

AdVnt Biotechnologies, LLC - Pro-Strip Rapid Screening System



GENERAL DESCRIPTION:

Pro-Strips were introduced in 2006 and are certified and designated by the DHS Safety Act. Pro-Strips is the first HHA designed to detect and identify multiple bio-threat agents using one sample. No additional collection kits or expensive readers are required. Each test is packaged in a protective, foil pouch then placed alongside our unique all-in-one buffer collection tube and instruction sheet and "Chain of Custody" label then sealed in a red mylar pouch which doubles as a re-sealable bio-hazard bag to aid in transportation.



Features include:

- Results in as little as 3 minutes
- Excellent detection capabilities
- No cross-reactivity to dozens of near neighbor strains including bacillus thuringiensis and bacillus globigii
- No Cross-reactivity to common household substances such as flour, yeast, baby powder, sugar, etc.
- Cost effective

TECHNICAL DESCRIPTION:

AdVnt's Bio-Warfare agent detection systems come in the form of an immunochromatography assay, designed to provide a quick presumptive identification of selected biological warfare agents. Polyclonal antibodies are used because of their superior sensitivity. Monoclonal antibodies are used for their high degree of specificity and sensitivity. These "capture" antibodies are able to grab onto to portion of an antigen with their antigen binding sites

Detector antibodies conjugate to colloidal gold allowing for visualization of the antibody. The capture antibodies are what make up the "T" or test line on the ticket. The collected agents are first introduced into a buffer solution that allows for transport across a wicking pad. As the sample makes its way across the pad it comes into contact with the antispecies line to indicate the test is working properly, then makes contact with the antibodies on the test line. If the antibodies bind with the sample the test line will indicate a positive result.

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			
MOBILE Laboratory			
DIAGNOSTIC Laboratory			
ANALYTICAL Laboratory			

CONTACT INFORMATION

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 Phoenix, AZ 85027

COST

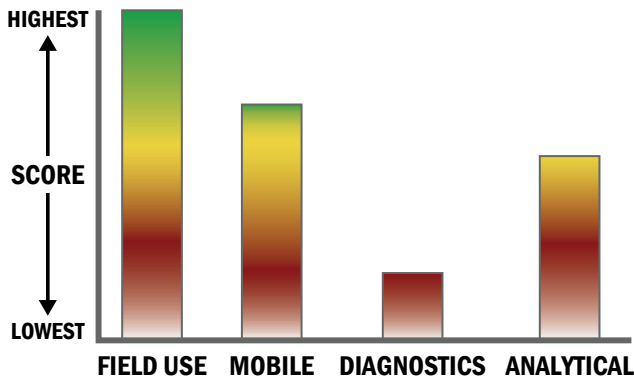
- \$699.50/system
- \$69.95/analysis

Survey Source

Vendor Supplied Information

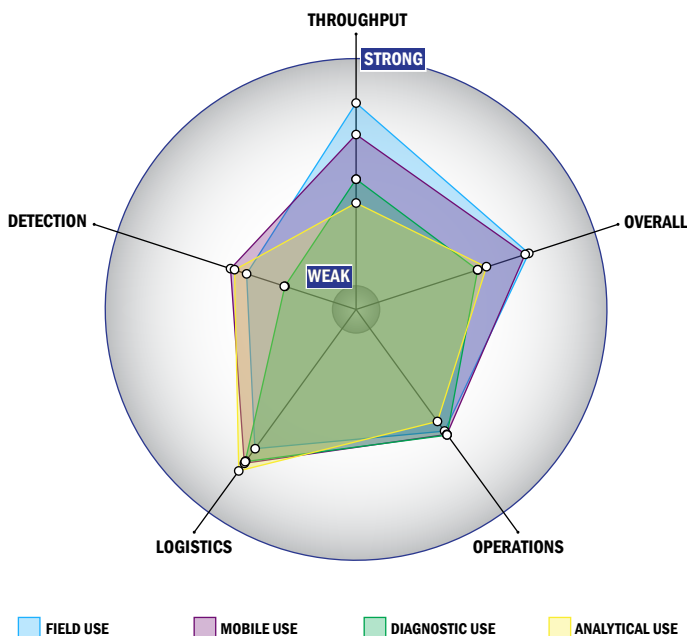
Scoring Analysis

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.



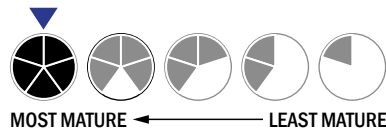
Evaluation Criteria

Throughput:

- Between 2 and 15 minutes for detection
- 1 sample, <10 tests/sample per run
- The system could be adapted to a semi-automated system with some effort
- Device or system is designed for a single use
- 0-1 solutions, buffer, eluents, and/or reagents
- 0 components
- Less than 5 minutes is required for set-up
- 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
- This system is not capable of transmitting data
- There is no electrical requirement



Operations:

- Can be used from 4 °C to 37 °C
- Components must be stored at room temperature (27 °C)
- Device or system has peak performance at normal relative humidity conditions
- Between 1 to 3 years shelf life
- Results can be viewed in real-time
- The system is not capable of autonomy

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%)
- 10,000-100,000 CFU per mL
- 10-100 ng per mL
- Spore lysis not necessary for detection by system