Bioneer Corporation - ExiStation Molecular Diagnostic Platform

GENERAL DESCRIPTION:

The ExiStation Molecular Diagnostic Platform is a semi-automated system that provides sample preparation and real-time diagnostics for a variety of clinical sample types and tests. The system allows for simultaneous parallel analysis of up to 6 different samples types and tests in under 4 hours making it the highest throughput system available.

TECHNICAL DESCRIPTION:

The ExiStation consists of 3 x ExiPrep 16 Dx systems, and ExiSpin and an Exicycler 96. The ExiPrep systems are sample prep devices capable of purifying DNA and RNA from a wide range of clinical samples and uses proprietary spherical magnetic nano-particles. Once the sample is purified, the ExiPrep 16 Dx will also set up the diagnostic qPCR reaction which is then taken to the ExiSpin. The ExiSpin is a combination centrifuge/vortexer that is used to mix and spin the reactions in a uniform manner ensuring world class reproducibility of the kits. Finally, after mixing and spinning in the ExiSpin, the samples are placed in the Exicycler 96 Real-Time thermal cycler. The Exicycler uses a peltier based thermal block and has 5-color optics with a 16 bit 2-d CCD camera for detection.

CONTACT INFORMATION

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COST

- $82,000/system
- $30/analysis

Tier Selection

Final tier assignment is based on overall product score.

Top Tier Second Tier Third Tier Fourth Tier Bottom Tier

RANKINGS

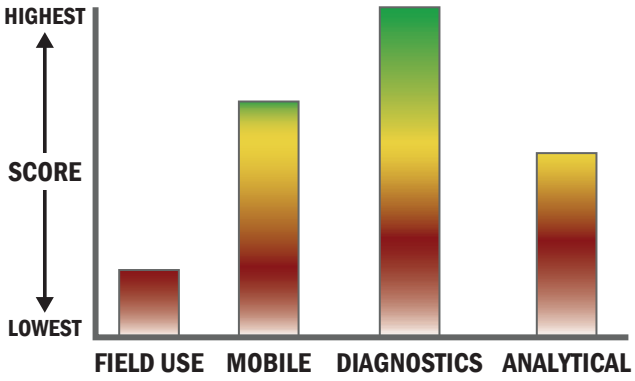
	Biological	Chemical	Radiological
FIELD USE System	Fourth Tier	N/A	N/A
MOBILE Laboratory	Third Tier	N/A	N/A
DIAGNOSTIC Laboratory	Second Tier	N/A	N/A
ANALYTICAL Laboratory	Second Tier	N/A	N/A

Survey Source

Vendor Supplied Information

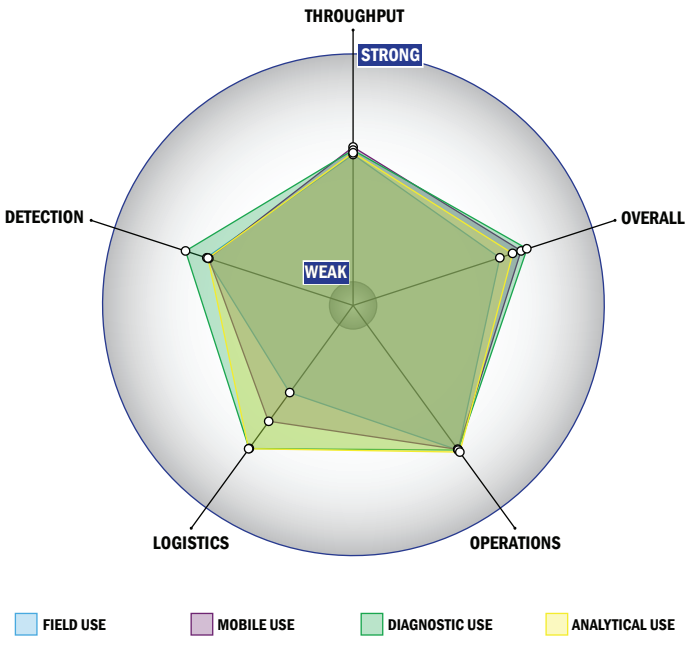
Scoring Analysis

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.



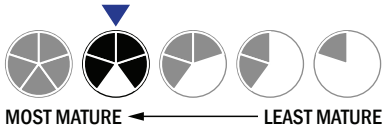
Evaluation Criteria

Throughput:

- Between 60 minutes and 8 hours for detection
- Multiple samples, multiple tests/sample per run
- 49-96 samples every 2 hours
- The system or device is currently semi-automated
- Device or system is intended for multiple detection assays
- 2 solutions, buffer, eluents, and/or reagents
- 5 or more components
- 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
- Approximately the size of a carry-on luggage suitcase
- More than 50 kg
- 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 room temperature (27 °C)
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life
- 5-10 years expected life
- Results can be viewed in real-time
- The system or device is currently fully autonomous
- 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 250 µL
- Excellent specificity. System has occasional false alarms under certain conditions (<2%)
- 1-100 CFU per mL
- 1-100 PFU per mL
- Fully automated spore lysis