



Rapid AST results directly from clinical samples

A fully-automated system for rapid antimicrobial susceptibility testing (AST), Q-linea's ASTar cuts the diagnostic time for infectious diseases and delivers clinically-actionable results in hours instead of days.

Early information on bacterial pathogens and their antimicrobial susceptibility is of key importance for managing sepsis patients. Within three to six hours, ASTar delivers true minimum inhibitory concentration (MIC) results directly from positive blood cultures and against a panel of up to 48 antimicrobials, thereby providing comprehensive coverage of gram-negative, gram-positive and fastidious pathogens. ASTar also combines high throughput with a capacity for running 30 to 50 patient samples per day, a user-friendly interface and load-and-go operation.

Key features

Phenotypic AST

- Directly from positive blood cultures
- True MIC results in 3 to 6 hours

Fully-automated analysis

- 12 samples analyzed, random-access
- Up to 50 samples per day
- Load-and-go workflow

Comprehensive AST panel

- Up to 48 antimicrobials possible
- 6–14 two-fold dilutions of each antimicrobial in panel
- Results generated from broth microdilution (CAMHB and fastidious)



Traditional workflow

o hours Patient blood draw Blood bottle incubation Culture cabinet alarm Gram stain Rapid ID Culture on plates Overnight incubation 0.5 McFarland prepared Susceptibility determination

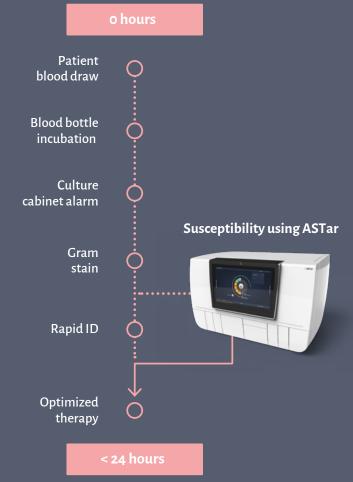
48-72 hours

Optimized

therapy

Workflow analysis performed by Q-linea at several European and US hospitals. Workflow may differ

ASTar workflow



ASTar meets your need for rapid and comprehensive AST

Several approaches for rapid pathogen identification (ID), e.g. molecular techniques and MALDI-TOF mass spectrometry, are available today. Our phenotypic AST solution can be combined with any of these rapid ID technologies, which augments current laboratory capabilities and meets the clinical need for more rapid results. Thanks to the broad AST panel, positive blood culture may be directly analyzed in the ASTar instrument without waiting for pathogen ID, delivering a comprehensive answer in just one test. Pathogen ID is only needed to create the final MIC results report.

Three simple steps for complete MIC results

ASTar simplifies the analysis workflow: less than one minute hands-on time is all that's needed. Simply transfer approx. 1 ml of positive blood culture to the sample preparation cartridge. Choose the AST disc and load. Scan and load the sample preparation cartridge and tap the START RUN icon on the touch screen to start the run. Pathogen ID can be entered before, during or after the run to generate true MIC results.



Choose AST disc and load

Q-linea's unique proprietary technology – the AST disc – allows automated time-lapse imaging of bacterial population growth in wells containing different concentrations of antimicrobial agents.



Scan and load cartridge

The sample preparation cartridge automatically isolates bacterial cells from the sample matrix and adjusts the concentration for a controlled inoculation to the AST disc.

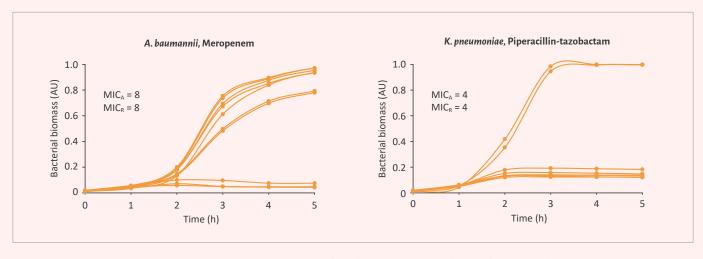


Tap START RUN

Proprietary algorithms translate visual information into MIC values. Based on EUCAST or CLSI breakpoints, MIC values are interpreted as S, I, or R.

Time lapse microscopy to measure bacterial biomass in broth microdilutions of antimicrobial agents

An image analysis algorithm continuously evaluates the collected images to quantify the accumulated bacterial biomass in the culturing chambers. When the incubation is completed, time-dependent bacterial biomass curves are compiled for each antibiotic type and concentration.



Biomass plotted over time for different specimen types and for a selected number of bacteria and antimicrobials combinations, each curve representing one concentration (mg/L). For each AST, ASTar-MIC (MIC_a) and reference BMD MIC (MIC_b) are noted.

Phenotypic MICs from both fastidouis and non-fastidious pathogens

Rapid AST analysis of positive blood culture bottles including automated sample preparation and image-based antimicrobial susceptibility testing in both standard CAMHB as well as CAMHB with additives to support the growth of fastidious pathogens.

Summary of overall Essential Agreement (EA) and overall Categorical Agreement (CA) for six-hour image-based AST data of non-fastidious pathogens isolated from blood cultures spiked with blood from healthy individuals and clinical isolates and grown to positivity. Total N = 672. Gram negative: *P. aeruginosa, E. coli, A. baumanni, P. mirabilis, K. pneumoniae, E. cloacae.* Gram positive: *S. aureus, E. faecalis, S. epidermidis.*

| Antimicrobial agent | Total no. of tests | EA (%) | CA (%) | No. of tests | | | | | |
|-------------------------------|-----------------------|--------|--------|--------------|----|-----|----|----|-----|
| | | | | S | 1 | R | mE | ME | VME |
| Amoxicillin-clavulanic acid | 27 | 96% | 100% | 9 | | 18 | | | |
| Ampicillin | 30 | 97% | 100% | 27 | | 3 | | | |
| Benzylpenicillin | 6 | 100% | 100% | | | 6 | | | |
| Cefotaxime | 48 | 100% | 81% | 22 | 3 | 23 | 9 | | |
| Cefoxitin | 10 | 90% | 80% | 6 | | 4 | | | 2 |
| Ceftazidime | 66 | 95% | 86% | 43 | 6 | 17 | 9 | | |
| Ceftolozane-tazobactam | 16 | 75% | 100% | 12 | | 4 | | | |
| Ciprofloxacin | 81 | 99% | 96% | 43 | 3 | 35 | 3 | | |
| Colistin | 38 | 92% | 100% | 26 | | 12 | | | |
| Daptomycin | 11 | 100% | 100% | 8 | | 3 | | | |
| Gentamicin | 64 | 98% | 95% | 39 | 3 | 22 | 3 | | |
| Levofloxacin | 14 | 100% | 100% | 3 | | 11 | | | |
| Meropenem | 81 | 91% | 100% | 78 | 3 | | | | |
| Piperacillin-tazobactam | 67 | 94% | 84% | 61 | 6 | | 6 | 5 | |
| Tetracycline | 14 | 100% | 93% | 4 | 3 | 7 | 1 | | |
| Tobramycin | 41 | 93% | 88% | 35 | | 6 | 5 | | |
| Trimethoprim/sulfamethoxazole | 11 | 100% | 100% | 8 | | 3 | | | |
| Vancomycin | 47 | 100% | 94% | 41 | | 6 | | | 3 |
| Total | 672 | 95.7% | 93.1% | 465 | 27 | 180 | 36 | 5 | 5 |

mE = minor error, ME = major error, VME = very major error

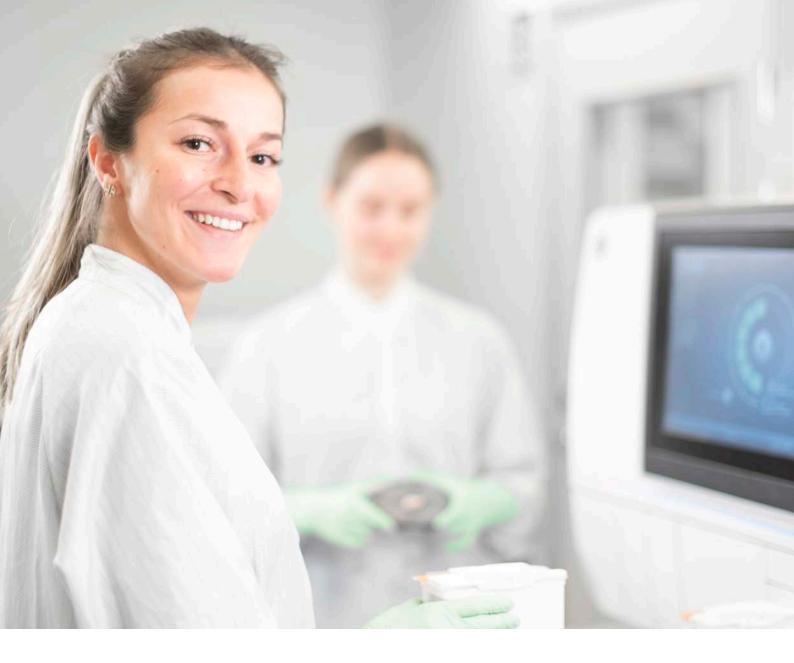
Summary of overall Essential Agreement (EA) and overall Categorical Agreement (CA) for six-hour image-based AST data of fastidious pathogens isolated from blood cultures spiked with blood from healthy individuals and clinical isolates and grown to positivity. Total N = 124.

| Streptococcus pneuomniae | Total no. of tests | EA (%) | CA (%) | No. of tests | | | | | | |
|--------------------------|-----------------------|--------|--------|--------------|---|----|----|----|-----|--|
| | | | | S | 1 | R | mE | ME | VME | |
| Ampicillin | 20 | 100% | 80% | 6 | | 14 | 4 | | | |
| Vancomycin | 17 | 100% | 100% | 17 | | | | | | |
| Cefotaxime | 19 | 100% | 89% | 6 | 7 | 6 | 2 | | | |
| Streptococcus mitis | | | | | | | | | | |
| Ampicillin | 11 | 90% | 100% | 11 | | | | | | |
| Vancomycin | 12 | 100% | 100% | 12 | | | | | | |
| Benzylpenicillin | 12 | 100% | 73% | 6 | 6 | | 2 | | | |
| Haemophilus influenzae | | | | | | | | | | |
| Cefotaxime | 11 | 91% | 91% | 1 | | 10 | | | 1 | |
| Ciprofloxacin | 11 | 100% | 100% | 8 | | 3 | | | | |
| Meropenem | 11 | 82% | 100% | 11 | | | | | | |

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Approximately 30% of the different bacteria-antibiotic combinations tested had a resistant or intermediate phenotype. To challenge the system, around 20% of all bacteria-antibiotic combinations had an MIC for that antibiotic on a clinical breakpoint. This explains why the overall CA is lower than the overall EA obtained in the overall data set.

Overall EA: 95.9% CA: 93.0%



All AST solutions built into one

The ASTar system can be extended to other types of clinical samples. The modular design of the sample preparation cartridge, in combination with the AST disc, allows for future adaptation to other sample types such as urine, respiratory, and sterile aspirates. ASTar is designed to also be run in a semi-automated mode, which facilitates cost-effective isolate analysis with comparable sample throughput as conventional systems, but in considerably less time.







Urine



Respiratory



Isolates

Fully automated

ASTar enables automated high-capacity sample analysis; 12 samples at a time, up to 50 samples per 24 hours-random-access.

50/day

Easy to use with an intuitive and user-friendly interface.

Broad AST panel

Optimized therapy in one go. The extensive Antimicrobial Susceptibility Testing capabilities of the ASTar disc delivers clinically actionable results in a single run.

48/test

Capacity for a broad antibiotics panel with up to 48 antibiotics in a single test.

True MIC results

Based on tried and tested technology. ASTar generates true MIC results from broth microdilution with 6 to 14 two-fold dilutions of each antimicrobial, in both CAMHB and fastidious media.





