Tetracore, Inc. - BioThreat Integrated Detection System

GENERAL DESCRIPTION:

BioThreat Integrated Detection System provides quick, reliable screening and confirmatory analysis of biothreats for both biologists in the laboratory and First Responders in the field. The BioThreat Alert® Reader and BioThreat Alert® strips provide a screening test for 9 different assays (Abrin, Anthrax, Bot Tox, Brucella, Orthopox, Plague, Ricin, SEB, and Tularemia) in less than 20 minutes. The reader is a fully functional ultra-mobile PC designed to enhance the speed and ease of testing. The interface has been designed to be large and simple, accommodating for various PPE worn by First Responders. Tetracore's T-COR 4TM Handheld Real-Time PCR Thermocycler provides superior confirmatory analysis for samples tested with BioThreat Alert® assays. The device operates connected to the BioThreat Alert® Reader via USB and runs either standard TaqMan® real-time PCR or Isothermal real-time fluorescence based amplification, which delivers confirmatory analysis in 10 minutes. It can process four independent samples and is capable of analyzing two targets per sample. Tetracore produces 18 dry real-time PCR and 4 dry Isothermal Assays for the T-COR 4TM with shelf lives exceeding 18 months at room temperature. The T-COR 4TM is an open system capable of running any customer's assay in either a wet or dry formulation. Identification of agents in powder samples, agents in environmental samples, bacteria, and viruses has been demonstrated in both devices.

TECHNICAL DESCRIPTION:

Provides screening and confirmation of biothreat samples. BioThreat Alert® strips are handheld lateral-flow immunochromatographic assays that use colloidal gold labeled antibodies. BioThreat Alert® Reader is a handheld PC coupled with additional hardware and software to allow analysis of the strips. T-COR 4TM is a handheld, battery-powered, peltier-based thermocycler designed for TaqMan® real-time PCR amplification and Isothermal real-time fluorescence based amplification. Designed with a proprietary, modular optical system, it can be modified to suit future requirements. The developed optical technology enables support of nucleic acid detection, polypeptide detection, and environmental sensing.

Tier Selection

Final tier assignment is based on overall product score.

Top Tier | Second Tier | Third Tier | Fourth Tier | Bottom Tier

RANKINGS

	Biological	Chemical	Radiological
FIELD USE System	●	N/A	N/A
MOBILE Laboratory	●	N/A	N/A
DIAGNOSTIC Laboratory	●	N/A	N/A
ANALYTICAL Laboratory	●	N/A	N/A

Survey Source

Vendor Supplied Information

CONTACT INFORMATION

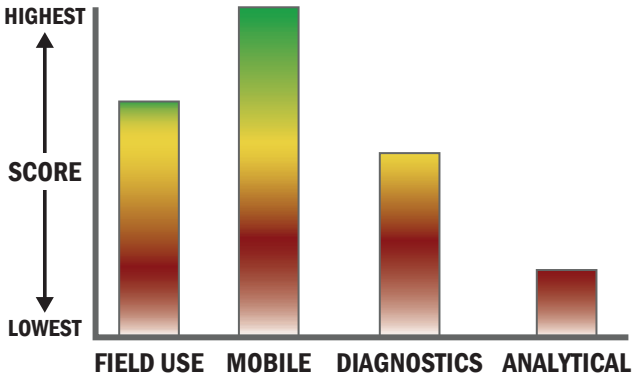
Tetracore, Inc.
9901 Belward Campus Drive Suite 300
Rockville, MD 20850
POC: Pete Pillay
240-268-5400
ppillay@tetracore.com
www.tetracore.com

COST

- $21,500/system
- $37/analysis

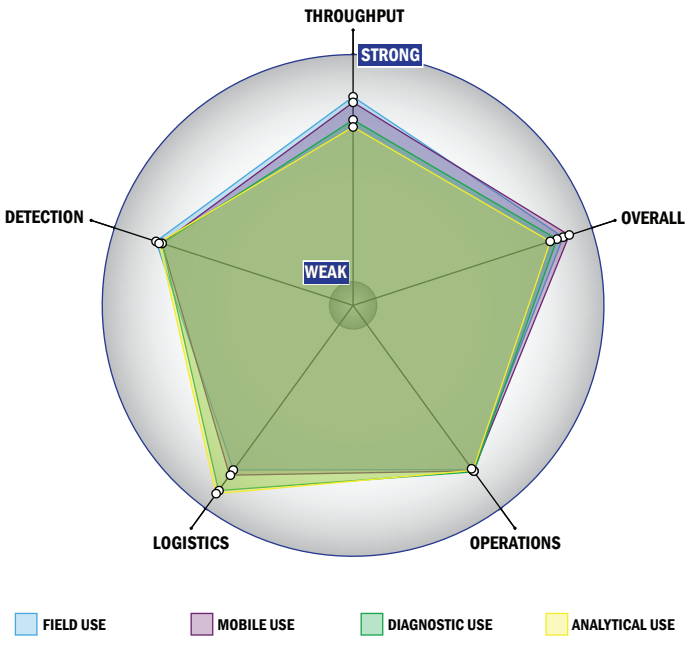
Scoring Analysis

System scores are compared across the four scenarios and ranked from highest to lowest.



Impact Chart

The Impact Chart is a spider graph representing specific categories and designed to give the reader a visual depiction of how a particular system is expected to operate across the four different scenarios. The score for each of the seven categories is presented as the percentage of the total possible score. Higher category scores extend the spokes of a graphic toward the outer edge of the chart. The area graphed for each of the four scenarios relates to how well the system performed in that scenario. Graphics for each of the four scenarios are super-imposed for ease of comparison.



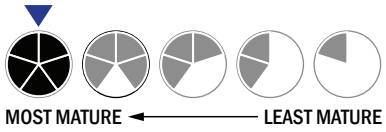
Evaluation Criteria

Throughput:

- Between 15 and 30 minutes for detection
- Multiple samples, multiple tests/sample per run
- 95-32 samples every 2 hours
- The system or device is currently fully automated
- Device or system is intended for multiple detection assays
- 0-1 solutions, buffer, eluents, and/or reagents
- 2 components
- No set-up of the system is required
- 3-5 steps are required for detection

Logistics:

- Very brief (minutes-hours) training and minimal technical skills
- Approximately the size of a toaster
- Between 1 and 5 kg
- Wireless and wired connections are available
- System or device uses batteries
- 4-8 hours battery life



Operations:

- Can be used from 4 °C to 41 °C
- Components must be stored at room temperature (27 °C)
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life
- 5-10 years expected life
- Results can be viewed in real-time
- The system is not capable of autonomy
- The system software is open but modification requires licensing
- The system hardware is open but modification requires licensing

Detection:

- Possible the system could receive 510K clearance, no current efforts at this time
- Possible the system could receive FDA approval, no current efforts at this time
- Less than 250 µL
- Superior specificity. System has a false alarm rate approaching zero (~0%)
- 1-100 CFU per mL
- 1-100 PFU per mL
- 1-10 ng per mL
- Spore lysis not necessary for detection by system