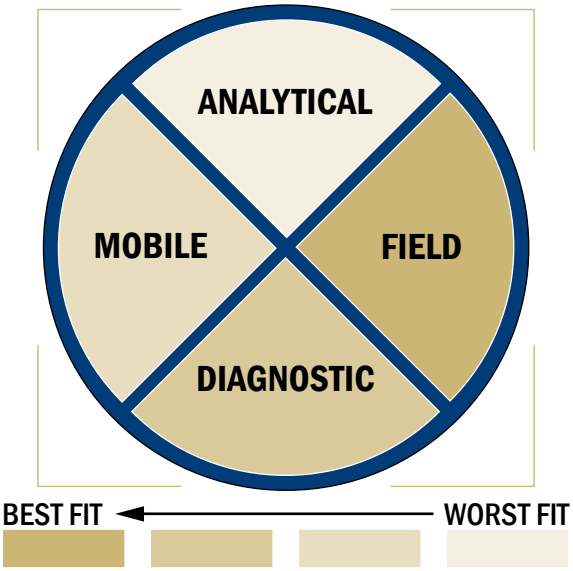
MCAD ranked in the middle third of all evaluated products for field use and earned 69% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Northrop Grumman MCAD	0.655
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Northrup Grumman
7055 Troy Hill Drive, Suite 500
Elkridge, MD 21075

Point of Contact:
Keith Uithoven
(410) 471-6513
(410) 865-5484
keith.uithoven@ngc.com

COST

- $350,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V or 220V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Detects airborne material in less than 1 second
- 32 samples/batch
- No liquid detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- A day of training and technical skills are required
- 5-10 minutes set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 0 components
- No cleaning required

Maintenance:
- Once a year service required
- Expected life is greater than 10 years
- No daily quality assurance procedures

Transportation:
- Larger than a home dishwasher
- More than 50 kg
- Reagent shelf life greater than 3 years

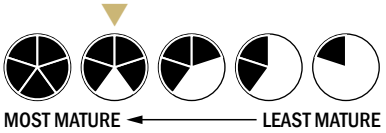
Ease of use/Utility:
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from -32°C to 49°C
- The peak performance of the device or system is at low relative humidity

Sensitivity:
- 10,000 ACPLA (Agent Containing Particles per Liter Air)

Maturity gauge:
- Hardware is commercially available. Biological Detection algorithms are in the brass board state.
- Is expected to be ready for commercialization within two calendar years
- Less than $1,000,000 required for advancement of device or system to commercialization
- Has been featured in peer reviewed scientific publications or independent evaluations



Microfluidic FRET Reader

by OmniSite BioDiagnostics, Inc.

CAPABLE OF DETECTING THE FOLLOWING:
Able to detect any organisms for which assay are developed.

DESCRIPTION:
This instrument is a compact fluorescence resonance energy transfer (FRET) reader, capable of rapid one-step immunoassays (without wash steps). Immuno FRET assays were developed for Bacillus cereus spores and E. coli bacteria (see Bruno et al., Biochem. Biophys. Res. Comm. Vol. 287:875-880, 2001). Assays are currently performed in 50 uL plastic or silicon cartridges, OmniSite is developing microfluidic cartridges that will contain freeze-dried immuno-FRET reagents that can be rehydrated by the sample and assayed within minutes.

TECHNOLOGY:
FRET is popular technique in the research and clinical diagnostic arenas for such popular assays as the TaqMan PCR assays, because it enables a high sensitivity "lights on" or "lights off" effect due to quenching or liberation of fluorescence with an absorbing molecule (quencher). In OmniSite's FRET format, Oregon Green dyes are quenched by QSY-7. The reader has a slider capable of holding eight or more single assay cartridges.

ANALYTICAL Laboratory Ranking

Microfluidic FRET Reader ranked in the middle third of all evaluated products for analytical laboratories and earned 66% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Microfluidic FRET Reader	0.594
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Microfluidic FRET Reader ranked in the highest third of all evaluated products for diagnostic laboratories and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Microfluidic FRET Reader	0.727
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Microfluidic FRET Reader 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
Best Score	0.883
Microfluidic FRET Reader	0.578
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

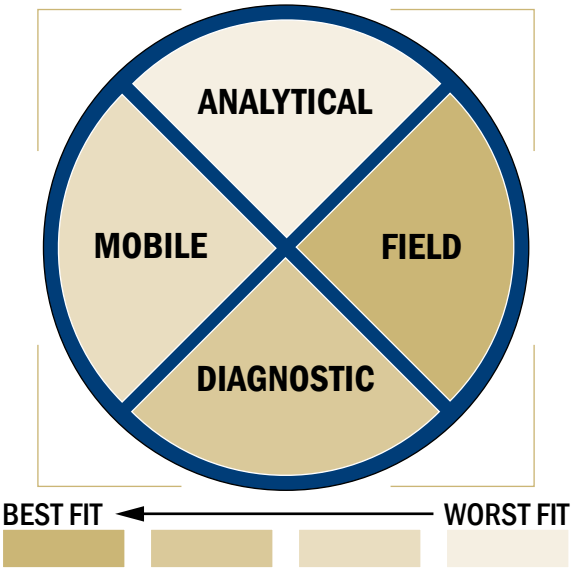
Microfluidic FRET Reader ranked in the highest third of all evaluated products for field use and earned 82% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Microfluidic FRET Reader	0.775
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
OmniSite BioDiagnostics, Inc.
101 West 6th Street, Suite 200
Austin, TX 78701

Point of Contact:
John G. Bruno
(512) 479-7732 x2202
(512) 494-0756 fax
bruno@spec.com

COST
- $0.10/sample plus cost of immunoassay
- $2,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V or battery requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 32 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 3 solutions or buffers used
- 1 component
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Less than once a year service required
- Expected life is greater than 10 years
- 10-20 minutes daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life greater than 3 years

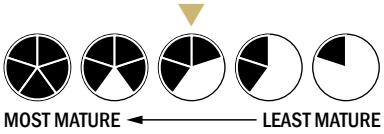
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- A single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- Components must be stored at 4 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1,000 CFU per ml

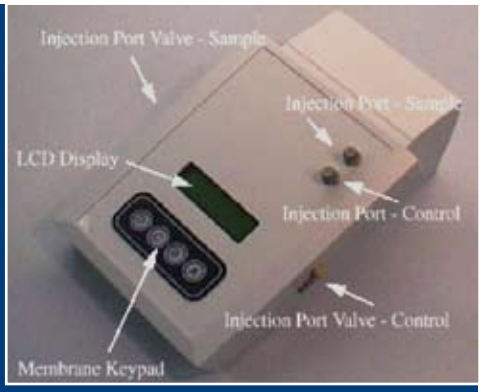
Maturity gauge:
- A few devices or systems exist (brass board)



Mini-PCR Fluorescence Reader

by OmniSite BioDiagnostics, Inc.

CAPABLE OF DETECTING THE FOLLOWING:
Able to detect any organisms/toxins for which assays are developed.



DESCRIPTION:
This instrument combines a compact thermal cycler for PCR with an epifluorescence head to detect and measure fluorescence intensity optically through a window on a microfluidic chip. The device reads TaqMan PCR FRET assays very rapidly and detects amplification within 5–10 cycles of PCR, faster than comparable PCR readers.

TECHNOLOGY:
The mini-PCR FRET reader, originally funded by NASA SBIR, is designed to detect PCR amplification of TaqMan assays in shuttle craft/space station workplace where microgravity environment precludes normal liquid handling methods for innovative use of microfluidic interconnections to prevent liquid spillage. OmniSite received high ratings from NASA for this Phase II SBIR funded device and is in the process of filing two patents for the innovative microfluidic chip design and the fluid interconnects that allow rapid and facile snapping of the chip into place in microgravity environment without liquid spillage.

ANALYTICAL Laboratory Ranking

Mini-PCR Fluorescence Reader ranked in the middle third of all evaluated products for analytical laboratories and earned 67% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Mini-PCR Fluor. Reader	0.607
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Mini-PCR Fluorescence Reader ranked in the highest third of all evaluated products for diagnostic laboratories and earned 79% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Mini-PCR Fluor. Reader	0.719
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Mini-PCR Fluorescence Reader 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
Best Score	0.883
Mini-PCR Fluor. Reader	0.584
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

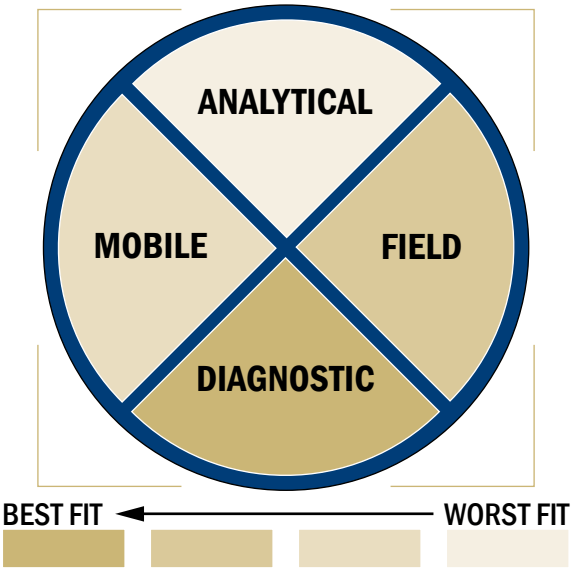
Mini-PCR Fluorescence Reader ranked in the highest third of all evaluated products for field use and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Mini-PCR Fluor. Reader	0.728
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
OmniSite BioDiagnostics, Inc.
101 West 6th Street, Suite 200
Austin, TX 78701

Point of Contact:
John G. Bruno
(512) 479-7732 x2202
(512) 494-0756 fax
bruno@spec.com

COST
- $0.50/sample plus cost of Taq enzyme
- $3,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V or battery electrical requirements
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 1 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief training
- Less than 5 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 1 component
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Less than once a year service required
- Expected life is greater than 10 years
- 10-20 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life between 1 and 3 years

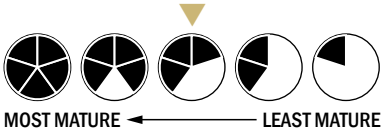
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4 °C to 45 °C
- Components must be frozen
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

Maturity gauge:
- A few devices or system exist (brass board)



Mobile Molecular Laboratory

by MJ Research

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, E. coli 0157: H7, Orthopox virus *(Assays developed)*

DESCRIPTION:
The Mobile Molecular Laboratory is a professional-quality DNA laboratory in a suitcase. It is appropriate for field investigation, education, or as a quick and inexpensive way to equip a lab just beginning DNA research. It features a MiniCycler thermal cycler, microcentrifuge, mini gel box, compact power supply, compact UV transilluminator, transilluminator photodocumentation system, insulating-foam cooler, benchtop enzyme chiller, 500ml polypropylene bottles, and rugged foam-lined plastic case. All instruments feature universal power adapters and detachable cord sets and are resistant to power surges.

TECHNOLOGY:
The system would use PCR-based assays, which would require running out the amplification products on pre-cast gels complete with ethidium bromide; results would require interpretation by user by observing gel on transilluminator or from a Polaroid photo of gel.

ANALYTICAL Laboratory Ranking

Mobile Molecular Laboratory ranked in the highest third of all evaluated products for analytical laboratories and earned 70% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Mobile Molecular Lab.	0.627
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Mobile Molecular Laboratory 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
Best Score	0.909
Mobile Molecular Lab.	0.549
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Mobile Molecular Laboratory ranked in the middle third of all evaluated products for mobile laboratories and earned 60% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Mobile Molecular Lab.	0.527
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

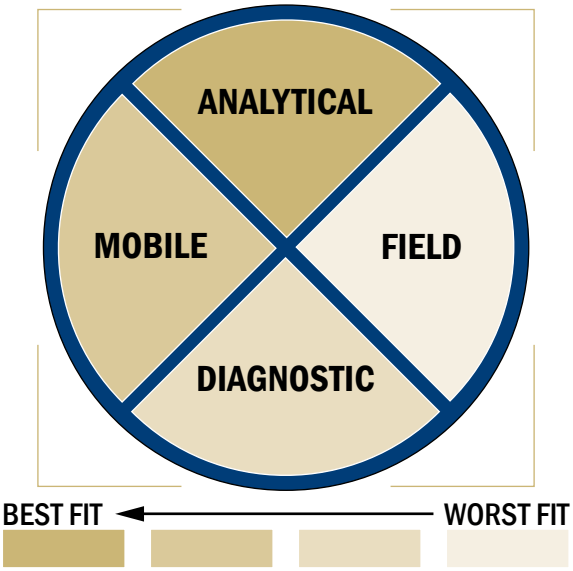
Mobile Molecular Laboratory ranked in the lowest third of all evaluated products for field use and earned 49% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Mobile Molecular Lab.	0.458
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

MJ Research, Inc.
590 Lincoln St.
Waltham, MA 02451
www.mjr.com

Point of Contact:
John Hansen
(617) 972-8157 x8157
(617) 923-8080 fax
johnh@mjr.com

COST

- Unknown/sample
- $6071.00 GSA price/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 2 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or approach is not amendable to automation

Training/Speed/Manpower:
- More than a day of training
- Greater than 20 minutes required for set-up
- Greater than 12 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- More often than every 6 months service required
- Expected life is 5-10 years
- 5-10 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life greater than 3 years if lyophilized

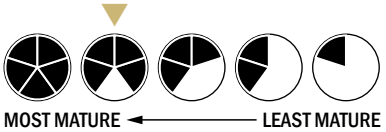
Ease of use/Utility:
- Can not view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System never able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from 4 °C to 37 °C
- Components must be stored at 4 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1,000 CFU per ml

Maturity gauge:
- Is commercially available



Morphix Chem Bio Detector

by Morphix Technologies

CAPABLE OF DETECTING THE FOLLOWING:
Detects gram positive and gram negative bacteria

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 Chem Bio Detector ranked in the lowest third of all evaluated products for analytical laboratories and earned 38% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Morphix Chem Bio Detector	0.344
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Morphix Chem Bio Detector 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
Best Score	0.909
Morphix Chem Bio Detector	0.499
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Morphix Chem Bio Detector ranked in the middle third of all evaluated products for mobile laboratories and earned 56% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Morphix Chem Bio Detector	0.492
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

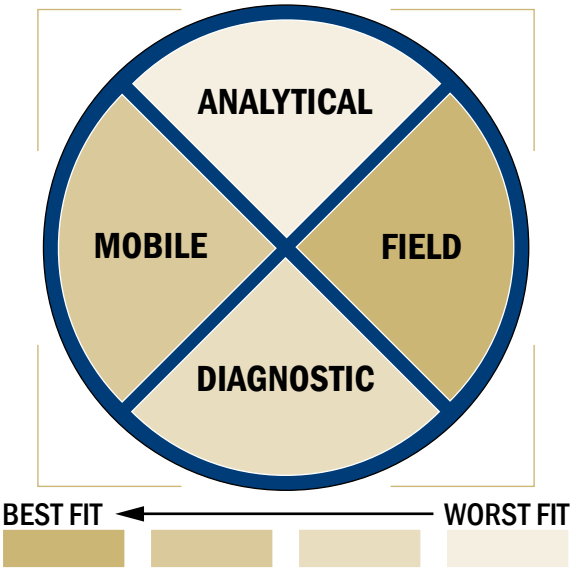
Morphix Chem Bio Detector ranked in the middle third of all evaluated products for field use and earned 62% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Morphix Chem Bio Detector	0.585
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
Morphix Technologies
2557 Production Road
Virginia Beach, VA 23454
www.morphtec.com

Point of Contact:
Kim Chapman
(757) 431-2260 x222
(757) 431-2255
kchapman@morphtec.com

COST
- <$25.00/sample
- <$1,500.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:
- System or device uses batteries or 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Real time bioaerosol detection
- 2 samples/batch
- Depends on the agent concentration in the aerosol
- The system or device is currently fully automated

Training/Speed/Manpower:
- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 2 components
- No cleaning required

Maintenance:
- Weekly change the sensor cartridge and charge the battery
- Expected life is between 1-3 years
- Less than 5 minutes daily quality assurance procedures

Transportation:
- Approximately the size of a soda can
- Less than 1 kg
- Reagent shelf life between 6 months and 1 year

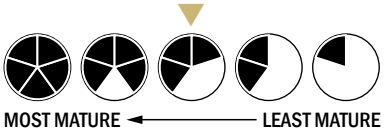
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 25°C to 45°C
- The effect of relative humidity on the device or system is unknown

Sensitivity:
- 100-1,000 CFU per ml

Maturity gauge:
- A few devices or systems exist (brass board)
- Is expected to be ready for commercialization within two calendar years
- $1,000,000 - $2,000,000 required to advance the device or system to commercialization
- Has not been featured in any peer reviewed scientific publications or independent evaluations



MSD Cartridge Reader

by Meso-Scale Discoveries

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, E. coli O157:H7, Francisella tularensis, Yersinia pestis, VEE virus, Botulinum toxin A, SEB, Ricin *(Assays developed)*

DESCRIPTION:
The Cartridge Reader is an electrochemiluminescence (ECL) based, portable system with all assay reagents contained in a stand-alone cartridge. Just add sample to the cartridge and the system will do the rest. Cartridges are capable of performing up to 20 tests per sample. The instrument is capable of rapid, highly sensitive measurements and detecting multiple analytes (up to 20 tests per sample) in a single cartridge. The system is being designed for use in the clinical diagnostics market. On top of superior detection capabilities across the spectrum of potential bioagents (viruses, bacteria and toxins,) the MSD instrument is easy to use and capable of providing results in 15 minutes without any user intervention. The Cartridge Reader is perfectly suited for the needs the first responder or a soldier out in the field.

TECHNOLOGY:
Electrochemiluminescence (ECL) is a well-developed, commercial technology for the detection and study of biomolecular interactions and function. ECL-based assays employ labels that emit light when electrochemically oxidized or reduced under appropriate chemical conditions. The existence of small, stable and highly efficient ECL labels makes the technique robust, sensitive and easy to implement. ECL detection is already widely used in the military for detection of biological agents. We have adapted the technology to allow ECL assays to be carried out on inexpensive disposable electrodes in a format that is compatible with multiplexed array-based measurements. Our systems are currently being evaluated at the Edgewood Chemical and Biological Center and USAMRIID. Assays are carried out on proprietary cartridges that have integrated electrodes that act as both a capture surface and an energy source for electrochemiluminescence excitation. The spatial control inherent in ECL induction and imaging detection allows for multiplexed array based measurement employing patterned arrays of binding reagents on an electrode surface. In addition, the cartridges contain all the necessary wet reagents to perform a measurement. Cartridges are capable of detecting up to 20 analytes per sample. The cartridges will be manufactured using well-established scalable techniques such as screen-printing that allow for high volume manufacturing at low cost. These assays are capable of highly sensitive detection with broad dynamic ranges. A cartridge can be read in under 15 minutes.

ANALYTICAL Laboratory Ranking

MSD Cartridge Reader ranked in the highest third of all evaluated products for analytical laboratories and earned 85% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
MSD Cartridge Reader	0.765
Lowest Score	0.217

Effectiveness, Biological Agents, Logistics, Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

MSD Cartridge Reader ranked in the highest third of all evaluated products for diagnostic laboratories and earned 93% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
MSD Cartridge Reader	0.846
Lowest Score	0.321

Effectiveness, Operations, Biological Agents, Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

MSD Cartridge Reader ranked in the highest third of all evaluated products for mobile laboratories and earned 90% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
MSD Cartridge Reader	0.794
Lowest Score	0.379

Logistics, Biological Agents, Effectiveness, Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

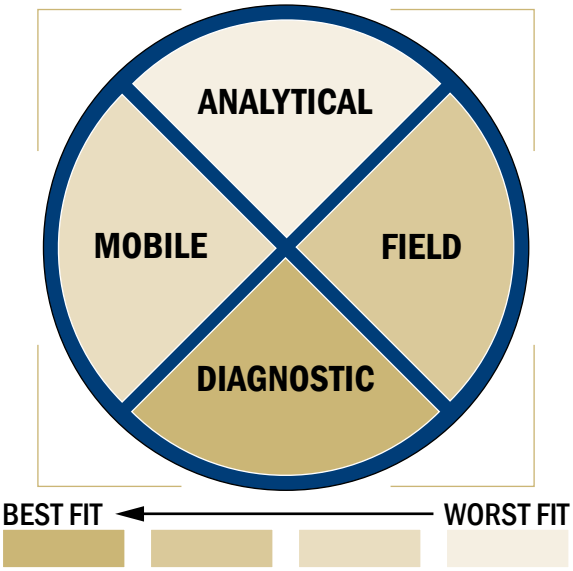
MSD Cartridge Reader ranked in the highest third of all evaluated products for field use and earned 85% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
MSD Cartridge Reader	0.798
Lowest Score	0.343

Logistics, Operations, Effectiveness, Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
ChemSensing, Inc.
60 Hazelwood Drive
Champaign, IL 61820
www.chemsensing.com

Point of Contact:
Joel Dryer
(847) 412-0010
(847) 412-0008 fax
joel@chemsensing.com

COST
- $10.00/sample
- Estimated $5000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has a 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 2 samples/batch or higher
- Less than 250ul needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- Very brief training
- 5-10 min set-up required
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 3 components
- Cleaning involves purging the system with air or nitrogen

Maintenance:
- 2 consumables or expendables needed
- Unknown service required
- Expected life measure is 1-3 years
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Less than 1 kg
- Shelf life between 6 months and 1 year

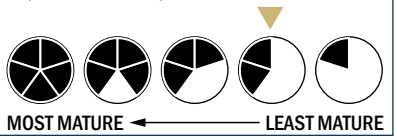
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System sometimes able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components must be stored at 25°C to 45°C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

Maturity gauge:
- Is expected to be ready for commercialization within one calendar year
- A few devices or systems exist (brass board)



MSD Sector Imager 6000

by Meso-Scale Discoveries

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, E. coli O157: H7, Francisella tularensis, Yersinia pestis, VEE virus, Botulinum toxin A, SEB, Ricin *(Assay developed)*

DESCRIPTION:

The Sector Imager 6000 (SI6000) is an electrochemiluminesence (ECL) based system using assay reagents that are directly immobilized on the electrode used to induce ECL. The carbon-based electrodes are in the form of standard microtiter plates with 96, 384 and 1,536 wells per plate. The centerpiece of this system is the cooled-CCD camera and telecentric lens which enable rapid, highly sensitive measurements. In addition, the use of screen-printed electrodes has enabled MSD to produce a machine capable of detecting of multiple analytes in one well (multiplexing.) The system was originally designed for use by the pharmaceutical industry in support of their high throughput screening efforts. On top of superior detection capabilities across the spectrum of potential bioagents (viruses, bacteria and toxins,) the MSD instruments are easy to use and capable of providing results in 30 minutes for over one thousand tests. The SI 6000 is perfectly suited for the needs of central lab demanding highly sensitive measurements in a rapid pace for a large volume of sample

TECHNOLOGY:

Electrochemiluminescence (ECL) is a well-developed, commercial technology for the detection and study of biomolecular interactions and function. ECL-based assays employ labels that emit light when electrochemically oxidized or reduced under appropriate chemical conditions. The existence of small, stable and highly efficient ECL labels makes the technique robust, sensitive and easy to implement. ECL detection is already widely used in the military for detection of biological agents. We have adapted the technology to allow ECL assays to be carried out on inexpensive disposable electrodes in a format that is compatible with multiplexed array-based measurements. Our systems are currently being evaluated at the Edgewood Chemical and Biological Center and USAMRIID. Assays are carried out on proprietary Multi-Array plates having integrated electrodes that act as both a capture surface and an energy source for electrochemiluminescence excitation. The spatial control inherent in ECL induction and imaging detection allows for multiplexed array based measurement employing patterned arrays of binding reagents on an electrode surface. A variety of plate formats have been designed to suit the broad range of needs of drug discovery and biological research – from the standard 96, 384 and 1536-well formats to custom Multi-Spot plates for performing multiple measurements in each well of specially designed 96 and 24-well plates. The 96-well plates are capable of detecting 4, 7 or 10 analytes per well. The 24-well plates are capable of detecting 25, 64 or 100 analytes per well. The plates are manufactured using well-established scalable techniques such as screen-printing that allow for high volume manufacturing at low cost. These assays are capable of highly sensitive detection with broad dynamic ranges. The SI600 is can perform over 1,000 determinations per minute.

ANALYTICAL Laboratory Ranking

MSD Sector Imager 6000 ranked in the highest third of all evaluated products for analytical laboratories and earned 88% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
MSD Sector Imager 6000	0.792
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

MSD Sector Imager 6000 ranked in the highest third of all evaluated products for diagnostic laboratories and earned 95% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
MSD Sector Imager 6000	0.866
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

MSD Sector Imager 6000 ranked in the highest third of all evaluated products for mobile laboratories and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
MSD Sector Imager 6000	0.681
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

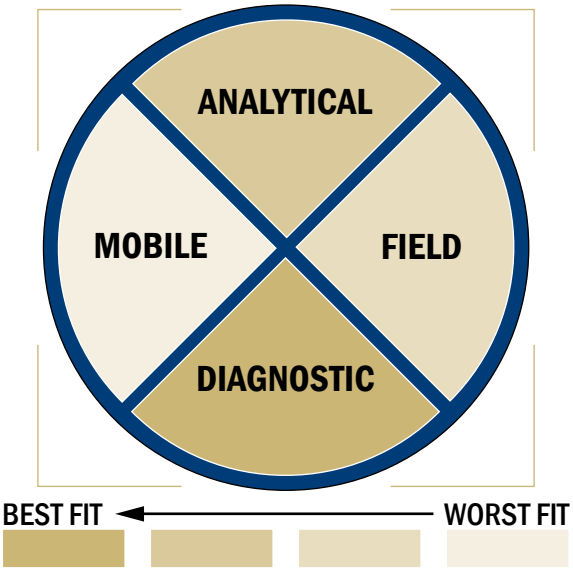
MSD Sector Imager 6000 ranked in the highest third of all evaluated products for field use and earned 83% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
MSD Sector Imager 6000	0.778
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

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www.meso-scale.com

Point of Contact:
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(240) 631-2522 x4622
(240) 632-2219 fax
vvasista@meso-scale.com

COST

- $4.00/assay
- $250,000/device or system

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirements
- The system or device does not require water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection in less than 20 min
- 384 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:

- An afternoon of training
- No set-up required
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple detections
- 0-1 solution or buffer used
- 1 component
- No cleaning required

Maintenance:

- 2 consumables or expendables needed
- Needs service less than once a year
- Expected life measure of 5-10 years
- No daily quality assurance procedures necessary

Transportation:

- Approximately the size of a home dishwasher
- More than 50 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- A single shaking or vortexing step
- System can interpret raw data or call a positive through internal software
- Assays available, and capable of detecting four or more agents or toxins within the same well
- Three additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:

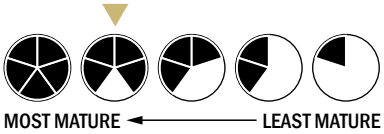
- Operated from 15 °C to 37 °C
- Components can be stored at room temperature
- The influence of relative humidity on the performance of the device or system is unknown

Sensitivity:

- 100-1,000 CFU per ml

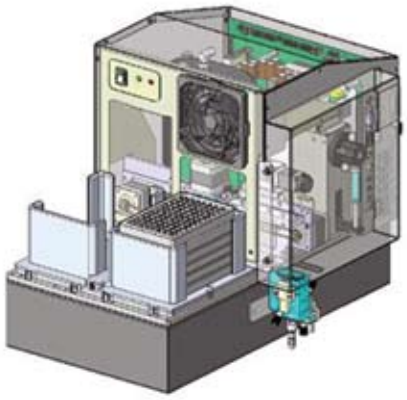
Maturity gauge:

- Is commercially available



MSD Sector PR 2

by Meso-Scale Discoveries



CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Coxiella burnetti, Brucella species, Yersinia pestis, Orthopox virus, Venezuelan equine encephalitis virus, E.coli O157:H7, Influenza virus, Botulinum toxin A, Staphylococcal toxin B, Ricin toxin Botulinum toxin B, Abrin toxin *(Assay developed);* Vibrio cholera *(Assay validated)*

DESCRIPTION:
The PR2 system is a compact automated detection system for carrying out multiplexed electrochemiluminescence (ECL) assays in an array format. Assays are carried out in proprietary disposable multi-well plates having integrated carbon ink electrodes. These electrodes act as solid phase supports for arrays of biological reagents (for example, antibodies or nucleic acids) and also provide the source of electrical energy for generating ECL signals. The use of array-based multiplexing allows for the detection of multiple analytes in each well of a multi-well plate (up to 25 per well of a 96-well plate). The PR2 uses a cooled CCD camera and molded lens to image ECL generated from arrays in MSD's plates. The inventive PR2 design allows the PR2 to maintain the sensitivity and multiplexing capability of MSD's high-throughput Sector Imager instruments but in a much smaller and portable foot-print. The PR2 has integrated pipetting, shaking and seal removal capabilities that provide the ability to carry out fully automated sample analysis using sealed plates that hold all the required biological reagents in a dry form. The system can unseal and use one well of a plate at a time so that individual samples can be measured without compromising the ability to use the remaining well at a later time. For higher throughput batch processing, the PR2 can also be used as a dedicated plate reader to analyze plates that have been processed off-line.

TECHNOLOGY:
The PR2 employs electrochemiluminescence (ECL) detection. ECL assays employ labels that emit light when electrochemically stimulated at an electrode. We attach these labels to biological binding reagents and use these in sold phase binding assays such as nucleic acid hybridization assays of sandwich immunoassays. The existence of small, stable and highly efficient ECL labels makes the technique robust, sensitive and easy to implement. We have adapted the technology to allow ECL assays to be carried out using biological arrays patterned on inexpensive disposable electrodes in a format that is compatible with multiplexed array-based measurements.

ANALYTICAL Laboratory Ranking

MSD Sector PR 2 ranked in the highest third of all evaluated products for analytical laboratories and earned 96% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
MSD Sector PR 2	0.864
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

MSD Sector PR 2 ranked in the highest third of all evaluated products for diagnostic laboratories and earned 99% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
MSD Sector PR 2	0.903
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

MSD Sector PR 2 ranked in the highest third of all evaluated products for mobile laboratories and earned 96% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
MSD Sector PR 2	0.846
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

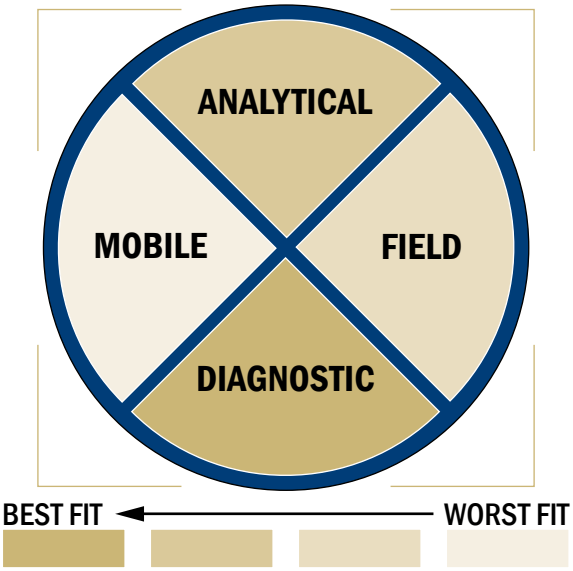
MSD Sector PR 2 ranked in the highest third of all evaluated products for field use and earned 36% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
MSD Sector PR 2	0.902
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
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Point of Contact:
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vvasista@meso-scale.com

COST
- $4.00/sample
- $80,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 minutes or less
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- An afternoon of training and some technical skills required
- Less than 5 minutes set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 1 component
- No cleaning required

Maintenance:
- Less than once a year service required
- Expected life is between 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 5 and 25 kg
- Reagent shelf life between 1 to 3 years

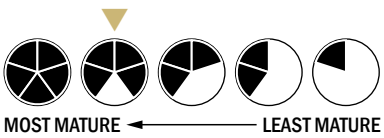
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- Components must be stored at room temperature
- The performance of the device or system is not influenced by relative humidity

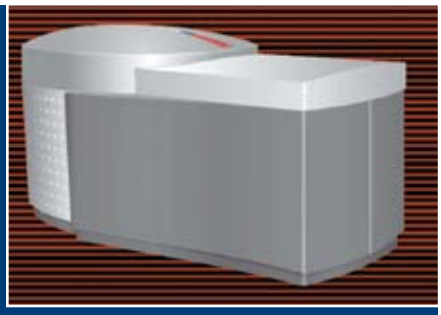
Sensitivity:
- 100-1,000 CFU per ml

Maturity gauge:
- Is commercially available
- Has been featured in peer reviewed scientific publications or independent evaluations



MSD Sector™ PR Plate Reader

by Meso-Scale Discoveries



CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Coxiella burnetti, Brucella species, Yersinia pestis, Orthopox virus, Venezuelan equine encephalitis virus, Botulinum toxin A, Staphylococcal toxin B, Ricin toxin, E.coli O157:H7, Influenza virus, Botulinum toxin B, Abrin toxin *(Assays developed);* Vibrio cholera *(Assay validated)*

DESCRIPTION:

The Sector PR plate readers are compact readers for carrying out electrochemiluminescence (ECL) assays. Assays are carried out in proprietary disposable multi-well plates having integrated carbon ink electrodes. These electrodes act as solid phase supports for immobilized biological reagents (for example, antibodies or nucleic acids) and also provide the source of electrical energy for generating ECL signals. The centerpiece of this system is an array of photodiodes which enable rapid, highly sensitive measurements. The photodiode array is used to simultaneously measure ECL from one row of wells. The array is scanned across the columns of the plate allowing a full plate to be read in roughly two minutes.

The Sector PR 100 and PR 400 readers are useful in a wide variety of applications ranging from life science research, pharmaceutical quality control and biowarfare agent detection. Biodefense applications have been driven by the systems superior detection capabilities across the spectrum of potential bioagents (viruses, bacteria and toxins). The MSD instruments are easy to use and extremely fast. The Sector PR 100 is a singleplex instrument while the Sector PR 400 allows for limited multiplexing (up to four measurements per well). The combination of a small light-weight form factor and sensitive rapid analysis makes the Sector PRs well suited for testing in a wide variety of settings from the central lab to the field.

TECHNOLOGY:

The Sector PR readers employ electrochemiluminescence (ECL) detection. ECL assays employ labels that emit light when electrochemically stimulated at an electrode. We attach these labels to biological binding reagents and use these in solid phase binding assays such as nucleic acid hybridization assays or sandwich immunoassays. The existence of small, stable and highly efficient ECL labels makes the technique robust, sensitive and easy to implement. We have adapted the technology to allow ECL assays to be carried out using biological reagents patterned on inexpensive disposable electrodes in a multi-well plate format.

ANALYTICAL Laboratory Ranking

MSD Sector PR ranked in the highest third of all evaluated products for analytical laboratories and earned 96% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
MSD Sector PR	0.868
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

MSD Sector PR ranked in the highest third of all evaluated products for diagnostic laboratories and earned 100% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
MSD Sector PR	0.909
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

MSD Sector PR ranked in the highest third of all evaluated products for diagnostic laboratories and earned 100% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
MSD Sector PR	0.834
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

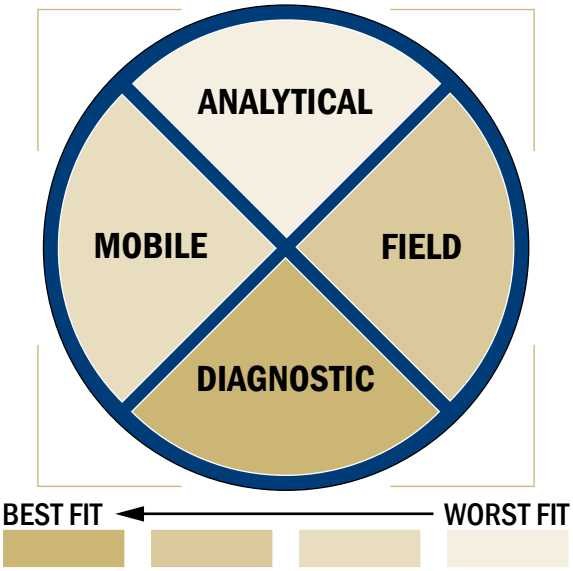
MSD Sector PR ranked in the highest third of all evaluated products for field use and earned 95% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
MSD Sector PR	0.893
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
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Point of Contact:
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(240) 632-2219 fax
vvasista@meso-scale.com

COST
- $4.00/sample
- $25,000.00/PR100; $50,000/PR400

Evaluation Criteria Provided by Vendor

System requirements:
- System or device uses batteries or has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 minutes or less
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training and some technical skills required
- No set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 1 component
- No cleaning required

Maintenance:
- Less than once a year service required
- Expected life is between 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 5 and 25 kg
- Reagent shelf life between 1 to 3 years

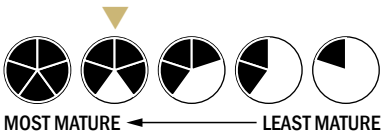
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- There is a single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- Components must be stored at room temperature
- The performance of the device or system is not influenced by relative humidity

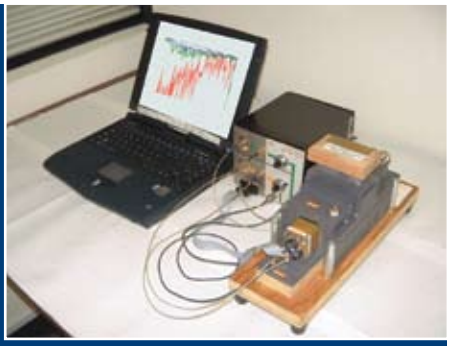
Sensitivity:
- 100-1,000 CFU per ml

Maturity gauge:
- Is commercially available
- Has been featured in peer reviewed scientific publications or independent evaluations



Multi-Photon Detection (MPD) Portable

by BioTraces, Inc.



CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Yersinia pestis, Brucella species, E. coli 0157:H7, Vibrio cholera, Corynebacterium diptheria, Burkholderia mallei, Burkholderia pseudomallei, Coxiella burnetti, Rickettsia prowazeki, Rift Valley fever virus, Orthopox virus, VEE virus, Hanta virus, Yellow fever virus, Dengue fever virus, MS-2 bacteriophage, Botulinum toxins A, B, E, SEB, T-2 toxin, Ricin, Saxitoxin, Shigatoxin, Conotoxins, Palytoxin *(Assays developed)*

DESCRIPTION:
Multi-Photon Detection (MPD) provides the new standard of sensitivity for immunological detection, quantification and identification of pathogens. MPD technology applies to the full spectrum of BW agents: viruses, bacteria and biotoxins.

TECHNOLOGY:
MPD technology utilizes unique photons detection methods. This system maps photon properties and rejects all non-specific events. Coincidence is used to diminish the background by a factor of more than thousand. The "introduced" tags are specifically recognized and counted. This unique technology provides the best possible sensitivity for both the nucleic-acid based and immunological detection, including accurate identification of pathogens. This method is compatible with the development of automated air and water safety monitoring that is fast and accurate. We developed the MPD enhanced immunoassays with about 1 fg/ml sensitivity for about 10 targets. We are currently extending this technology to P-chips with MPD read-out. The proposed BW agents detection system will consist of three parts: air intake/filtration sub-system, "biochemical wet chamber", and the MPD based immunodetection module.

ANALYTICAL Laboratory Ranking

MPD Portable ranked in the highest third of all evaluated products for analytical laboratories and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
MultiPhoton Detection Portable	0.759
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

MPD Portable ranked in the highest third of all evaluated products for diagnostic laboratories and earned 91% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
MultiPhoton Detection Portable	0.825
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.883
MultiPhoton Detection Portable	0.667
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

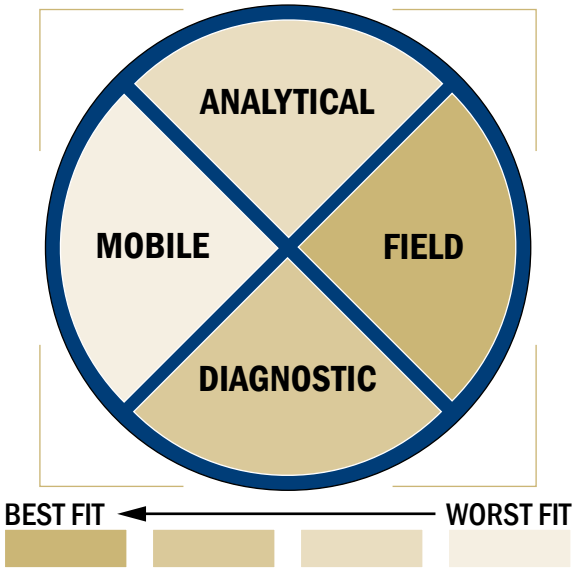
MPD Portable ranked in the highest third of all evaluated products for field use and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
MultiPhoton Detection Portable	0.759
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

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13455 Sunrise Valley Drive, Suite 200
Herndon, VA 20171
www.biotraces.com

Point of Contact:
A.K. Drukier
(703) 793-1550 x108
(703) 793-1564 fax
AKD@biotraces.com

COST

- $1.00/sample
- $30,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device uses batteries
- The system or device does require water aliquots
- The system or device does require an external air source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 96 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 2 solutions or buffers used
- 2 components
- Daily extensive wash required

Maintenance:
- 2 consumables or expendables needed
- Every 6 months service required
- Expected life is 3-5 years
- 5-10 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life between 6 months and 1 year

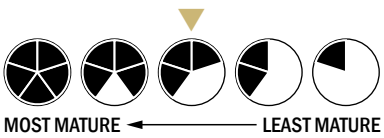
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- Sounds are produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at room temperature or 4°C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

Maturity gauge:
- A few devices or systems exist (brass board)



Multi-Photon Detection (MPD) Tabletop

by BioTraces, Inc.

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Yersinia pestis, Brucella species, E. coli 0157:H7, Vibrio cholera, Corynebacterium diptheria, Burkholderia mallei, Burkholderia pseudomallei, Coxiella burnetti, Rickettsia prowazeki, Rift Valley fever virus, Orthopox virus, VEE virus, Hanta virus, Yellow fever virus, Dengue fever virus, MS-2 bacteriophage, Botulinum toxins A, B, E, SEB, T-2 toxin, Ricin, Saxitoxin, Shigatoxin, Conotoxins, Palytoxin *(Assays developed)*

DESCRIPTION:
Multi-Photon Detection (MPD) provides the new standard of sensitivity for immunological detection, quantification and identification of pathogens. MPD technology applies to the full spectrum of BW agents: viruses, bacteria and biotoxins.

TECHNOLOGY:
MPD technology utilizes unique photons detection methods. This system maps photon properties and rejects all non-specific events. Coincidence is used to diminish the background by a factor of more than thousand. The "introduced" tags are specifically recognized and counted. This unique technology provides the best possible sensitivity for both the nucleic-acid based and immunological detection, including accurate identification of pathogens. This method is compatible with the development of automated air and water safety monitoring that is fast and accurate. We developed the MPD enhanced immunoassays with about 1 fg/ml sensitivity for about 10 targets. We are currently extending this technology to P-chips with MPD read-out. The proposed BW agents detection system will consist of three parts: air intake/filtration sub-system, "biochemical wet chamber", and MPD based immunodetection module.

ANALYTICAL Laboratory Ranking

MPD Tabletop ranked in the highest third of all evaluated products for analytical laboratories and earned 85% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
MultiPhoton Detection Tabletop	0.762
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

MPD Tabletop ranked in the highest third of all evaluated products for diagnostic laboratories and earned 91% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
MultiPhoton Detection Tabletop	0.827
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

MPD Tabletop ranked in the highest third of all evaluated products for mobile laboratories and earned 74% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
MultiPhoton Detection Tabletop	0.657
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

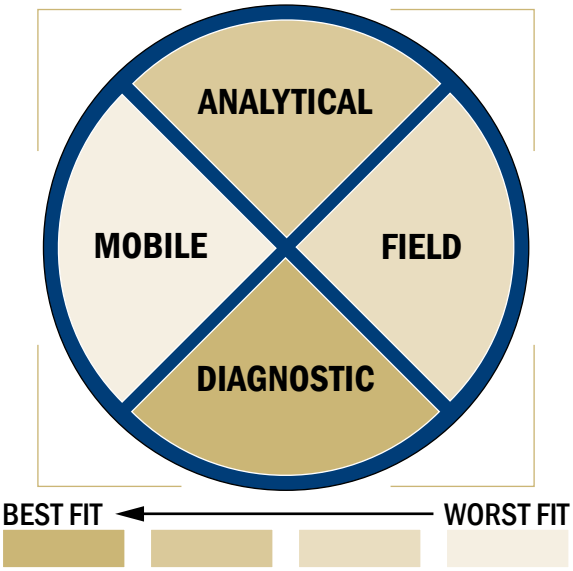
MPD Tabletop ranked in the highest third of all evaluated products for field use and earned 78% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
MultiPhoton Detection Tabletop	0.732
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

BioTraces, Inc.
13455 Sunrise Valley Drive, Suite 200
Herndon, VA 20171
www.biotraces.com

Point of Contact:
A.K. Drukier
(703) 793-1550 x108
(703) 793-1564 fax
AKD@biotraces.com

COST

- $1.00/sample
- $30,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110/220V (switch able) electrical requirement
- The system or device does require water aliquots
- The system or device does require an external air source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 96 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 2 solutions or buffers used
- 2 components
- Daily extensive wash required

Maintenance:
- 2 consumables or expendables needed
- Every 6 months service required
- Expected life is 3-5 years
- 5-10 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 6 months and 1 year

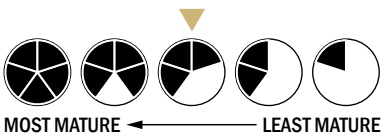
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- Sounds are produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at room temperature or 4°C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

Maturity gauge:
- A few devices or systems exist (brass board)



Mx3000P Real Time PCR System

by Stratagene Inc.

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Yersinia pestis, Brucella species, Orthopox virus *(Assays developed)*

DESCRIPTION:

The Mx3000P is a system for performing real-time quantitative PCR (QPCR). This technique allows researchers to quickly and easily quantify nucleic acids for studying gene expression, mutational analysis, disease state, gene dosage, and pathogen detection. QPCR measures PCR product accumulation during the exponential phase of the reaction and before amplification becomes vulnerable to limiting reagents and cycling variability. Fluorescent QPCR data provides accurate information on initial starting copy number. Using QPCR, amplification and detection are combined in a single step and in a single closed tube. This eliminates the need for numerous post-PCR manual steps, and reduces the possibility of introducing variability or laboratory contamination.

TECHNOLOGY:

The Mx3000P can be used to detect and quantify the amount of a specific sequence DNA or RNA present as starting template prior to a PCR amplification reaction. This is done using a technique known as real-time quantitative PCR. This technology is based on the measurement of the fluorescence of either a double stranded DNA binding dye such as SYBR Green or a fluorescent dye-bound probe based system like Taqman, Molecular Beacons, or Scorpions Probes. For any of these systems, the amount of fluorescence will increase as the amount of amplified PCR product increases. Based on the cycle number in the PCR reaction where your fluorescence rises above a threshold of background fluorescence (the threshold cycle, or Ct) you can calculate how much starting template you had in your amplification reaction. The more starting material you have, the earlier the cycle number at which the fluorescence will rise above the threshold. The Mx3000P combines the capabilities of a microplate fluorescence reader with a PCR thermocycler so fluorescence levels can be read as the PCR reaction progresses. It uses a tungsten halogen white light bulb to provide the excitation light, and the range of excitation is 350-750nm. There is a single optical channels in the instrument, but along this optical channel there are two filter wheels, one with a set of four excitation filters and one with a set of four emission filters. This allows you to specifically excite and measure the fluorescent signal for up to four different dyes in one tube.

ANALYTICAL Laboratory Ranking

Mx3000P Real Time PCR System ranked in the highest third of all evaluated products for analytical laboratories and earned 74% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Stratagene Mx3000P	0.665
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Mx3000P Real Time PCR System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 66% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Stratagene Mx3000P	0.598
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Mx3000P Real Time PCR System 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
Best Score	0.883
Stratagene Mx3000P	0.524
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

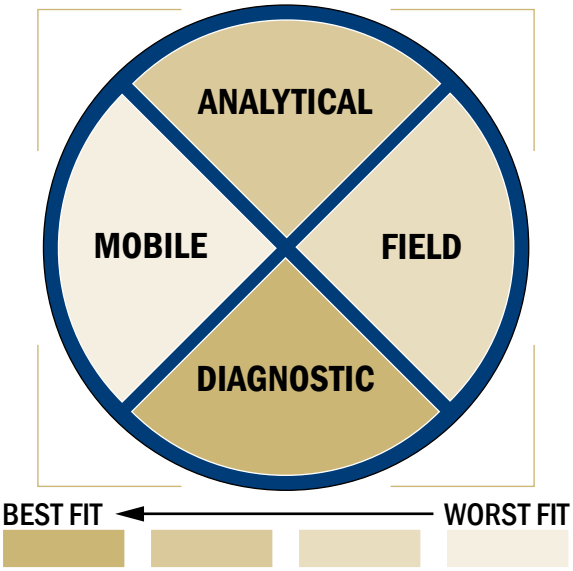
Mx3000P Real Time PCR System ranked in the middle third of all evaluated products for field use and earned 67% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Stratagene Mx3000P	0.634
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Stratagene Inc.
11011 North Torrey Pines Rd.
La Jolla, CA 92037
www.Mx3000P.com

Point of Contact:
Mike Metzler, Al Grafsky, or Owen Hardy
(800) 894-1304 x2
(858) 535-0034 fax
qpcrsystemssupport@stratagene.com

COST

- Variable/sample
- $24,995.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection in greater than 60 min
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or approach is not amenable to automation

Training/Speed/Manpower:

- More than a day of training
- No set-up required
- 6-8 manual steps required for detection

Re-use:

- Device or system is intended for multiple detections
- More than 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:

- 5 or more consumables or expendables needed
- Never needs service
- Expected life measure of 5-10 years
- No daily quality assurance procedures necessary

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 5-25 kg
- Shelf life between 1-3 years

Ease of use/Utility:

- Can view results “in real time”
- A single centrifugation step
- A single shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:

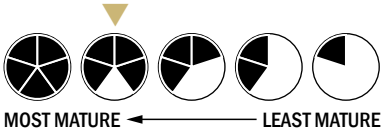
- Operated from 15 °C to 37 °C
- Components must be frozen
- Device or system has peak performance at normal relative humidity conditions only

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- Is commercially available



Mx3005P Real Time QPCR System

by Meso-Scale Discoveries

CAPABLE OF DETECTING THE FOLLOWING:

The Mx3005P will work with any published or commercially available primer and probe sets for detecting these targets.

DESCRIPTION:

The Mx3005P is a system for performing real-time quantitative PCR (QPCR). This technique allows researchers to quickly and easily quantify nucleic acids for studying gene expression, mutational analysis, disease state, gene dosage, and pathogen detection. QPCR measures PCR product accumulation during the exponential phase of the reaction and before amplification becomes vulnerable to limiting reagents and cycling variability. Fluorescent QPCR data provides accurate information on initial starting copy number. Using QPCR, amplification and detection are combined in a single step and in a single closed tube. This eliminates the need for numerous post-PCR manual steps, and reduces the possibility of introducing variability or laboratory contamination.

TECHNOLOGY:

The Mx3005P can be used to detect and quantify the amount of a specific sequence DNA or RNA present as starting template prior to a PCR amplification reaction. This is done using a technique known as real-time quantitative PCR. This technology is based on the measurement of the fluorescence of either a double stranded DNA binding dye such as SYBR Green or a fluorescent dye-bound probe based system like Taqman, Molecular Beacons, or Scorpions Probes. For any of these systems, the amount of fluorescence will increase as the amount of amplified PCR product increases. Based on the cycle number in the PCR reaction where your fluorescence rises above a threshold of background fluorescence (the threshold cycle, or Ct) you can calculate how much starting template you had in your amplification reaction. The more starting material you have, the earlier the cycle number at which the fluorescence will rise above the threshold. The Mx3005P combines the capabilities of a microplate fluorescence reader with a PCR thermocycler so fluorescence levels can be read as the PCR reaction progresses. It uses a tungsten halogen white light bulb to provide the excitation light, and the range of excitation is 350-750nm. There is a single optical channel, but along this optical channel there are two filter wheels. In the Mx3005P one filter wheel contains a set of four excitation filters and one a set of four emission filters. The motion of these filter wheels are controlled independently to allow any one of the excitation filters to be aligned with any one of the emission filters. This independent filter wheel control allows additional flexibility in the optical system to allow for applications such as FRET detection. The five filter positions allow you to specifically excite and measure the fluorescent signal for up to five different dyes in one tube in the Mx3005P.

ANALYTICAL Laboratory Ranking

Mx3005P Real Time QPCR System ranked in the highest third of all evaluated products for analytical laboratories and earned 75% of the utility points of the best score.

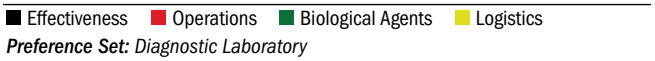
ALTERNATIVE	UTILITY
Best Score	0.901
Stratagene Mx3005P	0.673
Lowest Score	0.217

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Mx3005P Real Time QPCR System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 66% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Stratagene Mx3005P	0.604
Lowest Score	0.321

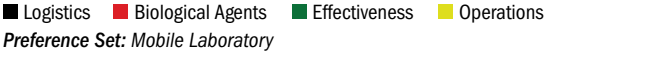


Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Mx3005P Real Time QPCR System ranked in the lowest third of all evaluated products for mobile laboratories and earned 52% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Stratagene Mx3005P	0.459
Lowest Score	0.379

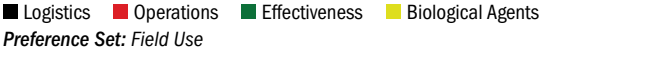


Preference Set: *Mobile Laboratory*

FIELD USE Ranking

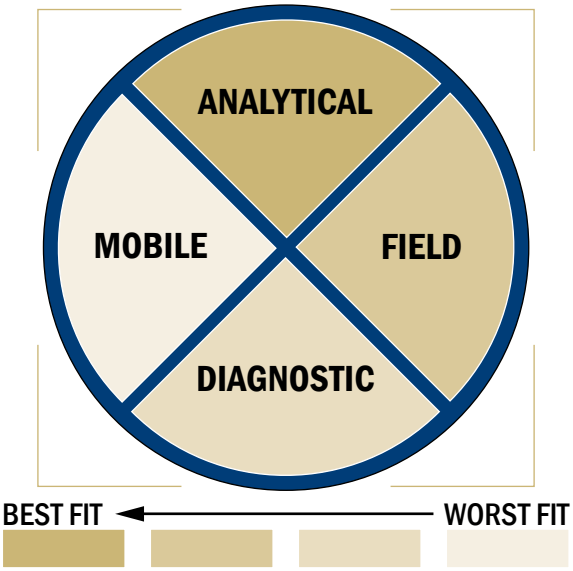
Mx3005P Real Time QPCR System ranked in the middle third of all evaluated products for field use and earned 60% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Stratagene Mx3005P	0.565
Lowest Score	0.343



Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Meso-Scale Discoveries
9238 Gaither
Gaithersburg, MD 20878
www.meso-scale.com

Point of Contact:
Vit Vasista
(240) 631-2522 x4622
(240) 632-2219 fax
vvasista@meso-scale.com

COST

- $0.50/sample plus cost of Taq enzyme
- $29,995.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V or 220V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 96 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device is not amenable to automation

Training/Speed/Manpower:
- More than a day of training and significant technical skills required
- 10-20 minutes set-up required
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:
- No service required
- Expected life is between 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Reagent shelf life between 1 to 3 years

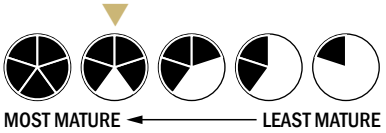
Ease of use/Utility:
- Can view results “in real time”
- There is a single centrifugation step
- There is a single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be frozen
- The performance of the device or system is influenced by relative humidity

Sensitivity:
- 100-1,000 CFU per ml

Maturity gauge:
- Is commercially available
- Has been featured in peer reviewed scientific publications or independent evaluations



Mx4000 Multiplex Quantitative PCR System

by Stratagene Inc.

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Yersinia pestis, Brucella species, Orthopox virus *(Commercially available as a freeze-dried reagent)*

DESCRIPTION:

The Mx4000 is a system for performing real-time quantitative PCR (QPCR). This technique allows researchers to quickly and easily quantify nucleic acids for studying gene expression, mutational analysis, disease state, gene dosage, and pathogen detection. QPCR measures PCR product accumulation during the exponential phase of the reaction and before amplification becomes vulnerable to limiting reagents and cycling variability. Fluorescent QPCR data provides accurate information on initial starting copy number. Using QPCR, amplification and detection are combined in a single step and in a single closed tube. This eliminates the need for numerous post-PCR manual steps, and reduces the possibility of introducing variability or laboratory contamination.

TECHNOLOGY:

The Mx4000 can be used to detect and quantify the amount of a specific sequence DNA or RNA present as starting template prior to a PCR amplification reaction. This is done using a technique known as real-time quantitative PCR. This technology is based on the measurement of the fluorescence of either a double stranded DNA binding dye such as SYBR Green or a fluorescent dye-bound probe based system like Taqman, Molecular Beacons, or Scorpions Probes. For any of these systems, the amount of fluorescence will increase as the amount of amplified PCR product increases. Based on the cycle number in the PCR reaction where your fluorescence rises above a threshold of background fluorescence (the threshold cycle, or Ct) you can calculate how much starting template you had in your amplification reaction. The more starting material you have, the earlier the cycle number at which the fluorescence will rise above the threshold. The Mx4000 combines the capabilities of a microplate fluorescence reader with a PCR thermocycler so fluorescence levels can be read as the PCR reaction progresses. It uses a tungsten halogen white light bulb to provide the excitation light, and the range of excitation is 350-750nm. There are four optical channels in the instrument, each with its own set of excitation and emission filters to specifically excite and measure the fluorescent signal for up to four different dyes in one tube.

ANALYTICAL Laboratory Ranking

Mx4000 Multiplex Quantitative PCR System ranked in the highest third of all evaluated products for analytical laboratories and earned 79% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Stratagene Mx 4000 Multiplex PCR Sys.	0.715
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Mx4000 Multiplex Quantitative PCR System ranked in the highest third of all evaluated products for diagnostic laboratories and earned 73% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Stratagene Mx 4000 Multiplex PCR Sys.	0.668
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Mx4000 Multiplex Quantitative PCR System 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
Best Score	0.883
Stratagene Mx 4000 Multiplex PCR Sys.	0.551
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

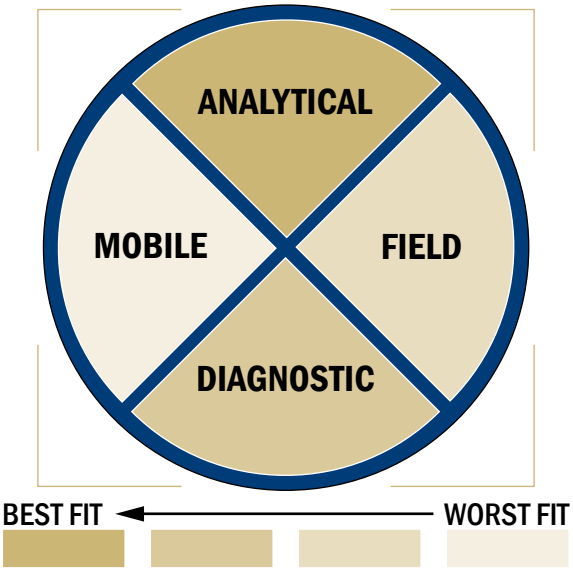
Mx4000 Multiplex Quantitative PCR System ranked in the middle third of all evaluated products for field use and earned 67% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Stratagene Mx 4000 Multiplex PCR Sys.	0.628
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Stratagene Inc.
11011 North Torrey Pines Rd.
La Jolla, CA 92037
www.Mx3000P.com

Point of Contact:
Mike Metzler
(800) 894-1304 x15434
(858) 535-0034 fax
tech_services@stratagene.com

COST

- Variable/sample
- $59,995.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection greater than 60 minutes
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:

- More than a day of training
- No set-up required
- 6-8 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:

- 5 or more consumables or expendables needed
- No service required
- Expected life is 5-10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a home dishwasher
- More than 50 kg
- Shelf life between 1 and 3 years

Ease of use/Utility:

- Can view results “in real time”
- Single centrifugation step
- Single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:

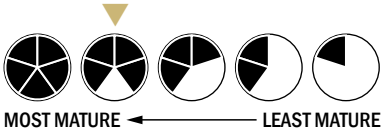
- Operated from 15 °C to 37 °C
- Components must be frozen
- Performance of the device or system has a peak performance at normal relative humidity conditions only

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- Is commercially available



NanoChip Molecular Biology Workstation

by Nanogen, Inc.

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, E. coli 0157:H7, Yersinia pestis, Orthopox virus *(Assays developed)*

DESCRIPTION:

The NanoChip Molecular Biology Workstation is an automated multi-purpose instrument that facilitates detection of known sequences, such as in the analysis of Single Nucleotide Polymorphisms (SNPs) and Short Tandem Repeats (STRs), using the NanoChip Electronic Microarray. The unique, open-architecture design permits researchers to define, select, and build their own test panels or select from predefined panels.

TECHNOLOGY:

Our fully integrated NanoChip System consists of three major subsystems: (1) the NanoChip Loader for loading samples on one to four NanoChip Cartridges, (2) the NanoChip Reader, a highly sensitive, laser-based fluorescence scanner for detection of assay results, and (3) computer hardware and software which automates import, analysis and export of sample information making data analysis simple. The NanoChip System is based on electronic addressing which involves placing charged molecules at specific test sites on a NanoChip microarray. Electronic addressing allows on-chip hybridization to occur within seconds compared to several hours in passive hybridization. In addition, DNA target molecules are electronically concentrated at the array sites, exceeding ca 1000 times the concentration in the bulk of solution. When a biotinylated sample solution is introduced onto the array, the negatively charged sample rapidly moves to the selected positively charged sites, where it is concentrated and bound to the streptavidin in the permeation layer. The array is then washed and another sample can be added. Site by site, row by row, an array of samples are assembled on the array. Such user-definable microchip arrays allow the customer to respond quickly to the ever evolving list of genes to be tested. The customer may analyze multiple genes from a single test site (representing one sample) or from multiple test sites (representing different samples). The customer also has the ability to electronically address multiplexed amplicons to a single test site. To date, we have developed two Analyte Specific Reagents (ASRs) - Factor V (Leiden) and Cystic Fibrosis and we offer research application notes for determining the following genes: Factor (II) prothrombin (coronary disease), Factor V/II multiplex (cardiovascular disease); MTHFR (cardiac function); hereditary hemochromatosis (venous thrombotic disease). This same platform has been used for development and testing of amplified DNA samples of biological warfare agents.

ANALYTICAL Laboratory Ranking

NanoChip Molecular Biology Workstation ranked in the highest third of all evaluated products for analytical laboratories and earned 72% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
NanoChip Workstation	0.648
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

NanoChip Molecular Biology Workstation ranked in the highest third of all evaluated products for diagnostic laboratories and earned 72% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
NanoChip Workstation	0.652
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

NanoChip Molecular Biology Workstation 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
Best Score	0.883
NanoChip Workstation	0.521
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

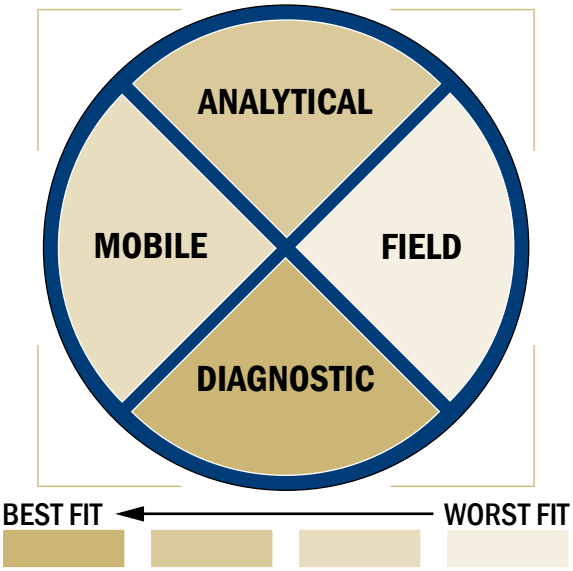
NanoChip Molecular Biology Workstation ranked in the lowest third of all evaluated products for field use and earned 53% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
NanoChip Workstation	0.498
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Nanogen, Inc
10398 Pacific Center Court
San Diego, CA 92121
www.nanogen.com

Point of Contact:
Sales Department
(877) NANOGEN

COST

- Unknown/sample
- $165,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 50 and 60 minutes
- 384 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- A day of training
- 10-20 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- More often than every 6 months service required
- Expected life is greater than 10 years
- 10-20 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- More than 50 kg
- Shelf life between 6 months and 1 year

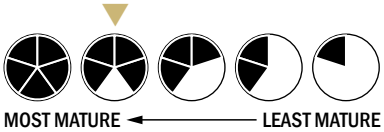
Ease of use/Utility:
- Cannot view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- Components must be stored at 4 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1,000-10,000 CFU per ml

Maturity gauge:
- Is commercially available



NIDS® Detection System

by ANP Technologies, Inc.

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Coxiella burnetti, Brucella species, E.coli O157:H7, Vibrio cholera, Yersinia pestis, Smallpox virus, Orthopox virus, Rift valley fever virus, Venezuelan equine encephalitis virus, Botulinum toxin A, Staphylococcal toxin B, Ricin toxin, Dengue fever virus, MS-2 bacteriophage, Botulinum toxin B *(Assays developed);* Influenza virus *(Assay validated)*

DESCRIPTION:

The NIDS® Detection System combines handheld immunoassays with a semi-automated reader to provide for the rapid and accurate detection of biothreat agents in aqueous samples. The biothreats comprise both BWA and non-BWA pathogens. The target must be water-borne, but the sample can be generated from surface swabs, aerosol collection, or natural water samples. The detection system provides an easy tool to be used either in the field or a laboratory setting and eliminates inter-personnel differences in interpreting assay results. The system can be used for both qualitative and quantitative analysis of samples. The user applies 100 µL of sample (3-4 drops) to the assay and allows the assay to develop for 10 - 15 minutes before inserting it into the reader. A simple push button operation provides a simple display of the assay results, with data being archived for subsequent transfer to a PDA or PC. The platform system can also be used as a diagnostic device in a point-of-care setting but does require specialized assays for use with medical samples.

TECHNOLOGY:

The assay is a lateral flow immunoassay that incorporates ANP Technologies' nanomanipulation technology to increase the assay sensitivity while reducing the false positive result rate. This is accomplished through the use of polymeric scaffolds that orient the detection antibodies so that their configuration is optimal for sensing the desired target pathogens. An image of the developed assay is automatically analyzed for positive results using proprietary algorithms that are more sensitive than the human eye.

ANALYTICAL Laboratory Ranking

NIDS Detection System ranked in the highest third of all evaluated products for analytical laboratories and earned 88% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
ANP NIDS	0.797
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

NIDS Detection System ranked in the highest third of all evaluated products for diagnostic laboratories and earned 96% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
ANP NIDS	0.874
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

NIDS Detection System ranked in the highest third of all evaluated products for mobile laboratories and earned 98% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
ANP NIDS	0.869
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

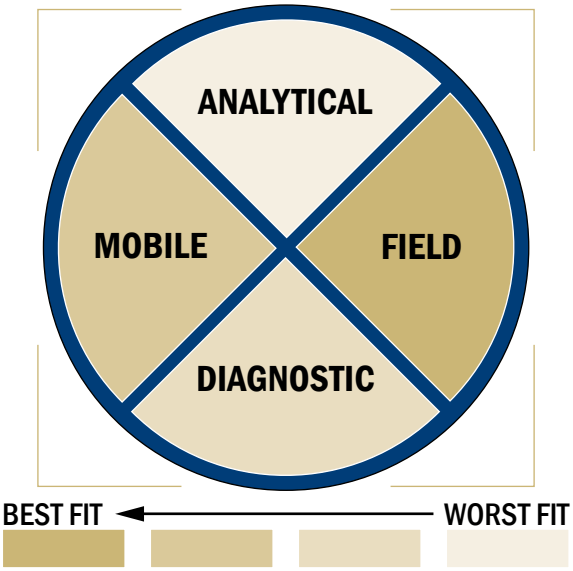
NIDS Detection System ranked in the highest third of all evaluated products for field use and earned 96% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
ANP NIDS	0.903
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

ANP Technologies, Inc.
824 Interchange Blvd.
Newark, DE 19711
www.anptinc.com

Point of Contact:
Robert Daniel
(302) 283-1730
(302) 283-1733 fax
robert@anptinc.com

COST

- To be determined

Evaluation Criteria Provided by Vendor

System requirements:

- System or device uses rechargeable batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection less than 20 minutes
- 2 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system with some effort

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 1 component
- Cleaned with alcohol or bleach

Maintenance:

- Less than once a year service required
- Expected life is between 3-5 years
- Less than 5 minutes required for daily quality assurance procedures

Transportation:

- Approximately the size of a soda can
- Less than 1 kg
- Reagent shelf life 1 to 3 years

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

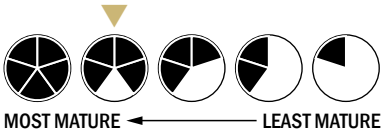
- Operated from 15°C to 37°C
- Components must be stored at room temperature
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1,000-10,000 CFU per ml

Maturity gauge:

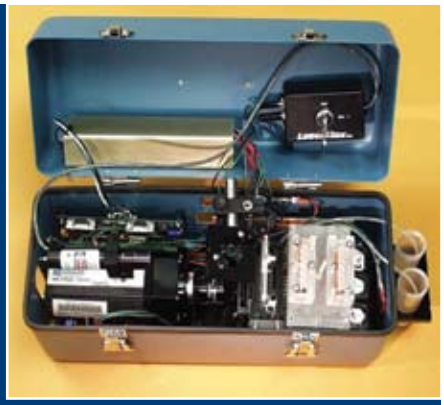
- Is commercially available
- Has been featured in peer reviewed scientific publications or independent evaluations



NRL Array Biosensor

by Naval Research Laboratory

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, E. coli O157:H7, Francisella tularensis, Vibrio cholera, Yersinia pestis, Brucella species, Botulinum toxin A &B, SEB, Ricin, Aflatoxin *(Assays developed)*



DESCRIPTION:
The array biosensor is an automated, portable detection device for simultaneous analysis of multiple samples for multiple analytes. It has progressed through a series of prototypes to obtain a reliable, small system to which a user can add six samples, with minimal, if any, sample preparation, and test for a variable number of targets. The current system weighs less than 6 kg and is operated using a laptop computer. The user places two reservoir modules in the system, one containing up to six samples and the other containing up to six cocktails of tracer reagents, and starts the assay. The fluidic system automatically runs the samples over the waveguide, exposes the waveguide to tracer, and washes out excess tracer. Image acquisition and data analysis are still performed offline, but the program to determine the boundaries of the spots and background controls and to calculate mean increase in fluorescence over the background is semi-automated. Applications explored to date include detection of infectious diseases and toxins in clinical fluids, food (liquids and homogenates), drinking water and environmental samples. In most cases, toxins can be detected at 0.1-1 ng/mL and bacteria at ~1000 cfu/mL without any target preconcentration. Assays for multiple targets are generally performed in 12 minutes; extending the time increases the sensitivity.

TECHNOLOGY:
The biochemical component of the multi-analyte biosensor consists of a patterned array of biological recognition elements ("capture" antibodies, oligosaccharides, antibiotics, other generic or specific receptors) immobilized on the surface of a planar waveguide. A fluorescence assay is performed on the patterned surface, yielding an array of fluorescent spots, the loci of which are used to identify what target is present. Signal transduction is accomplished by means of a diode laser for fluorescence excitation and a CCD camera for image capture. Data analysis software has been developed to quantify the fluorescent signals in each spot. The assays are fast, sensitive, and specific; up to 32 immunoassays have been conducted simultaneously on six independent samples. NRL has demonstrated the ability to detect proteins, toxins, bacteria, and viruses in a variety of physiological, food, and environmental matrices.

ANALYTICAL Laboratory Ranking

NRL Array Biosensor ranked in the highest third of all evaluated products for analytical laboratories and earned 94% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
NRL Array Biosensor	0.849
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

NRL Array Biosensor ranked in the highest third of all evaluated products for diagnostic laboratories and earned 94% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
NRL Array Biosensor	0.855
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

NRL Array Biosensor ranked in the highest third of all evaluated products for mobile laboratories and earned 92% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
NRL Array Biosensor	0.812
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

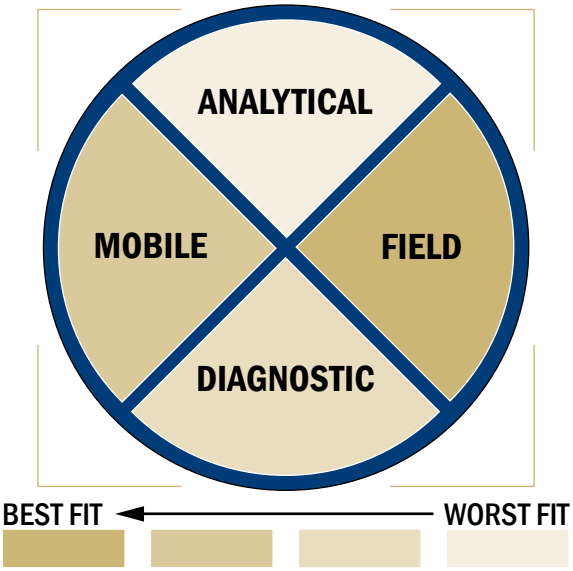
NRL Array Biosensor ranked in the highest third of all evaluated products for field use and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
NRL Array Biosensor	0.790
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
Naval Research Laboratory
Center for Bio/Molecular Science & Engineering, Code 6900
Washington, DC 20375-5348
cbmse.nrl.navy.mil

Point of Contact:
Frances Ligler
(202) 404-6002
(202) 404-8897 fax
fligler@cbmse.nrl.navy.mil

COST
- Unknown/sample
- $10,000/device or system

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 min or less
- 2 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- Very brief training
- Less than 5 min required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 2 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- Never needs service
- Expected life measure not applicable
- Less than 5 minutes required for daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 5-25 kg
- Shelf life between 6 months and 1 year

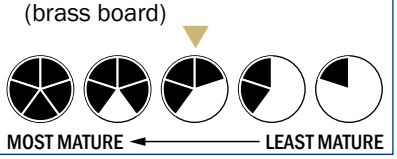
Ease of use/Utility:
- Ability to view results “in real time” depends upon application
- No centrifugation steps
- No shaking or vortexing steps
- System may be able to interpret raw data or call a positive through internal software in the future
- Assay available, and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- Sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4 °C to 37 °C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1,000 CFU per ml

Maturity gauge:
- Expected to be ready for commercialization within three or more calendar years
- A few systems or devices exist (brass board)



NucliSens EasyQ System

by bioMerieux

CAPABLE OF DETECTING THE FOLLOWING:
VEE virus *(Assay developed)*; Dengue fever virus *(Assay validated)*

DESCRIPTION:
The NucliSens EasyQ System combines isothermal (41C) nucleic acid sequence-based amplification (NASBA) and molecular beacon detection for Real-Time RNA assays using the NucliSens Basic Kit. RNA amplification assays are developed by the user with bioMerieux support. The system is designed for ease of use in low or large volume molecular testing laboratories. Amplification time is generally 60 minutes, with total time to result for amplification and detection of less than two hours for 48 samples. Commercially have done studies to link with automated and manual sample prep.

TECHNOLOGY:
The NucliSens EasyQ System combines nucleic acid sequenced-based amplification (NASBA) and real-time molecular beacon detection. The system is designed for ease of use and is equally suited to large or small volume molecular testing. Real-time NASBA amplification with molecular beacon detection equals rapid reaction time and often total time to result for amplification and detection in less than two hours and in some cases less than 15 minutes for 48 samples. NASBA technology is an isothermal process that uses three enzymes (AMV-RT, RNase H and T7 RNA polymerase) and target specific oligonucleotides. The reaction run at 41C, generating single stranded RNA as an end product. Windows based open software generates results, melting curve data and run performance information. The system is compact with a footprint of 16.5 x 16.5 in. combined with a small incubator and dedicated computer and centrifuge.

ANALYTICAL Laboratory Ranking

NucliSens EasyQ System ranked in the highest third of all evaluated products for analytical laboratories and earned 83% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
NucliSens EasyQ System	0.752
Lowest Score	0.217

Effectiveness, Biological Agents, Logistics, Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

NucliSens EasyQ System ranked in the highest third of all evaluated products for diagnostic laboratories and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
NucliSens EasyQ System	0.726
Lowest Score	0.321

Effectiveness, Operations, Biological Agents, Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

NucliSens EasyQ System ranked in the highest third of all evaluated products for mobile laboratories and earned 72% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
NucliSens EasyQ System	0.638
Lowest Score	0.379

Logistics, Biological Agents, Effectiveness, Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

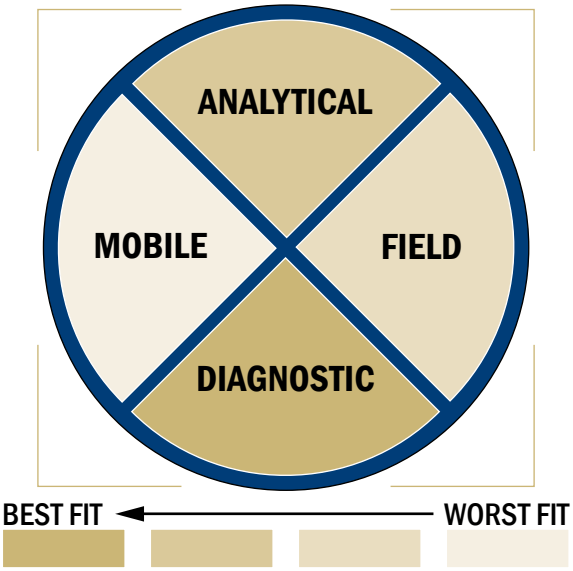
NucliSens EasyQ System ranked in the highest third of all evaluated products for field use and earned 82% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
NucliSens EasyQ System	0.772
Lowest Score	0.343

Logistics, Operations, Effectiveness, Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

bioMerieux
100 Rodolphe St.
Durham, NC 27712
www.biomerieux-usa.com

Point of Contact:
Lynell Grosso
(919) 620-2094
(919) 620-7019 fax
lynell.grosso@na.biomerieux.com

COST

- Approx. $10.00/sample
- $38,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection between 50 and 60 minutes
- 32 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:

- A day of training
- No set-up required
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 5 or more components
- Monthly maintenance required

Maintenance:

- 0-1 consumable or expendable needed
- Less than once a year service required
- Expected life is greater than 10 years
- No daily quality assurance procedures necessary

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility:

- Can view results “in real time”
- Single centrifugation step
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

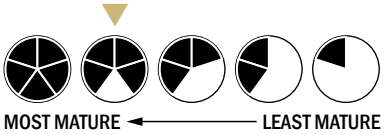
- Operated from 15 °C to 37 °C
- Components must be stored at 4 °C
- Device or system has peak performance at normal relative humidity conditions only

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- Is commercially available



Optical Immuno-assay

by Thermobiostar

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Botulinum toxin A, Ricin *(Assays developed)*

DESCRIPTION:
Thermobiostar currently produces a small, rapid (15-minute), easy to operate immuno-based detection assay. These assays are based on the change in refractive index of a small silicon based wafer due to deposition of enzymatic product following binding of a secondary, detection antibody to the target organism which has been captured by specific detection antibody adhered to the wafer. This technology, which currently exists for detection of clinically relevant infectious agents, such as streptococcus and influenza, is being adapted through a CRADA with the Naval Research Laboratory and modified for the rapid detection of environmental and potential bioterrorism agents. The assay is rapid, extremely sensitive (equivalent or better than ELISA) and is capable of quantitative detection. A further advantage of the assay is the capability to incorporate detection of multiple agents (10 or more) onto a single chip, greatly increasing the speed of agent detection. The assay, in its current configuration for clinically relevant infectious agents, is being used in many clinical laboratories and physicians' offices around the country.

TECHNOLOGY:
The assay is predicated on the change in refractive index associated with the formation of a thin–film created by deposition of enzymatic product resulting from reaction of enzyme, attached to detection antibody with its substrate. The operation of the assay is summarized by reacting the target antigen to the silicon wafer which has been derivatized with specific capture antibody. The antigen bound wafer is then further reacted with secondary, detection antibody conjugated with enzymatic probe. Visualization is conducted by further reaction of the wafer with substrate to form a thin-film, yielding a change in color of the chip which is readily detected by eye. The color changes from its normal red color to various shades of blue and ultimately white, depending on the concentration of antigen in the sample.

ANALYTICAL Laboratory Ranking

Optical Immuno-assay ranked in the middle third of all evaluated products for analytical laboratories and earned 66% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Optical Immuno-assay	0.591
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Optical Immuno-assay ranked in the highest third of all evaluated products for diagnostic laboratories and earned 73% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Optical Immuno-assay	0.667
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Optical Immuno-assay ranked in the highest third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Optical Immuno-assay	0.660
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

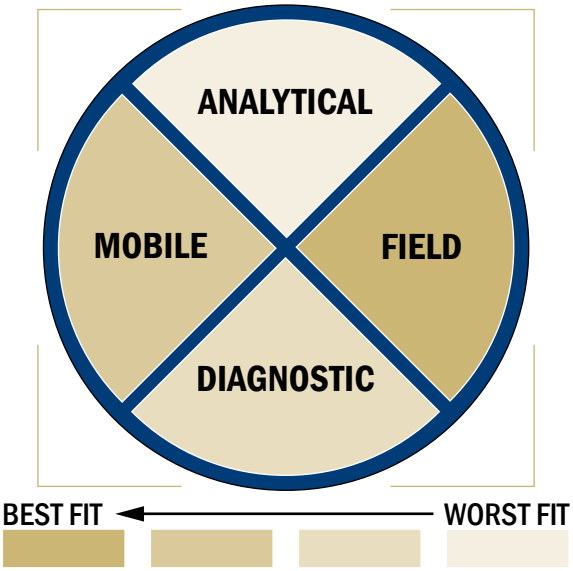
Optical Immuno-assay ranked in the highest third of all evaluated products for field use and earned 94% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Optical Immuno-assay	0.887
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Thermobiostar
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Boulder, CO 80301
www.thermobiostar.com

Point of Contact:
John Dorson
(800) 637-3717
(303) 581-6405 fax
j_Dorson@thermobiostar.com

COST

- Approx. $10.00/sample
- Approx. $10.00 /system or device

Evaluation Criteria Provided by Vendor

System requirements:
- No electrical requirement
- The system or device does require water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 20 and 30 minutes
- 384 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 3-5 manual steps required for detection

Re-use:
- Device or system is designed for single use
- 2 solutions or buffers used
- 4 components
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- No service required
- NA expected life
- No daily quality assurance procedures required

Transportation:
- Approximately the size of a soda can
- Less than 1 kg
- Shelf life between 6 months and 1 years

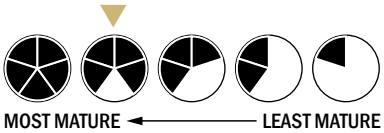
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 25 °C to 37 °C
- Components must be stored at 4 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 10,000-100,000 CFU per ml

Maturity gauge:
- Is commercially available



P-CAN Sensor™

by IBI

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Brucella species, E.coli O157:H7, Vibrio cholera, Yersinia pestis, Orthopox virus, Venezuelan equine encephalitis virus, Botulinum toxin A, Smallpox virus, Ricin toxin *(Assay developed);* Dengue fever virus, Rift valley fever virus *(Assay validated)*

DESCRIPTION:
The basis for this platform is CANARY™ technology, which provides a unique combination of speed, sensitivity, and flexibility for pathogen detection. CANARY™ provides the capability for detection of bacteria, viruses, and toxins in liquid or aerosol samples, and delivers a result within minutes of sample isolation. Use of CANARY™ with environmental samples is performed using an completely automated system called the PANTHER, described elsewhere in this survey. The sensor described here facilitates detection in liquid samples with a time to result of less than five minutes and a sensitivity of as few as 50 target organisms. This sensor system consists of a 16-channel centrifugal rotor that is positioned adjacent to a photomultiplier tube in a light-tight enclosure. A brief centrifugation step facilitates the interaction of the target with the detection reagent, resulting immediately in a luminescent output that is recorded in real time as the sample passes by the photomultiplier tube. The position of each tube in the rotor is monitored in tandem with the light output, enabling a determination of the presence or absence of pathogen in all tubes within one minute.

TECHNOLOGY:
The CANARY™ technology consists of B cell lines engineered to express a bioluminescent protein along with an antibody localized to the cell surface that recognizes a molecular target of interest. Binding of target to the surface-bound antibodies initiates a luminescent response within seconds, allowing for real-time detection of target. CANARY™ has a demonstrated sensitivity for most targets of as few as 50 organisms, achieved by virtue of the fact that interaction between target and B cell reagent can be efficiently facilitated by a short centrifugation step. Time to result in liquid samples is less than five minutes.

ANALYTICAL Laboratory Ranking

P-CAN ranked in the highest third of all evaluated products for analytical laboratories and earned 94% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
IBI P-CAN	0.843
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

P-CAN ranked in the highest third of all evaluated products for diagnostic laboratories and earned 96% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
IBI P-CAN	0.871
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

P-CAN ranked in the highest third of all evaluated products for mobile laboratories and earned 89% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
IBI P-CAN	0.789
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

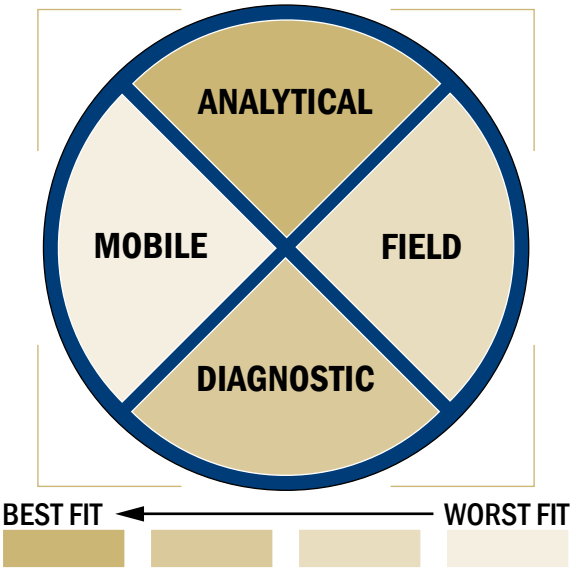
P-CAN ranked in the highest third of all evaluated products for field use and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
IBI P-CAN	0.752
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

IBI
387 Technology Drive
College Park, MD 20742
innovativebiosensors.com

Point of Contact:
Thomas Hazel
(301) 405-8466
(301) 314-7436
tom.hazel@innovativebiosensors.com

COST

- $28.00/sample
- $15,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection in 20 minutes or less
- 2 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes set-up required
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 2 solutions or buffers used
- 1 component
- No cleaning required

Maintenance:

- Once a year service required
- Expected life is between 3-5 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a toaster
- Between 1 and 5 kg
- Reagent shelf life between 1 to 6 months

Ease of use/Utility:

- Can view results “in real time”
- There are multiple centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:

- There are sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

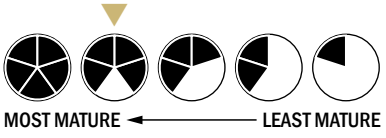
- Operated from 15 °C to 37 °C
- Components must be stored at 4 °C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 50-100 CFU per ml

Maturity gauge:

- A few devices or systems exist (brass board)
- Is expected to be ready for commercialization within one calendar year
- Less than $1,000,000 required for device or system to advance to commercialization
- Has not been featured in any peer reviewed scientific publications or independent evaluations



Palm-Cycler Thermocycler

by Corbett Research

CAPABLE OF DETECTING THE FOLLOWING:
Able to detect any organisms for which assays are developed.

DESCRIPTION:
The Palm-Cycler is designed to regulate temperatures in a small metal block based on user programs for temperature and cycling times. The Palm-Cycler is used to facilitate the enzymatic reactions necessary for many detection methods. It does not directly detect anything itself. There are a wide array of sequencing , DNA amplification, Real-Time and isothermal reaction assays that can be used on the Palm-Cycler.

TECHNOLOGY:
Overall, the Palm-Cycler is a very simple system to operate. The temperature can be regulated from 4°C-99°C in a 96 x 0.2ml, 384 x 0.1ml or 60 x 0.5ml block. The system utilizes a heated lid to prevent condensation and is controlled by an HP Journada, a pocket PC device.

ANALYTICAL Laboratory Ranking

Palm-Cycler ranked in the highest third of all evaluated products for analytical laboratories and earned 73% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Palm-Cycler PCR	0.659
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Palm-Cycler ranked in the highest third of all evaluated products for diagnostic laboratories and earned 74% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Palm-Cycler PCR	0.671
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Palm-Cycler 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
Best Score	0.883
Palm-Cycler PCR	0.591
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

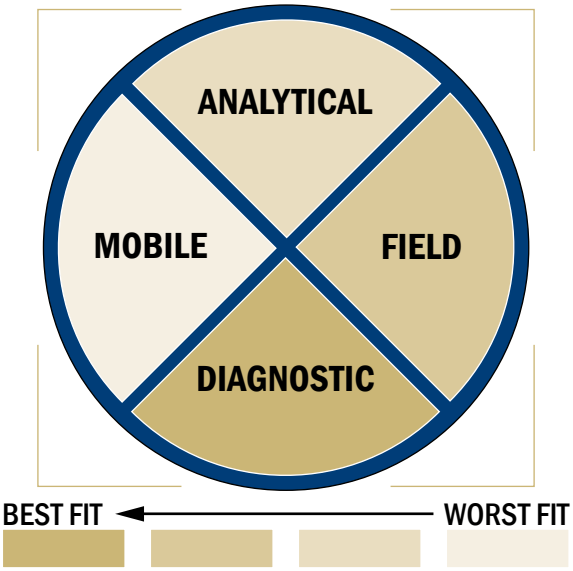
Palm-Cycler ranked in the highest third of all evaluated products for field use and earned 79% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Palm-Cycler PCR	0.741
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Corbett Research
1/14 Hilly Street
Mortlake, NSW 2137 Australia
www.corbettresearch.com

Point of Contact:
John Corbett
011-612-973-613-20
011-612-973-613-64 fax
john@corbettesearch.com

COST

- Unknown/sample
- $4,995.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Detection performed in greater than 60 minutes
- 96 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 2 solutions or buffers used
- 1 component
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Less than once a year service required
- Expected life is 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 1 and 3 years

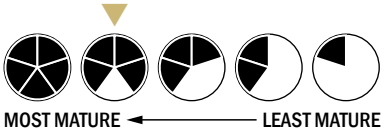
Ease of use/Utility:
- Cannot view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System is never able to interpret raw data or call a positive through internal software
- System cannot detect multiple biological agents or toxins detection within the same test
- Three additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:
- Operated from 4 °C to 45 °C
- Components must be stored at 4 °C, and stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

Maturity gauge:
- Is commercially available



PANTHER Autonomous Sensor

by MIT

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Brucella species, E.coli O157:H7, Vibrio cholera, Yersinia pestis, Orthopox virus, Botulinum toxin A *(Commercially available as a wet/frozen reagent);* Smallpox virus, Ricin toxin *(Assay developed);* Dengue fever virus, Rift valley fever virus, Venezuelan equine encephalitis virus *(Assay validated)*

DESCRIPTION:

We have incorporated the pathogen identification technology with the best-known combination of speed and sensitivity into a flexible bioaerosol sensor platform called PANTHER (Pathogen Alarm and Notification of Threatening Environmental Releases). A fully autonomous aerosol identification sensor based on PANTHER has been designed that would be capable of automatically collecting, processing, and identifying pathogen aerosols in response to as many as 30 independent triggered or timed aerosol collections. High-confidence collection and identification of bioaerosols in two minutes has been demonstrated using the core PANTHER sensor technology (see PANTHER CUB questionnaire for more details). This sensor was designed to provide bioaerosol identification performance that is as much as 10 times faster and 10 times more sensitive than that provided by existing sensors while increasing the number of analyses per test and reducing false positive rates, power requirements, and overall size and weight. The autonomous PANTHER sensor design eliminates the need for all liquid collection consumables and their associated fluid handling mechanisms. This enables it to be smaller, faster, and simpler than existing autonomous bioaerosol sensors while still including onboard environmental control for the PANTHER disks and transport mechanisms to allow it to automatically collect and analyze up to 30 aerosol samples. The autonomous PANTHER sensor design has a volume of less than 6 ft^3 and an estimated weight of 140 lbs (64 kg). This sensor design represents the full-capability automated aerosol identification sensor in the PANTHER family of mission-specific automated bioaerosol identification sensors useful as stand-alone bioaerosol sensors for site/building protection, portable sensors for field use by emergency responders, and rapid processing of environmental samples in the field or in the laboratory. NOTE: Because the revolutionary design of the PANTHER bioaerosol sensor conducts direct analyses of dry-collected samples, the questions in the survey that assume liquid samples are not directly relevant to this sensor. Questions related to throughput and processing requirements have been answered assuming a dry sample as collected by the PANTHER and additional comments have been added where necessary.

TECHNOLOGY:

PANTHER employs reagentless inertial impaction for aerosol collection coupled directly with CANARY B-cell pathogen identification technology in a configuration that eliminates the need for fluid transfer mechanisms and liquid collection consumables. All of the features required for aerosol collection, reagent storage, reagent delivery, and optical signal monitoring have been built into a simple, disposable, injection-molded disk that is automatically processed by the CUB sensor. A single PANTHER disk with a diameter the same as a standard CD or DVD is capable of collecting aerosol samples at up to 520 L/min (32 L/min/channel) and completing 16 independent assays on the collected sample simultaneously.

ANALYTICAL Laboratory Ranking

PANTHER Autonomous Sensor ranked in the highest third of all evaluated products for analytical laboratories and earned 91% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
MIT Panther	0.821
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

PANTHER Autonomous Sensor ranked in the highest third of all evaluated products for diagnostic laboratories and earned 95% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
MIT Panther	0.865
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

PANTHER Autonomous Sensor ranked in the highest third of all evaluated products for mobile laboratories and earned 87% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
MIT Panther	0.772
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

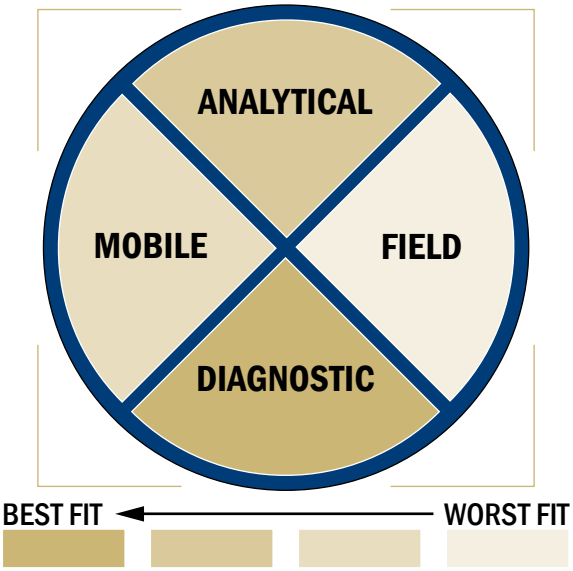
PANTHER Autonomous Sensor ranked in the middle third of all evaluated products for field use and earned 72% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
MIT Panther	0.677
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
MIT Lincoln Laboratory
244 Wood St.
Lexington, MA 02420

Point of Contact:
James Harper
(781) 981-0794
(781) 981-3867
harper@LL.mit.edu

COST
- $0.63/sample
- $100,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 minutes or less
- 32 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- A day of training
- 5-10 minutes set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 1 component
- No cleaning required

Maintenance:
- Every 6 months service required
- Expected life is greater than 10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- More than 50 kg
- Reagent shelf life between 1 to 6 months

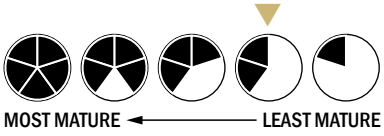
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- There are sounds produced that cannot be deactivated

Operational conditions:
- Operated from 4 °C to 45 °C
- Components must be stored at 4 °C or room temperature
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1,000 CFU per ml

Maturity gauge:
- Only one incomplete device or system exists (bread board)
- Is expected to be ready for commercialization within one calendar year
- Less than $1,000,000 required to advance device or system to commercialization
- Has not been featured in any peer reviewed scientific publications or independent evaluations



PANTHER CUB

by MIT

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Brucella species, E.coli O157:H7, Vibrio cholera, Yersinia pestis, Orthopox virus, Botulinum toxin A *(Commercially available as a wet/frozen reagent);* Smallpox virus, Ricin toxin *(Assay developed);* Dengue fever virus, Rift valley fever virus, Venezuelan equine encephalitis virus *(Assay validated)*

DESCRIPTION:

We have incorporated the pathogen identification technology with the best-known combination of speed and sensitivity into a flexible bioaerosol sensor platform called PANTHER (Pathogen Alarm and Notification of Threatening Environmental Releases). The first PANTHER sensor, the CUB, is a compact portable sensor capable of automatically collecting, processing and identifying pathogen aerosols. High-confidence collection and identification of bioaerosols in two minutes has been demonstrated using PANTHER CUB sensors that can ultimately be made for less than $20K in volume. CUB sensors currently weigh 37 lb. (17 kg) and fit in a volume of ~1 ft3, and further size and weight reductions are possible. The CUB design is simple and reliable: It has no fluidics, no liquid consumables, minimal moving parts, loads like a CD player, and automatically collects and analyzes aerosol samples. This sensor has been designed with modular upgrades in mind and can form the core of a family of mission-specific automated bioaerosol identification sensors useful as stand-alone bioaerosol sensors for site/building protection, portable sensors for field use by emergency responders, and rapid processing of environmental samples in the field or in the laboratory. NOTE: Because the revolutionary design of the CUB bioaerosol sensor conducts direct analyses of dry-collected samples, the questions in the survey that assume liquid samples are not directly relevant to this sensor. Questions related to throughput and processing requirements have been answered assuming a dry sample as collected by the PANTHER CUB and additional comments have been added where necessary.

TECHNOLOGY:

PANTHER employs reagentless inertial impaction for aerosol collection coupled directly with CANARY B-cell pathogen identification technology in a configuration that eliminates the need for fluid transfer mechanisms and liquid collection consumables. All of the features required for aerosol collection, reagent storage, reagent delivery, and optical signal monitoring have been built into a simple, disposable, injection-molded disk that is automatically processed by the CUB sensor. A single PANTHER disk with a diameter the same as a standard CD or DVD is capable of collecting aerosol samples at up to 520 L/min (32 L/min/channel) and completing 16 independent assays on the collected sample simultaneously.

ANALYTICAL Laboratory Ranking

PANTHER CUB ranked in the highest third of all evaluated products for analytical laboratories and earned 94% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
MIT Panther Cub	0.848
Lowest Score	0.217

Effectiveness, Biological Agents, Logistics, Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

PANTHER CUB ranked in the highest third of all evaluated products for diagnostic laboratories and earned 98% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
MIT Panther Cub	0.894
Lowest Score	0.321

Effectiveness, Operations, Biological Agents, Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

PANTHER CUB ranked in the highest third of all evaluated products for mobile laboratories and earned 95% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
MIT Panther Cub	0.839
Lowest Score	0.379

Logistics, Biological Agents, Effectiveness, Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

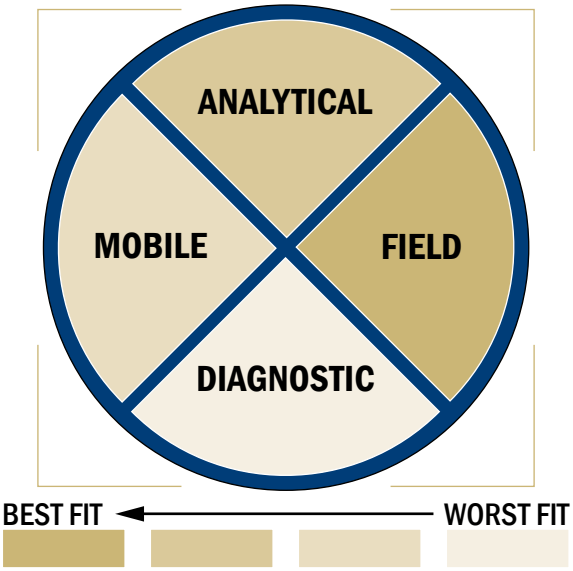
PANTHER CUB ranked in the highest third of all evaluated products for field use and earned 94% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
MIT Panther Cub	0.885
Lowest Score	0.343

Logistics, Operations, Effectiveness, Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
MIT Lincoln Laboratory
244 Wood St.
Lexington, MA 02420

Point of Contact:
James Harper
(781) 981-0794
(781) 981-3867
harper@LL.mit.edu

COST
- $0.63/sample
- Unknown/system

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 minutes or less
- 32 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 1 component
- No cleaning required

Maintenance:
- Once a year service required
- Expected life is greater than 10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 5 and 25 kg
- Reagent shelf life between 1 to 6 months

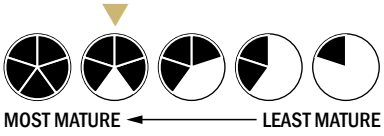
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- There are sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4 °C to 45 °C
- Components must be stored at 4 °C or room temperature
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1,000 CFU per ml

Maturity gauge:
- Is commercially available
- Has not been featured in any peer reviewed scientific publications or independent evaluations



PathAlert™

by Invitrogen

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Yersinia pestis, Smallpox virus, Orthopox virus, *(Commercially available as a freeze-dried reagent);* Brucella species, E.coli O157:H7, Ebola virus, Botulinum toxin A, Botulinum toxin B *(Assay developed)*

DESCRIPTION:

The PathAlert™ detection kit is a multiplex PCR system capable of detecting Bacillus anthracis (Anthrax), Yersinia pestis (Plague), Francisella tularensis (Tularemia), or Smallpox (Orthopox) in individual assays. The system is intended for use in stationary or mobile laboratory settings. The workflow is simple – following nucleic acid extraction of the sample (which may be performed by any commercial method including Invitrogen's ChargeSwitch™ product offering), PathAlert™ reagents are used to perform end-point PCR analysis and the amplification product is analyzed using the microfluidics based Agilent 2100 Bioanalyzer. PathAlert™ is specific due to multiple loci and the use of both amplification and size for detection; sensitive given proprietary PCR based technology; and flexible given future capabilities for multi-agent detection in single assays. The PathAlert™ kits and Agilent 2100 Bioanalyzer are COTS. The key advantage of the 2100 Bioanalyzer is the ability to perform multiplex detection, simultaneously interrogating collected samples (20 or more) for multiple bacteria and viruses. This results in dramatically reduced operating costs and a more efficient workflow. Using the electropherogram traces from the Bioanalyzer output, the operator is provided with a clear "yes/no" answer as to the presence of the pathogen specific amplification products. The PathAlert™ System has recently been included in the mobile laboratory developed for the Air Force by Battelle at Kirtland Air Force Base in Utah; used to ensure the safety of athletes in the recent Olympic games in Italy and in the Commonwealth Games in Australia; and in a number of other government and commercial settings.

TECHNOLOGY:

PathAlert™ kits include an optimized PCR supermix specific to the pathogen of interest and an external positive control for system validation. Critical kit components are: Taq polymerase, pre-complexed with antibodies for "hot start" PCR (for specificity and sensitivity); Uracil DNA Glycosylase (UDG) and dUTP (for the elimination of post-PCR cross-contamination); and an internal positive control, to identify potential PCR inhibition. The external positive control has been engineered to produce a unique amplicon size, thereby eliminating any concerns associated with false positives related to external control contamination. The microfluidics based Agilent 2100 Bioanalyzer uses capillary electrophoresis to provide amplicon sizing information.

ANALYTICAL Laboratory Ranking

PathAlert ranked in the highest third of all evaluated products for analytical laboratories and earned 93% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Invitrogen PathAlert	0.841
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

PathAlert ranked in the highest third of all evaluated products for diagnostic laboratories and earned 85% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Invitrogen PathAlert	0.770
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

PathAlert ranked in the highest third of all evaluated products for mobile laboratories and earned 86% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Invitrogen PathAlert	0.759
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

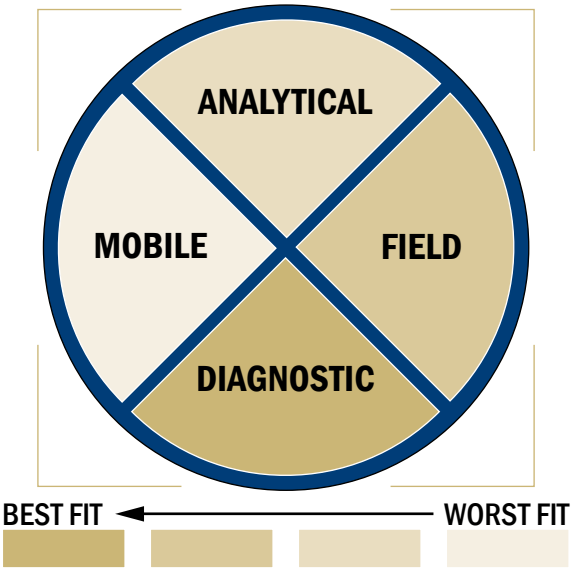
PathAlert ranked in the highest third of all evaluated products for field use and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Invitrogen PathAlert	0.758
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Invitrogen
7335 Executive Way
Frederick, MD 21704
www.invitrogen.com/pathogenresearch

Point of Contact:
Bill Folkerts
(240) 379-4209
Willem.Folkerts@invitrogen.com

COST

- $2.50-5.00/sample
- $25,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 96 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- An afternoon of training and some technical skills required
- No set-up required
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 3 components
- Cleaning of the Bioanalyzer requires the use of a multiple use water containing microfluidic chip

Maintenance:
- No service required
- Expected life is greater than 10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Reagent shelf life between 1 to 3 years

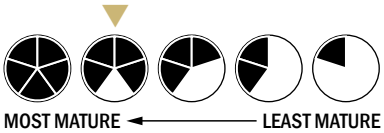
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- There is a single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from 4 °C to 37 °C
- Components must be frozen
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

Maturity gauge:
- Is commercially available
- Has been featured in peer reviewed scientific publications or independent evaluations



Portable NanoChip Molecular Biology Workstation

by Nanogen, Inc.

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, E. coli 0157:H7, Yersinia pestis, Orthopox virus, SEB *(Assays developed)*

DESCRIPTION:

The Portable NanoChip Molecular Biology Workstation is a miniaturized automated instrument that facilitates detection of known DNA sequences, primarily developed for the detection of biological warfare agents using the 400-site NanoChip Electronic Microarray. The unique, open-architecture design permits users to easily develop new assays for bacterial or viral identification as well as other genetic analysis applications. The Portable NanoChip System uses CMOS 400-site microarray embedded into a cartridge for electronic addressing of the DNA samples or probes onto the array. The fluorescent reporters are attached passively or actively and an optical system with CCD camera measures fluorescence at each array site. The samples are simply pipetted through a sample cup as well as some of the reagents needed in the tests and automatically pumped onto the microarray chip. Buffer and waste bottles are housed in the instrument. The software provides fully automated fluidic control, electronic addressing on the array as well as fluorescent image data display and interpretation.

TECHNOLOGY:

Nanogen's NanoChip technology is used in the instrument which is based on electronic addressing of charged molecules at specific test sites on the NanoChip microarray. Electronic addressing allows on-chip hybridization to occur within seconds compared to several hours in passive hybridization. In addition, DNA target molecules are electronically concentrated at the array sites, exceeding ca 1000 times the concentration in the bulk of solution. When a biotinylated sample or probe is introduced onto the array, the negatively charged molecules rapidly move to the selected positively charged sites, where it is concentrated and bound to the streptavidin in the permeation layer. The array is then washed and another sample can be added. Site by site, row by row, an array of samples are assembled on the array and fluorescence detected. The platform allows both electronic and thermal stringency assays to be developed which assure single base pair recognition. The customer may analyze multiple genes from a single test site (representing one sample) or from multiple test sites (representing different samples). The customer also has the ability to electronically address multiplexed amplicons to a single test site. DNA samples amplified by PCR, or strand displacement amplification (SDA) can be used in the analysis. In addition, Nanogen developed an on-chip SDA DNA amplification method for the detection of geological warfare agents. This method allows multiplexed amplification on the chip as well as detection of amplified products.

ANALYTICAL Laboratory Ranking

Portable NanoChip Molecular Biology Workstation ranked in the highest third of all evaluated products for analytical laboratories and earned 70% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Port. NanoChip Workstation	0.627
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Portable NanoChip Molecular Biology Workstation ranked in the highest third of all evaluated products for diagnostic laboratories and earned 72% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Port. NanoChip Workstation	0.650
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Portable NanoChip Molecular Biology Workstation ranked in the middle third of all evaluated products for mobile laboratories and earned 67% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Port. NanoChip Workstation	0.588
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

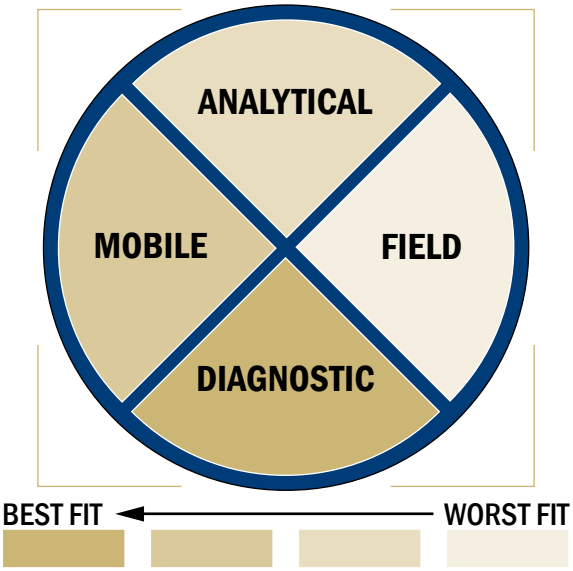
Portable NanoChip Molecular Biology Workstation ranked in the middle third of all evaluated products for field use and earned 56% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Port. NanoChip Workstation	0.531
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Nanogen, Inc.
10398 Pacific Center Court
San Diego, CA 92121
www.nanogen.com

Point of Contact:
Sales Department
(877) NANOGEN

COST

- Unknown/sample
- Unknown/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device uses batteries or 110V requirement
- The system or device does require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection between 40 and 50 minutes
- 32 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:

- An afternoon of training
- 5-10 minutes required for set-up
- 6-8 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:

- 5 or more consumables or expendables needed
- More often than every 6 months service required
- Expected life is greater than 10 years
- Less than 5 minutes required for daily assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility:

- Cannot view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

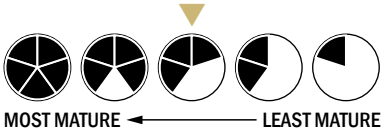
- Operated from 4 °C to 37 °C
- Components must be stored at 4 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1,000-10,000 CFU per ml

Maturity gauge:

- A few devices or systems exist (brass board)



Pro Strips™ Rapid Screening System

by Advnt

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Yersinia pestis, Botulinum toxin A, Botulinum toxin B, Staphylococcal toxin B, Ricin toxin
(Commercially available as wet/frozen reagent)

DESCRIPTION:
One Device - One Sample, Multiple threat recognition capabilities. Inspired by HAZMAT professionals, Pro Strips™ is the first and only Hand-Held Assay designed to detect and identify multiple threats using one small sample and one, simple to use device. Pro Strips advanced design revolutionizes speed, efficiency, and ease-of-use, while providing the highest degree of accuracy needed to correctly mitigate the risk associated with a biological threat. Each Hand-Held Assay is individually packaged and comes complete with everything needed to perform the test. No reader or additional collection kits required.

TECHNOLOGY:
Pro Strips™ biowarfare detection kits are a hand-held immunochromatographic assay which employs the use of labeled antibodies for detection.

ANALYTICAL Laboratory Ranking

Pro Strips ranked in the highest third of all evaluated products for analytical laboratories and earned 74% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Advnt Pro Strips	0.663
Lowest Score	0.217

Effectiveness, Biological Agents, Logistics, Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Pro Strips ranked in the highest third of all evaluated products for diagnostic laboratories and earned 85% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Advnt Pro Strips	0.770
Lowest Score	0.321

Effectiveness, Operations, Biological Agents, Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Pro Strips ranked in the highest third of all evaluated products for mobile laboratories and earned 90% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Advnt Pro Strips	0.794
Lowest Score	0.379

Logistics, Biological Agents, Effectiveness, Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

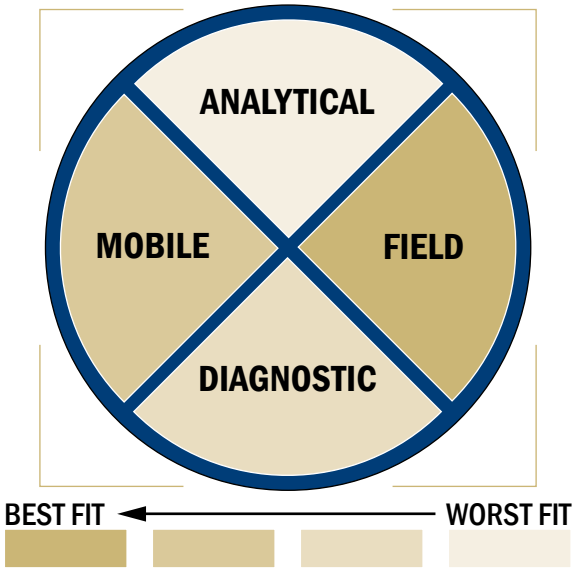
Pro Strips ranked in the highest third of all evaluated products for field use and earned 96% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Advnt Pro Strips	0.903
Lowest Score	0.343

Logistics, Operations, Effectiveness, Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Advnt
2102 West Quail Avenue, Suite 3
Phoenix, AZ 85027
www.advnt.org

Point of Contact:
Dan Faubion
(888) 223-3269
(623) 879-9697
danf@advnt.org

COST

- $13.99/Pro Strips 5 and $16.65/Pro Strips 3
- $69.95/Pro Strips 5 and $49.95/Pro Strips 3

Evaluation Criteria Provided by Vendor

System requirements:
- There is no electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection less than 20 minutes
- 2 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or device is not amenable to automation

Training/Speed/Manpower:
- Very brief (minutes-hours) training and minimal technical skills
- No set-up required
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for single use
- 0-1 solution or buffer used
- 1 component

Maintenance:
- No service required
- The expected life is unknown
- No daily quality assurance procedures

Transportation:
- Approximately the size of a soda can
- Less than 1 kg
- Reagent shelf life between 1 and 3 years

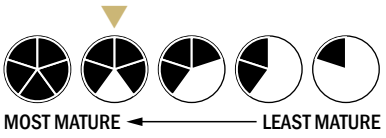
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- 1 shaking or vortexing step
- System cannot interpret raw data or call a positive through internal software
- Capable of detecting two or more biological agents or toxins within the same test
- No additional equipment required

Signature:
- There are no sounds that cannot be deactivated

Operational conditions:
- Operated from 4°C to 45°C
- Components must be stored at room temperature
- The performance of the device or system is influenced by relative humidity

Sensitivity:
- 1000-10,000 CFU per ml

Maturity gauge:
- Is commercially available
- Has been featured in peer reviewed scientific publications or independent evaluations



PROFILE-1 ATP Luminescence System

by New Horizons Diagnostics Corp.

CAPABLE OF DETECTING THE FOLLOWING:

Generic Bacterial/spore
(Commercially available as wet/frozen reagent)

DESCRIPTION:

New Horizon Diagnostics Corporation (NHD) manufactures a hand-held, generic detector for ATP in living systems with a no specificity, battery operated (AC-DC), luminometer that is capable of determining the presence of viable low levels of bacteria and spores. The protocol incorporates a method for the removal of non-bacterial cells as well as potential interferents. The System provides Real-Time results; 5 minutes for bacterial detection and 20 minutes for spore detection. The PROFILE System detects only viable organisms and has the capability to quantitate bacterial levels. PROFILE has received FDA 510(k) for human use (bacteria in urine), field validated by USDA for bacterial detection on meat carcasses, field tested by WHO labs for water samples, and tested by DOD for detection of spores. More recently, DARPA funded studies have demonstrated the utility of the System to detect and identify as low as 100 Bacillus anthracis spores in less than 30 minutes. Identification can be made via utilization of specific bacteriophage lytic enzymes or antibodies. The PROFILE is a field instrument that was incorporated in the original BIDS for air samples. There is also application for other environmental samples (powders, surfaces, etc.) water, food, as well as fuel oils. Detection limits are normally between 1000 and 100,000 cells, depending on the debris in the sample area, but the system can be adjusted to detect 100 or less cells. The System has been incorporated in a Bio-Screen "Triage" system for First Responders. As part of a "Layered" approach system, PROFILE received highest score for general detection in DOD study (ECBC-TR-171).

TECHNOLOGY:

Luminescence is the emission of light that does not derive energy from the temperature of the emitting body. It is caused by chemical, biochemical, or physical changes of a material in a sample. Luminescence techniques utilize this phenomenon to measure the presence of an analyte in a sample that exhibits this characteristic. This typically is achieved by the reaction of the analyte with a substrate that produces light. Luciferin-Luciferase (L/L) luminescence techniques are used to measure the adenosine triphosphate (ATP) content (pg/ml) in samples containing either vegetative bacterial cells or spores. Evaluation for the presence of total bio-mass from both bacterial and non-bacterial sources of ATP is achieved by suspending the collected samples in phosphate buffered saline (PBS), transferring an aliquot of the PBS suspension into a Filtravette, adding bacterial releasing agent (BRA), then adding L/L. The sample then reacts with the L/L, and the resulting Relative Light Units (RLU) indicative of the total ATP content, are measured. Identical techniques are used to prepare the bacterial cells for analysis with one additional step: a wash of the sample with somatic cell releasing agent (SRA) before adding BRA. The SRA wash is added to the Filtravette along with the sample and lyses all non-microbial (somatic and quenching) cells. These lysed cells are removed from the Filtravette via positive pressure, leaving the bacterial cells whole on the surface of the Filtravette.

ANALYTICAL Laboratory Ranking

Profile-1 ATP ranked in the highest third of all evaluated products for analytical laboratories and earned 83% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
PROFILE-1 ATP Lumin. Sys.	0.750
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Profile-1 ATP ranked in the highest third of all evaluated products for diagnostic laboratories and earned 87% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
PROFILE-1 ATP Lumin. Sys.	0.793
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Profile-1 ATP ranked in the highest third of all evaluated products for mobile laboratories and earned 90% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
PROFILE-1 ATP Lumin. Sys.	0.801
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

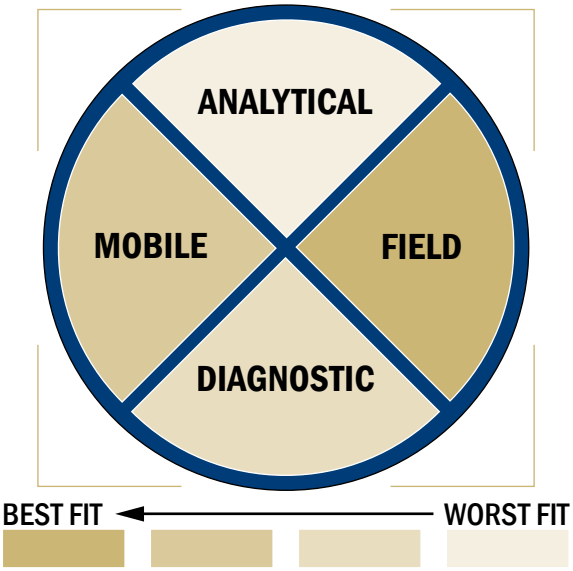
Profile-1 ATP ranked in the highest third of all evaluated products for field use and earned 94% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
PROFILE-1 ATP Lumin. Sys.	0.890
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

New Horizons Diagnostic Corp.
9110 Red Branch Rd.
Columbia, MD 21045
www.NHDiag.com

Point of Contact:
David Trudil
(410) 992-9357 x222
(410) 992-0328 fax
NHDiag@aol.com

COST

- $4.00-8.00/sample
- $4,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 32 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:
- Very brief training
- Less than 5 min required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is designed for single use
- 3 solutions or buffers used
- 3 components
- No cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- No service required
- Expected life is 5-10 years
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a soda can
- Less than 1 kg
- Shelf life between 1 and 3 years

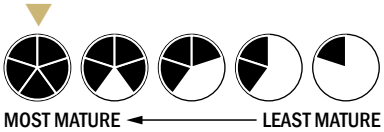
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System could be able to interpret raw data or call a positive through internal software in the future
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4 °C to 45 °C
- Components must be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1,000-10,000 CFU per ml

Maturity gauge:
- Is commercially available and meets military specifications

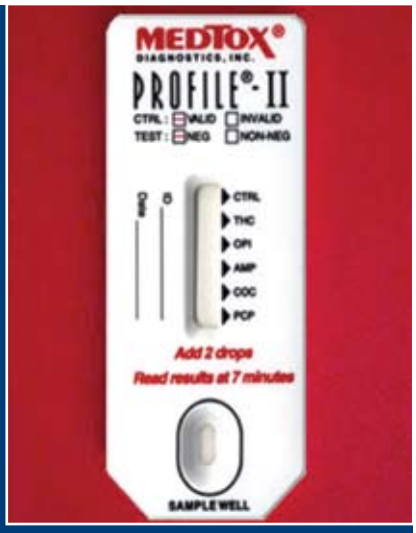


PROFILE-II

by MEDTOX

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Yersinia pestis, Botulinum toxins A, B, T-2 toxin, Ricin *(Assays developed)*



DESCRIPTION:

The device is a hand held manual system that is approximately 2 and 3/8 by 1 and ½ and ¼ inches. The device is contained in a poly foil aluminum package. The device was designed to perform immunoassays for the detection of drugs of abuse (currently over 40 configurations) but was also used for the detection of biological agents and toxins in liquid environmental samples. Many of the current users of our drug tests are state agencies where police, probation and parole officers have used hundreds of thousands of devices to run on-site drug tests. Environmental air and surface samples that are impinged or swabbed into a liquid sample buffer can also be tested on this device. The user-friendly device only requires the addition of two drops of liquid sample and can be read in 5 to 10 minutes.

TECHNOLOGY:

The MEDTOX 's test device utilizes a one step lateral flow immunochromatographic technology. When sample solution is applied to the device, a mobile particle (gold or latex) coated with antibody is hydrated and migrates on a nitrocellulose membrane. At select positions on the membrane a complementary binding pair member is immobilized. In the case of a competitive assay (drug test) positive drug samples will inhibit the formation of a visible line while drug free samples will permit the formation of a line at the binding pair member site. In the detection of bio-agents a positive sample will generate a visible line at the immobilized complementary antibody site. A bio-agent negative sample will generate no line at the immobilized binding site. Also present on the test device is an internal control that indicates that the proper sample volume was applied and that the reagents migrated to the end of the device. A visible control line must appear on each device to ensure that the proper test procedures were performed. The device can test environmental air and surface samples that are impinged or swabbed into a liquid sample buffer .The user-friendly device only requires the addition of two drops (100µl) of liquid sample and can be read in 5 to 10 minutes. Spores, vegetative bacteria and toxins have been detected in liquid samples with the MEDTOX device.

ANALYTICAL Laboratory Ranking

Profile-II ranked in the lowest third of all evaluated products for analytical laboratories and earned 42% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
PROFILE-II	0.380
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Profile-II 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
Best Score	0.909
PROFILE-II	0.572
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Profile-II ranked in the highest third of all evaluated products for mobile laboratories and earned 82% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
PROFILE-II	0.724
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

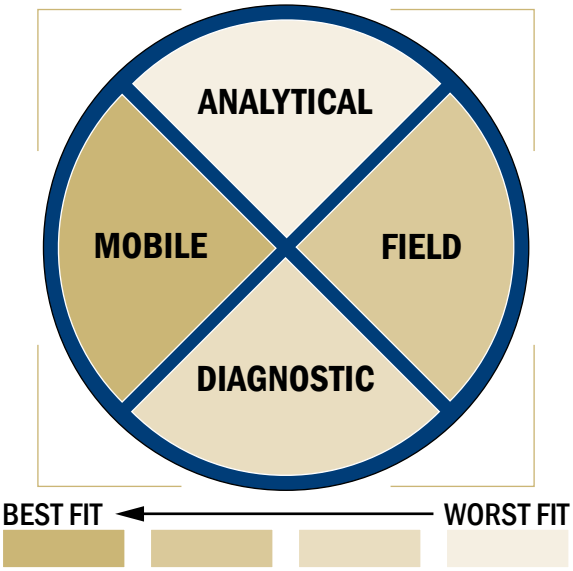
Profile-II ranked in the highest third of all evaluated products for field use and earned 82% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
PROFILE-II	0.772
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Medtox Diagnostics, Inc.
1238 Anthony Road
Burlington, NC 27215
www.medtox.com

Point of Contact:
Michael Turanchik
(336) 226-6311 x273
(336) 229-4471 fax
mturanchik@medtox.com

COST

- $20.00 - 75.00 depending on test configuration/ sample
- $20.00 - 75.00 depending on test configuration/ system or device

Evaluation Criteria Provided by Vendor

System requirements:
- No electrical requirements
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 minutes or less
- NA samples/batch
- Sample volume less than 250 ul
- The system or approach is not amendable to automation

Training/Speed/Manpower:
- Very brief training
- No set-up time required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for single use
- 0-1 solution or buffer used
- 2 components
- NA cleaning required

Maintenance:
- 2 consumables or expendables needed
- Never requires service
- Expected life is NA
- No daily quality assurance procedures necessary

Transportation:
- Approximately the size of a soda can
- Less than 1 kg
- Shelf life between 1 to 3 years

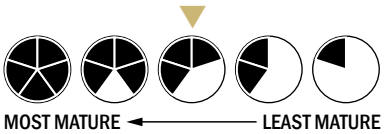
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- NA interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- No additional equipment needed

Signature:
- No sounds produced that cannot be deactivated
- NA BTUS

Operational conditions:
- Operated from 4 °C to 45 °C
- Components can be stored at room temperature
- Unknown if performance of the device or system is influenced by relative humidity

Sensitivity:
- Greater than 100,000 CFU per ml

Maturity gauge:
- A few devices or systems exist (brass board)



RAMP

by Response Biomedical Corp.

CAPABLE OF DETECTING THE FOLLOWING:

Francisella tularensis, Yersinia pestis *(Assays developed);* Bacillus anthracis, Smallpox virus, Orthopox virus, Botulinum toxin A, B, E, Ricin *(Commercially available as wet/frozen reagent)*

DESCRIPTION:

RAMP is a rapid qualitative immunochromatographic system for the screening of environmental samples such as for the presence of *B. anthracis* spores, ricin, botulinum toxin and orthopox viruses. The Reader is a scanning fluorometer and data analysis system used for the measurement of fluorescence in RAMP immunoassay applications. The Reader can be operated on battery power or powered via an AC Adapter. The RAMP Test Cartridge is a single-use disposable, analyte specific cartridge that is used to detect the level of an analyte in an aqueous sample. The operator prepares the appropriate sample according to the package insert and then places an aliquot into the sample well of the Test Cartridge. The Test Cartridge is then inserted into the RAMP Reader, which analyzes the sample and provides a result.

TECHNOLOGY:

RAMP assays are processed in disposable, single-use Test Cartridges. Each Cartridge houses an analyte-specific, mylar-backed nitrocellulose immunochromatographic strip on which the assay runs. The strip simultaneously runs a test reaction and an independent internal control reaction. The internal control has been incorporated into the RAMP System to provide reliable results by compensating for test-to-test variations. To perform an assay, the operator transfers a sample into the sample well of a Test Cartridge and inserts the Cartridge into the Reader. The sample is drawn by capillary action along the membrane. For example, in the Anthrax Test, BA spores present in the sample interact and bind with the mobile, fluorescently labeled anti-BA antibodies, forming an antibody-antigen complex. The complexes and labeled antibodies are subsequently captured at the detection and internal control zones. When the reaction in the Cartridge is complete, the Reader scans the test strip and detects fluorescence in the detection and the internal control zones and determines the concentration of BA spores. To accomplish this task, the Reader calculates the ratio between the concentrations of fluorescing particles in the detection and internal control zones. By calculating the final assay result as a ratio between the two measurements, the RAMP System automatically accounts for variations in sample and membrane properties. A “POSITIVE“ or “NEGATIVE “ test result is determined by the Reader. An assay result appears on the Reader’s display within 15 minutes of inserting the Cartridge. The result can also be stored, printed, or uploaded to a laboratory, hospital or other information system.

ANALYTICAL Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.901
Response Biomedical RAMP	0.706
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

RAMP ranked in the highest third of all evaluated products for diagnostic laboratories and earned 86% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Response Biomedical RAMP	0.778
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

RAMP ranked in the highest third of all evaluated products for mobile laboratories and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Response Biomedical RAMP	0.707
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

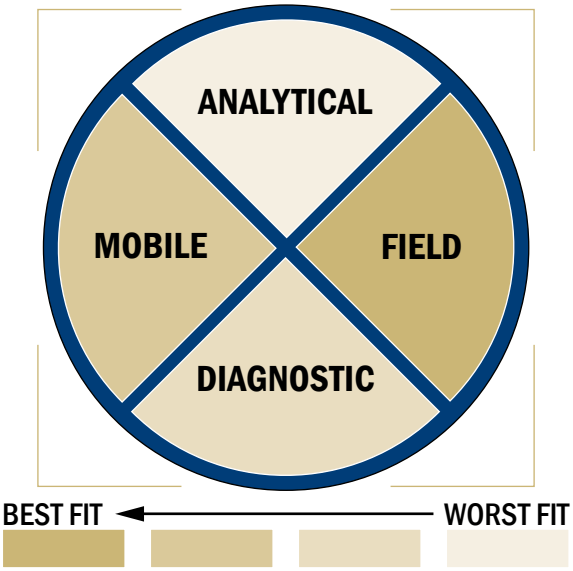
RAMP ranked in the highest third of all evaluated products for field use and earned 88% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Response Biomedical RAMP	0.837
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Response Biomedical Corp.
8081 Lougheed Highway
Burnaby, BC V5A 1W9 Canada
www.responsebio.com

Point of Contact:
David Trotter
(604) 681-4101 x210
(604) 412-9830 fax
dtrotter@responsebio.com

COST

- $25.00/sample
- $9,750.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection 20 minutes or less
- 1 sample/batch
- Less than 100 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:

- An afternoon of training
- No required set-up
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 2 components
- No cleaning required

Maintenance:

- 0-1 consumable or expendable needed
- No service required
- Expected life is greater than 10 years
- No daily quality assurance procedures required

Transportation:

- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life between 1-3 years

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- Sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

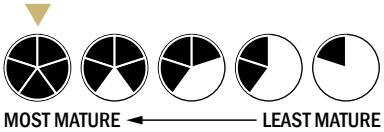
- Operated from 4 °C to 37 °C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1,000-10,000 CFU per ml

Maturity gauge:

- Is commercially available and meets military specifications



RAPID (Ruggedized Advanced Pathogen Identification Device)

by Idaho Technology

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, E. coli 0157:H7, Francisella tularensis, Yersinia pestis, Brucella species *(Commercially available as a freeze-dried reagent);* Smallpox virus, Orthopox virus, VEE virus *(Assay validated);* Bacillus anthracis, Ricin E. coli 0157:H7, Vibrio cholera, Francisella tularensis, Yersinia pestis, MS-2 bacteriophage, Botulinum toxin A, SEB *(Assays developed)*; Brucella species

DESCRIPTION:
RAPID is a fluorescent monitoring thermal cycler that is man-portable, impact resistant, and requires minimal training for operational use in military field hospitals and other austere environments. The system can be made operational within 30 minutes of arrival on site (includes setup and warm-up time) and is designed to prevent operator exposure to the samples being processed while preserving sample integrity. The system has a feature for clinical identification of pathogenic agents. The identification feature applies a specific identification technology to allow for pinpointing the presence of specific pathogens. The RAPID is used extensively by all branches of the U.S. DoD for biowarfare pathogen identification and well as food borne illness identification. It is rugged and field portable with simple push button software for field use while maintaining an advanced user interface for laboratory research applications.

TECHNOLOGY:
The RAPID is a high speed real-time air thermal-cycler that relies on specific DNA amplification for pathogen identification. We couple this with optimized freeze-dried reagents alleviating the need for any refrigeration or freezing of chemistry components for six months. We have validated freeze-dried assays for Anthrax, Brucella spp., Y. pestis, Tularemia, Salmonella, C.botulinum, Campylobacter, E.coli 0157, and L. monocytogenes.

ANALYTICAL Laboratory Ranking

RAPID ranked in the highest third of all evaluated products for analytical laboratories and earned 82% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Idaho Tech RAPID	0.737
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

RAPID ranked in the highest third of all evaluated products for diagnostic laboratories and earned 88% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Idaho Tech RAPID	0.804
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

RAPID ranked in the highest third of all evaluated products for mobile laboratories and earned 89% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Idaho Tech RAPID	0.785
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

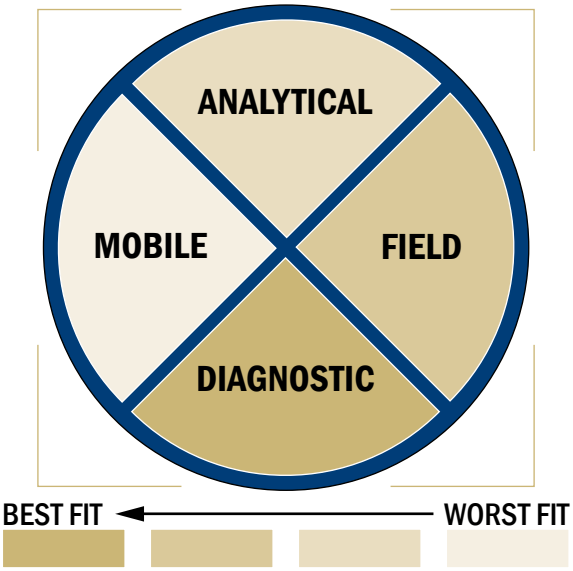
RAPID ranked in the highest third of all evaluated products for field use and earned 83% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Idaho Tech RAPID	0.782
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
Idaho Technology
390 Wakara Way
Salt Lake City, UT 84108
www.idahotech.com

Point of Contact:
Matt Scullion
(801) 736-6354 x327
(801) 588-0507 fax
matts@idahotech.com

COST
- $16.00/sample (duplicate reactions)
- $48,400.00 GSA/$60,000.00 non-GSA price/ system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 30 and 40 minutes
- 32 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- More than a day of training
- Less than 5 minutes required for set-up
- 9-12 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 5 or more components
- No cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- Needs service every 6 months
- Expected life is greater than 10 years
- No daily quality assurance procedures required

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 6 months and 1 year

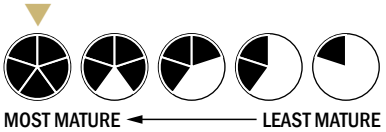
Ease of use/Utility:
- Can view results “in real time”
- Multiple centrifugation steps required
- Single shaking or vortexing step
- System able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:
- Operated from 4 °C to 45 °C
- Components must be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

Maturity gauge:
- Is commercially available and meets military specifications



Rapid Flu Test

by Cellex

CAPABLE OF DETECTING THE FOLLOWING:
Influenza virus *(Assay developed)*

DESCRIPTION:
Pandemic influenza could have devastating impact on our military capability. An important part of influenza pandemic preparedness is the availability of rapid and sensitive influenza diagnostic tests, which can be used for surveillance, early pandemic period monitoring, patient admission, and treatment decision. Current rapid flu tests are not sensitive (about 70% or lower) and labor intensive; the latter also increases the risk of occupational infection.

Our system is designed to be simple, sensitive, inexpensive and rapid for influenza diagnosis. This semi-automatic system uses only simple devices, including a handheld luminometer, a magnet and pasture pipet. The entire assay process takes less than 30 minutes with analytical sensitivity of less than 100 TCID50/mL or CEID50/mL for all viral stains tested. The device can store up to 100 test data, which can be transferred to a computer for further analysis if necessary. In addition, the device has a printing option with automated interpretation of the test results (positive or negative). We expect a substantially improved clinical sensitivity as well.

TECHNOLOGY:
The handheld detection device is essentially a luminometer. Detection technology is chemiluminescence that detects the neuraminidase activity of the influenza virus. The reagents consists of two proprietary components, an influenza virus capture reagent that can rapidly capture and concentrate the virus from a large sample volume and a chemical that generates light signal through the action of an exogenously added enzyme in a neuraminidase dependent manner. These two reagents work together for rapid and sensitive detection of influenza virus.

ANALYTICAL Laboratory Ranking

Rapid Flu Test ranked in the highest third of all evaluated products for analytical laboratories and earned 82% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Cellex Rapid Flu Test	0.726
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Rapid Flu Test ranked in the highest third of all evaluated products for diagnostic laboratories and earned 87% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Cellex Rapid Flu Test	0.769
Lowest Score	0.321

Effectiveness Biological Agents Logistics Operations

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Rapid Flu Test ranked in the highest third of all evaluated products for mobile laboratories and earned 73% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Cellex Rapid Flu Test	0.637
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

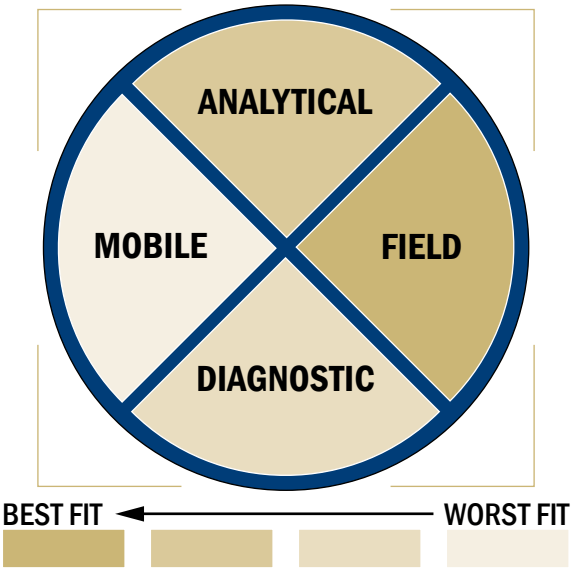
Rapid Flu Test ranked in the highest third of all evaluated products for field use and earned 85% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Cellex Rapid Flu Test	0.815
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Cellex
9700 Great Seneca Highway
Rockville, MD 20850
www.cellexinc.com

Point of Contact:
X. James Li
(301) 947-0202
(240) 269-4843
lix@cellexinc.com

COST

- $20.00/sample
- $1000.00/system or device

Evaluation Criteria Provided by Vendor

System Requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 20 and 30 minutes
- 20 samples/batch
- Greater than 250 ul volume needed per test for detection
- The system or device could be adapted easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes set-up required
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 3 solutions or buffers used
- 3 components
- No cleaning required

Maintenance:
- Once a year service required
- Expected life is between 1-3 years
- Less than 5 minutes required for daily quality assurance procedures

Transportation:
- Approximately the size of a soda can
- Less than 1 kg
- Reagent shelf life between 6 months and 1 year

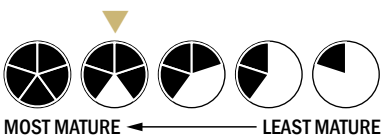
Ease of use/Utility:
- Cannot view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- Components must be stored at 25 °C to 37 °C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 TCID50 per ml of Influenza virus

Maturity gauge:
- Is commercially available
- Had not been featured in any peer reviewed scientific publications or independent evaluations



Rapid Flu Test (Automated)

by Cellex

CAPABLE OF DETECTING THE FOLLOWING:
Influenza virus *(Assay developed)*

DESCRIPTION:
Pandemic influenza could have a devastating impact on our military capability. An important part of influenza pandemic preparedness is the availability of rapid and sensitive influenza diagnostic tests, which can be used for surveillance, early pandemic period monitoring, patient admission, and treatment decision. Current rapid flu tests are not sensitive (about 70% or lower) and labor intensive; the latter also increases the risk of occupational infection. In addition, there is no automatic system that allows simultaneous rapid detection, nucleic acid recovery for PCR based genotyping, and live virus isolation for culture, all of which would be important tools for countering an influenza pandemic. This system uses a novel reagent for rapid viral capturing, cleaning and concentration, a novel chemiluminescence based system for rapid detection of influenza viral neuraminidase, and a fully developed instrument, which is compact and suitable for use in point-of-care or pandemic situations. This system will simultaneously isolate viral nucleic acids and live viruses. Therefore, this system will be able to perform three functions: rapid and sensitive influenza virus detection (based on neuraminidase activity), recovery of viral nucleic acids for genotyping, and live virus isolation for culture. All necessary reagents will be preloaded onto a cartridge that is compatible with the automatic instrument. This system can be easily adapted for rapid and sensitive detection of botulinum toxins, Bacillus anthracis lethal factor, ricin and many other toxins.

TECHNOLOGY:
The technology used in the instrument is called Magtration, which was developed by Precision Science Systems. It uses magnetic particles to transfer analytes from one well to another, which avoids the conventional liquid handling method. All necessary reagents and solutions are pre-filled into a cartridge, which completely eliminates any manual operation. All that an operator has to do is to place a sample vial inside the instrument, insert the cartridge and press the start button. The instrument performs influenza virus capture. The captured virus is split into three portions: one for rapid and sensitive flu virus detection based on neuraminidase-dependent chemiluminescent reaction, one for nucleic acid extraction to provide RT-PCR ready nucleic acids, and one for virus culture which involves mixing of culture cells with the virus bound to the capture reagent.

ANALYTICAL Laboratory Ranking

Rapid Flu Test (Automated) ranked in the highest third of all evaluated products for analytical laboratories and earned 82% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Cellex Rapid Flu Test - Automated	0.743
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Rapid Flu Test (Automated) ranked in the highest third of all evaluated products for diagnostic laboratories and earned 87% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Cellex Rapid Flu Test - Automated	0.792
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Rapid Flu Test (Automated) ranked in the highest third of all evaluated products for mobile laboratories and earned 73% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Cellex Rapid Flu Test - Automated	0.641
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

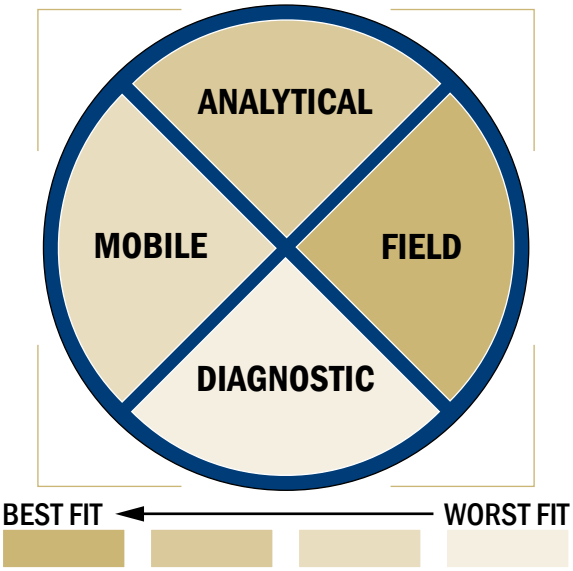
Rapid Flu Test (Automated) ranked in the highest third of all evaluated products for field use and earned 85% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Cellex Rapid Flu Test - Automated	0.802
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Cellex
9700 Great Seneca Highway
Rockville, MD 20850
www.cellexinc.com

Point of Contact:
X. James Li
(301) 947-0202
(240) 269-4843
lix@cellexinc.com

COST

- $20.00/sample
- $10,000.00/system or device

Evaluation Criteria Provided by Vendor

System Requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection between 20 and 30 minutes
- 6-12 samples/batch
- Greater than 250 ul volume needed per test for detection
- The system or device is fully automated

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- Greater than 20 minutes set-up required
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 0 components
- No cleaning required

Maintenance:

- Once a year service required
- Expected life is between 3-5 years
- Less than 5 minutes required for daily quality assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 25 and 50 kg
- Reagent shelf life between 6 months and 1 year

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

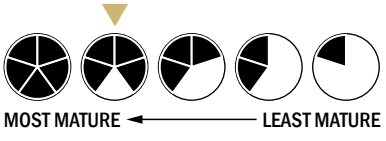
- Operated from 4 °C to 37 °C
- Components must be stored at 25 °C to 45 °C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1-100 TCID50 of Influenza virus per mls

Maturity gauge:

- Is commercially available with pending fee payments
- Less than $1,000,000 required to advance the system or device to commercialization
- Has not been featured in any peer reviewed scientific publications or independent evaluations



RAPTOR

by Research International & BAE Systems

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Ricin *(Commercially available as a freeze-dried reagent);* E. coli 0157:H7, Vibrio cholera, Francisella tularensis, Yersinia pestis, MS-2 bacteriophage, Botulinum toxin A, SEB *(Assays developed);* Brucella species *(Assay validated)*

DESCRIPTION:

The RAPTOR is a portable (14 lbs) MILSPEC-qualified bioassay system that was initially designed by Research International to U.S. Special Forces specifications and which is now being sold worldwide for evaluation as a biowarfare detection system. The battery-powered system can simultaneously detect the presence of up to four biological agents or toxins in a liquid sample at parts-per-billion concentration levels. It represents a novel integration of optics, fluidics, electronics, and software into one compact system that can automatically perform a user-defined, multistep, assay protocol using plastic optical waveguide biosensors mounted in a disposable assay coupon. The RAPTOR may be used in any context when an assay for a biological agent must be conducted in a short period of time with little or no sample preparation. The system is designed to be carried to a site and operated by non-technical personnel. Uses under active evaluation include both covert and overt operations by warfighters, homeland security applications such as first response, infrastructure protection and medical triage, and food and drinking water protection.

TECHNOLOGY:

The RAPTOR is a self-contained, 4-channel system for conducting these evanescent wave fluorometric assays to monitor biological agents, toxins, explosives, and chemical contaminants. It can automatically perform a multi-step assay protocol based on the fluorescent detection of reactions occurring at the surface of four individual optical waveguide sensors mounted in a disposable coupon. The sensors function independently allowing four different assays to be performed on a single sample.

The form factor of the waveguide sensor and the overall design of the RAPTOR make the system particularly well suited to performing fluoroimmunoassays conducted in the 'sandwich' format. Typically, a capture antibody is immobilized on the waveguide surface by physical adsorption. A sample is introduced and incubated for 1.5–7 minutes. The sample is then flushed and fluorophore-labeled secondary antibody is introduced to the waveguide. Following a second 1.5 minute incubation, the secondary antibody solution is recovered, the waveguide is rinsed, and the fluorescence signal is measured. This assay format makes it possible to detect a wide range of biomolecules, viruses, and bacteria with high specificity at 'ppb' concentrations. These miniature waveguide-based biosensors exhibit the sensitivity and specificity of an ELISA but tolerate very crude samples, exhibit extremely rapid assay times, consume minimal reagents, and are reusable. The sandwich assay format, as implemented with the RAPTOR, provides an assay protocol that is extremely resistant to sample contamination. First, essentially only fluorophore bound to the waveguide through a specific antibody-antigen-antibody reaction can be seen due to the evanescent wave excitation approach. Second, neither particulates nor soluble, fluorescent impurities will effect assay results since the fluorescent signal is detected after the waveguide has been rinsed.

ANALYTICAL Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.901
Research International RAPTOR	0.659
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

RAPTOR ranked in the highest third of all evaluated products for diagnostic laboratories and earned 85% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Research International RAPTOR	0.774
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

RAPTOR ranked in the highest third of all evaluated products for mobile laboratories and earned 91% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Research International RAPTOR	0.807
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

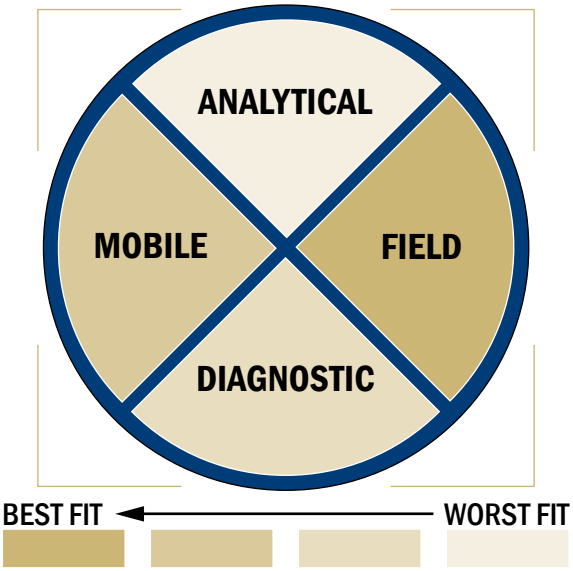
RAPTOR ranked in the highest third of all evaluated products for field use and earned 88% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Research International RAPTOR	0.831
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Research International, Inc.
In partnership with BAE Systems, Inc
17161 Beaton Road SE
Monroe, WA 98272
www.resrchintl.com

Point of Contact:
David McCrae
(360) 805-4930
(360) 863-0439 fax
davidmccrae@resrchintl.com

COST

- $1.00/sample
- $49,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device uses batteries
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection 20 minutes or less
- 2 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:

- A day of training
- 10-20 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 2 components
- Water and/or bleach cleaning required

Maintenance:

- 0-1 consumable or expendable needed
- Once a year service required
- Expected life is 3-5 years
- No daily quality assurance procedures required

Transportation:

- Approximately the size of a toaster
- Between 5 and 25 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

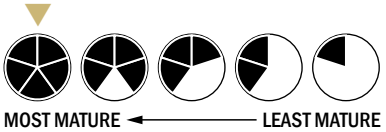
- Operated from 4 °C to 45 °C
- Components can be stored at 25 °C to 45 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- 10,000-100,000 CFU per ml

Maturity gauge:

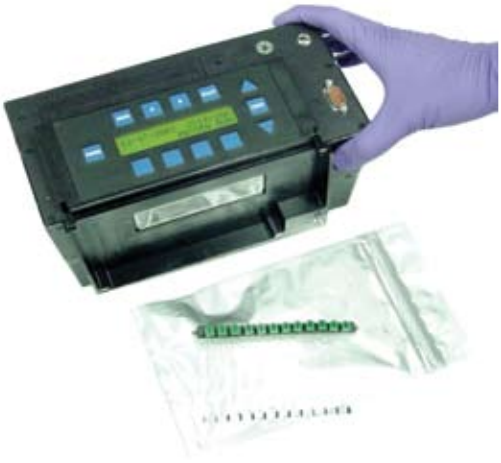
- Is commercially available and meets military specifications



RAZOR

by Idaho Technology

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, E. coli 0157:H7, Francisella tularensis, Yersinia pestis, Brucella species *(Commercially available as a freeze-dried reagent);* Smallpox virus, Orthopox virus, VEE virus *(Assay validated)*



DESCRIPTION:
Idaho Technology continues to set the standard in pathogen detection. RAZOR is a handheld, battery powered biological identification system. RAZOR uses IT's proven freeze dried reagents contained in pre-packaged pouches. RAZOR's dimensions are 4 x 8 x 12" (10 x 20 x 30 cm) and it weighs 10 lbs (4.5 kg).

TECHNOLOGY:
The basis of RAZOR's technology is polymerase chain reaction (PCR), a method of DNA amplification. RAZOR's accuracy, portability and ease of use make it the ideal device for field and onsite detection. RAZOR also has a fluorometer to measure DNA product and provide real-time detection. In a single RAZOR run, up to 12 samples can be analyzed (under 30 minutes) including positive controls, negative controls, and unknown samples.

ANALYTICAL Laboratory Ranking

RAZOR ranked in the highest third of all evaluated products for analytical laboratories and earned 75% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Idaho Tech RAZOR	0.674
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

RAZOR ranked in the highest third of all evaluated products for diagnostic laboratories and earned 86% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Idaho Tech RAZOR	0.782
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.883
Idaho Tech RAZOR	0.754
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

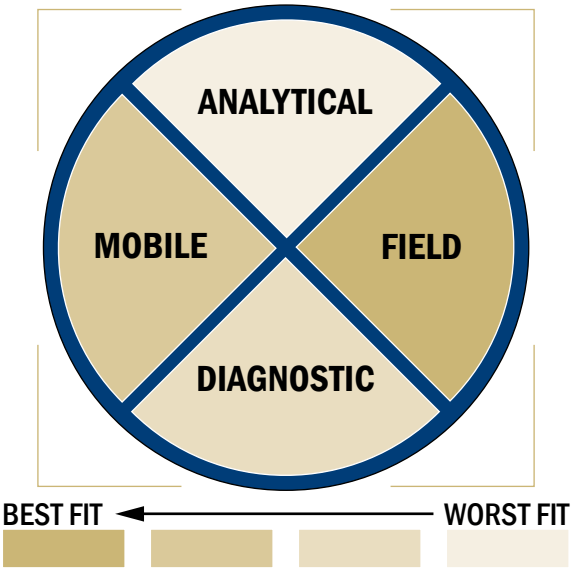
RAZOR ranked in the highest third of all evaluated products for field use and earned 88% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Idaho Tech RAZOR	0.826
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
Idaho Technology
390 Wakara Way
Salt Lake City, UT 84108
www.idahotech.com

Point of Contact:
David McCrae
(360) 805-4930
(360) 863-0439 fax
davidmccrae@resrchintl.com

COST
- >$30.00/sample
- Approx. $37,000/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 30 and 40 minutes
- 2 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:
- A day of training
- Less than 5 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 3 components
- No cleaning required

Maintenance:
- 3 consumables or expendables needed
- Less than once a year service required
- Expected life is 3-5 years
- No daily assurance procedures required

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life between 6 months and 1 year

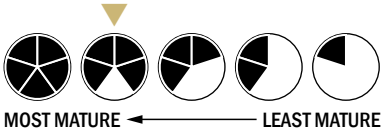
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4 °C to 45 °C
- Components must be stored at room temperature
- Performance not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

Maturity gauge:
- Is commercially available



RBI Robot

by ChemImage

CAPABLE OF DETECTING THE FOLLOWING:
None reported
(Generic detector)

DESCRIPTION:
The Raman Bio Identification (RBI) Detector is a reagentless chemical, biological and explosives (CBE) threat detection and identification system that can be completely mounted onto an unmanned ground vehicle (UGV). The RBI Detector has been designed to remotely detect and identify a broad range of CBE threats on environmental surfaces in a single measurement cycle. When the RBI Detector is configured on the UGV, an operator located in a safe or protected area can remotely drive it to the measurement site and assess the threat level. Being able to bring the sensor to the sample minimizes problems associated with sampling, such as cross contamination and pre-analysis decontamination, as well as the problems of sample disposal after analysis.

TECHNOLOGY:
The RBI Detector System is based on the Raman spectroscopic detection technology developed by ChemImage Corporation and validated in several U.S. Government-sponsored test programs. Raman detection offers clear advantages over immunoassay and DNA-based biological detection strategies, especially when configured for use on UGV systems.

ANALYTICAL Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.901
ChemImage RBI Robot	0.777
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

RBI Robot ranked in the highest third of all evaluated products for diagnostic laboratories and earned 87% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
ChemImage RBI Robot	0.791
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.883
ChemImage RBI Robot	0.719
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

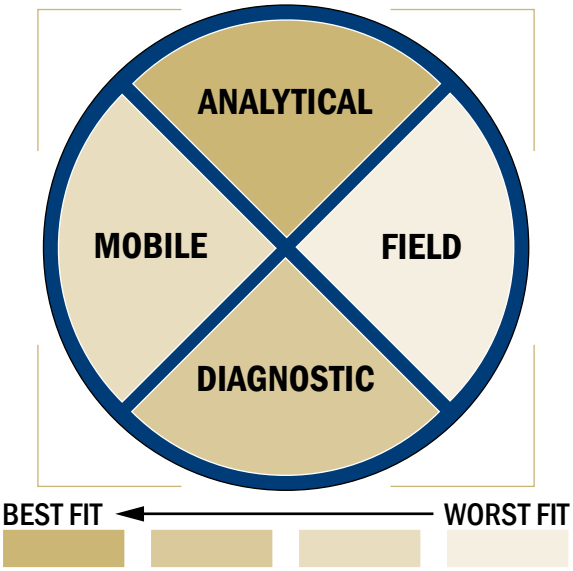
RBI Robot ranked in the middle third of all evaluated products for field use and earned 67% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
ChemImage RBI Robot	0.630
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
ChemImage
7301 Penn Ave
Pittsburgh, PA 15208
www.chemimage.com

Point of Contact:
Charles W. Gardner. PhD
(412) 241-7335 x212
(412) 241-7311
gardner@chemimage.com

COST
- $0.54/sample

Evaluation Criteria Provided by Vendor

System Requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 minutes or less
- 1 sample/batch
- Less than 10 ul volume needed per test for detection
- The system or device could be adapted into a semi-automated system with some effort

Training/Speed/Manpower:
- A day of training and technical skills are required
- 10-20 minutes of set-up required
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 2 components
- Cleaning with 5% bleach wipe

Maintenance:
- Every 6 months service required
- Expected life is greater than 10 years
- 10-20 minutes of daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 5 and 25 kg
- Reagent shelf life greater than 3 years

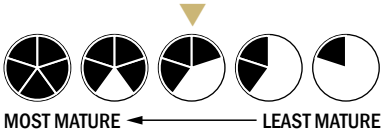
Ease of use/Utility:
- Can view results “in real time”
- There is a single centrifugation step
- There is a single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 25°C to 45°C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1000 CFU per ml

Maturity gauge:
- A few devices or systems exist (brass board)
- Is expected to be ready for commercialization within one calendar year
- Less than $1,000,000 required to advance the system to commercialization
- Has not been featured in any peer reviewed scientific publications or independent evaluations



RIDASCREEN ELISA Test Kit

by Idaho Technology

CAPABLE OF DETECTING THE FOLLOWING:
SEB, T-2 toxin, Saxitoxin, Shigatoxin *(Assay developed)*

DESCRIPTION:
RIDASCREEN test kits are all microwell ELISA based test kits.

TECHNOLOGY:
The basis of the test is an antigen-antibody reaction. The wells in the microtiter strips are coated with specific antibodies to mouse antibodies. By adding standards or the sample solutions, enzyme labeled toxin (enzyme conjugate), and anti-toxin antibodies, free and enzyme labeled toxin compete for the antibody binding sites of the anti-toxin antibodies, which themselves are bound simultaneously by the capture antibodies on the microtiter plate. Any unbound enzyme conjugate is then removed in a washing step. Enzyme substrate (urea peroxide) and chromogen (tetramethylbenzidine) are added to the wells and incubated. Bound enzyme conjugate converts the colorless chromogen into a blue product. The addition of the stop reagent leads to a color change from blue to yellow. The measurement is made photometrically at 450 nm (optional reference wavelength ³ 600 nm). The absorption is inversely proportional to the toxin concentration in the sample.

ANALYTICAL Laboratory Ranking

RIDASCREEN ELISA ranked in the lowest third of all evaluated products for analytical laboratories and earned 36% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
RIDASCREEN ELISA	0.326
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.909
RIDASCREEN ELISA	0.410
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.883
RIDASCREEN ELISA	0.539
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

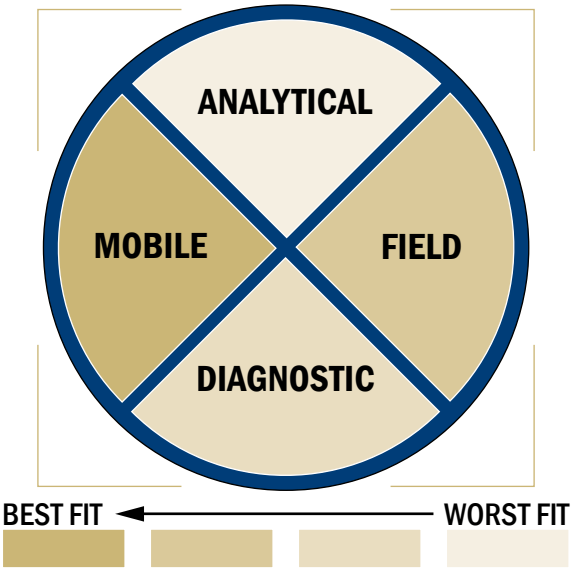
RIDASCREEN ELISA ranked in the middle third of all evaluated products for field use and earned 67% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
RIDASCREEN ELISA	0.631
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

R-Biopharm, Inc.
7950 Old US 27 South
Marshall, MI 49068
www.r-biopharm.com

Point of Contact:
Sean Tinkey
(269) 789-3033
(269) 789-3070 fax
s.tinkey@r-biopharm.com

COST

- $10.00/sample
- $450.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does require water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection greater than 60 minutes
- 32 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:

- An afternoon of training
- 5-10 minutes required for set-up
- 6-8 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:

- 3 consumables or expendables needed
- Once a year service required
- No daily quality assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 1 and 5 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- Single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- Four or more additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

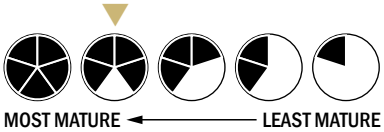
- Operated from 25 °C to 37 °C
- Components must be stored at 4 °C
- Peak performance of the device or system is at normal relative humidity only

Sensitivity:

- NA CFU per ml

Maturity gauge:

- Is commercially available



Rotor-Gene 3000 Real Time DNA Amplification System

by Corbett Research

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Yersinia pestis, Brucella species *(Assay developed)*

DESCRIPTION:
The Rotor-Gene is designed to measure an increase of amplified DNA fragments for quantitative and qualitative analysis. It uses chemistry platforms to detect any nucleic acid sequence from multiple sources (i.e. bacteria, viruses and spores from blood, tissue, soil and environmental samples.)

TECHNOLOGY:
Real-time detection system using various DNA amplification methods comprised of a thermal cycler to control the temperature of samples/reagents and a fluorometer to take fluorescent measurements at any time point. The machine measures DNA amplification via fluorescence to determine quantities of starting templates of genetic markers. The Rotor-Gene is an open chemistry platform capable of running isothermal assays (Invader, Roling Circle, NASBA, TMA) and temperature cycling assays such as PCR with all the current chemistry platforms (sybr, dual-labeled probes, molecular beacons, scorpions, hybridization probes). The flexible and user friendly software of the Rotor-Gene allows for data acquisition at any point during the cycling with multiple filter combinations. Using multiple LED's for excitation and a PMT for detection, the unit can multiplex up to four dyes in a single tube. The 6six emission filters on the standard system allow for a wide range of fluors to be detected (510, 555, 610, 585hp, 610hp 660hp).

ANALYTICAL Laboratory Ranking

Rotor-Gene 3000 ranked in the highest third of all evaluated products for analytical laboratories and earned 86% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Rotor-Gene DNA Amp. Sys.	0.775
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Rotor-Gene 3000 ranked in the highest third of all evaluated products for diagnostic laboratories and earned 85% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Rotor-Gene DNA Amp. Sys.	0.773
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Rotor-Gene 3000 ranked in the highest third of all evaluated products for mobile laboratories and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Rotor-Gene DNA Amp. Sys.	0.680
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

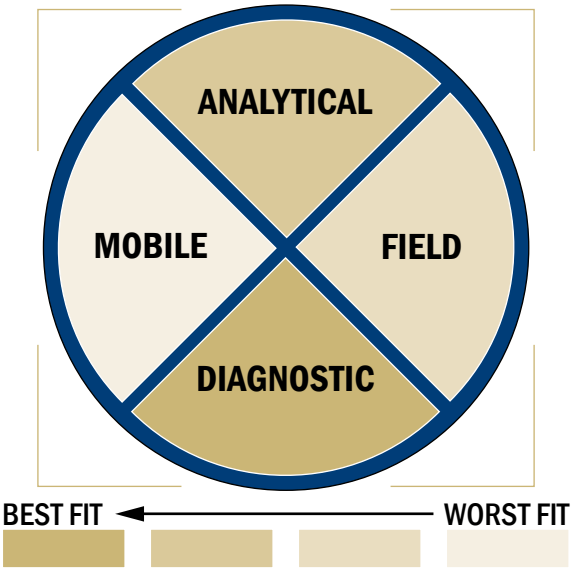
Rotor-Gene 3000 ranked in the highest third of all evaluated products for field use and earned 78% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Rotor-Gene DNA Amp. Sys.	0.741
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Corbett Research
1/14 Hilly Street
Mortlake, NSW 2137 Australia
www.corbettresearch.com

Point of Contact:
John Corbett
011-612-973-613-20
011-612-973-613-64 fax
john@corbettresearch.com

COST

- $0.50/sample plus cost of Taq enzyme
- $34,990.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device requires an external air source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection between 40 and 50 minutes
- 32 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system could be adapted into a semi-automated system with some effort

Training/Speed/Manpower:

- An afternoon of training
- Less than 5 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 2 solutions or buffers used
- 2 components
- No cleaning required

Maintenance:

- 2 consumables or expendables needed
- Once a year service required
- Expected life is greater than 10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 1 and 3 years

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- One additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:

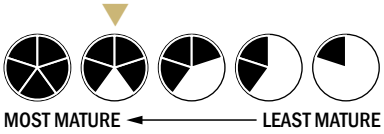
- Operated from 4 °C to 37 °C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- Is commercially available



RuggID Biological Detection System

by Nanosphere, Inc.

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Yersinia pestis, Smallpox virus *(Assay developed, Assay validated, Commercially available as a wet/frozen reagent);* Influenza virus, Botulinum toxin A, Botulinum toxin B, Ricin toxin *(Assay developed)*

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 is comprised of 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, which is controlled via the user interface on the RuggID reader, performs all microfluidic manipulations and temperature adjustments required for the assay. Once the assay is completed, the cartridge is removed and placed into the RuggID reader for analysis. The test is automatically analyzed and a definitive result is displayed as to the specific identification of bioagent or toxin. Key features of the RuggID system include: (1) Overall Simplicity. All assay steps after sample addition are automated. The intuitive user-interface on the RuggID requires minimal training. Objective data is provided eliminating user interpretation. (2) Field-Ready Device- it 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.

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, eliminating variability associated with amplification processes such as PCR. 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 ranked in the highest third of all evaluated products for analytical laboratories and earned 70% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Nanosphere RuggID	0.631
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

RuggID ranked in the middle third of all evaluated products for diagnostic laboratories and earned 69% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Nanosphere RuggID	0.630
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

RuggID ranked in the highest third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Nanosphere RuggID 0.666	0.666
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

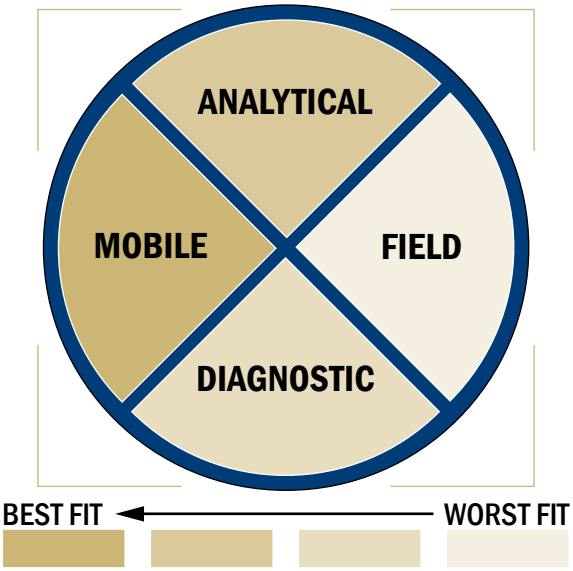
RuggID ranked in the middle third of all evaluated products for field use and earned 64% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Nanosphere RuggID	0.608
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Nanosphere, Inc.
4088 Commercial Ave
Northbrook, IL 60062
www.nanosphere.us

Point of Contact:
William Cork
(847) 400-9112
(847) 400-9199
wcork@nanosphere.us

COST

- $50.00/sample
- $85,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:

- System or device uses batteries or 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection greater than 60 minutes
- 32 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could be adapted to a fully automated system with some effort

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes set-up required
- 9-12 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 4 solutions or buffers used
- 1 component
- No cleaning required

Maintenance:

- Less than once a year service required
- Expected life is greater than 10 years
- Less than 5 minutes daily quality assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Reagent shelf life between 6 months and 1 year

Ease of use/Utility:

- Cannot view results “in real time”
- No centrifugation steps
- There are multiple shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

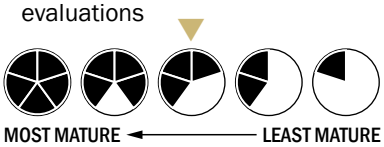
- Operated from 15°C to 30°C
- Components must be stored at room temperature
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1,000-10,000 CFU per ml

Maturity gauge:

- A few devices or systems exist (brass board)
- Is expected to be ready for commercialization within one calendar year
- Less than $1,000,000 required to advance the device or system to commercialization
- Has not been featured in any peer reviewed scientific publications or independent evaluations



SAIC BAND

by SAIC

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Burkholderia pseudomallei, Coxiella burnetti, Brucella species, E.coli O157: H7, Burkholderia mallei, Yersinia pestis, Rickettsia prowazekii, Marburg virus, Smallpox virus, Orthopox virus, Venezuelan equine encephalitis virus, Ebola virus, MS-2 bacteriophage, Botulinum toxin A, Staphylococcal toxin B, Ricin toxin *(Assay developed)*

DESCRIPTION:

The SAIC BAND prototype sensor has been developed by a team including SAIC, GHC Technologies, Ibis Biosciences, QTL BioSystems, MesoSystems, and Delphi Medical Systems under sponsorship from the DHS Homeland Security Advanced Research Projects Agency (HSARPA). The SAIC BAND prototype sensor is a fully-automated robotic system for collecting and analyzing urban air samples to detect airborne biological threats. It is a prototype for a sensor to be deployed nationwide as a BioWatch system upgrade. In its baseline configuration, our fieldable BAND system will detect 20 CDC Category A and B microbial pathogens and toxins with high sensitivity (bacteria and DNA genome viruses: 0.005 orgs/liter air, RNA genome viruses: 0.05 orgs/ liter air, toxins: 0.5 pg/liter air). The fieldable system will run continuously 24/7 providing detection assessments every three hours. It will run autonomously requiring only reagent reloading and minimal maintenance once every month. The SAIC BAND system will provide a robust method for rapid, specific detection of all relevant biothreat types: spore-forming and vegetative bacteria, DNA/RNA viruses, and toxins. It accomplishes threat DNA and RNA detection in a common process flow, based on highly-multiplexed PCR amplification and microarray readout. It performs toxin detection in a separate process flow using an antibody-based sandwich assay. The prototype system includes all the basic subsystems that will be in the fielded system with the exception of the environmental control, wireless communications, and long term reagent storage subsystems. The SAIC team has built three laboratory prototype systems, one of which has been tested at ECBC.

TECHNOLOGY:

Our sensor collects airborne particulates onto filter tape. Separate portions are used for DNA/RNA and toxin detection. The DNA/RNA portion is punched into a vial containing lysis buffer and glass beads and shaken. Lysate passes through a filter binding DNA and RNA. After rinsing, the nucelic acid elutes into three wells: two for multiplex-PCR, a third for RT-PCR. After amplification, products transfer onto a microarray for hybridization. The laser-excited microarray is imaged with a CCD. Image analysis quantifies threat presence. Multiple PCR primers per threat coupled with multiple microarray probes per PCR product yield high detection performance. A parallel immunoassay detects toxins.

ANALYTICAL Laboratory Ranking

SAIC BAND ranked in the highest third of all evaluated products for analytical laboratories and earned 90% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
SAIC BAND	0.812
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

SAIC BAND ranked in the highest third of all evaluated products for diagnostic laboratories and earned 83% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
SAIC BAND	0.751
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

SAIC BAND ranked in the highest third of all evaluated products for mobile laboratories and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
SAIC BAND	0.680
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

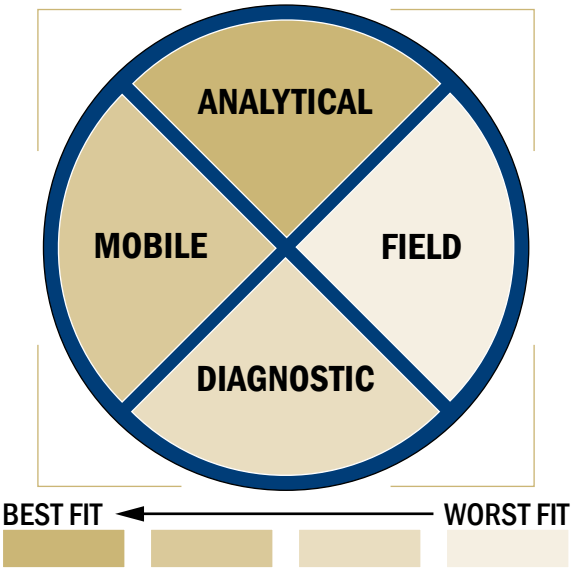
SAIC BAND ranked in the lowest third of all evaluated products for field use and earned 36% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
SAIC BAND	0.343
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
SAIC
10260 Campus Point Drive
San Diego, CA 92121
www.saic.com

Point of Contact:
David W. Robbin
(858) 826-6904
(858) 775-6904 cell
robbinsd@saic.com

COST
- <$3.00/sample
- $25,000.00/for a lot of 1000

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 1 sample/batch
- Less than 10 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- Very brief (minutes-hours) training and minimal technical skills
- Greater than 20 minutes set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 5 or more components
- Monthly cleaning is required. Also, decontamination after running positive samples is recommended

Maintenance:
- More often than every 6 months service required
- Expected life is between 3-5 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- More than 50 kg
- Reagent shelf life between 6 months and 1 year

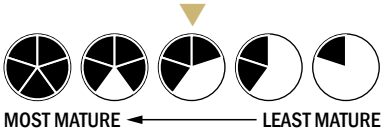
Ease of use/Utility:
- Cannot view results “in real time”
- There is a single centrifugation step
- There is a single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- Components must be stored at 4 °C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1,000 CFU per ml

Maturity gauge:
- A few devices or systems exist (brass board)
- Is expected to be ready for commercialization within two calendar years
- More than $2,000,000 required for device or system to advance to commercialization
- Has been featured in peer reviewed scientific publications or independent evaluations



Sherlock® Microbial Identification System

by MIDI, Inc.

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Corynebacterium diphtheria, Burkholderia pseudomallei, Brucella species, E.coli O157:H7, Vibrio cholera, Burkholderia mallei, Yersinia pestis *(Assay developed)*

DESCRIPTION:
MIDI, Inc has been developing automated microbial identification solutions for bio/pharma quality control, biodefense, research and clinical labs since 1985. The Sherlock® Microbial Identification System is used to identify over 1,500 bacterial species, including six bioterrorism agents using gas chromatography. The Sherlock® Microbial Identification System has both U.S. Department of Homeland Security and U.S. FDA 510(k) clearance for confirmation of the anthrax pathogen. Sherlock® DNA is an optional add-on to the Sherlock® Microbial Identification System that can identify bacteria using any DNA Sequencer. For over 20 years, MIDI, Inc. has been a Premier Channel Partner of Agilent Technologies. MIDI & MIDI Authorized distributors are the sole source for the Sherlock® Systems.

TECHNOLOGY:
The Sherlock® Microbial Identification System is based on gas chromatographic analysis of fatty acid methyl esters (GC-FAME). Each bacterial species has a unique set of fatty acids in their cell membrane. The MIDI sample procedure uses qualitative and quantitative information from the GC-FAME analysis to identify each bacteria. Sherlock pattern recognition algorithms are used to compare the unknown GC-FAME profile to stored libraries of known bacteria for the closest match. The Sherlock® DNA option uses analysis of the 16S rRNA to identify each bacteria. Sample preparation prepares the 16S rRNA for DNA Analysis and 500 base pairs are used for identification. The Sherlock software uses comparative DNA analysis for the closest match of the unknown bacteria to stored libraries of known bacteria. For definitive identification, with the Sherlock software, results of the GC-FAME analysis and DNA Sequence analysis can be combined into a polyphasic report, the only one of it's kind in the microbial identification marketplace.

ANALYTICAL Laboratory Ranking

MDI Sherlock ranked in the highest third of all evaluated products for analytical laboratories and earned 76% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
MIDI Sherlock	0.681
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

MDI Sherlock ranked in the highest third of all evaluated products for diagnostic laboratories and earned 75% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
MIDI Sherlock	0.684
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

MDI Sherlock ranked in the highest third of all evaluated products for mobile laboratories and earned 73% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
MIDI Sherlock	0.645
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

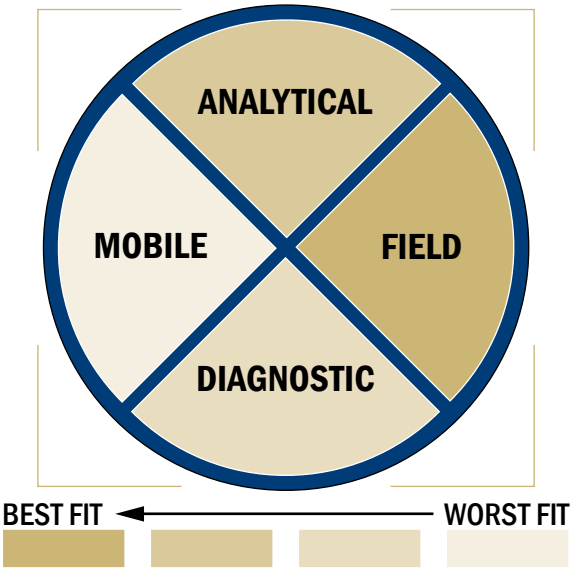
MDI Sherlock ranked in the highest third of all evaluated products for field use and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
MIDI Sherlock	0.726
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

MIDI, Inc.
125 Sandy Drive
Newark, DE 19713
www.midi-inc.com

Point of Contact:
Craig Kunitsky
(302) 737-4297
(302) 737-7781
sales@midi-inc.com

COST

- $5.00/sample
- $95,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device requires both an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection in 20 minutes or less
- 384 samples/batch or higher
- 2 mg pure bacterial culture needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:

- Two days of training and significant technical skills are required
- Greater than 20 minutes set-up required
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 3 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:

- Once a year service required
- Expected life is greater than 10 years
- 10-20 minutes daily quality assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 25 and 50 kg
- Reagent shelf life between 1 to 3 years

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- There are multiple shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting four or more biological agents or toxins within the same test
- Four or more additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:

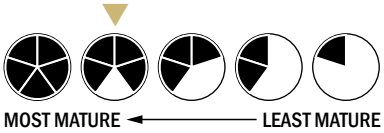
- Operated from 15 °C to 37 °C
- Components must be stored at room temperature
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 10,000-100,000 CFU per ml

Maturity gauge:

- Is commercially available
- Has been featured in peer reviewed scientific publications or independent evaluations



SMART (flowthrough)

by New Horizons Diagnostics Corp.

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, E.coli 0157:H7, Francisella tularensis, Vibrio cholera, Yersinia pestis, Brucella species, Botulinum toxins A, B, SEB, Ricin *(Assay validated);* Burkholderia mallei, Burkholderia pseudomallei, Coxiella burnetti, Rift Valley fever virus, Smallpox virus, VEE virus, Botulinum toxin E *(Assay developed)*

DESCRIPTION:

New Horizons Diagnostics (NHD) Corporation's SMART-II (lateral flow) screening assay includes a plastic cassette, which contains all the active ingredients, a bottle of Chase Buffer, and a plastic dropper. The assay is designed to act as a screen for the presence of a target organism. It is designed for environmental samples, not for human samples or for the diagnosis of disease. No known rapid screening assay is 100% sensitive or 100% specific; results should be confirmed by another method. The SMART assay must be utilized with the SWIPE collection system or similar validated collection system.

TECHNOLOGY:

In the Lateral Flow format, which is similar to an OTC pregnancy test, antibody coated colloidal gold particles are applied to a membrane surface and dried. When a test sample is applied, the gold conjugate reacts with the antigen that is present as it migrates across the length of the membrane to where it encounters a zone of capture antibody. Those antibody-gold conjugates, which have bound to antigen in the test sample, are then bound in the capture antibody zone, presenting a visually detectable line of color and indicating a positive test result. Sufficient antibody will be available to permit passage through the capture zone. These particles will then contact an area coated with an appropriate IgG fraction, where they will bind, producing a visible line of color. This line is the Control or Positive Reading Guide Line. The intent is to indicate that the reagents and test sample have successfully migrated the length of the membrane. Additionally, the "C" (Control) line provides the user/operator an example of what a positive should look like.

ANALYTICAL Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.901
SMART Tickets	0.618
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

SMART Tickets ranked in the highest third of all evaluated products for diagnostic laboratories and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
SMART Tickets	0.766
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

SMART Tickets ranked in the highest third of all evaluated products for mobile laboratories and earned 100% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
SMART Tickets	0.883
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

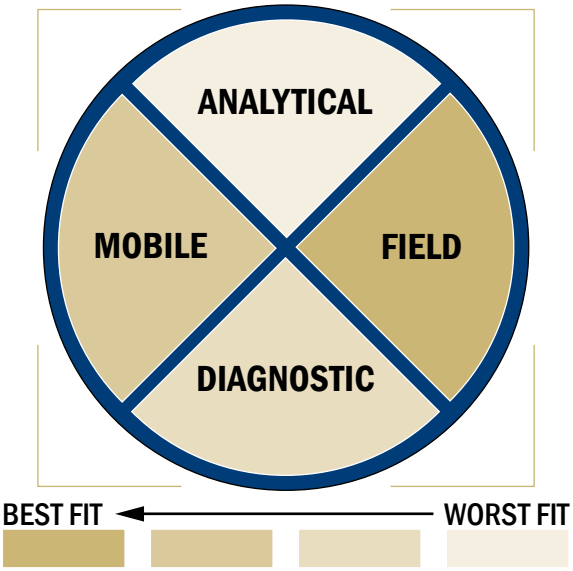
SMART Tickets ranked in the highest third of all evaluated products for field use and earned 96% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
SMART Tickets	0.906
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
New Horizons Diagnostic Corp.
9110 Red Branch Rd.
Columbia, MD 21045
www.NHDiag.com

Point of Contact:
David Trudil
(410) 992-9357 x222
(410) 992-0328 fax
NHDiag@aol.com

COST
- $15.00-32.00/sample
- $15.00-32.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- No electrical requirements
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 1 samples/batch
- Less than 100 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is designed for single use
- 0-1 solution or buffer used
- 2 components
- NA cleaning required

Maintenance:
- 2 consumables or expendables needed
- No service required
- NA expected life
- No daily quality assurance procedures

Transportation:
- Approximately the size of a soda can
- Less than 1 kg
- Shelf life between 1 and 3 years

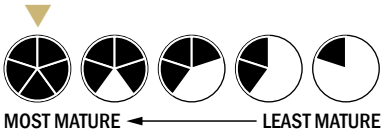
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System never able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4 °C to 37 °C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 10,000 - 100,000 CFU per ml

Maturity gauge:
- Is commercially available and meets military specifications



Smart Bio Sensor (SBS)

by Smiths Detection

CAPABLE OF DETECTING THE FOLLOWING:

Designed to detect biological particles and classify as vegetative or sporulated bacterium or virus. *(Generic Detector)*

DESCRIPTION:

The Smiths Detection Smart Bio Sensor (SBS) detects aerosolized biological warfare agents directly from the ambient air. It does so by continuously sampling the environment for the presence of passing clouds. The SBS uses a sophisticated algorithm to determine whether a detected cloud contains biological particles or background clutter.

Its semi-selective biochemical sensors allow the SBS to further classify a detected bioagent as bacterium, spore, virus or toxin. This technology is much less susceptible to false alarms than conventional bioparticle triggers and can be used to enhance the utility of more complex identification technologies. The SBS is designed for soldiers in the field, and can be deployed as a single point detector or a networked array of multiple systems. The SBS is one man-portable, fully autonomous during operation, and requires only a rapid change of its sensors when indicated by the system. Several SBS systems have been rigorously tested with a variety of bioagents, simulants and interferents at various venues over the last few years.

TECHNOLOGY:

The Smart Bio Sensor uses a multi-channel optical system to detect particles that are sampled from the air and trapped onto an array of semi-selective chemical sensors. The fluorescence output from the array is processed by an on-board computer to produce signal patterns that are characteristic of bioagents. Semi-quantitative information related to the number of particles on the sensors can also be derived. The bioagents are retained on the sensor substrates for confirmatory analysis or forensic archiving.

ANALYTICAL Laboratory Ranking

SBS ranked in the lowest third of all evaluated products for analytical laboratories and earned 42% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Smiths SBS	0.385
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

SBS 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
Best Score	0.909
Smiths SBS	0.504
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

SBS 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
Best Score	0.883
Smiths SBS	0.518
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

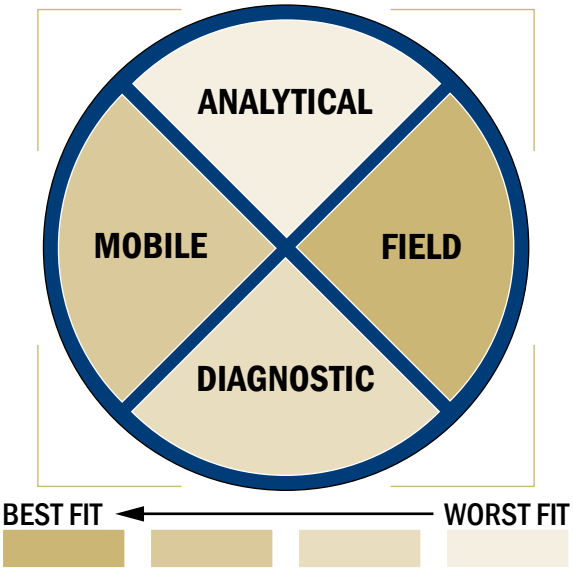
SBS ranked in the middle third of all evaluated products for field use and earned 61% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Smiths SBS	0.579
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Smiths Detection
451 D Street
Boston, MA 02210
www.smithsdetection.com

Point of Contact:
Mary Beth Tabacco, Ph.D.
(617) 443-0066
(617) 204-3080
marybeth.tabacco@smithsdetection.com

COST

- $75.00/sample
- $80,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:

- System or device uses batteries or has a 110V or 220V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Airborne bioagent detector with detection time less than 2 minutes
- Real-time detection of bioagents
- The system or device is currently fully automated

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- 5-10 minutes set-up required

Re-use:

- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 2 components
- Occasional cleaning of particulate residue

Maintenance:

- Once a year service required
- Expected life is unknown
- No daily quality assurance procedures

Transportation:

- Approximately the size of a toaster
- Between 5 and 25 kg
- Reagents shelf life between 6 months and 1 year

Ease of use/Utility:

- Can view results “in real time”
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

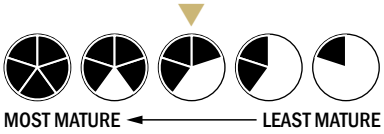
- Operated from 4 °C to 45 °C
- Components must be stored at 4 °C or room temperature
- The performance of the device or system is influenced by relative humidity

Sensitivity:

- 10,000-100,000 CFU per ml

Maturity gauge:

- A few devices or systems exist (brass board)
- Is expected to be ready for commercialization within one calendar year
- No money is required for device or system to advance to commercialization
- Has been featured in peer reviewed scientific publications or independent evaluations



Smart Cycler

by Cepheid

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, E. coli 0157:H7, Vibrio cholera, Francisella tularensis, Burkholderia mallei, Yersinia pestis, Coxiella burnetti, Rickettsia prowazekii, Brucella species, Smallpox virus, VEE virus, Hanta virus, Dengue fever virus, Orthopox virus, Ricin *(Assay developed)*

DESCRIPTION:

The Smart Cycler is a real-time, integrated DNA/RNA amplification, detection, and analysis system. Quantitation of the amplified product is achieved by measuring the increase in fluorescence during the PCR reaction. This is accomplished by incorporating an intercalating dye, such as SYBR Green, a fluorogenic probe, such as a TaqMan hybridization probe or a molecular beacon, or fluorogenic primers, such as Amplifluor or Scorpion primers. Features of the instrument include: *Random Access*- Up to sixteen different cycling protocols can be performed simultaneously in one processing block. Multiple experimental runs can be started at different times, allowing several operators to use the instrument concurrently. *Fast turnaround time*- Rapid thermal cycling is possible due to efficient heating and cooling of the sample using the specially designed tubes to achieve a high surface-to-volume ratio. *Accuracy*- Reduce the number of replicates with reliable quantification of target DNA by identifying the earliest PCR cycle in which the fluorescence signal is above background. Irreproducible results from endpoint analysis are eliminated.

TECHNOLOGY:

The Smart Cycler is a real-time, integrated DNA/RNA amplification, detection, and analysis system. Quantitation of the amplified product is achieved by measuring the increase in fluorescence during the PCR reaction.

ANALYTICAL Laboratory Ranking

Smart Cycler ranked in the highest third of all evaluated products for analytical laboratories and earned 96% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Smart Cycler PCR	0.866
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.909
Smart Cycler PCR	0.749
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Smart Cycler ranked in the highest third of all evaluated products for mobile laboratories and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Smart Cycler PCR	0.742
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

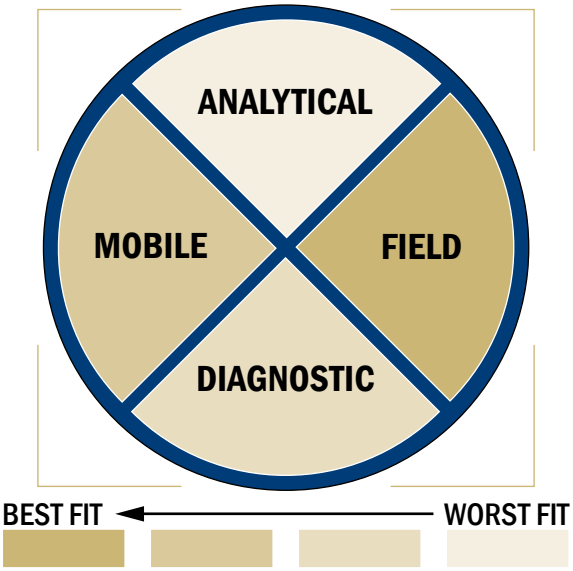
Smart Cycler ranked in the middle third of all evaluated products for field use and earned 73% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Smart Cycler PCR	0.692
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
www.smartcycler.com

Point of Contact:
Jeffrey Ryan
(888) 838-3222
(408) 734-1260 fax
ryan@cepheid.com

COST

- $2.50/sample
- $31,000.00-34,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection in greater than 60 minutes
- 32 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device could be adapted to a fully automated system with some effort

Training/Speed/Manpower:

- An afternoon of training
- 5-10 minutes required for set-up
- 9-12 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 2 solution or buffer used
- 3 components
- No cleaning required

Maintenance:

- 4 consumables or expendables needed
- Once a year service required
- Expected life is greater than 10 years
- No daily quality assurance procedures required

Transportation:

- Approximately the size of a carry-on luggage
- Between 5 and 25 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility:

- Can view results “in real time”
- A single centrifugation step
- No shaking or vortexing steps
- System is able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

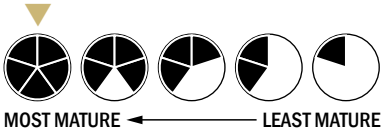
- Operated from 15 °C to 37 °C
- Components must be stored at 4 °C
- Peak performance of the device or system is at normal humidity conditions only

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- Is commercially available and meets military specifications



Staphylococcal Enterotoxin (SET) Visual Immunoassay (VIA)

by TECRA International Pty Ltd

CAPABLE OF DETECTING THE FOLLOWING:
Staphylococcal entertoxins A, B, C1, C2, C3, D and E

DESCRIPTION:
A rapid and simple screening test for detection of Staphylococcal enterotoxins A, B, C1, C2, C3, D and E in food, food related samples and enrichment cultures. The kit is designed for the direct screening of foods for the presence of any of the seven toxins, which may be detected at concentrations as low as 1 ng per mL within four hours. However, the kit cannot be used for the identification of a specific toxin type. For this purpose, the TECRA SET ID kit may be used. The ELISA can be used manually and the results read by eye. However, it can also be semi-automated with the use of microtitre plate readers and washers or fully automated for large scale testing. The kit is available in a 48 and 96 well formats.

TECHNOLOGY:
The TECRA SET VIA is an Enzyme-linked Immunoassay (ELISA) performed in a sandwich configuration.

ANALYTICAL Laboratory Ranking

SET VIA ranked in the middle third of all evaluated products for analytical laboratories and earned 49% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
TECRA Staph. Entero. VIA	0.445
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.909
TECRA Staph. Entero. VIA	0.408
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

SET VIA ranked in the middle third of all evaluated products for mobile laboratories and earned 64% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
TECRA Staph. Entero. VIA	0.565
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

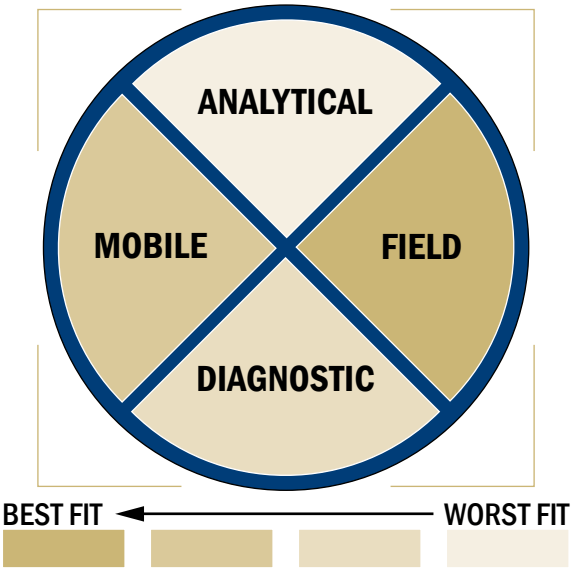
SET VIA ranked in the middle third of all evaluated products for field use and earned 70% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
TECRA Staph. Entero. VIA	0.663
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
TECRA International Pty Ltd
13 Rodborough Rd.
Frenchs Forest, NSW 2086 Australia
www.tecra.net

Point of Contact:
Nick Vale
+61 2 8977011
+61 2 9453 3422 fax
nick.vale@tecra.net

COST
- $7.00/sample
- $306.00 for 48 wells
- $556.00 for 96 wells/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- No electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 384 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 minutes required for set-up
- 9-12 manual steps required for detection

Re-use:
- Device or system is designed for single use
- More than 4 solutions or buffers used
- 5 or more components
- NA cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- No service required
- Expected life NA
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Less than 1 kg
- Shelf life between 6 months and 1 year

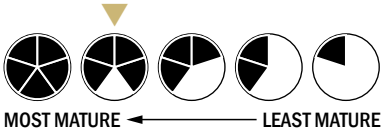
Ease of use/Utility:
- Can view results “in real time”
- Single centrifugation step
- No shaking or vortexing steps
- System not able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting multiple biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4 °C to 45 °C
- Components must be stored at 4 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- NA CFU per ml

Maturity gauge:
- Is commercially available



Stations of Robotic Monitoring (STORM)

by Edgewood Chemical Biological Center

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Yersinia pestis, Brucella species, Orthopox virus, Smallpox virus, VEE virus, Botulinum toxin A, SEB, Ricin

DESCRIPTION:
The STORM (STations Of Robotic Monitoring) was designed at ECBC to provide a reliable, high-throughput means of sample screening for biological warfare agents. Both the mobile and stationary analytical labs employ the STORM concept. STORM utilizes the "lessons learned" from a previous DoD effort, the Automated Biological Agent Testing System (ABATS). STORM utilizes the DNA extraction method from ABATS, but eliminates the full-system integration feature. This modification allows greater flexibility when dealing with an inconsistent number of samples. The STORM mobile laboratory, designed in conjunction with and manufactured by ENG Mobile Systems Inc. (Concord, CA), is a 24-foot, 5th wheel trailer with custom modifications for the accommodation of the Biomek FX automated liquid handling system (Beckman Coulter, Inc.), M1R analyzer (BioVeris Corporation), and ABI 7900 (Applied Biosystems, Inc.). It is equipped with a 6-foot Class II/B2 biological safety cabinet and a Class III glove box with outside access port to a pass-through chamber. The Biomek is contained within a HEPA-filtered chamber in order to protect the environment and operators from aerosols generated by the Biomek during the liquid handling process.

TECHNOLOGY:
Samples are analyzed by complimentary testing using both real time polymerase chain reaction (PCR) and electrochemiluminescent (ECL) technologies concurrently. The majority of the PCR assays were developed at ECBC and part of the JPEO-CBD Critical Reagent Repository (CRP). ECL assays are manufactured by BioVeris Corporation using CRP antibodies. Targets analyzed are determined by customer requirements, and targets can be changed or increased. Sample processing of 1-64 samples for all seven targets is completed within an eight hour work day.

ANALYTICAL Laboratory Ranking

STORM ranked in the highest third of all evaluated products for analytical laboratories and earned 87% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
ECBC STORM	0.784
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.909
ECBC STORM	0.654
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

STORM 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
Best Score	0.883
ECBC STORM	0.583
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

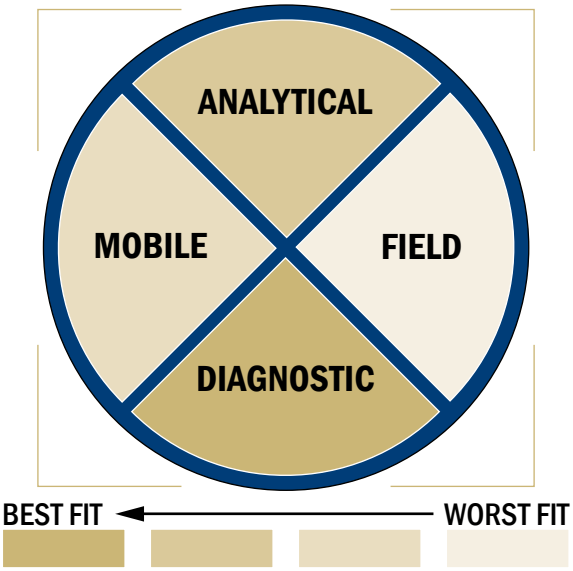
STORM ranked in the lowest third of all evaluated products for field use and earned 51% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
ECBC STORM	0.438
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Edgewood Chemical Biological Center
AMSRD-ECB-CB, Building E3330
Aberdeen Proving Ground, MD 21010
www.ecbc.army.mil

Point of Contact:
Ray Mastnjak
(410) 436-4735
raymond.mastnjak@us.army.mil

COST

- $300.00/sample for true unknown
- Approximately $900,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 220V electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in greater than 60 min
- 96 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- More than a day of training
- 10-20 min required for set-up
- 9-12 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- More than 4 solution or buffer used
- 5 or more components
- General decontamination with bleach is the only cleaning requirement

Maintenance:
- 5 or more consumable or expendable needed
- Needs service once a year
- Expected life measure of greater than 10 years
- 10-20 minutes required for daily quality assurance procedures

Transportation:
- Larger than a home dishwasher
- More than 50 kg
- Shelf life between 6 months and 1 year

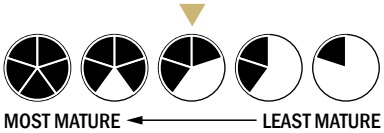
Ease of use/Utility:
- Cannot view results “in real time”
- There are multiple centrifugation steps
- There are multiple shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay available, and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- Components must be stored at 4 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1,000 CFU per ml

Maturity gauge:
- Expected to be ready for commercialization within three or more calendar years
- A few systems or devices exist (brass board)



T5000 Biosensor

by Ibis

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Corynebacterium diphtheria, Burkholderia pseudomallei, Coxiella burnetti, Brucella species, E.coli O157:H7, Vibrio cholera, Burkholderia mallei, Yersinia pestis, Rickettsia prowazekii, Marburg virus, Smallpox virus, Influenza virus, Orthopox virus, Venezuelan equine encephalitis virus, Ebola virus

DESCRIPTION:

SAIC and Ibis Biosciences developed T5000 biosensor technology under DARPA sponsorship. Ibis Biosciences manufactures the T5000, designed for automated laboratory-based detection of bacterial/viral biological threats as well as other key human and agricultural pathogens. The T5000 detects pathogens using broad range PCR amplification of genomic DNA coupled with mass spectrometry interrogation of PCR products and sophisticated maximum likelihood signal processing of the resulting mass spectra to determine identities and abundances of the various microbes whose predicted spectra best fit the observed spectra. The system analyzes liquid samples derived from environmental (air samples or surface swabs), clinical (throat swabs or blood) and other matrices. Standard laboratory equipment performs sample preparation: a plate-based bead beater to lyse microbes, a robot to isolate genomic threat DNA and RNA, a robot to format microtiter plates for PCR, and thermocyclers to amplify. The T5000 processes PCR products on 96-well plates with two to 16 wells per sample; an assay covering a viral genus requires two-four wells while a broad assay detecting most bacterial pathogens requires 16; six to 48 samples are processed per plate. The T5000 desalts input PCR products removing salts that would otherwise interfere with mass spectrometry. These products are flown through a mass spectrometer and analyzed to determine product base compositions and the identities and abundances of microbes in the input samples. Assays are available for broad detection of bacteria and viruses and for microbial strain-typing. Systems are deployed to the CDC, USAMRIID, NHRC, NBFAC, NIAID, and FBI.

TECHNOLOGY:

The T5000 uses broad range PCR primers that bind to conserved sites spanning hypervariable regions within genes required for microbial life. These regions are amplified until detectable by mass spectrometry. Hypervariable regions have base composition variations among different microbial species and strains. MS analysis determines the PCR products' base compositions which act as fingerprint-like signatures indicating organism identity. This allows a single assay to detect many different biological agents. Further, because this analysis yields detections for all species primed by our broad range primers, even ones with unknown sequence information, it detects unknown organisms including novel, emerging, and engineered organisms.

ANALYTICAL Laboratory Ranking

T5000 Biosensor ranked in the highest third of all evaluated products for analytical laboratories and earned 90% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
IBIS T5000	0.815
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

T5000 Biosensor ranked in the highest third of all evaluated products for diagnostic laboratories and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
IBIS T5000	0.701
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

T5000 Biosensor 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
Best Score	0.883
IBIS T5000	0.604
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

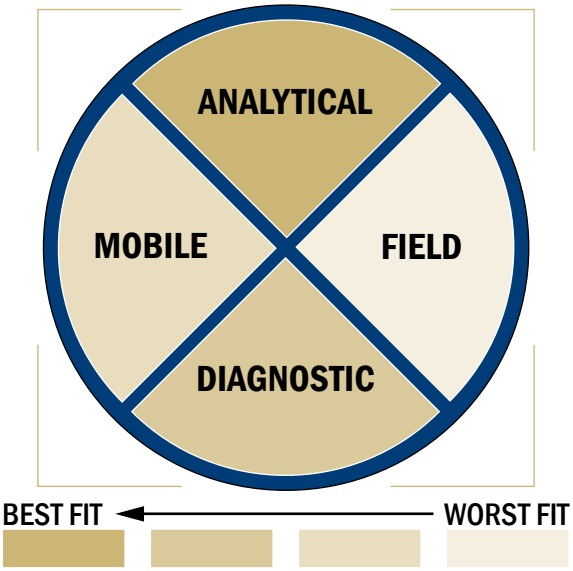
T5000 Biosensor ranked in the lowest third of all evaluated products for field use and earned 44% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
IBIS T5000	0.415
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
SAIC
10260 Campus Point Drive
San Diego, CA 92121
www.saic.com

Point of Contact:
David W. Robbins
(858) 826-6904
(858) 775-6904 (cell)
(858) 826-2225
robbinsd@saic.com

COST
- $50.00/sample
- $400,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device requires water aliquots
- The system or device requires an external gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 32 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- More than a day of training and significant technical skill required
- Greater than 20 minutes set-up required
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- More than 4 solution or buffer used
- 5 or more components
- Occasional decontamination required

Maintenance:
- More often than every 6 months service required
- Expected life is between 3-5 years
- 10-20 minutes of daily quality assurance procedures

Transportation:
- Larger than a home dishwasher
- More than 50 kg
- Reagent shelf life 1 to 6 months

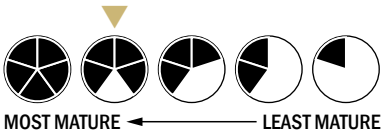
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- There is a single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- Four or more additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from 4 °C to 45 °C
- Components must be stored at 4 °C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

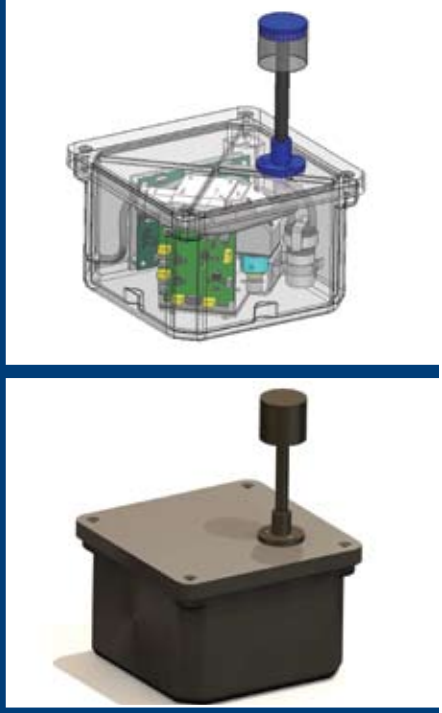
Maturity gauge:
- Is commercially available
- Has been featured in peer reviewed scientific publications or independent evaluations



TAC-BIO

by Edgewood Chemical Biological Center

CAPABLE OF DETECTING THE FOLLOWING:
None reported



DESCRIPTION:
The TAC-BIO is a small, solid-state, low cost, low power aerosol biological agent detector. It provides a generic detection capability. It does not require any consumables. The detector is capable of autonomous operation and will provide an alarm when threshold concentrations biological agents are present. When compared to currently available detectors, this detector will not only provide for a cost effect detection capability with reduced physical attributes, but also, offer novel opportunities to better protect the war fighter. This would include remote detection applications such as Unmanned Aerial Vehicle (UAV), Unmanned Ground Vehicle (UGV), and drop off sensing.

TECHNOLOGY:
The TAC-BIO detector is based on the established capability to detect biological aerosols using ultra-violet (UV) fluorescence. In the TAC-BIO, aerosolized particles are pulled through the detector via an air pump and exposed to UV radiation. The UV excites the fluorophores within the bio-agent particle, to include flavins, NADH, and tryptophan, and results in a fluorescent emission that is detected using photomultiplier tubes. The relative fluorescent and scattering signals produced by biological particles when subjected to these excitation sources is used to determine the presence of a biological agent threat.

ANALYTICAL Laboratory Ranking

TAC-BIO ranked in the lowest third of all evaluated products for analytical laboratories and earned 42% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
ECBC TAC-BIO	0.380
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

TAC-BIO 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
Best Score	0.909
ECBC TAC-BIO	0.502
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

TAC-BIO ranked in the middle third of all evaluated products for mobile laboratories and earned 60% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
ECBC TAC-BIO	0.528
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

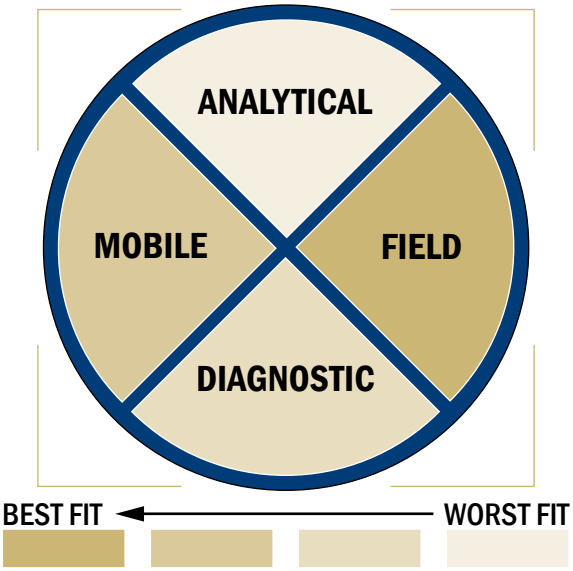
TAC-BIO ranked in the middle third of all evaluated products for field use and earned 62% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
ECBC TAC-BIO	0.586
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
Edgewood Chemical Biological Center
AMSRD-ECB-CB, Building E3330
Aberdeen Proving Ground, MD 21010
www.ecbc.army.mil

Point of Contact:
Ray Mastnjak
(410) 436-4735
raymond.mastnjak@us.army.mil

COST
- $0.00/sample
- $1,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 minutes or less
- 1 sample/batch
- The system or device is currently fully automated

Training/Speed/Manpower:
- Very brief (minutes-hours) training and minimal technical skills
- 5-10 minutes set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- No cleaning required

Maintenance:
- Expected life is between 1-3 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a soda can
- Between 1 and 5 kg
- Reagent shelf life greater than 3 years

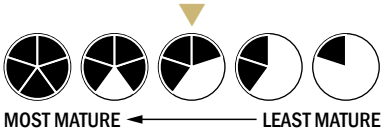
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System may be able to interpret raw data or call a positive through internal software in the future
- Capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 0°C to 50°C
- Unknown influence from relative humidity

Sensitivity:
- 100-150 ACPLA (Agent Containing Particles per Liter of Air)

Maturity gauge:
- A few devices or systems exist (brass board)
- Is expected to ready for commercialization within one calendar year
- Less than $1,000,000 required for advancement of device or system to ready for commercialization
- Has not been featured in any peer reviewed scientific publications or independent evaluations



TECRA UNIQUE™ Staphylococcal Enterotoxins

by TECRA International Pty Ltd

CAPABLE OF DETECTING THE FOLLOWING:
Staphylococcal toxin B *(Assay developed and validated)*

DESCRIPTION:
For the detection of pre-formed Staphylococcal enterotoxins (SET) in food and food-related samples within four hours; or to detect the production of SET after overnight enrichment of samples containing enterotoxigenic Staphylococcus spp. There are seven serologically distinct Staphylococcal enterotoxins: A, B, C1, C2, C3, D and E. UNIQUE SET is designed for the direct screening of foods for the presence of any of the seven toxins which may be detected at concentrations as low as 0.25ng /mL of sample. However, the kit cannot be used for the identification of a specific toxin type. For this purpose, the TECRA SET ID kit may be used. The ELISA can be used manually and the results read by eye. However, it can also be automated with the use of the TECRA UNIQUE PLUS instrument. There are 20 tests per pack.

TECHNOLOGY:
TECRA UNIQUE SET is essentially an Enzyme-Linked Immunosorbent Assay (ELISA) performed in a "sandwich" configuration. Rather than being carried out in a microtitre well plate, all reagents are provided in a single-test module and a UNIQUE stick performs both the capture and detection steps.

ANALYTICAL Laboratory Ranking

TECRA UNIQUE ranked in the middle third of all evaluated products for analytical laboratories and earned 49% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
TECRA UNIQUE	0.440
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

TECRA UNIQUE ranked in the lowest third of all evaluated products for diagnostic laboratories and earned 44% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
TECRA UNIQUE	0.400
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

TECRA UNIQUE 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
Best Score	0.883
TECRA UNIQUE	0.605
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

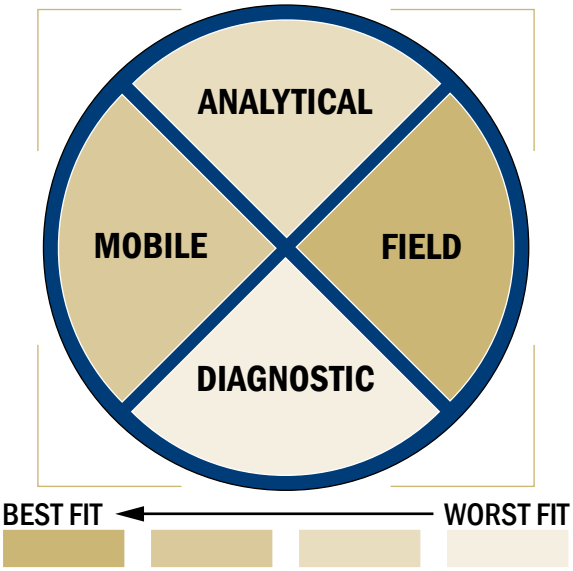
TECRA UNIQUE ranked in the middle third of all evaluated products for field use and earned 71% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
TECRA UNIQUE	0.674
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
TECRA International Pty Ltd
PO Box 6127 Frenchs Forest DC
Sydney, NSW 2086
Australia
www.tecra.net

Point of Contact:
Laura Gleeson
+61 2 8977 3035
+61 2 9453 3422
laura.gleeson@tecra.net

COST
- $12.00/sample
- $237.00/for 20 tests

Evaluation Criteria Provided by Vendor

System requirements:
- There is no electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 96 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:
- An afternoon of training and some technical skills required
- 10-20 minutes set-up required
- 9-12 manual steps required for detection

Re-use:
- Device or system is intended for single use
- More than 4 solutions or buffers used
- 1 components
- No cleaning required

Maintenance:
- No service required
- Expected life is between 1-3 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Less than 1 kg
- Reagents shelf life between 1 to 3 years

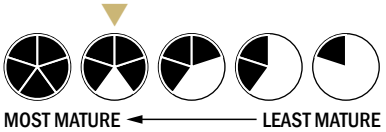
Ease of use/Utility:
- Cannot view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Capable of detecting multiple biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4 °C to 45 °C
- Components must be stored at 4 °C
- The effects of relative humidity are unknown

Sensitivity:
- 0.25 ng SET per ml

Maturity gauge:
- Is commercially available
- Has not been featured in peer reviewed scientific publications or independent evaluations



Tetracore Bio Threat Alert ELISA

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Francisella tularensis, Corynebacterium diphtheria, E.coli O157:H7, Yersinia pestis, Orthopox virus, MS-2 bacteriophage, Staphylococcal toxin B, Ricin toxin, Abrin toxin

DESCRIPTION:
The BioThreat Alert ELISA Kits were designed to detect biological agents in solution. While they are able to be used in the field by advanced teams, they are used more often in a laboratory setting. These kits were not intended for use on clinical samples. The BioThreat Alert ELISA Kits have better sensitivity than the BioThreat Alert Test Strips, and the ELISA format is friendly to samples from complex matrices such as food, surface swipes, unknown powders, air collected samples, air filters, etc. The optional "Positive/Negative" capture format helps to reduce matrix effects. The kits are available in either pre-coated with capture antibody format or non-coated format to allow for user flexibility. The BioThreat Alert ELISA Kits are often utilized by USDA and FDA laboratories.

TECHNOLOGY:
The BioThreat Alert ELISA Kit is a pre-packaged capture ELISA. The kit itself comes with a positive capture antibody, a negative capture antibody (if positive/negative format is purchased), a detector antibody, a conjugate, substrate, and protein blocking buffer, as well as one or two 96-well ELISA plates. The capture antibodies (target specific) are placed in the wells first, followed by the sample and detector antibodies (target specific), creating a very sensitive and very specific antibody "sandwich" that helps to eliminate false results. When the target substance is present in the well, the conjugate and the substrate produce a blue-colored product. This color change indicates a positive result and can be detected by any ELISA plate reader, as well as the naked eye.

ANALYTICAL Laboratory Ranking

Tetracore Bio Threat Alert ELISA ranked in the highest third of all evaluated products for analytical laboratories and earned 69% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Tetracore Bio Threat Alert ELISA	0.620
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Tetracore Bio Threat Alert ELISA ranked in the middle third of all evaluated products for diagnostic laboratories and earned 65% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Tetracore Bio Threat Alert ELISA	0.587
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Tetracore Bio Threat Alert ELISA ranked in the highest third of all evaluated products for mobile laboratories and earned 89% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Tetracore Bio Threat Alert ELISA	0.790
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

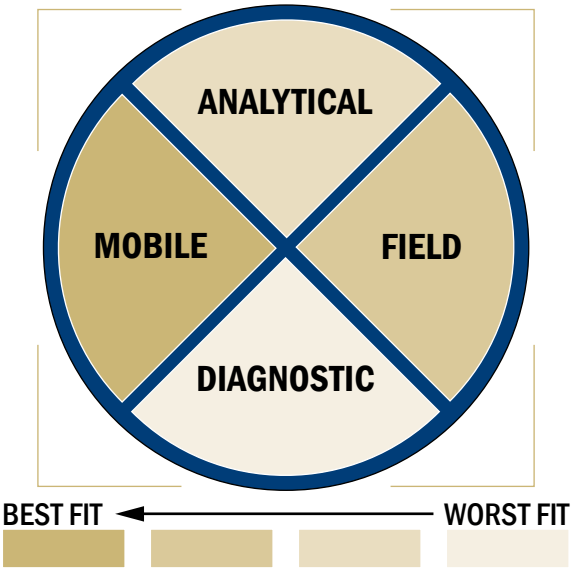
Tetracore Bio Threat Alert ELISA ranked in the highest third of all evaluated products for field use and earned 83% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Tetracore Bio Threat Alert ELISA	0.786
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

TetraCore
9901 Belward Campus Dr, Suite 300
Rockville, MD 20850
www.tetracore.com

Point of Contact:
Tom O'Brien
(240) 268-5400 x5401
(240) 268-1107
tobrien@tetracore.com

COST

- Unknown/sample
- $450.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:
- There is no electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 96 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- A day of training and technical skills required
- No set-up required
- Greater than 12 manual steps required for detection

Re-use:
- Device or system is intended for single use
- More than 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:
- No service required
- Expected life is N/A
- No daily quality assurance procedures

Transportation:
- Approximately the size of a soda can
- Less than 1 kg
- Reagent shelf life measure is between 6 months and 1 year

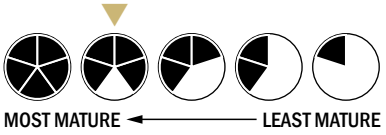
Ease of use/Utility:
- Can not view results "in real time"
- No centrifugation steps
- There are multiple shaking or vortexing steps
- System may be able to interpret raw data or call a positive through internal software in the future
- Assay not capable of detecting multiple biological agents or toxins within the same test
- Four or more additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 4°C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 10,000-100,000 CFU per mL

Maturity gauge:
- Is commercially available
- Has been features in peer reviewed scientific publications or independent evaluations



Threshold System

by Molecular Devices

CAPABLE OF DETECTING THE FOLLOWING:
Able to detect any organisms/ toxins for which antibodies are developed.

DESCRIPTION:
The Threshold system is used to detect and quantitate contaminants in biopharmaceuticals and sequence-specific DNA. Contaminants commonly analyzed with the Threshold system include total DNA, host cell proteins, bovine contaminants (BSA, IgG, insulin, transferrin), Proteins A and G, Bio-warfare agents, and any unique protein that can be bound by antibodies. The military uses Threshold for its Biological Integrated Detection System (BIDS). The technology is also used in ETG's BioDetector. The Threshold system's contaminant assays' proven advantages of speed, reproducibility, and reliability are incorporated into these new applications.

TECHNOLOGY:
The sample containing the analyte of interest is incubated with the appropriate binding proteins or oligonucleotide probes. The analyte will be bound by the binding proteins or hybridized to the probes to form a complex. The sample mixture is then filtered through a membrane where the analyte complex is captured and separated from the sample. The captured analyte complex will contain enzyme proportional to the amount of complexed analyte. The membrane is inserted into the Threshold reader which contains the silicon sensor. A kinetic measurement of the enzyme activity is completed in 90 seconds. This data is then processed by the Threshold software and quantitation is provided.

ANALYTICAL Laboratory Ranking

Threshold System ranked in the lowest third of all evaluated products for analytical laboratories and earned 24% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Threshold System	0.217
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Threshold System ranked in the lowest third of all evaluated products for diagnostic laboratories and earned 43% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Threshold System	0.387
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Threshold System ranked in the lowest third of all evaluated products for mobile laboratories and earned 47% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Threshold System	0.413
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

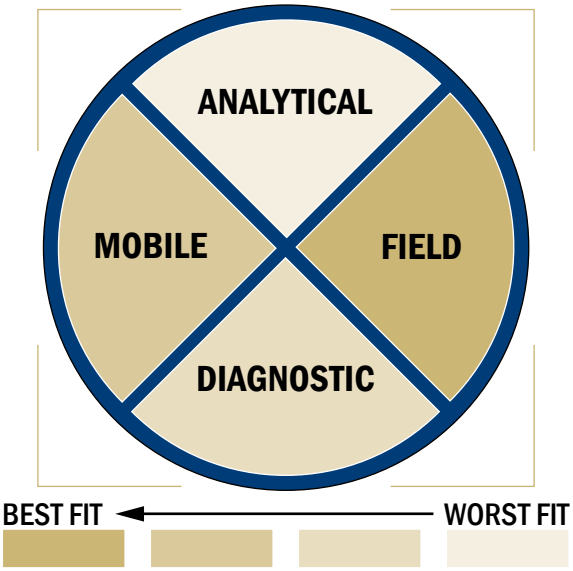
Threshold System ranked in the highest third of all evaluated products for field use and earned 75% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Threshold System	0.710
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Molecular Devices
1311 Orleans Dr.
Sunnyvale, CA 95128
www.moleculardevices.com

Point of Contact:
Emil Beitsayad
(408) 548-6326
(408) 747-3601 fax
Beitsayad@moldev.com

COST

- $3.25/sample
- $50,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V and 220V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 32 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or approach is not amendable to automation

Training/Speed/Manpower:
- More than a day of training
- Less than 5 minutes required for set-up
- Greater than 12 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- Once a year service required
- Expected life is greater than 10 years
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- More than 50 kg
- Shelf life between 6 months and 1 year

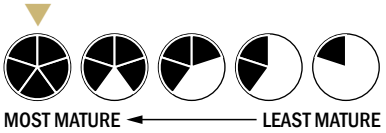
Ease of use/Utility:
- Can view results “in real time”
- Single centrifugation steps may be required
- Multiple shaking or vortexing steps
- System sometimes able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- Four or more additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- Components must be stored at 4 °C and frozen
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- Unknown CFU per ml

Maturity gauge:
- Is commercially available and meets military specifications



Transgenomic WAVE System

by Transgenomic

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Yersinia pestis, Shigatoxin *(Assays developed)*

DESCRIPTION:
The WAVE System is a mutation discovery system. It identifies SNPs, insertions, and deletions, and is one of the most sensitive mutation discovery methods known. The WAVEMAKER software provides a melting curve, a melt profile, and the prediction of the temperature to begin screening for mutation detection by entering the DNA sequence. WAVE Systems are fully automated, robust, versatile and cost effective, meeting the critical requirements of leading academic and biopharmaceutical laboratories worldwide.

TECHNOLOGY:
The Transgenomic WAVE System is a DHPLC (Denaturing-High Performance Liquid Chromatography) system. The system directly analyzes post-PCR product and is also used for oligonucleotide purification and analysis. It can also be used for total RNA purification and quantitation.

ANALYTICAL Laboratory Ranking

Transgenomic WAVE System 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
Best Score	0.901
Transgenomic WAVE Sys.	0.473
Lowest Score	0.217

Effectiveness, Biological Agents, Logistics, Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Transgenomic WAVE System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 57% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Transgenomic WAVE Sys.	0.518
Lowest Score	0.321

Effectiveness, Operations, Biological Agents, Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Transgenomic WAVE System ranked in the lowest third of all evaluated products for mobile laboratories and earned 49% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Transgenomic WAVE Sys.	0.432
Lowest Score	0.379

Logistics, Biological Agents, Effectiveness, Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

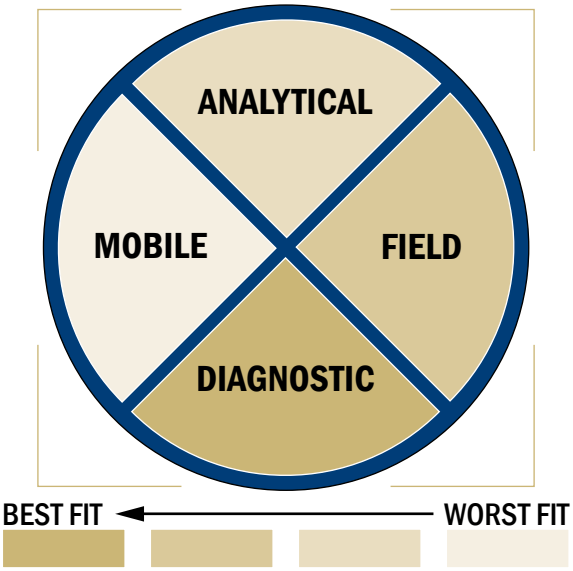
Transgenomic WAVE System ranked in the middle third of all evaluated products for field use and earned 61% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Transgenomic WAVE Sys.	0.574
Lowest Score	0.343

Logistics, Operations, Effectiveness, Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Transgenomic
12325 Emmet St.
Omaha, NE 68164
www.transgenomic.com

Point of Contact:
Will Jeffers
(410) 992-1690
(410) 598-7885 cell
(410) 992-3861 fax
wjeffers@transgenomic.com

COST

- $0.45-0.57/sample (post PCR)
- $49,950.00-90,000.00/system or device (excluding reagents)

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V and 220V electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection 20 minutes or less after performing PCR on the sample
- 384 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:

- More than a day of training
- Greater than 20 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 4 solutions or buffers used
- 1 components
- No cleaning required

Maintenance:

- 3 consumables or expendables needed
- Every six months service required
- Expected life is greater than 10 years
- 10 -20 minutes required for daily quality assurance procedures

Transportation:

- Approximately the size of a home dishwasher
- More than 50 kg
- Shelf life between 1 and 3 years

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System sometimes able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting two or more biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

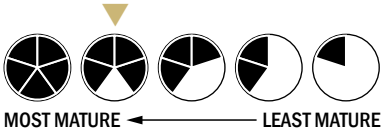
- Operated at 25 °C only
- Components must be stored at 4 °C and room temperature
- Device or system has peak performance at normal relative humidity conditions only

Sensitivity:

- Unknown CFU per ml

Maturity gauge:

- Is commercially available



Triage Meter

by Biosite Inc.

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus Anthracis
(Commercially available as a freeze-dried reagent)

DESCRIPTION:
The Triage meter consists of a microfluidic immunoassay protein chip (ticket) and a portable fluorometer to read the ticket. Triage measures multiple analytes simultaneously in any biological fluid using a single ticket, which makes it possible to simultaneously identifying all BW threat agents on one ticket. Biosite has also developed a highly specific (low false alarm rate) and sensitive immunoassay on Triage for the detection of Bacillus anthracis.

TECHNOLOGY:
The triage meter is a microfluidic immunoassay on a protein chip or ticket which is read by a portable fluorometer.

ANALYTICAL Laboratory Ranking

Triage Meter ranked in the middle third of all evaluated products for analytical laboratories and earned 66% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Triage Meter Tickets	0.596
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Triage Meter ranked in the highest third of all evaluated products for diagnostic laboratories and earned 81% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Triage Meter Tickets	0.736
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Triage Meter ranked in the highest third of all evaluated products for mobile laboratories and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Triage Meter Tickets	0.644
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

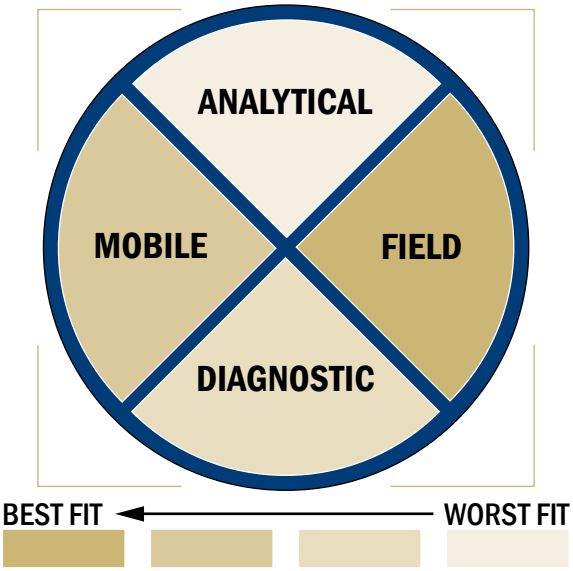
Triage Meter ranked in the highest third of all evaluated products for field use and earned 90% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Triage Meter Tickets	0.845
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Biosite Inc.
11030 Roselle St.
San Diego, CA 92121
www.biosite.com

Point of Contact:
Ferran Prat
(858) 597-4815 x3181
discovery@biosite.com

COST

- $25.00/sample
- $25.00/system or device, Approx. $4500.00 for reader

Evaluation Criteria Provided by Vendor

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 32 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for single use
- 0-1 solution or buffer used
- 1 component
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- Less than once a year service required
- Expected life is 3-5 years
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life between 6 months and 1 year

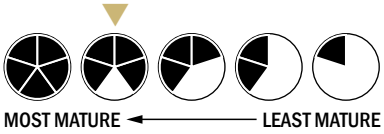
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- Components must be stored at 4 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 100-1,000 CFU per ml

Maturity gauge:
- Is commercially available



Upconverting Phosphor Technology (UPT) Handheld Sensor

by SRI International

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis, Orthopox virus, MS-2 bacteriophage, Ricin
(Assays developed)

DESCRIPTION:
The fieldable handheld biosensor is designed to sensitively detect the presence of low-levels of biological warfare agents in a variety of military operational environments. The system consists of several subsystems and disposable items. The system uses a lateral flow immunoassay test strip with upconverting phosphor technology (UPT) reporters. Sample collection is performed using the included surface sampling kit. Alternatively, if the unknown sample is already in liquid form, it may be directly applied to the test strip. Each lateral flow test strip is capable of screening the liquid sample for one to three different biological targets (e.g. toxins, viruses, and bacteria).

Following an incubation period of at least 15 minutes, the sensor analyzes the assay test strip. This is accomplished by sliding the reader cover door open, inserting the test strip into the slot, and initiating the scan using the Palm touch screen display. The strip is analyzed in about 45 seconds and the results are displayed on the reader screen and stored in the appropriate data file.

TECHNOLOGY:
The fieldable handheld biosensor is based on a new technology for sensitive detection of biological materials, known as the Upconverting Phosphor Technology (UPT). Upconverting phosphors are rare-earth doped ceramic materials with the unique property of emitting visible light upon excitation with near-infrared light. Known since 1966, SRI (under DARPA funding) has developed UPT for the sensitive detection of biological targets (e.g., bacteria, viruses, and toxins) in solution. The ability to perform highly multiplexed (i.e., multiple target) assays on a single sample is the first key advantage of UPTTM over conventional reporters such as molecular fluorescent dyes, colloidal gold and fluorescent microspheres. The second major advantage is that, due to the unique nature of the upconversion process itself—no other materials in nature upconvert—there is no optical background. Consequently, these materials can be detected in dirty environmental samples. Third, because single phosphor particles are detected using diode laser excitation sources and conventional optical systems, compact biosensors are possible that offer exquisite sensitivity. Finally, since their emission properties are a characteristic of the bulk ceramic material, the upconverting phosphors are photochemically stable with long lifetimes (years). Hence, the upconverting phosphors are ideal reporters for use in the field for sensitive, real-time detection and identification of pathogens with minimum false alarms. Furthermore, their stability means that UPT-based assays can be archived (and stored in a dry condition) for later analysis.

ANALYTICAL Laboratory Ranking

UPT Handheld Sensor ranked in the middle third of all evaluated products for analytical laboratories and earned 64% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
UPT Handheld Sensor	0.575
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations
Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

UPT Handheld Sensor ranked in the highest third of all evaluated products for diagnostic laboratories and earned 80% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
UPT Handheld Sensor	0.725
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics
Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

UPT Handheld Sensor 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
Best Score	0.883
UPT Handheld Sensor	0.620
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations
Preference Set: *Mobile Laboratory*

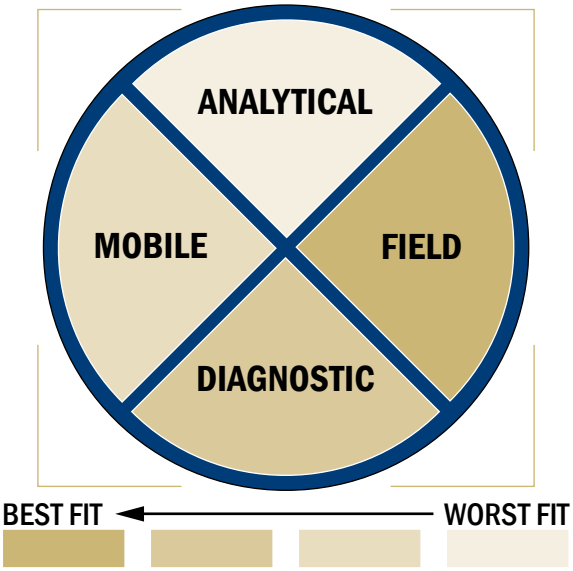
FIELD USE Ranking

UPT Handheld Sensor ranked in the highest third of all evaluated products for field use and earned 78% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
UPT Handheld Sensor	0.739
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents
Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
SRI International
333 Ravenswood Ave., Room 30626
Menlo Park, CA 94025
www.sri.com

Point of Contact:
David E. Cooper
(650) 859-3742
(650) 859-5036 fax
david.cooper@sri.com

COST
- $10.00/sample
- $25,000.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 2 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 2 components
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Once a year service required
- Expected life is 3-5 years
- No required daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life between 1 and 3 years

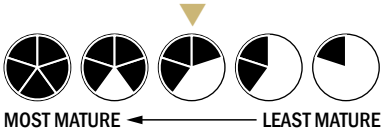
Ease of use/Utility:
- Can view results “in real time”
- No centrifugation steps
- There are no shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- Components must be stored at 4 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1,000-10,000 CFU per ml

Maturity gauge:
- A few devices or systems exist (brass board)



Verigene ID Assay System

by Nanosphere, Inc.

CAPABLE OF DETECTING THE FOLLOWING:
None reported

DESCRIPTION:
The Verigene platform is a universal molecular testing system that transcends the limitations of existing technologies. Verigene's superior performance is based on ClearRead™ technology that uses proprietary and patented nanoparticle probes to identify DNA, RNA and protein targets. This technology directly detects a target without amplification of nucleic acid, eliminating the variability associated with the amplification process (PCR). ClearRead™ also permits the simultaneous identification of multiple targets from a single sample. Nanosphere's Verigene™ ID is a stand-alone instrument designed to read light scatter from the gold nanoparticles. The device illuminates the test slide and uses inexpensive optics to deliver scattered light from the test sites to a photosensor. This detector is interfaced to an embedded microprocessor that allows automatic spot detection and data processing.

TECHNOLOGY:
For the detection of specific BWAs with gold probes, target-specific oligonucleotides are conjugated to gold nanoparticles at a very high density by using proprietary methods. The high density of oligonucleotides attached to the probe confers stability toward salt and temperature fluctuations, provides low non-specific binding to surfaces and has a significant impact on assay sensitivity and specificity. The chip-based detection assay is primarily a sandwich hybridization where the target is captured between surface-immobilized capture strands and the nanoparticle probe. The assay design requires that for detection to occur, both the capture and the probe bind the target. Therefore, assay specificity is derived from both the capture strand and the probe. Detection is achieved by a signal enhancement procedure that involves depositing a signal enhancement reagent at the test site in a strictly gold-dependent manner and measuring light scatter from the resulting enhanced gold nanoparticles. The enhancement step provides greater than 10^5-fold signal enhancement.

ANALYTICAL Laboratory Ranking

Verigene ID Assay System ranked in the lowest third of all evaluated products for analytical laboratories and earned 34% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Verigene ID	0.313
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Verigene ID Assay System ranked in the lowest third of all evaluated products for diagnostic laboratories and earned 40% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Verigene ID	0.364
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Verigene ID Assay System ranked in the lowest third of all evaluated products for mobile laboratories and earned 53% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Verigene ID	0.472
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

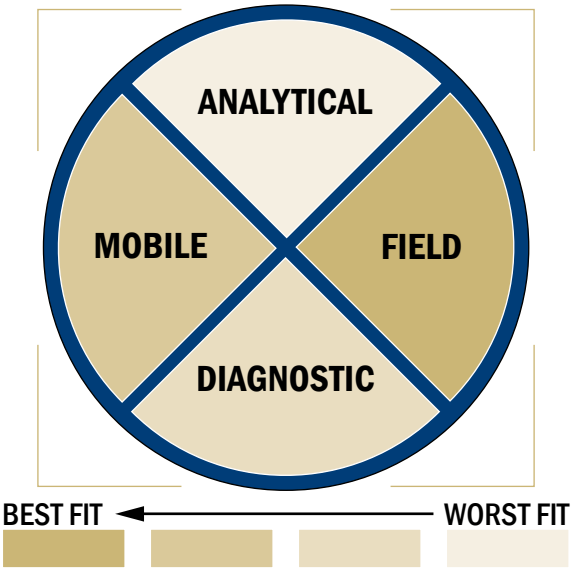
Verigene ID Assay System ranked in the middle third of all evaluated products for field use and earned 63% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Verigene ID	0.591
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Nanosphere, Inc.
4088 Commercial Ave
Northbrook, IL 60062
www.nanosphere.us

Point of Contact:
William Cork
(847) 400-9112
(847) 400-9199 fax
wcork@nanosphere.us

COST

- To Be Determined/sample
- To Be Determined/device or system

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection in 50-60 min
- 2 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:

- An afternoon of training
- Less than 5 min required for set-up
- 9-12 manual steps required for detection

Re-use:

- Device or system is intended for multiple detections
- More than 4 solution or buffer used
- 1 component
- No cleaning required

Maintenance:

- 5 or more consumables or expendables needed
- Needs service less than once a year
- Expected life measure of greater than 10 years
- No daily quality assurance procedures required

Transportation:

- Approximately the size of a toaster
- Between 1-5 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility:

- Cannot view results “in real time”
- No centrifugation steps
- Number of shaking or vortexing steps is unknown
- System can interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- Unknown number of additional equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

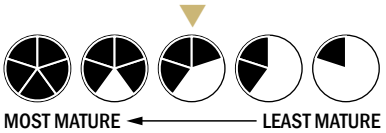
- Operated from 15 °C to 37 °C
- Components must be stored at 4 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- CFU per ml unknown

Maturity gauge:

- Expected to be ready for commercialization within one calendar year
- A few systems or devices exist (brass board)



Veritide Bacterial Spore Detector

by Veritide

CAPABLE OF DETECTING THE FOLLOWING:
Bacillus anthracis
(Assay developed)

DESCRIPTION:
The Veritide Bacterial Spore Detector is designed for non-invasive, rapid, reliable detection of bacterial spores in the field by first responders. It is intended to be used as an anthrax screening tool by fire departments, HazMat teams, police departments, airports, port security, postal services, building/facilities owners/managers, and any other first responder unit. Applications include biohazard detection, suspicious powder analysis, and decontamination validation. The detector is intended to be used with surface powder samples, but may also be used with liquid samples. The Veritide Bacterial Spore Detector is as easy to use as a flashlight, and is robust, lightweight and handheld. It uses optical detection technology and is therefore inherently non-invasive, ensuring that the sample being tested is not contaminated, consumed or destroyed. Results are returned within minutes, enabling multiple samples to be analyzed consecutively without extensive preparation and waiting time. No chemical reagents or wet chemistry are used, eliminating time-consuming and difficult sample preparation. No consumables are required for analysis. The detector is waterproof and designed for decontamination.

TECHNOLOGY:
The Veritide Bacterial Spore Detector is based on non-invasive optical detection technology. Optical recognition protocols are employed to detect the presence or absence of bacterial spores without physically contacting, contaminating, consuming or heating the sample. No reagents, antibodies, or wet chemistry are employed.

ANALYTICAL Laboratory Ranking

Veritide Bacterial Spore Detector ranked in the highest third of all evaluated products for analytical laboratories and earned 75% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Veritide Bacterial Spore Detector	0.675
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

Veritide Bacterial Spore Detector ranked in the highest third of all evaluated products for diagnostic laboratories and earned 84% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Veritide Bacterial Spore Detector	0.763
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

Veritide Bacterial Spore Detector 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
Best Score	0.883
Veritide Bacterial Spore Detector	0.628
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

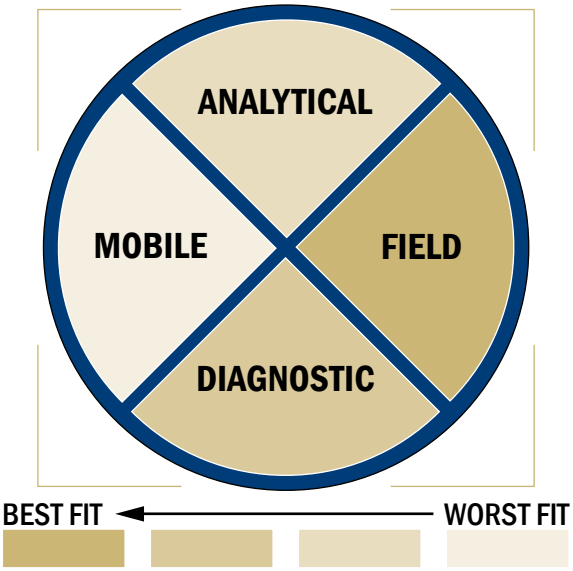
Veritide Bacterial Spore Detector ranked in the highest third of all evaluated products for field use and earned 78% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Veritide Bacterial Spore Detector	0.732
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Veritide
P.O. Box 13-761
Christchurch 8001
New Zealand
www.veritide.com

Point of Contact:
Andrew Rudge
+64 3 3795 975
+64 3 364 2511
a.rudge@veritide.com

COST

- $20,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:

- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection in 20 minutes or less
- 1 sample/batch
- The system or device is currently fully automated

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes set-up required
- 0-2 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 0-1 solution or buffer used
- The device must be wiped down with bleach solution if it becomes contaminated

Maintenance:

- Once a year service required
- Expected life is between 5-10 years
- Less than 5 minutes daily quality assurance procedures

Transportation:

- Approximately the size of a toaster
- Less than 1 kg

Ease of use/Utility:

- Cannot view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

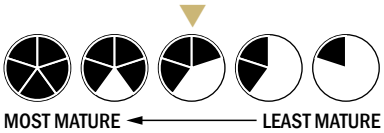
- Operated from 4 °C to 45 °C
- The effect of relative humidity is unknown

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- A few devices or systems exist (brass board)
- Is expected to be ready for commercialization within one calendar year
- Less than $1,000,000 required to advance the device or system to commercialization
- Has not been featured in any peer reviewed scientific publications or independent evaluations



Vero Tect

by Biral

CAPABLE OF DETECTING THE FOLLOWING:
Detects biological vs. non-biological particles

DESCRIPTION:
VeroTect is an aerosol analyzer that can be used to detect the presence of biological warfare agents in the atmosphere. It is a biosensor of ruggedized design suitable for field deployment. It works by measuring the size and shape of individual particles and measuring the fluorescence response of an aerosol sample. This information is combined using powerful analytical tools to interpret with a high degree of confidence whether an aerosol is biological or non biological. Its response is real time providing field commanders and first responders with an early warning capability to enable evasive action or appropriate protection measures to be undertaken.

TECHNOLOGY:
VeroTect uses real time optical (reagentless) technology to provide its biodetection capability. ASAS (Aerosol Size And Shape) technology was developed in conjunction with the University of Herfordshire and the UK MOD, Dstl Research Establishment at Porton Down in the UK. ASAS uses elastic scattering of laser light and biological characterization is performed using light induced fluorescence responses from the target aerosols.

ANALYTICAL Laboratory Ranking

VeroTect ranked in the lowest third of all evaluated products for analytical laboratories and earned 35% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Vero Tect	0.318
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

VeroTect ranked in the lowest third of all evaluated products for diagnostic laboratories and earned 38% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Vero Tect	0.345
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

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

ALTERNATIVE	UTILITY
Best Score	0.883
Vero Tect	0.486
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

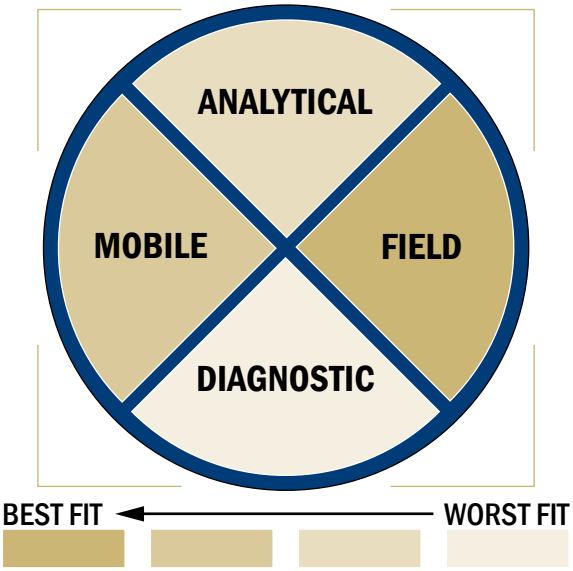
VeroTect ranked in the middle third of all evaluated products for field use and earned 64% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Vero Tect	0.606
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

BIRAL
PO Box 2, Portishead
Bristol, BS207JB
UK
www.biral.com

Point of Contact:
Steve Evans
+44 (0) 1275 847787
+44 (0) 1275 847303
sevans@biral.com

COST

- £72,000.00 GB Pounds sterling /device or system

Evaluation Criteria Provided by Vendor

System requirements:

- System is either mains operated or low voltage (24V) DC
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Real time aerosol detector

Training/Speed/Manpower:

- Very brief (minutes-hours) training and minimal technical skills
- 5-10 minutes set-up required

Re-use:

- Device or system is intended for continual use
- System must be decontaminated if exposed to a threat agent. Decontamination procedures are continually under review.

Maintenance:

- Once a year service required
- Expected life is greater than 10 years
- No daily quality assurance procedures

Transportation:

- Approximately the size of a carry-on luggage suitcase
- Between 25 and 50 kg
- Reagent shelf life greater than 3 years

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:

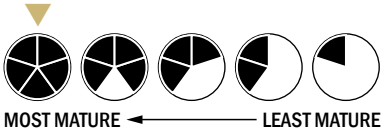
- Operated from -33 °C to 55 °C
- Components must be stored from 25 °C to 45 °C or room temperature
- The performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- Is commercially available and meets military specifications
- Has been featured in peer reviewed scientific publications or independent evaluations



VIP for EHEC

by BioControl Systems, Inc.

CAPABLE OF DETECTING THE FOLLOWING:
E. coli O157:H7, Salmonella, Listeria *(Assay validated)*

DESCRIPTION:
VIP family of rapid tests are patented, lateral flow immunoprecipitate assays for the detection of food pathogens. Each VIP test is totally self-contained. All the reagents have been systematically incorporated into the test device. After sample enrichment simply inoculate the VIP test. Results can be read after 10-20 minutes of room temperature incubation.

TECHNOLOGY:
Proprietary antibodies, with high specificity to E. coli O157:H7 antigens, are bound to chromogenic carrier and, separately, to solid support matrix. Reagents are incorporated in test units and produce visually discernible reaction product in presence of E. coli O157:H7. During initial hydration of test unit, E. coli O157:H7 reacts with antibody-chromogen complex to form antigen-antibody chromogen complex, which flows across lateral flow membrane and is bound by antibody immobilized on membrane. Positive reaction is indicated by presence of detection line positioned across the solid support in test sample window. Proper test completion is indicated by another line formed in test verification window. Absence of line in test verification window invalidates the test.

ANALYTICAL Laboratory Ranking

VIP for EHEC ranked in the highest third of all evaluated products for analytical laboratories and earned 68% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
VIP for EHEC	0.612
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

VIP for EHEC ranked in the highest third of all evaluated products for diagnostic laboratories and earned 83% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
VIP for EHEC	0.758
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

VIP for EHEC ranked in the highest third of all evaluated products for mobile laboratories and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
VIP for EHEC	0.683
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

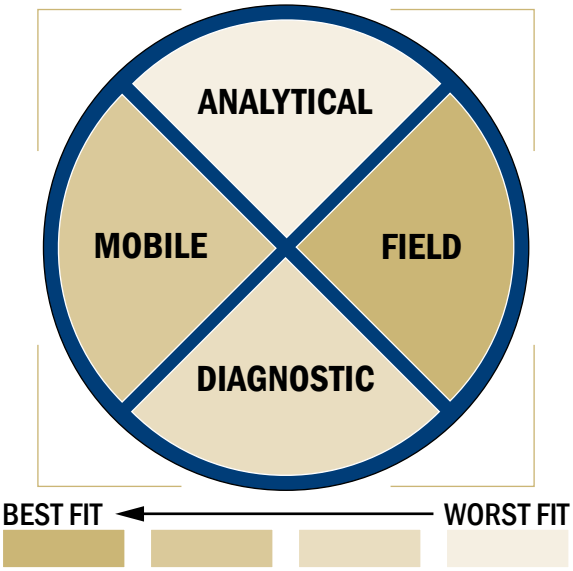
VIP for EHEC ranked in the highest third of all evaluated products for field use and earned 94% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
VIP for EHEC	0.882
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

BioControl Systems, Inc.
12822 SE 32nd St.
Bellevue, WA 98055
www.biocontrolsys.com

Point of Contact:
Maritta Ko
(425) 603-1123 x105
(425) 603-0070 fax
mko@biocontrolsys.com

COST

- $7.00-10.00/sample
- $6.00-8.00/system or device

Evaluation Criteria Provided by Vendor

System requirements:

- No electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection 20 minutes or less
- 1 sample/batch
- Less than 100 ul volume needed per test for detection
- The system or device is not amendable to automation

Training/Speed/Manpower:

- Very brief training
- No set-up required
- 0-2 manual steps required for detection

Re-use:

- Device or system is designed for single use
- 0-1 solution or buffer used
- 1 component
- No cleaning required

Maintenance:

- 0-1 consumable or expendable needed
- No service required
- NA expected life
- No daily quality assurance procedures required

Transportation:

- Approximately the size of a soda can
- Less than 1 kg
- Shelf life between 1 and 3 years

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps
- System not able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:

- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:

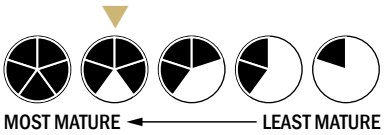
- Operated from 15 °C to 37 °C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Sensitivity:

- 1-100 CFU per ml

Maturity gauge:

- Is commercially available



xMAP

by Luminex Inc.

CAPABLE OF DETECTING THE FOLLOWING:

Bacillus anthracis, Francisella tularensis, Burkholderia pseudomallei, Coxiella burnetti, Brucella species, E.coli O157:H7, Vibrio cholera, Burkholderia mallei, Yersinia pestis, Smallpox virus, Influenza virus, Dengue fever virus, Orthopox virus, Venezuelan equine encephalitis virus, MS-2 bacteriophage, Botulinum toxin A, Botulinum toxin B, Staphylococcal toxin B, Ricin toxin, Abrin toxin *(Assay validated)*

DESCRIPTION:

The Luminex System is a flexible analyzer based on the principles of flow cytometry that is designed to meet the needs of laboratory medicine and the care of patients, as well being used in the research environment. 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.

TECHNOLOGY:

The Luminex 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. The second is a flow cytometry-based instrument, the Luminex analyzer, which integrates key xMAP detection components such as lasers, optics, advanced fluidics and high-speed digital signal processors. The third component is the IS 2.3 software, which is designed for template-based data acquisition with robust data regression analysis - ideal for the clinical laboratory setting.

ANALYTICAL Laboratory Ranking

xMAP ranked in the highest third of all evaluated products for analytical laboratories and earned 92% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Luminex xMAP	0.825
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

xMAP ranked in the highest third of all evaluated products for diagnostic laboratories and earned 78% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
Luminex xMAP	0.708
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

xMAP ranked in the highest third of all evaluated products for mobile laboratories and earned 77% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
Luminex xMAP	0.680
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

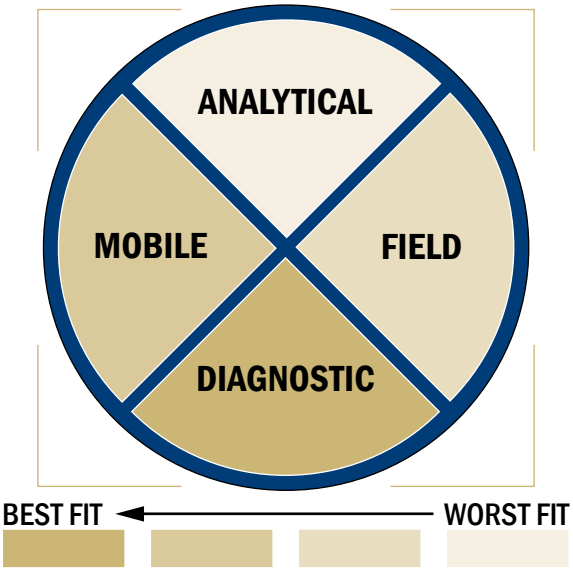
xMAP ranked in the middle third of all evaluated products for field use and earned 61% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Luminex xMAP	0.579
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Luminex Inc.
12212 Technology Blvd.
Austin, TX 78727-6115
www.Luminexcorp.com

Point of Contact:
Sales Department
(888) 219-8020
(512) 219-5195 fax

COST

- $2.00-3.00/sample
- $63,950.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:

- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:

- Single sample detection greater than 60 minutes
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:

- More than a day of training and significant technical skills required
- Greater than 20 minutes set-up required
- Greater than 12 manual steps required for detection

Re-use:

- Device or system is intended for multiple use
- 3 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:

- Less than once a year service required
- Expected life is greater than 10 years
- 5-10 minutes daily quality assurance procedures

Transportation:

- Approximately the size of a home dishwasher
- Between 5 and 25 kg
- Reagent shelf life between 6 months and 1 year

Ease of use/Utility:

- Can view results “in real time”
- No centrifugation steps
- There are multiple shaking or vortexing steps
- System may be able to interpret raw data or call a positive through internal software in the future
- Capable of detecting multiple biological agents or toxins within the same test
- Four or more additional pieces of equipment needed

Signature:

- There are sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:

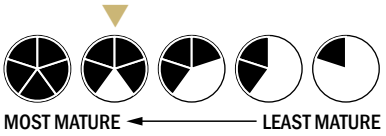
- Operated from 15°C to 37°C
- Components must be stored at 4°C
- The peak performance of the device or system is at normal relative humidity

Sensitivity:

- 100-1,000 CFU per ml

Maturity gauge:

- Is commercially available
- Has been featured in peer reviewed scientific publications or independent evaluations



XMX/2L-MIL

by Dycor

CAPABLE OF DETECTING THE FOLLOWING:
None reported

DESCRIPTION:
The XMX/2L-MIL is an aerosol separator, sample preparation, and high mass flow concentrator system, designed to operate under harsh field conditions. This system was designed to process and collect large concentrations of aerosols in the respirable range (1 to 10 microns in diameter) in relatively short periods of time. This system collects 530 (+/- 25) standard liters of air per minute, strips away all of the large dust particles (greater than 10 microns), and all of the very small micro debris (less than 1 micron), and concentrates the aerosols between 1 and 10 microns. The particles are then impinged into a liquid sample contained within a collection vial (normally sterile water or phosphate buffered saline). Once the sample is collected, the user removes the centrifuge tube for subsequent analysis (immunoassay, PCR, culturing). One of the primary issues in bioaerosol detection is the fact that one cannot obtain enough sample of interest to detect an airborne threat concentration that is lethal to humans. Our system concentrates approximately 530 liters of air per minute, cleans it up, and prepares a small aqueous aliquot to minimize dilution for detection, all simultaneously. Additionally, our XMX system is designed for use while wearing MOPP gear. There is superior system reliability and having only one moving part—the blower motor—reduces maintenance requirements and ensures a low MTBF. The XMX system is quick and easy to setup and tear down to minimize training and improper or incorrect usage.

TECHNOLOGY:
The XMX/2L-MIL sampler operates using principles of virtual impaction. Particles are accelerated through nozzle/gap combinations and are subjected to large aerodynamic forces generated by a perpendicular airflows moving at a high flow rate. Above a certain threshold, larger particles have sufficient momentum to cross the gap where smaller particles are deflected by the larger airflow and separated from the initial particle stream. The threshold sizes are determined by physical device and airflow design. In effect, this air sampler acts as an amplifier for particles within the size range 1-10µm and as a filter for particles outside of this range.

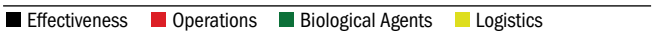
ANALYTICAL Laboratory Ranking
XMX/2L-MIL ranked in the lowest third of all evaluated products for analytical laboratories and earned 43% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
Dycor XMX	0.385
Lowest Score	0.217

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking
XMX/2L-MIL ranked in the middle third of all evaluated products for diagnostic laboratories and earned 59% of the utility points of the best score.

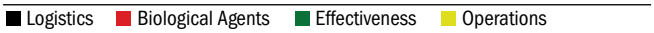
ALTERNATIVE	UTILITY
Best Score	0.909
Dycor XMX	0.537
Lowest Score	0.321



Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking
XMX/2L-MIL ranked in the middle third of all evaluated products for mobile laboratories and earned 69% of the utility points of the best score.

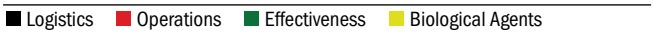
ALTERNATIVE	UTILITY
Best Score	0.883
Dycor XMX	0.611
Lowest Score	0.379



Preference Set: *Mobile Laboratory*

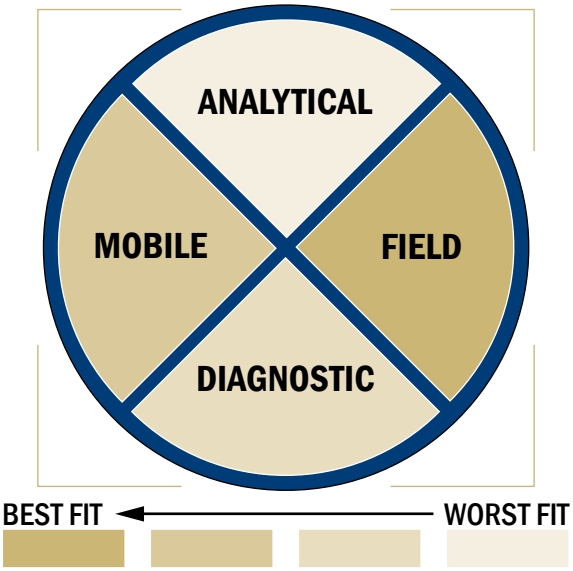
FIELD USE Ranking
XMX/2L-MIL ranked in the highest third of all evaluated products for field use and earned 89% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
Dycor XMX	0.843
Lowest Score	0.343



Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION
Dycor Technologies Ltd.
1851 - 94 Street
Edmonton, Alberta T6N 1E6
Canada
www.dycor.com

Point of Contact:
Antony Roth
(780) 486-0091 x2326
(780) 486-3535
apr@dycor.com

COST
- $1.00/sample

Evaluation Criteria Provided by Vendor

System requirements:
- System or device uses batteries or has 110V or 220V electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 minutes or less
- 96 samples/batch or higher
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- Very brief (minutes-hours) training and minimal technical skills
- Less than 5 minutes set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for single use
- 0-1 solution or buffer used
- 2 component
- No cleaning require

Maintenance:
- Less than once a year service required
- Expected life is greater than 10 years
- Less than 5 minutes daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Reagent shelf life greater than 3 years

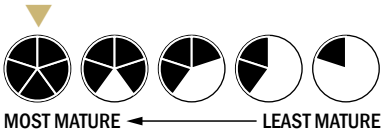
Ease of use/Utility:
- Cannot view results “in real time”
- No centrifugation steps
- No shaking or vortexing steps

Signature:
- No sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:
- Operated from 4 °C to 45 °C
- Components must be stored at 25 °C to 45 °C
- The performance of the device or system is not influenced by relative humidity

Sensitivity:
- 10,000-100,000 CFU per ml

Maturity gauge:
- Is commercially available and meets military specifications
- Has been featured in peer reviewed publications or independent evaluations



ZeptoMARK and SensiChip Product Line

by Zeptosens AG

CAPABLE OF DETECTING THE FOLLOWING:
Corynebacterium diptheria *(Assay developed)*

DESCRIPTION:
High sensitivity DNA and protein microarray system comprehending sample isolation and workup, assay performance, readout of results, data collection and data presentation. Applicability has been shown for determination of gene expression as a consequence of infection, medical treatment, cancer progression, stress, ageing. Applicability has been shown as well for the determination of protein expression and protein activation in drug development. System has been successfully applied for the high sensitivity determination and characterization of clinically relevant pathogenic bacteria with minimal sample preparation requirements.

TECHNOLOGY:
In contrast to competing microarray readout systems based on epifluorescence, Zeptosens is using planar waveguide detection. This results in facilitated sample workup requirements (more tolerant towards contamination) and about 50 fold increase of sensitivity. Lowest limit of detection: 1 attomol labeled DNA.

ANALYTICAL Laboratory Ranking

ZeptoMARK and SensiChip Product Line ranked in the highest third of all evaluated products for analytical laboratories and earned 74% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.901
ZeptoMARK and SensiChip	0.664
Lowest Score	0.217

Effectiveness Biological Agents Logistics Operations

Preference Set: *Analytical Laboratory*

DIAGNOSTIC Laboratory Ranking

ZeptoMARK and SensiChip Product Line ranked in the middle third of all evaluated products for diagnostic laboratories and earned 69% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.909
ZeptoMARK and SensiChip	0.623
Lowest Score	0.321

Effectiveness Operations Biological Agents Logistics

Preference Set: *Diagnostic Laboratory*

MOBILE Laboratory Ranking

ZeptoMARK and SensiChip Product Line ranked in the lowest third of all evaluated products for mobile laboratories and earned 52% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.883
ZeptoMARK and SensiChip	0.458
Lowest Score	0.379

Logistics Biological Agents Effectiveness Operations

Preference Set: *Mobile Laboratory*

FIELD USE Ranking

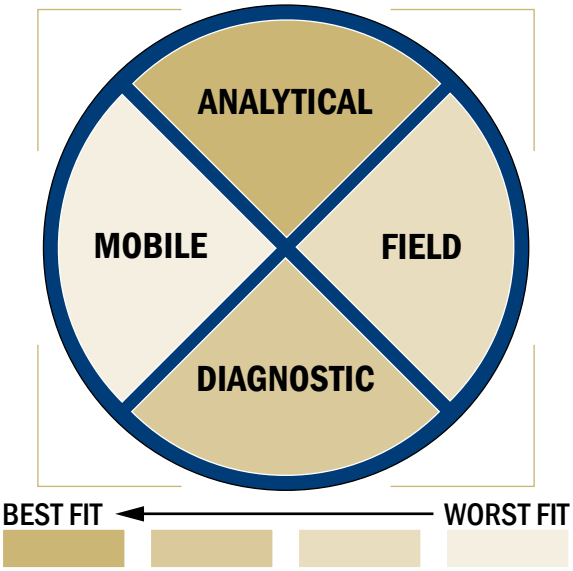
ZeptoMARK and SensiChip Product Line ranked in the lowest third of all evaluated products for field use and earned 54% of the utility points of the best score.

ALTERNATIVE	UTILITY
Best Score	0.943
ZeptoMARK and SensiChip	0.507
Lowest Score	0.343

Logistics Operations Effectiveness Biological Agents

Preference Set: *Field Use*

Summary of Analysis



CONTACT INFORMATION

Zeptosens AG
Benkenstrasse 254
Witterswil, CH-4108, Switzerland
www.zeptosens.com

Point of Contact:
Gerhard Kresbach
+41617268183
+41617268171 fax
gerhard.kresbach@zeptosens.com

COST

- $800.00/sample
- $130,000.00/device or system

Evaluation Criteria Provided by Vendor

System requirements:
- System or device has 110V electrical requirement
- The system or device does not requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 60 min or more
- 384 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- A day of training
- Greater than 20 min required for set-up
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 4 solution or buffer used
- 5 or more components
- No cleaning required, uses disposable cartridges

Maintenance:
- 4 consumable or expendable needed
- Needs service every 6 months
- Expected life measure of 5-10 years
- Less than 5 minutes required for daily quality assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- Between 25-50 kg
- Shelf life between 1-6 months

Ease of use/Utility:
- Cannot view results “in real time”
- No centrifugation steps
- A single shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from 15 °C to 37 °C
- Components can be stored at 4 °C
- Performance of the device or system is not influenced by relative humidity

Sensitivity:
- 1-100 CFU per ml

Maturity gauge:
- Is commercially available