

Operational Technologies Corporation - FLASH Reader



GENERAL DESCRIPTION:

The Fluorescent Assay Sandwich Handheld (FLASH) Reader is a second generation portable fluorometer with epifluorescence optics designed to rapidly and sensitively assess fluorescence emanating from magnetic bead-based sandwich assays. In particular, the FLASH Reader is customized to read OpTech's DNA Aptamer-based magnetic bead sandwich assays for a variety of foodborne pathogens, arboviruses, rickettsia and Leishmania parasites.



TECHNICAL DESCRIPTION:

The basic technology centers on epifluorescence using a 630 nm red laser and PMT to read DNA aptamer-based magnetic bead sandwich or FRET assays.

CONTACT INFORMATION

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COST

- \$4,500/system
- <\$2/analysis

Tier Selection

Final tier assignment is based on overall product score.

- Top Tier
- ◐ Second Tier
- Third Tier
- ◑ Fourth Tier
- Bottom Tier

RANKINGS

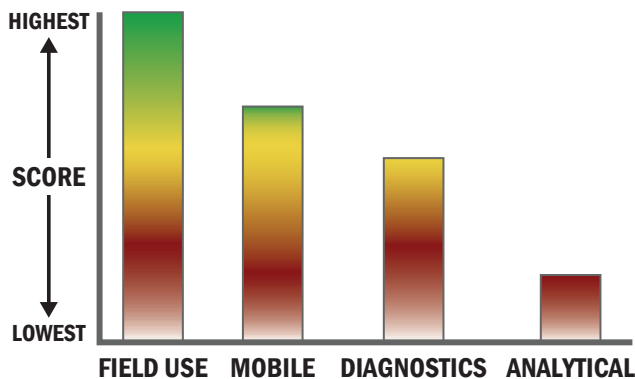
	Biological	Chemical	Radiological
FIELD USE System	◐	○	N/A
MOBILE Laboratory	●	○	N/A
DIAGNOSTIC Laboratory	◐	○	N/A
ANALYTICAL Laboratory	◐	◑	N/A

Survey Source

Vendor Supplied Information

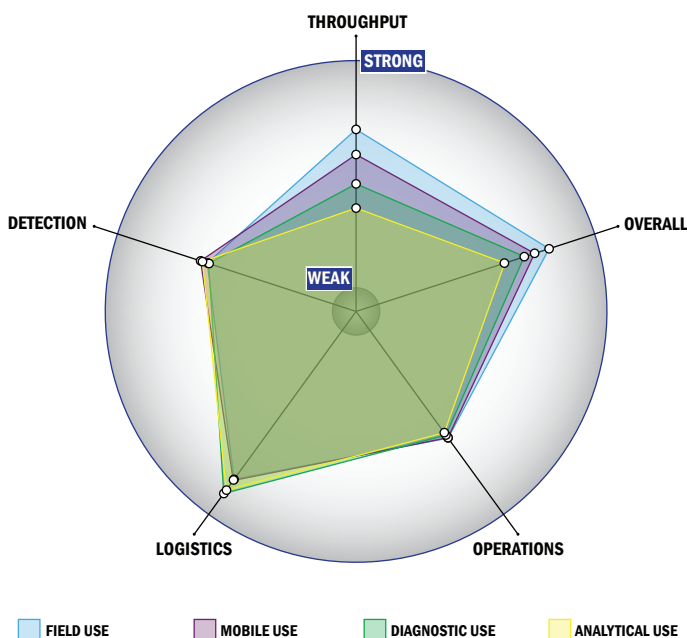
Scoring Analysis

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.



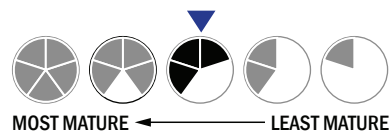
Evaluation Criteria

Throughput:

- Between 30 and 60 minutes for detection
- 1 sample, single test/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
- 2 components
- Less than 5 minutes is required for set-up
- 1-2 steps are required for detection

Logistics:

- Very brief (minutes-hours) training and minimal technical skills
- Approximately the size of a toaster
- Between 1 and 5 kg
- Wired connections are available
- System or device uses batteries
- 4-8 hours battery life



Operations:

- Can be used from 4 °C to 37 °C
- Components must be stored at room temperature (27 °C)
- Device or system has peak performance at normal relative humidity conditions
- Between 1 to 3 years shelf life
- Greater than 10 years expected life
- Results can be viewed in real-time
- The system could be adapted to a fully autonomous system with significant effort
- 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 FDA approval, no current efforts at this time
- Greater than 250 µL
- Good specificity. Consistently low level of false alarms (2-5%)
- 1-100 CFU per mL
- 100-1,000 PFU per mL
- 1-10 ng per mL
- Spore lysis not necessary for detection by system
- 3×10^{-5} - 1×10^{-4} mg/m³
- 1 ppm - 100 ppm