

Mesa Tech Intl, Inc. - MTIDx: Rapid Multiplexed Molecular Diagnostics in a Stand-Alone Low Cost Disposable Platform



GENERAL DESCRIPTION:

MITDx is a stand-alone (instrumentation independent), disposable, nucleic acid-based molecular diagnostic platform that integrates nucleic acid extraction, amplification and detection into one simple self-contained device for point of care or resource-limited settings. It does not require elaborate lab infrastructure, expense instrumentation and highly trained personnel. It has capability to detect and differentiate multiple pathogen targets, subtypes, antibiotic resistance from sample-to-answer in <45 minutes. The readout module can either be simple colorimetric Yes or No answers, or digital quantitative readout via the use of a cell phone-sized reader. The data collected from the diagnostic device has the option to be submitted to the remote data processing center via wireless or secure data transferring methods. The device has the option to be run on batteries or regular AC electricity outlets.



TECHNICAL DESCRIPTION:

The MTIDx platform relies on the novel integration of novel paper chromatography-based passive nucleic acid extraction, robust Oscillating nucleic acid amplification and colorimetric lateral flow-based hybridization detection into one simple cell-phone sized device. It employs greatly simplified engineering solutions that does not requires traditional active valves, pumps, moving parts, Peltier-based thermocycling apparatus etc. The fluid flow is controlled by the combination of gravity and capillary motion via a set of temperature-sensitive valves. The firing of the valves of controlled by a low cost, programmable, micro-controller unit.

CONTACT INFORMATION

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COST

- N/A/system
- \$20-\$50/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

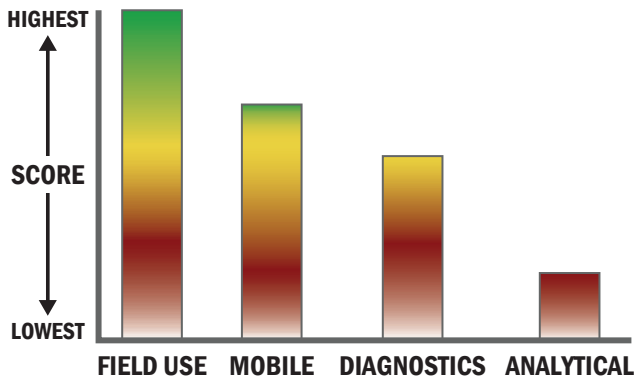
Survey Source

Vendor Supplied Information



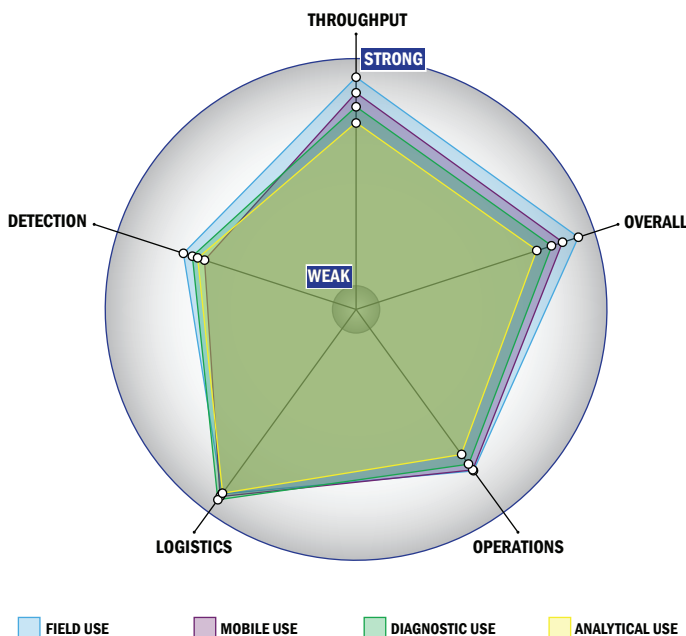
Scoring Analysis

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.



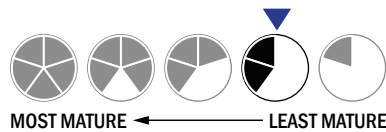
Evaluation Criteria

Throughput:

- Between 30 and 60 minutes for detection
- 1 sample, >10 tests/sample per run
- System is continuous and provides real time analysis with no defined tests/samples
- The system or device is currently fully automated
- Device or system is designed for a single use
- 0-1 solutions, buffer, eluents, and/or reagents
- 1 component
- 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
- Wireless and wired connections are available
- System or device uses batteries
- 4-8 hours battery life



Operations:

- Can be used from $< -21^{\circ}\text{C}$ to $> 42^{\circ}\text{C}$ (All temperatures)
- Performance is not influenced by relative humidity
- Between 6 months and 1 year shelf life
- Less than 1 year expected life
- Results can be viewed in real-time
- The system is not capable of autonomy
- The system does not employ any software
- The system is single use or this question does not apply to this device

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 100 μL
- Superior specificity. System has a false alarm rate approaching zero ($\sim 0\%$)
- 1-100 CFU per mL
- 1-100 PFU per mL
- 100-1,000 ng per mL
- Add on capability that is full or semi-automated for spore lysis