QTL Biosystems - BIOSENSOR 4000

GENERAL DESCRIPTION:

The BIOSENSOR 4000, built on the proven technology of the Biosensor 2200R, offers first responders and emergency medical technicians an automated instrument to further advance biological agent detection in the field, on the ambulance and in the laboratory. The BIOSENSOR 4000 fully automates the detection process from wet or dry sample introduction to result with no other user interaction required. The assay cartridge enables users to test simultaneously for up to eight pathogens. Unique bioassay technology offers excellent sensitivity and low false positives while offering ease of use in the field. This highly accurate detection method provides rapid measurement of multiple biohazards such as anthrax, ricin, botulism, SEB, tularemia, plague, smallpox and West Nile virus. Exclusive five minute time-to-answer allows first responders to make informed critical decisions more rapidly than any other biological agent detector. The BIOSENSOR 4000 employs dynamic surface generation, a patent pending type of immunomagnetic assay detection technology. The instrument and technology offer significant advantages over other field and lab based assay methods including better sensitivity, faster analysis, a user-friendly format, and detector stability within a wide range of climates. Results are displayed with a simple red (target present) or green (no target present) indication. As tests are nondestructive, samples may be retained as evidence. This instrument is IP 67 certified and permanently housed in a sturdy, light weight fully decon-able Pelican case. Research and development has demonstrated that the BIOSENSOR 4000 can identify targets in whole blood and can be utilized as a human diagnostic device.

TECHNICAL DESCRIPTION:

The BIOSENSOR 4000 employs dynamic surface generation, a patent pending type of immunomagnetic sandwich assay technology.

- MIX Sample is mixed with the sensing solution which contains: a magnetic component, a fluorescent component and receptors for the biological agent(s) of interest.
- BIND Sensing materials bind to target during incubation.
- MAGNETIZE All bound and unbound magnetic material is pulled to surface.
- WASH All remaining sensing and non-target material is washed away. False positives are virtually eliminated by removing potential interferents.
- READ Concentrated sample (pellet) is illuminated and emits a signal if target is present.

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

CONTACT INFORMATION

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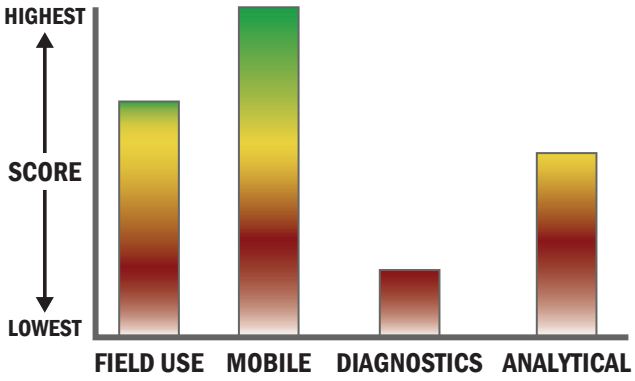
COST

- $17,995/system
- <$75/analysis

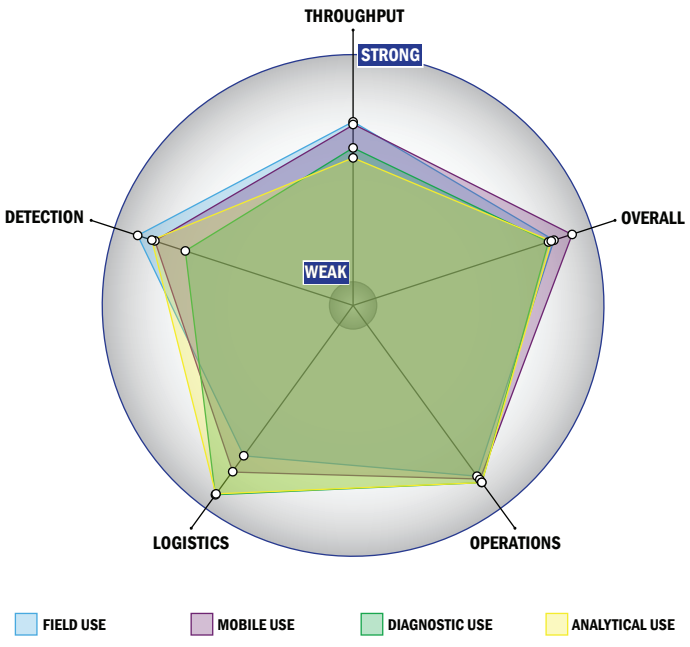
Scoring Analysis

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.



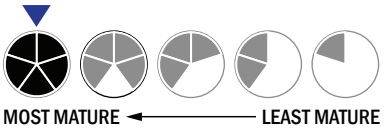
Evaluation Criteria

Throughput:

- Between 2 and 15 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
- 3 solutions, buffer, eluents, and/or reagents
- 1 component
- No set-up of the system is required for set-up
- 1-2 steps are required for detection

Logistics:

- Very brief (minutes-hours) training and minimal technical skills
- Approximately the size of a toaster
- Between 5 and 25 kg
- Wired connections are available
- System or device uses batteries
- 2-4 hours battery life



Operations:

- Can be used from 4 °C to 41 °C
- Components must be stored at room temperature (27 °C)
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life
- Greater than 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 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
- Superior specificity. System has a false alarm rate approaching zero (~0%)
- 100-1,000 CFU per mL
- 100-1,000 PFU per mL
- Less than 1 ng per mL
- Spore lysis not necessary for detection by system