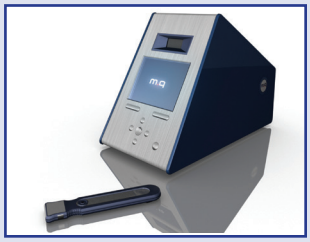
MBio Diagnostics, Inc. - MBio MQ

GENERAL DESCRIPTION:



The MBio MQ multiplexed assay system delivers quantitative fluorescence immunoassay results for panels of analytes – all from a single drop of blood, plasma, or serum. MQ is a simple reader and disposable cartridge system for point-of-care testing. MQ provides the data quality and multiple results of a clinical laboratory analyzer in an inexpensive format with workflow comparable to single analyte rapid diagnostic tests. Under design for a CLIA-waiver, the simple system uses minimal sample (5 to 10 microliters) and delivers results in less than 30 minutes. The MBio technologies fill an unmet need for near patient disease panels.

TECHNICAL DESCRIPTION:

MBio's diagnostic systems are all built on the company's LightDeck™ technology, a patent-protected fluorescence assay illumination method that is simultaneously simple, inexpensive and robust. It is a variation on planar waveguide technology, an approach that has been used for performing sensitive biological assays for over two decades. MBio's innovation has been to solve the light coupling reproducibility problem that has limited widespread use of the technology. The MBio MQ incorporates low cost consumer electronics (laser diodes and imagers) to create a robust reader device and for the MQ's single-use test cartridges.

CONTACT INFORMATION

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COST

- $5,000/system
- $5-$10/analysis

Tier Selection

Final tier assignment is based on overall product score.

Top Tier Second Tier Third Tier Fourth Tier Bottom Tier

RANKINGS

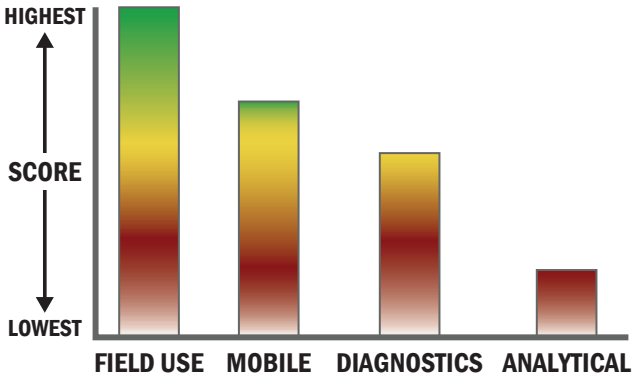
	Biological	Chemical	Radiological
FIELD USE System	Second Tier	N/A	N/A
MOBILE Laboratory	Third Tier	N/A	N/A
DIAGNOSTIC Laboratory	Third Tier	N/A	N/A
ANALYTICAL Laboratory	Third Tier	N/A	N/A

Survey Source

Vendor and Internet Supplied Information

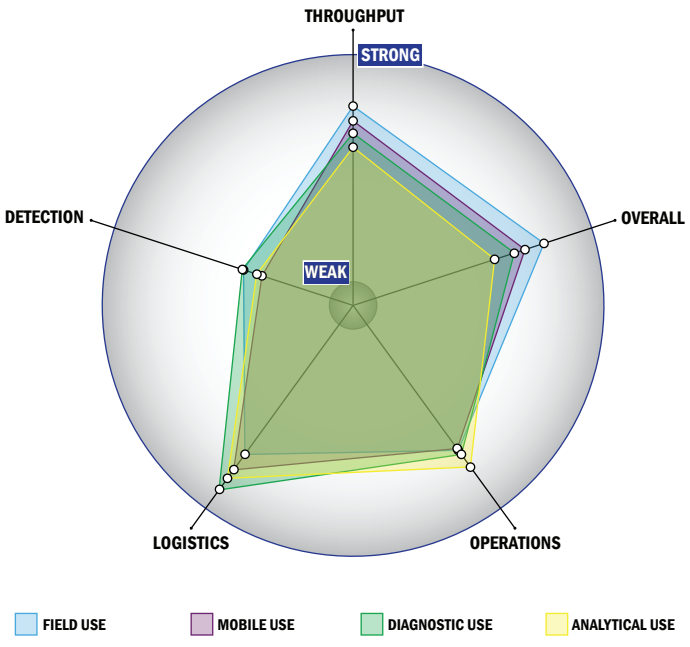
Scoring Analysis

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.



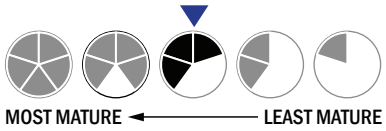
Evaluation Criteria

Throughput:

- Between 15 and 30 minutes for detection
- Multiple samples, multiple tests/sample per run
- Less than 32 samples every 2 hours
- The system or device is currently semi-automated
- Device or system is designed for a single use
- 0-1 solutions, buffer, eluents, and/or reagents
- 2 components
- Less than 5 minutes is required for set-up
- 1-2 steps are required for detection

Logistics:

- Very brief (minutes-hours) training and minimal technical skills
- Approximately the size of a toaster
- Between 1 and 5 kg
- System or device has 110V electrical requirement
- 4-8 hours battery life



Operations:

- Can be used from 25°C to 37°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
- Results can be viewed in real-time
- The system is not capable of autonomy
- 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 50 µL
- Excellent specificity. System has occasional false alarms under certain conditions (<2%)
- 10,000-100,000 PFU per mL
- 1-10 ng per mL