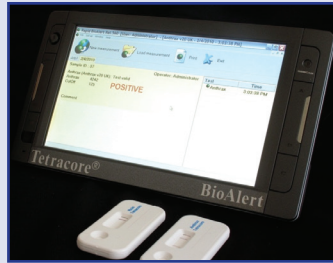


# Tetracore, Inc. - BioThreat Alert Reader and BioThreat Alert Strips



## GENERAL DESCRIPTION:

This new reader boasts many features designed to enhance the speed and the ease of testing for biological warfare agents. The BioThreat Alert® Reader is a fully functional ultra-mobile PC (UMPC), running Windows and capable of connecting to WiFi and Bluetooth signals. Users can interact with the reader with its touch screen or by connecting via USB with a keyboard/mouse. The user interface has been designed to be large and simple in order to aid First Responders who may be using various forms of PPE. Coupling this new reader with Tetracore's BioThreat Alert® strips creates a quick, reliable system for biodetection. BioThreat Alert® strips have been on the market for over 10 years and offer assays to detect Abrin, Anthrax, Bot Tox, Brucella, Orthopox, Plague, Ricin, SEB, and Tularemia. These robust handheld assays are capable of testing samples from a variety of matrices (soil, air, liquid, powder) in a matter of 15 minutes. Upon the completion of an assay, the BioThreat Alert® Reader can perform and record an accurate and objective analysis in merely 20 seconds. The software is also capable of generating a detailed report for each sample tested, which includes numerical output and a graphical representation of the results. The report can also be printed directly from the unit.



## TECHNICAL DESCRIPTION:

This detection system consists of two separate parts. The BioThreat Alert® strips are handheld lateral-flow immunochromatographic assays that use colloidal gold labeled antibodies for detection. The BioThreat Alert® Reader is a handheld PC coupled with additional hardware and software to allow for the analysis of the aforementioned strips. A camera attached to the rear of the device analyzes the strips' surface, measuring the optical density (reflection) and then determining a positive/negative result. The tray attached to the unit is capable of being modified to suit new assay types and designs in the future.

## CONTACT INFORMATION

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## COST

- \$5,500/system
- \$25/analysis

## Tier Selection

Final tier assignment is based on overall product score.

- Top Tier
- ◐ Second Tier
- Third Tier
- ◑ Fourth Tier
- Bottom Tier

### RANKINGS

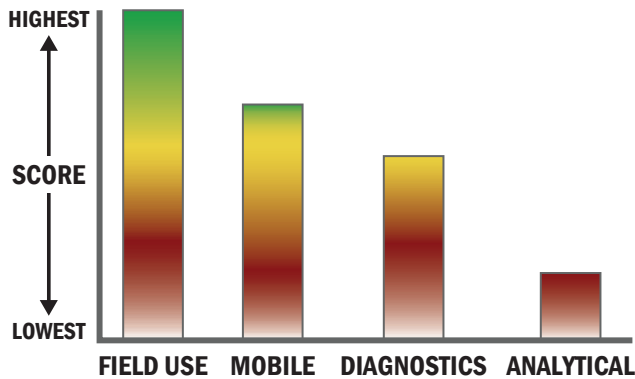
	Biological	Chemical	Radiological
<b>FIELD USE System</b>	●	○	○
<b>MOBILE Laboratory</b>	●	○	○
<b>DIAGNOSTIC Laboratory</b>	◐	○	○
<b>ANALYTICAL Laboratory</b>	◐	○	○

## Survey Source

Vendor Supplied Information

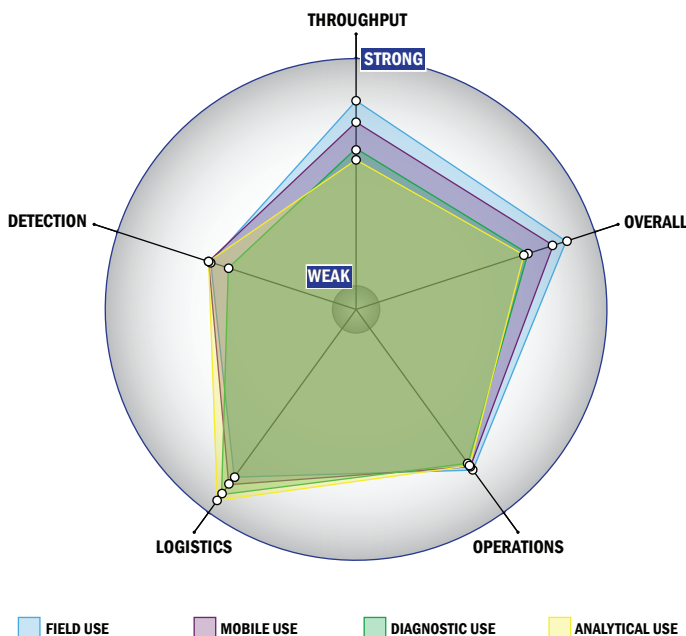
## Scoring Analysis

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.



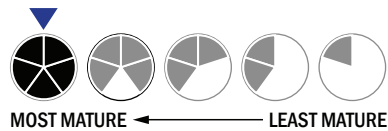
## Evaluation Criteria

### Throughput:

- Between 2 and 15 minutes for detection
- 1 sample, single test/sample per run
- 95-32 samples every 2 hours
- The system or device is currently fully automated
- Device or system is designed for a single use
- 0-1 solutions, buffer, eluents, and/or reagents
- 1 component
- Less than 5 minutes is required for set-up
- 1-2 steps are required for detection

### Logistics:

- Very brief (minutes-hours) training and minimal technical skills
- Approximately the size of a toaster
- Less than 1 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%)
- 10,000-100,000 CFU per mL
- 10,000-100,000 PFU per mL
- Spore lysis not necessary for detection by system

