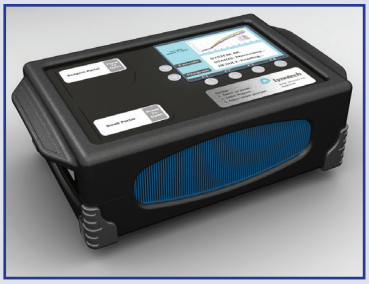
Lynntech, Inc. - BioAdvise Portable Detection Device

GENERAL DESCRIPTION:



The product is a deployable, low-power system for the screening of unknown powders and liquids for the presence of biological threat agents. The unit will be designed to interface with the laptops available in first responder vehicles; all system control and analysis functions will be carried out on the laptop. Minimal user training and experience will be required. After the user introduces a swab of unknown material into the system, the unit will automatically perform the steps of sample recovery, lysing, purification, real-time PCR amplification, and fluorescence detection in order to determine if the material contains genetic material with a sequence matching an on-board library of known threats.

TECHNICAL DESCRIPTION:

The unit will be capable of sample recovery, cell lysis, DNA purification, 19-plex real-time target amplification and subsequent fluorescence detection in a convective PCR cell. Hardware development will enable controlled generation of the thermal environment necessary for sample preparation, convective PCR and real-time detection and analysis of the fluorescence signals during the amplification process. Reagent stabilization will enable the PCR reagents to be stored on-cartridge for extended periods with minimal degradation.

CONTACT INFORMATION

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COST

- $50,000/system
- $125/analysis

Tier Selection

Final tier assignment is based on overall product score.

Top Tier · Second Tier · Third Tier · Fourth Tier · Bottom Tier

RANKINGS

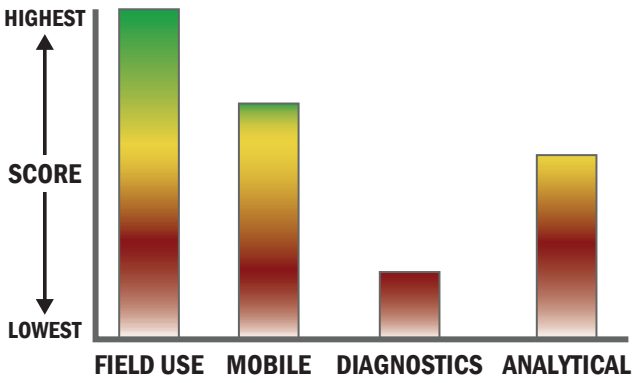
	Biological	Chemical	Radiological
FIELD USE System	Second Tier	N/A	N/A
MOBILE Laboratory	Second Tier	N/A	N/A
DIAGNOSTIC Laboratory	Third Tier	N/A	N/A
ANALYTICAL Laboratory	Second Tier	N/A	N/A

Survey Source

Vendor and Internet Supplied Information

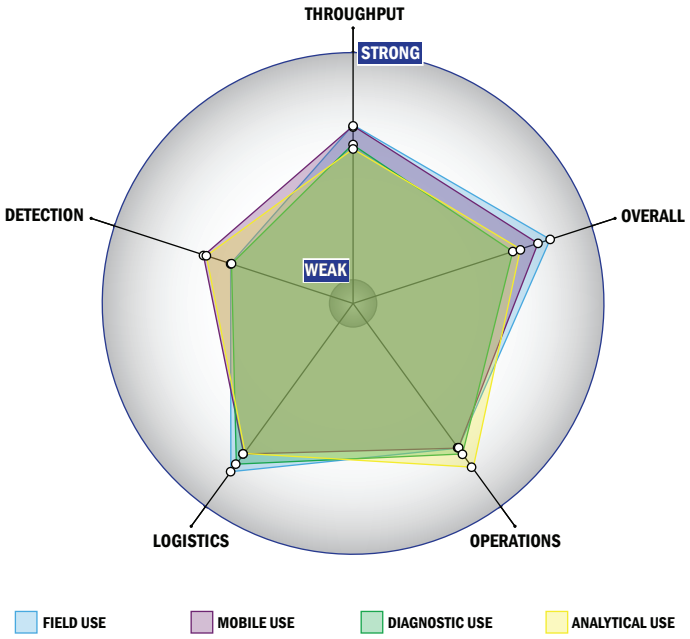
Scoring Analysis

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.



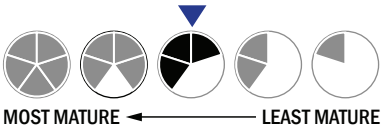
Evaluation Criteria

Throughput:

- Between 15 and 30 minutes for detection
- 1 sample, >10 tests/sample per run
- 349-96 samples every 2 hours
- The system or device is currently fully automated
- Device or system is intended for multiple detection assays
- 3 solutions, buffer, eluents, and/or reagents
- 1 component

Logistics:

- Very brief (minutes-hours) training and minimal technical skills
- Approximately the size of a toaster
- Between 5 and 25 kg
- Satellite, 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 frozen (-20°C)
- Performance is not influenced by relative humidity
- Between 6 months and 1 year shelf life
- 5-10 years expected life
- Results can 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:

- Not possible for the system to achieve 510K clearance
- Not possible for the system to achieve FDA approval
- Less than 250 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
- Fully automated spore lysis