Response Biomedical - RAMP Reader System

GENERAL DESCRIPTION:

The RAMP System is designed to provide First Responders, Military Personnel, and Public Safety Workers with rapid, on-site, reliable diagnostic information for biological testing. The RAMP System is utilized by First Responder Teams world-wide. The RAMP System consists of a portable scanning fluorescence Reader and single-use, disposable test cartridges. To use, a small sample is added to the test cartridge and then inserted into the Reader. RAMP provides a positive or negative result in minutes, with no additional user intervention. Tests are available for anthrax, ricin, botulinum and pox. RAMP is used for testing liquid, powder or invisible surface samples. A suspect surface, powder or liquid is sampled using a swab and then added to the supplied sample buffer. Then a portion of the sample is placed into the Test Cartridge that is then inserted into the RAMP Reader. There is no regular calibration or maintenance required with the RAMP system and the cartridges have an internal standard system that runs concurrently with every assay to eliminate environmental and assay-to-assay variability. This internal standard system is not available in earlier generation flow assays and is unique to the RAMP system. The system has consistently demonstrated to be 100% reliable in detecting anthrax at or above 4,000 spores and does not cross-react with interfering substances, such as baking powder, or with non-pathogenic strains of anthrax.

TECHNICAL DESCRIPTION:

RAMP is a system for testing the presence of *B. anthracis* spores, ricin, botulinum toxin and orthopox viruses. The Reader is a scanning immunoassay and data analysis system measuring fluorescence in RAMP cartridges. The Reader can be operated on battery power or AC. The RAMP Test Cartridge is a single-use analyte-specific test used to detect the presence of analyte in a sample. The operator prepares the sample, places an aliquot into the sample well of the Test Cartridge, inserts Cartridge into the RAMP Reader, which analyzes the sample and provides a result.

CONTACT INFORMATION

Response Biomedical
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COST

- $11,333/system
- $21-$27/analysis

Tier Selection

Final tier assignment is based on overall product score.

Top Tier Second Tier Third Tier Fourth Tier Bottom Tier

RANKINGS

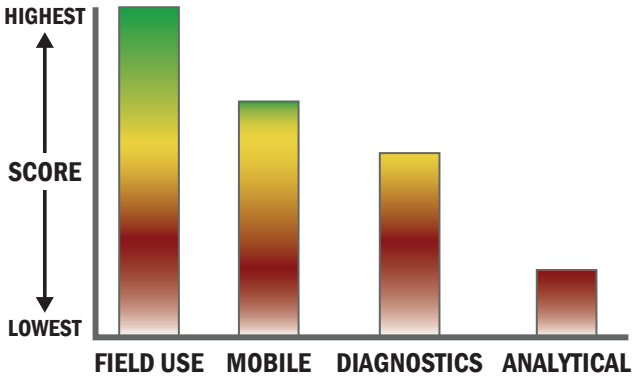
	Biological	Chemical	Radiological
FIELD USE System	Second Tier	N/A	N/A
MOBILE Laboratory	Second Tier	N/A	N/A
DIAGNOSTIC Laboratory	Third Tier	N/A	N/A
ANALYTICAL Laboratory	Third Tier	N/A	N/A

Survey Source

Vendor Supplied Information

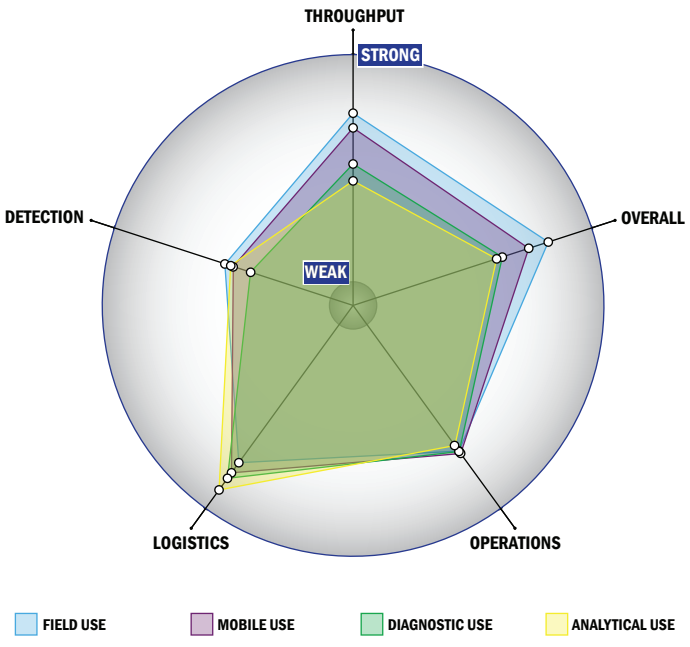
Scoring Analysis

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.



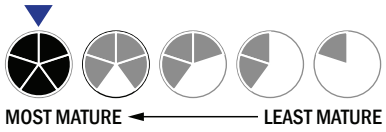
Evaluation Criteria

Throughput:

- Between 15 and 30 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
- 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 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)
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life
- Greater than 10 years expected life
- Results cannot be viewed in real-time
- The system is not capable of autonomy
- The system software is closed and not available for modification
- The system hardware is closed and not 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
- Less than 100 µL
- Superior specificity. System has a false alarm rate approaching zero (~0%)
- 1,000-10,000 CFU per mL
- 10,000-100,000 PFU per mL
- 10-100 ng per mL
- Spore lysis not necessary for detection by system