April 19, 2023

Selux Diagnostics, Inc
% Patricia Shrader
Regulatory Consultant
PBO Consulting
2212 East Pratt Street
Baltimore, Maryland 21231

Re: K211748
Trade/Device Name: Selux AST System; Model AST Gen 1.0
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System
Regulatory Class: Class II
Product Code: LON, LTT, LTW
Dated: June 4, 2021
Received: June 7, 2021

Dear Patricia Shrader:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211748

Device Name
Selux AST System

Indications for Use *(Describe)*

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

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

- **Amikacin**: *Pseudomonas aeruginosa*
- **Amoxicillin-Clavulanate**: *Escherichia coli, Klebsiella* species (including *K. oxytoca, K. pneumoniae*), *Proteus mirabilis*
- **Ampicillin**: *Escherichia coli, Proteus mirabilis*
- **Ampicillin-Sulbactam**: *Acinetobacter baumannii* complex*, Escherichia coli, Klebsiella* species (including *K. oxytoca, K. pneumoniae*), *Proteus mirabilis, Proteus vulgaris*
- **Aztreonam**: *Escherichia coli*
- **Cefazolin**: *Escherichia coli, Klebsiella pneumoniae*
- **Cefepime**: *Citrobacter freundii* complex, *Citrobacter koseri, Enterobacter cloacae* complex, *Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*
- **Cefoxitin**: *Escherichia coli, Klebsiella* species (including *K. oxytoca, K. pneumoniae*), *Morganella morganii*
- **Ceftazidime**: *Citrobacter* species (including *C. freundii* complex*, C. koseri*), *Enterobacter cloacae* complex*, Escherichia coli, Klebsiella* species (including *K. aerogenes, K. oxytoca, K. pneumoniae*), *Proteus mirabilis, Proteus vulgaris, Serratia marcescens*
- **Ceftazidime-Avibactam**: *Citrobacter freundii* complex, *Citrobacter koseri, Enterobacter cloacae* complex, *Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens*
- **Ceftriaxone**: *Citrobacter freundii* complex, *Citrobacter koseri, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis*
- **Ciprofloxacin**: *Citrobacter freundii* complex, *Citrobacter koseri, Enterobacter cloacae* complex*, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa*
- **Eravacycline**: *Citrobacter freundii* complex, *Enterobacter cloacae* complex, *Escherichia coli, Klebsiella oxytoca*
- **Ertapenem**: *Citrobacter freundii* complex, *Citrobacter koseri, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*
- **Gentamicin**: *Citrobacter* species (including *C. freundii* complex*, C. koseri*), *Enterobacter cloacae* complex*, Escherichia coli, Klebsiella* species (including *K. aerogenes, K. oxytoca, K. pneumoniae*), *Proteus* species (including *P. mirabilis, P. vulgaris*), *Pseudomonas aeruginosa, Serratia marcescens*
- **Imipenem-Relebactam**: *Citrobacter freundii* complex, *Citrobacter koseri, Escherichia coli, Klebsiella oxytoca, Pseudomonas aeruginosa*

- **Levofloxacin**: *Citrobacter freundii* complex, *Citrobacter koseri, Enterobacter cloacae* complex, *Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*
- **Meropenem**: *Citrobacter freundii* complex, *Citrobacter koseri, Enterobacter cloacae* complex, *Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens*
- **Meropenem-Vaborbactam**: *Citrobacter freundii* complex, *Citrobacter koseri, Enterobacter cloacae* complex, *Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Serratia marcescens*
- **Minocycline**: *Escherichia coli, Klebsiella* species (including *K. aerogenes, K. oxytoca, K. pneumoniae*)
- **Piperacillin-Tazobactam**: *Citrobacter koseri, Escherichia coli, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris*
- **Tobramycin**: *Pseudomonas aeruginosa*
- **Trimethoprim-Sulfamethoxazole**: *Enterobacter cloacae* complex, *Klebsiella* species (including *K. aerogenes, K. oxytoca, K. pneumoniae*)

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 Selux AST System, Antimicrobial Susceptibility Test System

Date prepared: April 9, 2023

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

Contact:
Eric Stern, Ph.D.
Tel. 617-945-9383

Subject Device

Trade Name:	Selux AST System
Common Name:	Antimicrobial Susceptibility Test System
Regulation Number:	21 CFR 866.1645
Regulation Name:	Fully automated short-term incubation cycle antimicrobial susceptibility system
Regulatory Class:	Class II
Product Code:	LON, LTT, LTW
Classification Panel:	83 (Microbiology)

Primary Predicate Device(s)

Trade Name:	BD Phoenix Automated Microbiology System- Ceftaroline 0.0156-4 µg/mL
Manufacturer:	Becton, Dickinson and Company
510(k) Reference:	K190905
Common Name:	Antimicrobial Susceptibility Test System
Regulation Number:	21 CFR 866.1645
Regulation Name:	Fully automated short-term incubation cycle antimicrobial susceptibility system
Regulatory Class:	Class II
Product Code:	LON
Classification Panel:	83 (Microbiology)

Device Description

The Selux AST System for antimicrobial susceptibility testing (AST) consists of a Sample Prep Station, an Inoculator, an Analyzer, a computer workstation, and the reagents and consumables required to perform AST testing. The system is operated via software that guides users through the manual sample preparation process and operates the automated Inoculator and Analyzer. The software includes an algorithm that enables the system to determine the susceptibilities of an organism to the variety of antimicrobials under test.

The system is designed so that only Gram stain information is required to initiate testing (to select the proper antimicrobial panel, gram-negative or gram-positive). While complete system testing can be performed without species-level identification (ID), this information is required for the system to report susceptibility results. Species ID can be performed by any appropriate method and this information can be either manually input to the Selux system or automatically downloaded from the laboratory information system (LIS) at any time, once the sample ID is entered into the LIS.

The system utilizes 384-well panels to provide parallel results for a large number of antimicrobials. Its average time-to-result is under 6 hours, as demonstrated in various studies.

Principle of Operation

The Selux platform 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 MIC by comparing growth data in each well. The Selux AST test requires that the Gram type (Classification) of the organism be known prior to testing as the information is necessary to select the proper AST panel to use. The organism identification (ID) need not be known for Selux AST processing to be performed. However, the organism ID is necessary for a result to be obtained 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.

To ensure accurate results, the Selux method initiates antimicrobial susceptibility assays only after sufficient microorganism replication has occurred. Following determination of sufficient growth, two complementary metabolic assays are performed that quantify microbial growth, namely an indicator assay to estimate the number of bacteria present and a surface binding assay. These data are input to an MIC-determining algorithm that provides results when organism IDs are available. The sufficient growth assay ensures that the metabolic reagents used for the high-sensitivity organism quantification assays are not added until after sufficient microbial growth has occurred. To get an accurate reading of microbial replication, the sufficient growth assay monitors growth in dedicated AST panel wells that contain organisms and cation-adjusted Mueller-Hinton Broth but no antimicrobials or probes. Sufficient growth assay wells are monitored by fluorescence to those wells which the standard viability assay pair resazurin/methylene blue have been added and/or by optical absorbance.

Two probe-based assays, a viability assay and a surface area assay, commence across all wells in the panel after the sufficient growth threshold has been met. Both of these assays are performed in each AST panel well, providing two complementary datasets for each well.

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.

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

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

- **Amikacin**: *Pseudomonas aeruginosa*
- **Amoxicillin-Clavulanate**: *Escherichia coli, Klebsiella* species (including *K. oxytoca, K. pneumoniae*), *Proteus mirabilis*
- **Ampicillin**: *Escherichia coli, Proteus mirabilis*
- **Ampicillin-Sulbactam**: *Acinetobacter baumannii* complex, *Escherichia coli, Klebsiella* species (including *K. oxytoca, K. pneumoniae*), *Proteus mirabilis, Proteus vulgaris*
- **Aztreonam**: *Escherichia coli*
- **Cefazolin**: *Escherichia coli, Klebsiella pneumoniae*
- **Cefepime**: *Citrobacter freundii* complex, *Citrobacter koseri, Enterobacter cloacae* complex, *Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*
- **Cefoxitin**: *Escherichia coli, Klebsiella* species (including *K. oxytoca, K. pneumoniae*), *Morganella morganii*
- **Ceftazidime**: *Citrobacter* species (including *C. freundii complex, C. koseri*), *Enterobacter cloacae complex, Escherichia coli, Klebsiella* species (including *K. aerogenes, K. oxytoca, K. pneumoniae*), *Proteus mirabilis, Proteus vulgaris, Serratia marcescens*
- **Ceftazidime-Avibactam**: *Citrobacter freundii* complex, *Citrobacter koseri, Enterobacter cloacae* complex, *Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens*
- **Ceftriaxone**: *Citrobacter freundii* complex, *Citrobacter koseri, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis*
- **Ciprofloxacin**: *Citrobacter freundii* complex, *Citrobacter koseri, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa*
- **Eravacycline**: *Citrobacter freundii* complex, *Enterobacter cloacae* complex, *Escherichia coli, Klebsiella oxytoca*
- **Ertapenem**: *Citrobacter freundii* complex, *Citrobacter koseri, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Serratia marcescens*

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

Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of the Selux AST System are substantially equivalent to the predicate, the BD Phoenix Automated Microbiology System- Ceftaroline 0.0156-4 µg/mL (K190905) in terms of intended use, application, user population, basic design, performance, and labeling.

Specification	Selux AST System	K190905
Device Trade Name	Selux AST System	BD Phoenix Automated Microbiology System- Ceftaroline 0.0156-4 µg/mL
Indication 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. The Selux Gram-Negative Panel is intended for use with the Selux AST System as an *in vitro* test to determine the susceptibility of isolated colonies of specific gram-negative bacilli to specific	The BD Phoenix Automated Microbiology System is intended for the in vitro rapid identification (ID) of aerobic and facultative anaerobic Gram-negative bacteria. The BD Phoenix Automated Microbiology System is also intended for the quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of aerobic and facultative anaerobic Gram-

Specification	Selux AST System	K190905
	antimicrobial agents when used as instructed.	negative bacteria isolates from pure culture.
Sources of Microorganisms	Bacterial colonies isolated from culture	Same
Technology	Automated growth-based detection	Same
Methodology	Determinations of MIC using serial two-fold dilution format	Same
Read Method	Automated	Same
Inoculation Method	Automated	Same
Result Reported	Report results as minimum inhibitory concentration (MIC) and categorical interpretation (S, I, R, NS)	Report results as minimum inhibitory concentration (MIC) and categorical interpretation (S, I, R)
General Device Characteristic Differences		
Antimicrobial Agent and Reporting Range	Amikacin: ≤2 to ≥256 µg/mL Amoxicillin-Clavulanate: ≤0.5 to ≥128 µg/mL Ampicillin: ≤0.25 to ≥128 µg/mL Ampicillin-Sulbactam: ≤0.5 to ≥128 µg/mL Aztreonam: ≤0.03 to ≥128 µg/mL Cefazolin: ≤0.12 to ≥128 µg/mL Cefepime: ≤0.25 to ≥128 µg/mL Cefoxitin: ≤1 to ≥128 µg/mL Ceftazidime: ≤2 to ≥64 µg/mL Ceftazidime-Avibactam: ≤0.12 to ≥64 µg/mL Ceftriaxone: ≤0.25 to ≥32 µg/mL Ciprofloxacin: ≤0.03 to ≥16 µg/mL Eravacycline: ≤0.016 to ≥4 µg/mL Ertapenem: ≤0.03 to ≥16 µg/mL Gentamicin: ≤0.06 to ≥64 µg/mL Imipenem-Relebactam: ≤0.03 to ≥128 µg/mL Levofloxacin: ≤0.06 to ≥32 µg/mL Meropenem: ≤0.5 to ≥64 µg/mL Meropenem-Vaborbactam: ≤0.06 to ≥64 µg/mL Minocycline: ≤1 to ≥64 µg/mL Piperacillin-Tazobactam: ≤4 to ≥512 µg/mL Tobramycin: ≤0.12 to ≥128 µg/mL Trimethoprim-Sulfamethoxazole: ≤0.12 to ≥32 µg/mL	Ceftaroline: ≤0.0156 to ≥8 µg/mL
IVD Functions	AST	ID and AST
Instrument	Selux AST System	BD Phoenix Automated Microbiology System

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

Reproducibility

Inter-site reproducibility was evaluated by testing a minimum of 25 isolates for each of the 24 antimicrobials at each of three test sites that participated in the clinical study. Each isolate was tested once at each site for a total of three results per isolate (minimum of 75 results per antimicrobial). Best-case inter-site reproducibility was ≥95% and worst-case inter-site reproducibility was ≥89% (see following table).

Selux AST System Inter-site Reproducibility				
	All organisms (combined)		Indicated organisms only	
Antimicrobial	Best-case (%)	Worst case (%)	Best-case (%)	Worst case (%)
Amikacin	98/104 (94.2%)	98/104 (94.2%)	92/98 (93.9%)	92/98 (93.9%)
Amoxicillin-Clavulanate	71/72 (98.6%)	70/72 (97.2%)	71/72 (98.6%)	70/72 (97.2%)
Ampicillin	72/75 (96.0%)	72/75 (96.0%)	68/69 (98.6%)	68/69 (98.6%)
Ampicillin-Sulbactam	74/75 (98.7%)	74/75 (98.7%)	66/66 (100%)	66/66 (100%)
Aztreonam	77/78 (98.7%)	75/78 (96.2%)	77/78 (98.7%)	75/78 (96.2%)
Cefazolin	77/81 (95.1%)	76/81 (93.8%)	68/72 (94.4%)	67/72 (93.1%)
Cefepime	77/78 (98.7%)	76/78 (97.4%)	77/78 (98.7%)	76/78 (97.4%)
Cefoxitin	70/72 (97.2%)	69/72 (95.8%)	70/72 (97.2%)	69/72 (95.8%)
Ceftazidime[1]	77/81 (95.1%)	71/81 (87.7%)	77/81 (95.1%)	71/81 (87.7%)
Ceftazidime-Avibactam	140/144 (97.2%)	139/144 (96.5%)	140/144 (97.2%)	139/144 (96.5%)
Ceftriaxone	140/141 (99.3%)	140/141 (99.3%)	140/141 (99.3%)	140/141 (99.3%)
Ciprofloxacin	74/75 (98.7%)	71/75 (94.7%)	74/75 (98.7%)	71/75 (94.7%)
Eravacycline	78/78 (100%)	78/78 (100%)	78/78 (100%)	78/78 (100%)
Ertapenem	143/145 (98.6%)	143/145 (98.6%)	143/145 (98.6%)	143/145 (98.6%)
Gentamicin	77/80 (96.3%)	77/80 (96.3%)	77/80 (96.3%)	77/80 (96.3%)
Imipenem	145/149 (97.3%)	140/149 (94.0%)	145/149 (97.3%)	140/149 (94.0%)
Imipenem-Relebactam	72/75 (96.0%)	72/75 (96.0%)	72/75 (96.0%)	72/75 (96.0%)
Levofloxacin	76/78 (97.4%)	76/78 (97.4%)	76/78 (97.4%)	76/78 (97.4%)
Meropenem	75/78 (96.2%)	73/78 (93.6%)	70/72 (97.2%)	68/72 (94.4%)
Meropenem-Vaborbactam	142/145 (97.9%)	132/145 (91.0%)	133/143 (93.0%)	133/143 (93.0%)
Minocycline	73/75 (97.3%)	73/75 (97.3%)	64/66 (97.3%)	64/66 (97.3%)
Piperacillin-Tazobactam	72/75 (96.0%)	69/75 (92.0%)	63/66 (95.5%)	60/66 (90.9%)
Tobramycin	74/78 (94.9%)	73/78 (93.6%)	74/78 (94.9%)	73/78 (93.6%)
Trimethoprim-Sulfamethoxazole	143/148 (96.6%)	142/148 (95.9%)	143/148 (96.6%)	142/148 (95.9%)

Intra-site reproducibility was evaluated at a single site that participated in the inter-site reproducibility testing and the clinical study. A minimum of 5 isolates for each antimicrobial were tested in triplicate at the site from three separate inoculums on three separate days for a minimum total of 45 results per antimicrobial. Best-case intra-site reproducibility was ≥95% and worst-case intra-site reproducibility was ≥89% (see following table).

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

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	Reporting Range	Breakpoints
Amikacin	AMK	*Pseudomonas aeruginosa*	≤0.12 to ≥256 µg/mL	≤16 / 32 / ≥64
Amoxicillin-Clavulanate	AMC	Enterobacterales	≤0.5 to ≥128 µg/mL	≤8 / 16 / ≥32
Ampicillin	AMP	Enterobacterales	≤0.25 to ≥128 µg/mL	≤8 / 16 / ≥32
Ampicillin-Sulbactam	SAM	*Acinetobacter baumannii* complex Enterobacterales	≤0.5 to ≥128 µg/mL	≤8 / 16 / ≥32
Aztreonam	ATM	Enterobacterales	≤0.03 to ≥128 µg/mL	≤4 / 8 / ≥16
Cefazolin	CFZ	Enterobacterales	≤0.12 to ≥128 µg/mL	≤1 / 2 / ≥4
Cefepime	FEP	Enterobacterales	≤0.25 to ≥128 µg/mL	≤2 / 4-8 / ≥16
Cefoxitin	FOX	Enterobacterales	≤1 to ≥128 µg/mL	≤4 / 8 / ≥16
Ceftazidime	CAZ	Enterobacterales	≤0.25 to ≥64 µg/mL	≤4 / 8 / ≥16

Antimicrobial	Abbreviation	Targeted Organism	Reporting Range	Breakpoints
Ceftazidime-Avibactam	CZA	Enterobacterales *Pseudomonas aeruginosa*	≤0.12 to ≥64 µg/mL	≤8 / ≥16
Ceftriaxone	CRO	Enterobacterales	≤0.25 to ≥32 µg/mL	≤1 / 2 / ≥4
Ciprofloxacin	CIP	Enterobacterales *Pseudomonas aeruginosa*	≤0.03 to ≥16 µg/mL	Enterobacterales: ≤0.25 / 0.5 / ≥1 *P. aeruginosa*: ≤0.5 / 1 / ≥2
Eravacycline	ERV	Enterobacterales	≤0.016 to ≥4 µg/mL	≤0.5 / -
Ertapenem	ETP	Enterobacterales	≤0.03 to ≥16 µg/mL	≤0.5 / 1 / ≥2
Gentamicin	GEN	Enterobacterales	≤0.06 to ≥64 µg/mL	≤4 / 8 / ≥16
Imipenem-Relebactam	IMR	Enterobacterales *Pseudomonas aeruginosa*	≤0.03 to ≥128 µg/mL	Enterobacterales: ≤1 / 2 / ≥4 *P. aeruginosa*: ≤2 / 4 / ≥8
Levofloxacin	LVX	Enterobacterales	≤0.06 to ≥32 µg/mL	≤0.5 / 1 / ≥2
Meropenem	MEM	Enterobacterales *Pseudomonas aeruginosa*	≤0.12 to ≥64 µg/mL	Enterobacterales: ≤1 / 2 / ≥4 *P. aeruginosa*: ≤2 / 4 / ≥8
Meropenem-Vaborbactam	MEV	Enterobacterales	≤0.06 to ≥64 µg/mL	≤4 / 8 / ≥16
Minocycline	MIN	Enterobacterales	≤0.25 to ≥64 µg/mL	≤4 / 8 / ≥16
Piperacillin-Tazobactam	TZP	Enterobacterales	≤0.25 to ≥512 µg/mL	≤16 / 32-64 / ≥128
Tobramycin	TOB	*Pseudomonas aeruginosa*	≤0.12 to ≥128 µg/mL	≤4 / 8 / ≥16
Trimethoprim-Sulfamethoxazole	SXT	Enterobacterales	≤0.12 to ≥32 µg/mL	≤2 / ≥4

Clinical performance testing on the Selux AST System was performed at three test sites. Contemporary and frozen clinical isolates from diverse geographic locations across the US were evaluated for performance as were banked challenge isolates, which were selected for their resistance profiles. A total of 1401 clinical (426 contemporary and 975 stock) and 222 challenge isolates from 12 Enterobacterales species, *Acinetobacter baumannii* complex, and *Pseudomonas aeruginosa* were tested to evaluate the Selux AST System performance for 24 antimicrobials. Depending on the spectrum of activity, breakpoints, and the claimed organisms (species/group)

for each antimicrobial on the panel, the number of datapoints for the various antimicrobial-organisms tested varied and ranged from 165 (e.g. *P. aeruginosa*/Imipenem-Relebactam) to 977 (e.g. Enterobacterales/Ertapenem).

Selux AST System performance was determined by comparing Selux AST System results with triplicate broth microdilution results performed at an independent reference laboratory. The Selux AST System meets performance criteria for each indication and is given in the following table, where performance is summarized by 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	# in CA	% CA	# R	# VMJ	# MAJ	# MIN
Amikacin	*Pseudomonas aeruginosa*	165	150	90.9	162	98.2	7	0	0	3
Amoxicillin-Clavulanate	Enterobacterales	457	437	95.6	423	92.6	110	1	2	31
Ampicillin	Enterobacterales	254	241	94.9	251	98.8	118	1	1	1
Ampicillin-Sulbactam	*Acinetobacter baumannii* complex	123	113	91.9	114	92.7	52	1	2	6
	Enterobacterales	574	556	96.9	479	83.4	202	0	5	90
Aztreonam	Enterobacterales	183	179	97.8	178	97.3	46	0	0	5
Cefazolin	Enterobacterales	358	339	94.7	287	80.2	215	1	0	70
Cefepime	Enterobacterales	882	833	94.4	845	95.8	127	2	10	25
Cefoxitin	Enterobacterales	583	538	92.3	461	79.1	103	3	8	111
Ceftazidime	Enterobacterales	787	752	95.6	759	96.4	208	1	1	26
Ceftazidime-Avibactam	Enterobacterales	815	793	97.3	810	99.4	32	0	5	0
	Pseudomonas aeruginosa	163	151	92.6	158	96.9	10	0	2	0
Ceftriaxone	Enterobacterales	668	650	97.3	657	98.4	188	1	4	3
Ciprofloxacin	Enterobacterales	818	791	96.7	787	96.2	177	2	3	26
	Pseudomonas aeruginosa	169	162	95.9	160	94.7	33	0	4	5
Eravacycline	Enterobacterales	487	478	98.2	480	98.6	54	2	1	0
Ertapenem	Enterobacterales	882	849	96.3	868	98.4	101	0	8	6
Gentamicin	Enterobacterales	741	713	96.2	733	98.9	113	1	1	6
	Pseudomonas aeruginosa	218	211	96.8	212	97.2	15	0	0	6
Imipenem-Relebactam	Enterobacterales	471	440	93.4	459	97.5	33	0	3	9
	Pseudomonas aeruginosa	165	159	96.4	162	98.2	6	0	0	3
Levofloxacin	Enterobacterales	784	753	96	744	94.9	161	1	6	33
Meropenem	Enterobacterales	833	801	96.2	816	98	83	1	12	4
	Pseudomonas aeruginosa	175	163	93.1	168	96	38	0	0	7
Meropenem-Vaborbactam	Enterobacterales	760	727	95.7	752	98.9	41	1	1	6
Minocycline	Enterobacterales	391	353	90.3	372	95.1	37	1	3	16
Piperacillin-Tazobactam	Enterobacterales	699	644	92.1	680	97.3	108	2	3	13
Tobramycin	*Pseudomonas aeruginosa*	166	155	93.4	162	97.6	14	0	1	3
Trimethoprim-Sulfamethoxazole	Enterobacterales	449	435	96.9	442	98.4	142	4	1	0

Conclusion

Based on our studies and testing, the Selux AST System was determined to be substantially equivalent to the predicate device (K190905).