Alexeter Technologies - Defender TSR System

GENERAL DESCRIPTION:

The Defender TSR System is designed to detect and identify the following biological agents, in the field, with a 15-minute test: anthrax, ricin, botulinum toxin, staphylococcal enterotoxin B, plague, tularemia, brucella and orthopox. The Defender TSR Reader, part of the system is an optical reader which evaluates the test strips, documents the results and delivers a report to the user. A protein detection test is also part of the system.

TECHNICAL DESCRIPTION:

Hand held immunochromatographic assays that use colloidal gold labeled antibodies, optional Reader for objective evaluation and documentation.

CONTACT INFORMATION

Alexeter Technologies

COST

- $15,000/system
- $26.00/analysis

Tier Selection

Final tier assignment is based on overall product score.

Top Tier Second Tier Third Tier Fourth Tier Bottom Tier

RANKINGS

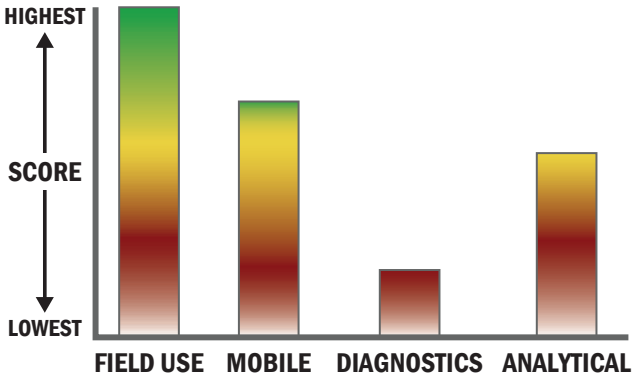
	Biological	Chemical	Radiological
FIELD USE System	Top Tier	N/A	N/A
MOBILE Laboratory	Top Tier	N/A	N/A
DIAGNOSTIC Laboratory	Fourth Tier	N/A	N/A
ANALYTICAL Laboratory	Third Tier	N/A	N/A

Survey Source

Vendor Supplied Information

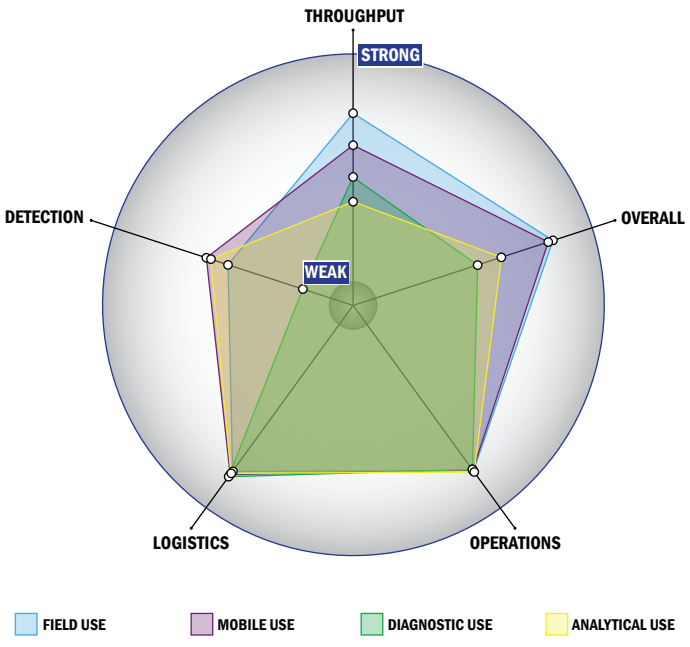
Scoring Analysis

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.



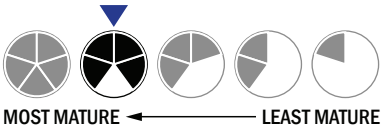
Evaluation Criteria

Throughput:

- Between 15 and 30 minutes for detection
- 1 sample, >10 tests/sample per run
- Less than 32 samples every 2 hours
- The system could be adapted to a semi-automated system with some effort
- Device or system is designed for a single use
- 0-1 solutions, buffer, eluents, and/or reagents
- 1 component
- Less than 5 minutes is required for set-up
- 3-5 steps are required for detection

Logistics:

- An afternoon of training and some technical skills required
- Approximately the size of a toaster
- Between 1 and 5 kg
- Wireless and wired connections are available
- System or device uses batteries
- 4-8 hours battery life



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
- 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 but modification requires licensing
- The system hardware is open but modification requires licensing

Detection:

- Not possible for the system to achieve 510K clearance
- Not possible for the system to achieve FDA approval
- Less than 50 µL
- Superior specificity. System has a false alarm rate approaching zero (~0%)
- 10,000-100,000 CFU per mL
- Greater than 100,000 PFU per mL
- 10-100 ng per mL
- Spore lysis not necessary for detection by system