Nanosphere, Inc. - Verigene System

GENERAL DESCRIPTION:

Nanosphere (Northbrook, IL) has developed the FDA-cleared Verigene® System, which is comprised of instrumentation and single use Verigene® Test Cartridges (IVDs) based on proprietary gold nanoparticle technology. With the Verigene System, users can accomplish sensitive, accurate, and rapid multiplex detection of nucleic acid and protein targets using enhanced signal-amplification techniques.

TECHNICAL DESCRIPTION:

We have developed a generically applicable, microarray based nano-probe test. The assay uses a multi-step robotic process, which relies on non-isotropically oriented antibodies on functionalized glass as multiplexed microarrays to capture targets from an assay sample. Functionalized, 130 angstrom diameter gold nano-probes (measured by static light scattering, 5 nm S.D.) also bind to the target through a molecular-scale complex containing antibodies. The target-bound molecular complex is then quantified through silver enhancement of the functionalized gold. Assays in this format can be rapidly configured and implemented for a wide array of potential biomarkers. For example we have demonstrated a robust and ultra-sensitive assay for cardiac troponin with an LOD of less than 500 femtograms per mL serum, and an overall CV of less than 20%. The assay also shows very low background, a broad dynamic range and over 3 logs of linear dose response.

CONTACT INFORMATION

Nanosphere, Inc.
4088 Commercial Ave
Northbrook, IL 60062
847-400-9000
info@nanosphere.us

COST

- $40,000/system
- $35-$85/analysis

Tier Selection

Final tier assignment is based on overall product score.

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

RANKINGS

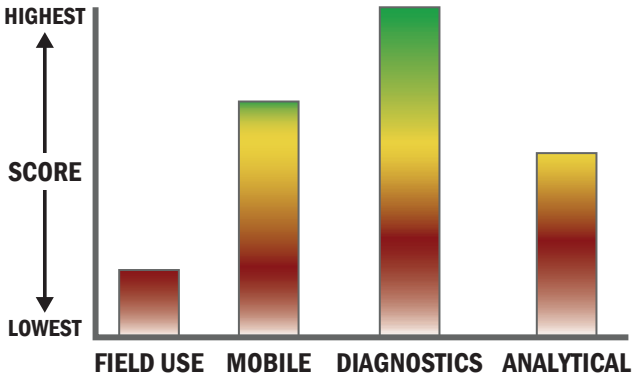
	Biological	Chemical	Radiological
FIELD USE System	Bottom Tier	N/A	N/A
MOBILE Laboratory	Bottom Tier	N/A	N/A
DIAGNOSTIC Laboratory	Top Tier	N/A	N/A
ANALYTICAL Laboratory	Bottom Tier	N/A	N/A

Survey Source

Vendor and Internet Supplied Information

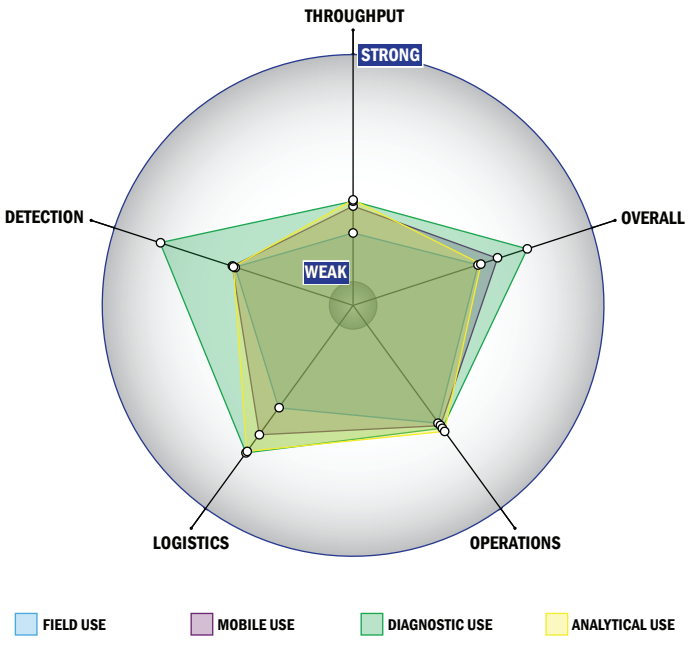
Scoring Analysis

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.



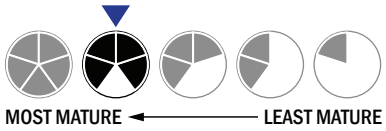
Evaluation Criteria

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
- 5 or more solutions, buffer, eluents, and/or reagents
- Less than 5 minutes is required for set-up
- 3-5 steps are required for detection

Logistics:

- An afternoon of training and some technical skills required
- Approximately the size of a carry-on luggage suitcase
- Between 25 and 50 kg
- Wired connections are available
- System or device has 110V electrical requirement



Operations:

- Can be used from 4 °C to 37 °C
- Performance is not influenced by relative humidity
- Between 6 months and 1 year shelf 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:

- System currently has 510k clearance
- System currently has FDA approval
- Less than 250 µL
- Superior specificity. System has a false alarm rate approaching zero (~0%)
- Less than 1 ng per mL
- Add on capability that is full or semi-automated for spore lysis