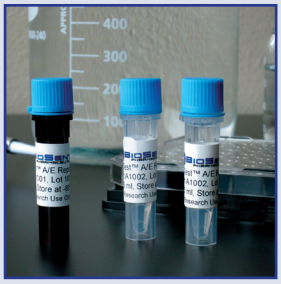
BioSentinel - BoTest Botulinum Neurotoxin Detection Assays

GENERAL DESCRIPTION:



BioSentinel's BoTest™ Botulinum Neurotoxin (BoNT) Detection Assays offer the most sensitive system available for the routine detection of BoNT serotypes A and E (BoTest™ A/E); and serotypes B, D, F, and G (BoTest™ B/D/F/G). Intended uses include high throughput drug discovery; food, environmental, and water testing; and research. The assay detects and quantifies the activity of BoNT. In addition, the BoTest Matrix A assay can be used to detect botulinum activity in complex matrices.

TECHNICAL DESCRIPTION:

The BoTest™ Assays utilize fluorescent reporters that give a ratiometric response when specifically cleaved by BoNT. The assay is run in a mix-and-read, 96 – 1536-well plate format. The reporter uses native BoNT substrates for improved enzyme binding and sensitivity and can be coupled to antibody-conjugated magnetic beads to allow for the detection of BoNT in complex matrices. The assays provide up to a 300-fold increase in sensitivity for BoNT activity compared to other co µL commercially available assays. The assays are provided in kits to ensure reagent consistency and reliability.

CONTACT INFORMATION

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Madison, WI 53711
POC: Ward Tucker
608-441-8174

COST

- $395/system
- $2/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	Fourth Tier	N/A	N/A
ANALYTICAL Laboratory	Fourth Tier	N/A	N/A

Notes

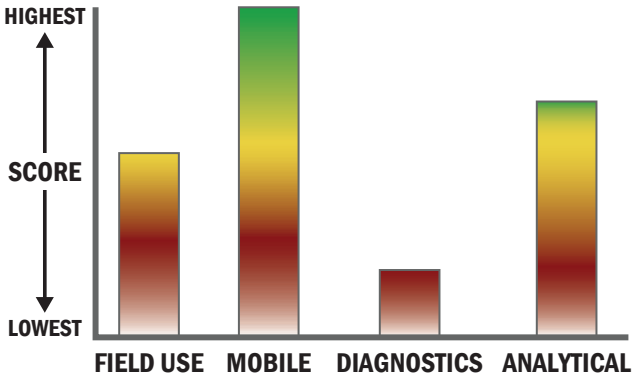
Can determine if toxin is active.

Survey Source

N/A

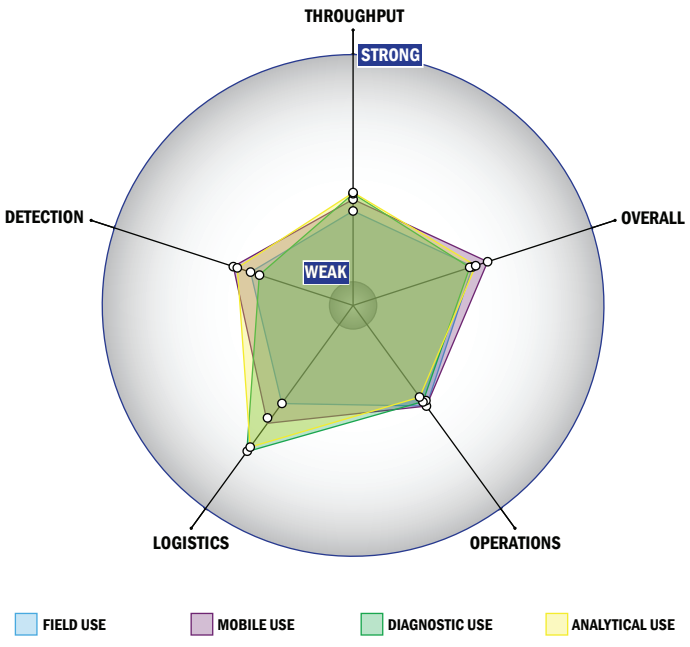
Scoring Analysis

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.



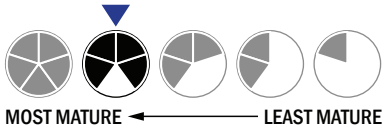
Evaluation Criteria

Throughput:

- Between 60 minutes and 8 hours for detection
- Multiple samples, single tests/sample per run
- 349-96 samples every 2 hours
- The system could easily be adapted into a fully automated system
- Device or system is intended for multiple detection assays
- 3 solutions, buffer, eluents, and/or reagents
- 5 or more components
- Greater than 20 minutes is required for set-up
- 3-5 steps are required for detection

Logistics:

- An afternoon of training and some technical skills required
- Between 5 and 25 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 frozen (-20°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 could be adapted to a fully autonomous system with significant effort
- The system software is open but modification requires licensing
- The system hardware is closed and not available for modification

Detection:

- Not possible for the system to achieve 510K clearance
- Possible the system could receive FDA approval, no current efforts at this time
- Less than 10 µL
- Good specificity. System has a consistently low level of false alarms (2-5%)
- Less than 1 ng per mL