IMARI 2026. Poster #71286
29-01-2026

A Pooled Performance and Adjudication Analysis of ASTar® Rapid Antimicrobial Susceptibility Testing System from Gram-negative Positive Blood Cultures (Updated)

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Background

Rapid phenotypic susceptibility results of Gram-negative (GN) positive blood cultures (PBC) can improve timely optimal antibiotic therapy and associated outcomes in patients with GN blood stream infections (BSI). The ASTar® rAST system (Q-linea) provides full phenotypic MIC results within 24 hours of blood culture collection (~6 hrs from run start), supporting timely optimal antibiotic therapy (Figure 1).

As with all rAST methods, performance must be comparable to standard of care (SoC) methods. Should discordance between methods occur, reference Broth Microdilution (BMD) can be used to adjudicate discrepancies.

We conducted a pooled analysis of ASTar performance on clinical and contrived Gram-negative (GN) positive blood cultures (PBCs). Any discrepancies between ASTar and SoC were evaluated by:

a) Re-testing with SoC AST systems, and/or
b) Adjudication by BMD

Figure 1. ASTar Instrument.

Materials and methods

- Analysis of AST results of Gram-negative (GN) isolates (n = 414) from 14 on-panel and two off-panel species tested using an ASTar Investigational Use Only BC G-Panel across five US clinical sites.
- The ASTar phenotypic and MIC results were compared to SoC across both retrospective clinical and contrived strains. Contrived strains included CDC Antimicrobial Resistance Isolate Bank (AR Isolate Bank (2)) isolates and clinical isolates with known resistance types.
- After pooling, data were reanalyzed using the updated 2025 FDA breakpoints. This reanalysis generated additional errors that were not present in the original dataset. As the study period had closed, isolates were not sent for re-adjudication.

Comparator methods

SoC testing was done using overnight subcultures in either MicroScan Walkaway (Beckman Coulter) at four sites; or Vitek 2 (BioMérieux) at one site.

Discrepancy resolution and adjudication

- Any available isolates with Very Major Errors (VMEs), Major Error (MEs) between ASTar and SoC underwent adjudication with repeat SoC testing and/or were tested using BMD. When available, Sensititre (Thermo Fisher) results were used in preference over BMD results from CDC AR Bank Isolates or Etest.
- Not all facilities performed SoC reruns or BMD adjudication for discrepant samples.
- Performance was evaluated across all facilities and in a subset of three facilities with discrepant samples that underwent higher rates of adjudication

Performance assessment parameters

Essential Agreement (EA), Very Major Errors (VMEs), Major Errors (MEs).
Performance was calculated pre-, partial-, and post-adjudication.

Results

Pathogen distribution

Across five clinical sites, a total of 414 Gram-negative isolates were evaluated, 317 (76.9%) of which were clinical isolates, and the remaining 95 (23.1%) of which were contrived isolates from the CDC AR Bank. (Table 2).

Table 2. Pathogen distribution

Pathogen - Clinical + Contrived (Spiked) across 5 institutions*	Total
Escherichia coli	177 (42.8%)
Klebsiella pneumoniae group	93 (22.5%)
Pseudomonas aeruginosa	33 (8.0%)
Enterobacter cloacae complex	29 (7.0%)
Proteus mirabilis	25 (6.0%)
Serratia marcescens	15 (3.6%)
Klebsiella oxytoca	14 (3.4%)
Klebsiella aerogenes	8 (1.9%)
Acinetobacter baumannii complex	6 (1.4%)
Citrobacter freundii complex	4 (1.0%)
Citrobacter koseri	3 (0.7%)
*Morganella morganii**	3 (0.7%)
*Haemophilus influenzae**	2 (0.5%)
Proteus vulgaris	2 (0.5%)
Total	**414**
Total Contrived/Spiked	**92 (22.2%)**

*Off panel pathogen.

Pre-, partial, and post-adjudication Agreement and Errors

- Following adjudication, ASTar overall Essential Agreement (EA) with SoC increased from 95.2% (five facilities) to 97.0% (three facilities).
- Categorical agreement (CA) increased from 92.6% (five facilities) to 93.4% (three facilities).
- Very Major Error (VME) rates improved from a pre-adjudication rate of 4.5%, to 2.7% partial-adjudication, to 1.6% post-adjudication.
- Major Error (ME) rates improved from a pre-adjudication rate of 1.9%, to 1.3% partial-adjudication, to 1.2% post-adjudication. (Table 3).

Table 3. Pre- and Post Adjudication Essential Agreement (EA), Categorical Agreement (CA), Very Major Errors (VME) and Major Errors (ME) Summary.

	Overall, EA (%, n/N)	Overall, CA (%, n/N)	VME (%)	ME (%)
Pre-adjudication (5 facilities)	95.2 (7,132/7,490)	92.6 (6,422/6,935)	4.5	1.9
Partial-adjudication (5 institutions)*	95.9 (7,181/7,490)	93.2 (6,459/6,933)	2.7	1.3
Post-adjudication (3 facilities) with >70% of discrepancies undergoing adjudication*	97.0 (4,609/4,752)	93.4 (4,054/4,342)	1.6	1.2

* Not all facilities performed discrepancy adjudication with either standard of care (SoC) repeat or broth microdilution (BMD).

Discrepancy resolution

- Of the 46 VMEs, 15/32 (46.9%) were resolved in favor of ASTar after repeat SoC testing (MicroScan/Vitek), and 16/29 (55.2%) were resolved to ASTar following BMD/CDC adjudication. Overall, 30/46 (65.2%) of VME discrepancies favored ASTar following adjudication with either repeat SoC and/or BMD adjudication.
- Of the 57 MEs, 11/42 (26.2%) were resolved in favor of ASTar after repeat SoC testing, and 23/44 (52.3%) were resolved to ASTar following BMD/CDC adjudication. Overall, 31/57 (54.4%) of ME discrepancies favored ASTar testing following adjudication with either repeat SoC and/or BMD adjudication. (Table 4).

Table 4. Summary of Adjudication of VMEs and MEs

Category	VMEs	MEs
Overall Rate Pre-Adjudication (%, 5 institutions)*	**4.5%**	**1.9%**
Overall Rate Post-Adjudication (%, 3 facilities)*	**1.6%**	**1.2%**
Total Before Rerun/BMD	46	57
Total Rerun MicroScan/Vitek	32	42
Total Resolved to ASTar Post Rerun	15	11
Total BMD/CDC MICs*	29	44
Total Resolved to ASTar Post BMD/CDC MICs	16	23
Total Resolved to ASTar Post Rerun + BMD/CDC MICs	30 (65.2%)	31 (54.4%)

* Not all facilities performed discrepancy adjudication with either standard of care (SoC) repeat or broth microdilution (BMD).

Definitions

Metric	Definition	Acceptable Criteria (CLSI M35)
Essential Agreement (EA)	% of results where MIC is ±1 doubling dilution of the reference	≥ 90% overall EA
Categorical Agreement (EA)	% of results where both systems yield the same interpretation (S/I/R)	≥ 90% overall CA
Very Major Error (VME)	False susceptible (test = S, reference = R)	≤ 3.0% of resistant results (1.5% for FDA)
Major Error (ME)	False resistant (test = R, reference = S)	≤ 3.0% of susceptible results

Conclusions

- ASTar provides rapid phenotypic results < 24 hours (2nd/3rd antibiotic dose) of blood culture collection in GN BSI (~6 hours post GN positive blood culture)
- This multisite pooled analysis utilizing an earlier version of the algorithm demonstrated that ASTar holds high agreement with SoC AST methods with EA and CA >90% before adjudication and improving further following discrepancy resolution
- Approximately two-thirds of evaluated VME discrepancies were resolved in favor of ASTar after repeat SoC testing or after reference BMD adjudication
- VME rate decreased by more than half, from a pre-adjudication rate of 4.5% to a post-adjudication rate of 1.6%
- Initial pre-adjudication ME rate was within acceptable limits (1.9%), and it further decreased post-adjudication to 1.2%
- Post-adjudication ASTar VME and EA rates were within acceptable limits for AST system evaluation and clinical use

Acknowledgements

We would like to thank the following Q-linea team members for their work on this pooled analysis: Eric Eriksson, Linde Brokmar, Martin Svedberg, Natalie Brown, Oliver Mainwaring.

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