A Pooled Performance Analysis of ASTar® Rapid Antimicrobial Susceptibility Testing System from *Pseudomonas aeruginosa* Positive and Contrived Blood Cultures

[1]Myers M, [2]Henry N, [2]Mutnal M, [3]Garrett E, [3]Bobenchik A, [4]Demessie G, [4]Yee R, [5]Cintrón M, [6]Marrero E, [6]Lauretta J, [7]Bao J, [7]Ponraj V, [1]Grawe J, [1]Gupta V* *Corresponding author: vikas.gupta@qlinea.com

[1]Q-linea, Uppsala, Sweden; [2]Baylor Scott and White Research Institute; [3]Penn State Hershey Medical Center, Hershey, PA; [4]George Washington University Hospital, Washington, DC; [5]Memorial Sloan Kettering Cancer Center, New York City, NY; [6]Lakeland Regional Health, Lakeland, FL; [7]Quest Diagnostics, Chantilly, VA

Background

Pseudomonas aeruginosa (PsA) bloodstream infections are associated with high patient mortality and substantial healthcare burden. There is a serious need for rapid and accurate antimicrobial susceptibility testing (AST) when caring for patients with this type of bloodstream infection.

To assess performance of the rapid AST system ASTar® (Q-linea AB) (Figure 1) and the newly-FDA-cleared BC G-Kit v2 (Table 1), a pooled analysis was conducted using both clinical and contrived PsA-positive blood cultures (PBCs).

The analysis evaluated discrepancy testing between ASTar and standard of care (SoC) methods, including:
1) repeat testing with SoC AST systems, and
2) adjudication with broth microdilution (BMD) as the reference method.

Figure 1. ASTar Instrument and kit consumables (cartridge and AST disc) *(not to scale)*

Methods

- Pooled AST results generated using ASTar (7 US sites) with the ASTar BC G- Kit panel (Investigational Use Only), were compared to SoC testing of PsA-positive blood cultures of overnight subcultures and contrived isolates (CDC AR Bank[1] and clinical sources). SoC testing was performed using Microscan WalkAway (4 sites) or Vitek 2 (3 sites).
- Performance was evaluated across 11 antipseudomonal antibiotics using 2025 FDA STIC interpretive criteria[2]: essential agreement (EA), categorical agreement (CA), very major errors (VME), and major errors (ME).
- Isolates with AST discrepancies underwent repeat testing using SoC methods and/or adjudication by BMD.
- Where available, BMD results from Sensititre (Thermo Fisher) were prioritized over BMD results from CDC AR Bank isolates.

Conclusions

- Overall EA and CA agreement between ASTar and SoC methods was > 90% for PsA-positive blood cultures, both pre- and post-adjudication.
- Post-adjudication VME and ME rates were within acceptable performance thresholds.
- Sixty percent (3 of 5) of evaluated VME discrepancies were resolved in favor of ASTar after repeat SoC testing or adjudication by reference BMD.

References

1. CDC & FDA Antimicrobial Resistance Isolate Bank: https://wwwn.cdc.gov/arisolatebank/
2. U.S. Food and Drug Administration. Antibacterial Susceptibility Test Interpretive Criteria. Available at: https://www.fda.gov/drugs/development-resources/antibacterial-susceptibility-test-interpretive-criteria

Results

A total of 71 PsA isolates were evaluated across 7 sites: 28.2% (20/71) were carbapenem-resistant, 21.1% (15/71) were multidrug-resistant, and 11.3% (8/71) were difficult-to-treat resistant.

High agreement was observed both pre- and post-adjudication:
- Overall EA of 96.3% (698/725) and 96.7% (701/725), pre- and post-adjudication
- Overall CA of 93.6% (644/688) and 94.3% (649/688), pre- and post-adjudication
- VME rates decreased from 3.7% (5/135) to 1.5% (2/133), following adjudication
- ME rates decreased from 1.0% (5/500) to 0.6% (3/500), following adjudication.

Overall, post-adjudication EA for all antibiotics was > 90%, and post-adjudication CA was > 90% for all antibiotics except aztreonam (86.9%) and cefepime (87.1%). Post-adjudication VME rates were < 3.0% for all antipseudomonal antibiotics, except for amikacin (33.3%) and tobramycin (12.5%) (Table 2).

Notably, 60% (3/5)of VMEs were resolved in favor of ASTar following repeat SoC testing or BMD adjudication, including aztreonam, ceftazidime-avibactam, and piperacillin-tazobactam.

Table 1. April 2024 (v1), ASTar BC G- FDA cleared panel.

Antimicrobial class	Antimicrobial agent	*A. baumanii* complex	*C. freundii* complex	*C. koseri*	*E. cloacae* complex	*E. coli*	*K. aerogenes*	*K. oxytoca*	*K. pneumoniae* group	*M. morganii*	*P. mirabilis*	*P. vulgaris*	*S. marcescens*	*P. aeruginosa*
Penicillin	Ampicillin					•					•			
β-lactam combination agents	Ampicillin-sulbactam[1]	•		•		•		•	•	•	•	•		
β-lactam combination agents	Ceftolozane-tazobactam[2]		•	•	•	•		•	•		•	•	•	•
β-lactam combination agents	Ceftazidime-avibactam[3]		•	•	•	•	•	•	•	•	•	•	•	•
β-lactam combination agents	Meropenem-vaborbactam[4]		•	•	•	•	•	•	•	•	•	•	•	
β-lactam combination agents	Piperacillin-tazobactam[2]	•	•	•		•	•		•	•	•	•	•	
Cephalosporin	Cefazolin			•		•		•	•		•			
Cephalosporin	Cefepime		•	•	•	•	•	•	•		•	•	•	•
Cephalosporin	Cefotaxime		•	•	•	•		•	•		•	•	•	
Cephalosporin	Ceftriaxone		•	•	•	•	•	•	•		•	•	•	
Cephalosporin	Cefoxitin			•		•		•	•		•			
Cephalosporin	Cefuroxime			•		•		•	•		•			
Cephalosporin	Ceftazidime	•	•	•	•	•	•	•	•	•	•	•	•	
Monobactam	Aztreonam		•	•	•	•	•	•	•	•	•	•	•	•
Carbapenem	Ertapenem		•	•	•	•		•	•		•	•	•	
Carbapenem	Meropenem	•	•	•	•	•	•	•	•	•	•	•	•	•
Aminoglycoside	Gentamicin		•	•				•	•	•	•	•	•	
Aminoglycoside	Tobramycin		•	•	•	•	•	•	•		•	•		•
Aminoglycoside	Amikacin	•	•	•	•	•	•	•	•	•	•	•	•	
Tetracycline	Tigecycline		•	•	•	•	•	•	•				•	
Fluoroquinolone	Ciprofloxacin		•	•	•	•	•	•	•	•	•	•	•	•
Fluoroquinolone	Levofloxacin		•	•	•	•	•	•	•	•	•	•	•	•
Miscellaneous	Trimethoprim-sulfamethoxazole[5]		•	•	•	•	•	•	•	•		•		

[1] Ampicillin-sulbactam in the ratio 2:1
[2] For susceptibility testing purposes, the concentration of tazobactam is fixed at 4 µg/mL
[3] For susceptibility testing purposes, the concentration of avibactam is fixed at 4 µg/mL
[4] For susceptibility testing purposes, the concentration of vaborbactam is fixed at 8 µg/mL
[5] Trimethoprim:sulfamethoxazole in the ratio 1:19

Table 2. April 2026 (v2). Pre- and Post Adjudication Essential Agreement (EA), Categorical Agreement (CA), Very Major Errors (VME) and Major Errors (ME) Summary.

	Pre-Adjudication				Post-Adjudication			
Antimicrobial	**EA % (n/N)**	**CA % (n/N)**	**VME % (n)**	**ME % (n)**	**EA % (n/N)**	**CA % (n/N)**	**VME % (n)**	**ME % (n)**
Amikacin †	98.4% (62/63)	98.4% (62/63)	33.3% (1)	0% (0)	98.4% (62/63)	98.4% (62/63)	33.3% (1*)	0% (0)
Aztreonam	90.2% (55/61)	85.2% (52/61)	6.3% (1)	2.5% (1)	91.8% (56/61)	86.9% (53/61)	0% (0)	2.4% (1)
Cefepime	92.9% (65/70)	87.1% (61/70)	0% (0)	2.0% (1)	92.9% (65/70)	87.1% (61/70)	0% (0)	2.0% (1)
Ceftazidime †	92.2% (59/64)	96.9% (62/64)	0% (0)	0% (0)	92.2% (59/64)	96.9% (62/64)	0% (0)	0% (0)
Ceftazidime-avibactam	96.9% (63/65)	93.8% (61/65)	14.3% (1)	5.2% (3)	98.5% (64/65)	98.5% (64/65)	0% (0)	1.8% (1)
Ceftolozane-tazobactam	100% (64/64)	95.3% (61/64)	0% (0)	0% (0)	100% (64/64)	95.3% (61/64)	0% (0)	0% (0)
Ciprofloxacin	98.6% (69/70)	95.7% (67/70)	0% (0)	0% (0)	98.6% (69/70)	95.7% (67/70)	0% (0)	0% (0)
Levofloxacin	98.6% (69/70)	91.4% (64/70)	0% (0)	0% (0)	98.6% (69/70)	91.4% (64/70)	0% (0)	0% (0)
Meropenem	98.6% (69/70)	97.1% (68/70)	0% (0)	0% (0)	98.6% (69/70)	97.1% (68/70)	0% (0)	0% (0)
Piperacillin-tazobactam †	97.0% (65/67)	95.5% (64/67)	5.3% (1)	0% (0)	98.5% (66/67)	97.0% (65/67)	0% (0)	0% (0)
Tobramycin	95.1% (58/61)	91.7% (22/24)	12.5% (1)	0% (0)	95.1% (58/61)	91.7% (22/24)	12.5% (1*)	0% (0)
Grand Total	**96.3% (698/725)**	**93.6% (644/688)**	**3.7% (5)**	**1.0% (5)**	**96.7% (701/725)**	**94.3% (649/688)**	**1.5% (2*)**	**0.6% (3)**

* Method of adjudication was repeat by comparator method and not adjudicated by BMD.
† Not FDA cleared

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