Battelle - Pacific Northwest National Laboratory - Rapid Detection of Ultra-Trace Levels of Pathogens

GENERAL DESCRIPTION:

A protocol has been optimized to enable rapid enrichment, concentration, purification and polymerase chain reaction (PCR) detection of pathogenic organisms. While the developed protocol is specifically for Listeria monocytogenes, other pathogenic organisms could also be processed with variations to the protocol. The sample preparation and detection approach is amenable to multiplexing to allow detection of multiple pathogens (bacterial and viral) in a single sample. The protocol was developed specifically for analyzing surface swabs from food processing plant surfaces, but could be adapted to other surfaces, bodily fluids, environmental samples, and food.

TECHNICAL DESCRIPTION:

We have investigated and developed unique enrichment broths to enable rapid enrichment (4-6 hours) of pathogenic organisms. We have also developed protocols to remove debris and interfering substances using a combination of filtration and immunomagnetic beads, which also provide a high degree of pathogen concentration and sample purification. We have also optimized PCR detection of Listeria monocytogenes.

CONTACT INFORMATION

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COST

- $30,000-$40,000/system
- $20-$30/analysis

Tier Selection

Final tier assignment is based on overall product score.

Top Tier | Second Tier | Third Tier | Fourth Tier | Bottom Tier

RANKINGS

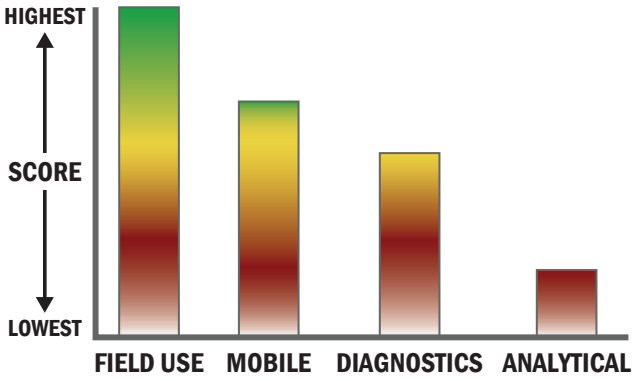
	Biological	Chemical	Radiological
FIELD USE System	Bottom Tier	N/A	N/A
MOBILE Laboratory	Bottom Tier	N/A	N/A
DIAGNOSTIC Laboratory	Bottom Tier	N/A	N/A
ANALYTICAL Laboratory	Bottom Tier	N/A	N/A

Survey Source

Vendor Supplied Information

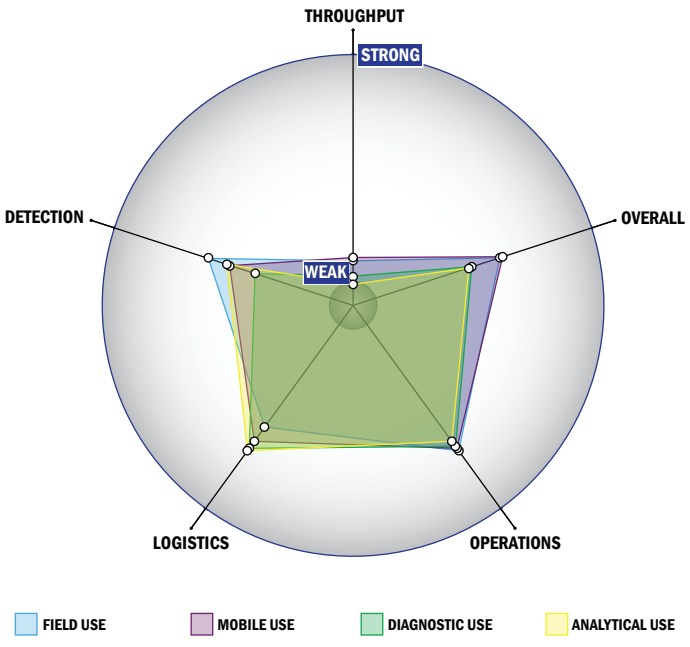
Scoring Analysis

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.



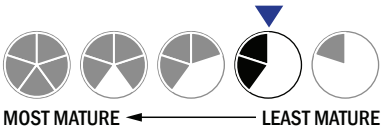
Evaluation Criteria

Throughput:

- Between 60 minutes and 8 hours for detection
- 1 sample, single test/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 intended for multiple detection assays
- 4 solutions, buffer, eluents, and/or reagents
- 5 or more components
- Less than 5 minutes is required for set-up
- Greater than 12 steps are required for detection

Logistics:

- An afternoon of training and some technical skills required
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Satellite, wireless and wired connections are available
- System or device has 110V electrical requirement



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 6 months and 1 year shelf life
- 3-5 years expected 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 and available for modification
- The system hardware is open and 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 10 µL
- Excellent specificity. System has occasional false alarms under certain conditions (<2%)
- 1-100 CFU per mL
- 1-100 PFU per mL
- Manual kit not integrated with the system handles spore lysis