

bioMerieux, Inc. - NucliSens easyQ



GENERAL DESCRIPTION:
Amplification and Detection of RNA and DNA using NASBA technology of clinical specimens from body fluids.




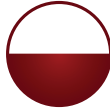





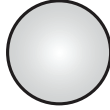

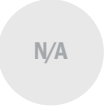
TECHNICAL DESCRIPTION:
Not provided.



CONTACT INFORMATION
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100 Rodolphe St.
Durham, NC 27712

COST

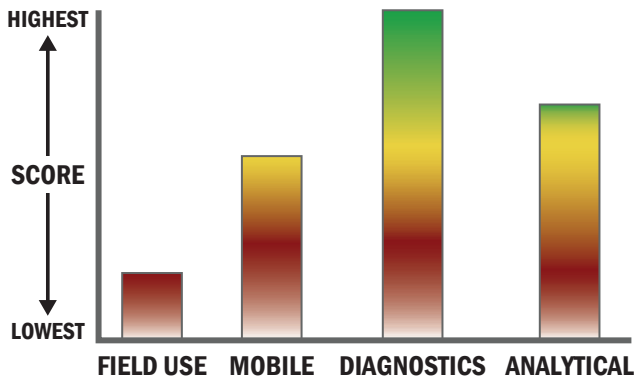
- \$38,000/system
- \$30/analysis

Tier Selection			
Final tier assignment is based on overall product score.			
<input checked="" type="radio"/> Top Tier <input checked="" type="radio"/> Second Tier <input type="radio"/> Third Tier <input type="radio"/> Fourth Tier <input checked="" type="radio"/> Bottom Tier			
RANKINGS			
	Biological	Chemical	Radiological
FIELD USE System			
MOBILE Laboratory			
DIAGNOSTIC Laboratory			
ANALYTICAL Laboratory			

Survey Source
Vendor and Internet Supplied Information

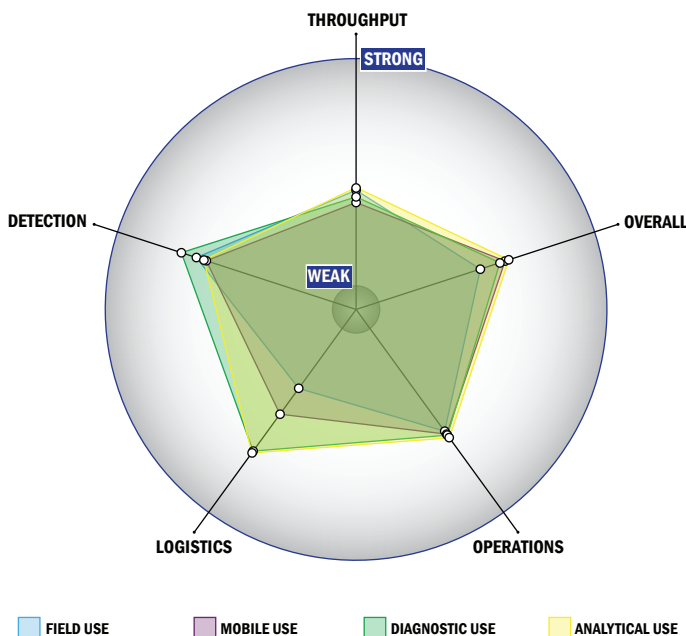
Scoring Analysis

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.



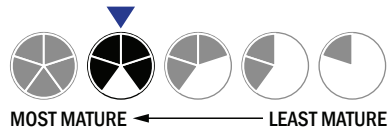
Evaluation Criteria

Throughput:

- Between 60 minutes and 8 hours for detection
- Multiple samples, single 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
- 0-1 solutions, buffer, eluents, and/or reagents
- 3 components
- Greater than 20 minutes is required for set-up
- 6-8 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 5 and 25 kg
- This system is not capable of transmitting data
- System or device has 110V electrical requirement



Operations:

- Can be used from 25 °C to 37 °C
- Components must be stored at 4 °C
- Device or system has peak performance at normal relative humidity conditions
- Between 1 to 3 years shelf life
- 3-5 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:

- Efforts are underway to achieve approval
- Less than 10 µL
- Excellent specificity. System has occasional false alarms under certain conditions (<2%)
- 1-100 CFU per mL
- 100-1,000 PFU per mL

