February 15, 2024

Selux Diagnostics, Inc
℅ Carrene Plummer
Senior Director, Regulatory Affairs
PBO Consulting
2212 East Pratt Street
Baltimore, Maryland 21231

Re: K223493
Trade/Device Name: PBC Separator
Regulation Number: 21 CFR 866.1650
Regulation Name: A Cellular Analysis System For Multiplexed Antimicrobial Susceptibility
Regulatory Class: Class II
Product Code: QZX, LON, LTT, LTW
Dated: January 23, 2024
Received: January 23, 2024

Dear Carrene Plummer:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief, General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K223493

Device Name
PBC Separator with Selux AST System

Indications for Use *(Describe)*
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, Klebsiella 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary for the PBC Separator with Selux AST System

Date prepared: February 15, 2024

Submitter:
Selux Diagnostics, Inc.
56 Roland St
Suite 106
Charlestown, MA 02129
Tel. 617-945-9383

Contact:
Carrene Plummer
Tel. 520-405-1462

Subject Device

Trade Name:	PBC Separator with Selux AST System
Common Name:	Antimicrobial Susceptibility Test System
Regulation Number:	21 CFR 866.1650
Regulation Name:	Positive Blood Culture Processor For Inoculum Preparation Used for Antimicrobial Susceptibility Testing
Regulatory Class:	Class II
Product Code:	QZX, LON, LTT, LTW
Classification Panel:	83 (Microbiology)

Predicate Device

Trade Name:	eQUANT System
Manufacturer:	Avails Medical, Inc.
510(k) Reference:	K231536
Common Name:	eQUANT System
Regulation Number:	21 CFR 866.1650
Regulation Name:	Positive Blood Culture Identification and AST Kit
Regulatory Class:	Class II
Product Code:	QZX, JTN
Classification Panel:	83 (Microbiology)

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 a tuned McFarland-equivalent inoculum from positive blood culture bottles that have rung positive on a continuous monitoring blood culture system. Inoculums containing monomicrobial, gram negative bacteria are used for AST processing with the Selux AST System. The Selux AST System includes a sample prep station (i.e., AST Workbench), an Inoculator, an Analyzer, Workbench Computer, and the reagents and consumables required to perform AST testing. The PBC Separator and all Selux AST System components are connected to a site workstation, which coordinates sample processing on all instruments. The PBC Separator contains embedded software and a graphical user interface that guides users through the

PBC Separator workflow. Once processing of the PBC sample is complete, the user transfers the tuned McFarland inoculum to the Selux AST System for further AST processing.

The PBC Separator with Selux AST System can only provide AST results for monomicrobial samples. Since the PBC Separator with Selux AST System do not perform identification (ID), the monomicrobial nature of the sample under test must be confirmed by an FDA-cleared direct-from-positive blood culture ID system.

While PBC Separator processing can be performed without species-level ID, this information is required for the Selux AST System to interpret and report susceptibility results. Species ID can be performed by any appropriate method and this information can be either manually input to the Selux AST System or automatically downloaded from the laboratory information system (LIS) at any time, once the sample ID is entered into the LIS.

The PBC Separator with the Selux AST System utilizes the Selux Gram Negative Panel, a 384-well panel that provides parallel results for the antimicrobials indicated for each sample type. The Selux AST System software masks non-indicated results. The average time-to-result for positive blood culture processed with the PBC Separator and Selux AST System is under 7 hours.

Principle of Operation

The PBC Separator automatically prepares a tuned bacterial inoculum directly from a blood culture bottle sample that "rang" positive on an FDA-cleared continuous monitoring blood culture system, including the Becton Dickinson BACTEC, the bioMerieux BacT/Alert 3D, and the bioMerieux Virtuo. The PBC Separator removes contaminants through repeated centrifugation-wash cycles and specific chemical lysis of mammalian cells and cell fragments. The PBC Separator utilizes an on-board spectrometer to tune the inoculum for the right cell density to perform AST.

Tuned inoculums are used with the Selux AST System. The Selux AST System performs AST similarly to the reference broth microdilution method by first incubating samples, then quantifying microbial growth in each well of an antimicrobial dilution series after a growth period, and finally determining the minimum inhibitory concentration (MIC) by comparing growth data in each well.

AST testing of PBC samples requires that the Gram type (classification) of the organism be known prior to testing on the Selux AST System as the information is necessary to select the proper AST panel to use. Organism identification (ID) is not needed to initiate testing with the Selux AST System. However, the organism ID is necessary for a result to be interpreted and reported because the MIC-determining algorithm is species-specific as is the interpretative Susceptible, Intermediate, or Resistant (SIR) determination. Any FDA-cleared method may be used to provide an ID including biochemical techniques, matrix-assisted laser desorption/isotherm mass spectrometry, and multiplex genetic assays.

Intended Use and Indications for Use

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

Indications for Use

The PBC Separator with the 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 and the Selux Gram Negative Panel. 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, Klebsiella 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.

Comparison of Technological Characteristics with the Predicate and Reference Devices

The technological characteristics of the PBC Separator are substantially equivalent to the primary predicate device, the eQUANT System (K231536) in terms of intended use, application, user population, basic design, performance, and labeling.

Device & Predicate Devices:	**K223494 Device**	**K231536 Predicate**
Device Trade Name	PBC Separator with Selux AST System	eQUANT System
Device Characteristics		
Indication for Use	The PBC Separator with the 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.	The eQUANT™ System is an automated inoculum preparation system that uses potentiometric sensing of oxidation-reduction 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 direct testing from positive blood culture before processing samples on the eQUANT™ System.

Device & Predicate Devices:	K223494 Device	K231536 Predicate
Source of Microorganisms	bacteria from positive blood cultures	Same
Indicated Antimicrobial/Organism Combinations	**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, Klebsiella 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*	**Amoxicillin/clavulanate**: *Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis* **Ampicillin**: *Escherichia coli* **Aztreonam**: *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens* and *Pseudomonas aeruginosa* **Cefazolin**: *Klebsiella pneumoniae* **Cefepime**: *Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens* and *Pseudomonas aeruginosa* **Ceftriaxone**: *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens* **Ertapenem**: *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens* **Gentamicin**: *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens* and *Pseudomonas aeruginosa* **Levofloxacin**: *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens,* and *Pseudomonas aeruginosa* **Meropenem**: *Acinetobacter spp., Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella*

Device & Predicate Devices:	K223494 Device	K231536 Predicate
	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*	*oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens,* and *Pseudomonas aeruginosa* **Piperacillin/tazobactam**: *Acinetobacter* spp*., Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens,* and *Pseudomonas aeruginosa* **Tobramycin:** *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Serratia marcescens,* and *Pseudomonas aeruginosa*

Device & Predicate Devices:	K223494 Device	K231536 Predicate
Technology	Uses lysis, centrifugation and sequential optical density measurements to generate a McFarland-equivalent suspension.	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.
Output/Results Reported	Liquid suspension of bacteria (McFarland equivalent) suitable for susceptibility testing.	Same
AST	Selux AST System	Kirby-Bauer disc diffusion

Despite the differences between the PBC Separator with Selux AST System and the predicate device, the overall risk and safety of system use is not affected.

Reproducibility

PBC Separator with Selux AST System Intra- and inter-site reproducibility was evaluated by testing a minimum of 5 samples for each of 9 representative antimicrobials at each of three sites (2 external, 1 internal). Each sample comprised an isolate that was seeded at approximately 10-10,000 CFU into a blood culture bottle with approximately 10 mL of fresh human blood from a healthy donor and then loaded into an FDA-cleared continuous monitoring blood culture system (BD BACTEC, bioMerieux BacT/ALERT 3D, or bioMerieux BacT/ALERT VIRTUO) until positive growth was detected. The positive blood culture bottle was then removed and processed using the PBC Separator and Selux AST System. Each sample was tested in triplicate using three different inoculums prepared by the PBC Separator on each of three days it was tested at each site. There is thus a minimum of $3 \times 3 = 9$ results per sample and $9 \times 5 = 45$ results per antimicrobial at a single site. The intra-site reproducibility is given in the following table. In each case, the best- and worst-case intra-site reproducibility was $\geq 95\%$.

Intra-Site Reproducibility			
Antimicrobial	**N**	**Best-Case**	**Worst-Case**
Ampicillin	45	100%	100%
Ampicillin-sulbactam	54	100%	100%
Amoxicillin-clavulanate	45	100%	100%
Cefazolin	45	100%	100%
Ceftazidime-avibactam	45	100%	100%
Ciprofloxacin	54	100%	100%
Gentamicin	54	100%	100%
Meropenem	63	98.4%	98.4%

Intra-Site Reproducibility			
Antimicrobial	**N**	**Best-Case**	**Worst-Case**
Minocycline	54	98.1%	98.1%

For inter-site reproducibility, there are a minimum of 3 × 3 × 3 = 27 results per sample and 27 × 5 = 135 results per antimicrobial. The inter-site reproducibility is given in the following table. In each case, the best- and worst-case intra-site reproducibility was ≥ 95%.

Inter-Site Reproducibility			
Antimicrobial	**N**	**Best-Case**	**Worst-Case**
Ampicillin	135	99.30%	99.30%
Ampicillin-sulbactam	162	100%	100%
Amoxicillin-clavulanate	135	100%	100%
Cefazolin	135	100%	100%
Ceftazidime-avibactam	135	100%	100%
Ciprofloxacin	162	100%	100%
Gentamicin	162	98.5%	98.5%
Meropenem	189	95.8%	95.8%
Minocycline	162	96.3%	96.3%

Other Analytical Studies:

Post-Positivity Sample Stability Study

The amount of time between the registration of positive growth for a sample and the initiation of processing with the PBC Separator was evaluated. Selux AST System MIC results from samples processed with the PBC Separator 16 hours after registering positive growth in a continuous monitoring blood culture system were compared with t = 0 hr control MIC results from samples processed on the PBC Separator immediately after registering positive growth. At least two replicates of one species from each indicated antimicrobial/organism reporting group was tested per drug per timepoint. Every antimicrobial agent at the 16-hour timepoint had essential agreement (EA) > 95%compared with the 0-hour timepoint. The total EA for all results at the 16-hour timepoint compared with the 0-hour timepoint was 99.6% (264/265 results in EA). Positive blood bottles should be processed promptly after ringing positive on a continuous blood culture monitoring system. In the case of unavoidable delays or if the need for sample re-testing arises, bottles must be processed within 16 hours post ring.

Blood Culture Bottle Compatibility Study

Eleven types of blood culture bottles listed below were evaluated with the PBC Separator with Selux AST System.

Bottle Type	Blood Culture System Compatibility
BACTEC Plus Aerobic	BD BACTEC
BACTEC Plus Anaerobic	BD BACTEC
BACTEC Standard Aerobic	BD BACTEC
BACTEC Standard Anaerobic	BD BACTEC
BACTEC Lytic Anaerobic	BD BACTEC
BACTEC Peds Plus	BD BACTEC
BacT/ALERT FA Plus	BacT/ALERT 3D, VIRTUO
BacT/ALERT FN Plus	BacT/ALERT 3D, VIRTUO
BacT/ALERT SA	BacT/ALERT 3D, VIRTUO
BacT/ALERT SN	BacT/ALERT 3D, VIRTUO
BacT/ALERT PF Plus	BacT/ALERT 3D, VIRTUO

Bacterial samples were seeded at clinically relevant concentrations into the blood culture bottles with the manufacturer recommended volume of healthy donor human blood. Seeded bottles were loaded into either a BD BACTEC or bioMérieux BacT/ALERT continuous monitoring blood culture system and incubated until positivity. Positive blood culture samples were then processed with the PBC Separator with Selux AST System. At least two replicates of one species from each indicated drug/organism reporting group was tested per bottle type and evaluated with all claimed antimicrobials. Aerobic bottles were seeded with *A. baumannii* (complex), *E. coli*, *K. pneumoniae*, and *P. aeruginosa*, and anaerobic bottles were seeded with *E. coli*, *K. pneumoniae*, *P. mirabilis*, and *M. morganii*.

Selux AST System MIC results from all tested bottle types showed >89.9% essential agreement (EA) to the reference method. Across all aerobic bottle types there was 99.3% EA (1629/1640 results in EA) and each aerobic bottle type had EA ≥ 98.5%. Across all anaerobic bottle types there was 99.5% EA (974/979 results in EA) and each anaerobic bottle type had EA ≥ 98.5%.

PBC Separator with Selux AST System performance with bioMérieux aerobic bottles is provided in the table below.

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%

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
Ampicillin-Sulbactam	*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%
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	25/28	89.3%[1]	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%

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		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.

PBC Separator with Selux AST System performance with BD BACTEC aerobic bottles is provided in the table below.

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	8/8	100.0%	3/3	100.0%	1/2	50.0%[1]
	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%

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
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%

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
	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.

PBC Separator with Selux AST System performance with anaerobic blood bottles is provided in the table below.

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	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%

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
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%

Interfering Substances Testing

The effect of the presence of endogenous and exogenous interferents that may be present in a blood culture was evaluated on the PBC Separator with Selux AST System. Studies were performed by seeding at least one species for each reporting group for each antimicrobial at clinically relevant concentrations into non-resin blood culture bottles with the manufacturer recommended volume of human blood. Potential interferents were seeded into the blood culture bottles at the time of bacterial seeding and prior to incubation in the blood culture system. Control samples to which no interferents were added were processed in parallel. Seeded bottles were loaded into a continuous monitoring blood culture system and incubated until positivity. Positive blood culture samples were then processed with the PBC Separator with Selux AST System.

Endogenous interferents evaluated on the system included red blood cells (RBCs), white blood cells (WBCs), platelets, triglycerides, gamma globulin, and conjugated and unconjugated bilirubin. Exogenous interferents included available oral antibiotics, including cefpodoxime, ciprofloxacin, penicillin, and gentamicin. Each was spiked into a non-resin blood culture bottle with healthy donor blood at the peak serum level for oral administration of each agent. Seeded microbial organisms were selected that had resistance to the exogenous antibiotic under test.

The PBC Separator with Selux AST System MIC results showed >89.9% EA for every interferent tested when compared with PBC Separator with Selux AST System results for the same organism run in a control condition (no interferent).

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%

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
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%

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
	Combined	13/13	100.0%	9/9	100.0%	10/10	100.0%	14/14	100.0%
Piperacillin-Tazobactam [1]	*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%

[1] An essential agreement <90% and very major errors were observed when testing Piperacillin-Tazobactam with *K. pneumoniae* with all evaluated potential endogenous interferents.

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%

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
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 [1]	*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] An essential agreement <90% and very major errors were observed when testing Piperacillin-Tazobactam with *K. pneumoniae* with all evaluated potential endogenous 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%

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

Carry-Over/Cross-Contamination Study

Evaluation of carry-over/cross-contamination on the PBC Separator was performed by alternately processing samples of *E. coli* and *K. pneumoniae* with different AST profiles. Seeded bottles were loaded into a continuous monitoring blood culture system and incubated until positivity. Five *E. coli* and five *K. pneumoniae* positive blood culture samples were loaded onto a PBC Separator across five runs. Each run comprised simultaneous processing of one *E. coli* and one *K. pneumoniae* sample. Samples were run on the Selux AST System. There were thus a total of five AST panels processed for each organism. Selux AST System MIC results showed >89.9% EA to the broth microdilution reference method result. The EA for *E. coli* was 100% (60/60 results in EA) and the EA for *K. pneumoniae* was 98.2% (54/55 results in EA). Additionally, there was no contamination observed on purity plates.

Clinical Studies

The following table gives the antimicrobial-organism combinations tested and includes the reporting range and breakpoints of each combination.

Antimicrobial	Abbreviation	Targeted Organism	Selux AST System Reporting Range	Breakpoints
Amikacin	AMK	*A. baumannii* (complex) Enterobacterales *P. aeruginosa*	≤0.12 to ≥256 ≤2 to ≥256 ≤0.12 to ≥256	≤16 / 32 / ≥64 ≤16 / 32 / ≥64 ≤16 / 32 / ≥64
Amoxicillin-Clavulanate	AMC	Enterobacterales	≤2 to ≥128	≤8 / 16 / ≥32
Ampicillin	AMP	Enterobacterales	≤2 to ≥128	≤8 / 16 / ≥32
Ampicillin-Sulbactam	SAM	*A. baumannii* (complex) Enterobacterales	≤2 to ≥128 ≤0.5 to ≥128	≤8 / 16 / ≥32 ≤8 / 16 / ≥32
Cefazolin	CFZ	Enterobacterales	≤0.12 to ≥128	≤2 / 4 / ≥8
Cefepime	FEP	Enterobacterales *P. aeruginosa*	≤0.5 to ≥32 ≤0.25 to ≥128	≤2 / 4-8 / ≥16 ≤8 / ≥16
Ceftazidime	CAZ	Enterobacterales *P. aeruginosa*	≤0.25 to ≥64 ≤0.25 to ≥256	≤4 / 8 / ≥16 ≤8 / ≥16
Ceftazidime-Avibactam	CZA	Enterobacterales *P. aeruginosa*	≤0.12 to ≥64 ≤0.12 to ≥64	≤8 / ≥16 ≤8 / ≥16
Ceftriaxone	CRO	Enterobacterales	≤0.25 to ≥32	≤1 / 2 / ≥4
Ciprofloxacin	CIP	Enterobacterales *P. aeruginosa*	≤0.03 to ≥16 ≤0.03 to ≥16	≤0.25 / 0.5 / ≥1 ≤0.5 / 1 / ≥2
Ertapenem	ETP	Enterobacterales	≤0.03 to ≥16	≤0.5 / 1 / ≥2
Gentamicin	GEN	Enterobacterales *P. aeruginosa*	≤1 to ≥64 ≤0.5 to ≥64	≤4 / 8 / ≥16 ≤4 / 8 / ≥16
Imipenem	IMP	*A. baumannii* (complex) Enterobacterales	≤0.5 to ≥64 ≤0.25 to ≥16	≤2 / 4 / ≥8 ≤1 / 2 / ≥4
Meropenem	MEM	*A. baumannii* (complex) Enterobacterales *P. aeruginosa*	≤0.12 to ≥64 ≤0.12 to ≥64 ≤0.12 to ≥64	≤2 / 4 / ≥8 ≤1 / 2 / ≥4 ≤2 / 4 / ≥8
Minocycline	MIN	*A. baumannii* (complex) Enterobacterales	≤0.25 to ≥64 ≤0.25 to ≥64	≤4 / 8 / ≥16 ≤4 / 8 / ≥16
Piperacillin-Tazobactam	TZP	*A. baumannii* (complex) Enterobacterales *P. aeruginosa*	≤4 to ≥512 ≤2 to ≥128 ≤0.25 to ≥512	≤16 / 32-64 / ≥128 ≤8 / 16 / ≥32 ≤16 / 32-64 / ≥128
Tobramycin	TOB	Enterobacterales *P. aeruginosa*	≤0.12 to ≥128	≤4 / 8 / ≥16

Clinical performance testing with the PBC Separator with Selux AST System was performed at four test sites using fresh positive blood culture samples left over from routine clinical care and seeded samples. Seeded samples were prepared using banked frozen isolates seeded at 10-10,000 CFU into blood culture bottles together with approximately 10 mL of fresh human blood from a healthy donor and then loaded into an FDA-cleared continuous monitoring blood culture system

until positive growth was detected. Positive blood bottles were tested with the PBC Separator and Selux AST System. Fresh positive blood culture samples were collected from two clinical sites serving all boroughs of New York City and seeded samples were chosen to represent geographic diversity across the continental U.S. A total of 469 clinical (162 fresh and 307 seeded) and 87 challenge isolates from 12 Enterobacterales species, *Acinetobacter baumannii* complex, and *Pseudomonas aeruginosa* were tested to evaluate the PBC Separator performance for 17 antimicrobials with the Selux AST System. Depending on the spectrum of activity, breakpoints, and the claimed organisms (species/group) for each antimicrobial on the panel, the number of datapoints for the various antimicrobial-organisms tested varied and ranged from 38 (e.g. *A. baumannii*/Amikacin) to 469 (e.g. Enterobacterales/Ciprofloxacin).

PBC Separator with Selux AST System performance was determined by comparing Selux AST System results from PBC Separator-prepared inoculums to triplicate broth microdilution results performed at an independent reference laboratory. The PBC Separator with the Selux AST System meets performance criteria for each indication and is given in the following table, where performance is summarized by drug and reporting group. Additionally, QC testing was performed every day testing was performed at each site and met the 95% performance criteria for all antimicrobials.

Antimicrobial	Organism Group	Total Tested	# in EA	% EA	Total Eval	# Eval in EA	% EA of Eval	# in CA	% CA	# R	# VMJ	# MAJ	# MIN
Amikican	*A. baumannii* (complex)	38	35	92.1	23	20	87	36	94.7	17	0	0	2
	Enterobacterales	216	208	96.3	24	16	66.7	213	98.6	8	0	0	3
	P. aeruginosa	44	42	95.5	43	41	95.3	40	90.9	6	0	0	4
Amoxicillin-Clavulanate	Enterobacterales	330	328	99.4	222	220	99.1	295	89.4	39	0	0	35
Ampicillin	Enterobacterales	149	148	99.3	4	3	75	148	99.3	96	0	0	1
Ampicillin-Sulbactam	*A. baumannii* (complex)	40	37	92.5	21	18	85.7	38	95	25	0	0	2
	Enterobacterales	352	347	98.6	303	298	98.3	306	86.9	135	0	0	46
Cefazolin	Enterobacterales	207	197	95.2	118	108	91.5	187	90.3	99	1	0	19
Cefepime	Enterobacterales	406	396	97.5	35	25	71.4	390	96.1	61	0	0	16
	P. aeruginosa	43	42	97.7	37	36	97.3	42	97.7	11	0	0	0
Ceftazidime	*Enterobacterales*	217	215	99.1	66	64	97	204	94	70	0	0	13
	P. aeruginosa	40	40	100	35	35	100	40	100	9	0	0	0
Ceftazidime-Avibactam	Enterobacterales	418	409	97.8	96	87	90.6	418	100	4	0	0	0
	P. aeruginosa	43	43	100	39	39	100	42	97.7	9	0	0	0
Ceftriaxone	Enterobacterales	373	370	99.2	18	15	83.3	370	99.2	111	0	1	2
Ciprofloxacin	Enterobacterales	469	461	98.3	82	74	90.2	457	97.4	117	0	1	11
	P. aeruginosa	43	43	100	32	32	100	42	97.7	13	0	0	1
Ertapenem	Enterobacterales	412	405	98.3	62	55	88.7	408	99	28	0	0	4
Gentamicin	Enterobacterales	466	459	98.5	33	26	78.8	459	98.5	64	0	1	6
	P. aeruginosa	43	42	97.7	31	30	96.8	42	97.7	8	0	0	1
Imipenem	*A. baumannii* (complex)	39	38	97.4	4	3	75	39	100	26	0	0	0
	Enterobacterales	213	205	96.2	14	6	42.9	209	98.1	20	0	1	3
Meropenem	*A. baumannii* (complex)	39	37	94.9	14	12	85.7	39	100	27	0	0	0
	Enterobacterales	394	388	98.5	19	13	68.4	390	99	19	0	0	4
	P. aeruginosa	43	40	93	28	25	89.3	39	90.7	13	0	0	4
Minocycline	*A. baumannii* (complex)	39	38	97.4	24	23	95.8	33	84.6	12	0	0	6
	Enterobacterales	218	209	95.9	193	184	95.3	195	89.4	32	0	2	21
Piperacillin-Tazobactam	*A. baumannii* (complex)	39	37	94.9	5	3	60	38	97.4	27	0	0	1
	Enterobacterales	320	313	97.8	36	29	80.6	312	97.5	37	0	1	7
	P. aeruginosa	43	42	97.7	40	39	97.5	42	97.7	9	0	0	1
Tobramycin	Enterobacterales	216	207	95.8	200	191	95.5	200	92.6	49	0	0	16
	P. aeruginosa	43	41	95.3	37	35	94.6	41	95.3	10	0	0	2

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

- Amikacin: *A. baumannii* (complex), *E. coli, K. pneumoniae*
- Amoxicillin-clavulanate: *K. pneumoniae*
- Ampicillin: *E. coli*
- Cefazolin: *E. coli, K. pneumoniae*
- Cefepime: *P. aeruginosa, C. freundii* complex, *K. oxytoca*
- Ceftazidime: *P. aeruginosa*

- Ciprofloxacin: *E. coli*
- Gentamicin: *E. coli, K. pneumoniae*
- Piperacillin-tazobactam: *A. baumannii* (complex), *E. coli, S. marcescens, C. koseri*

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

- Cefepime: *E. cloacae* (complex), *E. coli, K. pneumoniae*
- Ceftazidime: *E. coli, K. pneumoniae*
- Ceftazidime-avibactam: *C. freundii* (complex)*, C. koseri, E. coli, K. aerogenes, K. oxytoca, K. pneumoniae, M. morganii, P. mirabilis, P. vulgaris*
- Ceftriaxone: *C. freundii* (complex)*, C. koseri, K. aerogenes, K. oxytoca, P. mirabilis, S. marcescens*
- Ciprofloxacin: *C. freundii* (complex)*, C. koseri, E. cloacae* (complex), *K. aerogenes, K. oxytoca, M. morganii, P. mirabilis, P. vulgaris, S. marcescens*
- Ertapenem: *C. freundii* (complex)*, C. koseri, E. cloacae* (complex), *K. oxytoca, P. mirabilis, P. vulgaris, S. marcescens*
- Gentamicin: *P. mirabilis*
- Imipenem: *K. pneumoniae*
- Meropenem: *C. freundii* (complex)*, C. koseri, E. cloacae* (complex)*, K. oxytoca, K. pneumonia, M. morganii, P. mirabilis, P. vulgaris, S. marcescens*
- Minocycline: *A. baumannii* (complex)

***Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination: Ampicillin-Sulbactam: *K. oxytoca, M. morganii*

****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%.

Conclusion

Based on our studies and testing, the PBC Separator with Selux AST System was determined to be substantially equivalent to the predicate device (K231536).