TessArae, LLC - TessArray RPM-TEI Tropical and Emerging Infections Assay

GENERAL DESCRIPTION:

The TessArray® RPM-TEI (Tropical and Emerging Infections) assay simultaneously detects and definitively identifies more than 40 distinct classes of Category A, B, C and zoonotic biothreat agents, both viral and bacterial, as well as seven bacterial toxin genes, in a single assay in less than 24 hours. The assay generates agent-specific genomic sequence information as the output, and can easily discriminate between known, unknown, emerging, and deliberately altered pathogens to the subtype and/or strain level. The assay is designed for use by centralized testing laboratories to detect biothreat agents in clinical and environmental matrices, including whole blood, throat swabs, surfaces, air, and dirt.

TECHNICAL DESCRIPTION:

The TessArray RPM-TEI assay is based on resequencing microarray technology that runs on an Affymetrix® GeneChip® 3000 System. Genomic material (both RNA and DNA) extracted from the sample is amplified using locus-specific primers in highly multiplexed reactions (30-40 primer pairs/reaction) using a relaxed amplification strategy to maximize assay sensitivity. Amplified material is hybridized to the resequencing microarray under stringent conditions to maximize assay specificity. The TessArae Gene Cipher algorithm analyzes the resulting sequence data to detect and identify the agents present in the sample. RPM-TEI is the only assay that simultaneously maximizes both sensitivity and specificity.

CONTACT INFORMATION

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COST

- $219,000/system
- $300/analysis

Tier Selection

Final tier assignment is based on overall product score.

- 🟢 Top Tier
- 🟢 Second Tier
- ⚪ Third Tier
- 🌓 Fourth Tier
- 🔴 Bottom Tier

RANKINGS

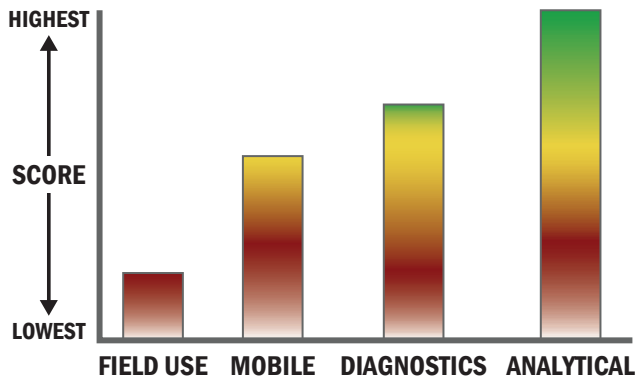|	Biological	Chemical	Radiological
FIELD USE System	🔴	N/A	N/A
MOBILE Laboratory	🔴	N/A	N/A
DIAGNOSTIC Laboratory	🌓	N/A	N/A
ANALYTICAL Laboratory	🌓	N/A	N/A

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.


FIELD USE   MOBILE USE   DIAGNOSTIC USE   ANALYTICAL USE
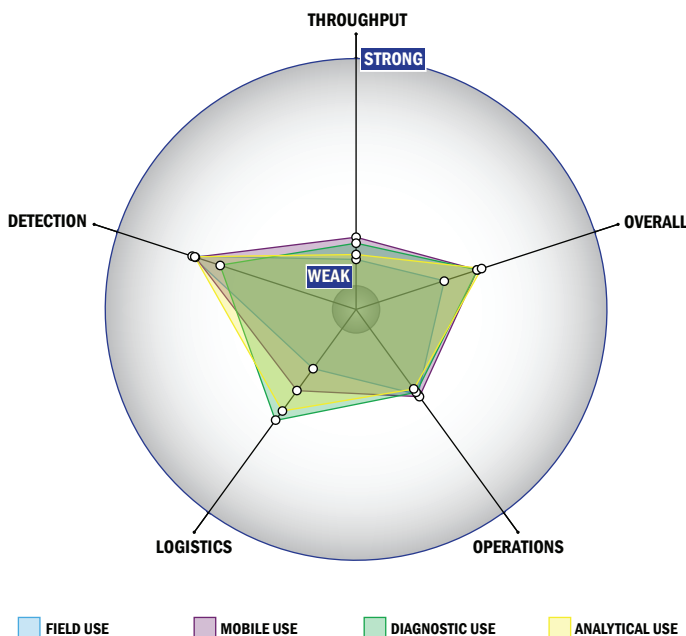
Evaluation Criteria

Throughput:
- Greater than 8 hours for detection
- Multiple samples, single tests/sample per run
- Less than 32 samples every 2 hours
- The system could be adapted to a semi-automated system with some effort
- Device or system is intended for multiple detection assays
- 5 or more solutions, buffer, eluents, and/or reagents
- 5 or more components
- Less than 5 minutes is required for set-up
- Greater than 12 steps are required for detection

Logistics:
- More than a day of training and significant technical skills are required
- Larger than a home dishwasher
- More than 50 kg
- Wireless and wired connections are available
- System or device has 110V electrical requirement

MOST MATURE ◄——— LEAST MATURE
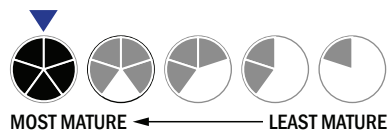
Operations:
- Can be used from 25°C to 37°C
- Components must be frozen (-20°C)
- Performance is not influenced by relative humidity
- Between 6 months and 1 year shelf life
- 5-10 years expected life
- Results cannot be viewed in real-time
- The system is not capable of autonomy
- The system software is closed and not available for modification
- The system hardware is closed and not available for modification

Detection:
- Less than 50 µL
- Superior specificity. System has a false alarm rate approaching zero (~0%)
- 1-100 CFU per mL
- 1-100 PFU per mL
- Manual kit not integrated with the system handles spore lysis