March 28, 2025

Selux Diagnostics, Inc.
Carrene Plummer
VP, Regulatory and Quality
56 Roland Street, Suite 206
Charlestown, Massachusetts 02129

Re: K244044
Trade/Device Name: PBC Separator with Selux AST System
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: December 30, 2024
Received: December 30, 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Courtney E. Chandler -S for

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

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

510(k) Number *(if known)*
K244044

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 or gram positive cocci 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 AST 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 aerogenes, 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

Inoculum preparation by the PBC Separator was evaluated for use with the Selux AST System and the Selux AST Gram Positive Panel. Performance was demonstrated for the antimicrobial agents and organisms identified below:
• Ampicillin: Enterococcus faecalis, Enterococcus faecium
• Ceftaroline: Staphylococcus aureus
• Daptomycin: Enterococcus faecalis, Enterococcus faecium, Staphylococcus aureus
• Linezolid: Enterococcus faecalis, Enterococcus faecium, Staphylococcus aureus
• Oxacillin: Staphylococcus aureus
• Vancomycin: Enterococcus faecalis, Enterococcus faecium, Staphylococcus aureus

The PBC Separator with Selux AST System Gram Positive Panel is a qualitative test for the following antimicrobial agents with the specific target organisms identified below:

• Cefoxitin Screen to predict mecA-mediated oxacillin resistance: Staphylococcus aureus

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

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

Date prepared: March 27, 2025

**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: | Separator for GN and GP Bacteria |
| 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: | PBC Separator with Selux AST System |
| Manufacturer: | Selux Diagnotics, Inc. |
| 510(k) Reference: | K223493 |
| Common Name: | Separator for GN and GP Bacteria |
| 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) |

**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 or gram positive bacteria are used for Antimicrobial Susceptibility Testing (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 does 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 a 384-well panel, either the Selux Gram-Negative Panel or Selux Gram-Positive 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 (S), Susceptible Dose Dependent (SDD), Intermediate (I), or Resistant (R) determination. Any FDA-cleared method may be used to provide an ID including biochemical techniques, matrix-assisted laser desorption/ionization 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 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 or gram positive cocci 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 AST 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 aerogenes, 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*

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

- **Ampicillin**: *Enterococcus faecalis, Enterococcus faecium*
- **Ceftaroline**: *Staphylococcus aureus*
- **Daptomycin**: *Enterococcus faecalis, Enterococcus faecium, Staphylococcus aureus*
- **Linezolid**: *Enterococcus faecalis, Enterococcus faecium, Staphylococcus aureus*
- **Oxacillin**: *Staphylococcus aureus*
- **Vancomycin**: *Enterococcus faecalis, Enterococcus faecium, Staphylococcus aureus*

The PBC Separator with Selux AST System Gram Positive Panel is a qualitative test for the following antimicrobial agents with the specific target organisms identified below:

- **Cefoxitin Screen** to predict mecA-mediated oxacillin resistance: *Staphylococcus aureus*

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 with Selux AST System for Gram-positive bacteria are substantially equivalent to the primary predicate device, the PBC Separator with Selux AST System for Gram-negative bacteria (K223493), in terms of intended use, application, user population, basic design, performance, and labeling.

| Device & Predicate Devices: | K244044<br>Candidate Device | K223493<br>Predicate Device |
|---|---|---|
| **Device Trade Name** | PBC Separator with Selux AST System – GN and GP | PBC Separator with Selux AST System - GN |
| **Device Characteristics** | | |
| **Indication 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 or gram positive cocci by Gram stain. Organism identification is required for AST result interpretation and reporting, per the Selux AST System Instructions 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. |
| **Source of Microorganisms** | Bacteria from positive blood cultures | Same |

| Device & Predicate Devices: | K244044<br>Candidate Device | K223493<br>Predicate Device |
|---|---|---|
| **Indicated Antimicrobial/Organism Combinations** | **Gram-Negative Organisms:**<br>**Amikacin:** *Acinetobacter baumannii* complex, *Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa*<br>**Amoxicillin-Clavulanate:** *Escherichia coli, Klebsiella species* (including *K. oxytoca, K. pneumoniae*), *Proteus mirabilis, Proteus vulgaris*<br>**Ampicillin:** *Escherichia coli, Proteus mirabilis*<br>**Ampicillin-Sulbactam**: *Acinetobacter baumannii complex, Citrobacter koseri, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis*<br>**Cefazolin**: *Escherichia coli, Klebsiella pneumoniae*<br>**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*<br>**Ceftazidime**: *Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa*<br>**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*<br>**Ceftriaxone**: *Citrobacter freundii complex, Citrobacter koseri, Enterobacter cloacae* | **Gram-Negative Organisms:**<br>**Amikacin:** *Acinetobacter baumannii* complex, *Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa*<br>**Amoxicillin-Clavulanate:** *Escherichia coli, Klebsiella species* (including *K. oxytoca, K. pneumoniae*), *Proteus mirabilis, Proteus vulgaris*<br>**Ampicillin:** *Escherichia coli, Proteus mirabilis*<br>**Ampicillin-Sulbactam**: *Acinetobacter baumannii complex, Citrobacter koseri, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis*<br>**Cefazolin**: *Escherichia coli, Klebsiella pneumoniae*<br>**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*<br>**Ceftazidime**: *Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa*<br>**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*<br>**Ceftriaxone**: *Citrobacter freundii complex, Citrobacter koseri, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca,* |

| Device & Predicate Devices: | K244044<br>Candidate Device | K223493<br>Predicate Device |
|---|---|---|
| | *complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Serratia marcescens*<br>**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*<br>**Ertapenem**: *Citrobacter freundii complex, Citrobacter koseri, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*<br>**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*<br>**Imipenem:** *Acinetobacter baumannii* complex, *Escherichia coli, Klebsiella pneumoniae*<br>**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*<br>**Minocycline:** *Acinetobacter baumannii* complex, *Escherichia coli,* | *Klebsiella pneumoniae, Proteus mirabilis, Serratia marcescens*<br>**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*<br>**Ertapenem**: *Citrobacter freundii complex, Citrobacter koseri, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*<br>**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*<br>**Imipenem:** *Acinetobacter baumannii* complex, *Escherichia coli, Klebsiella pneumoniae*<br>**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*<br>**Minocycline:** *Acinetobacter baumannii* complex, *Escherichia coli, Klebsiella pneumoniae*<br>**Piperacillin-Tazobactam:** *Acinetobacter baumannii* complex, |

| Device & Predicate Devices: | K244044<br>Candidate Device | K223493<br>Predicate Device |
|---|---|---|
| | *Klebsiella pneumoniae*<br>**Piperacillin-Tazobactam:** *Acinetobacter baumannii* complex, *Citrobacter koseri, Escherichia coli, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens, Pseudomonas aeruginosa*<br>**Tobramycin:** *Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa*<br><br>**Gram-Positive Organisms:**<br>**Ampicillin:** *Enterococcus faecalis, Enterococcus faecium*<br>**Ceftaroline:** *Staphylococcus aureus*<br>**Daptomycin:** *Enterococcus faecalis, Enterococcus faecium, Staphylococcus aureus*<br>**Linezolid:** *Enterococcus faecalis, Enterococcus faecium, Staphylococcus aureus*<br>**Oxacillin:** *Staphylococcus aureus*<br>**Vancomycin:** *Enterococcus faecalis, Enterococcus faecium, Staphylococcus aureus*<br><br>**Cefoxitin Screen to predict *mecA*-mediated oxacillin resistance**: *Staphylococcus aureus* | *Citrobacter koseri, Escherichia coli, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens, Pseudomonas aeruginosa*<br>**Tobramycin:** *Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa* |
| **Technology** | Uses lysis, centrifugation and sequential optical density measurements to generate a McFarland-equivalent suspension. | Same |
| **Output/Results Reported** | Liquid suspension of bacteria (McFarland equivalent) suitable for susceptibility testing. | Same |
| **AST** | Selux AST System | Same |

The only difference between the current and predicate device is in the supported antimicrobial agents and organisms in the indications for use. Despite the differences between the PBC Separator with Selux AST System for gram-negative and gram-positive bacteria 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 were evaluated by testing a minimum of 5 samples for each of 9 representative antimicrobials at each of three test 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 or bioMerieux BacT/ALERT VIRTUO) until positive growth was detected. The positive blood culture bottle was then removed and processed using the PBC Separator with 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 × 3 = 9 results per sample and 9 × 5 = 45 results per antimicrobial at a single site. The acceptance criteria were defined as ≥95% best-case reproducibility and a ≥89% worst-case reproducibility for inter- and intra-site reproducibility.

The intra-site reproducibility is given in the table below. In each case, the best-and worst-case intra-site reproducibility was ≥ 97%. The results of cefoxitin screen (FOX SCN) tests are either positive or negative.

| Intra-Site Reproducibility | | | |
|---|---|---|---|
| **Antimicrobial** | **N** | **Best-Case** | **Worst Case** |
| Ampicillin | 45 | 100% | 100% |
| Ceftaroline | 45 | 100% | 100% |
| Daptomycin | 90 | 100% | 100% |
| Linezolid | 90 | 98.9% | 98.9% |
| Oxacillin | 45 | 100% | 97.8% |
| Vancomycin | 81 | 100% | 100% |

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 table below. In each case, the best-case inter-site reproducibility was ≥ 95%, and worst-case inter-site reproducibility was ≥ 94%. The results of cefoxitin screen (FOX SCN) tests are either positive or negative. To assess the reproducibility of FOX SCN, test results were calculated as reproducible if they exactly matched the modal result of the isolate. Worst-case reproducibility is not applicable and was not calculated. The results of cefoxitin screen are 134/135 (99.3%) and 45/45 (100%) for inter-site and intra-site reproducibility, respectively.

| Inter-Site Reproducibility | | | |
|---|---|---|---|
| **Antimicrobial** | **N** | **Best-Case** | **Worst Case** |
| Ampicillin | 135 | 100% | 100% |
| Ceftaroline | 135 | 100% | 100% |
| Daptomycin | 270 | 100% | 100% |
| Linezolid | 270 | 99.6% | 99.6% |
| Oxacillin | 135 | 95.6% | 94.8% |
| Vancomycin | 243 | 100% | 100% |

**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 run with the PBC Separator 16 and 18 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 three replicates of one species from each indicated antimicrobial/organism reporting group were tested per drug per timepoint. The total EA for all results at the 16-hour and 18-hour timepoints compared with the 0-hour timepoint was 100.0% (30/30 results in EA). As noted in the Limitations section, 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 VIRTUO |
| BacT/ALERT FN Plus | BacT/ALERT VIRTUO |
| BacT/ALERT SA | BacT/ALERT VIRTUO |
| BacT/ALERT SN | BacT/ALERT VIRTUO |
| BacT/ALERT PF Plus | BacT/ALERT VIRTUO |

Eleven types of blood culture bottles incubated in BD BACTEC and bioMérieux BacT/ALERT VIRTUO continuous monitoring blood culture systems were evaluated with the PBC Separator with Selux AST System. Bacterial samples were seeded at clinically relevant concentrations into the blood culture bottles with the manufacturer recommended volume of human blood. 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. One isolate from each reporting group was tested with three replicates per bottle type and evaluated with all claimed antimicrobials. Aerobic and anaerobic bottles were seeded with *E. faecalis and S. aureus*.

Selux AST System MIC results from tested bottle types showed >89.9% essential agreement to the reference method. Across all aerobic bottle types there was 99.4% EA (179/180 results in EA) and each aerobic bottle type had EA of ≥96.7%. Across all anaerobic bottle types there was 99.3% EA (149/150 results in EA) and each anaerobic bottle type had EA of ≥96.7%. Cefoxitin Screen was considered separately since results are either positive or negative and showed 100% agreement with expected results except for Cefoxitin-Staphylococci, which demonstrated 66.7% (2/3) out-of-agreement results in BD BACTEC Aerobic Plus bottles.

PBC Separator with Selux AST System performance with Aerobic BD BACTEC bottles is provided below. All Selux System MIC results are compared to the reference method.

| Antimicrobial Agent | Organism Group | Standard Aerobic | | | Aerobic Plus | | | Peds Plus | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | # Results | #EA | %EA | # Results | #EA | %EA | # Results | #EA | %EA |
| Ampicillin | Enterococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| Ceftaroline | Staphylococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| Daptomycin | Enterococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Staphylococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Total | 6 | 6 | 100.0 | 6 | 6 | 100.0 | 6 | 6 | 100.0 |
| Linezolid | Enterococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Staphylococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Total | 6 | 6 | 100.0 | 6 | 6 | 100.0 | 6 | 6 | 100.0 |
| Oxacillin | Staphylococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| Vancomycin | Enterococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Staphylococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Total | 6 | 6 | 100.0 | 6 | 6 | 100.0 | 6 | 6 | 100.0 |
| All Antimicrobials | Enterococci | 12 | 12 | 100.0 | 12 | 12 | 100.0 | 12 | 12 | 100.0 |
| | Staphylococci | 18 | 18 | 100.0 | 18 | 17 | 94.4 | 18 | 18 | 100.0 |
| | Total | 30 | 30 | 100.0 | 30 | 29 | 96.7 | 30 | 30 | 100.0 |

PBC Separator with Selux AST System performance with Aerobic bioMérieux bottles is provided below. All Selux System MIC results are compared to the reference method.

| Antimicrobial Agent | Organism Group | SA(Standard Aerobic) | | | FAPlus (Resin Aerobic) | | | PF Plus (Pediatric) | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | # Results | #EA | %EA | # Results | #EA | %EA | # Results | #EA | %EA |
| Ampicillin | Enterococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| Ceftaroline | Staphylococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| Daptomycin | Enterococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Staphylococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Total | 6 | 6 | 100.0 | 6 | 6 | 100.0 | 6 | 6 | 100.0 |
| Linezolid | Enterococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Staphylococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Total | 6 | 6 | 100.0 | 6 | 6 | 100.0 | 6 | 6 | 100.0 |
| Oxacillin | Staphylococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| Vancomycin | Enterococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Staphylococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Total | 6 | 6 | 100.0 | 6 | 6 | 100.0 | 6 | 6 | 100.0 |
| All Antimicrobials | Enterococci | 12 | 12 | 100.0 | 12 | 12 | 100.0 | 12 | 12 | 100.0 |
| | Staphylococci | 18 | 18 | 100.0 | 18 | 18 | 100.0 | 18 | 18 | 100.0 |
| | Total | 30 | 30 | 100.0 | 30 | 30 | 100.0 | 30 | 30 | 100.0 |

PBC Separator with Selux AST System performance with Anaerobic BD BACTEC bottles is provide below. All Selux System MIC results are compared to the reference method.

| Antimicrobial Agent | Organism Group | Standard Anaerobic | | | Anaerobic Plus | | | Lytic Anaerobic | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | # Results | #EA | %EA | # Results | #EA | %EA | # Results | #EA | %EA |
| Ampicillin | Enterococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| Ceftaroline | Staphylococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| Daptomycin | Enterococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Staphylococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Total | 6 | 6 | 100.0 | 6 | 6 | 100.0 | 6 | 6 | 100.0 |
| Linezolid | Enterococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Staphylococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Total | 6 | 6 | 100.0 | 6 | 6 | 100.0 | 6 | 6 | 100.0 |
| Oxacillin | Staphylococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| Vancomycin | Enterococci | 3 | 3 | 100.0 | 3 | 2 | 66.7 | 3 | 3 | 100.0 |
| | Staphylococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Total | 6 | 6 | 100.0 | 6 | 5 | 83.3 | 6 | 6 | 100.0 |
| All Antimicrobials | Enterococci | 12 | 12 | 100.0 | 12 | 11 | 91.7 | 12 | 12 | 100.0 |
| | Staphylococci | 18 | 18 | 100.0 | 18 | 18 | 100.0 | 18 | 18 | 100.0 |
| | Total | 30 | 30 | 100.0 | 30 | 29 | 96.7 | 30 | 30 | 100.0 |

PBC Separator with Selux AST System performance with Anaerobic bioMérieux bottles is provided below. All Selux System MIC results are compared to the reference method.

| Antimicrobial Agent | Organism Group | FNPlus (Resin Anaerobic) | | | SN (Standard Anaerobic) | | |
|---|---|---|---|---|---|---|---|
| | | # Results | #EA | %EA | # Results | #EA | %EA |
| Ampicillin | Enterococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| Ceftaroline | Staphylococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| Daptomycin | Enterococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Staphylococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Total | 6 | 6 | 100.0 | 6 | 6 | 100.0 |
| Linezolid | Enterococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Staphylococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Total | 6 | 6 | 100.0 | 6 | 6 | 100.0 |
| Oxacillin | Staphylococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| Vancomycin | Enterococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Staphylococci | 3 | 3 | 100.0 | 3 | 3 | 100.0 |
| | Total | 6 | 6 | 100.0 | 6 | 6 | 100.0 |
| All Antimicrobials | Enterococci | 12 | 12 | 100.0 | 12 | 12 | 100.0 |
| | Staphylococci | 18 | 18 | 100.0 | 18 | 18 | 100.0 |
| | Total | 30 | 30 | 100.0 | 30 | 30 | 100.0 |

**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 for gram-positive organisms. Studies were performed by seeding the two most common gram-positive species isolated from blood cultures, *E. faecalis* and *S. aureus*, 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 were evaluated. 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.

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). Cefoxitin Screen was considered separately since results are either positive or negative. No interference was observed, i.e., results exactly matched the control result for all endogenous and exogenous interferents.

PBC Separator with Selux AST System performance is provided below for the following endogenous interferents: Red Blood Cells, White Blood Cells, and Platelets.

| Antimicrobial | Indicated Organism(s) | Red Blood Cells (20 g/dL) | | White Blood Cells (12,000 cells/µL) | | Platelets (450,000/µL) | |
|---|---|---|---|---|---|---|---|
| | | # EA / Total | %EA | # EA / Total | %EA | # EA / Total | %EA |
| Ampicillin | Enterococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| Ceftaroline | Staphylococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| Daptomycin | Enterococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| | Staphylococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| | Combined | 6/6 | 100.0% | 6/6 | 100.0% | 6/6 | 100.0% |
| Linezolid | Enterococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| | Staphylococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| | Combined | 6/6 | 100.0% | 6/6 | 100.0% | 6/6 | 100.0% |
| Oxacillin | Staphylococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| Vancomycin | Enterococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| | Staphylococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| | Combined | 6/6 | 100.0% | 6/6 | 100.0% | 6/6 | 100.0% |

PBC Separator with Selux AST System performance is provided below for the following endogenous interferents: Conjugated Bilirubin, Unconjugated Bilirubin, Triglycerides, and Gamma Globulins.

| Antimicrobial | Indicated Organism(s) | Conjugated Bilirubin (475 µmol/L) | | Unconjugated Bilirubin (684 µmol/L) | | Triglycerides (16.94 mmol/L) | | Gamma Globulins (16.94 mmol/L) | |
|---|---|---|---|---|---|---|---|---|---|
| | | # EA / Total | %EA | # EA / Total | %EA | # EA / Total | %EA | # EA / Total | %EA |
| Ampicillin | Enterococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| Ceftaroline | Staphylococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| Daptomycin | Enterococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| | Staphylococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| | Combined | 6/6 | 100.0% | 6/6 | 100.0% | 6/6 | 100.0% | 6/6 | 100.0% |
| Linezolid | Enterococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| | Staphylococci | 2/3 | 66.7% | 3/3 | 100.0% | 3/3 | 100.0% | 2/3 | 66.7% |
| | Combined | 5/6 | 83.3% | 6/6 | 100.0% | 6/6 | 100.0% | 5/6 | 83.3% |
| Oxacillin | Staphylococci | 3/3 | 100.0% | 3/3 | 100.0% | 2/3 | 66.7% | 3/3 | 100.0% |
| Vancomycin | Enterococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| | Staphylococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| | Combined | 6/6 | 100.0% | 6/6 | 100.0% | 6/6 | 100.0% | 6/6 | 100.0% |

PBC Separator with Selux AST System performance is provided below with the following exogenous interferents: Ciprofloxacin, Cefpodoxime, Gentamicin, and Penicillin.

| Antimicrobial | Indicated Organism(s) | Ciprofloxacin (3.6 µg/mL) | | Cefpodoxime (2.3 µg/mL) | | Gentamicin (6 µg/mL) | | Penicillin (6 µg/mL) | |
|---|---|---|---|---|---|---|---|---|---|
| | | # EA / Total | %EA | # EA / Total | %EA | # EA / Total | %EA | # EA / Total | %EA |
| Ampicillin | Enterococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| Ceftaroline | Staphylococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| Daptomycin | Enterococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| | Staphylococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| | Combined | 6/6 | 100.0% | 6/6 | 100.0% | 6/6 | 100.0% | 6/6 | 100.0% |
| Linezolid | Enterococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| | Staphylococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| | Combined | 6/6 | 100.0% | 6/6 | 100.0% | 6/6 | 100.0% | 6/6 | 100.0% |
| Oxacillin | Staphylococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| Vancomycin | Enterococci | 3/3 | 100.0% | 1/3 | 33.3% | 3/3 | 100.0% | 1/3 | 33.3% |
| | Staphylococci | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% | 3/3 | 100.0% |
| | Combined | 6/6 | 100.0% | 4/6 | 66.7% | 6/6 | 100.0% | 4/6 | 66.7% |

**Clinical Studies**

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

| Antimicrobial | Reporting Group | Reportable Range in Test Device | FDA Breakpoints | | | |
|---|---|---|---|---|---|---|
| | | | S | SDD | I | R |
| **Ampicillin** | Enterococci | ≤2 to ≥64 | ≤8 | | | ≥16 |
| **Ceftaroline** | *S. aureus* | ≤0.25 to ≥16 | ≤1 | 2-4 | | ≥8 |
| **Daptomycin** | *E. faecium* | 1 to ≥32 | | ≤4 | | ≥8 |
| | *E. faecalis* | ≤1 to ≥32 | ≤2 | | 4 | ≥8 |
| | *S. aureus* | ≤0.25 to ≥8 | ≤1 | | | |
| **Linezolid** | Enterococci | ≤0.5 to ≥16 | ≤2 | | 4 | ≥8 |
| | *S. aureus* | ≤1 to ≥32 | ≤4 | | | ≥8 |
| **Oxacillin** | *S. aureus* | ≤0.5 to ≥16 | ≤2 | | | ≥4 |
| **Vancomycin** | Enterococci | ≤1to ≥64 | ≤4 | | 8-16 | ≥32 |
| | *S. aureus* | ≤0.5 to ≥32 | ≤2 | | 4-8 | ≥16 |

Clinical performance testing with the PBC Separator with Selux AST System for gram-positive organisms was performed at three 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 and seeded samples were collected from clinical sites to represent geographic diversity across the continental U.S. A total of 247 clinical (64 fresh and 183 seeded) and 75 challenge isolates from 2 Enterococci species and *Staphylococcus aureus* were tested to evaluate the PBC Separator performance for 7 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 100 (e.g., *E. faecium*/Daptomycin) to 211 (e.g., Enterococci/Linezolid).

PBC Separator with Selux AST System performance for gram-positive organisms 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 table below, 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 | # S | # VMJ | # MAJ | # MIN |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AMP | Enterococci | 210 | 209 | 99.5 | 4 | 3 | 75 | 210 | 100 | 92 | 118 | 0 | 0 | - |
| CPT | Staphylococci | 111 | 110 | 99.1 | 55 | 54 | 98.2 | 105 | 94.6 | 0 | 109 | 0 | 0 | 6 |
| DAP | Enterococcus faecalis | 103 | 100 | 97.1 | 3 | 0 | 0 | 100 | 97.1 | 0 | 103 | 0 | 2 | 1 |
| | Enterococcus faecium | 100 | 94 | 94 | 12 | 6 | 50 | 98 | 98 | 0 | 100 | 0 | 2 | - |
| | Staphylococci | 108 | 108 | 100 | 0 | 0 | - | 108 | 100 | 0 | 108 | 0 | 0 | - |
| FOX SCN | Staphylococci | 109 | - | - | - | - | - | 109 | 100 | 54 | 55 | 0 | 0 | - |
| LNZ | Enterococci | 211 | 210 | 99.5 | 193 | 192 | 99.5 | 210 | 99.5 | 0 | 211 | 0 | 1 | 0 |
| | Staphylococci | 108 | 108 | 100 | 4 | 4 | 100 | 107 | 99.1 | 3 | 105 | 0 | 0 | - |
| OXA | Staphylococci | 107 | 107 | 100 | 4 | 4 | 100 | 107 | 100 | 51 | 56 | 0 | 0 | - |
| VAN | Enterococci | 209 | 198 | 94.7 | 21 | 10 | 47.6 | 202 | 96.7 | 70 | 139 | 0 | 3 | 4 |
| | Staphylococci | 106 | 106 | 100 | 18 | 18 | 100 | 106 | 100 | 0 | 106 | 0 | 0 | 0 |

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:

- Daptomycin: *E. faecium, S. aureus*
- Linezolid: *E. faecalis, S. aureus*

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:

- Ceftaroline: *S. aureus*
- Vancomycin: *E. faecalis*

## Conclusion

Based on the studies and testing conducted to demonstrate safety and effectiveness and the similarities between the current and predicate devices, the PBC Separator with Selux AST System for gram-negative and gram-positive bacteria was determined to be substantially equivalent to the predicate device (K223493).