

BioFire Diagnostics, Inc. - RAZOR EX BioThreat Detection System



GENERAL DESCRIPTION:

The advanced RAZOR® EX BioThreat Detection System utilizes Real-time PCR technology to deliver the most reliable and sensitive field detection and identification of biological pathogens. Designed specifically for use in the field, the RAZOR EX's compact and lightweight design allows it to be hand carried and minimal sample preparation requirements make it easy to use. Powder, swab, water, dry filter, or culture sample types work ideally with the RAZOR EX. Used with The 10® Target Screen Kit; the RAZOR EX simultaneously tests environmental samples for ten Category A and B BioThreat pathogens with reliable DNA-based results available in less than 30 minutes. Created for first responders and front line military troops, it is easily operated while working in protective equipment under extreme conditions. The stand-alone, battery powered instrument includes Bluetooth® capabilities for wireless data transmission, bar code reader for data input, and a bright, easy-to-read color screen. The RAZOR EX utilizes Idaho Technology's patented reagent pouch system—integrated freeze-dried reagents packaged in durable plastic pouches for incomparable ease of use. A variety of pre-formatted pouch configurations are available for biothreat, food screening, or water testing applications.



TECHNICAL DESCRIPTION:

Real-time Polymerase Chain Reaction (PCR) – a sensitive and specific molecular, enzymatic reaction that in the presence of a targeted pathogen, amplifies the target DNA. Tests are designed to detect novel and highly conserved regions specific to the pathogen of interest, which produce low error rates. The reaction is coupled with fluorescent probes that provide real-time detection.

CONTACT INFORMATION

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POC: Lou Banks

COST

- \$38,500/system
- \$200/analysis

Tier Selection

Final tier assignment is based on overall product score.

- Top Tier ● Second Tier ● Third Tier
● Fourth Tier ● Bottom Tier

RANKINGS

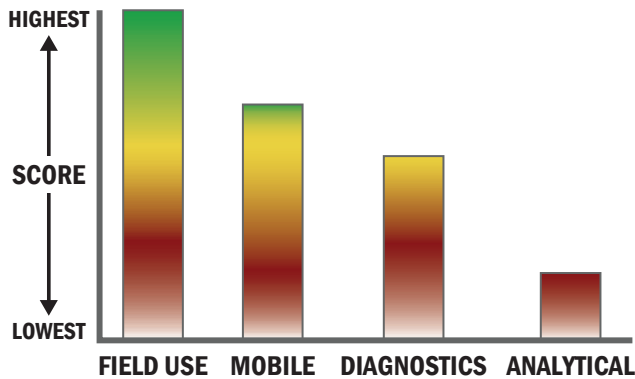
	Biological	Chemical	Radiological
FIELD USE System	●	N/A	N/A
MOBILE Laboratory	●	N/A	N/A
DIAGNOSTIC Laboratory	●	N/A	N/A
ANALYTICAL Laboratory	●	N/A	N/A

Survey Source

Vendor Supplied Information

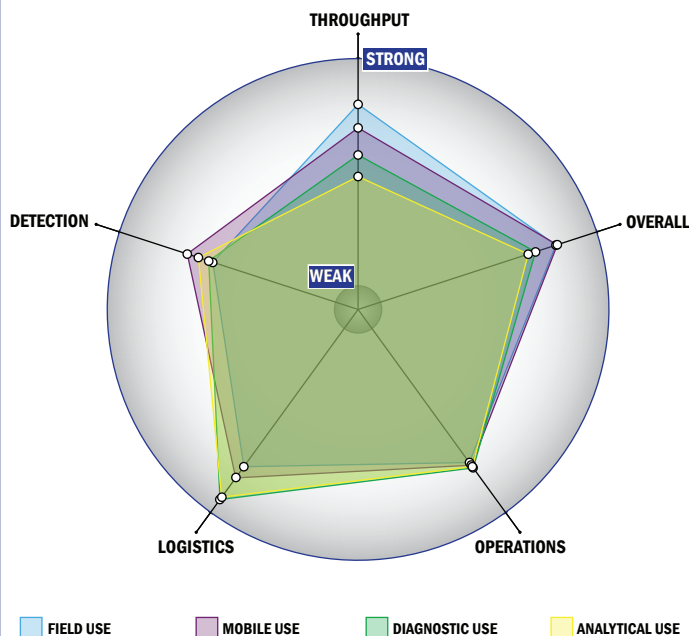
Scoring Analysis

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.



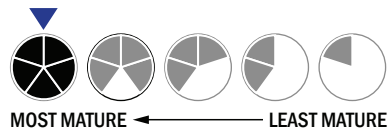
Evaluation Criteria

Throughput:

- Between 15 and 30 minutes for detection
- 1 sample, >10 tests/sample per run
- Less than 32 samples every 2 hours
- The system or device is currently semi-automated
- Device or system is intended for multiple detection assays
- 0-1 solutions, buffer, eluents, and/or reagents
- 1 component
- Less than 5 minutes is required for set-up
- 3-5 steps are required for detection

Logistics:

- Very brief (minutes-hours) training and minimal technical skills
- Approximately the size of a toaster
- Between 5 and 25 kg
- Wireless and wired connections are available
- System or device uses batteries
- 2-4 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 6 months and 1 year shelf life
- 5-10 years expected life
- Results can be viewed in real-time
- The system could be adapted to a fully autonomous system with some effort
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

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
- Greater than 250 µL
- Excellent specificity. System has occasional false alarms under certain conditions (<2%)
- 100-1,000 CFU per mL
- 100-1,000 PFU per mL
- Greater than 10,000 ng per mL
- Spore lysis not necessary for detection by system