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1. What is the brand name of your company's microbiology system?

LifeScale AST

LIAISON XL

LIAISON XS

2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.

FDA 510(k), 2024

FDA 510(k), 2011; CE Mark 2010

FDA 510(k), 2021; CE Mark 2019

3. What are the dimensions of the named product?

18.1" x 28.4" x 28.5"

59" H x 59" W x 36" D

28" H x 47" W x 30" D

4. What is the intended use or primary function of the product?

Rapid antimicrobial susceptibility testing

High-volume, random access chemiluminescence immunoassay floor model analyzer that automates and consolidates specialty testing

Low- to mid-volume, random access chemiluminescence immunoassay benchtop analyzer that automates and consolidates specialty testing

5. What types of specimen/sample does the product employ?

Positive blood cultures

Serum, plasma, urine, stool

Serum, plasma, urine, stool

6. What types of diseases, conditions, or analytes does the system detect?

Bacteria resistant to antimicrobial(s) leading to, for example, sepsis

Infection management, latent tuberculosis, infectious disease, metabolics, gastrointestinal, hepatitis + HIV, endocrine

Infection management, latent tuberculosis, infectious disease, metabolics, gastrointestinal, hepatitis + HIV, endocrine

7. Which methodology or clinical standard of care does the product use?

■ Other

■ Other

■ Other

8. If you answered "other," explain briefly.

Minimum inhibitory concentration (MIC) for Gram-negative bacteria from positive blood cultures (CLSI, FDA breakpoints) by utilizing the Company's Resonant Mass Measurement technology

Chemiluminescent immunoassay

Chemiluminescent immunoassay

9. What are the product's maximum specimen capacity and throughput under ideal conditions?

LifeScale AST can measure up to 5 x 96-well plates in an 8-hour shift

120 samples, up to 171 tests per hour

48 samples, up to 85 tests per hour

10. Briefly describe any automation or connectivity features or options

The LifeScale system includes a semi-automated specimen preparation station which inoculates the test panels. Remote diagnostic capability ensures optimum system performance

Laboratory automation system (track) ready, connectivity to LIS (host) and/or Middleware, integrated QC software, remote access, traceability via RFID technology

Connectivity to LIS (host) and/or middleware, integrated QC software, remote access, traceability via RFID technology, programmable automated daily priming

11. What is the typical training time for the product?

2-3 days on-site training

2 days on-site training; advanced customer training offered at vendor site

2 days on-site training

12. What types of technical support are available?

Telephone, email, and online

24/7 phone support, remote, and on-site support available

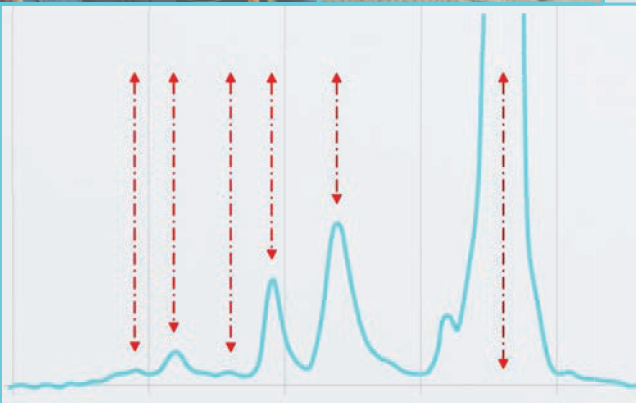
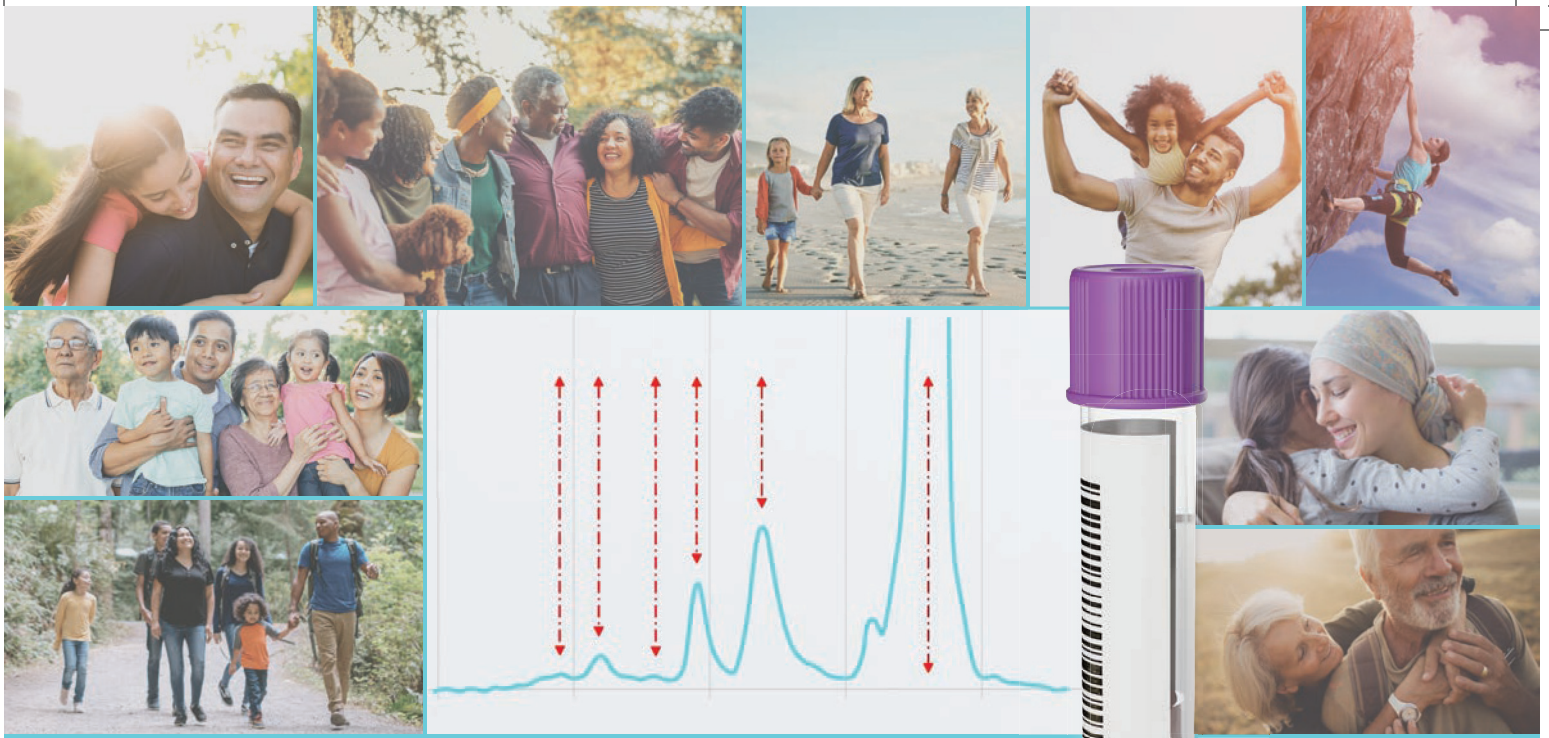
24/7 phone support, remote, and on-site support available

13. What capabilities, features, or accessories distinguish this product from others on the market?

Fast (4.5 hour) generation of clinically actionable MIC results from positive blood cultures powered by the company's Population Profiling software.

Automated specialty testing consolidation and continuous monitoring of processes, reagents, and consumables empowers timely and reliable results for better patient care.

Automated specialty testing consolidation and continuous monitoring of processes, reagents, and consumables empowers timely and reliable results for better patient care.



Every Sample Tells A Story



Tosoh G8 delivers HbA1c results with a detailed chromatographic representation of the patient sample, allowing you to see all that is behind the A1c number. The G8 detects most commonly occurring hemoglobin variants, ensuring the most accurate diagnosis every time.

G8 HbA1c Analyzer

Quickly quantify A1c and provide an accurate diabetes diagnosis using the G8 HbA1c Analyzer

- Less than 2% CVs
- Gold Standard HPLC technology for A1c testing
- Clear separation between labile A1c and stable A1c
- Proven instrument reliability and low maintenance



Come see us at **ADLM Booth 3801** for live demonstrations of our latest advancements in clinical diagnostics

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tosohbioscience.us

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DNA Electronics (DNAe)
 London, UK and facilities in Carlsbad, CA
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1. What is the brand name of your company's microbiology system?
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.
3. What are the dimensions of the named product?
4. What is the intended use or primary function of the product?
5. What types of specimen/sample does the product employ?
6. What types of diseases, conditions, or analytes does the system detect?
7. Which methodology or clinical standard of care does the product use?
8. If you answered "other," explain briefly.
9. What are the product's maximum specimen capacity and throughput under ideal conditions?
10. Briefly describe any automation or connectivity features or options
11. What is the typical training time for the product?
12. What types of technical support are available?
13. What capabilities, features, or accessories distinguish this product from others on the market?

LiDia-SEQ	Qnostics Meningitis/Encephalitis (ME) Evaluation Panel
In development, FDA Breakthrough Device Designation	RUO
Benchtop	
Diagnosis, point-of-care applications	Dedicated evaluation panel for validating a new meningitis/encephalitis (ME) assay or instrument to ensure that everything is working as expected
Blood	Qnostics offer exclusively whole pathogen control material which contains the full organism genome and is designed to mimic the performance of a patient sample.
Bloodstream infections (bacterial and fungal), anti-microbial resistance, proprietary breast cancer detection panels, other cancer panels	Escherichia coli, Haemophilus influenzae, Listeria monocytogenes, Neisseria meningitidis, Streptococcus agalactiae, Streptococcus pneumoniae, Cytomegalovirus, Enterovirus, Herpes Simplex Virus 1, Herpes Simplex Virus 2, Human Herpes Virus 6, Human Parechovirus, Varicella Zoster virus, Cryptococcus neoforman/gattii
■ Other	■ Other
The LiDia-SEQ platform is a first of its kind direct from sample, sample-to-result, point-of-care diagnostic platform utilising proprietary sample preparation, library preparation, next-generation sequencing, and bioinformatics technologies for different applications like BSI and oncology diagnostics.	Designed to provide a quality control solution for molecular infectious disease testing in molecular diagnostics laboratories and laboratories carrying out nucleic acid testing (NAT)
One sample per test	
All steps from sample-to-result: sample preparation, library preparation, sequencing, bioinformatic analysis, and clinical report	Connects to Acusera 24.7—our interlaboratory data management software. With the ability to generate real-time peer group data while also automatically calculating measurement uncertainty.
Few hours	Minimal preparation and training time required
	24/7 phone and email support, online educational material and references, on-site support (available in certain circumstances)
Next-generation sequencing at the point-of-care. Rapid turnaround time (few hours) from sample to clinical result (report). Comprehensive analysis to detect >1200 species of bacteria and fungi, and AMR profiles in a single test	Dedicated Evaluation Panel for validating a new assay or instrument to ensure that everything is working as expected. This ME Evaluation Panel has been designed with known performance on the BioFire FilmArray platform and is intended to be used with BioFire's verification pooling scheme for the FilmArray ME assay, but may also be used with other molecular diagnostic platforms.



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