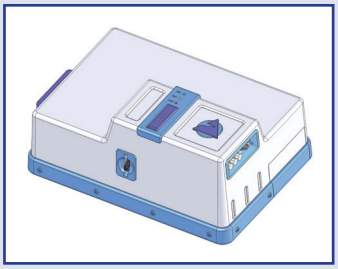
Research International, Inc. - AIR (Arrayed Imaging Reflectometry) Bioassay System

GENERAL DESCRIPTION:



The AIR System performs extremely sensitive label-free, multi-analyte immunoassays (64 to several hundred array elements) on a silicon chip mounted in an injection-molded disposable cartridge. Protein assays typically have 1 pg/mL sensitivity, and a 5 to 6 log detection range. Assay protocols are completely automated and fluidic operations are controlled by an on-board microprocessor. These protocols primarily consist of incubation, wash and optical read-out steps that may be conveniently modified for specific applications or conditions using Windows software. All sample and wash fluids are stored onboard the cartridge after an assay is completed- there is no possibility of post-analysis sample contact. The hardware is currently in its fourth generation. The AIR platform is highly amendable to multiplexing, allowing for rapid, simultaneous quantification of potentially 100's of analytes with no increase in assay complexity. This robust detection platform is novel in its combination of rapid testing, highly multiplexed capacity and low assay cost. AIR has also been adapted for use in the field and at the point of need.

TECHNICAL DESCRIPTION:

AIR is a silicon chip-based label-free biosensor platform, which enables the detection and quantification of virtually any probe-target analyte pair with a high degree of sensitivity. Detection occurs via optical sensing of the binding of sub-Angstrom layers to the functionalized substrate surface. As AIR is an essentially reagentless assay, typical target analysis takes under 30 minutes of processing time (limited only by binding kinetics of the probe-target), in contrast to labeled techniques, which require further processing (usually 2-3 additional chemistries after target hybridization) and result in longer test times (>2 hrs) and substantially increased reagent costs.

CONTACT INFORMATION

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COST

- $30,000/system
- ~$20/analysis

Tier Selection

Final tier assignment is based on overall product score.

Top Tier | Second Tier | Third Tier | Fourth Tier | Bottom Tier

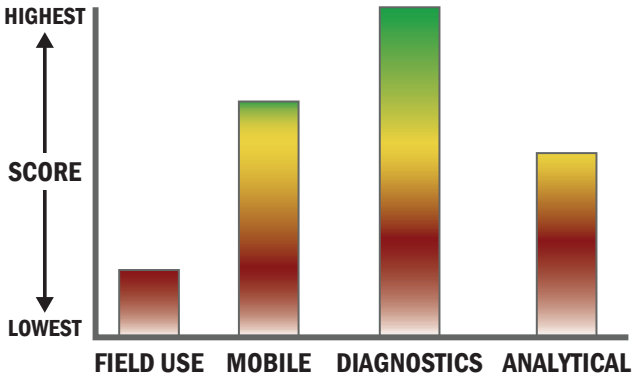
RANKINGS	Biological	Chemical	Radiological
FIELD USE System	Bottom Tier	N/A	N/A
MOBILE Laboratory	Bottom Tier	N/A	N/A
DIAGNOSTIC Laboratory	Third Tier	N/A	N/A
ANALYTICAL Laboratory	Third Tier	N/A	N/A

Survey Source

Vendor Supplied Information

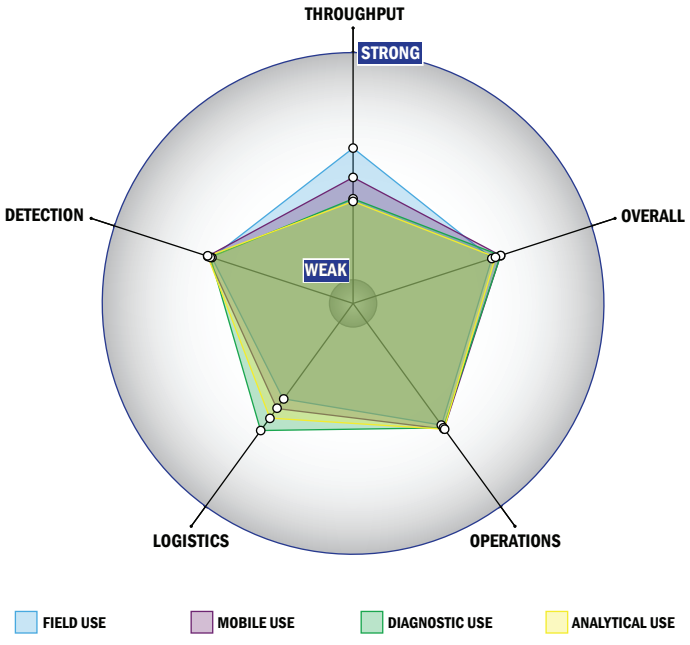
Scoring Analysis

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.



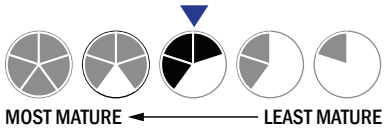
Evaluation Criteria

Throughput:

- Between 30 and 60 minutes for detection
- 1 sample, >10 tests/sample per run
- Less than 32 samples every 2 hours
- The system or device is currently fully automated
- Device or system is intended for multiple detection assays
- 0-1 solutions, buffer, eluents, and/or reagents
- 0 components
- Greater than 20 minutes is required for setup
- 1-2 steps are required for detection

Logistics:

- A day of training and technical skills are required
- Approximately the size of a toaster
- Between 5 and 25 kg
- Wireless and wired connections are available
- System or device has 110V electrical requirement



Operations:

- Can be used from 25°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 cannot 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 50 µL
- Good specificity. System has a consistently low level of false alarms (2-5%)
- 10,000-100,000 CFU per mL
- 10,000-100,000 PFU per mL
- 1-10 ng per mL
- Spore lysis not necessary for detection by system