

# Tetracore, Inc. - BioThreat Alert ELISA Kit(s)



## GENERAL DESCRIPTION:

Antigen Capture ELISA kit for detection of biothreat agents; designed to be performed in the lab using a plate washer/reader for quantitative analysis. The kit can be adapted for field use for qualitative analysis with some effort. The kit is designed for environmental samples and the like, and can test samples in many matrices.



## TECHNICAL DESCRIPTION:

ELISA: antigen capture employing capture and detector antibodies; most kits use monoclonal antibodies for detection.

## CONTACT INFORMATION

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## COST

- \$575-\$625/system
- N/A/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>			

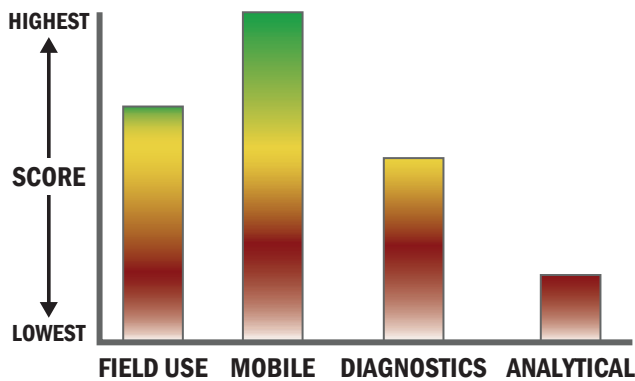
## Survey Source

Vendor Supplied Information



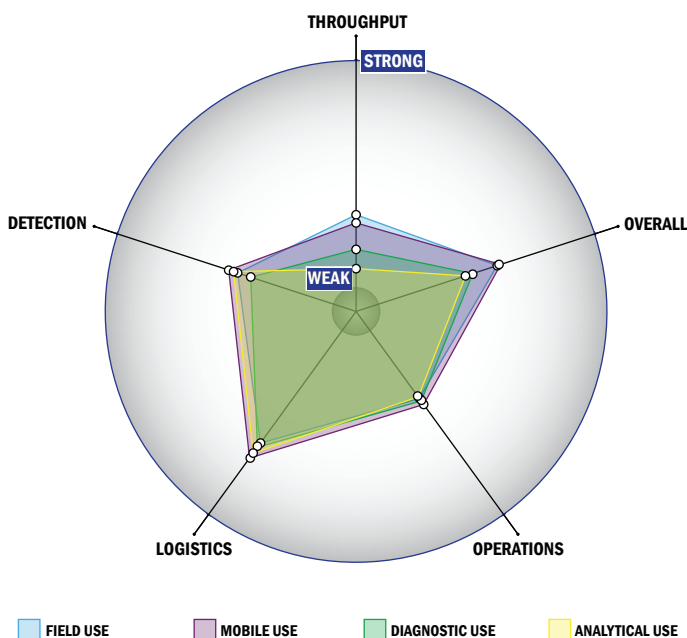
## Scoring Analysis

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.



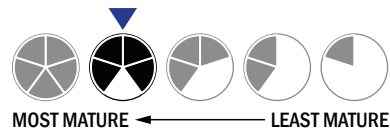
## Evaluation Criteria

### Throughput:

- Between 60 minutes and 8 hours for detection
- 1 sample, single test/sample per run
- 95-32 samples every 2 hours
- The system or approach is not amenable to full or semi-automation
- Device or system is designed for a single use
- 5 or more solutions, buffer, eluents, and/or reagents
- 2 components
- No set-up of the system is required
- Greater than 12 steps are required for detection

### Logistics:

- A day of training and technical skills are required
- Approximately the size of a soda can
- Less than 1 kg
- This system is not capable of transmitting data
- There is no electrical requirement



### Operations:

- Can be used from 25 °C to 37 °C
- Components must be stored at 4 °C
- Performance is not influenced by relative humidity
- Between 1 to 6 months shelf life
- The system could be adapted to a fully autonomous system\
- The system does not employ any software

### Detection:

- Possible the system could receive 510K clearance, no current efforts at this time
- Possible the system could receive FDA approval, no current
- Less than 100 µL
- Excellent specificity. System has occasional false alarms under certain conditions (<2%)
- 10,000-100,000 CFU per mL
- 1-10 ng per mL
- Spore lysis not necessary for detection by system