510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K223493

B Applicant

Selux Diagnostics, Inc

C Proprietary and Established Names

PBC Separator with Selux AST System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QZX	Class II	21 CFR 866.1650 - A Cellular Analysis System For Multiplexed Antimicrobial Susceptibility	MI - Microbiology
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 a substantial equivalence determination for the preparation of a McFarland Standard equivalent from positive blood culture samples using the PBC Separator to determine the

minimum inhibitory concentration of specific antimicrobial agents with specific Gram-negative organisms with the Selux AST System.

B Measurand:

Standardized suspension of gram-negative bacteria prepared from positive blood culture samples used in conjunction with the Selux AST System with the following antimicrobial agents:

Antimicrobial	**Reportable Range**
Amikacin	≤0.12 to ≥256 µg/mL
Amoxicillin-Clavulanate	≤2 to ≥128 µg/mL
Ampicillin	≤2 to ≥128 µg/mL
Ampicillin-Sulbactam	≤0.5 to ≥128 µg/mL
Cefazolin	≤0.12 to ≥128 µg/mL
Cefepime	≤0.5 to ≥128 µg/mL
Ceftazidime	≤0.25 to ≥256 µg/mL
Ceftazidime-Avibactam	≤0.12 to ≥64 µg/mL
Ceftriaxone	≤0.25 to ≥32 µg/mL
Ciprofloxacin	≤0.03 to ≥16 µg/mL
Ertapenem	≤0.03 to ≥16 µg/mL
Gentamicin	≤0.5 to ≥64 µg/mL
Imipenem	≤0.25 to ≥64 µg/mL
Meropenem	≤0.12 to ≥64 µg/mL
Piperacillin-Tazobactam	≤0.25 to ≥512 µg/mL
Tobramycin	≤0.12 to ≥128 µg/mL

C Type of Test:

Positive blood culture processor that prepares a tuned inoculum for use with the Selux AST System, a quantitative antimicrobial susceptibility test system that utilizes colorimetric, oxidation-reduction and growth-based strategies to determine the minimum inhibitory concentration (MIC) of specific antimicrobial agents for specific organisms.

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 PBC Separator with Selux AST System is an automated inoculum preparation system that uses lysis, centrifugation and sequential optical density measurements to generate a McFarland-equivalent suspension from positive blood culture samples that can be used for quantitative *in vitro* antimicrobial susceptibility testing by the Selux AST System. Samples are processed directly from blood culture samples identified as positive by a continuous monitoring blood culture system. Samples should be confirmed as monomicrobial, gram negative rods by Gram stain. Organism identification is required for AST result interpretation and reporting, per the Selux AST System instructions for use.

Inoculum preparation by the PBC Separator was evaluated for use with the Selux AST System.. Performance was demonstrated for the antimicrobial agents and organisms identified below:

Amikacin: *Acinetobacter baumannii* complex*, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa*

Amoxicillin-Clavulanate: *Escherichia coli, Klebsiella* species (including *K. oxytoca, K. pneumoniae), Proteus mirabilis, Proteus vulgaris*

Ampicillin: *Escherichia coli, Proteus mirabilis*

Ampicillin-Sulbactam: *Acinetobacter baumannii* complex*, Citrobacter koseri, Escherichia coli, K. pneumoniae, Proteus mirabilis*

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, Pseudomonas aeruginosa*

Ceftazidime: *Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa*

Ceftazidime-Avibactam: *Citrobacter freundii* complex*, Citrobacter koseri, Enterobacter cloacae* complex*, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens, Pseudomonas aeruginosa*

Ceftriaxone: *Citrobacter freundii* complex*, Citrobacter koseri, Enterobacter cloacae* complex*, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Serratia marcescens*

Ciprofloxacin: *Citrobacter freundii* complex*, Citrobacter koseri, Enterobacter cloacae* complex*, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens, Pseudomonas aeruginosa*

Ertapenem: *Citrobacter freundii* complex*, Citrobacter koseri, Enterobacter cloacae* complex*, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*

Gentamicin: *Citrobacter freundii* complex*, Citrobacter koseri, Enterobacter cloacae* complex*, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens, Pseudomonas aeruginosa*

Imipenem: *Acinetobacter baumannii* complex*, Escherichia coli, Klebsiella pneumoniae*

Meropenem: *Acinetobacter baumannii* complex*, Citrobacter freundii* complex*, Citrobacter koseri, Enterobacter cloacae* complex*, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens, Pseudomonas aeruginosa*

Minocycline: *Acinetobacter baumannii* complex*, Escherichia coli, Klebsiella pneumoniae*

Piperacillin-Tazobactam: *Acinetobacter baumannii* complex*, Citrobacter koseri, Escherichia coli, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens, Pseudomonas aeruginosa*

Tobramycin: *Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa*

Susceptibility test results are intended to be used in conjunction with other clinical and laboratory findings. Standard laboratory protocols for processing positive blood cultures should be followed to ensure availability of isolates for supplemental testing as needed. Additionally, subculture of positive blood culture is necessary for the susceptibility testing of organisms present in polymicrobial samples, for testing antimicrobial agents and species not indicated for testing with the device, for epidemiologic testing, and for recovery of organisms present in microbial samples.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

- The PBC Separator with Selux AST System cannot be used for any clinical specimens other than monomicrobial positive blood cultures.
- Performance of PBC Separator-prepared inoculum for use with the Selux AST System has only been established using the antimicrobials listed in the Indications for Use.
- Results from the Selux AST System obtained using inocula prepared by the PBC Separator should only be reported for antimicrobials and species indicated in the PBC Separator Indications for Use.
- The use of the PBC Separator with Selux AST System does not eliminate the need for subculture of the positive blood culture.
- If the subculture (purity) plate indicates the sample is polymicrobial, the AST results should be voided, and susceptibility testing on each isolate using a standard inoculum preparation should be performed.
- The performance of the PBC Separator has only been evaluated with the following blood culture bottles:
  - BD BACTEC Plus Aerobic
  - BD BACTEC Plus Anaerobic
  - BD BACTEC Standard Aerobic
  - BD BACTEC Standard Anaerobic
  - BD BACTEC Lytic Anaerobic
  - BD BACTEC Peds Plus
  - bioMérieux BacT/ALERT FA Plus Aerobic
  - bioMérieux BacT/ALERT FN Plus Anaerobic
  - bioMérieux BacT/ALERT SA Standard Aerobic
  - bioMérieux BacT/ALERT SN Standard Anaerobic
  - bioMérieux BacT/ALERT PF Plus Pediatric Aerobic
- PBC samples should be promptly prepared and loaded into the PBC Separator following bottle ring from a continuous monitoring blood culture system, where possible. In the case of instrument errors or if re-testing is needed, PBC samples must be processed within 16 hours post bottle ring.
- The tuned inoculum must be used within 45 minutes to maintain the appropriate organism concentration.

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

- Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination: Cefazolin-*E. coli* when the Selux AST System MIC from a PBC Separator inoculum is 4 µg/mL due to the occurrence of minor errors resulting in a category agreement below 90%.
- An essential agreement <90% and very major errors were observed when testing Piperacillin-Tazobactam with *K. pneumoniae* with all evaluated potential interferents.
- An essential agreement <90% and minor errors were observed when testing Tobramycin *with E. coli* and *K. pneumoniae* with the potential interferent cefpodoxime.
- The ability of the PBC Separator and 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.
  - Amoxicillin-Clavulanate: *P. mirabilis, P. vulgaris*
  - Cefepime: *C. freundii* complex*, C. koseri, K. aerogenes, P. mirabilis, P. vulgaris, S. marcescens*
  - Ceftazidime-Avibactam: *C. freundii* complex*, C. koseri, E. cloacae* complex*, E. coli, K. aerogenes, K. oxytoca, M. morganii, P. mirabilis, P. vulgaris, S. marcescens*
  - Ceftriaxone: *C. koseri, P. mirabilis*
  - Ciprofloxacin: *C. koseri, K. aerogenes, P. vulgaris*
  - Ertapenem: *C. freundii* complex*, K. aerogenes, K. oxytoca, M. morganii, P. mirabilis, P. vulgaris*
  - Gentamicin: *C. freundii* complex*, C. koseri, K. aerogenes, P. vulgaris, S. marcescens*
  - Meropenem: *C. freundii* complex*, C. koseri, E. cloacae* complex*, E. coli, K. oxytoca, M. morganii, P. mirabilis, P. vulgaris, S. marcescens*

D Special Instrument Requirements:

PBC Separator, software version 61.6 (instrument firmware)

Selux AST System, software version 1.7.110

IV Device/System Characteristics:

A Device Description:

The Positive Blood Culture (PBC) Separator with Selux AST System is an automated sample preparation instrument with associated consumables that uses lysis, centrifugation, and sequential optical density measurements to prepare tuned McFarland-equivalent suspensions from positive blood culture bottles that have rang positive on a continuous monitoring blood culture system. Inoculums containing monomicrobial, gram negative bacteria are used with the Selux AST System for quantitative minimum inhibitory concentration (MIC) determination of specific antimicrobial-organism combinations.

The PBC Separator is comprised of the instrument, software, and associated consumables. The PBC Separator can process up to two positive blood culture samples at once. Within a biosafety cabinet, 9 mL of blood from a positive blood culture bottle that has been confirmed as monomicrobial is transferred to the Selux Sample Tube. The Sample Tube is loaded into the

PBC Separator along with an empty final Inoculum tube and the PBC Separator Reagent Kit. The software also prompts the user to load racks of pipette tips as needed. The PBC Separator Reagent Kit serves as the waste receptable into which all biohazardous waste is deposited during the separation process and can be disposed of appropriately after processing.

After the samples are loaded, the user follows the prompts on the user interface to start processing, which requires 45-55 minutes based on if one or two samples are being processed. The PBC Separator software associates the barcode identifier on the Inoculum Tube with the barcode identifier on the Sample Tube and transmits this information to the Selux Site Services central workstation to ensure sample traceability. Within the instrument, the PBC Separator uses a series of centrifugation and lysis steps to remove blood components and most soluble components. Saline is added and optical density is determined to achieve a density suitable for AST (defined as 0.65-0.8 McFarland equivalent, when used with the Selux AST System).

The user is notified when the sample processing is completed and is prompted to retrieve the sample components within 45 minutes. The user then manually transfers the tuned inoculum in the Selux Inoculum Tube (a volume of 1 mL) to the Selux AST System Sample Prep station for AST processing. Within the Selux AST System, the appropriate panel will be inoculated, the panel will be processed, and AST results will be generated. A complete description of the Selux AST System can be found in the K211759 and K211748 decision summaries.

The Selux AST System is designed so that only Gram stain information is required to select the proper antimicrobial panel and initiate testing. Gram stain information is not needed to start sample processing with the PBC Separator but is required prior to AST so the appropriate panel can be selected. The PBC Separator with Selux AST System does not provide organism identification (ID). Although the PBC Separator sample processing and Selux AST System testing can be performed without species-level ID, an organism ID is needed for the Selux AST System to report AST results. Species ID can be performed by an appropriate FDA-cleared method and either entered manually into the Selux System or automatically downloaded from the applicable laboratory information system (LIS).

The PBC Separator and Selux AST System can provide results from positive blood culture in under 7 hours on average. Within the results interface, AST results will include the MIC values for each indicated antimicrobial. Antimicrobials that are indicated for use with the Selux AST System when testing from isolated colonies but not from inocula prepared with the PBC Separator will be noted as “NC” (not claimed) and MIC values will not be reported. The same is true for antimicrobials and/or organisms that are indicated for use with the Selux AST System when tested from positive blood culture inocula prepared by the PBC Separator. As shown in **Figure 1** below, the PBC Separator is integrated into the Selux AST System for preparing bacterial inocula from positive blood culture for use with the system, which includes the Inoculator and Analyzer instruments.

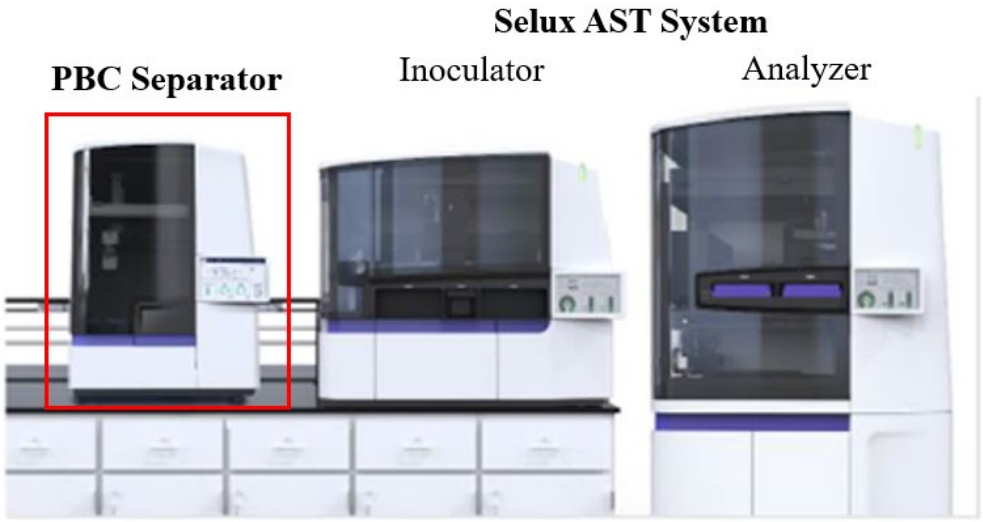

Figure 1. The PBC Separator as a component of the Selux AST System, which includes the Inoculator and Analyzer instruments.

The reportable MIC ranges are shown in **Table 1** below.

Table 1. Reportable MIC Ranges and Organism-Specific Breakpoints for Antimicrobials Tested with the PBC Separator with Selux AST System.

Antimicrobial	Indicated Organism Group	Selux AST System Reportable Range (µg/mL)	FDA-Recognized/Approved Breakpoints * (µg/mL)		
			S	I	R
Amikacin	*Acinetobacter baumannii* complex	≤0.12 to ≥256	≤16	32	≥64
	Enterobacterales	≤2 to ≥256	≤16	32	≥64
	Pseudomonas aeruginosa	≤0.12 to ≥256	≤16	32	≥64
Amoxicillin-Clavulanate	Enterobacterales	≤2 to ≥128	≤8	16	≥32
Ampicillin	Enterobacterales	≤2 to ≥128	≤8	16	≥32
Ampicillin-Sulbactam	*Acinetobacter baumannii* complex	≤2 to ≥128	≤8	16	≥32
	Enterobacterales	≤0.5 to ≥128	≤8	16	≥32
Cefazolin	Enterobacterales	≤0.12 to ≥128	≤2	4	≥8
Cefepime	Enterobacterales	≤0.5 to ≥32	≤2	4-8	≥16
	Pseudomonas aeruginosa	≤0.25 to ≥128	≤8	-	≥16
Ceftazidime	Enterobacterales	≤0.25 to ≥64	≤4	8	≥16
	Pseudomonas aeruginosa	≤0.25 to ≥256	≤8	-	≥16
Ceftazidime-Avibactam	Enterobacterales	≤0.12 to ≥64	≤8	-	≥16
	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	≤0.03 to ≥16	≤0.5	1	≥2
Ertapenem	Enterobacterales	≤0.03 to ≥16	≤0.5	1	≥2
Gentamicin	Enterobacterales	≤1 to ≥64	≤4	8	≥16
	Pseudomonas aeruginosa	≤0.5 to ≥64	≤4	8	≥16
Imipenem	*Acinetobacter baumannii* complex	≤0.5 to ≥64	≤2	4	≥8
	Enterobacterales	≤0.25 to ≥64	≤1	2	≥4
Meropenem	*Acinetobacter baumannii* complex	≤0.12 to ≥64	≤2	4	≥8

Antimicrobial	Indicated Organism Group	Selux AST System Reportable Range (µg/mL)	FDA-Recognized/Approved Breakpoints * (µg/mL)		
			S	I	R
	Enterobacterales	≤0.12 to ≥64	≤1	2	≥4
	Pseudomonas aeruginosa	≤0.12 to ≥64	≤2	4	≥8
Minocycline	*Acinetobacter baumannii* complex	≤0.25 to ≥64	≤4	8	≥16
	Enterobacterales	≤0.25 to ≥64	≤4	8	≥16
Piperacillin-Tazobactam	*Acinetobacter baumannii* complex	≤4 to ≥512	≤16	32-64	≥128
	Enterobacterales	≤2 to ≥128	≤8	16	≥32
	Pseudomonas aeruginosa	≤0.25 to ≥512	≤16	32-64	≥128
Tobramycin	Enterobacterales	≤0.12 to ≥128	≤4	8	≥16
	Pseudomonas aeruginosa	≤0.12 to ≥128	≤4	8	≥16

S, Susceptible; I, Intermediate; R, Resistant; -, no breakpoint (interpretive criterion) recognized
* FDA STIC Website https://www.fda.gov/drugs/development-resources/fda-recognized-antimicrobial-susceptibility-test-interpretive-criteria

B Principle of Operation:

See Device Description.

C Instrument Description Information:

1. Instrument Name:

   PBC Separator with Selux AST System

2. Specimen Identification:

   Gram stain analysis is performed prior to AST testing to select the appropriate panel but is not required prior to processing with the PBC Separator. Identification (ID) using an FDA-cleared method is required prior to result interpretation and reporting after Selux AST System processing.

   To ensure sample traceability, the PBC Separator software associates the barcode identifier on the Inoculum Tube with the barcode identifier on the Sample Tube and transmits this information to the Selux Site Services central workstation.

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

3. Specimen (PBC) Sampling and Handling:

   Positive blood culture samples must be processed immediately after ringing positive on a continuous monitoring blood culture system or within 16 hours of positivity should delays be unavoidable. The user aseptically transfers 9 mL of positive blood culture from the blood bottle into the Selux Sample Tube. The user then loads the Sample Tube, Inoculum Tube, and Reagent Kit into the PBC Separator and starts the process using the graphical interface on the instrument. After processing, the inoculum tube is collected and used with the downstream Selux AST System, following the instructions for use for that system.

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

4. Calibration:

The PBC Separator on-board spectrophotometer is calibrated by a trained service engineer at the time of installation. Additional weekly or as-needed calibrations should be performed by the user by following the QC workflow in the instructions for use (described below).

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

5. Quality Control:

Quality controls are performed to ensure that the PBC Separator works according to the intended use and performance specifications. The spectrophotometer within the PBC Separator should be calibrated weekly or as required. Following the PBC Separator Quality Control Verification procedure in the instructions for use, the user will initiate the PBC Separator QC workflow on the instrument interface. McFarland standards provided with the instrument (0.0 and 0.5 standards) are inserted into the spectrophotometer and three readings are taken, with the tube being rotated and re-inserted between each reading. The average readings for the 0.5 McFarland standard should be within the acceptable ranges defined in the instructions for use (0.44 – 0.56). The instructions for use outlines the steps to follow depending on the average readings obtained.

Quality control for AST testing should be conducted in accordance with the instructions for use for the Selux AST System and Gram-Negative Panel. Refer to the Decision Summary for K211748 for additional information.

V Substantial Equivalence Information:

A Predicate Device Name(s):
eQUANT System

B Predicate 510(k) Number(s):
K231536

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device: K223493	Predicate: K231536
Device Trade Name	PBC Separator with Selux AST System	eQUANT System
General Device Characteristic Similarities		
Indications for Use	The PBC Separator with Selux AST System is an automated inoculum preparation system that uses lysis, centrifugation and	The eQUANT System is an automated inoculum preparation system that uses potentiometric sensing of oxidation-reduction

Device & Predicate Device(s):	Device: K223493	Predicate: K231536
	sequential optical density measurements to generate a McFarland-equivalent suspension from positive blood culture samples that can be used for quantitative *in vitro* antimicrobial susceptibility testing by the Selux AST System. Samples are processed directly from blood culture samples identified as positive by a continuous monitoring blood culture system. Samples should be confirmed as monomicrobial, gram negative rods by Gram stain. Organism identification is required for AST result interpretation and reporting, per the Selux AST System instructions for use.	potential changes due to pathogen metabolism to generate a 0.5 McFarland-equivalent suspension (the eMcFarland or eMcF) from positive blood culture samples that can be used for direct, qualitative in vitro susceptibility testing by the agar disk diffusion test method (Kirby-Bauer). Samples are processed directly from blood culture samples identified as positive by a continuous monitoring blood culture system and confirmed as Gram-negative rods by Gram stain. Organism identification must be confirmed by an FDA cleared device for testing from positive blood culture before processing samples on the eQUANT System.
Indicated Antimicrobials	Amikacin Amoxicillin-Clavulanate Ampicillin Ampicillin-Sulbactam Cefazolin Cefepime Ceftazidime Ceftazidime-Avibactam Ceftriaxone Ciprofloxacin Ertapenem Gentamicin Imipenem Meropenem Minocycline Piperacillin-Tazobactam Tobramycin	Amoxicillin/clavulanate Ampicillin Aztreonam Cefazolin Cefepime Ceftriaxone Ertapenem Gentamicin Levofloxacin Meropenem Piperacillin/Tazobactam Tobramycin
Indicated Organisms	*Acinetobacter baumannii* complex *Citrobacter freundii* complex *Citrobacter koseri* *Enterobacter cloacae* complex *Escherichia coli* *Klebsiella spp.* *Morganella morganii*	*Acinetobacter* spp. *Citrobacter freundii* *Enterobacter cloacae* *Escherichia coli* *Klebsiella aerogenes* *Klebsiella pneumoniae* *Klebsiella oxytoca*

Device & Predicate Device(s):	Device: K223493	Predicate: K231536
	Proteus mirabilis *Proteus vulgaris* *Pseudomonas aeruginosa* *Serratia marcescens*	*Proteus mirabilis* *Proteus vulgaris* *Pseudomonas aeruginosa* *Serratia marcescens*
Sample Type	Aliquot from monomicrobial positive blood culture	Same
Output/Results Reporting	Liquid suspension (McFarland equivalent) of bacteria suitable for downstream susceptibility testing; no results reported	Same
General Device Characteristic Differences		
Technology	Uses a series of lysis and centrifugation steps and sequential optical density measurements to generate a tuned McFarland equivalent inoculum.	Measure pathogen concentration via potentiometric sensing of changes in oxidation-reduction potential (ORP) during pathogen metabolism. Uses species-specific and blood culture bottle specific algorithms to determine when a 0.5 McFarland equivalent concentration is reached.
Downstream Susceptibility Testing	Selux AST System	Kirby-Bauer Disk Diffusion

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-Ed33. *Performance Standards for Antimicrobial Susceptibility Testing*; 33rd Edition (March 2023)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Reproducibility testing for the PBC Separator with Selux AST System was conducted at three testing sites (two external and one internal site). Panel members included representative species indicated for use with each respective antimicrobial. As the Selux AST System (which includes all components other than the PBC Separator) and GN Panel had previously been cleared (K211759 and K211748), a truncated panel of antimicrobial agents include at

least one representative drug from each claimed drug class was 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 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 five representative isolates with on-scale MIC values for each antimicrobial, for a minimum of 135 results per antimicrobial (5 isolates x 3 sites x 3 replicates x 3 days = 135 results/antimicrobial). For some antimicrobials, an additional isolate was tested as well. Both best-case and worst-case inter-site reproducibility was ≥95% and were acceptable.

Since representative isolates of one of the claimed organism groups (*A. baumannii*) were not included in the initial reproducibility study, a supplemental study was conducted with antimicrobials analyzed in the reproducibility study that have *A. baumannii* complex claims (ampicillin-sulbactam, meropenem, and minocycline). Testing was performed on three instruments at a single internal site and data from all three systems were combined to assess inter-site reproducibility. Data from both studies are collated and summarized in **Table 2** below. Performance is summarized for each antimicrobial tested with all organisms. Inter-site reproducibility was determined to be acceptable.

Intra-site reproducibility was evaluated by testing a minimum of five representative isolates in triplicate on three days at one internal site for a minimum of 45 results per antimicrobial (5 isolates x 3 replicates x 3 days = 45 results/antimicrobial). Additional isolates were included for some antimicrobials. Best-case and worst-case intra-site reproducibility was acceptable (≥95%). As with the inter-site study, supplemental testing was conducted to analyze *A. baumannii* with associated antimicrobials. Data from both studies are collated and summarized in **Table 2** below. Performance is summarized for each antimicrobial tested with all organisms. Inter-site reproducibility was determined to be acceptable.

Table 2. Reproducibility of the PBC Separator with Selux AST System

Antimicrobial	Inter-site Reproducibility		Intra-site Reproducibility	
	Best-case (%)	Worst-case (%)	Best-case (%)	Worst-case (%)
Ampicillin	134/135 (99.3%)	134/135 (99.3%)	45/45 (100%)	45/45 (100%)
Ampicillin-sulbactam *	162/162 (100%)	162/162 (100%)	54/54 (100%)	54/54 (100%)
Amoxicillin-clavulanate	135/135 (100%)	135/135 (100%)	45/45 (100%)	45/45 (100%)
Cefazolin	135/135 (100%)	135/135 (100%)	45/45 (100%)	45/45 (100%)
Ceftazidime-avibactam	135/135 (100%)	135/135 (100%)	45/45 (100%)	45/45 (100%)
Ciprofloxacin	162/162 (100%)	162/162 (100%)	54/54 (100%)	54/54 (100%)
Gentamicin	160/162 (98.8%)	160/162 (98.8%)	54/54 (100%)	54/54 (100%)
Meropenem *	181/189 (95.8%)	181/189 (95.8%)	62/63 (98.4%)	62/63 (98.4%)
Minocycline *	156/162 (96.3%)	156/162 (96.3%)	53/54 (98.1%)	53/54 (98.1%)

** In instances where a representative species from a claimed organism group was not included in the original study, supplemental testing was conducted, and data were collated with original data.*

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

Endogenous/Exogenous Interfering Substances
An interfering substances study was performed to evaluate if substances naturally present or artificially introduced into blood culture bottles affected PBC Separator with Selux AST System performance. Selux AST System MIC results from PBC Separator-prepared samples were evaluated using seeded PBC samples with and without interfering substances. Representative organisms including at least one from each organism reporting group were evaluated with each claimed antimicrobial. Endogenous and exogenous interferents were spiked into blood culture bottles at or above clinically relevant concentrations alongside bacteria. Bottles were processed with a continuous monitoring blood culture system until positivity and processed with the PBC Separator. As this is a method-to-method comparison, essential agreement (EA) of ≥95% was deemed acceptable. Performance with potential endogenous and exogenous interferents is shown in **Tables 3-5.**

In general, the data were acceptable. There were a few instances in which EA was <95% for specific interferents, discussed below:

Endogenous Interferents

- Amikacin when tested with Triglycerides had an EA < 90% for *P. aeruginosa*. A single replicate was out of EA and was within category agreement (CA), and thus is not expected to impact clinical care; the data are acceptable.
- Piperacillin-Tazobactam had an EA < 90% across multiple conditions. This was due to very major errors with *K. pneumoniae*. The following limitation is included in the device labeling to address these errors:
    - *An essential agreement <90% and very major errors were observed when testing Piperacillin-Tazobactam with K. pneumoniae with all evaluated potential interferents.*

Exogenous Interferents

- Cefepime when tested with potential interferents Cefpodoxime and Gentamicin had EA < 90% for Enterobacterales. This was due to the inclusion of one strain of *K. pneumoniae* that was out of EA; however, when data were evaluated by strains, the performance was acceptable.
- Imipenem when tested with potential interferents Cefpodoxime and Gentamicin had EA < 90% for Enterobacterales. This was due to the inclusion of one strain of *K. pneumoniae* that was out of EA; however, when data were evaluated by strains, the performance was acceptable.
- Tobramycin when tested with potential interferent Cefpodoxime had an EA < 90% for Enterobacterales. This was due to one isolate of *E. coli* and one isolate of *K. pneumoniae* being out of EA. The out-of-EA results were within the intermediate breakpoint category, whereas the modal control results were susceptible. However, due to the overall study data, this was deemed acceptable.

- *An essential agreement <90% and minor errors were observed when testing Tobramycin with E. coli and K. pneumoniae with the potential interferent cefpodoxime.*

Table 3. Performance with potential endogenous interferents (part 1).

Antimicrobial	Indicated Organism(s)	Red Blood Cells (20 g/dL)		White Blood Cells (12,000 cells/µL)		Platelets (450,000/µL)		Gamma Globulins (50 g/L)	
		# EA / Total	% EA	# EA / Total	% EA	# EA / Total	% EA	# EA / Total	% EA
Amikacin	*A. baumannii* complex	2/2	100.0%	4/4	100.0%	3/3	100.0%	3/3	100.0%
	Enterobacterales	11/11	100.0%	5/5	100.0%	5/5	100.0%	10/10	100.0%
	P. aeruginosa	2/2	100.0%	5/5	100.0%	4/4	100.0%	4/4	100.0%
	Combined	15/15	100.0%	14/14	100.0%	12/12	100.0%	17/17	100.0%
Amoxicillin-Clavulanate	Enterobacterales	11/11	100.0%	5/5	100.0%	5/5	100.0%	10/10	100.0%
Ampicillin	Enterobacterales	9/9	100.0%	4/4	100.0%	4/4	100.0%	8/8	100.0%
Ampicillin-Sulbactam	*A. baumannii* complex	/2/	100.0%	4/4	100.0%	5/5	100.0%	4/4	100.0%
	Enterobacterales	11/11	100.0%	5/5	100.0%	5/5	100.0%	10/10	100.0%
	Combined	13/13	100.0%	9/9	100.0%	10/10	100.0%	14/14	100.0%
Cefazolin	Enterobacterales	11/11	100.0%	5/5	100.0%	5/5	100.0%	10/10	100.0%
Cefepime	Enterobacterales	11/11	100.0%	5/5	100.0%	5/5	100.0%	10/10	100.0%
	P. aeruginosa	2/2	100.0%	5/5	100.0%	4/4	100.0%	4/4	100.0%
	Combined	13/13	100.0%	10/10	100.0%	9/9	100.0%	14/14	100.0%
Ceftazidime	Enterobacterales	11/11	100.0%	5/5	100.0%	5/5	100.0%	10/10	100.0%
	P. aeruginosa	1/1	100.0%	4/4	100.0%	4/4	100.0%	2/2	100.0%
	Combined	12/12	100.0%	9/9	100.0%	9/9	100.0%	12/12	100.0%
Ceftazidime-Avibactam	Enterobacterales	11/11	100.0%	5/5	100.0%	5/5	100.0%	10/10	100.0%
	P. aeruginosa	2/2	100.0%	5/5	100.0%	4/4	100.0%	4/4	100.0%
	Combined	13/13	100.0%	10/10	100.0%	9/9	100.0%	14/14	100.0%
Ceftriaxone	Enterobacterales	11/11	100.0%	5/5	100.0%	5/5	100.0%	10/10	100.0%
Ciprofloxacin	Enterobacterales	11/11	100.0%	5/5	100.0%	5/5	100.0%	10/10	100.0%
	P. aeruginosa	2/2	100.0%	5/5	100.0%	4/4	100.0%	4/4	100.0%
	Combined	13/13	100.0%	10/10	100.0%	9/9	100.0%	14/14	100.0%
Ertapenem	Enterobacterales	11/11	100.0%	5/5	100.0%	5/5	100.0%	10/10	100.0%
Gentamicin	Enterobacterales	11/11	100.0%	5/5	100.0%	5/5	100.0%	10/10	100.0%
	P. aeruginosa	2/2	100.0%	5/5	100.0%	4/4	100.0%	4/4	100.0%
	Combined	13/13	100.0%	10/10	100.0%	9/9	100.0%	14/14	100.0%
Imipenem	*A. baumannii* complex	2/2	100.0%	4/4	100.0%	5/5	100.0%	4/4	100.0%
	Enterobacterales	11/11	100.0%	5/5	100.0%	5/5	100.0%	10/10	100.0%
	Combined	13/13	100.0%	9/9	100.0%	10/10	100.0%	14/14	100.0%
Meropenem	*A. baumannii* complex	2/2	100.0%	4/4	100.0%	5/5	100.0%	4/4	100.0%
	Enterobacterales	11/11	100.0%	5/5	100.0%	5/5	100.0%	10/10	100.0%
	P. aeruginosa	2/2	100.0%	5/5	100.0%	4/4	100.0%	4/4	100.0%
	Combined	15/15	100.0%	14/14	100.0%	14/14	100.0%	18/18	100.0%
Minocycline	*A. baumannii* complex	2/2	100.0%	4/4	100.0%	5/5	100.0%	4/4	100.0%
	Enterobacterales	11/11	100.0%	5/5	100.0%	5/5	100.0%	10/10	100.0%
	Combined	13/13	100.0%	9/9	100.0%	10/10	100.0%	14/14	100.0%
Piperacillin-Tazobactam	*A. baumannii* complex	2/2	100.0%	4/4	100.0%	3/6	60.0%	4/4	100.0%
	Enterobacterales	2/11	18.2%	1/5	20.0%	1/5	20.0%	2/10	20.0%
	P. aeruginosa	2/2	100.0%	5/5	100.0%	4/4	100.0%	4/4	100.0%
	Combined	6/15	40.0%	10/14	71.4%	8/14	57.1%	10/18	55.6%
Tobramycin	Enterobacterales	10/11	90.9%	4/5	80.0%	5/5	100.0%	9/10	90.0%
	P. aeruginosa	2/2	100.0%	5/5	100.0%	4/4	100.0%	4/4	100.0%
	Combined	12/13	92.3%	9/10	90.0%	9/9	100.0%	13/14	92.9%

Table 4. Performance with potential endogenous interferents (part 2).

Antimicrobial	Indicated Organism(s)	Conjugated Bilirubin (475 µmol/L)		Unconjugated Bilirubin (684 µmol/L)		Triglycerides (16.94 mmol/L)	
		# EA / Total	% EA	# EA / Total	% EA	# EA / Total	% EA
Amikacin	*A. baumannii* complex	2/2	100.0%	2/2	100.0%	1/1	100.0%
	Enterobacterales	11/11	100.0%	11/11	100.0%	7/7	100.0%
	P. aeruginosa	2/2	100.0%	2/2	100.0%	2/3	66.7% [1]
	Combined	15/15	100.0%	15/15	100.0%	10/11	100.0%
Amoxicillin-Clavulanate	Enterobacterales	11/11	100.0%	11/11	100.0%	7/7	100.0%
Ampicillin	Enterobacterales	9/9	100.0%	9/9	100.0%	5/5	100.0%
Ampicillin-Sulbactam	*A. baumannii* complex	2/2	100.0%	2/2	100.0%	3/3	100.0%
	Enterobacterales	11/11	100.0%	11/11	100.0%	7/7	100.0%
	Combined	13/13	100.0%	13/13	100.0%	10/10	100.0%
Cefazolin	Enterobacterales	11/11	100.0%	11/11	100.0%	7/7	100.0%
Cefepime	Enterobacterales	11/11	100.0%	11/11	100.0%	7/7	100.0%
	P. aeruginosa	2/2	100.0%	2/2	100.0%	3/3	100.0%
	Combined	13/13	100.0%	13/13	100.0%	10/10	100.0%
Ceftazidime	Enterobacterales	11/11	100.0%	11/11	100.0%	7/7	100.0%
	P. aeruginosa	2/2	100.0%	1/1	100.0%	3/3	100.0%
	Combined	13/13	100.0%	12/12	100.0%	10/10	100.0%
Ceftazidime-Avibactam	Enterobacterales	11/11	100.0%	11/11	100.0%	7/7	100.0%
	P. aeruginosa	2/2	100.0%	2/2	100.0%	3/3	100.0%
	Combined	13/13	100.0%	13/13	100.0%	10/10	100.0%
Ceftriaxone	Enterobacterales	11/11	100.0%	11/11	100.0%	7/7	100.0%
Ciprofloxacin	Enterobacterales	11/11	100.0%	11/11	100.0%	7/7	100.0%
	P. aeruginosa	2/2	100.0%	2/2	100.0%	3/3	100.0%
	Combined	13/13	100.0%	13/13	100.0%	10/10	100.0%
Ertapenem	Enterobacterales	11/11	100.0%	11/11	100.0%	7/7	100.0%
Gentamicin	Enterobacterales	11/11	100.0%	11/11	100.0%	7/7	100.0%
	P. aeruginosa	2/2	100.0%	2/2	100.0%	3/3	100.0%
	Combined	13/13	100.0%	13/13	100.0%	10/10	100.0%
Imipenem	*A. baumannii* complex	2/2	100.0%	2/2	100.0%	3/3	100.0%
	Enterobacterales	11/11	100.0%	11/11	100.0%	7/7	100.0%
	Combined	13/13	100.0%	13/13	100.0%	10/10	100.0%
Meropenem	*A. baumannii* complex	2/2	100.0%	2/2	100.0%	3/3	100.0%
	Enterobacterales	11/11	100.0%	11/11	100.0%	7/7	100.0%
	P. aeruginosa	2/2	100.0%	2/2	100.0%	3/3	100.0%
	Combined	15/15	100.0%	15/15	100.0%	13/13	100.0%
Minocycline	*A. baumannii* complex	2/2	100.0%	2/2	100.0%	3/3	100.0%
	Enterobacterales	11/11	100.0%	11/11	100.0%	7/7	100.0%
	Combined	13/13	100.0%	13/13	100.0%	10/10	100.0%
Piperacillin-Tazobactam	*A. baumannii* complex	2/2	100.0%	2/2	100.0%	2/3	66.7%
	Enterobacterales	3/11	27.3%	2/11	18.2%	2/7	28.6%
	P. aeruginosa	2/2	100.0%	2/2	100.0%	3/3	100.0%
	Combined	7/15	46.7%	6/15	40.0%	7/13	58.3%
Tobramycin	Enterobacterales	10/11	90.9%	10/11	90.9%	6/7	85.7%
	P. aeruginosa	2/2	100.0%	2/2	100.0%	3/3	100.0%
	Combined	12/13	92.3%	12/13	92.3%	9/10	90.0%

[1] A single replicate was out of EA and was within CA, and thus is not expected to impact clinical care; the data are acceptable

Table 5. Performance with potential exogenous interferents.

Antimicrobial	Indicated Organism(s)	Cefpodoxime (2.3 µg/mL)		Ciprofloxacin (3.6 µg/mL)		Gentamicin (24 µg/mL)		Penicillin (6.0 µg/mL)	
		# EA / Total	% EA	# EA / Total	% EA	# EA / Total	% EA	# EA / Total	% EA
Amikacin	*A. baumannii* complex	2/2	100.0%	2/2	100.0%	2/2	100.0%	2/2	100.0%
	Enterobacterales	9/9	100.0%	10/10	100.0%	10/10	100.0%	10/11	90.9%
	P. aeruginosa	2/2	100.0%	2/2	100.0%	2/2	100.0%	2/2	100.0%
	Combined	13/13	100.0%	14/14	100.0%	14/14	100.0%	14/15	93.3%
Amoxicillin-Clavulanate	Enterobacterales	9/9	100.0%	10/10	100.0%	10/10	100.0%	10/11	90.9%
Ampicillin	Enterobacterales	7/7	100.0%	8/8	100.0%	8/8	100.0%	9/9	100.0%
Ampicillin-Sulbactam	*A. baumannii* complex	2/2	100.0%	2/2	100.0%	2/2	100.0%	2/2	100.0%
	Enterobacterales	9/9	100.0%	10/10	100.0%	10/10	100.0%	11/11	100.0%
	Combined	11/11	100.0%	12/12	100.0%	12/12	100.0%	13/13	100.0%
Cefazolin	Enterobacterales	9/9	100.0%	10/10	100.0%	10/10	100.0%	11/11	100.0%
Cefepime	Enterobacterales	7/9	77.8%	9/10	90.0%	8/10	80.0%	11/11	100.0%
	P. aeruginosa	2/2	100.0%	2/2	100.0%	2/2	100.0%	2/2	100.0%
	Combined	9/11	81.8%	11/12	91.7%	10/12	83.3%	13/13	100.0%
Ceftazidime	Enterobacterales	9/9	100.0%	10/10	100.0%	10/10	100.0%	11/11	100.0%
	P. aeruginosa	0/0	N/A [1]	0/0	N/A [1]	1/1	100.0%	1/1	100.0%
	Combined	9/9	100.0%	10/10	100.0%	11/11	100.0%	12/12	100.0%
Ceftazidime-Avibactam	Enterobacterales	9/9	100.0%	10/10	100.0%	10/10	100.0%	10/11	90.9%
	P. aeruginosa	2/2	100.0%	2/2	100.0%	2/2	100.0%	2/2	100.0%
	Combined	11/11	100.0%	12/12	100.0%	12/12	100.0%	12/13	92.3%
Ceftriaxone	Enterobacterales	9/9	100.0%	10/10	100.0%	10/10	100.0%	11/11	100.0%
Ciprofloxacin	Enterobacterales	9/9	100.0%	10/10	100.0%	10/10	100.0%	11/11	100.0%
	P. aeruginosa	2/2	100.0%	2/2	100.0%	2/2	100.0%	2/2	100.0%
	Combined	11/11	100.0%	12/12	100.0%	12/12	100.0%	13/13	100.0%
Ertapenem	Enterobacterales	9/9	100.0%	10/10	100.0%	10/10	100.0%	11/11	100.0%
Gentamicin	Enterobacterales	9/9	100.0%	10/10	100.0%	10/10	100.0%	11/11	100.0%
	P. aeruginosa	2/2	100.0%	2/2	100.0%	2/2	100.0%	2/2	100.0%
	Combined	11/11	100.0%	12/12	100.0%	12/12	100.0%	13/13	100.0%
Imipenem	*A. baumannii* complex	2/2	100.0%	2/2	100.0%	2/2	100.0%	2/2	100.0%
	Enterobacterales	5/9	55.6%	9/10	90.0%	7/10	70.0%	11/11	100.0%
	Combined	7/11	63.6%	11/12	91.7%	9/12	75.0%	13/13	100.0%
Meropenem	*A. baumannii* complex	2/2	100.0%	2/2	100.0%	2/2	100.0%	2/2	100.0%
	Enterobacterales	9/9	100.0%	10/10	100.0%	10/10	100.0%	11/11	100.0%
	P. aeruginosa	2/2	100.0%	2/2	100.0%	2/2	100.0%	2/2	100.0%
	Combined	13/13	100.0%	14/14	100.0%	14/14	100.0%	15/15	100.0%
Minocycline	*A. baumannii* complex	2/2	100.0%	2/2	100.0%	2/2	100.0%	2/2	100.0%
	Enterobacterales	8/9	88.9%	10/10	100.0%	10/10	100.0%	11/11	100.0%
	Combined	11/11	100.0%	12/12	100.0%	12/12	100.0%	13/13	100.0%
Piperacillin-Tazobactam	*A. baumannii* complex	2/2	100.0%	2/2	100.0%	2/2	100.0%	2/2	100.0%
	Enterobacterales	9/9	100.0%	10/10	90.0%	10/10	100.0%	11/11	100.0%
	P. aeruginosa	2/2	100.0%	2/2	100.0%	2/2	100.0%	2/2	100.0%
	Combined	13/13	100.0%	14/14	91.7%	14/14	100.0%	15/15	100.0%
Tobramycin	Enterobacterales	7/9	77.8%	10/10	100.0%	10/10	100.0%	11/11	100.0%
	P. aeruginosa	2/2	100.0%	2/2	97.0%	2/2	100.0%	2/2	100.0%
	Combined	9/11	81.8%	12/12	100.0%	12/12	100.0%	13/13	100.0%

[1] Due to an error, results were not available in the control condition

4. Assay Reportable Range:

Not applicable.

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

Quality Control Testing. Quality control testing was performed each day that testing was conducted. Clinical sites conducted daily QC of the PBC Separator by measuring a 0.5 McFarland standard inoculum on each instrument in use, according to the PBC Separator instructions for use. During QC testing across all four clinical testing sites, triplicate OD readings of the 0.5 McFarland standard were averaged and compared to the acceptable range (0.44-0.56). The PBC Separator QC readings were within the expected OD range for 100% of the measurements.

Selux AST System QC was conducted in accordance with the instructions for use with the Gran-Negative Panel.

An additional QC study was conducted to verify the QC of the PBC Separator with Selux AST System as a whole. In this study, three CLSI-recommended ATCC QC strains (*E. coli* ATCC 25922, K. *pneumoniae* ATCC 700603, and *P. aeruginosa* ATCC 27853) were seeded in blood culture bottles, incubated until positivity, and processed with the PBC Separator. Inoculums were used with the Gram-Negative Panel on the Selux AST System. Testing was conducted at three sites (two external, one internal). Performance was evaluated as the frequency with which test results were within the expected QC MIC range for each antimicrobial at each site. All antimicrobials demonstrated ≥95% of samples within the acceptable QC range at each site and cumulatively. The data is presented in **Table 6** and all results were within the expected range.

Table 6. Performance of the PBC Separator with Selux AST System using QC strains seeded into blood culture bottles

Antimicrobial	QC Strain	Selux Dilution Range	Acceptable QC Range	Site 1		Site 2		Site 3		All Sites	
				N	% in Range	N	% in Range	N	% in Range	N	% in Range
Amikacin	*P. aeruginosa* ATCC 27853	≤0.12 to ≥256	1-4 µg/mL	20	100	27	100	25	100	72	100
Amoxicillin clavulanate	*K. pneumoniae* ATCC 700603	≤0.5 to ≥128	4-16 µg/mL	22	100	28	100	23	100	73	100
Ampicillin	*E. coli* ATCC 25922	≤0.25 to ≥128	2-8 µg/mL	15	100	29	100	21	100	65	100
Ampicillin-sulbactam	*K. pneumoniae* ATCC 700603	≤0.5 to ≥128	8-32 µg/mL	22	100	28	96.4	23	100	73	98.6
Cefazolin	*E. coli* ATCC 25922	≤0.12 to ≥128	1-4 µg/mL	15	100	29	100	21	100	65	100
Cefepime	*P. aeruginosa* ATCC 27853	≤0.25 to ≥128	0.5-4 µg/mL	20	100	27	100	25	100	72	100
Ceftazidime	*P. aeruginosa* ATCC 27853	≤0.25 to ≥256	1-4 µg/mL	20	100	27	96.3	25	100	72	98.6
Ceftazidime-avibactam	*K. pneumoniae* ATCC 700603	≤0.12 to ≥64	0.25-2 µg/mL	22	100	28	100	23	100	73	100
Ciprofloxacin	*P. aeruginosa* ATCC 27853	≤0.03 to ≥16	0.12-1 µg/mL	20	100	27	100	25	100	72	100
Gentamicin	*E. coli* ATCC 25922	≤0.06 to ≥64	0.25-1 µg/mL	15	100	27	100	21	100	63	100
Imipenem	*K. pneumoniae* ATCC 700603	≤0.016 to ≥64	0.06-0.5 µg/mL	22	100	28	100	23	95.7	73	98.6

Antimicrobial	QC Strain	Selux Dilution Range	Acceptable QC Range	Site 1		Site 2		Site 3		All Sites	
				N	% in Range	N	% in Range	N	% in Range	N	% in Range
Meropenem	*P. aeruginosa* ATCC 27853	≤0.12 to ≥64	0.12-1 µg/mL[1]	20	100	27	96.3	25	100	72	98.6
Minocycline	*E. coli* ATCC 25922	≤0.25 to ≥64	0.25-1 µg/mL[2]	15	100	27	100	21	95.2	63	98.4
Piperacillin-tazobactam	*K. pneumoniae* ATCC 700603	≤0.25 to ≥512	8-32 µg/mL	22	100	28	100	22	100	72	100
Tobramycin	*P. aeruginosa* ATCC 27853	≤0.12 to ≥128	0.25-1 µg/mL	20	100	27	100	25	100	72	100

[1] *The dilution 0.12 µg/mL is off-scale for Meropenem on the Selux AST System*
[2] *The dilution 0.25 µg/mL is off-scale for Minocycline on the Selux AST System*

The user is not instructed to perform QC testing with seeded blood culture bottles. Instead, the user should conduct QC for the PBC Separator and Selux AST System according to their respective instructions for use.

Positive Blood Culture Stability
The sponsor conducted testing to establish the stability of positive blood culture for use with the PBC Separator with Selux AST System. Blood bottles were seeded with human blood and representative isolates (including at least one from each claimed antimicrobial reporting group) and incubated to positivity on a continuous monitoring blood culture system (bioMérieux BACT/ALERT VIRUTO or BD BACTEC). After positivity, blood bottles were processed with the PBC Separator either immediately (0 h, baseline) or after being removed from the continuous monitoring system and being stored at room temperature for 16 hours. MIC results were generated using PBC Separator-prepared inoculums with the Selux AST System. Results at the 16-hour timepoint (t=16) were compared to modal MIC results at baseline (t=0) for each drug and organism reporting group. As this was a method-to-method comparison, EA ≥95% for each antimicrobial agent was considered acceptable. The data showed no observable effects on EA with the PBC Separator with Selux AST System when testing was conducted up to 16 hours after the bottle rang positive. All antimicrobial agents demonstrated >95% EA at the 16-hour timepoint. As noted in the instructions for use, all blood culture bottle samples should be tested promptly after ringing positive on a continuous monitoring system. In the case of unavoidable delays or if the need for re-testing arises, positive blood culture bottles may be tested up to 16 hours post ring.

Inoculum Density Check
The PBC Separator has an onboard densitometer and liquid handler that prepares tuned inoculums for AST. Daily QC testing of the PBC Separator at clinical sites was done to verify that the onboard densitometer was able to consistently detect an 0.5 McFarland inoculum (see Quality Control Testing above) and results were acceptable.

To further verify the microorganism turbidity, quantitative culture was performed to determine the inoculum densities of all samples in the QC analytical study, all samples in the reproducibility study other than *A. baumannii* samples, and at least 10% of clinical isolates. Data were provided as CFU/mL at the final dilution used in the wells of the Selux AST Panel, in accordance with the AST Special Controls Guidance, which is an additional 200-fold dilution factor from the final prepared suspension. The microorganism concentrations for inoculums prepared by the PBC Separator ranged from 5.0×10^3 CFU/mL to 1.9×10^6

CFU/mL. When adjusted, this correlates to 1.0 x 10^8 CFU/mL to 3.8 x 10^8 CFU/mL, which is within the expected range (when considering an 0.5 McFarland contains approximately 1-2x10^8 CFU/mL for *E. coli* ± 0.6 log difference, and the PBC Separator prepares inoculums to 0.65-0.8). The data are shown in **Table 7**.

Table 7. Concentrations of Inoculums prepared by the PBC Separator

Organism	Study Source	Number Tested	Sample Well Concentration (CFU/mL)			
			Mean	Min	Max	Std. Dev.
A. baumannii complex	Clinical	17	4.5E+05	1.2E+05	9.9E+05	2.29E+05
C. freundii complex	Clinical	7	7.3E+05	2.2E+05	1.2E+06	3.68E+05
C. koseri	Clinical	8	1.1E+06	4.1E+05	1.9E+06	4.74E+05
E. coli	Reproducibility, Clinical	275	5.1E+05	3.0E+04	1.5E+06	2.10E+05
K. aerogenes	Clinical	9	8.2E+05	2.5E+05	1.7E+06	5.40E+05
K. oxytoca	Clinical	9	6.0E+05	2.5E+05	1.4E+06	3.88E+05
K. pneumoniae	Reproducibility, Clinical	209	4.3E+05	6.0E+04	1.2E+06	1.86E+05
M. morgannii	Clinical	5	6.1E+05	1.1E+05	1.5E+06	5.10E+05
P. aeruginosa	Reproducibility, Clinical	10	7.3E+05	2.0E+05	1.1E+06	2.86E+05
P. mirabilis	Clinical	5	6.4E+05	5.0E+03	1.2E+06	4.57E+05
P. vulgaris	Clinical	17	5.3E+05	2.3E+05	9.5E+05	2.23E+05
S. marcescens	Clinical	6	6.5E+05	2.1E+05	1.3E+06	4.37E+05

Device Failure. The PBC Separator is equipped with self-checking mechanisms to identify run errors. There were nine instrument failures observed during the original and supplemental testing. All were detected at the time of failure by the instrument and resulted in excluded samples.

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.

8. Accuracy (Instrument):

   Not applicable.

9. Carry-Over:

The purpose of this study was to evaluate the potential for carry-over of samples prepared with the PBC separator. The PBC Separator instructions for use were followed to prepare samples of *E. coli* and *K. pneumoniae* during repeated runs. One replicate of *E. coli* and one replicate of *K. pneumoniae*, which were selected to have different AST profiles, were processed at the same time through a single PBC Separator with Selux AST System. A total of five runs were conducted, with each run containing one *E. coli* sample and one *K. pneumoniae* sample. Purity plates were prepared from the inoculums prepared by the PBC Separator. The MIC results from the Selux AST testing were compared to reference results. Performance was evaluated by reviewing purity plates and AST results. Performance was acceptable if there was zero purity plate contamination caused by the other species and >90% essential agreement (EA) compared with BMD reference results.

The purity plates did not show evidence of carry-over between *E. coli* and *K. pneumoniae* (i.e., single morphology colonies on each representative plate). MIC results from each species demonstrated >90% EA to the reference result. Additionally, the system did not report any faults due to high background or viability contamination. The data are acceptable.

Cross-contamination and carry-over with the Inoculator and Analyzer components of the Selux AST System was previously assessed and deemed acceptable in K211759.

B Comparison Studies:

1. Method Comparison with Reference:

Clinical performance testing was conducted with the PBC Separator with Selux AST System. Performance was evaluated using fresh positive blood culture (PBC) samples, PBC samples seeded with contemporary and stock clinical isolates, as well as PBC samples seeded with challenge isolates selected for their resistance profiles. Contemporary isolates were defined as isolates that had been collected and frozen and tested within six months of collection while stock isolates were tested six or more months after collection. Clinical isolates were collected from positive blood culture bottles confirmed to have gram negative bacteria by Gram stain at two clinical sites within the U.S. and testing was conducted at four sites (3 external, 1 internal).

A total of 469 clinical (162 fresh and 307 stock) and 87 challenge isolates from 12 different Enterobacterales species, *Acinetobacter baumannii* complex, and *Pseudomonas aeruginosa* were tested to evaluate the PBC Separator with Selux AST System performance for 17 antimicrobials. The number of datapoints for the various antimicrobial-organisms tested varied depending on the spectrum of activity, breakpoints, and the claimed organisms (species/group) for each antimicrobial on the panel. Datapoints ranged from 38 (e.g., Amikacin/*A. baumannii*) to 469 (e.g., Ciprofloxacin/Enterobacterales). Selux AST System MIC results from PBC Separator-prepared samples 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 high-level summary of the PBC Separator with Selux AST System performance is described below for each antimicrobial and indicated species. Complete details and results including EA, CA and error rate analyses are summarized in **Table 8** and trending analyses are summarized in **Table 9**.

Details of the performance for each drug/organism combination are provided below Table 8.

Table 8. PBC Separator with Selux AST System 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
Amikacin – *Acinetobacter baumannii* complex [Breakpoints (µg/mL): 16 (S), 32 (I), 64 (R)]													
Challenge Seeded	10	10	100	4	4	100	9	90	7	2	1	0	0
Fresh	1	1	100	0	0	NA	1	100	1	0	0	0	0
Clinical Seeded	27	24	88.89	19	16	84.21	26	96.3	9	16	1	0	0
Combined	38	35	92.11	23	20	86.96	36	94.74	17	18	2	0	0
Amikacin – Enterobacterales [Breakpoints (µg/mL): 16 (S), 32 (I), 64 (R)]													
Challenge Seeded	56	54	96.43	9	7	77.78	53	94.64	7	45	3	0	0
Fresh	98	94	95.92	16	12	75	98	100	0	98	0	0	0
Clinical Seeded	62	60	96.77	4	2	50	62	100	1	60	0	0	0
Combined	216	208	96.3	29	21	72.41	213	98.61	8	203	3	0	0
Amikacin – *Pseudomonas aeruginosa* [Breakpoints (µg/mL): 16 (S), 32 (I), 64 (R)]													
Challenge Seeded	16	15	93.75	15	14	93.33	13	81.25	6	10	3	0	0
Fresh	13	13	100	13	13	100	13	100	0	12	0	0	0
Clinical Seeded	15	14	93.33	15	14	93.33	14	93.33	0	14	1	0	0
Combined	44	42	95.45	43	41	95.35	40	90.91	6	36	4	0	0
Amoxicillin-Clavulanate – Enterobacterales [Breakpoints (µg/mL): 8 (S), 16 (I), 32 (R)]													
Challenge Seeded	56	56	100	45	45	100	49	87.5	19	23	7	0	0
Fresh	134	134	100	97	97	100	120	89.55	2	114	14	0	0
Clinical Seeded	140	138	98.57	80	78	97.5	126	90	18	103	14	0	0
Combined	330	328	99.39	222	220	99.1	295	89.39	39	240	35	0	0
Ampicillin – Enterobacterales [Breakpoints (µg/mL): 8 (S), 16 (I), 32 (R)]													
Challenge Seeded	28	28	100	0	0	NA	28	100	27	1	0	0	0
Fresh	74	73	98.65	2	1	50	73	98.65	49	24	1	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
Clinical Seeded	47	47	100	2	2	100	47	100	20	27	0	0	0
Combined	149	148	99.33	4	3	75	148	99.33	96	52	1	0	0
Ampicillin-Sulbactam – *Acinetobacter baumannii* complex [Breakpoints (µg/mL): 8 (S), 16 (I), 32 (R)]													
Challenge Seeded	10	10	100	9	9	100	10	100	10	0	0	0	0
Fresh	3	1	33.33	2	0	0	3	100	3	0	0	0	0
Clinical Seeded	27	26	96.3	11	10	90.91	25	92.59	12	14	2	0	0
Combined	40	37	92.5	22	19	86.36	38	95	25	14	2	0	0
Ampicillin-Sulbactam –Enterobacterales [Breakpoints (µg/mL): 8 (S), 16 (I), 32 (R)] [1]													
Challenge Seeded	58	58	100	37	37	100	55	94.83	45	4	3	0	0
Fresh	136	135	99.26	131	130	99.24	115	84.56	26	78	21	0	0
Clinical Seeded	158	154	97.47	135	131	97.04	136	86.08	64	82	22	0	0
Combined	352	347	98.58	303	298	98.35	306	86.93	135	164	46	0	0
Cefazolin –Enterobacterales [Breakpoints (µg/mL): 2 (S), 4 (I), 8 (R)] [2]													
Challenge Seeded	51	51	100	3	3	100	49	96.08	48	1	2	0	0
Fresh	95	90	94.74	70	65	92.86	84	88.42	32	56	11	0	0
Clinical Seeded	61	56	91.8	45	40	88.89	54	88.52	19	36	6	0	1
Combined	207	197	95.17	118	108	91.53	187	90.34	99	93	19	0	1
Cefepime – Enterobacterales [Breakpoints (µg/mL): 2 (S), 4-8 (I), 16 (R)]													
Challenge Seeded	48	46	95.83	13	11	84.62	44	91.67	27	15	4	0	0
Fresh	118	113	95.76	11	6	54.55	113	95.76	16	95	5	0	0
Clinical Seeded	240	237	98.75	13	10	76.92	233	97.08	18	219	7	0	0
Combined	406	396	97.54	37	27	72.97	390	96.06	61	329	16	0	0
Cefepime – *Pseudomonas aeruginosa* [Breakpoints (µg/mL): 8 (S), 16 (R)]													
Challenge Seeded	16	16	100	11	11	100	16	100	8	8	0	0	0
Fresh	12	12	100	12	12	100	12	100	1	11	0	0	0
Clinical Seeded	15	14	93.33	14	13	92.86	14	93.33	2	13	0	1	0
Combined	43	42	97.67	37	36	97.3	42	97.67	11	32	0	1	0
Ceftazidime – Enterobacterales [Breakpoints (µg/mL): 4 (S), 8 (I), 16 (R)]													
Challenge Seeded	57	57	100	25	25	100	51	89.47	37	17	6	0	0
Fresh	98	96	97.96	30	28	93.33	91	92.86	20	77	7	0	0
Clinical Seeded	62	62	100	12	12	100	62	100	13	46	0	0	0
Combined	217	215	99.08	67	65	97.01	204	94.01	70	140	13	0	0
Ceftazidime – *Pseudomonas aeruginosa* [Breakpoints (µg/mL): 8 (S), 16 (R)]													
Challenge Seeded	16	16	100	12	12	100	16	100	8	8	0	0	0
Fresh	10	10	100	10	10	100	10	100	0	10	0	0	0
Clinical Seeded	14	14	100	13	13	100	14	100	1	13	0	0	0
Combined	40	40	100	35	35	100	40	100	9	31	0	0	0
Ceftazidime-Avibactam – Enterobacterales [Breakpoints (µg/mL): 8 (S), 16 (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
Challenge Seeded	60	58	96.67	22	20	90.91	60	100	3	57	0	0	0
Fresh	118	116	98.31	9	7	77.78	118	100	0	118	0	0	0
Clinical Seeded	240	235	97.92	65	60	92.31	240	100	1	239	0	0	0
Combined	418	409	97.85	96	87	90.62	418	100	4	414	0	0	0
Ceftazidime-Avibactam – *Pseudomonas aeruginosa* [Breakpoints (µg/mL): 8 (S), 16 (R)]													
Challenge Seeded	16	16	100	13	13	100	15	93.75	8	8	0	0	1
Fresh	12	12	100	12	12	100	12	100	0	12	0	0	0
Clinical Seeded	15	15	100	14	14	100	15	100	1	14	0	0	0
Combined	43	43	100	39	39	100	42	97.67	9	34	0	0	1
Ceftriaxone – Enterobacterales [Breakpoints (µg/mL): 1 (S), 2 (I), 4 (R)]													
Challenge Seeded	61	61	100	2	2	100	61	100	51	10	0	0	0
Fresh	116	115	99.14	1	0	0	115	99.14	26	90	0	1	0
Clinical Seeded	196	194	98.98	15	13	86.67	194	98.98	34	161	2	0	0
Combined	373	370	99.2	18	15	83.33	370	99.2	111	261	2	1	0
Ciprofloxacin – Enterobacterales [Breakpoints (µg/mL): 0.25 (S), 0.5 (I), 1 (R)]													
Challenge Seeded	60	59	98.33	15	14	93.33	57	95	43	17	3	0	0
Fresh	145	141	97.24	25	21	84	140	96.55	36	106	4	1	0
Clinical Seeded	264	261	98.86	42	39	92.86	260	98.48	38	223	4	0	0
Combined	469	461	98.29	82	74	90.24	457	97.44	117	346	11	1	0
Ciprofloxacin – *Pseudomonas aeruginosa* [Breakpoints (µg/mL): 0.5 (S), 1 (I), 2 (R)]													
Challenge Seeded	16	16	100	8	8	100	16	100	11	5	0	0	0
Fresh	12	12	100	10	10	100	11	91.67	1	11	1	0	0
Clinical Seeded	15	15	100	14	14	100	15	100	1	13	0	0	0
Combined	43	43	100	32	32	100	42	97.67	13	29	1	0	0
Ertapenem – Enterobacterales [Breakpoints (µg/mL): 0.5 (S), 1 (I), 2 (R)]													
Challenge Seeded	59	57	96.61	15	13	86.67	58	98.31	17	41	1	0	0
Fresh	117	116	99.15	12	11	91.67	116	99.15	1	115	1	0	0
Clinical Seeded	236	232	98.31	35	31	88.57	234	99.15	10	223	2	0	0
Combined	412	405	98.3	62	55	88.71	408	99.03	28	379	4	0	0
Gentamicin – Enterobacterales [Breakpoints (µg/mL): 4 (S), 8 (I), 16 (R)]													
Challenge Seeded	59	55	93.22	16	12	75	56	94.92	28	29	3	0	0
Fresh	142	140	98.59	13	11	84.62	140	98.59	20	121	1	1	0
Clinical Seeded	264	263	99.62	8	7	87.5	262	99.24	16	247	2	0	0
Combined	466	459	98.5	37	30	81.08	459	98.5	64	398	6	1	0
Gentamicin – *Pseudomonas aeruginosa* [Breakpoints (µg/mL): 4 (S), 8 (I), 16 (R)]													
Challenge Seeded	16	15	93.75	6	5	83.33	15	93.75	8	7	1	0	0
Fresh	13	13	100	11	11	100	13	100	0	13	0	0	0
Clinical Seeded	14	14	100	14	14	100	14	100	0	14	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	43	42	97.67	31	30	96.77	42	97.67	8	34	1	0	0
Imipenem – *Acinetobacter baumannii* complex [Breakpoints (µg/mL): 2 (S), 4 (I), 8 (R)]													
Challenge Seeded	10	10	100	0	0	NA	10	100	10	0	0	0	0
Fresh	3	3	100	0	0	NA	3	100	3	0	0	0	0
Clinical Seeded	26	25	96.15	2	1	50	26	100	13	13	0	0	0
Combined	39	38	97.44	2	1	50	39	100	26	13	0	0	0
Imipenem – Enterobacterales [Breakpoints (µg/mL): 1 (S), 2 (I), 4 (R)]													
Challenge Seeded	57	54	94.74	6	3	50	55	96.49	12	43	2	0	0
Fresh	96	93	96.88	4	1	25	94	97.92	0	96	1	1	0
Clinical Seeded	60	58	96.67	4	2	50	60	100	8	52	0	0	0
Combined	213	205	96.24	14	6	42.86	209	98.12	20	191	3	1	0
Meropenem – *Acinetobacter baumannii* complex [Breakpoints (µg/mL): 2 (S), 4 (I), 8 (R)]													
Challenge Seeded	10	10	100	1	1	100	10	100	10	0	0	0	0
Fresh	3	3	100	0	0	NA	3	100	3	0	0	0	0
Clinical Seeded	26	24	92.31	13	11	84.62	26	100	14	12	0	0	0
Combined	39	37	94.87	14	12	85.71	39	100	27	12	0	0	0
Meropenem – Enterobacterales [Breakpoints (µg/mL): 1 (S), 2 (I), 4 (R)]													
Challenge Seeded	57	53	92.98	6	2	33.33	55	96.49	12	44	2	0	0
Fresh	113	112	99.12	2	1	50	112	99.12	0	113	1	0	0
Clinical Seeded	224	223	99.55	11	10	90.91	223	99.55	7	216	1	0	0
Combined	394	388	98.48	19	13	68.42	390	98.98	19	373	4	0	0
Meropenem – *Pseudomonas aeruginosa* [Breakpoints (µg/mL): 2 (S), 4 (I), 8 (R)]													
Challenge Seeded	16	14	87.5	10	8	80	13	81.25	10	5	3	0	0
Fresh	12	12	100	6	6	100	12	100	1	11	0	0	0
Clinical Seeded	15	14	93.33	12	11	91.67	14	93.33	2	12	1	0	0
Combined	43	40	93.02	28	25	89.29	39	90.7	13	28	4	0	0
Minocycline – *Acinetobacter baumannii* complex [Breakpoints (µg/mL): 4 (S), 8 (I), 16 (R)]													
Challenge Seeded	10	10	100	10	10	100	6	60	3	3	4	0	0
Fresh	3	3	100	3	3	100	3	100	3	0	0	0	0
Clinical Seeded	26	25	96.15	11	10	90.91	24	92.31	6	18	2	0	0
Combined	39	38	97.44	24	23	95.83	33	84.62	12	21	6	0	0
Minocycline – Enterobacterales [Breakpoints (µg/mL): 4 (S), 8 (I), 16 (R)]													
Challenge Seeded	58	56	96.55	48	46	95.83	46	79.31	13	41	11	1	0
Fresh	98	93	94.9	93	88	94.62	89	90.82	11	79	8	1	0
Clinical Seeded	62	60	96.77	52	50	96.15	60	96.77	8	52	2	0	0
Combined	218	209	95.87	193	184	95.34	195	89.45	32	172	21	2	0
Piperacillin-Tazobactam – *Acinetobacter baumannii* complex [Breakpoints (µg/mL): 16 (S), 32-64 (I), 128 (R)]													
Challenge Seeded	10	10	100	0	0	NA	10	100	10	0	0	0	0
Fresh	3	3	100	0	0	NA	3	100	3	0	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
Clinical Seeded	26	25	96.15	3	2	66.67	25	96.15	14	12	1	0	0
Combined	39	38	97.44	3	2	66.67	38	97.44	27	12	1	0	0
Piperacillin-Tazobactam – Enterobacterales [Breakpoints (µg/mL): 8 (S), 16 (I), 32 (R)]													
Challenge Seeded	55	54	98.18	14	13	92.86	53	96.36	21	32	2	0	0
Fresh	104	101	97.12	15	12	80	100	96.15	1	96	4	0	0
Clinical Seeded	161	158	98.14	14	11	78.57	159	98.76	15	145	1	1	0
Combined	320	313	97.81	43	36	83.72	312	97.5	37	273	7	1	0
Piperacillin-Tazobactam –*Pseudomonas aeruginosa* [Breakpoints (µg/mL): 16 (S), 32-64 (I), 128 (R)]													
Challenge Seeded	16	16	100	9	9	100	16	100	7	8	0	0	0
Fresh	12	11	91.67	11	10	90.91	11	91.67	1	11	1	0	0
Clinical Seeded	15	15	100	13	13	100	15	100	2	13	0	0	0
Combined	43	42	97.67	33	32	96.97	42	97.67	10	32	1	0	0
Tobramycin – Enterobacterales [Breakpoints (µg/mL): 4 (S), 8 (I), 16 (R)]													
Challenge Seeded	57	55	96.49	45	43	95.56	50	87.72	31	22	7	0	0
Fresh	98	92	93.88	96	90	93.75	91	92.86	12	81	7	0	0
Clinical Seeded	61	60	98.36	59	58	98.31	59	96.72	6	55	2	0	0
Combined	216	207	95.83	200	191	95.5	200	92.59	49	158	16	0	0
Tobramycin – *Pseudomonas aeruginosa* [Breakpoints (µg/mL): 4 (S), 8 (I), 16 (R)]													
Challenge Seeded	16	16	100	10	10	100	15	93.75	8	8	1	0	0
Fresh	12	11	91.67	12	11	91.67	12	100	1	11	0	0	0
Clinical Seeded	15	14	93.33	15	14	93.33	14	93.33	1	14	1	0	0
Combined	43	41	95.35	37	35	94.59	41	95.35	10	33	2	0	0

[1] *Due to low CA (61.9%), K. oxytoca and M. morganii claims are not indicated for testing with the PBC Separator with Selux AST System for Ampicillin-Sulbactam. Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination: Ampicillin-Sulbactam: K. oxytoca, M. morganii*

[2] *Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination: Cefazolin-E. coli when the Selux AST System MIC is 4 µg/mL due to the occurrence of minor errors, that were in essential agreement, resulting in a category agreement below 90%.*

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

Amikacin. A total of 38 *A. baumannii* isolates were evaluated with amikacin. The combined results from clinical and challenge isolate testing demonstrated and EA of 92.11% and CA of 94.74%. There were 2 minor, 0 major, and 0 very major errors. Overall, performance is acceptable.

A total of 216 Enterobacterales isolates were evaluated with amikacin. The combined results from clinical and challenge isolate testing demonstrated and EA of 96.3% and CA of 98.61%. There were 3 minor, 0 major, and 0 very major errors. Overall, performance is acceptable.

A total of 44 *P. aeruginosa* isolates were evaluated with amikacin. The combined results from clinical and challenge isolate testing demonstrated and EA of 95.45% and CA of 90.91%. There were 4 minor, 0 major, and 0 very major errors. Overall, performance is acceptable.

Amoxicillin-Clavulanate. A total of 330 Enterobacterales isolates were evaluated with amoxicillin-clavulanate. The combined results from clinical and challenge isolate testing demonstrated and EA of 99.39% and CA of 89.39% which was considered acceptable since all of the categorical errors were minor, and the EA of the evaluable results was good (>95%). When evaluating results by individual species, *E. coli* had CA <90% which was considered acceptable since all of the categorical errors were minor, and the EA of evaluable results was good (>95%). Overall, performance is acceptable.

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

Ampicillin. A total of 149 Enterobacterales isolates were evaluated with ampicillin. The combined results from clinical and challenge isolate testing demonstrated and EA of 99.33% and CA of 99.33%. There were 1 minor, 0 major, and 0 very major errors. Overall, performance is acceptable.

Ampicillin-Sulbactam. A total of 40 *Acinetobacter baumannii* isolates were evaluated with ampicillin-sulbactam. The combined results from clinical and challenge isolate testing demonstrated and EA of 92.50% and CA of 95.00%. There were 2 minor, 0 major, and 0 very major errors. Overall, performance is acceptable.

A total of 352 Enterobacterales isolates were evaluated with ampicillin-sulbactam. The combined results from clinical and challenge isolate testing demonstrated and EA of 98.58% and CA of 86.93%, which was considered acceptable since all of the categorical errors were minor, and the EA of the evaluable results was good (>95%). When evaluating results by individual species, *E. coli, K. oxytoca,* and *M. morganii* had CA <90%. *E. coli* had a CA of 82.69%, which was considered acceptable due to the high EA (98.72%) and high evaluable EA (98.64%). Although *K. oxytoca* and *M. morganii* both had high evaluable EA (100% and 95.0%, respectively), both demonstrated a CA of 61.9% which is significantly below the 90% threshold recommended in the AST Special Controls and considered unacceptable. The following limitation is included in the device labeling to restrict reporting of *K. oxytoca* and *M. morganii* due to unacceptable performance:

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

- *Ampicillin-Sulbactam: K. oxytoca, M. morganii*

Cefazolin. A total of 207 Enterobacterales isolates were evaluated with cefazolin. The combined results from clinical and challenge isolate testing demonstrated and EA of 95.17% and CA of 90.34%. There were 17 minor, 0 major, and 1 (1/51 = 1.96%) very major errors. When evaluating results by individual species, *E. coli* had CA <90% (85.12%) and an evaluable EA of <90% (86.67%). The following limitation is included in the device labeling to address this performance issue:

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

- *Cefazolin: E. coli when the Selux AST System MIC is 4 µg/mL due to the occurrence of minor errors, that were in essential agreement, resulting in a category agreement below 90%.*

Cefepime. A total of 406 Enterobacterales isolates were evaluated with cefepime. The combined results from clinical and challenge isolate testing demonstrated and EA of 97.54% and CA of 96.06%. There were 16 minor, 0 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. freundii* complex, *C. koseri, K. aerogenes, P. mirabilis, P. vulgaris,* and *S. marcescens* isolates.

A total of 43 *Pseudomonas aeruginosa* isolates were evaluated with cefepime. The combined results from clinical and challenge isolate testing demonstrated and EA of 97.67% and CA of 97.67%. There were 0 minor, 1 (1/32 = 3.12%) major, and 0 very major errors. Due to the lack of an intermediate interpretive criterion, further analysis of the major error was performed, and adjustments were made by considering the MIC values of the error compared to the reference MIC value. The major error had an MIC value that was in essential agreement with the reference MIC value. Therefore, the adjusted major error rate is 0% (0/32), which is acceptable. Overall, performance is acceptable.

Ceftazidime. A total of 217 Enterobacterales isolates were evaluated with ceftazidime. The combined results from clinical and challenge isolate testing demonstrated and EA of 99.08% and CA of 94.01%. There were 13 minor, 0 major, and 0 very major errors. Overall, performance is acceptable.

A total of 40 *Pseudomonas aeruginosa* isolates were evaluated with ceftazidime. The combined results from clinical and challenge isolate testing demonstrated and EA of 100.0% and CA of 100.0%. There were 0 minor, 0 major, and 0 very major errors. Overall, performance is acceptable.

Ceftazidime-Avibactam. A total of 418 Enterobacterales isolates were evaluated with ceftazidime-avibactam. The combined results from clinical and challenge isolate testing demonstrated and EA of 97.85% and CA of 100.0%. There were 0 minor, 0 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. freundii* complex, *C. koseri, E. cloacae* complex, *E. coli, K. aerogenes, K. oxytoca, M. morganii, P. mirabilis, P. vulgaris,* and *S. marcescens* isolates.

A total of 43 *Pseudomonas aeruginosa* isolates were evaluated with ceftazidime-avibactam. The combined results from clinical and challenge isolate testing demonstrated and EA of 100.0% and CA of 97.67%. There were 0 minor, 0 major, and 1 very major (1/9 = 11.11%) errors. Due to the lack of an intermediate interpretive criterion, further analysis of the very major error was performed, and adjustments were made by considering the MIC values of the

error compared to the reference MIC value. The very major error had an MIC value that was in essential agreement with the reference MIC value. Therefore, the adjusted very major error rate is 0% (0/9), which is acceptable.

Ceftriaxone. A total of 373 Enterobacterales isolates were evaluated with ceftriaxone. The combined results from clinical and challenge isolate testing demonstrated and EA of 99.2% and CA of 99.2%. There were 2 minor, 1 major (1/261 = 0.38%), 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. mirabilis* isolates.

Ciprofloxacin. A total of 469 Enterobacterales isolates were evaluated with ciprofloxacin. The combined results from clinical and challenge isolate testing demonstrated and EA of 98.29% and CA of 97.44%. There were 11 minor, 1 major (1/346 = 0.29%), and 0 very major errors. Overall, the performance is acceptable.

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

A total of 43 *Pseudomonas aeruginosa* isolates were evaluated with ciprofloxacin. The combined results from clinical and challenge isolate testing demonstrated and EA of 100.0% and CA of 97.67%. There were 1 minor, 0 major, and 0 very major errors. Overall, the performance is acceptable.

Ertapenem. A total of 412 Enterobacterales isolates were evaluated with ertapenem. The combined results from clinical and challenge isolate testing demonstrated and EA of 98.30% and CA of 99.03%. There were 4 minor, 0 major, and 0 very major errors. Overall, the performance is acceptable.

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

Gentamicin. A total of 466 Enterobacterales isolates were evaluated with gentamicin. The combined results from clinical and challenge isolate testing demonstrated and EA of 98.50% and CA of 98.50%. There were 6 minor, 1 major (1/398 = 0.25%), and 0 very major errors. Overall, the performance is acceptable.

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

A total of 43 *Pseudomonas aeruginosa* isolates were evaluated with gentamicin. The combined results from clinical and challenge isolate testing demonstrated and EA of 97.67% and CA of 97.67%. There were 1 minor, 0 major, and 0 very major errors. Overall, the performance is acceptable.

Imipenem. A total of 39 *Acinetobacter baumannii* complex isolates were evaluated with imipenem. The combined results from clinical and challenge isolate testing demonstrated and EA of 97.44% and CA of 100.0%. There were 0 minor, 0 major, and 0 very major errors. Overall, the performance is acceptable.

A total of 213 Enterobacterales isolates were evaluated with imipenem. The combined results from clinical and challenge isolate testing demonstrated and EA of 96.24% and CA of 98.12%. There were 3 minor, 1 major (1/191 = 0.52%), and 0 very major errors. Overall, the performance is acceptable.

Meropenem. A total of 39 *Acinetobacter baumannii* complex isolates were evaluated with meropenem. The combined results from clinical and challenge isolate testing demonstrated and EA of 94.87% and CA of 100.0%. There were 0 minor, 0 major, and 0 very major errors. Overall, the performance is acceptable.

A total of 394 Enterobacterales isolates were evaluated with meropenem. The combined results from clinical and challenge isolate testing demonstrated and EA of 98.48% and CA of 98.98%. There were 4 minor, 0 major, and 0 very major errors. Overall, the performance is acceptable.

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

A total of 43 *Pseudomonas aeruginosa* isolates were evaluated with meropenem. The combined results from clinical and challenge isolate testing demonstrated and EA of 93.02% and CA of 90.70%. There were 4 minor, 0 major, and 0 very major errors. Overall, the performance is acceptable.

Minocycline. A total of 39 *Acinetobacter baumannii* complex isolates were evaluated with minocycline. The combined results from clinical and challenge isolate testing demonstrated and EA of 97.44% and CA of 84.82%, which was considered acceptable since all of the categorical errors were minor, and the EA of the evaluable results was good (>95%). There were 6 minor, 0 major, and 0 very major errors. Overall, the performance is acceptable.

A total of 218 Enterobacterales were evaluated with minocycline. The combined results from clinical and challenge isolate testing demonstrated and EA of 95.87% and CA of 89.45%, which was considered acceptable since all of the categorical errors were minor, and the EA of the evaluable results was good (>95%). There were 21 minor, 2 major (2/172 = 1.16%), and 0 very major errors. When evaluating results by individual species, *K. pneumoniae* had CA <90% which was considered acceptable since all of the categorical errors were minor, and the EA of evaluable results was good (>90%). Overall, the performance is acceptable.

Piperacillin-Tazobactam. A total of 39 *Acinetobacter baumannii* complex isolates were evaluated with piperacillin-tazobactam. The combined results from clinical and challenge isolate testing demonstrated and EA of 97.44% and CA of 97.44%. There were 1 minor, 0 major, and 0 very major errors. Overall, the performance is acceptable.

A total of 320 Enterobacterales isolates were evaluated with piperacillin-tazobactam. The combined results from clinical and challenge isolate testing demonstrated and EA of 97.81% and CA of 97.50%. There were 7 minor, 1 major (1/273 = 0.36%), and 0 very major errors. Overall, the performance is acceptable.

A total of 43 *Pseudomonas aeruginosa* isolates were evaluated with piperacillin-tazobactam. The combined results from clinical and challenge isolate testing demonstrated and EA of 97.67% and CA of 97.67%. There were 1 minor, 0 major, and 0 very major errors. Overall, the performance is acceptable.

Tobramycin. A total of 216 Enterobacterales isolates were evaluated with Tobramycin. The combined results from clinical and challenge isolate testing demonstrated and EA of 95.83% and CA of 92.59%. There were 16 minor, 0 major, and 0 very major errors. Overall, the performance is acceptable.

A total of 43 *Pseudomonas aeruginosa* isolates were evaluated with Tobramycin. The combined results from clinical and challenge isolate testing demonstrated and EA of 95.35% and CA of 95.35%. There were 2 minor, 0 major, and 0 very major errors. Overall, the performance is acceptable.

Trending

A trending analysis was conducted using the combined data (fresh, clinical seeded and challenge seeded) to evaluate antimicrobial-organism combinations for which for which Selux MIC results were determined to be one or more doubling dilutions lower or higher than the reference result (**Table 9**). 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.

Table 9. PBC Separator with Selux AST System –Trending

Abx	Organism Name	Total On Scale for Trending	>= 1 Dilution Lower # (%)	Exact #	>= 1 Dilution Higher # (%)	Percent Difference (95% CI)	Significant Trending Noted
Amikacin	*Acinetobacter baumannii*	23	16 (69.57)	5	2 (8.7)	-61% (-77%, -34%)	**Yes**
Amikacin	*Escherichia coli*	50	38 (76)	7	5 (10)	-66% (-77%, -48%)	**Yes**
Amikacin	*Klebsiella pneumoniae*	14	10 (71.43)	3	1 (7.14)	-64% (-82%, -29%)	**Yes**
Amikacin	*Pseudomonas aeruginosa*	44	17 (38.64)	20	7 (15.91)	-23% (-39%, -4%)	No
Amoxicillin-Clavulanate	*Escherichia coli*	155	34 (21.94)	104	17 (10.97)	-11% (-19%, -3%)	No
Amoxicillin-Clavulanate	*Klebsiella oxytoca*	9	3 (33.33)	5	1 (11.11)	-22% (-55%, 17%)	No
Amoxicillin-Clavulanate	*Klebsiella pneumoniae*	68	31 (45.59)	31	6 (8.82)	-37% (-49%, -22%)	**Yes**

Abx	Organism Name	Total On Scale for Trending	>= 1 Dilution Lower # (%)	Exact #	>= 1 Dilution Higher # (%)	Percent Difference (95% CI)	Significant Trending Noted
Amoxicillin-Clavulanate	*Proteus mirabilis*	1	0 (0)	0	1 (100)	100% (-12%, 100%)	Yes *
Amoxicillin-Clavulanate	*Proteus vulgaris*	21	3 (14.29)	9	9 (42.86)	29% (1%, 51%)	No
Ampicillin	*Escherichia coli*	64	60 (93.75)	2	2 (3.12)	-91% (-95%, -79%)	**Yes**
Ampicillin	*Proteus mirabilis*	4	3 (75)	0	1 (25)	-50% (-79%, 14%)	**Yes**
Ampicillin-Sulbactam	*Acinetobacter baumannii*	26	9 (34.62)	10	7 (26.92)	-8% (-31%, 17%)	No
Ampicillin-Sulbactam	*Citrobacter koseri*	20	4 (20)	13	3 (15)	-5% (-29%, 19%)	No
Ampicillin-Sulbactam	*Escherichia coli*	152	19 (12.5)	88	45 (29.61)	17% (8%, 26%)	No
Ampicillin-Sulbactam	*Klebsiella pneumoniae*	112	34 (30.36)	60	18 (16.07)	-14% (-25%, -3%)	No
Ampicillin-Sulbactam	*Proteus mirabilis*	22	0 (0)	16	6 (27.27)	27% (7%, 48%)	No
Cefazolin	*Escherichia coli*	121	68 (56.2)	30	23 (19.01)	-37% (-48%, -25%)	**Yes**
Cefazolin	*Klebsiella pneumoniae*	86	50 (58.14)	34	2 (2.33)	-56% (-66%, -44%)	**Yes**
Cefepime	*Citrobacter freundii* complex	4	4 (100)	0	0 (0)	-100% (-100%, -31%)	**Yes**
Cefepime	*Enterobacter* cloacae complex	7	0 (0)	2	5 (71.43)	71% (21%, 92%)	**Yes**
Cefepime	*Escherichia coli*	31	5 (16.13)	4	22 (70.97)	55% (31%, 71%)	**Yes**
Cefepime	*Klebsiella oxytoca*	2	2 (100)	0	0 (0)	-100% (-100%, -7%)	**Yes**
Cefepime	*Klebsiella pneumoniae*	19	3 (15.79)	5	11 (57.89)	42% (11%, 64%)	**Yes**
Cefepime	*Morganella morganii*	1	1 (100)	0	0 (0)	-100% (-100%, 12%)	Yes *
Cefepime	*Proteus vulgaris*	1	1 (100)	0	0 (0)	-100% (-100%, 12%)	Yes *
Cefepime	*Pseudomonas aeruginosa*	43	19 (44.19)	20	4 (9.3)	-35% (-51%, -16%)	**Yes**
Ceftazidime	*Escherichia coli*	108	10, (9.26)	23	75, (69.44)	60% (49%, 69%)	**Yes**
Ceftazidime	*Klebsiella pneumoniae*	60	7, (11.67)	9	44, (73.33)	62% (45%, 73%)	**Yes**
Ceftazidime	*Pseudomonas aeruginosa*	40	14, (35)	24	2, (5)	-30% (-46%, -13%)	**Yes**
Ceftazidime-Avibactam	*Citrobacter freundii* complex	20	4, (20)	4	12, (60)	40% (10%, 62%)	**Yes**
Ceftazidime-Avibactam	*Citrobacter koseri*	20	0, (0)	1	19, (95)	95% (70%, 99%)	**Yes**
Ceftazidime-Avibactam	*Enterobacter cloacae* complex	33	6, (18.18)	13	14, (42.42)	24% (2%, 44%)	No

Abx	Organism Name	Total On Scale for Trending	>= 1 Dilution Lower # (%)	Exact #	>= 1 Dilution Higher # (%)	Percent Difference (95% CI)	Significant Trending Noted
Ceftazidime-Avibactam	*Escherichia coli*	79	2, (2.53)	12	65, (82.28)	80% (68%, 87%)	**Yes**
Ceftazidime-Avibactam	*Klebsiella aerogenes*	17	1, (5.88)	2	14, (82.35)	76% (45%, 89%)	**Yes**
Ceftazidime-Avibactam	*Klebsiella oxytoca*	21	2, (9.52)	1	18, (85.71)	76% (48%, 88%)	**Yes**
Ceftazidime-Avibactam	*Klebsiella pneumoniae*	77	5, (6.49)	20	52, (67.53)	61% (47%, 71%)	**Yes**
Ceftazidime-Avibactam	*Morganella morganii*	21	1, (4.76)	2	18, (85.71)	81% (54%, 91%)	**Yes**
Ceftazidime-Avibactam	*Proteus mirabilis*	22	0, (0)	0	22, (100)	100% (79%, 100%)	**Yes**
Ceftazidime-Avibactam	*Proteus vulgaris*	22	0, (0)	1	21, (95.45)	95% (73%, 99%)	**Yes**
Ceftazidime-Avibactam	*Pseudomonas aeruginosa*	40	9, (22.5)	29	2, (5)	-18% (-33%, -2%)	No
Ceftazidime-Avibactam	*Serratia marcescens*	23	5 (21.74)	10	8 (34.78)	13% (-13%, 37%)	No
Ceftriaxone	*Citrobacter freundii* complex	19	4 (21.05)	0	15 (78.95)	58% (26%, 76%)	**Yes**
Ceftriaxone	*Citrobacter koseri*	20	0 (0)	1	19 (95)	95% (70%, 99%)	**Yes**
Ceftriaxone	*Enterobacter cloacae* complex	29	10 (34.48)	1	18 (62.07)	28% (2%, 49%)	No
Ceftriaxone	*Escherichia coli*	9	5 (55.56)	1	3 (33.33)	-22% (-55%, 20%)	No
Ceftriaxone	*Klebsiella aerogenes*	18	0 (0)	1	17 (94.44)	94% (68%, 99%)	**Yes**
Ceftriaxone	*Klebsiella oxytoca*	21	2 (9.52)	1	18 (85.71)	76% (48%, 88%)	**Yes**
Ceftriaxone	*Klebsiella pneumoniae*	88	40 (45.45)	1	47 (53.41)	8% (-7%, 22%)	No
Ceftriaxone	*Proteus mirabilis*	22	0 (0)	0	22 (100)	100% (79%, 100%)	**Yes**
Ceftriaxone	*Serratia marcescens*	23	1 (4.35)	5	17 (73.91)	70% (43%, 84%)	**Yes**
Ciprofloxacin	*Citrobacter freundii* complex	18	0 (0)	2	16 (88.89)	89% (61%, 97%)	**Yes**
Ciprofloxacin	*Citrobacter koseri*	19	0 (0)	0	19 (100)	100% (76%, 100%)	**Yes**
Ciprofloxacin	*Enterobacter cloacae* complex	32	1 (3.12)	3	28 (87.5)	84% (64%, 92%)	**Yes**
Ciprofloxacin	*Escherichia coli*	86	61 (70.93)	10	15 (17.44)	-53% (-64%, -40%)	**Yes**
Ciprofloxacin	*Klebsiella aerogenes*	6	0 (0)	1	5 (83.33)	83% (28%, 97%)	**Yes**
Ciprofloxacin	*Klebsiella oxytoca*	8	0 (0)	4	4 (50)	50% (7%, 78%)	**Yes**
Ciprofloxacin	*Klebsiella pneumoniae*	25	8 (32)	11	6 (24)	-8% (-31%, 16%)	No
Ciprofloxacin	*Morganella morganii*	7	0 (0)	3	4 (57.14)	57% (9%, 84%)	**Yes**
Ciprofloxacin	*Proteus mirabilis*	21	2 (9.52)	2	17 (80.95)	71% (43%, 85%)	**Yes**

Abx	Organism Name	Total On Scale for Trending	>= 1 Dilution Lower # (%)	Exact #	>= 1 Dilution Higher # (%)	Percent Difference (95% CI)	Significant Trending Noted
Ciprofloxacin	*Proteus vulgaris*	20	1 (5)	1	18 (90)	85% (58%, 93%)	**Yes**
Ciprofloxacin	*Pseudomonas aeruginosa*	41	15 (36.59)	21	5 (12.2)	-24% (-41%, -6%)	No
Ciprofloxacin	*Serratia marcescens*	23	2 (8.7)	11	10 (43.48)	35% (9%, 55%)	**Yes**
Ertapenem	*Citrobacter freundii* complex	19	1 (5.26)	3	15 (78.95)	74% (44%, 87%)	**Yes**
Ertapenem	*Citrobacter koseri*	19	0 (0)	0	19 (100)	100% (76%, 100%)	**Yes**
Ertapenem	*Enterobacter cloacae* complex	32	3 (9.38)	8	21 (65.62)	56% (33%, 72%)	**Yes**
Ertapenem	*Escherichia coli*	19	5 (26.32)	6	8 (42.11)	16% (-14%, 42%)	No
Ertapenem	*Klebsiella aerogenes*	16	6 (37.5)	5	5 (31.25)	-6% (-36%, 25%)	No
Ertapenem	*Klebsiella oxytoca*	8	0 (0)	0	8 (100)	100% (54%, 100%)	**Yes**
Ertapenem	*Klebsiella pneumoniae*	52	21 (40.38)	4	27 (51.92)	12% (-7%, 29%)	No
Ertapenem	*Morganella morganii*	5	2 (40)	1	2 (40)	0% (-46%, 46%)	No
Ertapenem	*Proteus mirabilis*	19	0 (0)	0	19 (100)	100% (76%, 100%)	**Yes**
Ertapenem	*Proteus vulgaris*	22	0 (0)	1	21 (95.45)	95% (73%, 99%)	**Yes**
Ertapenem	*Serratia marcescens*	17	0 (0)	2	15 (88.24)	88% (59%, 97%)	**Yes**
Gentamicin	*Enterobacter cloacae* complex	3	2 (66.67)	0	1 (33.33)	-33% (-72%, 32%)	**Yes**
Gentamicin	*Escherichia coli*	37	2 (67.57)	10	2 (5.41)	-62% (-76%, -42%)	**Yes**
Gentamicin	*Klebsiella oxytoca*	1	1 (100)	0	0 (0)	-100% (-100%, 12%)	Yes *
Gentamicin	*Klebsiella pneumoniae*	27	13 (48.15)	11	3 (11.11)	-37% (-56%, -13%)	**Yes**
Gentamicin	*Morganella morganii*	1	0 (0)	1	0 (0)	0% (-79%, 79%)	No
Gentamicin	*Proteus mirabilis*	3	0 (0)	0	3 (100)	100% (21%, 100%)	**Yes**
Gentamicin	*Proteus vulgaris*	1	0 (0)	0	1 (100)	100% (-12%, 100%)	Yes *
Gentamicin	*Pseudomonas aeruginosa*	42	18 (42.86)	16	8 (19.05)	-24% (-41%, -4%)	No
Gentamicin	*Serratia marcescens*	1	1 (100)	0	0 (0)	-100% (-100%, 12%)	Yes *
Imipenem	*Acinetobacter baumannii*	2	0, (0)	1	1, (50)	50% (-27%, 91%)	Yes *
Imipenem	*Escherichia coli*	2	0, (0)	0	2, (100)	100% (7%, 100%)	Yes *
Imipenem	*Klebsiella pneumoniae*	15	2, (13.33)	2	11, (73.33)	60% (25%, 78%)	**Yes**

Abx	Organism Name	Total On Scale for Trending	>= 1 Dilution Lower # (%)	Exact #	>= 1 Dilution Higher # (%)	Percent Difference (95% CI)	Significant Trending Noted
Meropenem	*Acinetobacter baumannii*	28	15, (53.57)	5	8, (28.57)	-25% (-47%, 1%)	No
Meropenem	*Citrobacter freundii* complex	20	0, (0)	0	20, (100)	100% (77%, 100%)	**Yes**
Meropenem	*Citrobacter koseri*	20	0, (0)	1	19, (95)	95% (70%, 99%)	**Yes**
Meropenem	*Enterobacter cloacae* complex	32	1, (3.12)	2	29, (90.62)	88% (68%, 94%)	**Yes**
Meropenem	*Escherichia coli*	3	1, (33.33)	0	2, (66.67)	33% (-32%, 72%)	Yes *
Meropenem	*Klebsiella oxytoca*	21	0, (0)	0	21, (100)	100% (78%, 100%)	**Yes**
Meropenem	*Klebsiella pneumoniae*	82	3, (3.66)	5	74, (90.24)	87% (76%, 92%)	**Yes**
Meropenem	*Morganella morganii*	12	1, (8.33)	1	10, (83.33)	75% (36%, 89%)	**Yes**
Meropenem	*Proteus mirabilis*	17	0, (0)	0	17, (100)	100% (74%, 100%)	**Yes**
Meropenem	*Proteus vulgaris*	10	0, (0)	0	10, (100)	100% (61%, 100%)	**Yes**
Meropenem	*Pseudomonas aeruginosa*	43	12, (27.91)	13	18, (41.86)	14% , (-6%, 32%)	No
Meropenem	*Serratia marcescens*	15	0, (0)	0	15, (100)	100% (71%, 100%)	**Yes**
Minocycline	*Acinetobacter baumannii*	33	4 (12.12)	14	15 (45.45)	33% (12%, 51%)	**Yes**
Minocycline	*Escherichia coli*	128	25 (19.53)	66	37 (28.91)	9% (-1%, 20%)	No
Minocycline	*Klebsiella pneumoniae*	81	20 (24.69)	35	2 (32.1)	7% (-6%, 21%)	No
Piperacillin-Tazobactam	*Acinetobacter baumannii*	4	1 (25)	0	3 (75)	50% (-14%, 79%)	**Yes**
Piperacillin-Tazobactam	*Citrobacter koseri*	2	2 (100)	0	0 (0)	-100% (-100%, -7%)	**Yes**
Piperacillin-Tazobactam	*Escherichia coli*	32	21 (65.62)	4	7 (21.88)	-44% (-61%, -20%)	**Yes**
Piperacillin-Tazobactam	*Klebsiella pneumoniae*	27	7 (25.93)	6	14 (51.85)	26% (0%, 48%)	No
Piperacillin-Tazobactam	*Morganella morganii*	2	1 (50)	0	1 (50)	0% (-57%, 57%)	No
Piperacillin-Tazobactam	*Pseudomonas aeruginosa*	34	13 (38.24)	15	6 (17.65)	-21% (-40%, 1%)	No
Piperacillin-Tazobactam	*Serratia marcescens*	5	3 (60)	1	1 (20)	-40% (-73%, 16%)	**Yes**
Tobramycin	*Escherichia coli*	126	41 (32.54)	60	25 (19.84)	-13% (-23%, -2%)	No
Tobramycin	*Klebsiella pneumoniae*	90	27 (30)	44	19 (21.11)	-9% (-21%, 4%)	No
Tobramycin	*Pseudomonas aeruginosa*	43	17 (39.53)	20	6 (13.95)	-26% (-42%, -7%)	No

** Although trending was observed, insufficient isolates are included to appropriately evaluate trending*

Analysis of trending indicated that PBC Separator with Selux AST System MIC values for certain antimicrobial/organism combinations tended to be at least one doubling dilution lower than the reference MIC value. The following statement is included as a footnote to the AST performance table:

> PBC Separator with Selux AST System MIC values for the following antimicrobial/organism combinations tended to be at least one doubling dilution lower than the reference MIC value:
> - Amikacin: *Acinetobacter baumannii, Escherichia coli, Klebsiella pneumoniae*
> - Amoxicillin-Clavulanate: *Klebsiella pneumoniae*
> - Ampicillin: *Escherichia coli, Proteus mirabilis*
> - Cefazolin: *Escherichia coli, Klebsiella pneumoniae*
> - Cefepime: *Citrobacter freundii* complex*, Klebsiella oxytoca, Pseudomonas aeruginosa*
> - Ceftazidime: *Pseudomonas aeruginosa*
> - Ceftriaxone: *Citrobacter freundii* complex, *Citrobacter koseri, Klebsiella aerogenes, Klebsiella oxytoca, Proteus mirabilis, Serratia marcescens*
> - Ciprofloxacin: *Escherichia coli*
> - Gentamicin: *Enterobacter cloacae* complex, *Escherichia coli, Klebsiella pneumoniae, Serratia marcescens*
> - Piperacillin-tazobactam: *Acinetobacter baumannii* complex, *Citrobacter koseri, Escherichia coli, Serratia marcescens*

Analysis of trending indicated that PBC Separator with Selux AST System MIC values for certain antimicrobial/organism combinations tended to be at least one doubling dilution higher than the reference MIC value. The following statement is included as a footnote to the AST performance table:

> PBC Separator with Selux AST System MIC values for the following antimicrobial/organism combinations tended to be at least one doubling dilution higher than the reference MIC value:
> - Cefepime: *Enterobacter cloacae* complex*, Escherichia coli, Klebsiella pneumoniae*
> - Ceftazidime: *Escherichia coli, Klebsiella pneumoniae*
> - Ceftazidime-Avibactam: *Citrobacter freundii* complex, *Citrobacter koseri, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris*
> - Ciprofloxacin: *Citrobacter freundii* complex, *Citrobacter koseri, Enterobacter cloacae* complex, *Klebsiella aerogenes, Klebsiella oxytoca, Morganella morganii, Proteus mirabilis, Serratia marcescens*
> - Ertapenem: *Citrobacter freundii* complex, *Citrobacter koseri, Enterobacter cloacae* complex, *Klebsiella oxytoca, Proteus mirabilis, Serratia marcescens*
> - Gentamicin: *Proteus mirabilis*
> - Imipenem: *Klebsiella pneumoniae*
> - Meropenem: *Citrobacter freundii* complex, *Citrobacter koseri, Enterobacter cloacae* complex, *Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*
> - Minocycline: *Acinetobacter baumannii* complex

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 interpretive criteria for the antimicrobials evaluated with the PBC Separator with Selux AST System are listed in **Table 10** below.

Table 10. FDA-Approved or Recognized Interpretive Criteria[1]

Antimicrobial	Indicated Organism Group	Minimum Inhibitory Concentration (µg/mL)		
		S	I	R
Amikacin	*Acinetobacter baumannii* complex	≤16	32	≥64
	Enterobacterales	≤16	32	≥64
	Pseudomonas aeruginosa	≤16	32	≥64
Amoxicillin-Clavulanate	Enterobacterales	≤8	16	≥32
Ampicillin	Enterobacterales	≤8	16	≥32
Ampicillin-Sulbactam	*Acinetobacter baumannii* complex	≤8	16	≥32
	Enterobacterales	≤8	16	≥32
Cefazolin	Enterobacterales	≤2	4	≥8
Cefepime	Enterobacterales	≤2	4-8	≥16
	Pseudomonas aeruginosa	≤8	-	≥16
Ceftazidime	Enterobacterales	≤4	8	≥16
	Pseudomonas aeruginosa	≤8	-	≥16
Ceftazidime-Avibactam	Enterobacterales	≤8	-	≥16
	Pseudomonas aeruginosa	≤8	-	≥16
Ceftriaxone	Enterobacterales	≤1	2	≥4
Ciprofloxacin	Enterobacterales	≤0.25	0.5	≥1
	Pseudomonas aeruginosa	≤0.5	1	≥2
Ertapenem	Enterobacterales	≤0.5	1	≥2

Antimicrobial	Indicated Organism Group	Minimum Inhibitory Concentration (µg/mL)		
		S	I	R
Gentamicin	Enterobacterales	≤4	8	≥16
	Pseudomonas aeruginosa	≤4	8	≥16
Imipenem	*Acinetobacter baumannii* complex	≤2	4	≥8
	Enterobacterales	≤1	2	≥4
Meropenem	*Acinetobacter baumannii* complex	≤2	4	≥8
	Enterobacterales	≤1	2	≥4
	Pseudomonas aeruginosa	≤2	4	≥8
Minocycline	*Acinetobacter baumannii* complex	≤4	8	≥16
	Enterobacterales	≤4	8	≥16
Piperacillin-Tazobactam	*Acinetobacter baumannii* complex	≤16	32-64	≥128
	Enterobacterales	≤8	16	≥32
	Pseudomonas aeruginosa	≤16	32-64	≥128
Tobramycin	Enterobacterales	≤4	8	≥16
	Pseudomonas aeruginosa	≤4	8	≥16

S = Susceptible; I = Intermediate; R = Resistant; - = no interpretive criterion recognized
[1] FDA-Recognized Antimicrobial Susceptibility Test Interpretive Criteria Website: https://www.fda.gov/drugs/development-resources/fda-recognized-antimicrobial-susceptibility-test-interpretive-criteria

F Other Supportive Instrument Performance Characteristics Data:

Blood bottle compatibility

Eleven different blood culture bottle types from two different blood culture systems (**Table 11**) were evaluated with the PBC Separator with Selux AST System to determine if bottle type influenced AST results. Blood culture bottles were seeded with at least one isolate from each reporting group at clinically relevant concentrations, incubated to positivity, and processed with the PBC Separator and Selux AST System with all indicated antimicrobials. Anaerobic blood bottles were tested only using Enterobacterales.

Table 11. Blood culture bottles and systems used in the blood bottle compatibility study

Continuous Monitoring System	Blood Culture Bottle	Fill Volume
BD BACTEC	Plus Aerobic medium	8 – 10 mL
	Plus Anaerobic medium	8 – 10 mL
	Standard Aerobic medium	8 – 10 mL
	Standard Anaerobic medium	5 – 7 mL
	Lytic Anaerobic medium	8 – 10 mL
	Peds Plus medium	1 – 3 mL
bioMérieux BACT/ALERT VIRTUO	FA Plus (resin aerobic)	8 – 10 mL
	FN Plus (resin anaerobic)	8 – 10 mL
	SA (standard aerobic)	8 – 10 mL
	SN (standard anaerobic)	8 – 10 mL
	PF Plus (pediatric resin aerobic)	8 – 10 mL

MIC results from the Selux AST System were compared to modal BMD reference results, with an EA ≥90% being deemed acceptable. All drug-organism combinations demonstrated EA ≥90% for each blood bottle type (**Tables 12-14**) with the following exceptions:

- bioMérieux BacT/ALERT SA (standard aerobic): Ciprofloxacin-Enterobacterales – demonstrated an EA of 89.3% (25/28). The out-of-agreement results were due to two minor errors for *E. coli* and one very major error for *K. pneumoniae* tested at 0.25 µg/mL. The clinical data included 2,667 MIC results from this bottle type (including 826 MIC results from *K. pneumoniae* and 698 MIC results from *E. coli*) with acceptable performance. Given the totality of data, overall performance is considered acceptable.
- BD BACTEC Peds Plus: Amikacin-*A. baumannii* complex – demonstrated an EA of 50.0% (1/2) due to one result being out of EA. The overall EA was acceptable for Amikacin with BD BACTEC Peds Plus. Based on the totality of data, the performance is acceptable.
- BD BACTEC Peds Plus: Minocycline-*A. baumannii* complex – demonstrated an EA of 0.0% (0/2), yielding a combined EA of 83.3% (10/12). The out-of-agreement results were within categorical agreement (Selux MIC of 4 µg/mL and reference result of 1 µg/mL) and therefore should not impact clinical decisions or patient care. The results are deemed acceptable.
- BD BACTEC Plus Aerobic: Minocycline-*A. baumannii* complex – demonstrated an EA of 66.7% (2/3). The out-of-agreement results were within categorical agreement (Selux MIC of 4 µg/mL and reference result of 1 µg/mL) and therefore should not impact clinical decisions or patient care. The results are deemed acceptable.
- bioMérieux BacT/ALERT FA Plus: Minocycline-*A. baumannii* complex – demonstrated an EA of 66.7% (2/3). The out-of-agreement results were within categorical agreement (Selux MIC of 4 µg/mL and reference result of 1 µg/mL) and therefore should not impact clinical decisions or patient care. The results are deemed acceptable.
- bioMérieux BacT/ALERT PF Plus: Minocycline-*A. baumannii* complex – demonstrated an EA of 66.7% (2/3). The out-of-agreement results were within categorical agreement (Selux MIC of 4 µg/mL and reference result of 1 µg/mL) and therefore should not impact clinical decisions or patient care. The results are deemed acceptable.
- BD BACTEC Lytic Anaerobic medium: Ciprofloxacin-Enterobacterales – demonstrated an EA of 85.7% (12/14). The out-of-agreement results were two very major errors from testing of *M. morganii*. The following limitation is suggested:
    - *The PBC Separator with Selux AST System cannot be used with BD Lytic Anaerobic bottles for M. morganii-ciprofloxacin.*

Table 12. PBC Separator with Selux AST System performance with bioMérieux aerobic bottles

Antimicrobial	Indicated Organism(s)	bioMérieux BacT/ALERT SA		bioMérieux BacT/ALERT FA Plus		bioMérieux BacT/ALERT PF Plus	
		# EA / Total	% EA	# EA / Total	% EA	# EA / Total	% EA
Amikacin	*A. baumannii* complex	9/9	100.0%	3/3	100.0%	3/3	100.0%
	Enterobacterales	28/28	100.0%	9/9	100.0%	8/8	100.0%
	P. aeruginosa	6/6	100.0%	3/3	100.0%	3/3	100.0%
	Combined	43/43	100.0%	15/15	100.0%	14/14	100.0%
Amoxicillin-Clavulanate	Enterobacterales	28/28	100.0%	9/9	100.0%	8/8	100.0%
Ampicillin	Enterobacterales	22/22	100.0%	7/7	100.0%	6/6	100.0%
Ampicillin-Sulbactam	*A. baumannii* complex	9/9	100.0%	3/3	100.0%	3/3	100.0%

Antimicrobial	Indicated Organism(s)	bioMérieux BacT/ALERT SA		bioMérieux BacT/ALERT FA Plus		bioMérieux BacT/ALERT PF Plus	
		# EA / Total	% EA	# EA / Total	% EA	# EA / Total	% EA
	Enterobacterales	28/28	100.0%	9/9	100.0%	8/8	100.0%
	Combined	37/37	100.0%	12/12	100.0%	11/11	100.0%
Cefazolin	Enterobacterales	28/28	100.0%	9/9	100.0%	8/8	100.0%
Cefepime	Enterobacterales	28/28	100.0%	9/9	100.0%	8/8	100.0%
	P. aeruginosa	6/6	100.0%	3/3	100.0%	3/3	100.0%
	Combined	34/34	100.0%	12/12	100.0%	11/11	100.0%
Ceftazidime	Enterobacterales	28/28	100.0%	9/9	100.0%	8/8	100.0%
	P. aeruginosa	3/3	100.0%	2/2	100.0%	3/3	100.0%
	Combined	31/31	100.0%	11/11	100.0%	11/11	100.0%
Ceftazidime-Avibactam	Enterobacterales	28/28	100.0%	9/9	100.0%	8/8	100.0%
	P. aeruginosa	6/6	100.0%	3/3	100.0%	3/3	100.0%
	Combined	34/34	100.0%	12/12	100.0%	11/11	100.0%
Ceftriaxone	Enterobacterales	28/28	100.0%	9/9	100.0%	8/8	100.0%
Ciprofloxacin	Enterobacterales [1]	25/28	89.3%	9/9	100.0%	8/8	100.0%
	P. aeruginosa	6/6	100.0%	3/3	100.0%	3/3	100.0%
	Combined	31/34	91.2%	12/12	100.0%	11/11	100.0%
Ertapenem	Enterobacterales	28/28	100.0%	9/9	100.0%	8/8	100.0%
Gentamicin	Enterobacterales	28/28	100.0%	9/9	100.0%	8/8	100.0%
	P. aeruginosa	6/6	100.0%	3/3	100.0%	3/3	100.0%
	Combined	34/34	100.0%	12/12	100.0%	11/11	100.0%
Imipenem	*A. baumannii* complex	9/9	100.0%	3/3	100.0%	3/3	100.0%
	Enterobacterales	28/28	100.0%	9/9	100.0%	8/8	100.0%
	Combined	37/37	100.0%	12/12	100.0%	11/11	100.0%
Meropenem	*A. baumannii* complex	9/9	100.0%	3/3	100.0%	3/3	100.0%
	Enterobacterales	28/28	100.0%	9/9	100.0%	8/8	100.0%
	P. aeruginosa	6/6	100.0%	3/3	100.0%	3/3	100.0%
	Combined	43/43	100.0%	15/15	100.0%	14/14	100.0%
Minocycline	*A. baumannii* complex	9/9	100.0%	2/3	66.7%	2/3	66.7%
	Enterobacterales	28/28	100.0%	9/9	100.0%	8/8	100.0%
	Combined	37/37		11/12	91.7%	10/11	90.9%
Piperacillin-Tazobactam	*A. baumannii* complex	9/9	100.0%	3/3	100.0%	3/3	100.0%
	Enterobacterales	26/28	92.9%	9/9	100.0%	8/8	100.0%
	P. aeruginosa	6/6	100.0%	3/3	100.0%	3/3	100.0%
	Combined	41/43	95.3%	15/15	100.0%	14/14	100.0%
Tobramycin	Enterobacterales	28/28	100.0%	9/9	100.0%	8/8	100.0%
	P. aeruginosa	6/6	100.0%	3/3	100.0%	3/3	100.0%
	Combined	34/34	100.0%	12/12	100.0%	11/11	100.0%

[1] Ciprofloxacin tested with Enterobacterales derived from bioMérieux BacT/ALERT SA bottles demonstrated an EA <90%. The data were deemed acceptable based on the totality of data.

Table 13. PBC Separator with Selux AST System performance with BD BACTEC aerobic bottles

Antimicrobial	Indicated Organism(s)	BD BACTEC Standard Aerobic		BD BACTEC Plus Aerobic		BD BACTEC Peds Plus	
		# EA / Total	% EA	# EA / Total	% EA	# EA / Total	% EA
Amikacin	*A. baumannii* complex [1]	8/8	100.0%	3/3	100.0%	1/2	50.0%
	Enterobacterales	11/11	100.0%	10/10	100.0%	10/10	100.0%
	P. aeruginosa	6/6	100.0%	2/2	100.0%	3/3	100.0%
	Combined	25/25	100.0%	15/15	100.0%	14/15	93.3%
Amoxicillin-Clavulanate	Enterobacterales	11/11	100.0%	10/10	100.0%	10/10	100.0%
Ampicillin	Enterobacterales	5/5	100.0%	8/8	100.0%	8/8	100.0%
Ampicillin-Sulbactam	*A. baumannii* complex	8/8	100.0%	3/3	100.0%	2/2	100.0%
	Enterobacterales	11/11	100.0%	10/10	100.0%	10/10	100.0%
	Combined	19/19	100.0%	13/13	100.0%	12/12	100.0%
Cefazolin	Enterobacterales	11/11	100.0%	10/10	100.0%	10/10	100.0%
Cefepime	Enterobacterales	11/11	100.0%	10/10	100.0%	10/10	100.0%
	P. aeruginosa	6/6	100.0%	2/2	100.0%	3/3	100.0%
	Combined	17/17	100.0%	12/12	100.0%	13/13	100.0%
Ceftazidime	Enterobacterales	11/11	100.0%	10/10	100.0%	10/10	100.0%
	P. aeruginosa	5/5	100.0%	1/1	100.0%	2/2	100.0%
	Combined	16/16	100.0%	11/11	100.0%	12/12	100.0%
Ceftazidime-Avibactam	Enterobacterales	11/11	100.0%	10/10	100.0%	10/10	100.0%
	P. aeruginosa	6/6	100.0%	2/2	100.0%	3/3	100.0%
	Combined	17/17	100.0%	12/12	100.0%	13/13	100.0%
Ceftriaxone	Enterobacterales	11/11	100.0%	10/10	100.0%	10/10	100.0%
Ciprofloxacin	Enterobacterales	11/11	100.0%	10/10	100.0%	10/10	100.0%
	P. aeruginosa	6/6	100.0%	3/3	100.0%	3/3	100.0%
	Combined	17/17	100.0%	13/13	100.0%	13/13	100.0%
Ertapenem	Enterobacterales	11/11	100.0%	10/10	100.0%	10/10	100.0%
Gentamicin	Enterobacterales	11/11	100.0%	10/10	100.0%	10/10	100.0%
	P. aeruginosa	6/6	100.0%	3/3	100.0%	3/3	100.0%
	Combined	17/17	100.0%	13/13	100.0%	13/13	100.0%
Imipenem	*A. baumannii* complex	8/8	100.0%	3/3	100.0%	2/2	100.0%
	Enterobacterales	11/11	100.0%	10/10	100.0%	10/10	100.0%
	Combined	19/19	100.0%	13/13	100.0%	12/12	100.0%
Meropenem	*A. baumannii* complex	8/8	100.0%	3/3	100.0%	2/2	100.0%
	Enterobacterales	11/11	100.0%	10/10	100.0%	10/10	100.0%
	P. aeruginosa	6/6	100.0%	2/2	100.0%	3/3	100.0%
	Combined	25/25	100.0%	15/15	100.0%	15/15	100.0%
Minocycline	*A. baumannii* complex	8/8	100.0%	3/3	66.7%	0/2	0.0%
	Enterobacterales	11/11	100.0%	10/10	100.0%	10/10	100.0%
	Combined	19/19	100.0%	2/2	100.0%	10/12	83.3%
Piperacillin-Tazobactam	*A. baumannii* complex	8/8	100.0%	3/3	100.0%	2/2	100.0%
	Enterobacterales	11/11	100.0%	10/10	100.0%	10/10	100.0%
	P. aeruginosa	6/6	100.0%	2/2	100.0%	3/3	100.0%
	Combined	25/25	100.0%	15/15	100.0%	15/15	100.0%
Tobramycin	Enterobacterales	11/11	100.0%	10/10	100.0%	10/10	100.0%
	P. aeruginosa	6/6	100.0%	2/2	100.0%	3/3	100.0%
	Combined	17/17	100.0%	12/12	100.0%	13/13	100.0%

[1] Amikacin tested with *A. baumannii* derived from BD BACTEC Peds Plus bottles demonstrated an EA <90%. The data were deemed acceptable based on the totality of data.

Table 14. PBC Separator with Selux AST System performance with anaerobic blood bottles

Drug	Organism Group	BD BACTEC Standard Anaerobic		BD BACTEC Plus Anaerobic		BD BACTEC Lytic Anaerobic		bioMerieux BacT/ALERT SN		bioMerieux BacT/ALERT FN Plus	
		#EA / Tot	%EA	#EA / Tot	%EA	#EA / Tot	%EA	#EA / Tot	%EA	#EA / Tot	%EA
Amikacin	Enterobacterales	13/13	100.00%	9/9	100.00%	10/10	100.00%	6/6	100.00%	9/9	100.00%
Amoxicillin-clavulanate	Enterobacterales	15/15	100.00%	11/11	100.00%	12/12	100.00%	8/8	100.00%	11/11	100.00%
Ampcillin	Enterobacterales	13/13	100.00%	9/9	100.00%	10/10	100.00%	6/6	100.00%	9/9	100.00%
Ampicillin-sulbactam	Enterobacterales	17/17	100.00%	13/13	100.00%	13/14	92.90%	10/10	100.00%	13/13	100.00%
Cefazolin	Enterobacterales	13/13	100.00%	9/9	100.00%	10/10	100.00%	6/6	100.00%	9/9	100.00%
Cefepime	Enterobacterales	17/17	100.00%	13/13	100.00%	14/14	100.00%	10/10	100.00%	13/13	100.00%
Ceftazidime	Enterobacterales	13/13	100.00%	9/9	100.00%	10/10	100.00%	6/6	100.00%	9/9	100.00%
Ceftazidime-avibactam	Enterobacterales	17/17	100.00%	13/13	100.00%	14/14	100.00%	10/10	100.00%	13/13	100.00%
Ceftriaxone	Enterobacterales	15/15	100.00%	11/11	100.00%	12/12	100.00%	8/8	100.00%	11/11	100.00%
Ciprofloxacin [1]	Enterobacterales	17/17	100.00%	13/13	100.0%	12/14	85.7%	10/10	100.00%	12/13	92.30%
Ertapenem	Enterobacterales	17/17	100.00%	13/31	100.00%	14/14	100.00%	10/10	100.00%	13/31	100.00%
Gentamicin	Enterobacterales	17/17	100.00%	13/13	100.00%	14/14	100.00%	10/10	100.00%	13/13	100.00%
Imipenem	Enterobacterales	13/13	100.00%	9/9	100.00%	10/10	100.00%	6/6	100.00%	9/9	100.00%
Meropenem	Enterobacterales	17/17	100.00%	13/13	100.00%	14/14	100.00%	10/10	100.00%	13/13	100.00%
Minocycline	Enterobacterales	13/13	100.00%	9/9	100.00%	10/10	100.00%	6/6	100.00%	9/9	100.00%
Piperacillin-tazobactam	Enterobacterales	17/17	100.00%	13/13	100.00%	14/14	100.00%	10/10	100.00%	13/13	100.00%
Tobramycin	Enterobacterales	13/13	100.00%	9/9	100.00%	10/10	100.00%	6/6	100.00%	9/9	100.00%

[1] The PBC Separator with Selux AST System cannot be used with BD Lytic Anaerobic bottles for *M. morganii*-ciprofloxacin

Polymicrobial testing

A study demonstrating that AST suspensions prepared by the PBC Separator from polymicrobial blood culture do not adversely affect performance of the Selux AST System was not conducted. Instead, the Selux AST System will be restricted to reporting results for samples prepared by the PBC Separator that were determined to be monomicrobial by Gram stain and an FDA-cleared identification method. The Intended Use reflects this, and it was deemed acceptable to include the following labeling limitation in the instructions for use:

> *The PBC Separator with Selux AST System should not be used with any clinical specimens other than monomicrobial positive blood cultures.*

VIII Proposed Labeling:

The labeling supports or 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 incorporated by reference a breakpoint change

protocol that was reviewed and accepted by FDA in submission K211748. 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/DevelopmentApprovalProcess/DevelopmentResources/ucm410971.htm). The protocol outlined the specific procedures and acceptance criteria that Selux intends to use to evaluate the Selux AST System when revised breakpoints for indicated drugs are published on the FDA STIC webpage. The breakpoint change protocol included with the submission indicated that if specific criteria are met, Selux will update the Selux AST System 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.