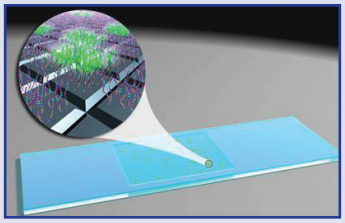
Lawrence Livermore National Laboratory - Lawrence Livermore Microbial Detection Array (LLMDA)

GENERAL DESCRIPTION:



LLMDA is a broad-spectrum microarray with over 360,000 probes that can detect all sequenced bacteria, viruses, fungi, protozoa, and archaea as of the probe design date. It was designed for laboratory analysis of complex samples that were not negative for available PCR assays. LLMDA fills the gap between PCR panels and metagenomic sequencing for biodefense, biosurveillance, human/animal/plant health, food and product safety, etc.

TECHNICAL DESCRIPTION:

LLMDA uses microarray technologies that provide probes of at least 60bp. Originally developed using NimbleGen array technology, it has also been transitioned to Agilent. The array probes are designed at family, species, and strain taxonomic levels to ensure that novel strains and even species might be recognized.

CONTACT INFORMATION

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COST

- $200,000/system
- <$500/analysis

Tier Selection

Final tier assignment is based on overall product score.

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

RANKINGS

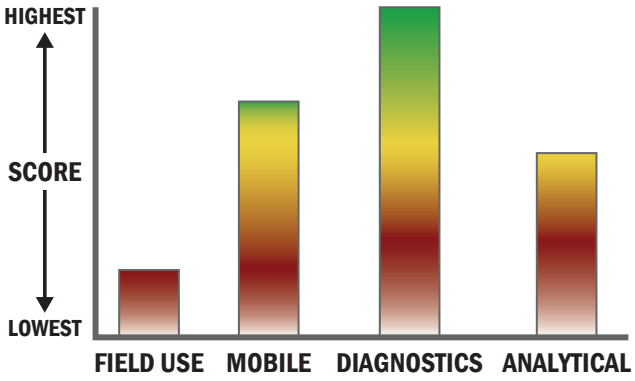
	Biological	Chemical	Radiological
FIELD USE System	Bottom Tier	N/A	N/A
MOBILE Laboratory	Bottom Tier	N/A	N/A
DIAGNOSTIC Laboratory	Third Tier	N/A	N/A
ANALYTICAL Laboratory	Fourth Tier	N/A	N/A

Survey Source

Vendor Supplied Information

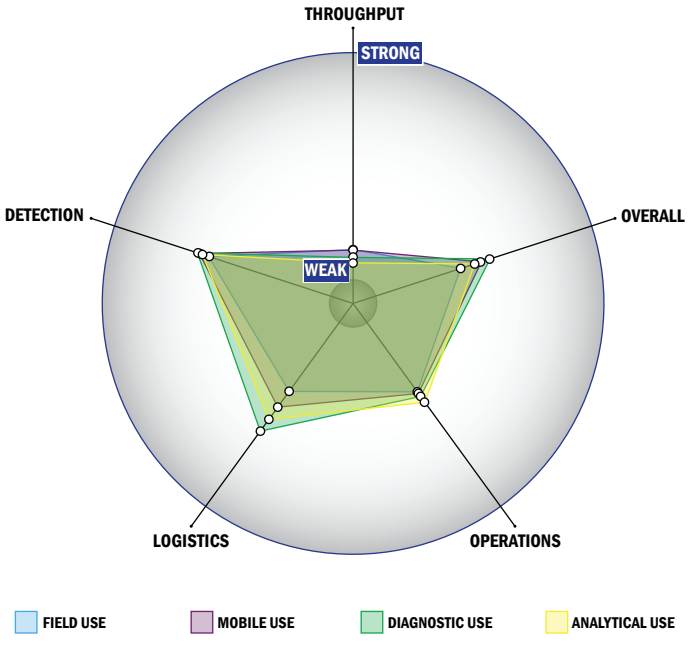
Scoring Analysis

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.



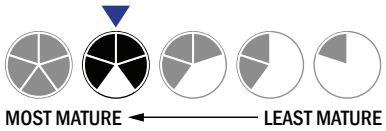
Evaluation Criteria

Throughput:

- Greater than 8 hours 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
- 4 solutions, buffer, eluents, and/or reagents
- 4 components
- No set-up of the system is required
- 9-12 steps are required for detection

Logistics:

- More than a day of training and significant technical skills are required
- Approximately the size of a carry-on luggage suitcase
- Between 25 and 50 kg
- Wired connections are available
- System or device has 110V electrical requirement



Operations:

- Can be used from 25°C to 37°C
- Components must be stored at 4°C
- Device or system has peak performance at normal relative humidity conditions
- Between 1 to 6 months shelf 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 is single use or this question does not apply to this device

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
- Good specificity. System has a consistently low level of false alarms (2-5%)
- 100-1,000 CFU per mL
- 1,000-10,000 PFU per mL
- Manual kit not integrated with the system handles spore lysis