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## Introduction

-Lactam agents are commonly used as the primary therapeutic options for serious infections caused by Enterobacterales isolates.

- Accurate susceptibility results for -lactam/ -lactamase inhibitors (BL/BLIs) are crucial to treat Enterobacterales infections.
- The VITEK® 2 Advanced Expert System (AES) provides standardized phenotypic interpretation of MIC results based on an extensive database of MIC distributions and prevalent resistance mechanisms in Enterobacterales isolates.
- In this study, the BL/BLI susceptibility results from the VITEK® 2 AES were compared to the CLSI broth microdilution method (BMD) results against 513 molecularly characterized Enterobacterales isolates from North and Latin America.

## Materials and Methods

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- A total of 407 clinical isolates were collected from 73 hospitals in 7 countries as part of the SENTRY Antimicrobial Surveillance Program during 2016–2019; an additional 106 isolates were from the CDC & US FDA Antibiotic Resistance Bank (Figure 1).
- Isolates were grouped into the following main group/species: *K. pneumoniae* (*n*=177), *E. coli* (*n*=134), *E. cloacae* species complex (*n*=72), and other Enterobacterales species (*n*=130; Figure 2A).

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- Broth microdilution (BMD) susceptibility testing for amoxicillin-clavulanic acid, ampicillin-sulbactam, piperacillin-tazobactam, ceftazidime-avibactam, ceftolozane-tazobactam, and meropenem-vaborbactam was conducted according to CLSI M07 guidelines using frozen-form, 96-well plates produced by JMI Laboratories.
- All isolates were tested by the VITEK® 2 with 9.02 software version using N802 and XN15 AST cards.
- MIC results were generated using the AES in the Global Clinical and Laboratory Studies Institute (CLSI)-based + Natural Resistance (NATR) mode and were reviewed by a microbiologist.
- CLSI clinical breakpoints were applied.
- Discordant results were repeated by both methods using the same inoculum.
- Essential (EA) and categorical agreement (CA) rates and error rates, such as very major (VME), major (ME), and minor error (mE) rates, were calculated based on the CLSI guidelines.

- Whole genome sequencing (WGS) was performed on isolates that met the following criteria by BMD:
  - *E. coli* and *K. pneumoniae* isolates displaying MIC values ≥2 mg/L for at least 2 of the following -lactams: aztreonam, cefepime, ceftazidime, or ceftriaxone; and/or
  - Enterobacterales isolates displaying meropenem and/or imipenem MIC results >1 mg/L.
- Enterobacterales isolates that did not meet the criteria for molecular characterization were considered wildtype.

## Results

- Among the isolates that met the molecular criteria, 211 harbored carbapenemase genes (41.1%), while 122 and 32 isolates carried ESBL (23.8%) and transferrable AmpC (6.2%) genes, respectively (Figure 2B).
- A total of 148 isolates were considered wildtype by acquired -lactamase genes.
- Table 1 and Figures 3A and 3B display the VITEK® 2 EA and CA rates compared to BMD for each organism group.
- EA and CA rates were ≥90% for ampicillin-sulbactam, ceftazidime-avibactam, and meropenem-vaborbactam, except for *K. pneumoniae* (ceftazidime-avibactam EA, 85.3%) and other Enterobacterales (ampicillin-sulbactam CA, 84.0%).
  - Ampicillin-sulbactam displayed 1 VME and 7 mE against other Enterobacterales (Table 1).
- Amoxicillin-clavulanic acid EA rates were ≥90% for all organism groups, and CA rates were 89.3%, 88.8%, 98.6%, and 95.8% for *K. pneumoniae*, *E. coli*, *E. cloacae* complex, and other Enterobacterales, respectively (Table 1).
  - Amoxicillin-clavulanic acid discordances were mostly due to mE (35 occurrences) (Table 1).
  - Two VME and 3 ME were also noted (Table 1).
- Piperacillin-tazobactam EA rates were ≥90% for all organism groups, and CA rates were 93.2% (*K. pneumoniae*), 89.6% (*E. coli*), 87.3% (*E. cloacae* complex), and 89.4% (other Enterobacterales).
  - A total of 2 VME, 5 ME, and 38 mE were observed for piperacillin-tazobactam (Table 1).
- EA/CA rates were ≥90% for ceftolozane-tazobactam against *K. pneumoniae* and other Enterobacterales and were 89.6%/87.3% and 84.5%/87.3% against *E. coli* and *E. cloacae* complex, respectively.
  - Ceftolozane-tazobactam discordances were due to 1 VME, 12 ME, and 29 mE (Table 1).
- Table 2 displays the occurrence of VME and ME split by -lactamase content.

[illegible] 2. C [illegible] (n =513) [illegible]

[illegible] 3. T [illegible] 2 [illegible] A [illegible] CA [illegible]

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