Epistem - Genedrive



GENERAL DESCRIPTION: Senedrive™ offers rapid detection of NA targets in a fully integrated, compact (12cm x 17cm x 9cm) and lightweight (550g) unit. It can detect multiple targets simultaneously using room temperature stable reagents. Single button operation allows use by untrained operators. DECENDENCENCENCENCENCE Genedrive™ uses hybrid thermal engine technology which enables rapid thermal cycling within a compact, low power unit.	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
CONTACT INFORMATION Epistem 48 Grafton Street Manchester, M13 9XX, UK POC: Ben Cobb Director, Diagnostics 07787 565123 or 0161 606 7258 b.cobb@epistem.co.uk www.epistem.co.uk www.epistem.co.uk *\$4,000/system *\$45/analysis	MOBILE Laboratory
	DIAGNOSTIC Laboratory
	ANALYTICAL Laboratory

Notes

The current version does not integrate sample preparation.

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 15 and 30 minutes for detection
- 1 sample, >10 tests/sample per run
- Less than 32 samples every 2 hours
- The system or device is currently semi-automated
- Device or system is intended for multiple detection assays
- 0-1 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
- Approximately the size of a soda can
- Less than 1 kg
- Wireless and wired connections are available
- System or device uses batteries
- 1-2 hours battery life



Operations:

- Can be used from < -21°C to > 42°C (All temperatures)
- Components must be stored at room temperature (27 ° C)
- Between 1 to 3 years shelf life
- 3-5 years expected life
- Results cannot 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:

- 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 100 µL
- Excellent specificity. System has occasional false alarms under certain conditions (<2%)
- 100-1,000 CFU per mL
- 100-1,000 PFU per mL
- Add on capability that is full or semi-automated for spore lysis