

MedMira, Inc. - Multiplo Rapid Test for the Detection of Antibodies



GENERAL DESCRIPTION:

MedMira's unique Rapid Vertical Flow (RVF) Technology™ features simple steps and instant results. Its current single disease product portfolio for infectious diseases is comprised of Reveal HIV, Reveal HP, and Reveal TP. Its current offer for multiplex product line (the Multiplo) includes combination of testing solution for HIV1/2, hepatitis B and C and syphilis. These tests can be deployed at all possible settings such as POCT, over the counter (OTC), and laboratories. These types of tests also eliminate the need for cold chain transport. MedMira's world-class technology offers a number of distinct advantages: speed, multiplex testing, quality and value. MedMira diagnostics are the fastest rapid flow-through diagnostics for multiplex testing of infectious diseases in the world. In less than three minutes, users can perform the test and have an instant result. MedMira's technology is unique in its ability to detect multiple biomarkers specific to several diseases on a single cartridge using a single specimen.



TECHNICAL DESCRIPTION:

The technology facilitates the formation of highly specific antigen-antibody reactions allowing disease-specific biomarkers in human whole blood, serum or plasma to be captured and visualized on a unique membrane. The simple test procedure involves adding the specimen to the device and allowing it to flow through the membrane. If the specimen contains the target antibodies or antigens, they are captured on the test membrane and can be visually interpreted immediately after the addition of a detection reagent. Our technology platform is unique in its ability to detect multiple biomarkers specific to several diseases using a single cartridge. Our Multiplo line of rapid tests for HIV, Hepatitis B and C, and syphilis uses the platform's advanced capabilities to deliver up to four test results using one test cartridge and one drop of specimen.

CONTACT INFORMATION

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COST

- N/A/system
- \$25-\$30/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		N/A	N/A
MOBILE Laboratory		N/A	N/A
DIAGNOSTIC Laboratory		N/A	N/A
ANALYTICAL Laboratory		N/A	N/A

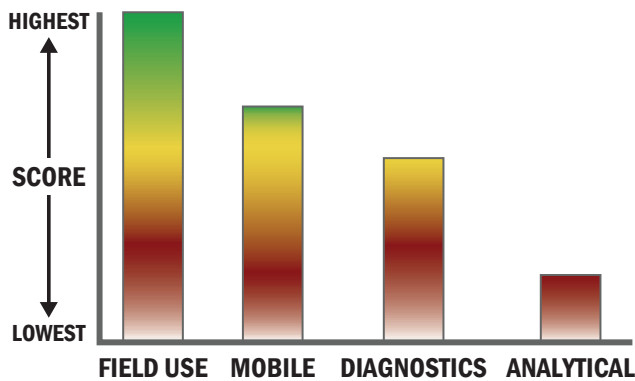
Survey Source

Vendor Supplied Information



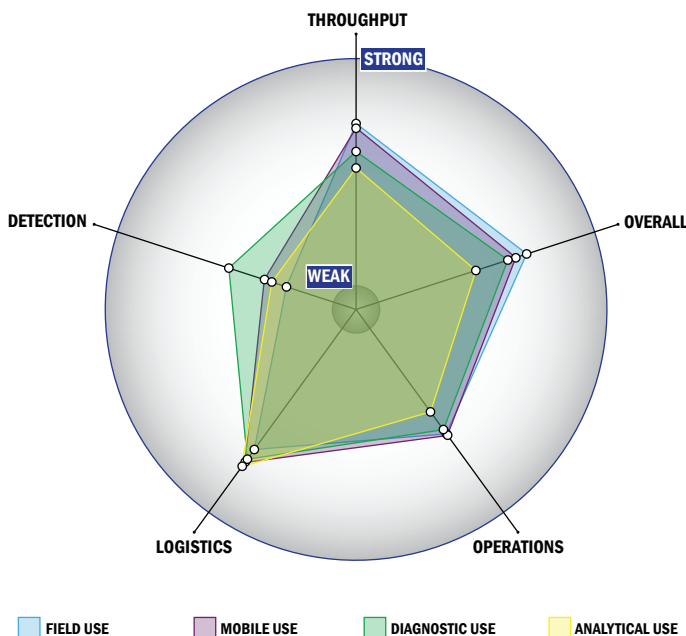
Scoring Analysis

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.



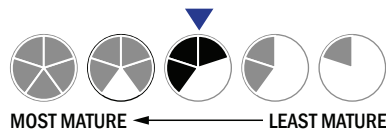
Evaluation Criteria

Throughput:

- Between 2 and 15 minutes for detection
- Multiple samples, multiple tests/sample per run
- 95-32 samples every 2 hours
- The system or approach is not amenable to full or semi-automation
- Device or system is designed for a single use
- 0-1 solutions, buffer, eluents, and/or reagents
- 3 components
- No set-up of the system is required
- 1-2 steps are required for detection

Logistics:

- Very brief (minutes-hours) training and minimal technical skills
- Approximately the size of a soda can
- Less than 1 kg
- This system is not capable of transmitting data
- There is no 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
- The system is not capable of autonomy

Detection:

- Efforts are underway to achieve FDA approval
- Less than 50 µL
- Excellent specificity. System has occasional false alarms under certain conditions (<2%)
- Manual kit not integrated with the system handles spore lysis