

Bio-Rad Laboratories - Bio-Plex 2200



GENERAL DESCRIPTION:

Fully automated, random access multiplex system designed for Autoimmune and Infectious disease testing in human serum or plasma. The system is designed to up to 22 specific analytes per assay panel. The system is utilized in diagnostic testing in hospital laboratories.



TECHNICAL DESCRIPTION:

BioPlex 2200 Immunoassay use heterogeneous sets of 8 micron paramagnetic Beads. The beads are infused with various ratios of fluorescent dyes creating unique bead sets. Beads are coated with recombinant and / or native antibodies, antigens specific to a certain assay. Bead sets are then mixed together into a single reagent pack for testing and the simultaneous detection of multiple analytes from a single sample. The system uses a dual laser detection system to process a minimum 150 assay readings per analyte. Detection system is capable of reading 100,000 beads per minute.

CONTACT INFORMATION

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COST

- \$385,000/system
- \$1.00-\$15.00/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	●	○	○
MOBILE Laboratory	●	○	○
DIAGNOSTIC Laboratory	●	○	○
ANALYTICAL Laboratory	●	○	○

Notes

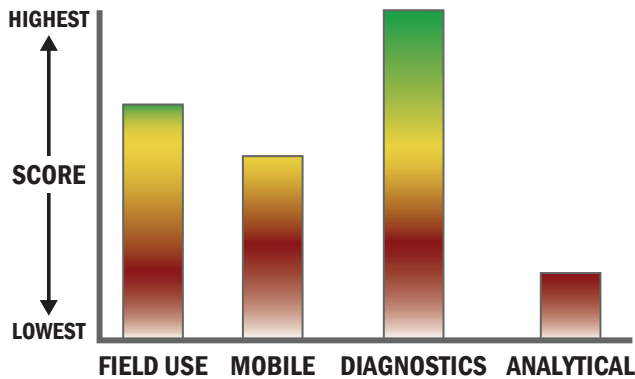
xMap technology also used on Luminex MAGPIX device.

Survey Source

Vendor and Internet Supplied Information

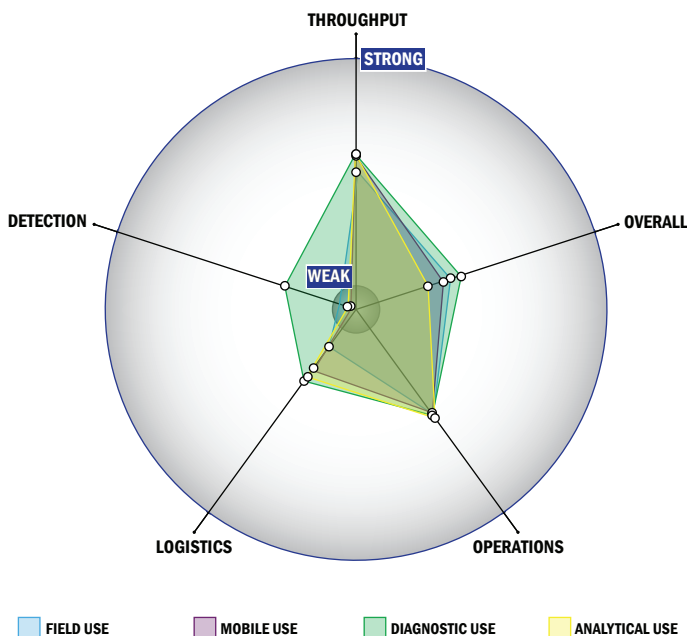
Scoring Analysis

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.



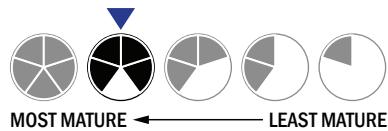
Evaluation Criteria

Throughput:

- Between 30 and 60 minutes for detection
- Multiple samples, multiple 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
- 5 or more solutions, buffer, eluents, and/or reagents
- 2 components
- 5-10 minutes is required for set-up
- 1-2 steps are required for detection

Logistics:

- More than a day of training and significant technical skills are required
- Larger than a home dishwasher
- More than 50 kg
- Wired connections are available
- System or device has 110V electrical requirement



Operations:

- Can be used from 4 °C to 37 °C
- Components must be stored at room temperature (27 °C)
- Device must be used in a temperature stable, dry environment for optimum performance
- Between 1 to 3 years shelf life
- 5-10 years expected 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 hardware is closed and not available for modification

Detection:

- System currently has 510k clearance
- System currently has FDA approval
- Less than 250 µL
- Fair specificity. System has a consistent level of false alarms (5-10%)

