Smiths Detection - Bio-Seeq PLUS Biological Agent Identifier

GENERAL DESCRIPTION:

The Bio-Seeq PLUS is a field portable high precision PCR instrument that detects and identifies trace levels of high threat biological agents, both bacterial and viral, through DNA replication. The instrument is designed for use in the hot zone by an operator wearing PPE. It is exceptionally easy to learn to operate and utilize effectively. The instrument has 6 fully independent Thermocycler Optics Modules that each operate separate assay analyses. The instrument software is designed for users with limited experience with biological agent testing, providing easy to follow prompts to guide the user through the entire analysis process. The instrument has been commercially available since 2008 and has an excellent reliability track record and very long Mean Time Between Failure period.

Newly formulated assays and instrument parameters introduced in 2012 increase MDL sensitivity by ~1000X while increasing shelf life to 18 months and making the assays easier to use.

New assays have recently been introduced as well. Assays are now available to identify Bio Agents that cause Anthrax (separate pX01 and pX02 assays), Plague, Tularemia, Brucellosis, Q Fever and Pan Orthopox as well as a Training Assay and simulant powders.

TECHNICAL DESCRIPTION:

The Bio-Seeq PLUS utilizes Linear After The Exponential Polymerase Chain Reaction (LATE-PCR) technology. It operates by replicating a segment of the target agent DNA and incorporating fluorescent tags to each successive replicate. In this way it is able to detect and amplify very small quantities of target agent DNA, down to as low as 10s to 100s of copies, and provide a high response when the target agent is present. Each assay incorporates an internal control to assure that the amplification results are valid.

CONTACT INFORMATION

Smiths Detection
21 Commerce Dr.
Danbury, CT 06810
www.smithsdetection.com

COST

- $35,000/system
- $29/analysis

Tier Selection

Final tier assignment is based on overall product score.

Top Tier Second Tier Third Tier
Fourth Tier Bottom Tier

RANKINGS

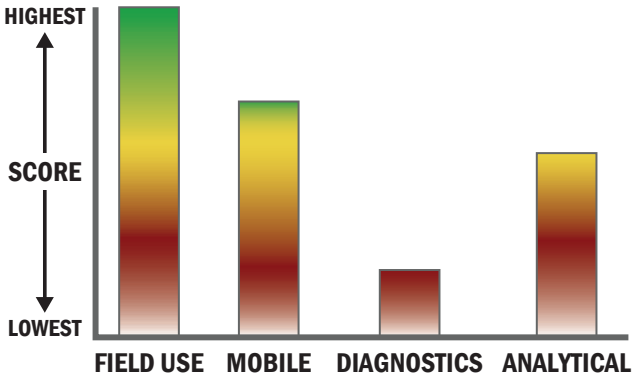
	Biological	Chemical	Radiological
FIELD USE System	Second Tier	N/A	N/A
MOBILE Laboratory	Second Tier	N/A	N/A
DIAGNOSTIC Laboratory	Third Tier	N/A	N/A
ANALYTICAL Laboratory	Third Tier	N/A	N/A

Survey Source

Vendor Supplied Information

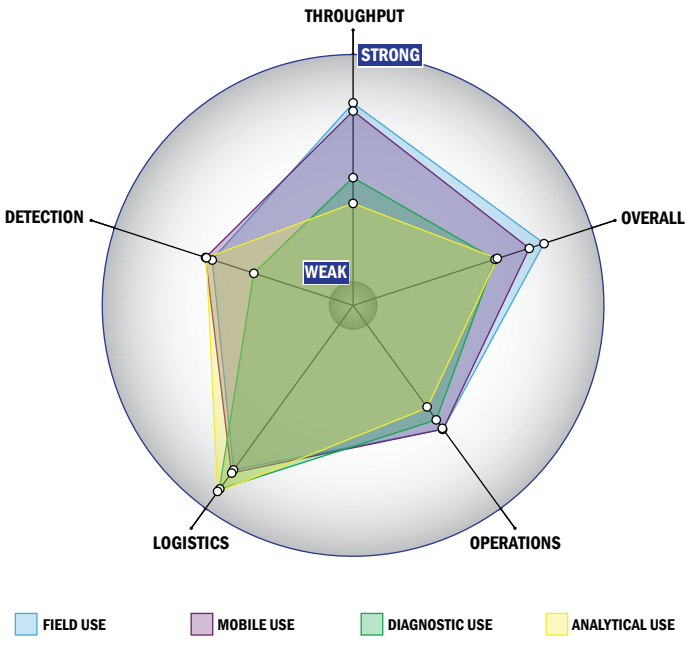
Scoring Analysis

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.



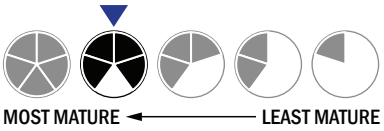
Evaluation Criteria

Throughput:

- Between 30 and 60 minutes for detection
- Multiple samples, single tests/sample per run
- Less than 32 samples every 2 hours
- The system or approach is not amenable to full or semi-automation
- Device or system is intended for multiple detection assays
- 0-1 solutions, buffer, eluents, and/or reagents
- 1 component
- 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
- Wireless and wired connections are available
- System or device uses batteries
- 2-4 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
- 5-10 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 50 µL
- Superior specificity. System has a false alarm rate approaching zero (~0%)
- 1,000-10,000 CFU per mL
- 1,000-10,000 PFU per mL
- Spore lysis not necessary for detection by system