A proof-of-concept evaluation of rapid MIC-based antimicrobial susceptibility testing from colonies using ASTar®

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Background

A major part of clinical microbiology standard of care (SoC) antimicrobial susceptibility testing (AST) is testing of colonies from overnight culture. SoC AST is often performed overnight, further delaying results.
ASTar® is a fully automated phenotypic rapid AST system that delivers minimum inhibitory concentration (MIC) and categorical interpretation (S/I/R) results in approximately six hours when testing is performed directly from positive blood cultures[1]. (*Fig 1*).

In this investigational-use-only study, we evaluated the performance of an experimental ASTar workflow when AST was initiated directly from non-blood isolated colonies.

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

Conclusions

- Earlier availability of susceptibility information may help improve management of severe bacterial infections other than bacteraemia
- This feasibility study of the ASTar rapid AST system direct from isolated colonies indicates good overall antibiotic performance against highly-resistant Gram-negative pathogens
- These findings support the potential future use of ASTar for early availability of actionable AST results directly from non-blood isolated colonies

Materials and methods

A total of 219 isolates from the CDC Antibiotic Resistance Bank (CDC AR Bank)[2], Antibacterial Resistance Leadership Group Biorepository (ARLG Biorepository)[3], American Type Culture Collection (ATCC)[4], and previously-collected clinical isolates were included, representing 12 Gram-negative species or species groups.

This experimental workflow is outside the current claims for the ASTar BC G- Kit but represents a potential for future validation. A kit designed for isolated colonies is under development.

- Isolates were cultured overnight on Tryptic Soy Agar (TSA-S) plates with 5% sheep blood.
- 3-5 colonies were resuspended in 2 mL of Cation-Adjusted Mueller-Hinton Broth (CAMHB), where 1 mL was loaded in a standard ASTar® BC G- Kit cartridge.
- Samples were processed in ASTar, including fully-automated preparation of a controlled inoculum where no manual sample concentration measurement or dilution is required (target 5 x 10^5 CFU/mL in CAMHB).
- Minimum inhibitory concentration (MIC) values were determined using prototype algorithms, and EUCAST breakpoints were applied for categorical (S/I/R) interpretation.
- Essential agreement (EA), categorical agreement (CA), very major errors (VME), major errors (ME), and minor errors (mE) were evaluated based on reference BMD for each isolate using EUCAST breakpoints v. 15.0, 2025.

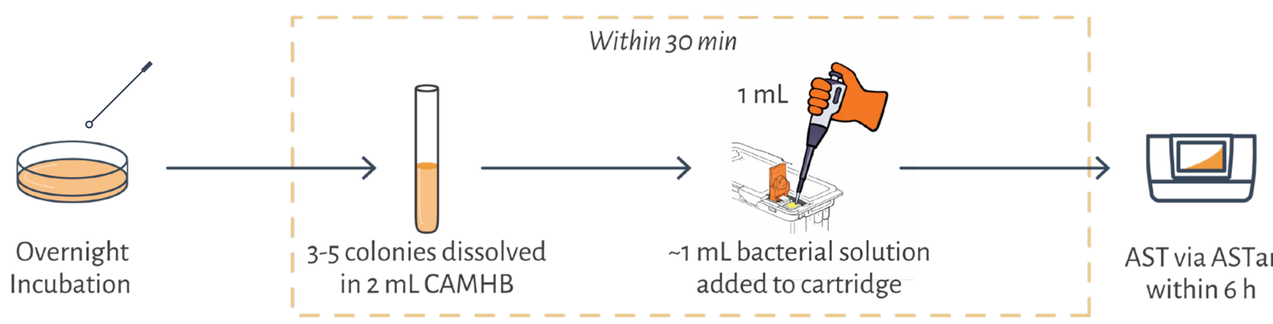
References

1. Göransson, J et al. "Performance of a System for Rapid Phenotypic Antimicrobial Susceptibility Testing of Gram Negative Bacteria Directly from Positive Blood Culture Bottles." Journal of clinical microbiology vol. 61,3 (2023): e0152522. doi:10.1128/jcm.01525-22
2. CDC & FDA Antimicrobial Resistance Isolate Bank: https://wwwn.cdc.gov/arisolatebank/
3. American Type Culture Collection (ATCC): https://www.atcc.org
4. Antibacterial Resistance Leadership Group (ARLG) Biorepository: https://arlg.org/laboratory-center-strain-access/
5. The European Committee on Antimicrobial Susceptibility Testing. Breakpoint tables for interpretation of MICs and zone diameters. Version 15.0 2025. http://www.eucast.org

Results

Workflow

Rapid AST from Gram-negative colonies was run using ASTar in this Isolate G- investigation-use-only kit.



Resistance distribution

Across 219 Gram-negative isolates evaluated, 83.1% were *Enterobacterales*, 11.0% were *P. aeruginosa*, and 5.9% were *A. baumannii*.

- Of these Gram-negative pathogens evaluated, 22.1% were ESBL-E, 33.8% were Carb-NS, 43.4% were MDR, and 16.9% were DTR.
- Of 182 *Enterobacterales* evaluated, 31.3% were Carb-NS, 42.3% were MDR, and 11.0% were DTR
- Of 74 Carb-NS isolates evaluated, 44 were meropenem NS for a rate of 20.1% (44/219)

Table 1. Gram-negative isolates and antimicrobial resistance distribution for bacteria evaluated using EUCAST breakpoints v. 15.0.

Pathogen	Isolates, % (n)	ESBL-E % (n)	Carb NS % (n)	MDR % (n)	DTR % (n)
Escherichia coli	26.5% (58)	20.7% (12)	37.9% (22)	50.0% (29)	8.6% (5)
Klebsiella pneumoniae	17.8% (39)	17.9% (7)	56.4% (22)	71.8% (28)	33.3% (13)
Pseudomonas aeruginosa	11.0% (24)	-	54.2% (13)	66.7% (16)	54.2% (13)
Enterobacter cloacae complex	7.8% (17)	-	47.1% (8)	47.1% (8)	11.8% (2)
Acinetobacter baumannii	5.9% (13)	-	30.8% (4)	15.4% (2)	30.8% (4)
Klebsiella oxytoca	5.9% (13)	30.8% (4)	7.7% (1)	15.4% (2)	0% (0)
Proteus mirabilis	5.5% (12)	33.3% (4)	0% (0)	33.3% (4)	0% (0)
Serratia marcescens	5.0% (11)	-	9.1% (1)	18.2% (2)	0% (0)
Citrobacter freundii	4.1% (9)	-	11.1% (1)	11.1% (1)	0% (0)
Klebsiella aerogenes	4.1% (9)	-	22.2% (2)	33.3% (3)	0% (0)
Citrobacter koseri	3.2% (7)	-	0% (0)	0% (0)	0% (0)
Proteus vulgaris	3.2% (7)	-	0% (0)	0% (0)	0% (0)
Grand total	**219**	**27.0% (27/122)***	**33.8% (74)†**	**43.4% (95)**	**16.9% (37)**

ESBL-E, extended-spectrum beta-lactamase-producing *Enterobacterales*; Carb NS, carbapenem non-susceptible; MDR, multidrug-resistant; DTR, difficult-to-treat resistance.
* ESBL-E that are not Carb NS; † 44/74 Carb NS are meropenem NS for a rate of 20.1% (44/219)

Antibiotic performance

Across *Enterobacterales*, *P. aeruginosa*, and *A. baumannii* isolates evaluated, the EA% and CA% were >90% except for EA% for *A. baumannii* being 88.1%.

Table 2. Overall antibiotic performance in Gram-negative isolates by pathogen group using EUCAST breakpoints.

Pathogen Group	EA % (n/N)	CA % (n/N)	VME % (n/N)	ME % (n/N)	mE % (n/N)
Enterobacterales	94.0% (3,471/3,694)	96.5% (3,169/3284)	3.0% (36/1,212)	2.1% (41/1,989)	1.2% (38/3,284)
Pseudomonas aeruginosa	96.9% (278/287)	94.3% (248/263)	4.7% (5/107)	0.0% (0/92)	3.8% (10/263)
Acinetobacter baumannii	88.1% (148/168)	94.4% (85/90)	0.0% (0/33)	5.8% (3/52)	2.2% (2/90)
Grand total	**93.9% (3,897/4,149)**	**96.3% (3,502/3,637)**	**3.0% (41/1,352)**	**2.1% (44/2,133)**	**1.4% (50/3,637)**

EA, essential agreement; CA, categorical agreement; VME, very major errors; ME, major errors; mE, minor errors

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