Advanced Analytical Technologies, Inc. (AATI) - Fragment Analyzer

GENERAL DESCRIPTION:

The FRAGMENT ANALYZER(TM) is capable of analyzing a variety of DNA and RNA fragments for identification. The instrument can be coupled with end-point PCR (polymerase chain reaction) for the determination pathogens such as salmonella, shigella, etc. The system is designed for laboratory analysis, and is versatile and adaptable for many matrices. The system is based on the use of capillary electrophoresis, and can analyze either 12 or 96 samples simultaneously. It can be used in a variety of applications, including end-point PCR (pathogen detection), genetic mutation screening, and as a tool to estimate the quality of genomic DNA and fragmented DNA for DNA sequencing.

TECHNICAL DESCRIPTION:

Currently, real-time PCR (RT-PCR) is used as a method for the detection of pathogens. Multiplex RT-PCR can be used to analyze the presence or absence of multiple pathogens. The drawback to these technologies is that a false-positive reaction may occur. With the FRAGMENT analyzer technology, coupled with PCR or RT-PCR, the fragments can be analyzed after a positive response to confirm that the amplified DNA fragments are in fact the fragments of interest. The FRAGMENT Analyzer(TM) uses either 12 - or 96 capillaries to analyze samples in parallel, allowing users to evaluate a very large number of samples in a short period of time. Up to 3000 samples/day can be analyzed in a 96-channel system and 300 samples/day in a 12-channel system. The system is based on the use of a low-cost light-emitting diode detection technology, allowing the instrument cost to be one of the lowest in the industry.

CONTACT INFORMATION

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COST

- $36,000/system
- $1/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	Third Tier	N/A	N/A
MOBILE Laboratory	Second Tier	N/A	N/A
DIAGNOSTIC Laboratory	Second Tier	N/A	N/A
ANALYTICAL Laboratory	Second Tier	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.
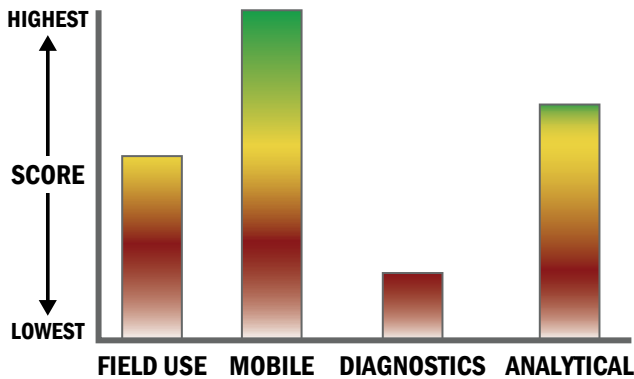
Impact Chart

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.
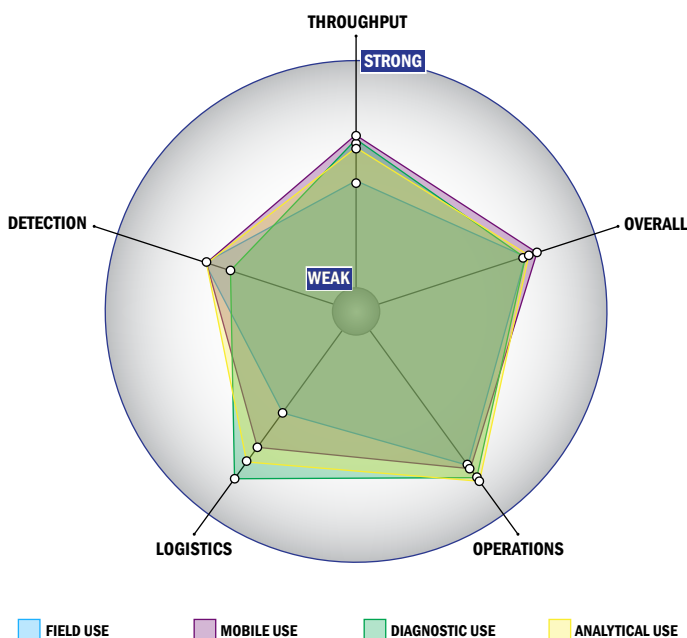

Evaluation Criteria

Throughput:
- Between 30 and 60 minutes for detection
- Multiple samples, multiple tests/sample per run
- 349-96 samples in 2 hours
- The system or device is currently semi-automated
- Device or system is intended for multiple detection assays
- 3 solutions, buffer, eluents, and/or reagents
- 3 components
- No set-up of the system is required
- Almost instantaneous, no downtime

Logistics:
- A day of training and technical skills are required
- Approximately the size of a carry-on luggage suitcase
- Between 25 and 50 kg
- Wired connections are available
- System or device has 110V electrical requirement
- 2–4 hours battery life
- Is commercially available

MOST MATURE ← LEAST MATURE
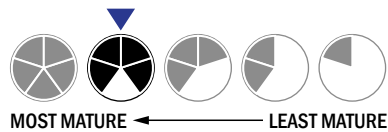
Operations:
- Can be used from 4°C to 41°C
- Components must be frozen (-20°C)
- Performance is not influenced by relative humidity
- Between 1 to 3 years shelf life
- Greater than 10 years expected life
- Results can be viewed in real-time
- The system could easily be adapted into a fully autonomous system
- The system software is open and available for modification
- The system hardware is open and available for modification

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 50 µL
- Superior specificity. System has a false alarm rate approaching zero (~0%)
- 1-100 CFU/mL of original sample
- 100-1,000 PFU/mL of original sample
- Manual kit not integrated with the system handles spore lysis