

Envionics - Envi Assay System and ChemPro Reader Module



GENERAL DESCRIPTION:

Envi Assay System is intended for rapid on-site identification of biological material. The system has manual test tickets for Ricin toxin, Botulinum toxin, SEB toxin, Anthrax and Smallpox. The system also contains a reader module that is used to read the test results.



TECHNICAL DESCRIPTION:

The test tickets are based on Immunoassay technology that uses either gold- or fluorescence labelled antibodies. The reader module has a two-wavelength camera that is capable of reading both labels. The Reader module can be connected to a ChemPro100 Chemical Detector or to a PC.

CONTACT INFORMATION

Envionics Oy
Graanintie 5 50100
Mikkeli, Finland

COST

- \$15,000/system
- \$20-\$30/analysis

Tier Selection

Final tier assignment is based on overall product score.

- Top Tier
- ◐ Second Tier
- Third Tier
- ◑ Fourth Tier
- Bottom Tier

RANKINGS

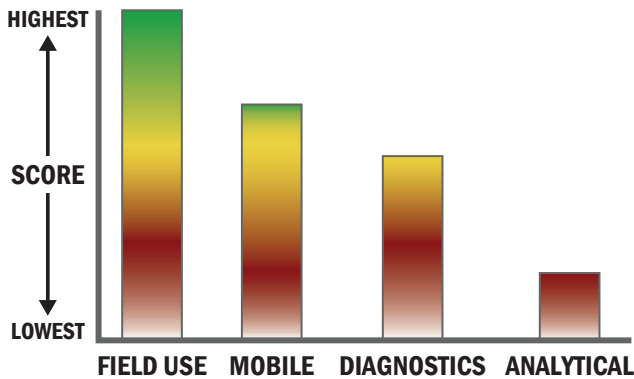
	Biological	Chemical	Radiological
FIELD USE System	●	N/A	N/A
MOBILE Laboratory	◐	N/A	N/A
DIAGNOSTIC Laboratory	○	N/A	N/A
ANALYTICAL Laboratory	◑	N/A	N/A

Survey Source

Vendor Supplied Information

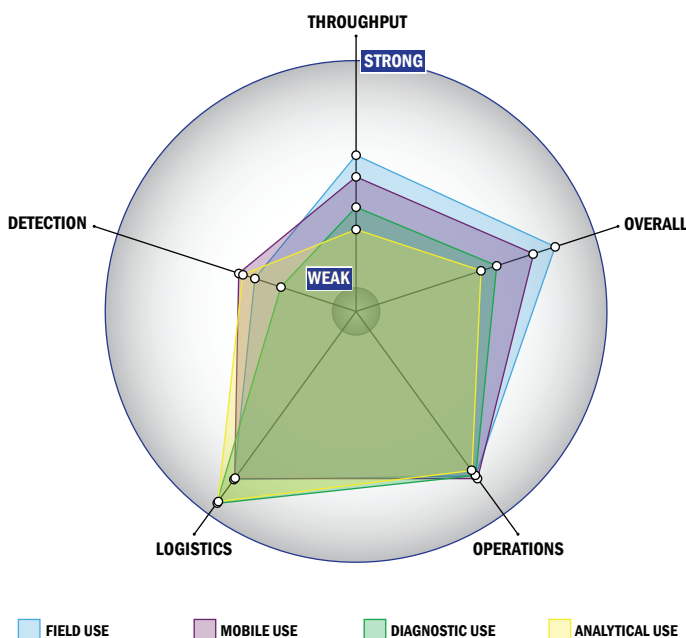
Scoring Analysis

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.



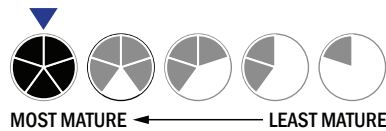
Evaluation Criteria

Throughput:

- Between 2 and 15 minutes for detection
- 1 sample, single test/sample per run
- 95-32 samples every 2 hours
- The system or approach is not amenable to full or semi-automation
- Device or system is designed for a single use
- 0-1 solutions, buffer, eluents, and/or reagents
- 3 components
- Less than 5 minutes is required for set-up
- 3-5 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
- System or device uses batteries
- 4-8 hours battery life



Operations:

- Can be used from 4 °C to 41 °C
- Components must be stored at room temperature (27 °C)
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life
- Results cannot be viewed in real-time
- The system is not capable of autonomy
- The system software is open and available for modification
- The system hardware is open and available for modification

Detection:

- Not possible for the system to achieve 510K clearance
- Not possible for the system to achieve FDA approval
- Less than 10 µL
- Good specificity. System has a consistently low level of false alarms (2-5%)
- Greater than 100,000 CFU per mL
- Greater than 100,000 PFU per mL
- 10-100 ng per mL
- Spore lysis not necessary for detection by system

