ASTar Phenotypic ESBL Indication from Positive Blood Cultures Correlated with bla$_{CTX-M}$ Genotype

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Background

ESBL-producing Enterobacterales (ESBL-E) can be identified phenotypically by elevated minimum inhibitory concentrations (MICs) to selected β-lactam agents and genotypically by detection of associated resistance genes, most commonly bla$_{CTX-M}$.

The ASTar System provides phenotypic MIC results in ~6 hours from assay start — about 36-40 hours earlier than standard of care (SoC) methods (Figure 1).

Pooled antibiogram data from positive blood culture (PBC) data were analyzed to compare ASTar phenotypic ESBL-E and non-ESBL-E classifications with bla$_{CTX-M}$ genotypic results.

Methods

- Pooled results from four US facilities were analyzed by comparing bla$_{CTX-M}$ genotypes with MIC results from prospective and contrived PBCs tested using the ASTar BC G- Kit panel (IUO) and standard-of-care (SoC) instruments for *E. coli, K. pneumoniae, K. oxytoca*, and *P. mirabilis* (Table 1).
- Across four institutions, three used MicroScan WalkAway and one used Vitek2 as standard-of-care instruments. For molecular testing, BCID2 was used at three sites and Verigene at one.
- Samples with MIC results ≥2 µg/mL for at least one of Ceftazidime, Ceftriaxone, Cefotaxime, or Aztreonam were considered phenotypically indicative of ESBL activity as identified by ASTar according to CLSI M100 35 Ed (Table 2) and classified as ESBL-E (IUO).
- ASTar performance for bla$_{CTX-M}$-positive and bla$_{CTX-M}$-negative isolates was assessed for essential agreement (EA), categorical agreement (CA), very major errors (VME), and major errors (ME).

A portion of the data was generated using an earlier version of the software (investigational use only, IUO, 2023) Therefore, the performance characteristics of the current FDA-cleared version (April 2026, v2), including algorithms and claims, may differ from those reflected in this dataset.

Conclusions

- High agreement was observed between bla$_{CTX-M}$ genotype and ASTar phenotypic ESBL indication among Enterobacterales from PBCs.
- ASTar identified a subset of presumed ESBL-E samples not detected by commercial molecular assays, with SoC AST results supporting these findings.
- The results indicate future potential for the ASTar System to provide MIC-based ESBL-E indication significantly earlier than SoC.

References

1. Clinical and Laboratory Standards Institute. Performance Standards for Antimicrobial Susceptibility Testing. 35th ed. CLSI supplement M100. CLSI; 2025.

Results

A total of 237 Enterobacterales isolates were evaluated, of which 48 (20.3%) were bla$_{CTX-M}$-positive and 59 (24.9%) were ESBL-E (Table 1).

Phenotypic correlation of ESBL-E by ASTar aligned with bla$_{CTX-M}$ genotype for 226/237 samples. bla$_{CTX-M}$ was not detected in 18.6 % (11/59) of ESBL-E while bla$_{CTX-M}$ was identified in 0.0% (0/178) of phenotypic Non-ESBL-E (Table 1).

The EA% for ASTar was > 90% for ceftriaxone, cefotaxime, and aztreonam and was 87.7% for ceftazidime, indicating the ability of ASTar to use multiple antibiotics to identify ESBL-E isolates (Table 2).

The EA, CA, VME and ME rate for ASTar was 94.3%, 91.7%, 0.9% and 3.0%, respectively in ESBL-E isolates (Table 3).

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

Table 1. Distribution of phenotypic resistance indicating ESBL-E* and bla$_{CTX-M}$ positive in ENT.

Pathogen	N (%)	ESBL-E + Carba S (n, %)	ESBL-E + Carba S and bla$_{CTX-M}$ Pos	ESBL-E + Carba S and bla$_{CTX-M}$ Neg	Non-ESBL-E and bla$_{CTX-M}$ Pos
ENT Total	**237**	**59 (24.9%)**	**48 (81.4%)**	**11 (18.6%)**	**0 (0.0%)**
Escherichia coli	133 (56.1%)	31 (23.3%)	25 (80.6%)	6 (19.4%)	0 (0.0%)
Klebsiella pneumoniae group	73 (30.8%)	22 (30.1%)	19 (86.4%)	3 (13.6%)	0 (0.0%)
Proteus mirabilis	20 (8.4%)	3 (15.0%)	3 (100.0%)	0 (0.0%)	0 (0.0%)
Klebsiella oxytoca	11 (4.6%)	3 (27.3%)	1 (33.3%)	2 (66.7%)	0 (0.0%)

*ESBL-E, extended-spectrum beta-lactamase-producing Enterobacterales; Carb S, carbapenem susceptible; * ESBL-E that are not Carb NS*

Table 2. ASTar performance of bla$_{CTX-M}$ positive ENT post-adjudication.

Pathogen	EA n/N (%)	CA n/N (%)	VME n/N (%)	ME n/N (%)
Aztreonam	35/38 (92.1%)	36/38 (94.7%)	0/34 (0.0%)	0/3 (0.0%)
Cefotaxime	34/35 (97.1%)	26/26 (100.0%)	0/26 (0.0%)	0/0 (0.0%)
Ceftazidime	50/57 (87.7%)	50/57 (87.7%)	0/46 (0.0%)	1/6 (16.7%)
Ceftriaxone	50/51 (98.0%)	51/51 (100.0%)	0/50 (0.0%)	0/1 (0.0%)

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

Table 3. Overall ASTar antibiotic performance for non-ESBL-E and ESBL-E

Non-ESBL-E				ESBL-E (including Carb-NS)			
EA % n/N	CA % n/N	VME % n/N	ME % n/N	EA % n/N	CA % n/N	VME % n/N	ME % n/N
98.6% (2692/2729)	94.5% (2333/2470)	1.6% (2/127)	0.0% (17/2287)	94.3% 1447/1534)	91.7% 1323/1442)	0.9% (8/906)	3.0% (14/472)

ESBL-E, extended-spectrum beta-lactamase-producing Enterobacterales; Carb NS, carbapenem non-susceptible; EA, essential agreement; CA, categorical agreement; VME, very major errors; ME, major error

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