BioFire Diagnostics, Inc. - FilmArray Pathogen Detection System

GENERAL DESCRIPTION:

The FilmArray System is a user friendly automated pathogen identification system. The dual use platform with integrated sample preparation is capable of analyzing clinical and environmental samples automatically testing for multiple pathogens simultaneously from a raw sample. The lightweight, small footprint instrument processes a sample, analyzes the data and reports results in one hour. Consumable pouches are freeze dried and room temperature stable. ITI's current test panels are for respiratory disease and biothreat with its development pipeline to include, gastrointestinal disease, sepsis, and sexually transmitted disease panels. The system is intended for clinical diagnostic use and environmental testing. It is simple to use requiring little training and network capable with connectivity to the national health information network and composite health care system available.

TECHNICAL DESCRIPTION:

The FilmArray integrates sample preparation into a highly multiplexed Polymerase Chain Reaction (PCR) system developed for the point-of-care diagnostic market. The single sample instrument uses a consumable pouch that integrates sample preparation and nested multiplex PCR. Integrated sample preparation provides ease-of-use while the highly multiplexed PCR provides both the sensitivity of PCR and the ability to test for up to 30 different organisms simultaneously.

CONTACT INFORMATION

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COST

- $49,500/system
- $129/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	Third Tier	N/A	N/A
MOBILE Laboratory	Second Tier	N/A	N/A
DIAGNOSTIC Laboratory	Top Tier	N/A	N/A
ANALYTICAL Laboratory	Second Tier	N/A	N/A

Notes

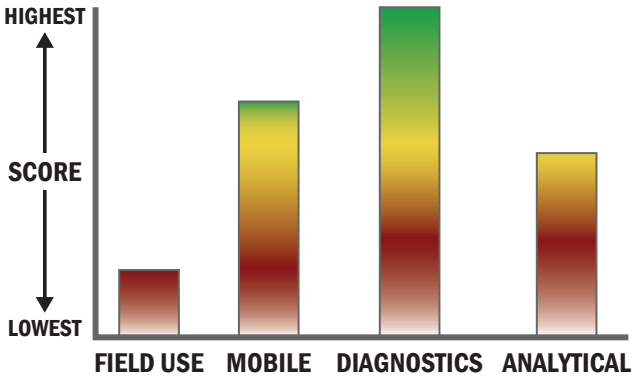
Selected as Next Generation Diagnostics System (NGDS) prototypes.

Survey Source

Vendor Supplied Information

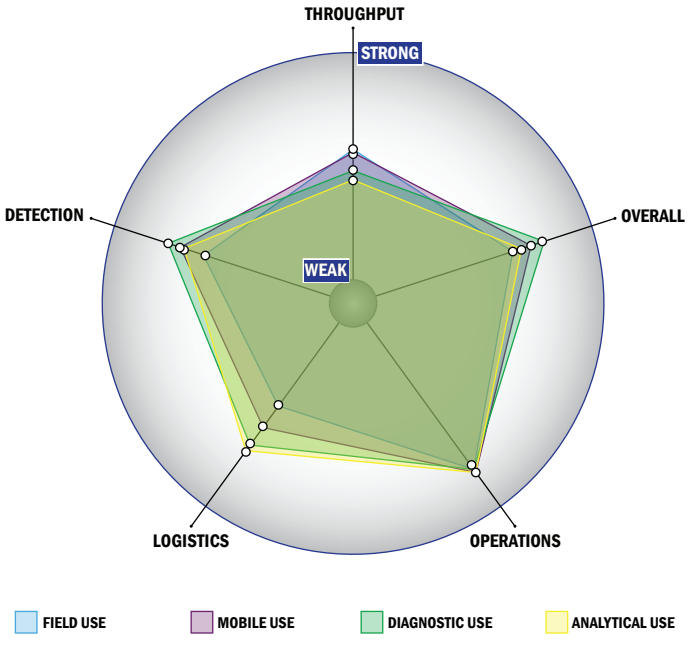
Scoring Analysis

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.



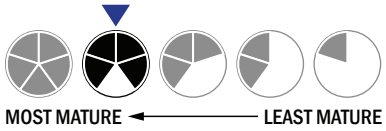
Evaluation Criteria

Throughput:

- Between 30 and 60 minutes for detection
- 1 sample, >10 tests/sample per run
- Less than 32 samples every 2 hours
- The system or device is currently fully automated
- Device or system is intended for multiple detection assays
- 2 solutions, buffer, eluents, and/or reagents
- 3 components
- 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 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 6 months and 1 year shelf life
- Greater than 10 years expected life
- Results cannot 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 open and available for modification

Detection:

- System currently has 510k clearance
- System currently has FDA approval
- Less 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
- Fully automated spore lysis