AdVnt Biotechnologies, LLC - BADD Single Agent Detection Test

GENERAL DESCRIPTION:

BADD Single Agent Detection Test is certified and designated by DHS under the Safety Act and is the first HHA designed to detect and identify multiple bio-threat agents using one sample. Each test is packaged in a protective foil pouch then placed alongside our unique all-in-one buffer collection tube then sealed in a red Mylar pouch which doubles as a re-sealable bio-hazard bag. Our BADD line of products is the HHA of choice for inclusion in North America's entire premiere Biological Hazmat Training Programs.

Features include:

- No Electronic Readers or additional collection kits required
- Results in as little as 3 minutes
- Excellent detection capabilities
- No cross-reactivity to dozens of near neighbor strains
- No Cross-reactivity to common household substances such as flour, yeast, baby powder, sugar, etc.
- Portable, easy to carry and easy to store
- Cost effective
- Easily deployable

TECHNICAL DESCRIPTION:

AdVnt Biotechnologies BADD Single Agent Detection Test is a colloidal gold/antibody conjugate-based immunoassay designed to provide a quick presumptive identification of selected biological agents. Antibodies are carefully selected based on their superior specificity and affinity levels. The sample is collected with a specially designed bottle that is then applied to the BADD test device. The target binds first to the detection antibody that is conjugated to gold particles. The target agent – loaded gold particles diffuse through the nitrocellulose membrane and pass Test line marked "T". There, another specific antibody is coated on membrane at this place, the target agent – gold particles were bound specifically and become visible as Test line T. Conjugate-specific antibodies that apply on the membrane are functioning as Control line marked "C". Here, the residual gold conjugate is capture and formed a well visible line during the incubation time.

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

CONTACT INFORMATION

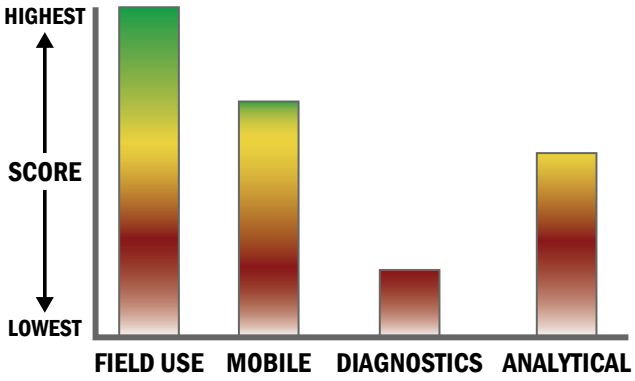
AdVnt Biotechnologies, LLC
22510 N. 18th Dr.
Phoenix, AZ. 85027
412-423-2100

COST

- $24.50/system
- N/A/analysis

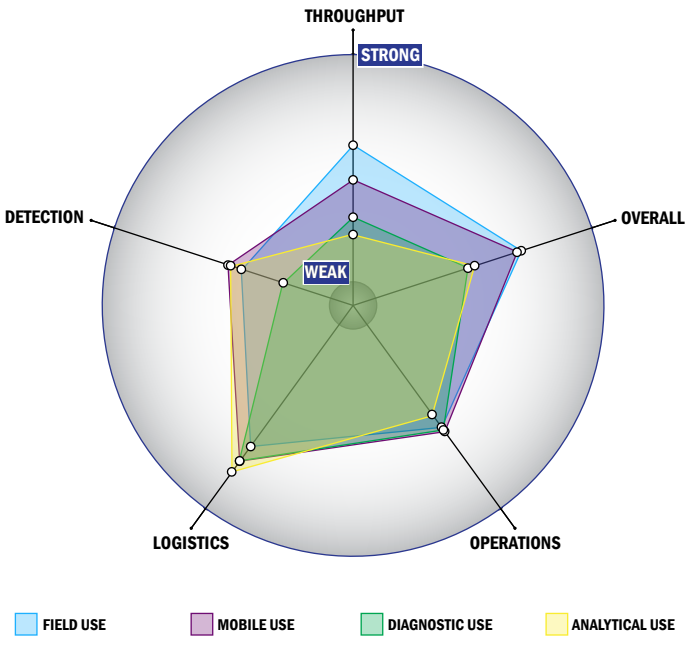
Scoring Analysis

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.



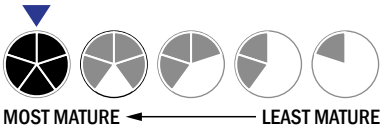
Evaluation Criteria

Throughput:

- Between 15 and 30 minutes for detection
- 1 sample, single test/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 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
- The system does not employ any software

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