# 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
# DECISION SUMMARY
ASSAY ONLY

## I Background Information:

### A 510(k) Number
K211748

### B Applicant
Selux Diagnostics, Inc

### C Proprietary and Established Names
Selux AST System; Model AST Gen 1.0

### D Regulatory Information

| Product Code(s) | Classification | Regulation Section | Panel |
|---|---|---|---|
| LON | Class II | 21 CFR 866.1645 - Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System | MI - Microbiology |
| LTT | Class II | 21 CFR 866.1640 - Antimicrobial susceptibility test powder | MI - Microbiology |
| LTW | Class II | 21 CFR 866.1640 - Antimicrobial susceptibility test powder | MI - Microbiology |

## II Submission/Device Overview:

### A Purpose for Submission:
To obtain substantial equivalence determination for Gram-negative organisms tested with the Selux AST System to determine the minimum inhibitory concentration of specific antimicrobials with specific Gram-negative organisms.

### B Measurand:

| Antimicrobial | Reportable Range |
|---|---|
| Amikacin | ≤0.12 to ≥256 µg/mL |
| Amoxicillin-Clavulanate | ≤0.5 to ≥128 µg/mL |
| Ampicillin | ≤0.25 to ≥128 µg/mL |
| Ampicillin-Sulbactam | ≤0.5 to ≥128 µg/mL |

| Antimicrobial | Reportable Range |
|---|---|
| Aztreonam | ≤0.03 to ≥128 µg/mL |
| Cefazolin | ≤0.12 to ≥128 µg/mL |
| Cefepime | ≤0.25 to ≥128 µg/mL |
| Cefoxitin | ≤1 to ≥128 µg/mL |
| Ceftazidime | ≤0.25 to ≥64 µg/mL |
| Ceftazidime-Avibactam | ≤0.12 to ≥64 µg/mL |
| Ceftriaxone | ≤0.25 to ≥32 µg/mL |
| Ciprofloxacin | ≤0.03 to ≥16 µg/mL |
| Eravacycline | ≤0.016 to ≥4 µg/mL |
| Ertapenem | ≤0.03 to ≥16 µg/mL |
| Gentamicin | ≤0.06 to ≥64 µg/mL |
| Imipenem-Relebactam | ≤0.03 to ≥128 µg/mL |
| Levofloxacin | ≤0.06 to ≥32 µg/mL |
| Meropenem | ≤0.12 to ≥64 µg/mL |
| Meropenem-Vaborbactam | ≤0.06 to ≥64 µg/mL |
| Minocycline | ≤0.25 to ≥64 µg/mL |
| Piperacillin-Tazobactam | ≤0.25 to ≥512 µg/mL |
| Tobramycin | ≤0.12 to ≥128 µg/mL |
| Trimethoprim-Sulfamethoxazole | ≤0.12 to ≥32 µg/mL |

**C Type of Test:**

Quantitative antimicrobial susceptibility test (AST) system that utilizes colorimetric, oxidation-reduction and growth-based strategies to determine the minimum inhibitory concentration (MIC) of specific antimicrobial-organism combinations.

## III Intended Use/Indications for Use:

**A Intended Use(s):**

The Selux AST System is intended to be used for the automated quantitative or qualitative susceptibility testing for most clinically significant aerobic microorganisms. The Selux AST System does not provide organism identification.

**B Indication(s) for Use:**

The Selux Gram-Negative Panel is intended for use with the Selux AST System as an *in vitro* test to determine the susceptibility of isolated colonies of specific gram-negative bacilli to specific antimicrobial agents when used as instructed.

The Selux Gram-Negative Panel is a quantitative test for the following antimicrobial agents with the specific organisms identified below:

- Amikacin: *Pseudomonas aeruginosa*
- Amoxicillin-Clavulanate: *Escherichia coli, Klebsiella* species (including *K. oxytoca, K. pneumoniae*), *Proteus mirabilis*
- Ampicillin: *Escherichia coli, Proteus mirabilis*
- Ampicillin-Sulbactam: *Acinetobacter baumannii* complex*, Escherichia coli, Klebsiella* species (including *K. oxytoca, K. pneumoniae*), *Proteus mirabilis, Proteus vulgaris*
- Aztreonam: *Escherichia coli*

- Cefazolin: *Escherichia coli, Klebsiella pneumoniae*
- Cefepime: *Citrobacter freundii* complex, *Citrobacter koseri, Enterobacter cloacae* complex, *Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*
- Cefoxitin: *Escherichia coli, Klebsiella* species (including *K. oxytoca, K. pneumoniae*), *Morganella morganii*
- Ceftazidime: *Citrobacter* species (including *C. freundii* complex*, C. koseri*), *Enterobacter cloacae* complex*, Escherichia coli, Klebsiella* species (including *K. aerogenes, K. oxytoca, K. pneumoniae*), *Proteus mirabilis, Proteus vulgaris, Serratia marcescens*
- Ceftazidime-Avibactam: *Citrobacter freundii* complex*, Citrobacter koseri, Enterobacter cloacae* complex*, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens*
- Ceftriaxone: *Citrobacter freundii* complex, *Citrobacter koseri, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis*
- Ciprofloxacin: *Citrobacter freundii* complex, *Citrobacter koseri, Enterobacter cloacae* complex, *Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa*
- Eravacycline: *Citrobacter freundii* complex, *Enterobacter cloacae* complex, *Escherichia coli, Klebsiella oxytoca*
- Ertapenem: *Citrobacter freundii* complex, *Citrobacter koseri, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*
- Gentamicin: *Citrobacter* species (including *C. freundii* complex*, C. koseri*), *Enterobacter cloacae* complex, *Escherichia coli, Klebsiella* species (including *K. aerogenes, K. oxytoca, K. pneumoniae*), *Proteus* species (including *P. mirabilis, P. vulgaris), Pseudomonas aeruginosa, Serratia marcescens*
- Imipenem-Relebactam: *Citrobacter freundii* complex, *Citrobacter koseri, Escherichia coli, Klebsiella oxytoca, Pseudomonas aeruginosa*
- Levofloxacin: *Citrobacter freundii* complex, *Citrobacter koseri, Enterobacter cloacae* complex, *Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*
- Meropenem: *Citrobacter freundii* complex, *Citrobacter koseri, Enterobacter cloacae* complex, *Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens*
- Meropenem-Vaborbactam: *Citrobacter freundii* complex, *Citrobacter koseri, Enterobacter cloacae* complex, *Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Serratia marcescens*
- Minocycline: *Escherichia coli, Klebsiella* species (including *K. aerogenes, K. oxytoca, K. pneumoniae*)
- Piperacillin-Tazobactam: *Citrobacter koseri, Escherichia coli, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris*
- Tobramycin: *Pseudomonas aeruginosa*
- Trimethoprim-Sulfamethoxazole: *Enterobacter cloacae* complex, *Klebsiella* species (including *K. aerogenes, K. oxytoca, K. pneumoniae*)

**C Special Conditions for Use Statement(s):**

- Rx - For Prescription Use Only

The following limitations were added to the device labeling based on performance demonstrated in the current submission:

- The ability of the Selux AST system to detect resistance in the following antimicrobial/organism combinations is unknown because an insufficient number of resistant isolates were available at the time of comparative testing:
  - Ampicillin-Sulbactam: *Proteus vulgaris*
  - Cefepime: *Klebsiella aerogenes, Morganella morganii, Proteus vulgaris, Serratia marcescens*
  - Cefoxitin: *Klebsiella oxytoca*
  - Ceftazidime-avibactam: *Citrobacter koseri, Klebsiella aerogenes, Klebsiella oxytoca, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*
  - Ciprofloxacin: *Citrobacter koseri, Proteus vulgaris*
  - Eravacycline: *Escherichia coli, Klebsiella oxytoca*
  - Ertapenem: *Citrobacter koseri, Klebsiella oxytoca, Morganella morganii, Proteus mirabilis, Proteus vulgaris*
  - Gentamicin: *Klebsiella aerogenes, Morganella morganii, Proteus vulgaris, Serratia marcescens*
  - Imipenem-Relebactam: *Citrobacter koseri, Klebsiella aerogenes, Klebsiella oxytoca*
  - *Levofloxacin: Citrobacter koseri*
  - Meropenem: *Citrobacter koseri, Klebsiella oxytoca, Morganella morganii, Proteus vulgaris*
  - Meropenem-vaborbactam: *Citrobacter koseri, Klebsiella aerogenes, Klebsiella oxytoca, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*
  - Minocycline: *Klebsiella oxytoca*
  - Piperacillin-tazobactam: *Citrobacter koseri, Proteus mirabilis, Proteus vulgaris*

- Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):
  - Amikacin: *Acinetobacter baumannii*
  - Ampicillin: *Proteus mirabilis* when the Selux MIC is 2 µg/mL due to one very major error
  - Ampicillin-Sulbactam: *Proteus vulgaris* when the Selux MIC is 32 µg/mL due to 3 major errors
  - Aztreonam: *Pseudomonas aeruginosa*
  - Cefazolin: *Proteus mirabilis*
  - Cefepime: *Klebsiella aerogenes* when the Selux MIC is ≥64 µg/mL due to 2 major errors, *Pseudomonas aeruginosa*
  - Cefoxitin: *Proteus mirabilis, Proteus vulgaris*
  - Ceftazidime: *Acinetobacter baumannii, Pseudomonas aeruginosa*
  - Ceftriaxone: *Enterobacter cloacae, Serratia marcescens*
  - Ciprofloxacin: *Serratia marcescens*
  - Eravacycline: *Klebsiella pneumoniae*
  - Ertapenem: *Citrobacter freundii* complex when the Selux MIC is 2, 4, or 8 µg/mL due to 3 major errors, *Enterobacter cloacae, Klebsiella aerogenes*
  - Gentamicin: *Pseudomonas aeruginosa* when the Selux MIC is ≤0.06 µg/mL

- Imipenem: *Acinetobacter baumannii*
- Imipenem-Relebactam: *Klebsiella oxytoca* when the Selux MIC is 4 µg/mL due to one major error, *Klebsiella aerogenes, Klebsiella pneumoniae*
- Levofloxacin: *Citrobacter freundii* complex when the Selux MIC is 2 µg/mL due to 2 major errors, *Klebsiella aerogenes* when the Selux MIC is 2 µg/mL due to one major error, *Pseudomonas aeruginosa*
- Meropenem: *Acinetobacter baumannii, Citrobacter freundii* complex when the Selux MIC is 16 or 32 µg/mL due to 3 major errors, *Serratia marcescens* when the Selux MIC is 16 or 32 µg/mL due to 4 major errors
- Meropenem-Vaborbactam: *Proteus mirabilis, Proteus vulgaris*
- Minocycline: *Acinetobacter baumannii, Escherichia coli, Klebsiella pneumoniae* when the Selux MIC is 4 µg/mL due to 2 very major errors
- Piperacillin-Tazobactam: Acin*etobacter baumannii, Citrobacter freundii, Enterobacter cloacae, Klebsiella aerogenes, Pseudomonas aeruginosa, Serratia marcescens*
- Trimethoprim-Sulfamethoxazole: *Citrobacter freundii, Escherichia coli*

**D Special Instrument Requirements:**
Selux AST System, Software version 1, subversion 8.168

## IV Device/System Characteristics:

### A Device Description:

The Selux AST System is an antimicrobial susceptibility test (AST) system that consists of a Sample Prep Station, an Inoculator, an Analyzer, a computer workstation, and the reagents and consumables required to perform AST testing. The system is operated via software that guides users through the manual sample preparation process and operates the automated Inoculator and Analyzer. The software includes an algorithm that enables the system to determine the susceptibility of an organism to the variety of antimicrobials provided in the Selux AST panels. The system is designed so that only Gram stain information is required to initiate testing to select the gram-negative or gram-positive antimicrobial panel. While complete system testing can be performed without species-level identification, this information is required for the system to report susceptibility results. Species identification information can be either manually input to the Selux system or automatically downloaded from the laboratory information system (LIS) at any time, once the sample ID is entered into the LIS.

The Selux AST Systems provides the following consumables: AST panels, panel lids, tubes and caps for sample prep, troughs for inoculator, McFarland Standards for densitometer performance checks, inoculator pipette tips, inoculator waste bins, inoculator growth media, inoculator cleaning solution, analyzer reagent packs, analyzer liquid waste disinfectant tablets, analyzer absorbent waste pads, and an analyzer solid waste bag.

The Selux AST System is divided into three primary AST steps performed at three different stations: workbench (for sample preparation), panel inoculator (for inoculation), and AST analyzer (for antimicrobial susceptibility testing), as described in detail in the Device Description section of K211759.

The Selux AST System with the Gram-Negative Panel can determine the MIC of various antimicrobials when tested against specific organisms **Table 1.**

**Table 1.** Reportable MIC Ranges and Organism-Specific Breakpoints for Antimicrobials included in the Selux AST System, Gram-Negative Panel

| Antimicrobial | Organism Group | Selux AST System Reportable Range (µg/mL) | FDA-Recognized/ Approved Breakpoints (µg/mL) | | |
|---|---|---|---|---|---|
| | | | S | I | R |
| Amikacin | *Pseudomonas aeruginosa* | ≤0.12 to ≥256 | ≤16 | 32 | ≥64 |
| Amoxicillin-Clavulanate | Enterobacterales | ≤0.5 to ≥128 | ≤8 | 16 | ≥32 |
| Ampicillin | Enterobacterales | ≤0.25 to ≥128 | ≤8 | 16 | ≥32 |
| Ampicillin-Sulbactam | *Acinetobacter baumannii* complex<br>Enterobacterales | ≤0.5 to ≥128 | ≤8 | 16 | ≥32 |
| Aztreonam | Enterobacterales | ≤0.03 to ≥128 | ≤4 | 8 | ≥16 |
| Cefazolin | Enterobacterales | ≤0.12 to ≥128 | ≤1 | 2 | ≥4 |
| Cefepime | Enterobacterales | ≤0.25 to ≥128 | ≤2 | 4-8 | ≥16 |
| Cefoxitin | Enterobacterales | ≤1 to ≥128 | ≤4 | 8 | ≥16 |
| Ceftazidime | Enterobacterales | ≤0.25 to ≥64 | ≤4 | 8 | ≥16 |
| Ceftazidime-Avibactam | Enterobacterales<br>*Pseudomonas aeruginosa* | ≤0.12 to ≥64 | ≤8 | - | ≥16 |
| Ceftriaxone | Enterobacterales | ≤0.25 to ≥32 | ≤1 | 2 | ≥4 |
| Ciprofloxacin | Enterobacterales | ≤0.03 to ≥16 | ≤0.25 | 0.5 | ≥1 |
| | *Pseudomonas aeruginosa* | | ≤0.5 | 1 | ≥2 |
| Eravacycline | Enterobacterales | ≤0.016 to ≥4 | ≤0.5 | - | - |
| Ertapenem | Enterobacterales | ≤0.03 to ≥16 | ≤0.5 | 1 | ≥2 |
| Gentamicin | Enterobacterales<br>*Pseudomonas aeruginosa* | ≤0.06 to ≥64 | ≤4 | 8 | ≥16 |
| Imipenem-Relebactam | Enterobacterales | ≤0.03 to ≥128 | ≤1 | 2 | ≥4 |
| | *Pseudomonas aeruginosa* | | ≤2 | 4 | ≥8 |
| Levofloxacin | Enterobacterales | ≤0.06 to ≥32 | ≤0.5 | 1 | ≥2 |
| Meropenem | Enterobacterales | ≤0.12 to ≥64 | ≤1 | 2 | ≥4 |
| | *Pseudomonas aeruginosa* | | ≤2 | 4 | ≥8 |
| Meropenem-Vaborbactam | Enterobacterales | ≤0.06 to ≥64 | ≤4 | 8 | ≥16 |
| Minocycline | Enterobacterales | ≤0.25 to ≥64 | ≤4 | 8 | ≥16 |
| Piperacillin-Tazobactam | Enterobacterales | ≤0.25 to ≥512 | ≤16 | 32-64 | ≥128 |
| Tobramycin | *Pseudomonas aeruginosa* | ≤0.12 to ≥128 | ≤4 | 8 | ≥16 |
| Trimethoprim-Sulfamethoxazole | Enterobacterales | ≤0.12 to ≥32 | ≤2 | - | ≥4 |

S, Susceptible; I, Intermediate; R, Resistant; -, no breakpoint (interpretive criterion) recognized

**B Principle of Operation:**

The Selux AST test requires that the Gram type of the organism be known prior to testing as the information is necessary to select the proper AST panel to use (i.e., gram-positive or gram-negative). The organism identification (ID) is not needed for Selux AST processing to be performed; however, the organism ID is necessary for a final result to be reported.

The Selux AST System performs antimicrobial susceptibility testing similar to the gold-standard broth microdilution method. To get an accurate reading of microbial growth, the sufficient growth assay monitors growth in dedicated AST panel wells that contain organisms and cation-adjusted Mueller-Hinton Broth but no antimicrobials or probes. Sufficient growth assay wells are monitored by fluorescence to those wells which the standard metabolism-based viability assay pair resazurin/methylene blue have been added and/or by optical absorbance. Two probe-based assays commence across all wells in the panel after the threshold in the sufficient growth well has been met. The "viability assay" uses a fluorescent metabolic probe as an indicator of cellular activity and the "surface area assay" uses a fluorescent cationic probe that binds microorganism surfaces as a proxy for cellular surface area. The viability and surface area assays are performed in each AST panel well, providing two complementary datasets for each well. These data are input to an MIC-determining algorithm that provides results when organism IDs are available.

Refer to the K211759 Decision Summary for additional information on the Selux AST System.

## V Substantial Equivalence Information:

### A Predicate Device Name(s):
BD Phoenix Automated Microbiology System - GN Ceftaroline (0.0156-4 µg/mL)

### B Predicate 510(k) Number(s):
K190905

### C Comparison with Predicate(s):

| Device & Predicate Device(s): | Device: K211748 | Predicate: K190905 |
|---|---|---|
| Device Trade Name | Selux AST System | BD Phoenix Automated Microbiology System – GN Ceftaroline (0.0156-4 µg/mL) |
| **General Device Characteristic Similarities** | | |
| Intended Use/Indications For Use | The Selux AST System is intended to be used for the automated quantitative or qualitative susceptibility testing for most clinically significant aerobic microorganisms. The Selux AST System does not provide organism identification.<br><br>The Selux Gram-Negative Panel is intended for use with the Selux AST System as an *in vitro* test to determine the susceptibility of isolated colonies of specific gram-negative bacilli to specific antimicrobial agents when used as instructed.* | The BD Phoenix Automated Microbiology System is intended for *in vitro* quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of most Gram-negative aerobic and facultative anaerobic bacteria isolates from pure culture for *Enterobacteriaceae* and Non-*Enterobacteriaceae* and most Gram-positive bacteria isolates from pure culture belonging to the genera *Staphylococcus, Enterococcus* and *Streptococcus*. |
| Source of Microorganisms | Bacterial colonies isolated from culture | Same |
| Technology | Automated growth-based detection using metabolic indicators to detect organism growth | Automated growth based enhanced by use of a redox indicator (colorimetric oxidation-reduction) to detect organism growth |
| Panel Type | Gram-negative | Same |

| Device & Predicate Device(s): | Device: K211748 | Predicate: K190905 |
|---|---|---|
| Read Method | Automated | Same |
| Inoculation Method | Automated | Same |
| Result Reported | Report results as minimum inhibitory concentration (MIC) and categorical interpretation (S, I, R, NS) | Report results as minimum inhibitory concentration (MIC) and categorical interpretation (S, I, R) |
| Indicated Species | *Acinetobacter baumannii* complex, specific Enterobacterales species, and *Pseudomonas aeruginosa* | Specific Enterobacterales species |
| **General Device Characteristic Differences** | | |
| Antimicrobial Agent and Reporting Range | Amikacin ≤0.12 to ≥256 µg/mL<br>Amoxicillin-Clavulanate ≤0.5 to ≥128 µg/mL<br>Ampicillin ≤0.25 to ≥128 µg/mL<br>Ampicillin-Sulbactam ≤0.5 to ≥128 µg/mL<br>Aztreonam ≤0.03 to ≥128 µg/mL<br>Cefazolin ≤0.12 to ≥128 µg/mL<br>Cefepime ≤0.25 to ≥128 µg/mL<br>Cefoxitin ≤1 to ≥128 µg/mL<br>Ceftazidime ≤0.25 to ≥64 µg/mL<br>Ceftazidime-Avibactam ≤0.12 to ≥64 µg/mL<br>Ceftriaxone ≤0.25 to ≥32 µg/mL<br>Ciprofloxacin ≤0.03 to ≥16 µg/mL<br>Eravacycline ≤0.016 to ≥4 µg/mL<br>Ertapenem ≤0.03 to ≥16 µg/mL<br>Gentamicin ≤0.06 to ≥64 µg/mL<br>Imipenem ≤0.016 to ≥64 µg/mL<br>Imipenem-Relebactam ≤0.03 to ≥128 µg/mL<br>Levofloxacin ≤0.06 to ≥32 µg/mL<br>Meropenem ≤0.12 to ≥64 µg/mL<br>Meropenem-Vaborbactam ≤0.06 to ≥64 µg/mL<br>Minocycline ≤0.25 to ≥64 µg/mL<br>Piperacillin-Tazobactam ≤0.25 to ≥512 µg/mL<br>Tobramycin ≤0.12 to ≥128 µg/mL<br>Trimethoprim-Sulfamethoxazole ≤0.12 to ≥32 µg/mL | Ceftaroline 0.0156-4 µg/mL |
| IVD Functions | AST | ID and AST |
| Instrument | Selux AST System | BD Phoenix Automated Microbiology System |

* The Selux Gram-Negative Panel is a quantitative test for the antimicrobial agents with the specific organisms listed in section III.B (Indications for Use Statement).

## VI Standards/Guidance Documents Referenced:

- FDA Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA (Issued August 28, 2009)
- CLSI M100-M30, "Performance Standards for Antimicrobial Susceptibility Testing"; Thirtieth Edition (January 2020)

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

1. Precision/Reproducibility:

Reproducibility testing for the Selux AST System with the Gram-Negative Panel was conducted at 3 testing sites (2 external and 1 internal site). Panel members generally consisted of species indicated for use with each respective antimicrobial. To accommodate the numerous antimicrobial/organism combinations being tested concurrently, up to three non-indicated species, within an indicated genus or family, were considered acceptable for testing. Reproducibility was determined from the total number (and percent) of results that fell within one dilution (+/- one doubling dilution) of the modal MIC result for quantitative assays divided by the total number of results. Reproducibility was evaluated between sites (inter-site) and within sites (intra-site). Both best-case (assumes that off-scale results are within one dilution of the mode) and worst-case (assumes that off-scale results are more than one dilution of the mode) performance was determined for each antimicrobial, as outlined in the AST Special Controls Guidance.

In the initial study, inter-site reproducibility was evaluated at three sites by testing at least 25 isolates with on-scale MIC values for each antimicrobial, for a minimum of 75 results per antimicrobial (25 isolates x 3 sites = 75 results/antimicrobial). In general, best-case inter-site reproducibility was acceptable (≥95%) and a sufficient number of results obtained (≥75 results). However, antimicrobials with inter-site worst-case reproducibility of <89% or an insufficient number of results generated (i.e., <75) in the initial study were further evaluated in a supplemental study in which testing was performed with three instruments. Data from both studies are collated and summarized in **Table 2**. Performance is summarized for each antimicrobial tested with all organisms as well as indicated organisms only. Inter-site reproducibility was determined to be acceptable.

**Table 2.** Inter-site Reproducibility of Selux AST System (Gram Negative Panel)

| | All organisms (combined) | | Indicated organisms only | |
|---|---|---|---|---|
| **Antimicrobial** | **Best-case (%)** | **Worst-case (%)** | **Best-case (%)** | **Worst-case (%)** |
| Amikacin | 98/104 (94.2%) | 98/104 (94.2%) | 92/98 (93.9%) | 92/98 (93.9%) |
| Amoxicillin-Clavulanate | 77/78 (98.7%) | 76/78 (97.4%) | 71/72 (98.6%) | 70/72 (97.2%) |
| Ampicillin | 72/75 (96%) | 72/75 (96%) | 68/69 (98.6%) | 68/69 (98.6%) |
| Ampicillin-Sulbactam | 74/75 (98.7%) | 74/75 (98.7%) | 69/69 (100%) | 69/69 (100%) |
| Aztreonam | 77/78 (98.7%) | 75/78 (96.2%) | 77/78 (98.7%) | 75/78 (96.2%) |
| Cefazolin[a] | 77/81 (95.1%) | 76/81 (93.8%) | 68/72 (94.4%) | 67/72 (93.1%) |
| Cefepime | 77/78 (98.7%) | 76/78 (97.4%) | 77/78 (98.7%) | 76/78 (97.4%) |
| Cefoxitin | 73/75 (97.3%) | 72/75 (96.0%) | 70/72 (97.2%) | 69/72 (95.8%) |
| Ceftazidime | 77/81 (95.1%) | 76/81 (93.8%) | 77/81 (95.1%) | 76/81 (93.8%) |
| Ceftazidime-Avibactam | 140/144 (97.2%) | 139/144 (96.5%) | 140/144 (97.2%) | 139/144 (96.5%) |
| Ceftriaxone | 140/141 (99.3%) | 140/141 (99.3%) | 140/141 (99.3%) | 140/141 (99.3%) |
| Ciprofloxacin[a] | 74/75 (98.7%) | 71/75 (94.7%) | 74/75 (98.7%) | 71/75 (94.7%) |
| Eravacycline | 78/78 (100%) | 78/78 (100%) | 78/78 (100%) | 78/78 (100%) |
| Ertapenem | 143/145 (98.6%) | 143/145 (98.6%) | 143/145 (98.6%) | 143/145 (98.6%) |
| Gentamicin[a] | 77/80 (96.3%) | 77/80 (96.3%) | 77/80 (96.3%) | 77/80 (96.3%) |
| Imipenem | 145/149 (97.3%) | 140/149 (94.0%) | 145/149 (97.3%) | 140/149 (94.0%) |
| Imipenem-Relebactam | 71/75 (94.7%) | 71/75 (94.7%) | 71/75 (94.7%) | 71/75 (94.7%) |
| Levofloxacin | 76/78 (97.4%) | 76/78 (97.4%) | 73/75 (97.3%) | 73/75 (97.3%) |
| Meropenem | 75/78 (96.2%) | 73/78 (93.6%) | 70/72 (97.2%) | 68/72 (94.4%) |
| Meropenem-Vaborbactam | 142/145 (97.9%) | 132/145 (91.0%) | 142/145 (97.9%) | 132/145 (91.0%) |

| | All organisms (combined) | | Indicated organisms only | |
|---|---|---|---|---|
| **Antimicrobial** | **Best-case (%)** | **Worst-case (%)** | **Best-case (%)** | **Worst-case (%)** |
| Minocycline[a] | 73/75 (97.3%) | 73/75 (97.3%) | 64/66 (97.3%) | 64/66 (97.3%) |
| Piperacillin-Tazobactam[a] | 72/75 (96.0%) | 69/75 (92.0%) | 63/66 (95.5%) | 60/66 (90.9%) |
| Tobramycin | 74/78 (94.9%) | 73/78 (93.6%) | 74/78 (94.9%) | 73/78 (93.6%) |
| Trimethoprim-Sulfamethoxazole | 143/148 (96.6%) | 142/148 (95.9%) | 143/148 (96.6%) | 142/148 (95.9%) |

[a] In instances where the original study had lower than the required number, supplemental testing was conducted and data collated with original data.

Intra-site reproducibility was evaluated by testing a minimum of five isolates in triplicate on three days at one internal site for each antimicrobial to generate a minimum of 45 results per antimicrobial (5 isolates x 3 replicates x 3 days = 45 results/antimicrobial). In general, best-case intra-site reproducibility was acceptable (≥95%) and a sufficient number of results obtained (≥45 results). However, antimicrobials with worst-case reproducibility <89% or an insufficient number of results generated (i.e., <45) in the initial study were further evaluated in a supplemental study. Data from both studies are collated and summarized in **Table 3**. Performance is summarized for each antimicrobial tested with all organisms as well as indicated organisms only. Intra-site reproducibility was determined to be acceptable.

**Table 3.** Intra-site Reproducibility of Selux AST System (Gram Negative Panel)

| | All organisms (combined) | | Indicated organisms only | |
|---|---|---|---|---|
| **Antimicrobial** | **Best-case (%)** | **Worst-case (%)** | **Best-case (%)** | **Worst-case (%)** |
| Amoxicillin-Clavulanate | 63/63 (100%) | 63/63 (100%) | 63/63 (100%) | 63/63 (100%) |
| Ampicillin | 45/45 (100%) | 45/45 (100%) | 45/45 (100%) | 45/45 (100%) |
| Ampicillin-Sulbactam | 72/72 (100%) | 72/72 (100%) | 72/72 (100%) | 72/72 (100%) |
| Aztreonam | 71/74 (95.9%) | 68/74 (91.9%) | 71/74 (95.9%) | 68/74 (91.9%) |
| Cefazolin | 61/63 (96.8%) | 61/63 (96.8%) | 61/63 (96.8%) | 61/63 (96.8%) |
| Cefepime | 45/47 (95.7%) | 45/47 (95.7%) | 45/47 (95.7%) | 45/47 (95.7%) |
| Cefoxitin | 54/54 (100%) | 54/54 (100%) | 54/54 (100%) | 54/54 (100%) |
| Ceftazidime | 92/93 (98.9%) | 91/93 (97.8%) | 92/93 (98.9%) | 91/93 (97.8%) |
| Ceftazidime-Avibactam | 47/47 (100%) | 43/47 (91.5%) | 47/47 (100%) | 43/47 (91.5%) |
| Eravacycline | 103/103 (100%) | 99/103 (96.1%) | 103/103 (100%) | 99/103 (96.1%) |
| Gentamicin | 116/121 (95.9%) | 116/121 (95.9%) | 116/121 (95.9%) | 116/121 (95.9%) |
| Imipenem-Relebactam | 72/76 (94.7%) | 72/76 (94.7%) | 72/76 (94.7%) | 72/76 (94.7%) |
| Levofloxacin | 179/181 (98.9%) | 174/181 (96.1%) | 179/181 (98.9%) | 174/181 (96.1%) |
| Meropenem | 57/58 (98.3%) | 56/58 (96.6%) | 57/58 (98.3%) | 56/58 (96.6%) |
| Meropenem-Vaborbactam | 45/47 (95.7%) | 43/47 (91.5%) | 45/47 (95.7%) | 43/47 (91.5%) |
| Piperacillin-Tazobactam | 54/56 (96.4%) | 54/56 (96.4%) | 54/56 (96.4%) | 54/56 (96.4%) |
| Trimethoprim-Sulfamethoxazole | 62/65 (95.4%) | 61/65 (93.8%) | 62/65 (95.4%) | 61/65 (93.8%) |

[a] In instances where the original study had lower than the required number, supplemental testing was conducted and data collated with original data.

2. Linearity:
   Not applicable

3. Analytical Specificity/Interference:
   Not Applicable

4. Assay Reportable Range:
   Not applicable

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   **Quality Control Testing**. The Selux AST System software contains QC Sets (A, B, C) such that when the Gram-Negative Panel is selected, the system will indicate the appropriate QC strains to be prepared for testing. CLSI-recommended QC strains and expected QC ranges for use with the Gram-Negative Panel are summarized in **Table 4**, which also includes the designation of the QC set as appropriate for each antimicrobial. Notably, QC Set A comprises gram-positive ATCC QC organisms which is acceptable to use for QC testing of the Gram-Negative Panel provided that QC is run concurrently with Set B and/or C, which comprise gram-negative ATCC QC organisms. This is necessary because the metabolic assay in the Selux AST System utilizes an additional biochemical reagent, an electron transfer agent, exclusively with gram-negative organisms. The following QC reporting scheme is included in the device labeling (and is supported by software information) to ensure that gram-negative organisms will be processed correctly by the Selux AST System:
   - *Gram-Negative Panel QC failure when testing gram-positive QC organisms*: clinical results should not be reported for the antimicrobial(s) in which QC failed but may be reported for the antimicrobials for which QC passed.
   - *Gram-Negative Panel QC failure when testing gram-negative QC organisms*:
     - If all gram-negative organisms fail QC: all QC results (including those when testing gram-positive organisms) should be considered failed and clinical results should not be reported for any antimicrobial.
     - If one (or fewer than all) gram-negative organisms fail QC: clinical results should not be reported for the antimicrobial(s) in which QC failed but may be reported for the antimicrobials for which QC passed (including those when testing gram-positive organisms).

**Table 4.** CLSI-Recommended QC Organisms for Gram-Negative Panel

| Antimicrobial | Abbreviation | QC Set | QC Strain | Expected QC Range (µg/mL) |
|---|---|---|---|---|
| Amikacin | AMK | A | ATCC 29213 [a] | 1-4 |
| Amoxicillin-Clavulanate | AMC | B | ATCC 700603 | 4-16 |
| Ampicillin | AMP | C | ATCC 25922 | 2-8 |
| Ampicillin-Sulbactam | SAM | B | ATCC 700603 | 8-32 |
| Aztreonam | ATM | C | ATCC 25922 | 0.06-0.25 |
| Cefazolin | CFZ | C | ATCC 25922 | 1-4 |
| Cefepime | FEP | A | ATCC 29213 [a] | 1-4 |
| Cefoxitin | FOX | C | ATCC 25922 | 2-8 |
| Ceftazidime | CAZ | A | ATCC 29213 [a] | 4-16 |
| Ceftazidime-Avibactam | CZA | B | ATCC 700603 | 0.25-2 |

| Antimicrobial | Abbreviation | QC Set | QC Strain | Expected QC Range (µg/mL) |
|---|---|---|---|---|
| Ceftriaxone | CRO | A | ATCC 29213 [a] | 1-8 |
| Ciprofloxacin | CIP | A | ATCC 29213 [a] | 0.12-0.5 |
| Eravacycline | ERV | C | ATCC 25922 | 0.016-0.12 |
| Ertapenem | ETP | A | ATCC 29213 [a] | 0.06-0.25 |
| Gentamicin | GEN | A | ATCC 29212 [a] | 4-16 |
| Imipenem | IMP | B | ATCC 700603 | 0.06-0.5 |
| Imipenem-Relebactam | IMR | C | ATCC BAA-2814 | 0.06-0.5 |
| Levofloxacin | LVX | A | ATCC 29212 [a] | 0.25-2 |
| Meropenem | MEM | A | ATCC 29212 [a] | 2-8 |
| Meropenem-Vaborbactam | MEV | C | ATCC BAA-2814 | 0.12-0.5 |
| Minocycline | MIN | A | ATCC 29212 [a] | 1-4 |
| Piperacillin-Tazobactam | TZP | B | ATCC 700603 | 8-32 |
| Tobramycin | TOB | A | ATCC 29212 [a] | 8-32 |
| Trimethoprim-Sulfamethoxazole | SXT | C | ATCC 25922 | 0.12-0.5[b] |

[a] Set A comprises gram-positive ATCC QC organisms which is acceptable to use for QC testing of the Gram-Negative Comprehensive panel provided that QC is run concurrently with Set B and/or C, which comprise gram-negative ATCC QC organisms. This is necessary because the metabolic assay in the Selux AST System utilizes an additional biochemical reagent, an electron transfer agent, exclusively with gram-negative organisms. This ensures that gram-negative organisms will be processed correctly by the Selux AST System.

[b] Expected QC range for SXT in CLSI M100 is ≤0.5; Selux AST reporting range for SXT is ≤0.12 to ≥32 µg/mL. Selux MIC results of ≤0.5 µg/mL were considered acceptable.

Quality control testing was performed each day that testing was conducted. CLSI-recommended QC strains for each antimicrobial (described in **Table 4**) were tested a sufficient number of times (i.e., at least 20 times/site) at each testing site using the Selux AST System. QC testing of the broth microdilution reference method was performed at a single, central site. In some cases, the site used CLSI-recommended QC organisms that were different from QC organisms tested with the Selux AST System. This is noted in **Table 5**.

QC expected ranges and results for the Selux AST System with Gram-Negative panel are summarized in **Table 5**. For all antimicrobials, greater than 95% of results were within the expected range, which is acceptable.

*Due to an administrative error, reference data for minocycline and tobramycin was not previously included in Table 5. This data is included in the updated table for both minocycline and tobramycin testing of E. coli ATCC 25922.*

**Table 5.** QC Results for the Selux AST System Assay with Gram Negative Panel

| Antimicrobial | QC Strain | Expected Range (µg/mL) | No. in Range (%) | |
|---|---|---|---|---|
| | | | Reference | Selux |
| Amikacin | *S. aureus* ATCC 29213 | 1-4 | 56/56 (100) | 218/219 (99.5) |
| Amoxicillin | *K. pneumoniae* ATCC 700603[a] | ≥128[c] | 4747 (100) | 219/221 (99.1) |
| Amoxicillin-Clavulanate | *K. pneumoniae* ATCC 700603 | 4-16 | 49/50 (98.0) | 211/221 (95.5) |
| Ampicillin | *E. coli* ATCC 25922 | 2-8 | 47/48 (97.9) | 210/210 (100) |
| | *K. pneumoniae* ATCC 700603[a] | ≥128[c] | 50/50 (100) | 219/221 (99.1) |
| Ampicillin-Sulbactam | *K. pneumoniae* ATCC 700603 | 8-32 | 46/47 (97.9) | 221/221 (100) |
| Aztreonam | *E. coli* ATCC 25922 | 0.06-0.25 | 56/57 (98.2) | 210/210 (100) |

| Antimicrobial | QC Strain | Expected Range (µg/mL) | No. in Range (%) | |
|---|---|---|---|---|
| | | | Reference | Selux |
| Cefazolin | *E. coli* ATCC 25922 | 1-4 | 53/53 (100) | 210/210 (100) |
| Cefepime | *S. aureus* ATCC 29213 | 1-4 | 54/55 (98.2) | 218/219 (99.5) |
| Cefoxitin | *E. coli* ATCC 25922 | 2-8 | 45/46 (97.8) | 209/210 (99.5) |
| Ceftazidime | *S. aureus* ATCC 29213 | 4-16 | NT | 217/219 (99.1) |
| | *E. coli* ATCC 25922[b] | 0.06-0.5 | 56/57 (98.2) | NT |
| | *K. pneumoniae* ATCC 700603[a] | 16-64 | 66/66 (100) | 218/221 (98.6) |
| Ceftazidime-Avibactam | *K. pneumoniae* ATCC 700603 | 0.25-2 | 59/59 (100) | 221/221 (100) |
| Ceftriaxone | *S. aureus* ATCC 29213 | 1-8 | 45/49 (97.8) | 218/219 (99.5) |
| Ciprofloxacin | *S. aureus* ATCC 29213 | 0.12-0.5 | 57/58 (98.3) | 218/219 (99.5) |
| Eravacycline | *E. coli* ATCC 25922 | 0.016-0.12 | 49/49 (100) | 210/210 (100) |
| Ertapenem | *S. aureus* ATCC 29213 | 0.06-0.25 | 51/51 (100) | 217/219 (99.1) |
| Gentamicin | *E. faecalis* ATCC 29212 | 4-16 | 51/53 (96.2) | 216/217 (99.5) |
| Imipenem | *K. pneumoniae* ATCC 700603 | 0.06-0.5 | 64/64 (100) | 221/221 (100) |
| | *K. pneumoniae* ATCC BAA-2814[a] | 16-64 | 65/65 (100) | 210/210 (100) |
| Imipenem-Relebactam | *K. pneumoniae* ATCC BAA-2814 | 0.06-0.5 | 65/65 (100) | 207/210 (98.6) |
| Levofloxacin | *E. faecalis* ATCC 29212 | 0.25-2 | 38/40 (95.0) | 89/90 (98.9) |
| Meropenem | *E. faecalis* ATCC 29212 | 2-8 | 55/56 (98.2) | 217/217 (100) |
| Meropenem-Vaborbactam | *K. pneumoniae* ATCC BAA-2814 | 0.12-0.5 | 48/49 (98.0) | 204/210 (97.1) |
| Minocycline | *E. faecalis* ATCC 29212 | 1-4 | NT | 216/217 (99.5) |
| | *E. coli* ATCC 25922[b] | 0.25-1 | 43/44 (97.7) | NT |
| Piperacillin-Tazobactam | *K. pneumoniae* ATCC 700603 | 8-32 | 66/66 (100) | 221/221 (100) |
| Tobramycin | *E. faecalis* ATCC 29212 | 8-32 | NT | 211/217 (97.2) |
| | *E. coli* ATCC 25922[b] | 0.25-1 | 52/53 (98.1) | NT |
| Trimethoprim-Sulfamethoxazole | *E. coli* ATCC 25922 | 0.12-0.5[b] | 44/100 (100) | 208/210 (99.0) |

NT: Not tested

[a] Tested to confirm the integrity of the QC strain for testing with the beta-lactam/beta-lactam-inhibitor combination antimicrobial.

[b] BMD reference method testing was performed at a single, central site which utilized their standard, CLSI-recommended QC organisms.

[c] Expected QC range in CLSI M100 is >128; highest concentration of Amoxicillin and Ampicillin on the Selux AST result panel is 128 µg/mL. Selux MIC results of ≥128 µg/mL were considered acceptable.

**Inoculum Density Check**: Refer to the K211759 decision summary for description and results since studies were performed concurrently.

**Device Failure**: Refer to the K211759 decision summary for description and results since studies were performed concurrently.

**Growth Failure Rate**: There were 13 growth failures (13/1401 tests = 0.93%) when using the Gram-Negative Panel on the Selux AST System. All samples that generated Selux results also generated reference method results.

**Purity Check**: Purity plates were prepared from the inoculum suspensions of every sample tested. AST results were only reported for pure isolates; data generated from plates that generated multiple colony morphologies was excluded from analyses.

6. Detection Limit:

Not Applicable

7. Assay Cut-Off:
   Not Applicable

## B Comparison Studies:

1. Method Comparison with Predicate Device:
   Clinical performance testing on the Selux AST System was initially performed at three U.S. test sites (2 external, 1 internal). For instances in which testing was required to supplement existing data from the original study and support specific claims, testing was performed on three Selux AST System instruments at two testing sites.

   Performance was evaluated using contemporary and stock frozen clinical isolates as well as challenge isolates, which were selected for their resistance profiles. Clinical isolates of non-fastidious bacteria were recovered from cultures of clinical specimens (e.g., blood, stool, urine, respiratory, wound, aspirates) from diverse geographic locations across the U.S.

   Contemporary frozen isolates were defined as isolates that had been collected and frozen within six months of testing while stock frozen isolates were tested six or more months after collection.

   A total of 1401 clinical (426 contemporary and 975 stock) and 222 challenge isolates from 12 Enterobacterales species, *Acinetobacter baumannii* complex, and *Pseudomonas aeruginosa* were tested to evaluate the Selux AST System performance for 24 antimicrobials using the Selux Gram-Negative panel. Depending on the spectrum of activity, breakpoints and the claimed organisms (species/group) for each antimicrobial on the panel, the number of datapoints for the various antimicrobial-organisms tested varied and ranged from 165 (e.g. *P. aeruginosa*/Imipenem-Relebactam) to 977 (e.g. Enterobacterales/Ertapenem). Selux results were compared to the modal value of triplicate broth microdilution reference results performed at an independent reference laboratory.

   Performance was determined generally based on criteria outlined in the Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems including essential agreement (EA), categorical agreement (CA), and categorical errors (minor, major and very major errors). EA was calculated as the percentage of Selux MIC results that were within plus or minus one serial two-fold dilution of the reference result. CA was calculated as the percentage of Selux interpretive results (S/I/R) that were identical to the interpretive results of the reference result. EA of evaluable results (on-scale Selux and reference results or results in which an off-scale result was at least two doubling dilutions from the on-scale result) were also calculated. Performance was considered acceptable if the EA and CA were ≥90%, major error rate was ≤3%, and very major error rate was ≤2%.

   A trending analysis using combined clinical and challenge isolate results was also conducted to evaluate antimicrobial-organism combinations for which Selux MIC results were determined to be one or more doubling dilutions lower or higher than the reference result. MIC results that were off-scale for both the reference and Selux were not considered in the trending analysis. Antimicrobial-organism combinations for which the difference between the percentage of isolates with higher or lower MIC values was ≥ 30% with a statistically

significant confidence interval were considered to have evidence of trending and is addressed in the labeling.

A high-level summary of the Selux AST System performance using the Gram-Negative Panel is described below for each antimicrobial and indicated species. Complete details and results including EA, CA and error rate analyses are summarized in **Table 6** and trending analyses are summarized in **Table 7**.

**Amikacin.** A total of 111 *A. baumannii* isolates were evaluated with amikacin. The combined results from clinical and challenge isolate testing demonstrated an EA of 55.0% and CA of 86.5%, which is not acceptable. There were 6 minor, 8 major (8/80 = 10%) and 1 very major (1/25 = 4%) errors, which is not acceptable. Due to the unacceptable performance for *A. baumannii*, this drug/organism combination is not indicated for use with the Selux AST System. The following limitation is included in the device labeling to restrict reporting of *A. baumannii* due to unacceptable performance:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):
> - Amikacin: *Acinetobacter baumannii*

A total of 165 *P. aeruginosa* isolates were evaluated with amikacin. The combined results from clinical and challenge isolate testing demonstrated an EA of 90.9% and CA of 98.2%. There were 3 minor, 0 major and 0 very major errors. Overall, performance is acceptable.

Analysis of trending indicated that MIC values for *P. aeruginosa* tended to be one doubling dilution lower than the reference MIC value. The following statement is included in the device labeling as a footnote to the AST performance table:

> Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution lower than the reference MIC value:
> - Amikacin: *Pseudomonas aeruginosa*

**Amoxicillin-Clavulanate.** A total of 593 Enterobacterales isolates (indicated species: 179 *E. coli*, 48 *K. oxytoca*, 142 *K. pneumoniae*, 88 *P. mirabilis*; non-indicated species: 74 *C. koseri*, 62 *P. vulgaris*) were evaluated with amoxicillin-clavulanate. The combined results from clinical and challenge isolate testing demonstrated an EA of 93.3% and CA of 92.8%. There were 37 minor, 5 major and 1 very major errors. When evaluating results by individual species, *E. coli* had a CA of 88.7% due to 17 minor, 1 major and 0 very major errors which was determined to be acceptable since the majority of categorical errors were minor and the EA of evaluable results was good (96.5%). *P. mirabilis* had one very major error (1/8 = 16.7%), which was considered a random error due to the limited number of resistant isolates tested.

Analysis of trending indicated that MIC values for *K. pneumoniae* tended to be one doubling dilution lower than the reference MIC value. The following statement is included as a footnote to the AST performance table:

Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution lower than the reference MIC value:

- Amoxicillin-Clavulanate: *Klebsiella pneumoniae*

**Ampicillin.** A total of 254 Enterobacterales isolates (165 *E. coli*, 89 *P. mirabilis*) were evaluated with ampicillin. The combined results from clinical and challenge isolate testing demonstrated an EA of 94.9% and CA of 98.8%. There was 1 minor, 1 major and 1 very major error. When evaluating results by individual species, *P. mirabilis* had 1 major error (1/60 = 1.7%) and 1 very major error (1/26 = 3.8%) at a Selux MIC value of 2 µg/mL which represents 4.5% (4/89) of results with this drug/organism combination. The following limitation is included in the device labeling to address the very major error:

Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):

- Ampicillin: *Proteus mirabilis* when the Selux MIC is 2 µg/mL due to one very major error

Analysis of trending indicated that MIC values for *E. coli* tended to be one doubling dilution lower than the reference MIC value. The following statement is included as a footnote to the AST performance table:

Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution lower than the reference MIC value:

- Ampicillin: *Escherichia coli*

**Ampicillin-Sulbactam.** A total of 123 *A. baumannii* isolates were evaluated with ampicillin-sulbactam. The combined results from clinical and challenge isolate testing demonstrated an EA of 91.9% and CA of 92.7%. There were 6 minor, 2 major and 1 very major error. Overall, performance is acceptable.

A total of 574 Enterobacterales isolates (204 *E. coli*, 29 *K. oxytoca*, 116 *K. pneumoniae*, 75 *M. morganii*, 88 *P. mirabilis,* 62 *P. vulgaris*) were evaluated with ampicillin-sulbactam. The combined results from clinical and challenge isolate testing demonstrated an EA of 96.9% and CA of 83.5%. There were 90 minor, 5 major and 0 very major errors. When evaluating results by individual species, *K. oxytoca* and *P. mirabilis* each had CA <90% which was considered acceptable since all of the categorical errors were minor and the EA of evaluable results was good (>95%). *P. vulgaris* had a CA of 45.2% due to 31 minor errors as well as 3 major errors (3/43 = 7.0%) at a Selux MIC value of 32 µg/mL which represents 9.7% (6/62) of results with this drug/organism combination. *M. morganii* had a CA of 72% due to 19 minor and 2 major errors (2/4 = 50%), which is not acceptable. Due to the unacceptable performance for *M. morganii*, this drug/organism combination is not indicated for use with the Selux AST System. The following limitation is included in the device labeling address the *P. vulgaris* major errors and restrict reporting of *M. morganii* due to unacceptable performance:

Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):

- Ampicillin-Sulbactam: *Morganella morganii; Proteus vulgaris* when the Selux MIC is 32 µg/mL due to 3 major errors

A limitation statement is included in the device labeling to address the lack of testing with resistant *P. vulgaris* isolates.

Analysis of trending indicated that MIC values for *K. oxytoca* tended to be one doubling dilution lower than the reference MIC value while MIC values for *P. vulgaris* tended to be one doubling dilution higher than the reference MIC value. The following statements are included as a footnote to the AST performance table:

> Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution lower than the reference MIC value:
> - Ampicillin-Sulbactam: *Klebsiella oxytoca*
>
> Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution higher than the reference MIC value:
> - Ampicillin-Sulbactam: *Proteus vulgaris*

**Aztreonam.** A total of 183 Enterobacterales isolates (183 *E. coli*) were evaluated with aztreonam. The combined results from clinical and challenge isolate testing demonstrated an EA of 97.8% and CA of 97.3%. There were 5 minor, 0 major and 0 very major errors. Overall, performance is acceptable.

A total of 219 *P. aeruginosa* isolates were evaluated with aztreonam. The combined results from clinical and challenge isolate testing demonstrated an EA of 91.3% and CA of 87.7%. There were 20 minor, 3 major (3/158 = 1.9%) and 4 very major (4/48 = 8.3%) errors. Due to the unacceptable performance for *P. aeruginosa*, this drug/organism combination is not indicated for use with the Selux AST System. The following limitation is included in the device labeling to restrict reporting of *P. aeruginosa* due to unacceptable performance:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):
> - Aztreonam: *Pseudomonas aeruginosa*

**Cefazolin.** A total of 412 Enterobacterales isolates (indicated species: 177 *E. coli*, 115 *K. pneumoniae*, 66 *P. mirabilis*; non-indicated species: 54 *C. koseri*) were evaluated with cefazolin. The combined results from clinical and challenge isolate testing demonstrated an EA of 94.2% and CA of 74.8%. There were 102 minor, 1 major and 1 very major errors. When evaluating results by individual species, *E. coli* and *K. pneumoniae* each had CA <90% which was considered acceptable since most of the categorical errors were minor and the EA of evaluable results was good (>90%). *P. mirabilis* had an EA of 86.4% and an EA of evaluable results of 84.8% (50/59), which is not acceptable. Due to the unacceptable performance for *P. mirabilis*, this drug/organism combination is not indicated for use with the Selux AST System. The following limitation statement is included in the device labeling to restrict reporting of *P. mirabilis* due to unacceptable performance:

Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combinations:

- Cefazolin: *Proteus mirabilis*

Analysis of trending indicated that MIC values for *C. koseri*, *E. coli* and *K. pneumoniae* tended to be one doubling dilution lower than the reference MIC value. The following statement is included as a footnote to the AST performance table:

> Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution lower than the reference MIC value:
>
> - Cefazolin: *Citrobacter koseri, Escherichia coli, Klebsiella pneumoniae*

**Cefepime.** A total of 956 Enterobacterales isolates (77 *C. freundii* complex, 74 *C. koseri*, 77 *E. cloacae* complex, 170 *E. coli*, 52 *K. aerogenes*, 29 *K. oxytoca,* 111 *K. pneumoniae*, 75 *M. morganii,* 88 *P. mirabilis,* 100 *P. vulgaris,* 103 *S. marcescens*) were evaluated with cefepime. The combined results from clinical and challenge isolate testing demonstrated an EA of 94.8% and CA of 96.0%. There were 26 minor, 10 major and 2 very major errors. When evaluating results by individual species, *M. morganii* had 1 very major error (1/1 = 100%) and *P. vulgaris* had 1 very major error (1/2 = 50%), which were considered random errors due to the insufficient number of resistant isolates tested. *K. aerogenes* had 2 major errors (2/51 = 3.9%) at Selux MIC values of ≥64 µg/mL which represents 5.8% (3/52) of results with this drug/organism combination. The following limitation is included in the device labeling to address the major errors:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):
>
> - Cefepime: *Klebsiella aerogenes* when the Selux MIC is to ≥64 µg/mL due to two major errors

A total of 215 *P. aeruginosa* isolates were evaluated with cefepime. The combined results from clinical and challenge isolate testing demonstrated an EA of 87.4% and CA of 86.8%. There were 0 minor, 13 major (13/178 = 7.3%) and 7 very major (7/37 = 18.9%) errors. Due to the lack of an intermediate interpretive criterion, further analysis of the errors was performed and adjustments were made by considering the MIC values of the errors compared to the reference MIC value. Nine of the 13 major errors and 6 of the 7 very major errors had an MIC value that was in essential agreement with the reference MIC value. Therefore, the adjusted major error rate is 2.2% (4/178), which is acceptable. However, the adjusted very major error rate is 2.7% (1/37) which is not acceptable. Due to the unacceptable performance for *P. aeruginosa*, this drug/organism combination is not indicated for use with the Selux AST System. The following limitation is included in the device labeling to restrict reporting of *P. aeruginosa* due to unacceptable performance:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):
>
> - Cefepime: *Pseudomonas aeruginosa*

A limitation statement is included in the device labeling to address the lack of testing with resistant *K. aerogenes, M. morganii, P. vulgaris* and *S. marcescens* isolates.

Analysis of trending indicated that MIC values for *C. freundii*, *C. koseri*, *E. cloacae*, *E. coli, K. aerogenes, K. oxytoca, M. morganii, P. mirabilis, P. vulgaris, S. marcescens* tended to be one doubling dilution higher than the reference MIC value. The following statement is included as a footnote to the AST performance table:

> Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution higher than the reference MIC value:
> - Cefepime: *Citrobacter freundii*, *Citrobacter koseri*, *Enterobacter cloacae* complex, *Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*

**Cefoxitin.** A total of 637 Enterobacterales isolates (indicated species:168 *E. coli*, 29 *K. oxytoca,* 133 *K. pneumoniae*, 64 *M. morganii,* 89 *P. mirabilis,* 100 *P. vulgaris*; non-indicated species: 54 *C. koseri*) were evaluated with cefoxitin. The combined results from clinical and challenge isolate testing demonstrated an EA of 92.3% and CA of 80.2%. There were 114 minor, 9 major and 3 very major errors. When evaluating results by individual species, *K. oxytoca* and *M. morganii* had CA of <90% which was considered acceptable since most of the categorical errors were minor and the EA of evaluable results was good (>90%). *P. mirabilis* had a CA of 88.8% due to 6 minor, 2 major (2/75 = 2.7%) and 2 very major (2/7 = 28.6%) errors, which is not acceptable. *P. vulgaris* had an EA of 86% and a CA of 53% due to 46 minor errors and 1 major error (1/53 = 1.9%), which is not acceptable. Due to the unacceptable performance for *P. mirabilis* and *P. vulgaris*, these drug/organism combinations are not indicated for use with the Selux AST System. The following limitation is included in the device labeling to restrict reporting of *P. mirabilis* and *P. vulgaris* due to unacceptable performance:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):
> - Cefoxitin: *Proteus mirabilis, Proteus vulgaris*

A limitation statement is included in the device labeling to address the lack of testing with resistant *K. oxytoca* and *P. vulgaris* isolates.

There was no evidence of trending observed with any indicated species with cefoxitin.

**Ceftazidime.** A total of 127 *A. baumannii* isolates were evaluated with ceftazidime. The combined results from clinical and challenge isolate testing demonstrated an EA of 86.6% and CA of 94.5%. There were 7 minor, 0 major and 0 very major error. In addition, the EA of evaluable results was 81.5% (75/92). Due to the unacceptable performance for *A. baumannii*, this drug/organism combination is not indicated for use with the Selux AST System. The following limitation is included in the device labeling to restrict reporting of *A. baumannii* due to unacceptable performance:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):
> - Ceftazidime: *Acinetobacter baumannii*

A total of 787 Enterobacterales isolates (64 *C. freundii,* 55 *C. koseri,* 84 *E. cloacae,* 186 *E. coli*, 36 *K. aerogenes,* 29 *K. oxytoca,* 145 *K. pneumoniae*, 66 *P. mirabilis,* 55 *P. vulgaris,* 67 *S. marcescens*) were evaluated with ceftazidime. The combined results from clinical and challenge isolate testing demonstrated an EA of 95.6% and CA of 96.4%. There were 26 minor, 1 major and 1 very major errors. Overall, performance is acceptable.

A total of 224 *P. aeruginosa* isolates were evaluated with ceftazidime. The combined results from clinical and challenge isolate testing demonstrated an EA of 88.0% and CA of 93.3%. There were 9 major (9/178 = 5.1%) and 6 very major (6/46 = 13%) errors. Due to the lack of an intermediate interpretive criterion, further analysis of the errors was performed and adjustments were made by considering the MIC values of the errors compared to the reference MIC value. One of the 9 major errors and 1 of the 6 very major errors had an MIC value that was in essential agreement with the reference MIC value. Therefore, the adjusted major error rate is 4.5% (8/177) and the adjusted very major error rate is 10.9% (5/46), which is not acceptable. Due to the unacceptable performance for *P. aeruginosa*, this drug/organism combination is not indicated for use with the Selux AST System. The following limitation is included in the device labeling to restrict reporting of *P. aeruginosa* due to unacceptable performance:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):
> - Ceftazidime: *Pseudomonas aeruginosa*

Analysis of trending indicated that MIC values for *C. freundii* complex, *C. koseri*, *E. cloacae*, *K. aerogenes, K. oxytoca, K. pneumoniae, P. mirabilis, P. vulgaris,* and *S. marcescens* tended to be one doubling dilution higher than the reference MIC value. The following statement is included as a footnote to the AST performance table:

> Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution higher than the reference MIC value:
> - Ceftazidime: *Citrobacter freundii* complex, *Citrobacter koseri*, *Enterobacter cloacae*, *Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*

**Ceftazidime-avibactam.** A total of 815 Enterobacterales isolates (61 *C. freundii,* 54 *C. koseri,* 75 *E. cloacae,* 170 *E. coli*, 52 *K. aerogenes,* 28 *K. oxytoca,* 126 *K. pneumoniae*, 62 *M. morganii,* 66 *P. mirabilis,* 55 *P. vulgaris,* 66 *S. marcescens*) were evaluated with ceftazidime-avibactam. The combined results from clinical and challenge isolate testing demonstrated an EA of 97.3% and CA of 99.4%. There were 5 major and 0 very major errors. Overall, performance is acceptable.

A total of 163 *P. aeruginosa* isolates were evaluated with ceftazidime-avibactam. The combined results from clinical and challenge isolate testing demonstrated an EA of 89.6% and CA of 96.9%. There were 4 major errors (4/153 = 2.6%) and 1 very major error (1/10 = 10%). Due to the lack of an intermediate interpretive criterion, further analysis of the errors was performed and adjustments were made by considering the MIC values of the errors compared to the reference MIC value. Two of the 4 major errors and 1 of the 1 very major errors had an MIC value that was in essential agreement with the reference MIC value.

Therefore, the adjusted major error rate is 1.3% (2/153) and the adjusted very major error rate is 0% (0/10), which is acceptable.

A limitation statement is included in the device labeling to address the lack of testing with resistant *C. koseri, K. aerogenes, K. oxytoca, M. morganii, P. mirabilis, P. vulgaris* and *S. marcescens* isolates.

Analysis of trending indicated that MIC values for *C. freundii*, *C. koseri, E. coli, K. aerogenes, K. oxytoca, M. morganii, P. mirabilis,* and *P. vulgaris* tended to be one doubling dilution higher than the reference MIC value. The following statement is included as a footnote to the AST performance table:

> Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution higher than the reference MIC value:
> - Ceftazidime-avibactam: *Citrobacter freundii*, *Citrobacter koseri, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Morganella morganii, Proteus mirabilis, Proteus vulgaris*

**Ceftriaxone.** A total of 722 Enterobacterales isolates (64 *C. freundii,* 54 *C. koseri,* 84 *E. cloacae,* 175 *E. coli*, 35 *K. aerogenes,* 29 *K. oxytoca,* 109 *K. pneumoniae*, 67 *P. mirabilis,* 105 *S. marcescens*) were evaluated with ceftriaxone. The combined results from clinical and challenge isolate testing demonstrated an EA of 97.5% and CA of 98.5%. There were 3 minor, 4 major and 4 very major errors. When evaluating results by individual species, *E. cloacae* had 3 very major errors (3/34 = 8.8%) and *S. marcescens* had 1 very major error (1/12 = 8.3%), which are not acceptable. Due to the unacceptable performance for *E. cloacae* and *S. marcescens*, these drug/organism combinations are not indicated for use with the Selux AST System. The following limitation is included in the device labeling to restrict reporting of *E. cloacae* and *S. marcescens* due to unacceptable performance:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):
> - Ceftriaxone: *Enterobacter cloacae, Serratia marcescens*

Analysis of trending indicated that MIC values for *C. freundii*, *C. koseri, E. coli, K. aerogenes, K. oxytoca,* and *P. mirabilis* tended to be one doubling dilution higher than the reference MIC value. The following statement is included as a footnote to the AST performance table:

> Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution higher than the reference MIC value:
> - Ceftriaxone: *Citrobacter freundii*, *Citrobacter koseri, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Proteus mirabilis*

**Ciprofloxacin.** A total of 818 Enterobacterales isolates (62 *C. freundii,* 55 *C. koseri,* 76 *E. cloacae,* 170 *E. coli*, 32 *K. aerogenes,* 29 *K. oxytoca,* 105 *K. pneumoniae*, 63 *M. morganii,* 67 *P. mirabilis,* 55 *P. vulgaris,* 104 *S. marcescens*) were evaluated with ciprofloxacin. The combined results from clinical and challenge isolate testing demonstrated an EA of 96.7% and CA of 96.2%. There were 26 minor, 3 major and 2 very major errors. When evaluating

results by individual species, *S. marcescens* had 2 very major errors (2/12 = 16.7%), which is not acceptable. Due to the unacceptable performance for *S. marcescens*, this drug/organism combination is not indicated for use with the Selux AST System.The following limitation is included in the device labeling to restrict reporting of *S. marcescens* due to unacceptable performance:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):
> - Ciprofloxacin: *Serratia marcescens*

A total of 169 *P. aeruginosa* isolates were evaluated with ciprofloxacin. The combined results from clinical and challenge isolate testing demonstrated an EA of 95.9% and CA of 94.7%. There were 5 minor, 4 major and 0 very major errors. Overall, performance is acceptable.

A limitation statement is included in the device labeling to address the lack of testing with resistant *C. koseri* and *P. vulgaris* isolates.

Analysis of trending indicated that MIC values for *P. aeruginosa* tended to be one doubling dilution lower than the reference MIC value while MIC values for *C. freundii, C. koseri, E. cloacae, E. coli*, *K. aerogenes, K. oxytoca, M. morganii,* and *P. vulgaris* tended to be one doubling dilution higher than the reference MIC value. The following statements are included as a footnote to the AST performance table:

> Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution lower than the reference MIC value:
> - Ciprofloxacin: *Pseudomonas aeruginosa*
>
> Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution higher than the reference MIC value:
> - Ciprofloxacin: *Citrobacter freundii, Citrobacter koseri, Enterobacter cloacae, Escherichia coli*, *Klebsiella aerogenes, Klebsiella oxytoca, Morganella morganii, Proteus vulgaris*

**Eravacycline.** A total of 487 Enterobacterales isolates (62 *C. freundii,* 78 *E. cloacae,* 167 *E. coli*, 47 *K. oxytoca,* 133 *K. pneumoniae*) were evaluated with eravacycline. The combined results from clinical and challenge isolate testing demonstrated an EA of 98.2% and CA of 98.6%. There were 4 major and 3 very major errors. When evaluating results by individual species, *E. cloacae* had 3 major errors (3/59 = 5.1%), *K. oxytoca* had 1 very major error (1/1 =100%), and *K. pneumoniae* had 2 very major errors (2/30 = 6.7%). Due to the lack of an intermediate interpretive criterion (eravacycline only has a "susceptible" category), further analysis of the errors was performed and adjustments were made by considering the MIC values of the errors compared to the reference MIC value. Two of the 3 *E. cloacae* major errors and 1 of the 1 *K. oxytoca* very major errors had an MIC value that was in essential agreement with the reference MIC value. Therefore, the adjusted major error rate for *E. cloacae* is 1.7% (1/59) and the adjusted very major error rate for *K. oxytoca* is 0% (0/1), which is acceptable. None of the 2 *K. pneumoniae* very major errors were in essential agreement resulting in an unacceptable very major error rate. Due to the unacceptable

performance for *K. pneumoniae*, this drug/organism combination is not indicated for use with the Selux AST System. The following limitation is included in the device labeling to restrict reporting of *K. pneumoniae* due to unacceptable performance:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):
> - Eravacycline: *Klebsiella pneumoniae*

A limitation statement is included in the device labeling to address the lack of testing with resistant *E. coli* and *K. oxytoca* isolates.

Analysis of trending indicated that MIC values for *C. freundii* tended to be one doubling dilution higher than the reference MIC value. The following statement is included as a footnote to the AST performance table:

> Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution higher than the reference MIC value:
> - Eravacycline: *Citrobacter freundii*

**Ertapenem.** A total of 977 Enterobacterales isolates (56 *C. freundii,* 74 *C. koseri,* 95 *E. cloacae,* 210 *E. coli*, 55 *K. aerogenes,* 28 *K. oxytoca,* 141 *K. pneumoniae,* 62 *M. morganii*, 88 *P. mirabilis*, 100 *P. vulgaris,* 68 *S. marcescens*) were evaluated with ertapenem. The combined results from clinical and challenge isolate testing demonstrated an EA of 94.7% and CA of 97.4%. There were 11 minor, 14 major and 0 very major errors. When evaluating results by individual species, *C. freundii* had 3 major errors (3/53 = 5.7%) at Selux MIC values of 2, 4 and 8 µg/mL which represent 5.4% (3/56) of results from this drug/organism combination. *E. cloacae* had an EA of 80%, a CA of 88.4%, and 6 major errors (6/70 = 8.6%), which is not acceptable. *K. aerogenes* had an EA of 80% and 2 major errors (2/50 = 4%), which is not acceptable. Due to the unacceptable performance for *E. cloacae* and *K. aerogenes*, these drug/organism combinations are not indicated for use with the Selux AST System. The following limitation is included in the device labeling to address the *C. freundii* major errors and restrict reporting of *E. cloacae* and *K. aerogenes* due to unacceptable performance:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):
> - Ertapenem: *Citrobacter freundii* when the Selux MIC is 2, 4 or 8 µg/mL due to 3 major errors, *Enterobacter cloacae, Klebsiella aerogenes*

A limitation statement is included in the device labeling to address the lack of testing with resistant *C. koseri, K. oxytoca, M. morganii, P. mirabilis,* and *P. vulgaris* isolates.

Analysis of trending indicated that MIC values for *M. morganii* tended to be one doubling dilution lower than the reference MIC value while MIC values for *C. freundii, C. koseri, E. coli*, *P. mirabilis*, *P. vulgaris* and *S. marcescens* tended to be one doubling dilution higher than the reference MIC value. The following statements are included as footnotes to the AST performance table:

Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution lower than the reference MIC value:

- Ertapenem: *Morganella morganii*

Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution higher than the reference MIC value:

- Ertapenem: *Citrobacter freundii, Citrobacter koseri, Escherichia coli*, *Proteus mirabilis, Proteus vulgaris, Serratia marcescens*

**Gentamicin.** A total of 817 Enterobacterales isolates (indicated species: 56 *C. freundii,* 74 *C. koseri,* 95 *E. cloacae,* 210 *E. coli*, 55 *K. aerogenes,* 28 *K. oxytoca,* 141 *K. pneumoniae,* 88 *P. mirabilis*, 100 *P. vulgaris,* 68 *S. marcescens;* non-indicated species: 62 *M. morganii*) were evaluated with gentamicin. The combined results from clinical and challenge isolate testing demonstrated an EA of 96.0% and CA of 98.8%. There were 7 minor, 1 major and 2 very major errors. When evaluating results by individual species, *M. morganii* had 1 very major error (1/8 = 12.5%) and *P. mirabilis* had 1 very major error (1/6 = 16.7%), which were considered random errors due to the limited number of resistant isolates tested.

A total of 218 *P. aeruginosa* were evaluated with gentamicin. The combined results from clinical and challenge isolate testing demonstrated an EA of 88.5% and CA of 97.3%. There were 6 minor, 0 major and 0 very major errors. Restriction of reporting MIC values of ≤ 0.06 µg/mL (lowest reportable MIC value that represents 4.1% (9/218) of results from this drug/organism combination) improved the EA to 90.4%, which is acceptable. The following limitation statement is included in the device labeling to restrict reporting of *P. aeruginosa* due to the low EA:

Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combinations:

- Gentamicin: *Pseudomonas aeruginosa* when the Selux MIC is ≤ 0.06 µg/mL

A limitation statement is included in the device labeling to address the lack of testing with resistant *K. aerogenes, M. morganii, P. vulgaris,* and *S. marcescens* isolates.

Analysis of trending indicated that MIC values for *C. freundii*, *E. cloacae* complex, *E. coli, K. oxytoca,* and *K. pneumoniae* tended to be one doubling dilution lower than the reference MIC value while MIC values for *S. marcescens* tended to be one doubling dilution higher than the reference MIC value. The following statements are included as footnotes to the AST performance table:

Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution lower than the reference MIC value:

- Gentamicin: *Citrobacter freundii*, *Enterobacter cloacae*, *Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae*

Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution higher than the reference MIC value:

- Gentamicin: *Serratia marcescens*

**Imipenem.** A total of 126 *A. baumannii* isolates were evaluated with imipenem. The combined results from clinical and challenge isolate testing demonstrated an EA of 88.9% and CA of 98.4%. There were 0 minor, 0 major and 2 very major errors (2/62 = 3.2%), which is not acceptable. Due to the unacceptable performance for *A. baumannii*, this drug/organism combination is not indicated for use with the Selux AST System. The following limitation statement is included in the device labeling to restrict reporting of *A. baumannii* due to the unacceptable performance:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combinations:
> - Imipenem: *Acinetobacter baumannii*

**Imipenem-relebactam.** A total of 471 Enterobacterales isolates (55*C. freundii,* 55 *C. koseri,* 172 *E. coli*, 31 *K. aerogenes,* 27 *K. oxytoca,* 131 *K. pneumoniae*) were evaluated with imipenem-relebactam. The combined results from clinical and challenge isolate testing demonstrated an EA of 93.4% and CA of 97.5%. There were 9 minor, 3 major and 0 very major errors. When evaluating results by individual species, *K. oxytoca* had 1 major error (1/27 = 3.7%) at a Selux MIC value of 4 µg/mL which represents 3.7% (1/27) of results from this drug/organism combination. *K. aerogenes* and *K. pneumoniae* had an EA <90%, which is not acceptable. Due to the unacceptable performance for *K. aerogenes* and *K. pneumoniae*, these drug/organism combinations are not indicated for use with the Selux AST System. The following limitation is included in the device labeling to address the *K. oxytoca* major error and restrict reporting of *K. aerogenes* and *K. pneumoniae* due to unacceptable performance:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):
> - Imipenem-relebactam: *Klebsiella oxytoca* when the Selux MIC is 4 µg/mL due to one major error, *Klebsiella pneumoniae*, *Klebsiella aerogenes*

A total of 165 *P. aeruginosa* isolates were evaluated with imipenem-relebactam. The combined results from clinical and challenge isolate testing demonstrated an EA of 96.4% and CA of 98.2%. There were 3 minor, 0 major and 0 very major errors. Overall, performance was acceptable.

A limitation statement is included in the device labeling to address the lack of testing with resistant *C. koseri, K. aerogenes,* and *K. oxytoca* isolates.

Analysis of trending indicated that MIC values for *C. freundii* tended to be one doubling dilution lower than the reference MIC value while MIC values for *K. oxytoca* tended to be one doubling dilution higher than the reference MIC value. The following statements are included as footnotes to the AST performance table:

> Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution lower than the reference MIC value:
> - Imipenem-relebactam: *Citrobacter freundii*
>
> Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution higher than the reference MIC value:

- Imipenem-relebactam: *Klebsiella oxytoca*

**Levofloxacin.** A total of 784 Enterobacterales isolates (63 *C. freundii,* 54 *C. koseri,* 75 *E. cloacae*, 171 *E. coli*, 32 *K. aerogenes,* 27 *K. oxytoca,* 110 *K. pneumoniae,* 62 *M. morganii*, 67 *P. mirabilis,* 55 *P. vulgaris,* 68 *S. marcescens*) were evaluated with levofloxacin. The combined results from clinical and challenge isolate testing demonstrated an EA of 96.1% and CA of 94.9%. There were 33 minor, 6 major and 1 very major errors. When evaluating results by individual species, *K. aerogenes* had 1 major error (1/30 = 3.3%) at a Selux MIC value of 2 µg/mL, which represents 3.1% (1/32) of results from this drug/organism combination. *C. freundii* had 2 major errors (2/55 = 3.6%) at a Selux MIC value of 2 µg/mL which represent 4.8% (3/63) of results from this drug/organism combination, as well as 1 very major error (1/7 = 14.3%), which was considered a random error due to the limited number of resistant isolates tested. The following limitation is included in the device labeling to address the major errors:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):
> - Levofloxacin: *Citrobacter freundii* when the Selux MIC is 2 µg/mL due to two major errors, *Klebsiella aerogenes* when the Selux MIC is 2 µg/mL due to one major error

A total of 171 *P. aeruginosa* isolates were evaluated with levofloxacin. The combined results from clinical and challenge isolate testing demonstrated an EA of 94.2% and CA of 90.1%. There were 14 minor, 1 major and 2 very major errors (2/42 = 4.8%), which is not acceptable. Due to the unacceptable performance for *P. aeruginosa*, this drug/organism combination is not indicated for use with the Selux AST System. The following limitation is included in the device labeling to restrict reporting of *P. aeruginosa* due to unacceptable performance:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):
> - Levofloxacin: *Pseudomonas aeruginosa*

A limitation statement is included in the device labeling to address the lack of testing with resistant *C. koseri* isolates.

Analysis of trending indicated that MIC values for *C. freundii*, *C. koseri, E. cloacae*, *E. coli, K. aerogenes, K. oxytoca, K. pneumoniae, M. morganii, P. mirabilis,* and *P. vulgaris* tended to be one doubling dilution higher than the reference MIC value. The following statement is included as a footnote to the AST performance table:

> Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution higher than the reference MIC value:
> - Levofloxacin: *C. freundii*, *C. koseri, E. cloacae*, *E. coli, K. aerogenes, K. oxytoca, K. pneumoniae, M. morganii, P. mirabilis, P. vulgaris*

**Meropenem.** A total of 126 *A. baumannii* isolates were evaluated with meropenem. The combined results from clinical and challenge isolate testing demonstrated an EA of 86.5%

and CA of 98.4%. There were 0 minor, 2 major (2/63 = 3.2%) and 0 very major errors. Due to the unacceptable performance for *A. baumannii*, this drug/organism combination is not indicated for use with the Selux AST System. The following limitation statement is included in the device labeling to restrict reporting of *A. baumannii* due to the unacceptable performance:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combinations:
> - Meropenem: *Acinetobacter baumannii*

A total of 865 Enterobacterales isolates (indicated species: 78 *C. freundii,* 74 *C. koseri,* 74 *E. cloacae*, 166 *E. coli*, 27 *K. oxytoca,* 126 *K. pneumoniae,* 62 *M. morganii*, 66 *P. mirabilis,* 55 *P. vulgaris,* 105 *S. marcescens;* non-indicated species: 32 *K. aerogenes*) were evaluated with meropenem. The combined results from clinical and challenge isolate testing demonstrated an EA of 96.3% and CA of 98.0%. There were 4 minor, 12 major and 1 very major errors. When evaluating results by individual species, *C. freundii* has 3 major errors (3/74 = 4.1%) at Selux MIC values of 16 and 32 µg/mL, which represent 6.4% (5/78) of results from this drug/organism combination. *S. marcescens* had 4 major errors (4/101 = 4.0%) at Selux MIC value of 16 and 32 µg/mL, which represent 6.7% (7/105) of results from this drug/organism combination, as well as 1 very major error (1/4 = 25%) which was considered a random error due to the limited number of resistant isolates tested. The following limitations are included in the device labeling to address the major errors:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):
> - Meropenem: *Citrobacter freundii* complex when the Selux MIC is 16 or 32 µg/mL due to 3 major errors, *Serratia marcescens* when the Selux MIC is 16 or 32 µg/mL due to 4 major errors

A total of 175 *P. aeruginosa* isolates were evaluated with levofloxacin. The combined results from clinical and challenge isolate testing demonstrated an EA of 93.1% and CA of 96.0%. There were 7 minor, 0 major and 0 very major errors. Overall, performance was acceptable.

A limitation is included in the device labeling to address the lack of testing with resistant *C. koseri, K. oxytoca, M. morganii, P. vulgaris* isolates.

Analysis of trending indicated that MIC values for *C. freundii*, *C. koseri, E. cloacae*, *K. aerogenes, K. oxytoca, K. pneumoniae, M. morganii, P. mirabilis, P. vulgaris,* and *S. marcescens* tended to be one doubling dilution higher than the reference MIC value. The following statement is included as a footnote to the AST performance table:

> Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution higher than the reference MIC value:
> - Meropenem: *Citrobacter freundii*, *Citrobacter koseri, Enterobacter cloacae*, *Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*

**Meropenem-vaborbactam.** A total of 865 Enterobacterales isolates (indicated species: 64 *C. freundii,* 54 *C. koseri,* 70 *E. cloacae*, 167 *E. coli*, 50 *K. aerogenes,* 47 *K. oxytoca,* 113 *K. pneumoniae,* 64 *M. morganii*, 66 *P. mirabilis,* 65 *S. marcescens;* non-indicated species: 100 *P. vulgaris*) were evaluated with meropenem-vaborbactam. The combined results from clinical and challenge isolate testing demonstrated an EA of 91.7% and CA of 96.9%. There were 10 minor, 16 major and 1 very major errors. When evaluating results by individual species, *P. mirabilis* had an EA of 62%, CA of 97.0%, 2 minor, 0 major and 0 very major errors. *P. vulgaris* had an EA of 62%, CA of 81%, 15 major errors (15/100 = 15%). Due to the unacceptable performance for *P. mirabilis* and *P. vulgaris*, these drug/organism combinations are not indicated for use with the Selux AST System.The following limitation is included in the device labeling to restrict reporting due to unacceptable performance:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):
> - Meropenem-vaborbactam: *Proteus mirabilis*; *Proteus vulgaris*

A limitation is included in the device labeling to address the lack of testing with resistant *C. koseri, K. aerogenes, K. oxytoca, M. morganii, P. mirabilis, P. vulgaris,* and *S. marcescens* isolates.

Analysis of trending indicated that MIC values for *C. freundii*, *C. koseri, E. cloacae* complex, *E. coli, K. aerogenes, K. oxytoca, K. pneumoniae, M. morganii,* and *S. marcescens* tended to be one doubling dilution higher than the reference MIC value. The following statement is included as a footnote to the AST performance table:

> Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution higher than the reference MIC value:
> - Meropenem-vaborbactam: *Citrobacter freundii*, *Citrobacter koseri, Enterobacter cloacae* complex, *Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Serratia marcescens*

**Minocycline.** A total of 199 *A. baumannii* isolates were evaluated with minocycline. The combined results from clinical and challenge isolate testing demonstrated an EA of 88.9% and CA of 91.0%. There were 13 minor, 5 major (5/150 = 3.3%) and 0 very major errors. Due to the unacceptable performance for *A. baumannii*, this drug/organism combination is not indicated for use with the Selux AST System. The following limitation statement is included in the device labeling to restrict reporting of *A. baumannii* due to unacceptable performance:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combinations:
> - Minocycline: *Acinetobacter baumannii*

A total of 404 Enterobacterales isolates (198 *E. coli*, 53 *K. aerogenes,* 27 *K. oxytoca,* 126 *K. pneumoniae*) were evaluated with minocycline. The combined results from clinical and challenge isolate testing demonstrated an EA of 89.6% and CA of 94.3%. There were 16 minor, 3 major and 4 very major errors. When evaluating results by individual species, *E. coli* had an EA of 87.4% as well as 8 minor, 2 major (2/182 = 1.1%) and 1 very major (1/7 =

14.3%) errors, which was considered a random error due to the limited number of resistant isolates tested. *K. aerogenes* had 1 very major error (1/3 = 33.3%), which was considered a random error due to the limited number of resistant isolates tested. *K. pneumoniae* had an EA of 88.9% and 2 very major errors (2/33 = 6.1%) at a Selux MIC of 4. Restricting *K. pneumoniae* reporting at a Selux MIC of 4 µg/mL, which represents 6.3% (8/126) of results from this drug/organism combination addresses both very major errors and improves EA to 89.8%. Due to the unacceptable performance for *E. coli*, this drug/organism combination is not indicated for use with the Selux AST System. The following limitation statement is included in the device labeling to restrict reporting of *E. coli* due to unacceptable performance and address the *K. pneumoniae* very major errors:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):
> - Minocycline: *Escherichia coli*, *Klebsiella pneumoniae* when the Selux MIC is 4 µg/mL due to two very major errors

A limitation is included in the device labeling to address the lack of testing with resistant *K. oxytoca* isolates.

There was no evidence of trending observed with Enterobacterales with minocycline.

**Piperacillin-tazobactam.** A total of 113 *A. baumannii* isolates were evaluated with piperacillin-tazobactam. The combined results from clinical and challenge isolate testing demonstrated an EA of 81.4% and CA of 91.2%. There were 9 minor errors, 0 major errors and 1 very major error (1/58 = 1.7%). Due to the unacceptable performance for *A. baumannii*, this drug/organism combination is not indicated for use with the Selux AST System. The following limitation statement is included in the device labeling to restrict reporting of *A. baumannii* due to unacceptable performance:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combinations:
> - Piperacillin-tazobactam: *Acinetobacter baumannii*

A total of 926 Enterobacterales isolates (indicated species: 75 *C. koseri,* 176 *E. coli,* 142 *K. pneumoniae,* 75 *M. morganii,* 88 *P. mirabilis,* 55 *P. vulgaris,* 60 *S. marcescens;* non-indicated species: 78 *C. freundii,* 96 *E. cloacae,* 53 *K. aerogenes,* 28 *K. oxytoca*) were evaluated with piperacillin-tazobactam. The combined results from clinical and challenge isolate testing demonstrated an EA of 90.2% and CA of 94.8%. There were 35 minor, 9 major and 4 very major errors. When evaluating results by individual species, *C. freundii* had an EA of 79.5%, CA of 84.6% as well as 11 minor, 0 major, and 1 very major (1/11 = 9.1%) errors. *E. cloacae* had an EA and CA of 86.5% as well as 9 minor and 4 major (4/61 = 6.6%) errors. *K. aerogenes* had an EA of 86.8% as well as 2 minor and 2 major (2/42 = 4.8%) errors. *S. marcescens* had an EA of 66.7% as well as 1 minor and 1 very major (1/2) error, which was considered a random error due to the limited number of resistant isolates tested. Due to the unacceptable performance for reporting of *C. freundii, E. cloacae, K. aerogenes* and *S. marcescens*, these drug/organism combinations are not indicated for use with the Selux AST System. The following limitation statement is included in the device labeling to

restrict reporting of *C. freundii, E. cloacae, K. aerogenes* and *S. marcescens* due to unacceptable performance:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):
> - Piperacillin-tazobactam: *Citrobacter freundii, Enterobacter cloacae, Klebsiella aerogenes, Serratia marcescens*

A total of 217 *P. aeruginosa* isolates were evaluated with piperacillin-tazobactam. The combined results from clinical and challenge isolate testing demonstrated an EA of 80.7% and CA of 83.9%. There were 27 minor errors, 2 major errors (2/167 = 1.2%), and 6 very major errors (6/28 = 21.4%). Due to the unacceptable performance for *P. aeruginosa*, this drug/organism combination is not indicated for use with the Selux AST System. The following limitation statement is included in the device labeling to restrict reporting of *P. aeruginosa* due to unacceptable performance:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combinations:
> - Piperacillin-tazobactam: *Pseudomonas aeruginosa*

A limitation is included in the device labeling to address the lack of testing with resistant *C. koseri, P. mirabilis,* and *P. vulgaris* isolates.

Analysis of trending indicated that MIC values for *K. oxytoca* and *K. pneumoniae* tended to be one doubling dilution lower than the reference MIC value while MIC values for *M. morganii, P. mirabilis* and *P. vulgaris* tended to be one doubling dilution higher than the reference MIC value. The following statements are included as a footnote to the AST performance table:

> Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution lower than the reference MIC value:
> - Piperacillin-tazobactam: *Klebsiella oxytoca, Klebsiella pneumoniae*
>
> Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution higher than the reference MIC value:
> - Piperacillin-tazobactam: *Morganella morganii, Proteus mirabilis, Proteus vulgaris*

**Tobramycin.** A total of 166 *P. aeruginosa* isolates were evaluated with tobramycin. The combined results from clinical and challenge isolate testing demonstrated an EA of 93.4% and CA of 97.6%. There were 3 minor errors, 1 major error (1/150 = 0.7%), and 0 very major errors (6/28 = 21.4%). Overall, performance was acceptable.

There was no evidence of trending observed with *P. aeruginosa* with tobramycin.

**Trimethoprim-Sulfamethoxazole.** A total of 526 Enterobacterales isolates (indicated species: 76 *E. cloacae,* 203 *E. coli*, 32 *K. aerogenes,* 29 *K. oxytoca,* 109 *K. pneumoniae;* non-indicated species: 77 *C. freundii*) were evaluated with trimethoprim-sulfamethoxazole. The combined

results from clinical and challenge isolate testing demonstrated an EA of 97.0% and CA of 98.5%. There were 0 minor, 2 major and 6 very major errors. When evaluating results by individual species, *C. freundii* had 1 very major error (1/17 = 5.9%), *E. coli* had 4 very major errors (4/67 = 6.0%), *K. pneumoniae* had 2 major (2/61 = 3.3%) and 1 very major (1/28 = 3.6%) errors. Due to the lack of an intermediate interpretive criterion, further analysis of the errors was performed and adjustments were made by considering the MIC values of the errors compared to the reference MIC value. One of the 2 major errors and 1 of the 1 very major errors from *K. pneumoniae* had an MIC value that was in essential agreement with the reference MIC value. Therefore, *K. pneumoniae* has an adjusted major error rate of 1.6% (1/61) and an adjusted very major error rate of 0% (0/28), which is acceptable. Due to the unacceptable performance for *C. freundii* and *E. coli*, these drug/organism combinations are not indicated for use with the Selux AST System. The following limitation statement is included in the device labeling to restrict reporting of *C. freundii* and *E. coli*:

> Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination(s):
> - Trimethoprim-Sulfamethoxazole: *Citrobacter freundii, Escherichia coli*

Analysis of trending indicated that MIC values for *E. cloacae, K. aerogenes, K. oxytoca,* and *K. pneumoniae* tended to be one doubling dilution higher than the reference MIC value. The following statement is included as a footnote to the AST performance table:

> Selux MIC values for the following antimicrobial/organism combinations tended to be one doubling dilution higher than the reference MIC value:
> Trimethoprim-Sulfamethoxazole: *Enterobacter cloacae, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae*

**Table 6.** Selux AST System – Gram-Negative Panel Performance

| | Tot | No. EA | EA % | Eval EA Tot | No. Eval EA | Eval EA % | No. CA | CA % | No. R or NS | No. S | min | maj | vmj |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| [a]Amikacin - *Acinetobacter baumannii* [Breakpoints (µg/mL): 16 (S), 32 (I), 64 (R)] | | | | | | | | | | | | | |
| Clinical | 86 | 47 | 54.65 | 77 | 38 | 49.35 | 78 | 90.7 | 14 | 69 | 3 | 4 | 1 |
| Challenge | 25 | 14 | 56 | 16 | 5 | 31.25 | 18 | 72 | 11 | 11 | 3 | 4 | 0 |
| Combined | 111 | 61 | 54.95 | 93 | 43 | 46.24 | 96 | 86.49 | 25 | 80 | 6 | 8 | 1 |
| Amikacin - *Pseudomonas aeruginosa* [Breakpoints (µg/mL): 16 (S), 32 (I), 64 (R)] | | | | | | | | | | | | | |
| Clinical | 159 | 145 | 91.19 | 158 | 144 | 91.14 | 156 | 98.11 | 3 | 154 | 3 | 0 | 0 |
| Challenge | 6 | 5 | 83.33 | 5 | 4 | 80 | 6 | 100 | 4 | 2 | 0 | 0 | 0 |
| Combined | 165 | 150 | 90.91 | 163 | 148 | 90.8 | 162 | 98.18 | 7 | 156 | 3 | 0 | 0 |
| Amoxicillin-Clavulanate – Enterobacterales [Breakpoints (µg/mL): 8 (S), 16 (I), 32 (R)] | | | | | | | | | | | | | |
| Clinical | 502 | 463 | 92.23 | 454 | 415 | 91.41 | 460 | 91.63 | 40 | 412 | 37 | 4 | 1 |
| Challenge | 91 | 90 | 98.9 | 49 | 48 | 97.96 | 90 | 98.9 | 71 | 19 | 0 | 1 | 0 |
| Combined | 593 | 553 | 93.25 | 503 | 463 | 92.05 | 550 | 92.75 | 111 | 431 | 37 | 5 | 1 |
| Ampicillin: Enterobacterales [Breakpoints (µg/mL): 8 (S), 16 (I), 32 (R)] | | | | | | | | | | | | | |
| Clinical | 247 | 234 | 94.74 | 138 | 125 | 90.58 | 244 | 98.79 | 111 | 135 | 1 | 1 | 1 |
| Challenge | 7 | 7 | 100 | 0 | 0 | NA | 7 | 100 | 7 | 0 | 0 | 0 | 0 |
| Combined | 254 | 241 | 94.88 | 138 | 125 | 90.58 | 251 | 98.82 | 118 | 135 | 1 | 1 | 1 |
| Ampicillin-Sulbactam: *Acinetobacter baumannii* [Breakpoints (µg/mL): 8 (S), 16 (I), 32 (R)] | | | | | | | | | | | | | |
| Clinical | 121 | 111 | 91.74 | 111 | 101 | 90.99 | 112 | 92.56 | 50 | 65 | 6 | 2 | 1 |
| Challenge | 2 | 2 | 100 | 2 | 2 | 100 | 2 | 100 | 2 | 0 | 0 | 0 | 0 |
| Combined | 123 | 113 | 91.87 | 113 | 103 | 91.15 | 114 | 92.68 | 52 | 65 | 6 | 2 | 1 |
| Ampicillin-Sulbactam: Enterobacterales [Breakpoints (µg/mL): 8 (S), 16 (I), 32 (R)] | | | | | | | | | | | | | |

| | Tot | No. EA | EA % | Eval EA Tot | No. Eval EA | Eval EA % | No. CA | CA % | No. R or NS | No. S | min | maj | vmj |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Clinical | 518 | 502 | 96.91 | 475 | 459 | 96.63 | 433 | 83.59 | 163 | 279 | 81 | 4 | 0 |
| Challenge | 56 | 54 | 96.43 | 26 | 24 | 92.31 | 46 | 82.14 | 39 | 11 | 9 | 1 | 0 |
| Combined | 574 | 556 | 96.86 | 501 | 483 | 96.41 | 479 | 83.45 | 202 | 290 | 90 | 5 | 0 |
| [a]Aztreonam: Enterobacterales [Breakpoints (µg/mL): 4 (S), 8 (I), 16 (R)] | | | | | | | | | | | | | |
| Clinical | 159 | 156 | 98.11 | 144 | 141 | 97.92 | 154 | 96.86 | 22 | 129 | 5 | 0 | 0 |
| Challenge | 24 | 23 | 95.83 | 10 | 9 | 90 | 24 | 100 | 24 | 0 | 0 | 0 | 0 |
| Combined | 183 | 179 | 97.81 | 154 | 150 | 97.4 | 178 | 97.27 | 46 | 129 | 5 | 0 | 0 |
| Aztreonam: *Pseudomonas aeruginosa* [Breakpoints (µg/mL): 8 (S), 16 (I), 32 (R)] | | | | | | | | | | | | | |
| Clinical | 208 | 189 | 90.87 | 202 | 183 | 90.59 | 181 | 87.02 | 37 | 158 | 20 | 3 | 4 |
| Challenge | 11 | 11 | 100 | 4 | 4 | 100 | 11 | 100 | 11 | 0 | 0 | 0 | 0 |
| Combined | 219 | 200 | 91.32 | 206 | 187 | 90.78 | 192 | 87.67 | 48 | 158 | 20 | 3 | 4 |
| Cefazolin: Enterobacterales [Breakpoints (µg/mL): 1 (S), 2 (I), 4 (R)] | | | | | | | | | | | | | |
| Clinical | 368 | 344 | 93.48 | 290 | 266 | 91.72 | 264 | 71.74 | 174 | 99 | 102 | 1 | 1 |
| Challenge | 44 | 44 | 100 | 0 | 0 | NA | 44 | 100 | 44 | 0 | 0 | 0 | 0 |
| Combined | 412 | 388 | 94.17 | 290 | 266 | 91.72 | 308 | 74.76 | 218 | 99 | 102 | 1 | 1 |
| Cefepime: Enterobacterales [Breakpoints (µg/mL): 2 (S), 4-8 (I), 16 (R)] | | | | | | | | | | | | | |
| Clinical | 905 | 857 | 94.7 | 127 | 79 | 62.2 | 867 | 95.8 | 78 | 810 | 26 | 10 | 2 |
| Challenge | 51 | 49 | 96.08 | 17 | 15 | 88.24 | 51 | 100 | 49 | 2 | 0 | 0 | 0 |
| Combined | 956 | 906 | 94.77 | 144 | 94 | 65.28 | 918 | 96.03 | 127 | 812 | 26 | 10 | 2 |
| [a]Cefepime: *Pseudomonas aeruginosa* [Breakpoints (µg/mL): 8 (S), - (I), 16 (R)] | | | | | | | | | | | | | |
| Clinical | 208 | 182 | 87.5 | 203 | 177 | 87.19 | 188 | 90.38 | 30 | 178 | 0 | 13 | 7 |
| Challenge | 7 | 6 | 85.71 | 2 | 1 | 50 | 7 | 100 | 7 | 0 | 0 | 0 | 0 |
| Combined | 215 | 188 | 87.44 | 205 | 178 | 86.83 | 195 | 90.7 | 37 | 178 | 0 | 13 | 7 |
| Cefoxitin: Enterobacterales [Breakpoints (µg/mL): 4 (S), 8 (I), 16 (R)] | | | | | | | | | | | | | |
| Clinical | 600 | 551 | 91.83 | 576 | 527 | 91.49 | 474 | 79 | 71 | 394 | 114 | 9 | 3 |
| Challenge | 37 | 37 | 100 | 15 | 15 | 100 | 37 | 100 | 35 | 2 | 0 | 0 | 0 |
| Combined | 637 | 588 | 92.31 | 591 | 542 | 91.71 | 511 | 80.22 | 106 | 396 | 114 | 9 | 3 |
| [a]Ceftazidime: *Acinetobacter baumannii* [Breakpoints (µg/mL): 8 (S), 16 (I), 32 (R)] | | | | | | | | | | | | | |
| Clinical | 121 | 105 | 86.78 | 90 | 74 | 82.22 | 114 | 94.21 | 52 | 61 | 7 | 0 | 0 |
| Challenge | 6 | 5 | 83.33 | 2 | 1 | 50 | 6 | 100 | 5 | 1 | 0 | 0 | 0 |
| Combined | 127 | 110 | 86.61 | 92 | 75 | 81.52 | 120 | 94.49 | 57 | 62 | 7 | 0 | 0 |
| Ceftazidime: Enterobacterales [Breakpoints (µg/mL): 4 (S), 8 (I), 16 (R)] | | | | | | | | | | | | | |
| Clinical | 670 | 635 | 94.78 | 140 | 105 | 75 | 642 | 95.82 | 95 | 563 | 26 | 1 | 1 |
| Challenge | 117 | 117 | 100 | 11 | 11 | 100 | 117 | 100 | 113 | 4 | 0 | 0 | 0 |
| Combined | 787 | 752 | 95.55 | 151 | 116 | 76.82 | 759 | 96.44 | 208 | 567 | 26 | 1 | 1 |
| [a]Ceftazidime: *Pseudomonas aeruginosa* [Breakpoints (µg/mL): 8 (S), - (I), 16 (R)] | | | | | | | | | | | | | |
| Clinical | 211 | 185 | 87.68 | 205 | 179 | 87.32 | 196 | 92.89 | 34 | 177 | 0 | 9 | 6 |
| Challenge | 13 | 12 | 92.31 | 8 | 7 | 87.5 | 13 | 100 | 12 | 1 | 0 | 0 | 0 |
| Combined | 224 | 197 | 87.95 | 213 | 186 | 87.32 | 209 | 93.3 | 46 | 178 | 0 | 9 | 6 |
| Ceftazidime-avibactam: Enterobacterales [Breakpoints (µg/mL): 8 (S), - (I), 16 (R)] | | | | | | | | | | | | | |
| Clinical | 772 | 751 | 97.28 | 211 | 190 | 90.05 | 767 | 99.35 | 2 | 770 | 0 | 5 | 0 |
| Challenge | 43 | 42 | 97.67 | 11 | 10 | 90.91 | 43 | 100 | 30 | 13 | 0 | 0 | 0 |
| Combined | 815 | 793 | 97.3 | 222 | 200 | 90.09 | 810 | 99.39 | 32 | 783 | 0 | 5 | 0 |
| Ceftazidime-avibactam: *Pseudomonas aeruginosa* [Breakpoints (µg/mL): 8 (S), - (I), 16 (R)] | | | | | | | | | | | | | |
| Clinical | 157 | 140 | 89.17 | 153 | 136 | 88.89 | 153 | 97.45 | 5 | 152 | 0 | 4 | 0 |
| Challenge | 6 | 6 | 100 | 2 | 2 | 100 | 5 | 83.33 | 5 | 1 | 0 | 0 | 1 |
| Combined | 163 | 146 | 89.57 | 155 | 138 | 89.03 | 158 | 96.93 | 10 | 153 | 0 | 4 | 1 |
| Ceftriaxone: Enterobacterales [Breakpoints (µg/mL): 1 (S), 2 (I), 4 (R)] | | | | | | | | | | | | | |
| Clinical | 666 | 648 | 97.3 | 68 | 50 | 73.53 | 655 | 98.35 | 134 | 530 | 3 | 4 | 4 |
| Challenge | 56 | 56 | 100 | 1 | 1 | 100 | 56 | 100 | 54 | 1 | 0 | 0 | 0 |
| Combined | 722 | 704 | 97.51 | 69 | 51 | 73.91 | 711 | 98.48 | 188 | 531 | 3 | 4 | 4 |
| Ciprofloxacin: Enterobacterales [Breakpoints (µg/mL): 0.25 (S), 0.5 (I), 1 (R)] | | | | | | | | | | | | | |
| Clinical | 770 | 743 | 96.49 | 150 | 123 | 82 | 739 | 95.97 | 130 | 622 | 26 | 3 | 2 |

| | Tot | No. EA | EA % | Eval EA Tot | No. Eval EA | Eval EA % | No. CA | CA % | No. R or NS | No. S | min | maj | vmj |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Challenge | 48 | 48 | 100 | 6 | 6 | 100 | 48 | 100 | 47 | 1 | 0 | 0 | 0 |
| Combined | 818 | 791 | 96.7 | 156 | 129 | 82.69 | 787 | 96.21 | 177 | 623 | 26 | 3 | 2 |
| Ciprofloxacin: *Pseudomonas aeruginosa* [Breakpoints (µg/mL): 0.5 (S), 1 (I), 2 (R)] | | | | | | | | | | | | | |
| Clinical | 159 | 152 | 95.6 | 147 | 140 | 95.24 | 150 | 94.34 | 23 | 132 | 5 | 4 | 0 |
| Challenge | 10 | 10 | 100 | 1 | 1 | 100 | 10 | 100 | 10 | 0 | 0 | 0 | 0 |
| Combined | 169 | 162 | 95.86 | 148 | 141 | 95.27 | 160 | 94.67 | 33 | 132 | 5 | 4 | 0 |
| Eravacycline: Enterobacterales [Breakpoints (µg/mL): 0.5 (S), - (I), - (R)] | | | | | | | | | | | | | |
| Clinical | 441 | 432 | 97.96 | 436 | 427 | 97.94 | 434 | 98.41 | 23 | 418 | 0 | 4 | 3 |
| Challenge | 46 | 46 | 100 | 39 | 39 | 100 | 46 | 100 | 31 | 15 | 0 | 0 | 0 |
| Combined | 487 | 478 | 98.15 | 475 | 466 | 98.11 | 480 | 98.56 | 54 | 433 | 0 | 4 | 3 |
| Ertapenem: Enterobacterales [Breakpoints (µg/mL): 0.5 (S), 1 (I), 2 (R)] | | | | | | | | | | | | | |
| Clinical | 880 | 832 | 94.55 | 123 | 75 | 60.98 | 857 | 97.39 | 31 | 842 | 9 | 14 | 0 |
| Challenge | 97 | 93 | 95.88 | 14 | 10 | 71.43 | 95 | 97.94 | 90 | 7 | 2 | 0 | 0 |
| Combined | 977 | 925 | 94.68 | 137 | 85 | 62.04 | 952 | 97.44 | 121 | 849 | 11 | 14 | 0 |
| Gentamicin: Enterobacterales [Breakpoints (µg/mL): 4 (S), 8 (I), 16 (R)] | | | | | | | | | | | | | |
| Clinical | 745 | 713 | 95.7 | 704 | 672 | 95.45 | 735 | 98.66 | 60 | 679 | 7 | 1 | 2 |
| Challenge | 72 | 71 | 98.61 | 20 | 19 | 95 | 72 | 100 | 61 | 11 | 0 | 0 | 0 |
| Combined | 817 | 784 | 95.96 | 724 | 691 | 95.44 | 807 | 98.78 | 121 | 690 | 7 | 1 | 2 |
| Gentamicin: *Pseudomonas aeruginosa* [Breakpoints (µg/mL): 4 (S), 8 (I), 16 (R)] | | | | | | | | | | | | | |
| Clinical | 208 | 183 | 87.98 | 200 | 175 | 87.5 | 202 | 97.12 | 7 | 195 | 6 | 0 | 0 |
| Challenge | 10 | 10 | 100 | 2 | 2 | 100 | 10 | 100 | 8 | 2 | 0 | 0 | 0 |
| Combined | 218 | 193 | 88.53 | 202 | 177 | 87.62 | 212 | 97.25 | 15 | 197 | 6 | 0 | 0 |
| [a]Imipenem: *Acinetobacter baumannii* [Breakpoints (µg/mL): 2 (S), 4 (I), 8 (R)] | | | | | | | | | | | | | |
| Clinical | 121 | 107 | 88.43 | 77 | 63 | 81.82 | 119 | 98.35 | 57 | 64 | 0 | 0 | 2 |
| Challenge | 5 | 5 | 100 | 1 | 1 | 100 | 5 | 100 | 5 | 0 | 0 | 0 | 0 |
| Combined | 126 | 112 | 88.89 | 78 | 64 | 82.05 | 124 | 98.41 | 62 | 64 | 0 | 0 | 2 |
| Imipenem-Relebactam: Enterobacterales [Breakpoints (µg/mL): 1 (S), 2 (I), 4 (R)] | | | | | | | | | | | | | |
| Clinical | 433 | 406 | 93.76 | 427 | 400 | 93.68 | 422 | 97.46 | 4 | 428 | 8 | 3 | 0 |
| Challenge | 38 | 34 | 89.47 | 37 | 33 | 89.19 | 37 | 97.37 | 29 | 8 | 1 | 0 | 0 |
| Combined | 471 | 440 | 93.42 | 464 | 433 | 93.32 | 459 | 97.45 | 33 | 436 | 9 | 3 | 0 |
| Imipenem-Relebactam: *Pseudomonas aeruginosa* [Breakpoints (µg/mL): 2 (S), 4 (I), 8 (R)] | | | | | | | | | | | | | |
| Clinical | 158 | 152 | 96.2 | 158 | 152 | 96.2 | 155 | 98.1 | 3 | 153 | 3 | 0 | 0 |
| Challenge | 7 | 7 | 100 | 4 | 4 | 100 | 7 | 100 | 3 | 4 | 0 | 0 | 0 |
| Combined | 165 | 159 | 96.36 | 162 | 156 | 96.3 | 162 | 98.18 | 6 | 157 | 3 | 0 | 0 |
| Levofloxacin: Enterobacterales [Breakpoints (µg/mL): 0.5 (S), 1 (I), 2 (R)] | | | | | | | | | | | | | |
| Clinical | 732 | 701 | 95.77 | 235 | 204 | 86.81 | 692 | 94.54 | 112 | 600 | 33 | 6 | 1 |
| Challenge | 52 | 52 | 100 | 7 | 7 | 100 | 52 | 100 | 49 | 3 | 0 | 0 | 0 |
| Combined | 784 | 753 | 96.05 | 242 | 211 | 87.19 | 744 | 94.9 | 161 | 603 | 33 | 6 | 1 |
| [a]Levofloxacin: *Pseudomonas aeruginosa* [Breakpoints (µg/mL): 1 (S), 2 (I), 4 (R)] | | | | | | | | | | | | | |
| Clinical | 159 | 149 | 93.71 | 148 | 138 | 93.24 | 142 | 89.31 | 30 | 117 | 14 | 1 | 2 |
| Challenge | 12 | 12 | 100 | 3 | 3 | 100 | 12 | 100 | 12 | 0 | 0 | 0 | 0 |
| Combined | 171 | 161 | 94.15 | 151 | 141 | 93.38 | 154 | 90.06 | 42 | 117 | 14 | 1 | 2 |
| [a]Meropenem: Acinetobacter baumannii [Breakpoints (µg/mL): 2 (S), 4 (I), 8 (R)] | | | | | | | | | | | | | |
| Clinical | 121 | 104 | 85.95 | 42 | 25 | 59.52 | 119 | 98.35 | 58 | 63 | 0 | 2 | 0 |
| Challenge | 5 | 5 | 100 | 0 | 0 | NA | 5 | 100 | 5 | 0 | 0 | 0 | 0 |
| Combined | 126 | 109 | 86.51 | 42 | 25 | 59.52 | 124 | 98.41 | 63 | 63 | 0 | 2 | 0 |
| Meropenem: Enterobacterales [Breakpoints (µg/mL): 1 (S), 2 (I), 4 (R)] | | | | | | | | | | | | | |
| Clinical | 805 | 776 | 96.4 | 54 | 25 | 46.3 | 789 | 98.01 | 25 | 777 | 4 | 12 | 0 |
| Challenge | 60 | 57 | 95 | 25 | 22 | 88 | 59 | 98.33 | 59 | 1 | 0 | 0 | 1 |
| Combined | 865 | 833 | 96.3 | 79 | 47 | 59.49 | 848 | 98.03 | 84 | 778 | 4 | 12 | 1 |
| Meropenem: *Pseudomonas aeruginosa* [Breakpoints (µg/mL): 2 (S), 4 (I), 8 (R)] | | | | | | | | | | | | | |
| Clinical | 159 | 148 | 93.08 | 131 | 120 | 91.6 | 152 | 95.6 | 23 | 131 | 7 | 0 | 0 |
| Challenge | 16 | 15 | 93.75 | 11 | 10 | 90.91 | 16 | 100 | 15 | 1 | 0 | 0 | 0 |

| | Tot | No. EA | EA % | Eval EA Tot | No. Eval EA | Eval EA % | No. CA | CA % | No. R or NS | No. S | min | maj | vmj |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Combined | 175 | 163 | 93.14 | 142 | 130 | 91.55 | 168 | 96 | 38 | 132 | 7 | 0 | 0 |
| Meropenem-vaborbactam: Enterobacterales [Breakpoints (µg/mL): 4 (S), 8 (I), 16 (R)] | | | | | | | | | | | | | |
| Clinical | 817 | 748 | 91.55 | 152 | 83 | 54.61 | 791 | 96.82 | 4 | 810 | 9 | 16 | 1 |
| Challenge | 43 | 41 | 95.35 | 12 | 10 | 83.33 | 42 | 97.67 | 37 | 6 | 1 | 0 | 0 |
| Combined | 860 | 789 | 91.74 | 164 | 93 | 56.71 | 833 | 96.86 | 41 | 816 | 10 | 16 | 1 |
| [a]Minocycline: *Acinetobacter baumannii* [Breakpoints (µg/mL): 4 (S), 8 (I), 16 (R)] | | | | | | | | | | | | | |
| Clinical | 196 | 174 | 88.78 | 96 | 74 | 77.08 | 178 | 90.82 | 38 | 148 | 13 | 5 | 0 |
| Challenge | 3 | 3 | 100 | 3 | 3 | 100 | 3 | 100 | 1 | 2 | 0 | 0 | 0 |
| Combined | 199 | 177 | 88.94 | 99 | 77 | 77.78 | 181 | 90.95 | 39 | 150 | 13 | 5 | 0 |
| Minocycline: Enterobacterales [Breakpoints (µg/mL): 4 (S), 8 (I), 16 (R)] | | | | | | | | | | | | | |
| Clinical | 381 | 341 | 89.5 | 339 | 299 | 88.2 | 358 | 93.96 | 30 | 334 | 16 | 3 | 4 |
| Challenge | 23 | 21 | 91.3 | 15 | 13 | 86.67 | 23 | 100 | 13 | 9 | 0 | 0 | 0 |
| Combined | 404 | 362 | 89.6 | 354 | 312 | 88.14 | 381 | 94.31 | 43 | 343 | 16 | 3 | 4 |
| [a]Piperacillin-Tazobactam: *Acinetobacter baumannii* [Breakpoints (µg/mL): 16(S), 32-64 (I), 128 (R)] | | | | | | | | | | | | | |
| Clinical | 108 | 87 | 80.56 | 31 | 10 | 32.26 | 98 | 90.74 | 53 | 51 | 9 | 0 | 1 |
| Challenge | 5 | 5 | 100 | 1 | 1 | 100 | 5 | 100 | 5 | 0 | 0 | 0 | 0 |
| Combined | 113 | 92 | 81.42 | 32 | 11 | 34.38 | 103 | 91.15 | 58 | 51 | 9 | 0 | 1 |
| Piperacillin-Tazobactam: Enterobacterales [Breakpoints (µg/mL): 16(S), 32-64 (I), 128 (R)] | | | | | | | | | | | | | |
| Clinical | 815 | 728 | 89.33 | 641 | 554 | 86.43 | 768 | 94.23 | 56 | 730 | 35 | 8 | 4 |
| Challenge | 111 | 107 | 96.4 | 36 | 32 | 88.89 | 110 | 99.1 | 92 | 19 | 0 | 1 | 0 |
| Combined | 926 | 835 | 90.17 | 677 | 586 | 86.56 | 878 | 94.82 | 148 | 749 | 35 | 9 | 4 |
| [a]Piperacillin-Tazobactam: *Pseudomonas aeruginosa* [Breakpoints (µg/mL): 16(S), 32-64 (I), 128 (R)] | | | | | | | | | | | | | |
| Clinical | 211 | 170 | 80.57 | 208 | 167 | 80.29 | 177 | 83.89 | 22 | 167 | 26 | 2 | 6 |
| Challenge | 6 | 5 | 83.33 | 5 | 4 | 80 | 5 | 83.33 | 6 | 0 | 1 | 0 | 0 |
| Combined | 217 | 175 | 80.65 | 213 | 171 | 80.28 | 182 | 83.87 | 28 | 167 | 27 | 2 | 6 |
| Tobramycin: *Pseudomonas aeruginosa* [Breakpoints (µg/mL): 4 (S), 8 (I), 16 (R)] | | | | | | | | | | | | | |
| Clinical | 158 | 147 | 93.04 | 152 | 141 | 92.76 | 154 | 97.47 | 6 | 150 | 3 | 1 | 0 |
| Challenge | 8 | 8 | 100 | 2 | 2 | 100 | 8 | 100 | 8 | 0 | 0 | 0 | 0 |
| Combined | 166 | 155 | 93.37 | 154 | 143 | 92.86 | 162 | 97.59 | 14 | 150 | 3 | 1 | 0 |
| Trimethoprim Sulfamethoxazole: Enterobacterales [Breakpoints (µg/mL): 2 (S), - (I), 4 (R)] | | | | | | | | | | | | | |
| Clinical | 480 | 464 | 96.67 | 52 | 36 | 69.23 | 472 | 98.33 | 116 | 364 | 0 | 2 | 6 |
| Challenge | 46 | 46 | 100 | 2 | 2 | 100 | 46 | 100 | 43 | 3 | 0 | 0 | 0 |
| Combined | 526 | 510 | 96.96 | 54 | 38 | 70.37 | 518 | 98.48 | 159 | 367 | 0 | 2 | 6 |

[a] Due to unacceptable performance, do not report Selux MIC results for these drug/organism combinations.

**EA** – Essential Agreement
**CA** – Category Agreement
**EVAL** – Evaluable isolates
**R** – Resistant isolates
**NS** – Non-susceptible isolates
**S** – Susceptible isolates
**min** – minor errors
**maj** – major errors
**vmj** – very major errors

**Table 7.** Selux AST System – Gram-Negative Panel Trending

| Drug | Organism Name | Total On Scale for Trending | ≥ 1 Dilution Lower # (%) | Exact # (%) | ≥ 1 Dilution Higher # (%) | Percent Difference (95% CI) | Significant Trending Noted[a] |
|---|---|---|---|---|---|---|---|
| Amikacin | *Pseudomonas aeruginosa* | 164 | 76 (46.34) | 78 | 10 (6.1) | -40% (-48%, -31%) | Yes |
| Amoxicillin-Clavulanate | *Escherichia coli* | 179 | 64 (35.75) | 97 | 18 (10.06) | -26% (-34%, -17%) | No |
| Amoxicillin-Clavulanate | *Klebsiella oxytoca* | 48 | 21 (43.75) | 18 | 9 (18.75) | -25% (-41%, -6%) | No |
| Amoxicillin-Clavulanate | *Klebsiella pneumoniae* | 142 | 89 (62.68) | 46 | 7 (4.93) | -58% (-66%, -48%) | Yes |
| Amoxicillin-Clavulanate | *Proteus mirabilis* | 88 | 11 (12.5) | 42 | 35 (39.77) | 27% (14%, 39%) | No |
| Ampicillin | *Escherichia coli* | 84 | 64 | 18 | 2 | -74% | Yes |

| Drug | Organism Name | Total On Scale for Trending | ≥ 1 Dilution Lower # (%) | Exact # (%) | ≥ 1 Dilution Higher # (%) | Percent Difference (95% CI) | Significant Trending Noted[a] |
|---|---|---|---|---|---|---|---|
| | | | (76.19) | | (2.38) | (-82%, -62%) | |
| Ampicillin | *Proteus mirabilis* | 81 | 25 (30.86) | 42 | 14 (17.28) | -14% (-26%, 0%) | No |
| Ampicillin-sulbactam | *Acinetobacter baumannii* (complex) | 123 | 32 (26.02) | 60 | 31 (25.2) | -1% (-12%, 10%) | No |
| Ampicillin-sulbactam | *Escherichia coli* | 198 | 53 (26.77) | 118 | 27 (13.64) | -13% (-21%, -5%) | No |
| Ampicillin-sulbactam | *Klebsiella oxytoca* | 29 | 17 (58.62) | 8 | 4 (13.79) | -45% (-63%, -20%) | Yes |
| Ampicillin-sulbactam | *Klebsiella pneumoniae* | 116 | 50 (43.1) | 35 | 31 (26.72) | -16% (-28%, -4%) | No |
| Ampicillin-sulbactam | *Morganella morganii* | 75 | 9 (12) | 47 | 19 (25.33) | 13% (1%, 26%) | No |
| Ampicillin-sulbactam | *Proteus mirabilis* | 88 | 11 (12.5) | 58 | 19 (21.59) | 9% (-2%, 20%) | No |
| Ampicillin-sulbactam | *Proteus vulgaris* | 62 | 2 (3.23) | 27 | 33 (53.23) | 50% (35%, 62%) | Yes |
| Aztreonam | *Escherichia coli* | 179 | 73 (40.78) | 81 | 25 (13.97) | -27% (-35%, -18%) | No |
| Cefazolin | *Escherichia coli* | 171 | 81 (47.37) | 69 | 21 (12.28) | -35% (-44%, -26%) | Yes |
| Cefazolin | *Klebsiella pneumoniae* | 113 | 67 (59.29) | 29 | 17 (15.04) | -44% (-54%, -32%) | Yes |
| Cefepime | *Citrobacter freundii* (complex) | 77 | 11 (14.29) | 7 | 59 (76.62) | 62% (48%, 72%) | Yes |
| Cefepime | *Citrobacter koseri* | 72 | 0 (0) | 0 | 72 (100) | 100% (93%, 100%) | Yes |
| Cefepime | *Enterobacter cloacae* (complex) | 77 | 13 (16.88) | 9 | 55 (71.43) | 55% (40%, 66%) | Yes |
| Cefepime | *Escherichia coli* | 158 | 21 (13.29) | 8 | 129 (81.65) | 68% (59%, 75%) | Yes |
| Cefepime | *Klebsiella aerogenes* | 41 | 2 (4.88) | 0 | 39 (95.12) | 90% (74%, 95%) | Yes |
| Cefepime | *Klebsiella oxytoca* | 20 | 5 (25) | 1 | 14 (70) | 45% (14%, 66%) | Yes |
| Cefepime | *Klebsiella pneumoniae* | 111 | 38 (34.23) | 13 | 60 (54.05) | 20% (7%, 32%) | No |
| Cefepime | *Morganella morganii* | 17 | 1 (5.88) | 0 | 16 (94.12) | 88% (58%, 95%) | Yes |
| Cefepime | *Proteus mirabilis* | 86 | 3 (3.49) | 2 | 81 (94.19) | 91% (81%, 95%) | Yes |
| Cefepime | *Proteus vulgaris* | 90 | 4 (4.44) | 4 | 82 (91.11) | 87% (77%, 92%) | Yes |
| Cefepime | *Serratia marcescens* | 98 | 3 (3.06) | 2 | 93 (94.9) | 92% (83%, 95%) | Yes |
| Cefoxitin | *Escherichia coli* | 166 | 41 (24.7) | 87 | 38 (22.89) | -2% (-11%, 7%) | No |
| Cefoxitin | *Klebsiella oxytoca* | 29 | 6 (20.69) | 16 | 7 (24.14) | 3% (-18%, 24%) | No |
| Cefoxitin | *Klebsiella pneumoniae* | 109 | 27 (24.77) | 62 | 20 (18.35) | -6% (-17%, 5%) | No |
| Cefoxitin | *Morganella morganii* | 59 | 10 (16.95) | 39 | 10 (16.95) | 0% (-14%, 14%) | No |

| Drug | Organism Name | Total On Scale for Trending | ≥ 1 Dilution Lower # (%) | Exact # (%) | ≥ 1 Dilution Higher # (%) | Percent Difference (95% CI) | Significant Trending Noted[a] |
|---|---|---|---|---|---|---|---|
| Ceftazidime | *Citrobacter freundii* (complex) | 53 | 12 (22.64) | 12 | 29 (54.72) | 32% (14%, 48%) | Yes |
| Ceftazidime | *Citrobacter koseri* | 45 | 1 (2.22) | 2 | 42 (93.33) | 91% (77%, 96%) | Yes |
| Ceftazidime | *Enterobacter cloacae* (complex) | 52 | 9 (17.31) | 10 | 33 (63.46) | 46% (28%, 60%) | Yes |
| Ceftazidime | *Escherichia coli* | 74 | 31 (41.89) | 9 | 34 (45.95) | 4% (-12%, 20%) | No |
| Ceftazidime | *Klebsiella aerogenes* | 29 | 2 (6.9) | 7 | 20 (68.97) | 62% (38%, 77%) | Yes |
| Ceftazidime | *Klebsiella oxytoca* | 23 | 2 (8.7) | 3 | 18 (78.26) | 70% (42%, 83%) | Yes |
| Ceftazidime | *Klebsiella pneumoniae* | 73 | 12 (16.44) | 9 | 52 (71.23) | 55% (40%, 66%) | Yes |
| Ceftazidime | *Proteus mirabilis* | 63 | 1 (1.59) | 4 | 58 (92.06) | 90% (79%, 95%) | Yes |
| Ceftazidime | *Proteus vulgaris* | 50 | 2 (4) | 1 | 47 (94) | 90% (76%, 95%) | Yes |
| Ceftazidime | *Serratia marcescens* | 56 | 3 (5.36) | 9 | 44 (78.57) | 73% (58%, 83%) | Yes |
| Ceftazidime-avibactam | *Citrobacter freundii* (complex) | 61 | 11 (18.03) | 15 | 35 (57.38) | 39% (22%, 53%) | Yes |
| Ceftazidime-avibactam | *Citrobacter koseri* | 54 | 0 (0) | 6 | 48 (88.89) | 89% (76%, 95%) | Yes |
| Ceftazidime-avibactam | *Enterobacter cloacae* (complex) | 75 | 19 (25.33) | 27 | 29 (38.67) | 13% (-2%, 27%) | No |
| Ceftazidime-avibactam | *Escherichia coli* | 136 | 15 (11.03) | 20 | 101 (74.26) | 63% (53%, 71%) | Yes |
| Ceftazidime-avibactam | *Klebsiella aerogenes* | 52 | 2 (3.85) | 11 | 39 (75) | 71% (55%, 81%) | Yes |
| Ceftazidime-avibactam | *Klebsiella oxytoca* | 28 | 3 (10.71) | 4 | 21 (75) | 64% (40%, 78%) | Yes |
| Ceftazidime-avibactam | *Klebsiella pneumoniae* | 73 | 23 (31.51) | 19 | 31 (42.47) | 11% (-5%, 26%) | No |
| Ceftazidime-avibactam | *Morganella morganii* | 62 | 1 (1.61) | 3 | 58 (93.55) | 92% (81%, 96%) | Yes |
| Ceftazidime-avibactam | *Proteus mirabilis* | 65 | 0 (0) | 2 | 63 (96.92) | 97% (88%, 99%) | Yes |
| Ceftazidime-avibactam | *Proteus vulgaris* | 55 | 0 (0) | 2 | 53 (96.36) | 96% (85%, 99%) | Yes |
| Ceftazidime-avibactam | *Pseudomonas aeruginosa* | 158 | 70 (44.3) | 63 | 25 (15.82) | -28% (-38%, -19%) | No |
| Ceftazidime-avibactam | *Serratia marcescens* | 66 | 10 (15.15) | 33 | 23 (34.85) | 20% (5%, 33%) | No |
| Ceftriaxone | *Citrobacter freundii* (complex) | 49 | 8 (16.33) | 7 | 34 (69.39) | 53% (34%, 67%) | Yes |
| Ceftriaxone | *Citrobacter koseri* | 27 | 1 (3.7) | 0 | 26 (96.3) | 93% (72%, 97%) | Yes |
| Ceftriaxone | *Escherichia coli* | 44 | 7 (15.91) | 1 | 36 (81.82) | 66% (47%, 78%) | Yes |
| Ceftriaxone | *Klebsiella aerogenes* | 34 | 6 (17.65) | 3 | 25 (73.53) | 56% (33%, 71%) | Yes |
| Ceftriaxone | *Klebsiella oxytoca* | 29 | 5 (17.24) | 1 | 23 (79.31) | 62% (37%, 77%) | Yes |

| Drug | Organism Name | Total On Scale for Trending | ≥ 1 Dilution Lower # (%) | Exact # (%) | ≥ 1 Dilution Higher # (%) | Percent Difference (95% CI) | Significant Trending Noted[a] |
|---|---|---|---|---|---|---|---|
| Ceftriaxone | *Klebsiella pneumoniae* | 107 | 52 (48.6) | 2 | 53 (49.53) | 1% (-12%, 14%) | No |
| Ceftriaxone | *Proteus mirabilis* | 37 | 5 (13.51) | 0 | 32 (86.49) | 73% (53%, 84%) | Yes |
| Ciprofloxacin | *Citrobacter freundii* (complex) | 57 | 14 (24.56) | 7 | 36 (63.16) | 39% (21%, 53%) | Yes |
| Ciprofloxacin | *Citrobacter koseri* | 36 | 1 (2.78) | 1 | 34 (94.44) | 92% (75%, 96%) | Yes |
| Ciprofloxacin | *Enterobacter cloacae* (complex) | 68 | 14 (20.59) | 5 | 49 (72.06) | 51% (35%, 64%) | Yes |
| Ciprofloxacin | *Escherichia coli* | 170 | 51 (30) | 17 | 102 (60) | 30% (20%, 40%) | Yes |
| Ciprofloxacin | *Klebsiella aerogenes* | 30 | 0 (0) | 2 | 28 (93.33) | 93% (75%, 98%) | Yes |
| Ciprofloxacin | *Klebsiella oxytoca* | 28 | 1 (3.57) | 6 | 21 (75) | 71% (48%, 84%) | Yes |
| Ciprofloxacin | *Klebsiella pneumoniae* | 23 | 7 (30.43) | 5 | 11 (47.83) | 17% (-10%, 42%) | No |
| Ciprofloxacin | *Morganella morganii* | 58 | 3 (5.17) | 6 | 49 (84.48) | 79% (65%, 87%) | Yes |
| Ciprofloxacin | *Proteus mirabilis* | 24 | 9 (37.5) | 5 | 10 (41.67) | 4% (-22%, 30%) | No |
| Ciprofloxacin | *Proteus vulgaris* | 17 | 3 (17.65) | 3 | 11 (64.71) | 47% (14%, 68%) | Yes |
| Ciprofloxacin | *Pseudomonas aeruginosa* | 151 | 62 (41.06) | 74 | 15 (9.93) | -31% (-40%, -22%) | Yes |
| Eravacycline | *Citrobacter freundii* (complex) | 62 | 2 (3.23) | 32 | 28 (45.16) | 42% (28%, 54%) | Yes |
| Eravacycline | *Enterobacter cloacae* (complex) | 76 | 13 (17.11) | 47 | 16 (21.05) | 4% (-9%, 16%) | No |
| Eravacycline | *Escherichia coli* | 167 | 40 (23.95) | 99 | 28 (16.77) | -7% (-16%, 1%) | No |
| Eravacycline | *Klebsiella oxytoca* | 47 | 4 (8.51) | 30 | 13 (27.66) | 19% (3%, 34%) | No |
| Ertapenem | *Citrobacter freundii* (complex) | 24 | 3 (12.5) | 5 | 16 (66.67) | 54% (27%, 72%) | Yes |
| Ertapenem | *Citrobacter koseri* | 72 | 0 (0) | 0 | 72 (100) | 100% (93%, 100%) | Yes |
| Ertapenem | *Escherichia coli* | 210 | 11 (5.24) | 11 | 188 (89.52) | 84% (78%, 88%) | Yes |
| Ertapenem | *Klebsiella oxytoca* | 3 | 1 (33.33) | 1 | 1 (33.33) | 0% (-53%, 53%) | No |
| Ertapenem | *Klebsiella pneumoniae* | 23 | 10 (43.48) | 6 | 7 (30.43) | -13% (-38%, 14%) | No |
| Ertapenem | *Morganella morganii* | 10 | 7 (70) | 2 | 1 (10) | -60% (-81%, -17%) | Yes |
| Ertapenem | *Proteus mirabilis* | 85 | 2 (2.35) | 0 | 83 (97.65) | 95% (87%, 98%) | Yes |
| Ertapenem | *Proteus vulgaris* | 98 | 0 (0) | 1 | 97 (98.98) | 99% (93%, 100%) | Yes |
| Ertapenem | *Serratia marcescens* | 65 | 6 (9.23) | 11 | 48 (73.85) | 65% (49%, 75%) | Yes |
| Gentamicin | *Citrobacter freundii* (complex) | 64 | 41 (64.06) | 22 | 1 (1.56) | -62% (-73%, -49%) | Yes |

| Drug | Organism Name | Total On Scale for Trending | ≥ 1 Dilution Lower # (%) | Exact # (%) | ≥ 1 Dilution Higher # (%) | Percent Difference (95% CI) | Significant Trending Noted[a] |
|---|---|---|---|---|---|---|---|
| Gentamicin | *Citrobacter koseri* | 54 | 23 (42.59) | 23 | 8 (14.81) | -28% (-43%, -11%) | No |
| Gentamicin | *Enterobacter cloacae* (complex) | 74 | 36 (48.65) | 31 | 7 (9.46) | -39% (-51%, -25%) | Yes |
| Gentamicin | *Escherichia coli* | 173 | 84 (48.55) | 78 | 11 (6.36) | -42% (-50%, -34%) | Yes |
| Gentamicin | *Klebsiella aerogenes* | 31 | 8 (25.81) | 18 | 5 (16.13) | -10% (-29%, 11%) | No |
| Gentamicin | *Klebsiella oxytoca* | 29 | 14 (48.28) | 15 | 0 (0) | -48% (-66%, -28%) | Yes |
| Gentamicin | *Klebsiella pneumoniae* | 126 | 58 (46.03) | 62 | 6 (4.76) | -41% (-50%, -31%) | Yes |
| Gentamicin | *Proteus mirabilis* | 64 | 12 (18.75) | 29 | 23 (35.94) | 17% (2%, 32%) | No |
| Gentamicin | *Proteus vulgaris* | 55 | 13 (23.64) | 27 | 15 (27.27) | 4% (-13%, 20%) | No |
| Gentamicin | *Pseudomonas aeruginosa* | 211 | 68 (32.23) | 79 | 64 (30.33) | -2% (-11%, 7%) | No |
| Gentamicin | *Serratia marcescens* | 68 | 3 (4.41) | 23 | 42 (61.76) | 57% (43%, 68%) | Yes |
| Imipenem-Relebactam | *Citrobacter freundii* (complex) | 54 | 28 (51.85) | 19 | 7 (12.96) | -39% (-53%, -22%) | Yes |
| Imipenem-Relebactam | *Citrobacter koseri* | 55 | 18 (32.73) | 24 | 13 (23.64) | -9% (-25%, 8%) | No |
| Imipenem-Relebactam | *Escherichia coli* | 172 | 40 (23.26) | 101 | 31 (18.02) | -5% (-14%, 3%) | No |
| Imipenem-Relebactam | *Klebsiella oxytoca* | 27 | 0 (0) | 19 | 8 (29.63) | 30% (11%, 48%) | Yes |
| Imipenem-Relebactam | *Pseudomonas aeruginosa* | 162 | 22 (13.58) | 119 | 21 (12.96) | -1% (-8%, 7%) | No |
| Levofloxacin | *Citrobacter freundii* (complex) | 60 | 6 (10) | 12 | 42 (70) | 60% (44%, 71%) | Yes |
| Levofloxacin | *Citrobacter koseri* | 54 | 0 (0) | 0 | 54 (100) | 100% (91%, 100%) | Yes |
| Levofloxacin | *Enterobacter cloacae* (complex) | 68 | 0 (0) | 5 | 63 (92.65) | 93% (82%, 97%) | Yes |
| Levofloxacin | *Escherichia coli* | 169 | 13 (7.69) | 31 | 125 (73.96) | 66% (58%, 73%) | Yes |
| Levofloxacin | *Klebsiella aerogenes* | 32 | 1 (3.12) | 1 | 30 (93.75) | 91% (72%, 96%) | Yes |
| Levofloxacin | *Klebsiella oxytoca* | 27 | 1 (3.7) | 4 | 22 (81.48) | 78% (54%, 89%) | Yes |
| Levofloxacin | *Klebsiella pneumoniae* | 84 | 9 (10.71) | 13 | 62 (73.81) | 63% (50%, 73%) | Yes |
| Levofloxacin | *Morganella morganii* | 61 | 4 (6.56) | 3 | 54 (88.52) | 82% (68%, 89%) | Yes |
| Levofloxacin | *Proteus mirabilis* | 65 | 3 (4.62) | 9 | 53 (81.54) | 77% (63%, 85%) | Yes |
| Levofloxacin | *Proteus vulgaris* | 55 | 1 (1.82) | 6 | 48 (87.27) | 85% (72%, 92%) | Yes |
| Levofloxacin | *Serratia marcescens* | 68 | 15 (22.06) | 34 | 19 (27.94) | 6% (-9%, 20%) | No |
| Meropenem | *Citrobacter freundii* (complex) | 78 | 2 (2.56) | 1 | 75 (96.15) | 94% (84%, 97%) | Yes |

| Drug | Organism Name | Total On Scale for Trending | ≥ 1 Dilution Lower # (%) | Exact # (%) | ≥ 1 Dilution Higher # (%) | Percent Difference (95% CI) | Significant Trending Noted[a] |
|---|---|---|---|---|---|---|---|
| Meropenem | *Citrobacter koseri* | 72 | 0 (0) | 1 | 71 (98.61) | 99% (91%, 100%) | Yes |
| Meropenem | *Enterobacter cloacae* (complex) | 74 | 5 (6.76) | 6 | 63 (85.14) | 78% (66%, 86%) | Yes |
| Meropenem | *Escherichia coli* | 5 | 2 (40) | 0 | 3 (60) | 20% (-32%, 60%) | No |
| Meropenem | *Klebsiella oxytoca* | 27 | 0 (0) | 0 | 27 (100) | 100% (82%, 100%) | Yes |
| Meropenem | *Klebsiella pneumoniae* | 106 | 14 (13.21) | 15 | 77 (72.64) | 59% (47%, 69%) | Yes |
| Meropenem | *Morganella morganii* | 62 | 1 (1.61) | 1 | 60 (96.77) | 95% (85%, 98%) | Yes |
| Meropenem | *Proteus mirabilis* | 66 | 1 (1.52) | 3 | 62 (93.94) | 92% (82%, 96%) | Yes |
| Meropenem | *Proteus vulgaris* | 51 | 0 (0) | 0 | 51 (100) | 100% (90%, 100%) | Yes |
| Meropenem | *Pseudomonas aeruginosa* | 167 | 52 (31.14) | 77 | 38 (22.75) | -8% (-18%, 1%) | No |
| Meropenem | *Serratia marcescens* | 102 | 3 (2.94) | 2 | 97 (95.1) | 92% (84%, 96%) | Yes |
| Meropenem-vaborbactam | *Citrobacter freundii* (complex) | 57 | 0 (0) | 1 | 56 (98.25) | 98% (88%, 100%) | Yes |
| Meropenem-vaborbactam | *Citrobacter koseri* | 48 | 0 (0) | 0 | 48 (100) | 100% (90%, 100%) | Yes |
| Meropenem-vaborbactam | *Enterobacter cloacae* (complex) | 52 | 0 (0) | 1 | 51 (98.08) | 98% (87%, 100%) | Yes |
| Meropenem-vaborbactam | *Escherichia coli* | 29 | 4 (13.79) | 0 | 25 (86.21) | 72% (49%, 84%) | Yes |
| Meropenem-vaborbactam | *Klebsiella aerogenes* | 50 | 0 (0) | 1 | 49 (98) | 98% (87%, 100%) | Yes |
| Meropenem-vaborbactam | *Klebsiella oxytoca* | 47 | 0 (0) | 0 | 47 (100) | 100% (89%, 100%) | Yes |
| Meropenem-vaborbactam | *Klebsiella pneumoniae* | 100 | 4 (4) | 6 | 90 (90) | 86% (77%, 91%) | Yes |
| Meropenem-vaborbactam | *Morganella morganii* | 64 | 0 (0) | 35 | 29 (45.31) | 45% (32%, 57%) | Yes |
| Meropenem-vaborbactam | *Serratia marcescens* | 60 | 0 (0) | 1 | 59 (98.33) | 98% (89%, 100%) | Yes |
| Minocycline | *Escherichia coli* | 198 | 43 (21.72) | 83 | 72 (36.36) | 15% (6%, 23%) | No |
| Minocycline | *Klebsiella aerogenes* | 52 | 17 (32.69) | 30 | 5 (9.62) | -23% (-38%, -7%) | No |
| Minocycline | *Klebsiella oxytoca* | 27 | 3 (11.11) | 15 | 9 (33.33) | 22% (0%, 42%) | No |
| Minocycline | *Klebsiella pneumoniae* | 126 | 38 (30.16) | 66 | 22 (17.46) | -13% (-23%, -2%) | No |
| Piperacillin-tazobactam | *Citrobacter koseri* | 75 | 15 (20) | 49 | 11 (14.67) | -5% (-17%, 7%) | No |
| Piperacillin-tazobactam | *Escherichia coli* | 175 | 47 (26.86) | 91 | 37 (21.14) | -6% (-15%, 3%) | No |
| Piperacillin-tazobactam | *Klebsiella oxytoca* | 27 | 11 (40.74) | 15 | 1 (3.7) | -37% (-56%, -15%) | Yes |
| Piperacillin-tazobactam | *Klebsiella pneumoniae* | 132 | 80 (60.61) | 37 | 15 (11.36) | -49% (-58%, -38%) | Yes |

| Drug | Organism Name | Total On Scale for Trending | ≥ 1 Dilution Lower # (%) | Exact # (%) | ≥ 1 Dilution Higher # (%) | Percent Difference (95% CI) | Significant Trending Noted[a] |
|---|---|---|---|---|---|---|---|
| Piperacillin-tazobactam | *Morganella morganii* | 64 | 12 (18.75) | 16 | 36 (56.25) | 38% (21%, 51%) | Yes |
| Piperacillin-tazobactam | *Proteus mirabilis* | 70 | 15 (21.43) | 12 | 43 (61.43) | 40% (24%, 53%) | Yes |
| Piperacillin-tazobactam | *Proteus vulgaris* | 50 | 0 (0) | 16 | 34 (68) | 68% (52%, 79%) | Yes |
| Tobramycin | *Pseudomonas aeruginosa* | 162 | 25 (15.43) | 91 | 46 (28.4) | 13% (4%, 22%) | No |
| Trimethoprim Sulfamethoxazole | *Enterobacter cloacae* (complex) | 72 | 17 (23.61) | 11 | 44 (61.11) | 38% (22%, 51%) | Yes |
| Trimethoprim Sulfamethoxazole | *Klebsiella aerogenes* | 32 | 2 (6.25) | 1 | 29 (90.62) | 84% (64%, 92%) | Yes |
| Trimethoprim Sulfamethoxazole | *Klebsiella oxytoca* | 22 | 0 (0) | 0 | 22 (100) | 100% (79%, 100%) | Yes |
| Trimethoprim Sulfamethoxazole | *Klebsiella pneumoniae* | 66 | 6 (9.09) | 5 | 55 (83.33) | 74% (60%, 83%) | Yes |

[a]Significant trending as determined by a statistically significant confidence interval.

***Characterized Resistance Mechanisms***. The molecular characteristics of the challenge isolates evaluated in the clinical study, provided by the FDA-CDC AR Isolate Bank, are provided in **Table 8**.

**Table 8**. Molecular characteristics of resistance markers in challenge isolates.

| Antimicrobial | Drug-Class Specific | Truncated Porins |
|---|---|---|
| Amikacin | aac(3)-IIa, aac(3)-Id, aac(6')-II, aadA6, ant(2")-Ia, aph(3')-Ic, aph(3')-VIa, armA, strA, strB,aac(3)-Ia | |
| Amoxicillin-Clavulanate | CMY-2, CMY-4, CMY-42, CMY-6, CTX-M-15, CTX-M-2, KPC-2, KPC-3, NDM-1, NDM-5, NDM-7, OXA-1, OXA-10, OXA-181, OXA-2, OXA-232, OXA-9, SHV-1, SHV-100, SHV-11, SHV-12, SHV-26, SHV-28, SHV-30, SHV-83, TEM-1A, TEM-1B, VIM-1, VIM-27 | OmpC2, OmpK35, OmpK36, OmpF |
| Ampicillin | CMY-42, CTX-M-15, KPC-3, NDM-5, OXA-1, OXA-9, SHV-12, TEM-1A, TEM-1B | |
| Ampicillin-Sulbactam | CMY-4, CMY-6, CMY-42, CTX-M-2, CTX-M-15, KPC-3, NDM-1, NDM-5, NDM-7, OXA-1, OXA-10, OXA-2, OXA-23, OXA-232, OXA-69, OXA-9, SHV-11, SHV-12, SHV-83, TEM-1A, TEM-1B, TEM-1D, VIM-27 | OmpF, OmpK35, OmpK36 |
| Aztreonam | carB-2, CMY-2, CMY-4, CMY-42, CMY-6, CTX-M-15, KPC-2, KPC-3, NDM-1, NDM-5, OXA-1, OXA-2, OXA-10, OXA-50, OXA-9, SHV-12, TEM-1A, TEM-1B, VEB-1, VEB-5 | OmpF |
| Cefazolin | CMY-2, CMY-4, CMY-42, CMY-6, CTX-M-15, CTX-M-2, KPC-2, NDM-1, OXA-1, OXA-10, OXA-181, OXA-232, OXA-9, SHV-1, SHV-11, SHV-12, SHV-154, SHV-26, SHV-83, TEM-1A, TEM-1B, VEB-5 | OmpF, OmpK35, OmpK36 |
| Cefepime | ACT-7, ACT-16, carB-2, CMY-42, CMY-6, CTX-M-15, CTX-M-2, IMP-1, KPC-2, KPC-6, NDM-1, OXA-1, OXA-10, OXA-181, OXA-2, OXA-232, OXA-50, OXA-9, PAO, SHV-1, SHV-100, SHV-11, SHV-12, SHV-26, SHV-28, SHV-83, TEM-1A, TEM-1B, VEB-1, VEB-5, VIM-1 | OmpC2, OmpK35, OmpK36, OmpF |
| Cefoxitin | CMY-4, CMY-42, CMY-6, CTX-M-15, CTX-M-2, KPC-2, NDM-1, NDM-7, OXA-1, OXA-10, OXA-181, OXA-2, OXA-232, OXA-9, SHV-1, SHV-100, SHV-11, SHV-12, SHV-28, SHV-83, TEM-1A, TEM-1B | OmpC2, OmpK35, OmpK36, OmpF |
| Ceftazidime | ACT-7, ACT-16, ADC-25, CMY-2, CMY-4, CMY-42, CMY-6, CTX-M-15, CTX-M-2, IMP-1, IMP-8, KPC-2, KPC-3, KPC-6, NDM-1, NDM-5, NDM-7, OXA-1, OXA-10, OXA-181, OXA-2, OXA-23, OXA-232, OXA-24, OXA-50, OXA-65, OXA-66, OXA-69, OXA-71, OXA-9, OXA-94, PAO, SHV-1, SHV-100, SHV-11, SHV-12, SHV-26, SHV-28, SHV-30, SHV-5, SHV-83, SME-3, TEM-1A, TEM-1B, TEM-1D, VEB-1, VEB-5, VIM-1, VIM-2, VIM-27 | OmpC2, OmpF, OmpK35, OmpK36 |
| Ceftazidime-Avibactam | ACT-7, CMY-4, CMY-42, CMY-6, CTX-M-15, IMP-1, IMP-8, NDM-1, NDM-5, NDM-7, OXA-1, OXA-10, OXA-101, OXA-181, OXA-2, OXA-232, OXA-50, OXA-9, PAO, SHV-100, SHV-11, SHV-12, SHV-26, SHV-28, SHV-30, SME-3, TEM-1A, TEM-1B, VEB-1, VIM-1, VIM-2, VIM-2 | OmpC2, OmpF, OmpK35 |
| Ceftriaxone | ACT-7, CMY-2, CMY-4, CMY-42, CTX-M-15, CTX-M-2, KPC-2, NDM-1, NDM-7, OXA-1, OXA-10, OXA-181, OXA-232, OXA-9, SHV-100, SHV-11, SHV-12, SHV-26, SHV-28, SHV-83, SME-3, TEM-1A, TEM-1B, VEB-5, VIM-27 | OmpC2, OmpK35, OmpK36, OmpF |
| Ciprofloxacin | QnrB1, QnrB7, QnrS1, oqxA, oqxB,QnrB34 | OmpC2, OmpK35, OmpK36, OmpF |
| Eravacycline | tet(A), tet(D), tet(G), tet(R) | OmpC2, OmpK35 |
| Ertapenem | ACT-16, ACT-7, CMY-2, CMY-4, CMY-42, CMY-6, CTX-M-15, CTX-M-2, IMP-8, KPC-2, KPC-6, NDM-1, NDM-5, NDM-7, OXA-1, OXA-10, OXA-181, OXA-2, OXA-232, OXA-9, SHV-1, SHV-100, SHV-11, SHV-12, SHV-154, SHV-26, SHV-28, SHV-83, SME-3, TEM-1A, TEM-1B, VEB-5, VIM-27 | OmpC2, OmpK35, OmpK36, OmpF |
| Gentamicin | aac(3)-IIa, aac(3)-IId, aac(3)-Id, aac(6')-IIa, aac(6')-IIc, aac(6')-Ian, aac(6')-Ib-cr, aac(6')-II, aadA1, aadA2, aadA5, aadA6, aadB, ant(2")-Ia, aph(3')-Ia, aph(3')-Ib, aph(3')-VI, aph(3')-XV, aph(6)-Id, armA, rmtB, rmtC, rmtG, strA, strB,aac(6')-Ib | OmpC2, OmpK35, OmpK36, OmpF |
| Imipenem | ADC-25, OXA-23, OXA-24, OXA-65, OXA-66, OXA-69, OXA-71, SHV-5, TEM-1D | |
| Imipenem-Relebactam | BCR1, CMY-4, CMY-42, CMY-6, CTX-M-15, IMP-1, KPC-2, KPC-3, NDM-1, NDM-5, NDM-7, OXA-1, OXA-10, OXA-181, OXA-2, OXA-232, OXA-50, OXA-9, PAO, SHV-1, SHV-100, SHV-11, SHV-12, SHV-26, SHV-28, SHV-30, TEM-1A, TEM-1B, VIM-1, VIM-2, VIM-27 | OmpC2, OmpK35, OmpK36, OmpF |
| Levofloxacin | QnrB1, QnrB34, QnrB7, QnrS1, oqxA, oqxB,norA | OmpC2, OmpF, OmpK35, OmpK36 |
| Meropenem | ACT-7, ADC-25, BCR1, carB-2, CMY-4, CMY-42, CMY-6, CTX-M-15, IMP-1, KPC-2, NDM-1, NDM-5, NDM-7, OXA-1, OXA-10, OXA-101, OXA-181, OXA-2, OXA-23, OXA-232, OXA-24, OXA-50, OXA-65, OXA-66, OXA-69, OXA-71, OXA-9, OXA-94, PAO, SHV-1, SHV-100, SHV-11, SHV-12, SHV-28, SHV-5, SME-3, TEM-1A, TEM-1B, TEM-1D, VEB-1, VIM-2, VIM-27 | OmpC2, OmpF, OmpK35 |
| Meropenem-Vaborbactam | CMY-4, CMY-42, CMY-6, CTX-M-15, KPC-2, NDM-1, NDM-5, NDM-7, OXA-1, OXA-10, OXA-181, OXA-2, OXA-232, OXA-9, SHV-1, SHV-100, SHV-11, SHV-12, SHV-28, TEM-1A, TEM-1B, VIM-27 | OmpC2, OmpK35, OmpK36, OmpF |
| Minocycline | tet(A), tet(A), tet(D), tet(K), tet(R),tet(38) | OmpK35 |
| Piperacillin-Tazobactam | ACT-7, ACT-16, ADC-25, carB-2, CMY-2, CMY-4, CMY-42, CMY-6, CTX-M-15, KPC-2, KPC-3, KPC-6, NDM-1, NDM-5, NDM-7, OXA-1, OXA-10, OXA-181, OXA-2, OXA-23, OXA-232, OXA-24, OXA-50, OXA-65, OXA-69, OXA-71, OXA-9, OXA-94, SHV-1, SHV-100, SHV-11, SHV-12, SHV-26, SHV-28, SHV-5, TEM-1A, TEM-1B, TEM-1D, VIM-27 | OmpC2, OmpF, OmpK35 |
| Tobramycin | aac(6')-II, aadA1, aadA6, aadB, ant(2")-Ia, strA, strB,aac(3)-Id | |
| Trimethoprim-Sulfamethoxazole | dfrA1, dfrA12, dfrA14, dfrA15, dfrA17, dfrA29, dfrB5 | OmpC2, OmpK35, OmpK36, OmpF |

***Non-indicated species***. As required under 511A(b)(2)(C)(ii)(I) of the Federal Food, Drug and Cosmetic Act, the following statement is included in the Precautions section of the device labeling to address testing and reporting of non-indicated species:

> Per the FDA-Recognized Susceptibility Test Interpretive Criteria Website, the safety and efficacy of antimicrobial drugs, for which antimicrobial susceptibility is tested by this AST device, may or may not have been established in adequate and well-controlled clinical trials for treating infections due to microorganisms outside of those found in the indications and usage in the drug label. The clinical significance of susceptibility information in those instances is unknown. The approved labeling for specific antimicrobial drugs provides the uses for which the antimicrobial drug is approved.

2. Matrix Comparison:
Not applicable.

## C Clinical Studies:

1. Clinical Sensitivity:
   Not applicable.

2. Clinical Specificity:
   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):
   Not applicable.

## D Clinical Cut-Off:

Not applicable.

## E Expected Values/Reference Range:

The FDA-recognized/approved susceptibility test interpretive criteria (breakpoints) for the antimicrobials evaluated with the Selux AST System are listed in the table below.

**Table 9.** FDA-Approved or Recognized Interpretive Criteria[1]

| Antimicrobial | Organism | Minimum Inhibitory Concentration (µg/mL) | | |
|---|---|---|---|---|
| | | S | I | R |
| Amikacin | *Pseudomonas aeruginosa* | ≤16 | 32 | ≥64 |
| Amoxicillin-Clavulanate | Enterobacterales | ≤8 | 16 | ≥32 |
| Ampicillin | Enterobacterales | ≤8 | 16 | ≥32 |
| Ampicillin-sulbactam | *Acinetobacter* spp., Enterobacterales | ≤8 | 16 | ≥32 |
| Aztreonam | Enterobacterales | ≤4 | 8 | ≥16 |
| Cefazolin | Enterobacterales | ≤1 | 2 | ≥4 |
| Cefepime | Enterobacterales | ≤2 | 4-8 | ≥16 |
| Cefoxitin | Enterobacterales | ≤4 | 8 | ≥16 |
| Ceftazidime | Enterobacterales | ≤4 | 8 | ≥16 |
| Ceftazidime-Avibactam | Enterobacterales, *Pseudomonas aeruginosa* | ≤8 | - | ≥16 |
| Ceftriaxone | Enterobacterales | ≤1 | 2 | ≥4 |
| Ciprofloxacin | Enterobacterales | ≤0.25 | 0.5 | ≥1 |
| Ciprofloxacin | *Pseudomonas aeruginosa* | ≤0.5 | 1 | ≥2 |
| Eravacycline | Enterobacterales | ≤0.5 | - | - |
| Ertapenem | Enterobacterales | ≤0.5 | 1 | ≥2 |
| Gentamicin | Enterobacterales, *Pseudomonas aeruginosa* | ≤4 | 8 | ≥16 |
| Imipenem-Relebactam | Enterobacterales | ≤1 | 2 | ≥4 |
| Imipenem-Relebactam | *Pseudomonas aeruginosa* | ≤2 | 4 | ≥8 |

| Antimicrobial | Organism | Minimum Inhibitory Concentration (µg/mL) | | |
|---|---|---|---|---|
| | | S | I | R |
| Levofloxacin | Enterobacterales | ≤0.5 | 1 | ≥2 |
| Meropenem | Enterobacterales | ≤1 | 2 | ≥4 |
| Meropenem | *Pseudomonas aeruginosa* | ≤2 | 4 | ≥8 |
| Meropenem-Vaborbactam | Enterobacterales | ≤4 | 8 | ≥16 |
| Minocycline | Enterobacterales | ≤4 | 8 | ≥16 |
| Piperacillin-tazobactam | *Pseudomonas aeruginosa* | ≤16 | 32-64 | ≥128 |
| Tobramycin | *Pseudomonas aeruginosa* | ≤4 | 8 | ≥16 |
| Trimethoprim-Sulfamethoxazole | Enterobacterales | ≤2 | - | ≥4 |

S = Susceptible; I = Intermediate; R = Resistant; - = no interpretive criterion recognized
[1] According to the FDA-Recognized Antimicrobial Susceptibility Test Interpretive Criteria Website https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm4 10971.htm

## VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

## IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

To support the implementation of changes to FDA-recognized susceptibility test interpretive criteria (i.e., breakpoints), this submission included a breakpoint change protocol that was reviewed and accepted by FDA. This protocol addresses future revisions to device labeling in response to breakpoint changes that are recognized on the FDA STIC webpage (https://www.fda.gov/drugs/development-resources/fda-recognized-antimicrobial-susceptibility-test-interpretive-criteria). The protocol outlined the specific procedures and acceptance criteria that Selux intends to use to evaluate the Selux AST System when revised breakpoints for the following antimicrobials are published on the FDA STIC webpage: Amikacin, Amoxicillin-Clavulanate, Ampicillin, Ampicillin-sulbactam, Aztreonam, Cefazolin, Cefepime, Cefoxitin, Ceftazidime, Ceftazidime-Avibactam, Ceftriaxone, Ciprofloxacin, Eravacycline, Ertapenem, Gentamicin, Imipenem-Relebactam, Levofloxacin, Meropenem, Meropenem-Vaborbactam, Minocycline, Piperacillin-Tazobactam, Tobramycin, Trimethoprim-Sulfamethoxazole.

The breakpoint change protocol included with the submission indicated that if specific criteria are met, Selux will update the device label to include (1) the new breakpoints, (2) an updated performance section after re-evaluation of data in this premarket notification with the new breakpoints, and (3) any new limitations as determined by their evaluation.