Akonni Biosystems, Inc. - TruArray

GENERAL DESCRIPTION:

The Akonni TruArray is a portable microarray in vitro diagnostic device employing a dual nucleic acid and immunoassay test methodology to increase diagnostic confidence limits of rare and emerging infectious diseases. The platform includes sample preparation, reagents, microarray detection, and all hardware and software to run an end-to-end protocol. Because of the unique attributes of gel element arrays and the disposable fluidic cartridge, Akonni can offer a user the ability to analyze for hundreds of genetic- or immuno-based disease traits in one, rapid, simple to use platform. The state-of-the-art technology can easily be adapted to custom DHHS or DOD applications and can be quickly re-configured for new or emerging infectious disease targets. Military, EMT and medical personnel could use the portable device, with minimal training and expense, to identify the presence of pathogens.

TECHNICAL DESCRIPTION:

The platform employs a patented sample preparation technology (TruTip) for rapid (<4 mins) extraction, purification and concentration of nucleic acid from clinical and environmental samples. The core gel-drop microarray technology was exclusively licensed from Argonne National Laboratory whom led the development of the technology throughout the 1990s under funding from the Human Genome Program and from DOD's DARPA biodefense program. The biological assay (PCR and immunocapture) was developed by USAMRIID and ported over to Akonni's microarray chip under a DTRA program. Subsequently, Akonni obtained a license from USAMRIID and its affiliates, to the nucleic acid sequences, primers and probes.

CONTACT INFORMATION

Akonni Biosystems, Inc.
400 Sagner Ave., Suite 300
Frederick, MD 21701
POC: Charles Daitch
301-698-0101
info@akonni.com

COST

- $40,000/system
- $30/analysis

Tier Selection

Final tier assignment is based on overall product score.

Top Tier | Second Tier | Third Tier | Fourth Tier | Bottom Tier

RANKINGS

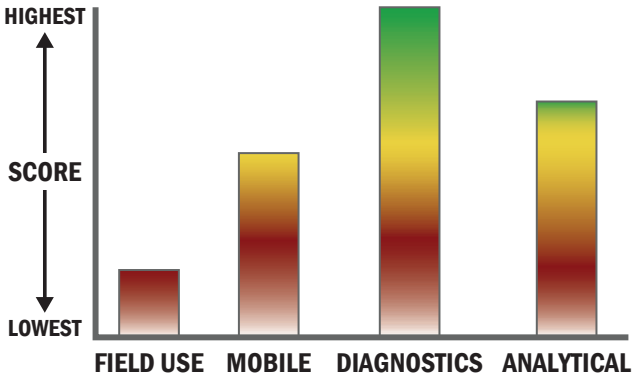
	Biological	Chemical	Radiological
FIELD USE System	Fourth Tier	N/A	N/A
MOBILE Laboratory	Third Tier	N/A	N/A
DIAGNOSTIC Laboratory	Second Tier	N/A	N/A
ANALYTICAL Laboratory	Top Tier	N/A	N/A

Survey Source

Vendor and Internet Supplied Information

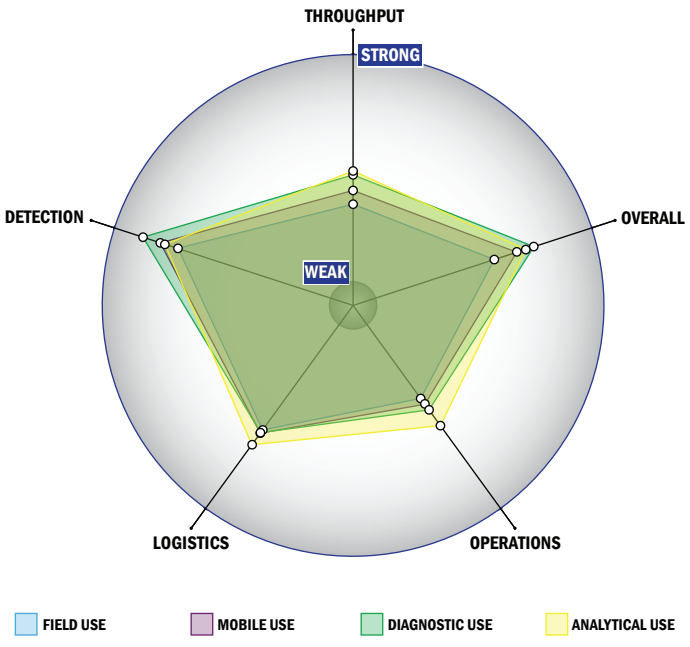
Scoring Analysis

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.



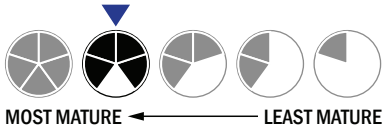
Evaluation Criteria

Throughput:

- Between 15 and 30 minutes for detection
- 1 sample, >10 tests/sample per run
- 749-350 samples every 2 hours
- The system or device is currently semi-automated
- Device or system is intended for multiple detection assays
- 4 solutions, buffer, eluents, and/or reagents
- 3 components
- 5-10 minutes is required for set-up
- 9-12 steps are required for detection

Logistics:

- An afternoon of training and some technical skills required
- Approximately the size of a toaster
- Between 5 and 25 kg
- Wireless and wired connections are available
- System or device has 110V electrical requirement
- 1-2 hours battery life



Operations:

- Can be used from 4 °C to 37 °C
- Components must be frozen (-20 °C)
- Between 6 months and 1 year shelf life
- Results cannot be viewed in real-time
- The system could be adapted to a fully autonomous system with significant effort
- The system software is open but modification requires licensing
- The system hardware is open but modification requires licensing

Detection:

- Efforts are underway to achieve 510K clearance
- System currently has FDA approval
- Greater than 250 µL
- 100-1,000 CFU per mL
- 100-1,000 PFU per mL
- 1-10 ng per mL
- Semi-automated spore lysis