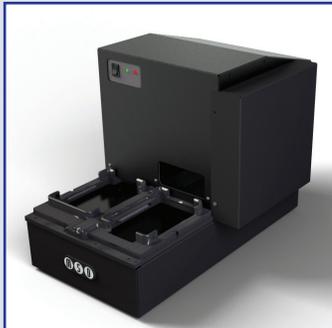


Meso Scale Diagnostics (MSD), LLC - SECTOR® PR2 Model 1800



GENERAL DESCRIPTION:

The SECTOR® PR2 instrument product line uses MSD's MULTI-ARRAY® electrochemiluminescence (ECL) technology to carry out highly sensitive, multiplexed immunoassays for biothreat agents. The PR2 instruments work with MSD's MULTI-ARRAY® 96-well assay plates. Each well of the plate has an array of up to 25 different antibodies to enable multiple targets (including bacteria, viruses, toxins and internal process controls) to be measured simultaneously. To provide stability and ease of use, the plates are sealed and contain all the required antibody reagents in dry format. The PR2 product line has been used to test a wide variety of sample types including many clinical sample types, dry filter unit extracts, aerosol samples, food and beverage samples, water, and soil samples. MSD's MULTI-ARRAY biodefense assays have undergone a range of sensitivity, near neighbor, interferent, and suspicious powder testing.



The PR2 Model 1800 instrument is a plate reader that is used for final readout of MULTI-ARRAY plates. Assay processing consists of sample introduction into the plate (125 µL), incubation (15-30 minutes), and wash steps prior to readout on the PR2 Model 1800 instrument. Using this semi-automated approach enables very high throughput testing of samples. With a 5 minute read time for 96-well plates, the PR2 Model 1800 instrument can test 1000+ samples per hour each in multiplex format up to 25-plex. The instrument includes a graphical user interface for analysis of results and an on-board database for storage of results.

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 interferences. 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			
MOBILE Laboratory			
DIAGNOSTIC Laboratory			
ANALYTICAL Laboratory			

Notes

In use by DoD Laboratories.

CONTACT INFORMATION

Meso Scale Defense, a division of Meso Scale Diagnostics (MSD®), LLC
 POC: Charles Clinton
 240-631-2522 x4617
 cclinton@mesoscale.com
 www.mesoscale.com

Survey Source

Vendor Supplied Information

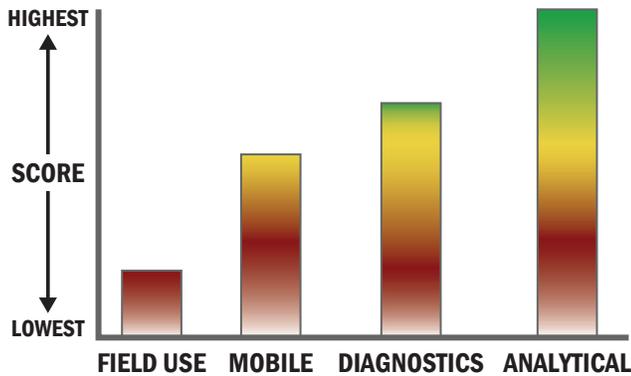
COST

- \$80,000/system
- ~\$4.50/analysis



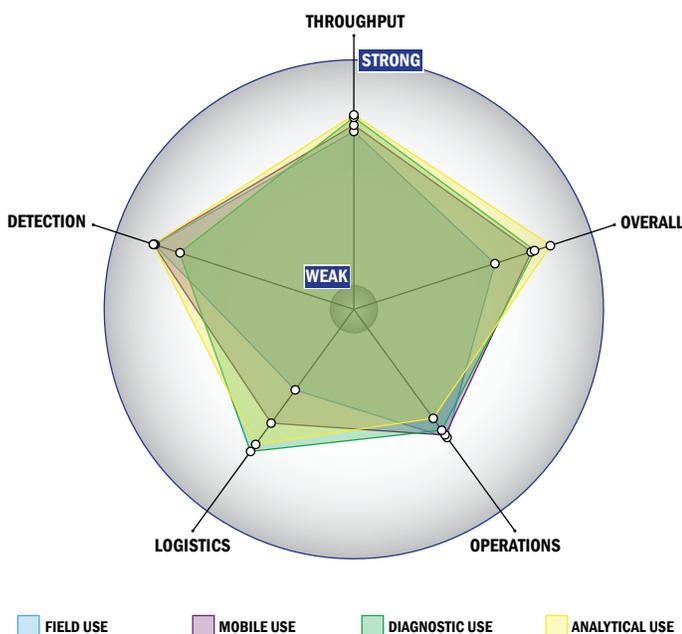
Scoring Analysis

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.



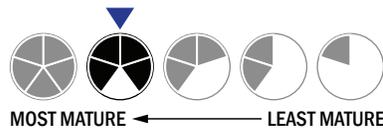
Evaluation Criteria

Throughput:

- Between 15 and 30 minutes for detection
- Multiple samples, multiple tests/sample per run
- Greater than 750 samples every 2 hours
- The system or device is currently semi-automated
- Device or system is intended for multiple detection assays
- 2 solutions, buffer, eluents, and/or reagents
- 3 components
- Less than 5 minutes is required for set-up
- 3-5 steps are required for detection

Logistics:

- A day of training and 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 4 °C to 41 °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 could easily be adapted into a fully autonomous system
- 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
- Superior specificity. System has a false alarm rate approaching zero (~0%)
- 100-1,000 CFU per mL
- 100-1,000 PFU per mL
- Less than 1 ng per mL
- Spore lysis not necessary for detection by system