A Multi-Site Evaluation of a rapid antimicrobial susceptibility testing (rAST) instrument: The Q-linea ASTar® System for positive blood culture samples.

Jason Chew[1], Kerryanne Brown[2], Steve Davies[3], Jennifer Monkhouse[2], Rachael Houghton[2], Joanne Bullivant[3], Toby Hampshire[1].
[1]Thermo Fisher Scientific - Basingstoke (United Kingdom), [2]Whiston Hospital - St Helens (United Kingdom), [3]Sheffield Teaching Hospital NHS Foundation Trust - Sheffield (United Kingdom)

BACKGROUND

The Q-linea ASTar System delivers reportable results for susceptibility testing (AST) direct from positive blood cultures in 6hrs, significantly faster when compared to traditional AST methods that can take up to 72 hrs from a blood culture system flagging growth (figure 1). The ASTar System offers the potential to positively impact patient outcomes associated with Gram negative bacterial bloodstream infections (BSI), that are often linked with deteriorating conditions such as sepsis.

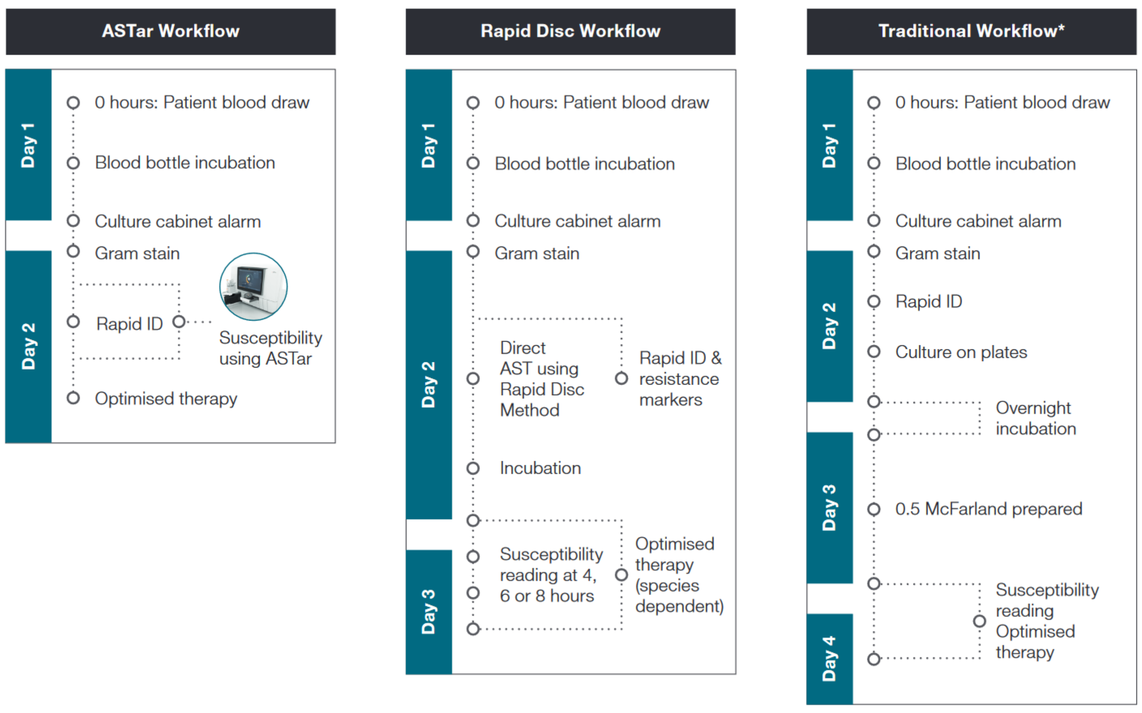

Figure 1. Workflow comparison of ASTar System with the *Rapid Disc Diffusion* and traditional methods.

The ASTar System is a fully automated random access analyser, allowing users to randomly add up to 12 samples for processing at any one time. Consumables consist of the test disc, sample preparation cartridge and frozen insert (figure 2).

With a ~6-hour runtime, the test format offers the broadest combination of antimicrobials and dilution ranges in a single test for Gram-negative bacteria, supporting clinicians managing critically ill patients with blood stream infections, particularly when therapeutic drug monitoring practices are in use. The AST disc (figure 2a) contains more than 300 wells providing comprehensive reports with true MICs for 14 key Gram negative organisms, including *Haemophilus influenzae*.

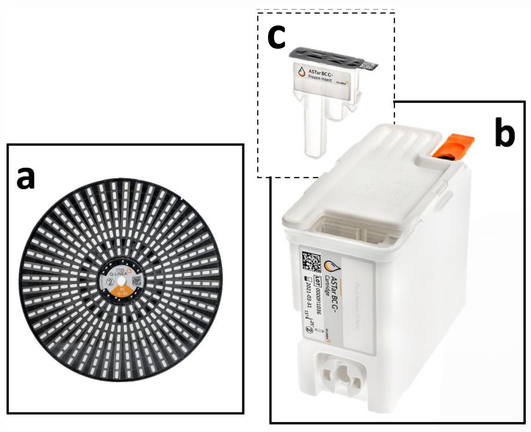

Figure 2.
a) AST disc: Design with ample space for 23 antimicrobials with 6-14 two-fold dilutions, covering 235 dilutions.

b) Sample cartridge: Generates a clean, controlled inoculum, dilution and growth medium adaptation.

c) Frozen insert: Inserted into cartridge to deliver reagents for sample preparation and fastidious organisms

MATERIALS

Evaluation of system performance was undertaken at three sites: Whiston Hospital (UK), Northern General Hospital Sheffield (UK) and St Franziskus-Hospital Muenster (DE). Comparative data for the three laboratories was generated alongside contrasting in-house standards of care (SOC) workflows (in-house AST methods) and operating hours.

Three systems were operating for a total of 133 days across three sites. Laboratory and clinical data were collected from hospital patients with confirmed bacterial BSI (n=229). 3308 datapoints were analysed to determine the essential agreement (ASTar System vs Sensititre System) defined as minimal inhibitory concentrations (MICs) within ±1 two-fold dilution.

RESULTS

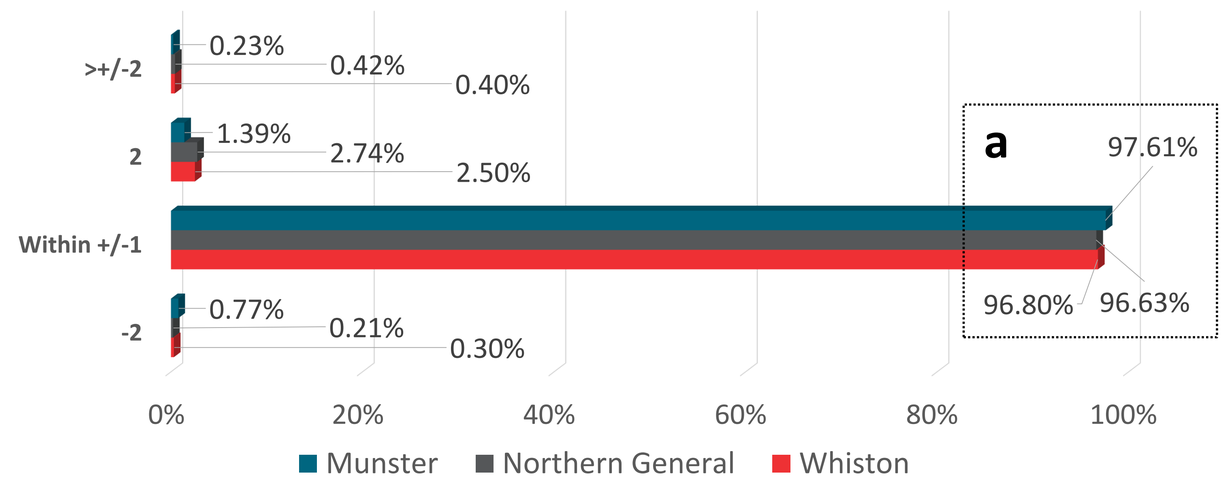

Figure 3. Comparison of MIC results for clinical isolates generated by ASTar System (test) vs Sensititre System (reference) methodologies.
a) Essential agreement for each evaluation site

Data from each site was combined and reported collectively. Peak determination within 24 hours was 17.1 samples. <5% of clinical samples processed were unlisted organisms not included in the current intended use, and 2.2% were lost due to system errors. Total datapoints for Whiston (n=718), Northern General (n=1423) and St Franziskus-Hospital (n=1297) yielded an average Essential Agreement of 97.01%; individual sites obtained 96.8%, 96.63% and 97.61% respectively (figure 3). A minor (non-significant) positive trend was observed with 18% of ASTar test datapoints within +1 two-fold dilution, when compared to 4.5% within -1 two-fold dilution.

CONCLUSIONS

Antibiotic Sensitivities were delivered up to 14 hours faster than current standard of care for sites using Vitek 2 and up to 24 hours for multi-point. The system showed robust equivalent performance to SOC and ease of use with hands on time requiring ~3 minutes by medical lab assistant level staff with minimal training needed.

CE Claim

- System reliability and performance proved to be concordant with Q-Linea CE mark claim
  - >95% essential agreement.
  - Claimed organism list covered >95% of samples processed.
  - Compatibility of blood culture bottle types : BACTEC™ and BacT/Alert®.
  - <5 minutes hands on time. Average 2 – 3 minutes.

Actionable Results

- Communicated opportunities for:
  - de-escalation, including options to impact Initiation of appropriate therapy.
  - Antimicrobial dosing optimization.
  - Initiation of targeted therapy.

Ease of Use

- Automated high-capacity random access sample analysis with no requirement to batch samples.
  - An intuitive user interface and with simple load and go workflow that requires minimal user training and expert knowledge.

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2. Karam, G., Chastre, J., Wilcox, M. H., & Vincent, J. L. (2016). Antibiotic strategies in the era of multidrug resistance. Critical Care, 20(1), 1–9. https://doi.org/10.1186/s13054-016-1320-7

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