

# IntegenX, Inc. - RapidHIT 200 Rapid DNA Profiling System



## GENERAL DESCRIPTION:

IntegenX™ created the RapidHIT™ 200 Human DNA Identification System. RapidHIT is the first fully automated sample-to-answer system for STR-based Human Identification (HID). The system is based on the integration of IntegenX's proprietary, patented and licensed microfluidic technologies and STR-based chemistry. Reagents are provided in single use disposable cartridges are loaded on the system with up to eight buccal swab samples and sample processing is initiated with no further user interaction. The system extracts DNA from the samples and performs STR amplification, electrophoretic separation and software analysis to generate full DNA profiles in about 90 minutes. For the U.S. market, the results data are saved in CODIS-compatible format within the embedded GeneMarker HID® software (SoftGenetics®, LLC). Other data formats will be available as needed.



## TECHNICAL DESCRIPTION:

The core IntegenX technologies include the development, fabrication and programmability of low-cost, microfluidic devices. The key IntegenX technology is the Microscale On-chip Valve (MOVE™). MOVE valves are externally actuated pneumatically-driven miniaturized on-chip valves. MOVE valves can be opened or closed by applying a vacuum or pressure to an air chamber formed by a flexible membrane layer. By combining three or more valves, on-chip MOVE diaphragm micropumps can be formed to transport and process samples. These micropumps control fluidic flow, can readily manipulate volumes from 20 nL to 100 µL, and are excellent in handling paramagnetic beads. MOVE routers can be made from four or more valves to rapidly and effectively mix two nanofluidic streams in seconds, a feature that has been elusive in microfluidics. The second key IntegenX technological breakthrough has been the adaptation of paramagnetic bead technology to work with large volume, "real world" samples, and collapse the targeted contents to a scale suitable for integration with downstream microfluidic devices. A novel feature of the MOVE pumps is their ability to move and capture beads which is not straightforward in other microfluidics devices. The third key IntegenX technology is DevLink™ software. DevLink is a robust, industrial-strength, distributed instrumentation control platform with an object-oriented application architecture implemented in C# using Microsoft's .NET Framework. DevLink defines a set of communication and command protocols within a standardized automation architecture. As a result, DevLink forms the basis for both internal breadboard-system development as well as commercial product releases at IntegenX.

## 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
<b>FIELD USE System</b>	<span style="color: grey;">○</span>	N/A	N/A
<b>MOBILE Laboratory</b>	<span style="color: red;">◐</span>	N/A	N/A
<b>DIAGNOSTIC Laboratory</b>	<span style="color: red;">●</span>	N/A	N/A
<b>ANALYTICAL Laboratory</b>	<span style="color: red;">●</span>	N/A	N/A

## Survey Source

Vendor Supplied Information

## CONTACT INFORMATION

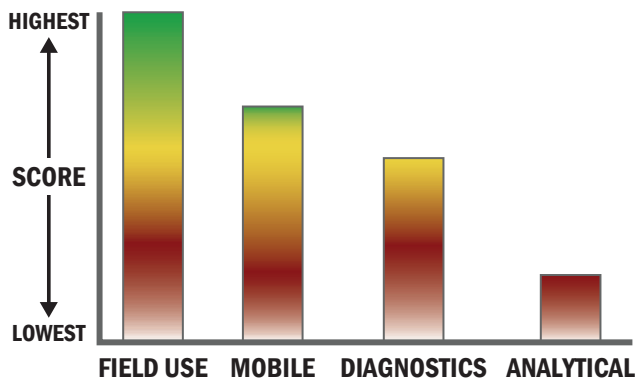
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## COST

- \$245,000/system
- \$350/analysis

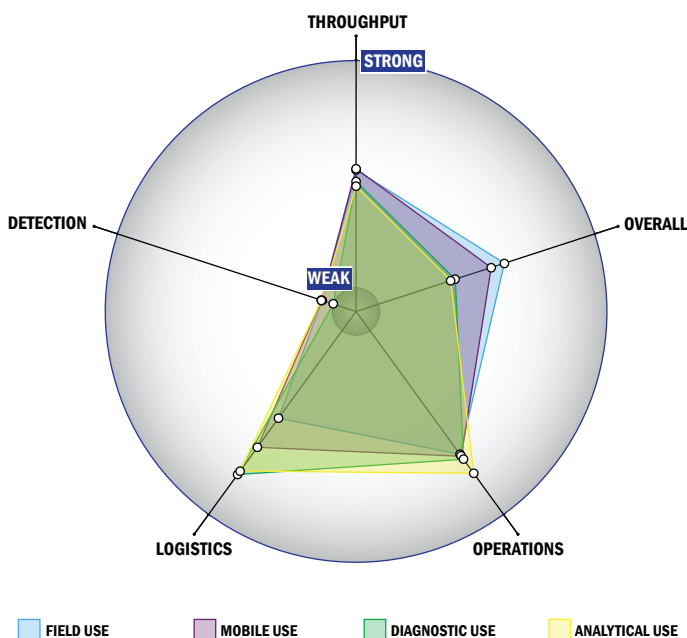
## Scoring Analysis

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.



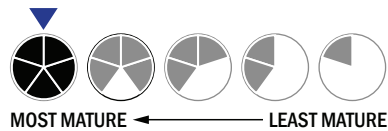
## Evaluation Criteria

### Throughput:

- Between 60 minutes and 8 hours for detection
- Multiple samples, single tests/sample per run
- Less than 32 samples every 2 hours
- The system or device is currently fully automated
- Device or system is designed for a single use
- 5 or more solutions, buffer, eluents, and/or reagents
- 0 components
- Less than 5 minutes is required for set-up
- Automatic detection

### Logistics:

- Very brief (minutes-hours) training and minimal technical skills
- Approximately the size of a carry-on luggage suitcase
- More than 50 kg
- Wireless and wired connections are available
- System or device has 110V electrical requirement
- 1-2 hours battery life



### Operations:

- Can be used from 4 °C to 37 °C
- Components must be stored at 4 °C
- Performance is not influenced by relative humidity
- Between 6 months and 1 year shelf life
- 5-10 years expected life
- Results can be viewed in real-time
- The system could be adapted to a fully autonomous system with some effort
- 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%)

