BioFire Diagnostics, Inc. - R.A.P.I.D. BioThreat Detection System

GENERAL DESCRIPTION:

The Ruggedized Advanced Pathogen Identification Device (R.A.P.I.D.) is a portable real-time PCR system designed to identify biological agents. Because of its rugged design, reliability, and sensitivity it has become the standard for the U.S. DoD and other militaries around the world. The R.A.P.I.D. is the ideal choice for mobile analytical labs and field hospitals. The instrument integrates Idaho Technology's LightCycler ® Instrument technology into a portable, impact resistant package. Distinctive software allows simple "push-button" use of the R.A.P.I.D. System by military field personnel with minimal training. R.A.P.I.D.'s open platform supports multiple chemistries and sample matrices including environmental and food samples. Used with Idaho Technology's commercial freeze-dried pathogen test kits or customized reactions, R.A.P.I.D. provides quick, safe, and accurate field identification of pathogens.

TECHNICAL DESCRIPTION:

R.A.P.I.D. employs real-time Polymerase Chain Reaction (PCR).

CONTACT INFORMATION

BioFire Diagnostics, Inc.
390 Wakara Way
Salt Lake City, UT 84108
POC: Lou Banks
801-736-6354
Lou.banks@biofiredx.com
www.biofiredx.com

COST

- $55,000/system
- $24.75/analysis

Tier Selection

Final tier assignment is based on overall product score.

Top Tier Second Tier Third Tier Fourth Tier Bottom Tier

RANKINGS

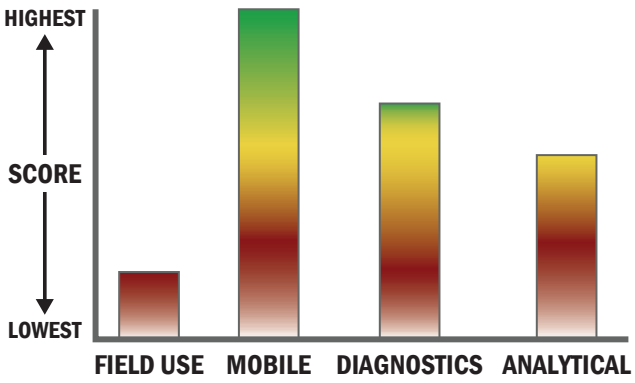
	Biological	Chemical	Radiological
FIELD USE System	Fourth Tier	N/A	N/A
MOBILE Laboratory	Third Tier	N/A	N/A
DIAGNOSTIC Laboratory	Third Tier	N/A	N/A
ANALYTICAL Laboratory	Third Tier	N/A	N/A

Survey Source

Vendor Supplied Information

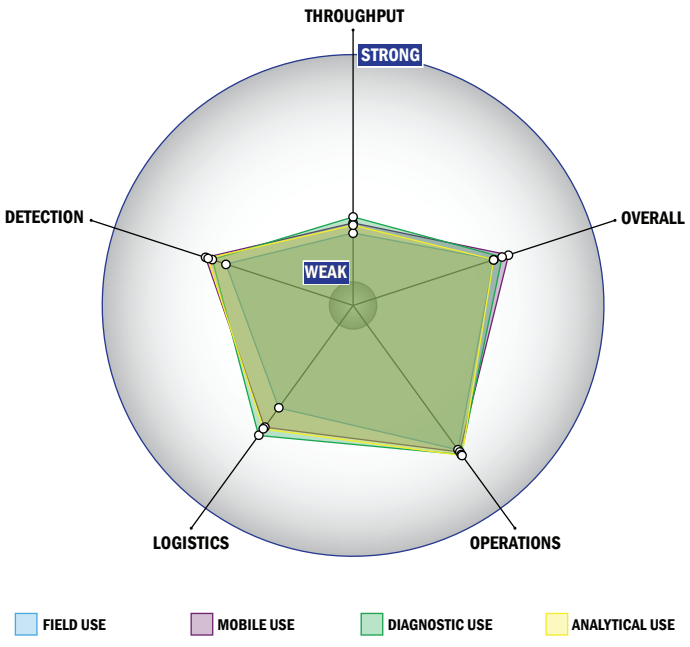
Scoring Analysis

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.



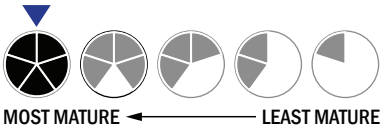
Evaluation Criteria

Throughput:

- Between 30 and 60 minutes for detection
- Multiple samples, multiple tests/sample per run
- Less than 32 samples every 2 hours
- The system could be adapted to a semi-automated system with some effort
- Device or system is intended for multiple detection assays
- 4 solutions, buffer, eluents, and/or reagents
- 5 or more components
- Less than 5 minutes is required for set-up
- Greater than 12 steps are required for detection

Logistics:

- More than a day of training and significant technical skills are required
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Wireless and wired connections are available
- System or device has 110V electrical requirement



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 6 months 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 and available for modification
- The system hardware is open and available for modification

Detection:

- Possible the system could receive 510K clearance, no current efforts at this time
- Possible the system could receive 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
- 1,000-10,000 PFU per mL
- Manual kit not integrated with the system handles spore lysis