Diagnostic Biosensors, LLC - Field System

GENERAL DESCRIPTION:

The system is designed for use in the field and by consumers. It generates quantitative assay results for samples from a broad range of complex liquid matrixes including blood, urine, and wastewater. Precision electronic detector elements are embedded into a single consumable sample handling cartridge. Customer-supplied capture molecules, and other dried assay reagents, are placed in the cartridge during production. Low cost per assay is achieved through design for manufacturing. Detection elements are commercially available for development of assays and systems. The detector element production process does not harm sensitive biomolecules. Finished detector elements can be machine - assembled into higher level systems without harming onboard biomolecules. The total system is available as a brass board assay development environment. The underlying commercial data acquisition system allows for configurations as a stand-alone custom device or as a user-configurable experimental station. The instrument communicates with a laptop or smart phone via standard USB 2.0 or Bluetooth. Battery power versions are available, standard is 110V AC.

TECHNICAL DESCRIPTION:

The fundamental detection element is a giant magnetoresistive (GMR) sensor array chip that counts the biospecifically bound magnetic labels at its surface. Magnetic labels are available for a wide range of detectable species including antibodies, DNA, RNA, proteins, toxins, bacteria, cells, and chemicals. The tiny plastic sample handling cartridge contains the detector elements and an interface to the handheld instrument. There are peer reviewed accounts of magnetoresistive biosensors detecting many analytes of interest including, Biological Warfare Agents, proteomic breast and colon cancer markers, food pathogens (e-coli, cryptosporidium), immunological lung cancer markers (IL-6), and more.

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	Third Tier	N/A
MOBILE Laboratory	Third Tier	Third Tier	N/A
DIAGNOSTIC Laboratory	Third Tier	Second Tier	N/A
ANALYTICAL Laboratory	Third Tier	Third Tier	N/A

Survey Source

Vendor Supplied Information

CONTACT INFORMATION

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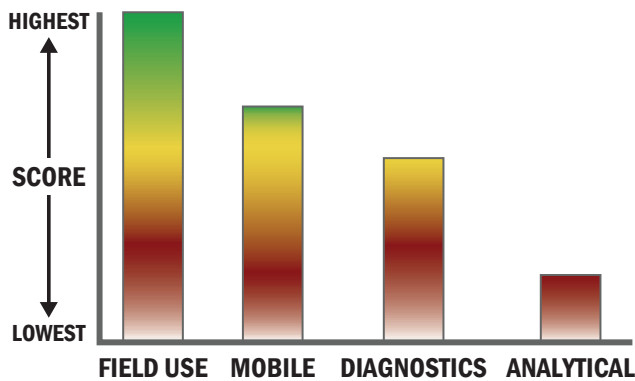www.DiagnosticBiosensors.com

COST

- $5,000/system
- $5/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.


| FIELD USE | MOBILE USE | DIAGNOSTIC USE | ANALYTICAL USE |
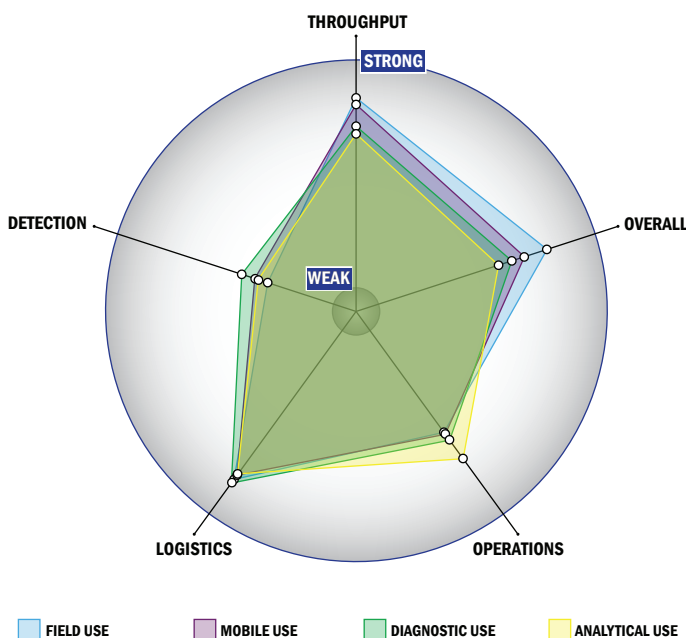
Evaluation Criteria

Throughput:
- Between 2 and 15 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
- 1 component
- Less than 5 minutes is required for set-up
- 1-2 steps are required for detection

Logistics:
- An afternoon of training and some technical skills required
- Less than 1 kg
- Satellite, wireless and wired connections are available
- System or device uses batteries
- 4-8 hours battery life

MOST MATURE ← → LEAST MATURE
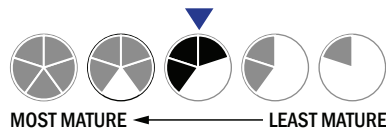
Operations:
- Can be used from 4°C to 41°C
- Components must be stored at 4°C
- Between 6 months and 1 year shelf life
- 3-5 years expected life
- Results can be viewed in real-time
- The system could easily be adapted into a fully autonomous system
- The system software is open and available for modification
- 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 10 μL
- Good specificity. System has a consistently low level of false alarms (2-5%)
- Greater than 10,000 ng per mL
- 100 ppm-1 ppt
- Possible system could be adapted to identify aerosolized chemical agent
- Possible system could be adapted to identify liquid chemical agent

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