BioFire Diagnostics, Inc. - JBAIDS (Joint Biological Agent Identification and Diagnostic System)

GENERAL DESCRIPTION:

JBAIDS is the DoD standard platform used to positively identify specific biological warfare agents in a dual-purpose role: for diagnostic applications in a clinical environment and for environmental and food sample confirmatory testing. JBAIDS provides timely, reliable answers to field commanders and medical laboratory officers to support critical decision making and countermeasures and aid in determining appropriate medical intervention. The JBAIDS is an FDA cleared diagnostic system.

TECHNICAL DESCRIPTION:

The JBAIDS instrument is a ruggedized, portable real-time PCR instrument using TaqMan PCR amplification for detection of biological threat agents. The instrument is composed of an air thermocycler that amplifies specific DNA and RNA sequences using PCR and a fluorimeter that measures fluorescence signals associated with production of PCR product (amplicon) during the course of the reaction. Analysis of PCR data is achieved by associated software that automatically makes positive or negative calls for 16 biological threat agents.

CONTACT INFORMATION

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COST

- $55,000/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
FIELD USE System	Fourth Tier	N/A	N/A
MOBILE Laboratory	Third Tier	N/A	N/A
DIAGNOSTIC Laboratory	Second Tier	N/A	N/A
ANALYTICAL Laboratory	Third Tier	N/A	N/A

Notes

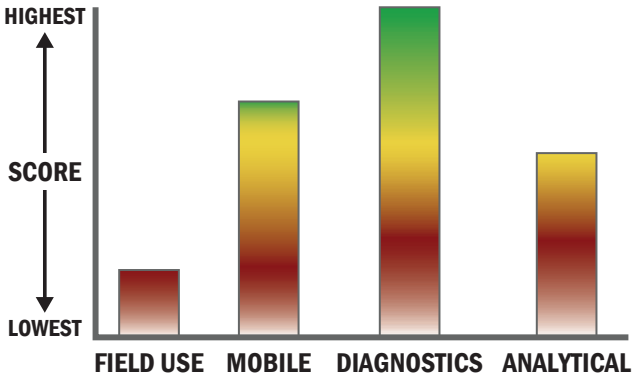
The JBAIDS is a currently fielded DoD system which is scheduled to be replaced with the Next Generation Diagnostic System.

Survey Source

Vendor Supplied Information

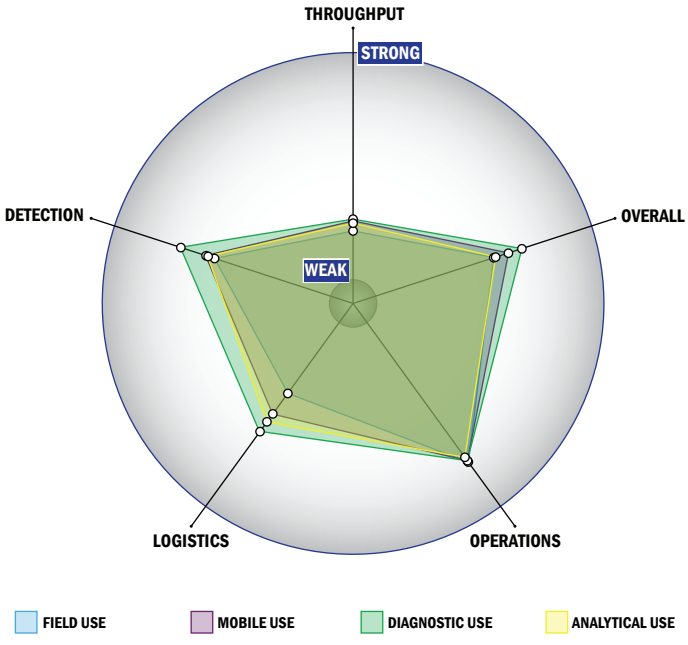
Scoring Analysis

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.



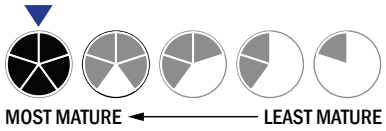
Evaluation Criteria

Throughput:

- Between 60 minutes and 8 hours for detection
- Multiple samples, multiple tests/sample per run
- 95-32 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
- This system is not capable of transmitting data
- 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 3 years shelf life
- Greater than 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:

- System currently has 510k clearance
- System currently has FDA approval
- 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