New Horizons Diagnostics - Bioluminometer

GENERAL DESCRIPTION:

Total ATP tests have been developed (3M Clean Trace) in recent years, but they measure total biomass and do not differentiate ATP derived from bacteria. We have taken the proven total ATP methodology; improved sensitivity, eliminated false positives from non-bacteria cells, and eliminated false negatives from quenching agents often present in these samples. Thus we have a rapid, point-of-care bacteria detection system that only detects live bacteria. The test system is portable and can be taken into the field for monitoring of bacteria and easily used by non-laboratory personnel. Test time is under one minute. Detection limits go down to 100 CFU. The product is commercial and currently is used for bacteria detection in healthcare, food and water applications.

TECHNICAL DESCRIPTION:

This kit detects the presence of living bacterial cells by measuring the amount of ATP in the sample. ATP is a cellular metabolite present in all living cells; the amount of ATP in a sample is proportional to the number of living cells. The test can distinguish bacteria from human cells through the use of sample preparation methods that release ATP selectively from microbial cells. The system has two main components: a microluminometer to read ATP-induced luminescence and a "Filtravette" (a filter device and cuvette combined) to concentrate cells from a sample solution and remove chemical contaminants. Samples and solutions are processed through the filtravette using an empty syringe. After the sample is processed, a solution is applied to remove non-microbial sources of ATP. Then a microbial lysis solution is added to the filtravette followed by a luciferase solution that produces light in the presence of ATP. After pipette mixing, the filtravette is placed in the reader and the intensity of emitted light (luminescence) is recorded.

CONTACT INFORMATION

New Horizons Diagnostics
1450 South Rolling Road
Baltimore, MD 21227

COST

- $5,000/system
- $5/analysis

Tier Selection

Final tier assignment is based on overall product score.

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

RANKINGS

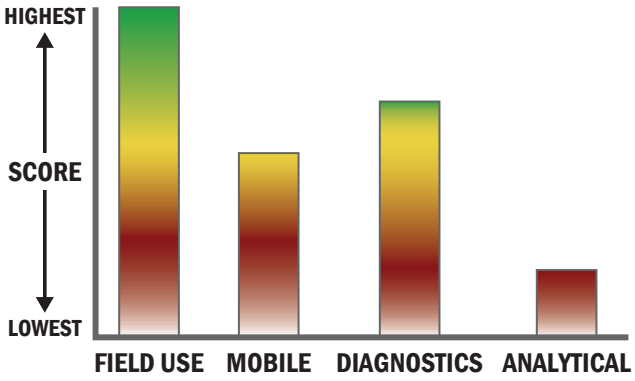
	Biological	Chemical	Radiological
FIELD USE System		N/A	N/A
MOBILE Laboratory		N/A	N/A
DIAGNOSTIC Laboratory		N/A	N/A
ANALYTICAL Laboratory		N/A	N/A

Survey Source

Vendor Supplied Information

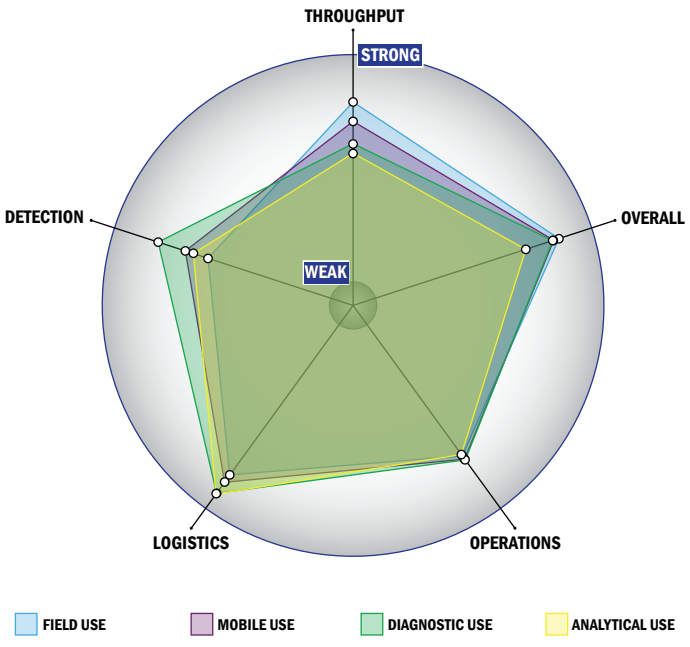
Scoring Analysis

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.



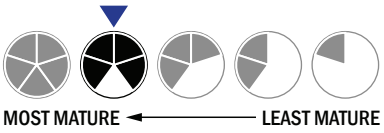
Evaluation Criteria

Throughput:

- 2 minutes or less for detection
- 1 sample, single test/sample per run
- 349-96 samples every 2 hours
- The system could easily be adapted into a fully automated system
- Device or system is intended for multiple detection assays
- 2 solutions, buffer, eluents, and/or reagents
- 1 component
- No set-up of the system is required
- 3-5 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
- Components must be stored at room temperature (27°C)
- Performance is not influenced by relative humidity
- Between 6 months and 1 year shelf life
- 3-5 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:

- System currently has 510k clearance
- System currently has FDA approval
- Less than 50 µL
- Excellent specificity. System has occasional false alarms under certain conditions (<2%)
- 1-100 CFU per mL
- Semi-automated spore lysis