Q-linea AB - ASTRID

GENERAL DESCRIPTION:

The ASTRID system is a fully automated system for determination of pathogen identity and antibiotics susceptibility direct from patient blood samples. The system accepts freshly sampled blood bottles, thus not requiring a positive blood culture. ASTRID is based on a proprietary molecular technology platform, which is distinct from PCR. After sample and consumable insertion at analysis start, no manual intervention is needed up to analysis result. Pathogens are identified (ID) within 6-8 hours from sample taken. Based on pathogen ID, expert rules automatically launch a pathogen-specific phenotypic determination of the antibiotics susceptibility pattern, with Minimum Inhibitory Concentration (MIC) values delivered within another 4 hours. The pathogen panel contains 40+ pathogens, including gram-negative bacteria, gram-positive bacteria, fungi and selected resistance marker genes. The pathogen-specific AST is performed using up to six antibiotics, and several antibiotics panels will be available. The Limit of Detection of the system is 10 CFU of pathogens per milliliter (ml) blood sample. Sample volume is 10 ml. The ASTRID system is currently under development with clinical studies for CE-IVD marking planned to 2017. Clinical studies for FDA approval are planned shortly thereafter. Q-linea currently has four pre-clinical studies on-going with hospitals in Scandinavia, and on-going collaboration discussions with several US hospitals. The ASTRID platform is versatile and will be adapted to other areas. E.g. urinary tract infections, respiratory tract infections and meningitis will be part of the product plan and e.g. wound swabs could be taken into consideration in the future.

TECHNICAL DESCRIPTION:

The ASTRID system is based on a proprietary universal platform for molecular sample analysis, offering identification of both nucleic acids and proteins. While the current ASTRID development plan focuses on identification of nucleic acids, analysis of proteins, e.g. biomarkers and/or toxins, can in the future be added to the ASTRID scope. Preparation of blood samples is based on a combination of proprietary and licensed technology, enhanced and fully automated by Q-linea. Identification of nucleic acids is enabled by PadLock Probe (PLP) technology, combining state-of-the art sensitivity and a limit of detection similar to that of PCR, even in a high background of irrelevant nucleic acids. The technology further enables highly multiplexed analyses, 100+ agents. These qualities make PLP a powerful molecular tool compared to competing technologies. Protein detection is enabled by the Proximity Ligation Assay (PLA) technology, which is related to the PLP technology since it is based on the same chain of molecular events, thereby giving PLA similarly high selectivity. The PLA technology has a sensitivity that is between 10-1000 times better than ELISA. The PLA/PEA technology enables multiplexing capabilities of 90+ agents. For signal amplification, the platform utilizes Rolling Circle Amplification (RCA) and Circle-To-Circle Amplification (C2CA).

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

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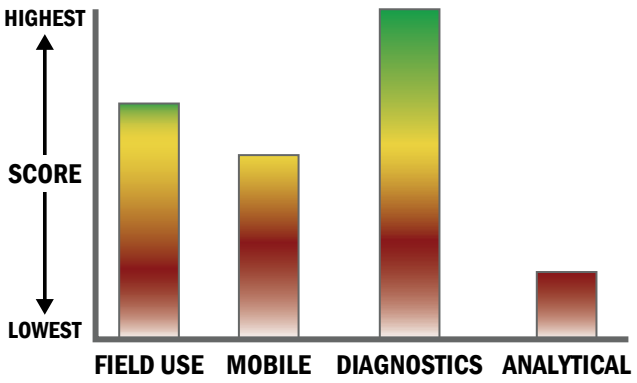
COST

- N/A/system
- N/A/analysis

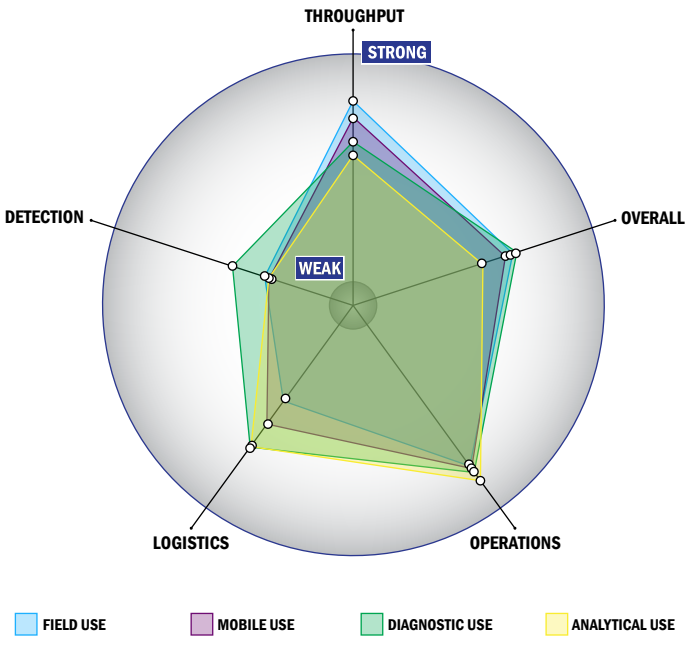
Scoring Analysis

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.



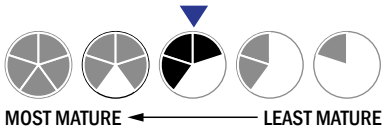
Evaluation Criteria

Throughput:

- Between 60 minutes and 8 hours for detection
- Multiple samples, multiple tests/sample per run
- Less than 32 samples every 2 hour
- The system or device is currently fully automated
- Device or system is intended for multiple detection assays
- 0-1 solutions, buffer, eluents, and/or reagents
- 2 components
- Less than 5 minutes is required for set-up
- Automatic detection

Logistics:

- An afternoon of training and some technical skills required
- Approximately the size of a home dishwasher
- Between 25 and 50 kg
- Wireless and wired connections are available
- System or device has 110V electrical requirement
- The device is not intended for portable use



Operations:

- Can be used from 4 °C to 37 °C
- Components must be stored at room temperature (27 °C)
- Yes, device or system has peak performance at normal relative humidity conditions
- Between 1 to 3 years shelf life
- Greater than 10 years expected life
- Results can be viewed in real-time
- The system or device is currently fully autonomous
- The system software is open but modification requires licensing
- The system hardware is closed and not available for modification

Detection:

- Efforts are underway to achieve 510kclearance
- Efforts are underway to achieve FDA approval
- Greater than 250 µl
- Excellent specificity. System has occasional false alarms under certain conditions (<2%)
- 1-100 CFU per ml
- System does not detect spores