Biothreat Detection IMASS

GENERAL DESCRIPTION:

The Biothreat Detection IMASS™ is used to directly sample powders, surfaces or liquids using an integrated sponge, then eight immunoassay strips are run simultaneously from the sample giving results for eight biothreat agents in 15 minutes from a single sample.

TECHNICAL DESCRIPTION:

Lateral Flow Immunoassay. A test strip, usually made of nitrocellulose, includes signal and capture reagents specific to the biothreat target of interest. Antibody is striped onto the membrane (capture reagent) and Antibody is attached (conjugated) onto signal reagent (gold particle). Sample is added at one end of the stick, and runs along the test laterally, if the target is present a line, the gold capture agent will bind to the agent and the agent will bind to the antibody striped on the membrane to form a coloured line.

CONTACT INFORMATION

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COST

- $127
- 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

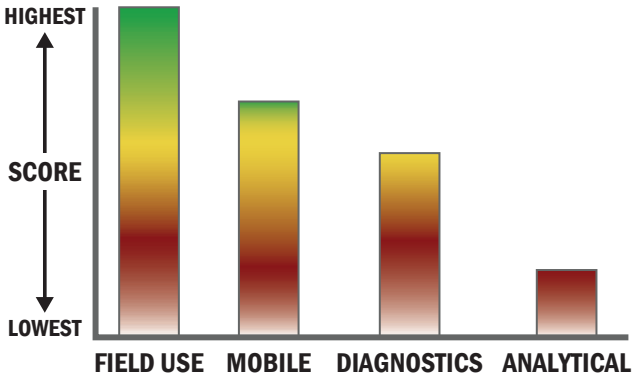
	Biological	Chemical	Radiological
FIELD USE System		N/A	N/A
MOBILE Laboratory		N/A	N/A
DIAGNOSTIC Laboratory		N/A	N/A
ANALYTICAL Laboratory		N/A	N/A

Survey Source

Vendor Supplied Information

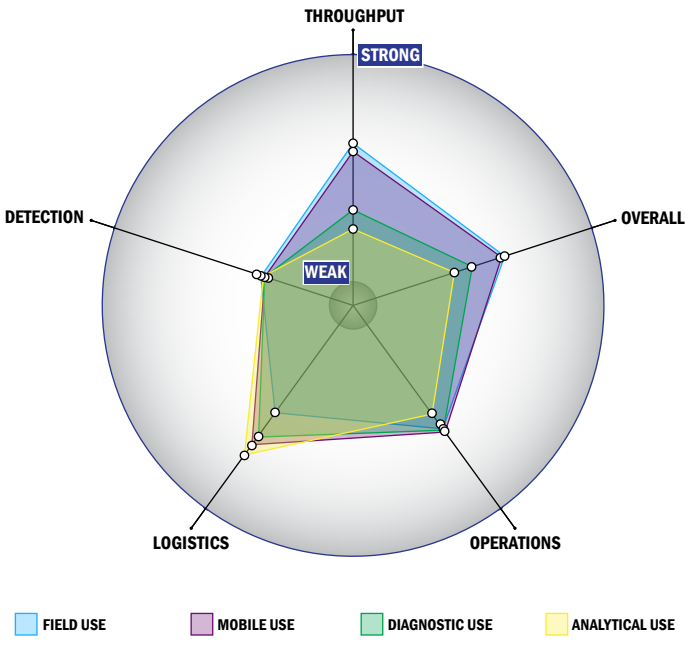
Scoring Analysis

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.



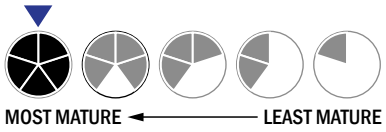
Evaluation Criteria

Throughput:

- Between 2 and 15 minutes for detection
- 1 sample, <10 tests/ sample per run
- Less than 32 samples every 2 hour
- The system or approach is not amenable to full or semi-automation
- Device or system is designed for a single use
- 0-1 solutions, buffer, eluents, and/or reagents
- 0 components
- No set-up of the system is required
- 3-5 steps are required for detection

Logistics:

- Very brief (minutes-hours) training and minimal technical skills
- Approximately the size of a soda can
- Less than 1 kg
- This system is not capable of transmitting data
- System or device requires multiple outlets or a dedicated circuit breaker



Operations:

- Can be used from 4 °C to 37 °C
- This system does not require consumable components
- Device or system has peak performance at normal relative humidity conditions
- Between 1 to 3 years shelf life
- This system or device is single use and does not have an expected life
- The system is not capable of autonomy
- The system does not employ any software
- The system is single use or this question does not apply to this device

Detection:

- Not possible for the system to achieve 510K clearance
- Not possible for the system to achieve FDA approval
- Less than 50 µl
- Good specificity. System has a consistently low level of false alarms (2-5%)
- 10,000-100,000 CFU per ml
- 1-10 ng per ml
- Spore lysis not necessary for detection by system