

Meso Scale Diagnostics (MSD), LLC - Cartridge Reader



GENERAL DESCRIPTION:

The Cartridge Reader system uses MSD's MULTI-ARRAY® electrochemiluminescence (ECL) technology to enable highly sensitive multiplexed immunoassay measurements in a compact, fully-automated format. The Cartridge Reader system consists of a compact reader instrument (12.5 lbs., 9" H x 8" W x 14" D) and single-use disposable cartridges



that can conduct multiplexed measurements of up to 20 targets or controls per sample. The cartridges include integrated microfluidics to allow for fully automated sample processing and analysis without user intervention. Two cartridge types are available: one for analyzing liquid samples and the other for swab samples. To run an assay, the sample (liquid or swab) is inserted into the appropriate cartridge and the cartridge is then capped and loaded into the reader. All subsequent processing steps, including swab extraction (swab cartridge) and multiplexed ECL detection are fully automated. The system can detect and measure bacteria, viruses, and toxins with limits of detection many times lower than lateral flow immunoassays. The system is extremely simple to operate and provides a result in about 15 minutes. The Cartridge Reader system is still under development for laboratory and point-of-care clinical and environmental testing applications and is not yet commercially released. However, the instrument has been tested at DoD technology readiness evaluations (TREs) and has been through clinical evaluations in the U.S. and other locations worldwide for influenza diagnostics.

TECHNICAL DESCRIPTION:

MSD's PR2 and Cartridge Reader instruments employ MSD's MULTI-ARRAY® technology that combines electrochemiluminescence (ECL) detection and array-based multiplexed measurements. ECL immunoassays enable highly sensitive measurement of samples for the presence of bacteria, viruses, and toxins. The measurements are performed on arrays printed on carbon ink electrodes that are incorporated into multi-well assay plates and cartridges. MULTI-ARRAY technology consistently has been demonstrated to provide high performance measurement capability in a wide range of matrices and in the presence of many interferents. While MULTI-ARRAY technology is primarily used for immunoassays, the technology can also be used for multiplexed nucleic acid measurements.

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 | ◐ | ○ N/A | ○ N/A |
| MOBILE Laboratory | ● | ○ N/A | ○ N/A |
| DIAGNOSTIC Laboratory | ◐ | ○ N/A | ○ N/A |
| ANALYTICAL Laboratory | ● | ○ N/A | ○ N/A |

CONTACT INFORMATION

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Survey Source

Vendor Supplied Information

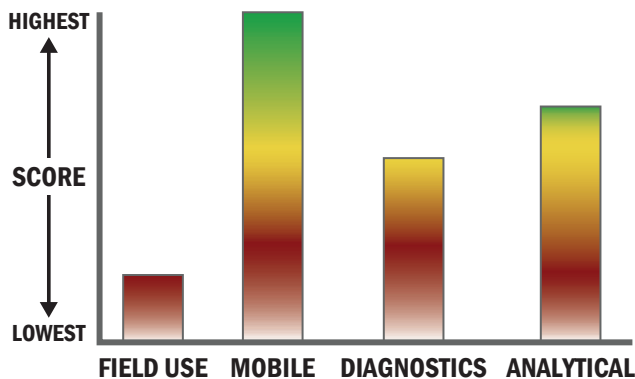
COST

N/A



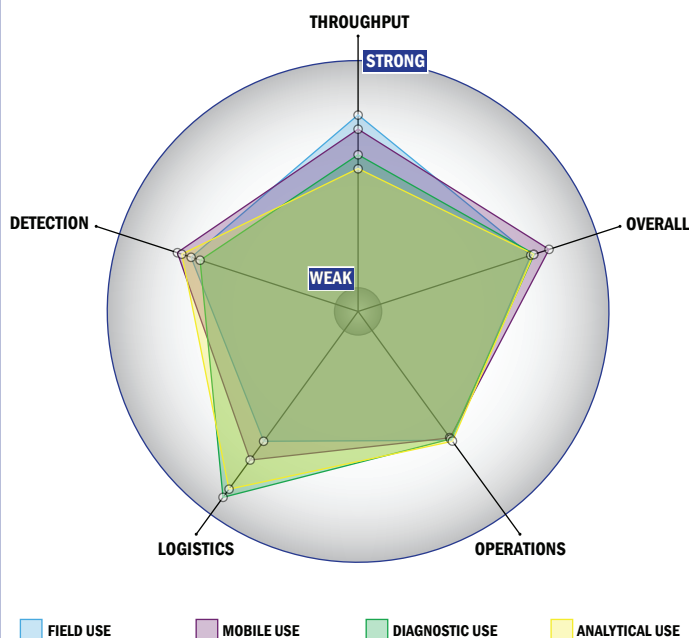
Scoring Analysis

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.



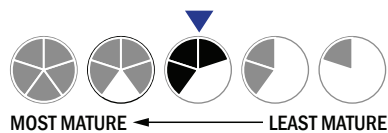
Evaluation Criteria

Throughput:

- Between 15 and 30 minutes for detection
- 1 sample, >10 tests/sample per run
- Less than 32 samples every 2 hours
- The system or device is currently fully automated
- Device or system is intended for multiple detection assays
- 0-1 solutions, buffer, eluents, and/or reagents
- 2 components
- Less than 5 minutes is required for set-up
- Automatic detection

Logistics:

- Very brief (minutes-hours) training and minimal technical skills
- Approximately the size of a toaster
- Between 5 and 25 kg
- Wired connections are available
- System or device has 110V electrical requirement
- 4-8 hours battery life



Operations:

- Can be used from 4 °C to 37 °C
- Components must be stored at 4 °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 could be adapted to a fully autonomous system with some effort
- 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 250 µL
- Excellent specificity. System has occasional false alarms under certain conditions (<2%)
- 1,000-10,000 CFU per mL
- 10,000-100,000 PFU per mL
- Less than 1 ng per mL
- Spore lysis not necessary for detection by system