

Rapid Diagnostek, Inc. - IntelliProbe



GENERAL DESCRIPTION:

This is a highly versatile platform. The system consists of a cell phone-sized instrument that uses disposable sensors. Sensors can be for a single analyte or can be made as a multiplexed array on a single sensor. All sensor formats will be compatible with the same instrument. The system is intended for use at the point of sample collection, regardless of environment. Skills sufficient to use a cell phone are far above what is required to operate the system. While the first product will be a hand held device, the technology can also be configured as a low volume bench-top or a high throughput laboratory instrument. Test samples can be any untreated biological fluid, environmental sample, or a prepared solution or suspension of a material to be tested.



TECHNICAL DESCRIPTION:

A bulk acoustic shear-wave thin-film resonator coated with a capture ligand is operated at its fundamental resonance frequency as it is exposed to a test sample. As target analyte is captured the phase of the signal shifts. The rate of phase change is proportional to concentration of target analyte in the sample. A second identical resonator on the sensor is coated as a reference that is non-reactive with the target analyte but will undergo any non-specific changes that the capture ligand on the test resonator experiences (pH, temperature, viscosity, non-specific protein binding, etc.). The net difference between the test and reference phase shifts is due solely to target analyte binding.

CONTACT INFORMATION

Rapid Diagnostek, Inc.
 1301 Gateway Circle, Suite 400
 Hudson, WI 54016
 POC: Richard A. Van Deusen, CTO

COST

- <\$250/system
- >\$3/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

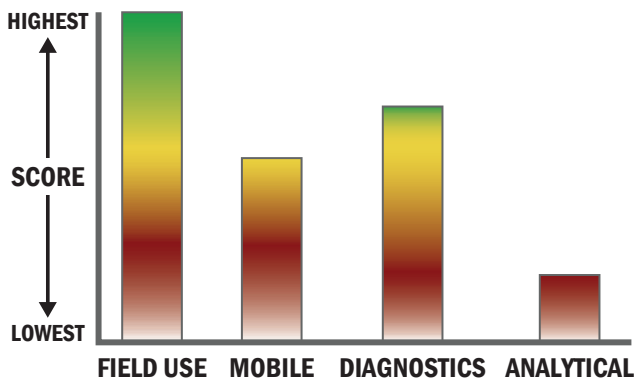
Survey Source

Vendor and Internet Supplied Information



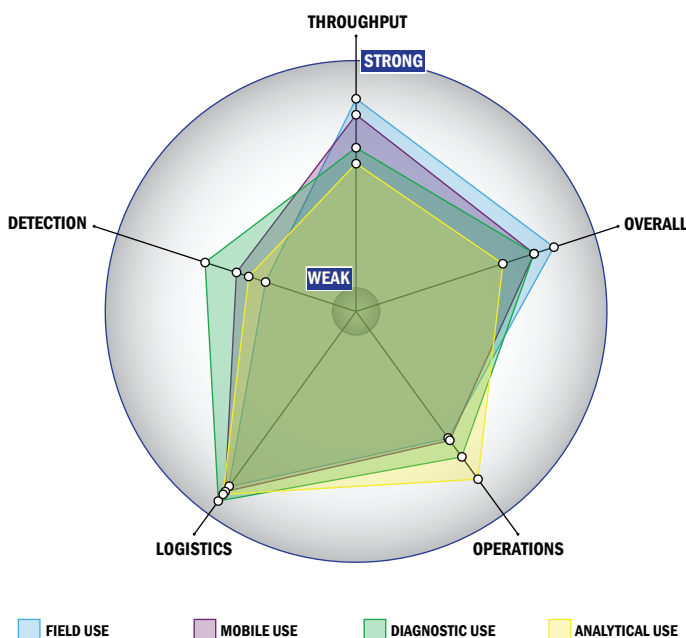
Scoring Analysis

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.



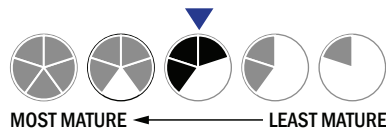
Evaluation Criteria

Throughput:

- 2 minutes or less for detection
- 1 sample, single test/sample per run
- The system or device is currently semi-automated
- Device or system is intended for multiple detection assays
- 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
- Wired connections are available
- System or device uses batteries
- 4-8 hours battery life



Operations:

- Can be used from 4 °C to 41 °C
- Performance is not influenced by relative humidity
- 3-5 years expected life
- Results can be viewed in real-time
- The system or device is currently fully autonomous
- The system software is open and available for modification
- The system hardware is open and available for modification

Detection:

- Efforts are underway to achieve 510K clearance
- Efforts are underway to achieve FDA approval
- Less than 50 µL
- 1,000-10,000 CFU per mL