

# Cepheid - GeneXpert System



## GENERAL DESCRIPTION:

The GeneXpert System is a closed, self-contained, fully-integrated and automated platform that represents a paradigm shift in the automation of molecular analysis, producing accurate results in a timely manner with minimal risk of contamination. The GeneXpert System is the only system to combine on-board sample preparation with real-time PCR (polymerase chain reaction) amplification and detection functions for fully integrated and automated nucleic acid analysis. The system is designed to purify, concentrate, detect and identify targeted nucleic acid sequences thereby delivering answers directly from unprocessed samples. Modular in design, the GeneXpert System has a variety of configurations to meet the broad range of testing demands of any clinical environment. The Cepheid GeneXpert System makes biothreat agent detection possible in minutes – all from unprepared samples. This easy-to-use, automated and highly accurate real-time PCR instrument combines the ingenuity of more than 30 patents into a sophisticated genetic tool for first responders. A patented, disposable, cartridge test for anthrax is available now, and can be performed on-site – delivering critical answers in critical situations.



## TECHNICAL DESCRIPTION:

The GeneXpert System fully integrates and automates the three processes required for real-time PCR-based molecular testing: sample preparation, amplification, and detection, all in one cartridge. On-demand. Just load a biological sample and the system does the rest.

## CONTACT INFORMATION

Cepheid  
 904 Caribbean Drive  
 Sunnyvale, CA 94089  
 POC: Chinmay Sheth

## COST

- \$79,200/system
- \$50/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
<b>FIELD USE System</b>	<span style="border: 1px solid black; border-radius: 50%; width: 40px; height: 40px; display: inline-block;"></span>	<span style="border: 1px solid black; border-radius: 50%; width: 40px; height: 40px; display: inline-block; background-color: #ccc;">N/A</span>	<span style="border: 1px solid black; border-radius: 50%; width: 40px; height: 40px; display: inline-block; background-color: #ccc;">N/A</span>
<b>MOBILE Laboratory</b>	<span style="border: 1px solid black; border-radius: 50%; width: 40px; height: 40px; display: inline-block; background: linear-gradient(to bottom, red 50%, white 50%);"></span>	<span style="border: 1px solid black; border-radius: 50%; width: 40px; height: 40px; display: inline-block; background-color: #ccc;">N/A</span>	<span style="border: 1px solid black; border-radius: 50%; width: 40px; height: 40px; display: inline-block; background-color: #ccc;">N/A</span>
<b>DIAGNOSTIC Laboratory</b>	<span style="border: 1px solid black; border-radius: 50%; width: 40px; height: 40px; display: inline-block; background: linear-gradient(to bottom, green 50%, white 50%);"></span>	<span style="border: 1px solid black; border-radius: 50%; width: 40px; height: 40px; display: inline-block; background-color: #ccc;">N/A</span>	<span style="border: 1px solid black; border-radius: 50%; width: 40px; height: 40px; display: inline-block; background-color: #ccc;">N/A</span>
<b>ANALYTICAL Laboratory</b>	<span style="border: 1px solid black; border-radius: 50%; width: 40px; height: 40px; display: inline-block; background: linear-gradient(to bottom, red 50%, white 50%);"></span>	<span style="border: 1px solid black; border-radius: 50%; width: 40px; height: 40px; display: inline-block; background-color: #ccc;">N/A</span>	<span style="border: 1px solid black; border-radius: 50%; width: 40px; height: 40px; display: inline-block; background-color: #ccc;">N/A</span>

## Notes

In use by U.S. Postal screening systems

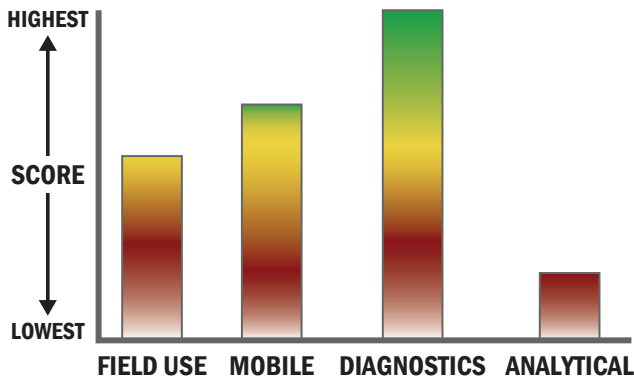
## Survey Source

Vendor Supplied Information



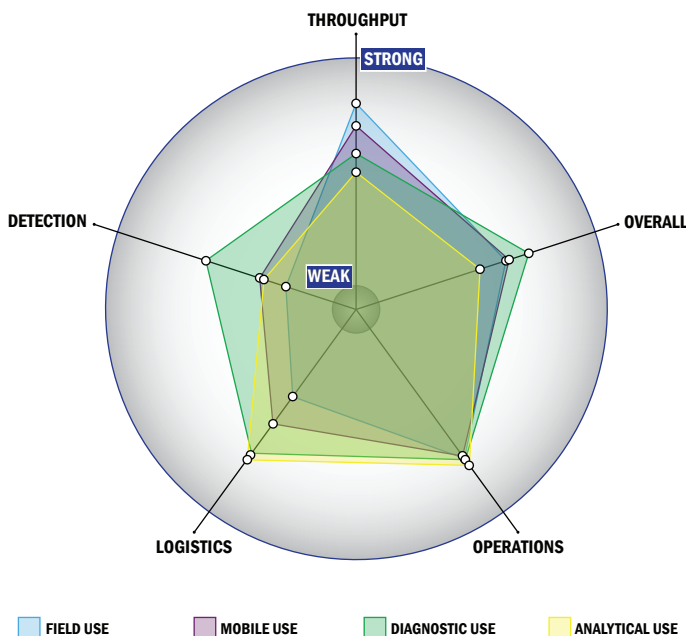
## Scoring Analysis

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.



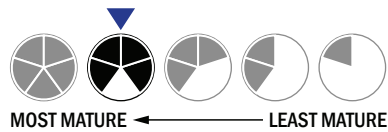
## Evaluation Criteria

### Throughput:

- Between 60 minutes and 8 hours for detection
- 1 sample, <10 tests/sample per run
- 349-96 samples every 2 hours
- The system or device is currently fully automated
- 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
- 1-2 steps are required for detection

### Logistics:

- Very brief (minutes-hours) training and minimal technical skills
- Between 5 and 25 kg
- Wired connections are available
- System or device has 110V electrical requirement



### 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
- Greater than 10 years expected life
- Results can be viewed in real-time
- The system is not capable of autonomy
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

### Detection:

- System currently has 510k clearance
- System currently has FDA approval
- Less than 250 µL
- Excellent specificity. System has occasional false alarms under certain conditions (<2%)
- Fully automated spore lysis