20/20 BioResponse - BioCheck

GENERAL DESCRIPTION:

BioCheck® is a field deployable test to screen unknown powders for the presence of biological material. Designed for ease of use, high sensitivity and fast result delivery, BioCheck functions as presumptive test for an initial biological screen and can deliver a result in under five minutes. Normally, the BioCheck test will be performed prior to any pathogen specific tests are undertaken to determine whether there is justification for the time and cost for other tests to be performed. As a highly sensitive field test for positive protein identification, BioCheck was designed specifically to quickly rule out the presence of any biological pathogen and quickly allow decisions to be made confidently regarding the next steps for additional testing in a white powder / suspicious powder decision matrix or SOP. BioCheck test kits do not require any instrumentation, have no power requirements, and are rugged. Each kit is individually packaged with a very small form factor and are completely disposable after use. Extensively tested and validated, BioCheck has been shown to detect minute amounts of biological material when testing unknown powders. Recent US Army ECBC testing showed sensitivity to as little as 100 µg of Ricin and 1 x 107 cfu of *B. anthracis* spores.

TECHNICAL DESCRIPTION:

BioCheck is a patented field test that functions as a colormetric assay that detects protein in solid materials and gives a color change when even minute amounts of protein are present. Specifically optimized in sensitivity and specificity its LOD is calibrated to give a high positive predictive value.

CONTACT INFORMATION

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COST

- $26.20/system
- N/A/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

Notes

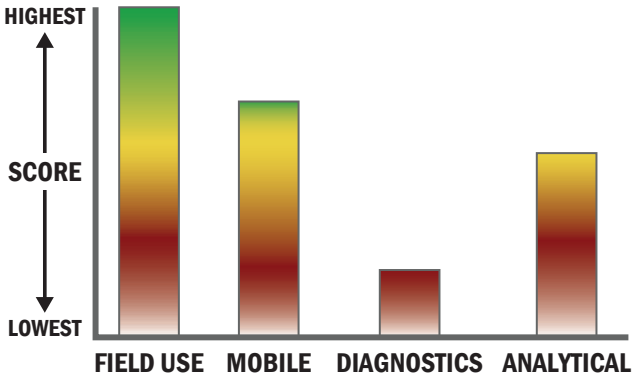
General suspicious powder test kit used by first responders.

Survey Source

Vendor Supplied Information

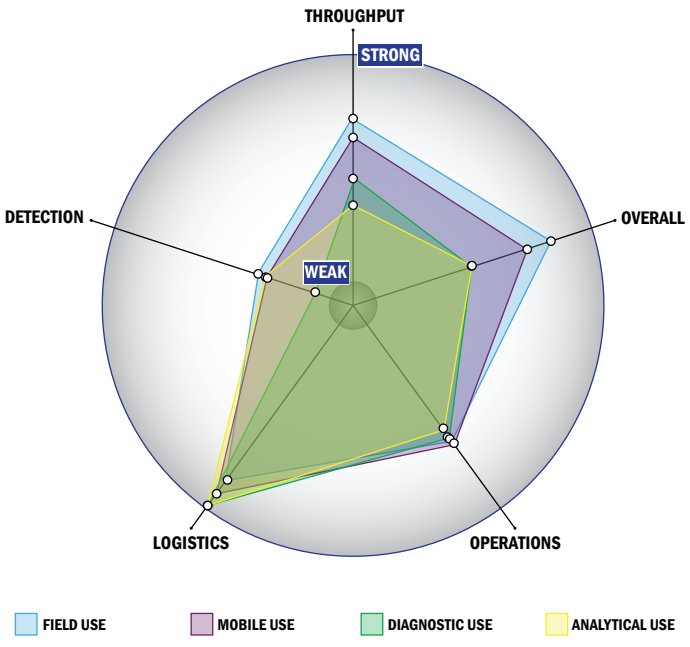
Scoring Analysis

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.



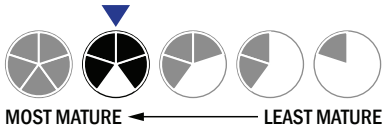
Evaluation Criteria

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
- 2 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
- This system is not capable of transmitting data
- 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 can be viewed in real-time
- The system is not capable of autonomy

Detection:

- Not possible for the system to achieve 510K clearance
- Not possible for the system to achieve FDA approval
- This system does not test liquids
- Superior specificity. System has a false alarm rate approaching zero (~0%)
- Greater than 100,000 CFU per mL
- Greater than 100,000 PFU per mL
- 1,000-10,000 ng per mL
- Spore lysis not necessary for detection by system