January 18, 2023

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

Re: K211759
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211759

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-Positive Panel is intended for use with the Selux AST System as an *in vitro* test to determine the susceptibility of isolated colonies of specific *Staphylococcus* species and *Enterococcus* species to specific antimicrobial agents when used as instructed.

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

- **Ampicillin:** *Enterococcus faecium, Enterococcus faecalis*
- **Clindamycin:** *Staphylococcus aureus, Staphylococcus epidermidis*
- **Ceftaroline:** *Staphylococcus aureus*
- **Daptomycin:** *Staphylococcus aureus, Enterococcus faecalis*
- **Delafloxacin:** *Staphylococcus aureus, Staphylococcus haemolyticus, Enterococcus faecalis*
- **Eravacycline:** *Staphylococcus aureus, Enterococcus faecalis*
- **Erythromycin:** *Staphylococcus aureus*
- **Linezolid:** *Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus haemolyticus, Enterococcus faecium, Enterococcus faecalis*
- **Levofloxacin:** *Enterococcus faecium, Enterococcus faecalis,* methicillin-susceptible *Staphylococcus aureus*
- **Minocycline:** *Staphylococcus aureus*
- **Oxacillin:** *Staphylococcus aureus, Staphylococcus lugdunensis*
- **Penicillin:** *Enterococcus faecium, Enterococcus faecalis, Staphylococcus aureus*
- **Trimethoprim:** *Staphylococcus aureus,* Coagulase-Negative Staphylococci (including *S. capitus, S. haemolyticus, S. saprophyticus, S. simulans)*
- **Vancomycin:** *Staphylococcus aureus, Coagulase-Negative Staphylococci (CoNS) (including S. capitus, S. cohnii, S. epidermidis, S. haemolyticus, S. hominis, S. intermedius group, S. lugdunensis, S. saprophyticus, S. schleiferi, S. simulans) Enterococcus faecium, Enterococcus faecalis*

The Selux 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, Staphylococcus lugdunensis*

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: December 10, 2022

Submitter:
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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- Vancomycin 0.5-32 µg/mL
Manufacturer:	Becton, Dickinson and Company
510(k) Reference:	K131331
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[7] 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.[8] 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-Positive Panel is intended for use with the Selux AST System as an *in vitro* test to determine the susceptibility of isolated colonies of specific *Staphylococcus* species and *Enterococcus* species to specific antimicrobial agents when used as instructed.

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

- **Ampicillin**: *Enterococcus faecium, Enterococcus faecalis*
- **Clindamycin**: *Staphylococcus aureus, Staphylococcus epidermidis*
- **Ceftaroline:** *Staphylococcus aureus*
- **Daptomycin**: *Staphylococcus aureus, Enterococcus faecalis*
- **Delafloxacin**: *Staphylococcus aureus, Staphylococcus haemolyticus, Enterococcus faecalis*
- **Eravacycline**: *Staphylococcus aureus, Enterococcus faecalis*
- **Erythromycin**: *Staphylococcus aureus*
- **Linezolid**: *Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus haemolyticus, Enterococcus faecium, Enterococcus faecalis*
- **Levofloxacin**: *Enterococcus faecium, Enterococcus faecalis,* methicillin-susceptible *Staphylococcus aureus*
- **Minocycline**: *Staphylococcus aureus*
- **Oxacillin**: *Staphylococcus aureus, Staphylococcus lugdunensis*
- **Penicillin**: *Enterococcus faecium, Enterococcus faecalis, Staphylococcus aureus*
- **Trimethoprim**: *Staphylococcus aureus,* Coagulase-Negative Staphylococci (CoNS) (including *S. capitis, S. haemolyticus, S. saprophyticus, S. simulans*)
- **Vancomycin**: *Staphylococcus aureus,* Coagulase-Negative Staphylococci (CoNS) (including *S. capitis, S. cohnii, S. epidermidis, S. haemolyticus, S. hominis, S. intermedius group, S. lugdunensis, S. saprophyticus, S. schleiferi, S. simulans*) *Enterococcus faecium, Enterococcus faecalis*

The Selux 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, Staphylococcus lugdunensis*

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- Vancomycin 0.5-32 µg/mL (K131331) in terms of intended use, application, user population, basic design, performance, and labeling.

Specification	Selux AST System	K131331
Device Trade Name	Selux AST System	BD Phoenix Automated Microbiology System- Vancomycin 0.5-32 µg/mL

Specification	Selux AST System	K131331
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-Positive Panel is intended for use with the Selux AST System as an *in vitro* test to determine the susceptibility of isolated colonies of specific *Staphylococcus* species and *Enterococcus* species to specific antimicrobial agents when used as instructed.	The BD Phoenix Automated Microbiology System is intended for the in vitro rapid identification (ID) of gram positive bacteria from pure culture belonging to the genera *Staphylococcus, Enterococcus*, other gram positive cocci and gram positive bacilli. The BD Phoenix Automated Microbiology System is also intended for the quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of most gram positive bacteria isolates from pure culture belonging to the genera *Staphylococcus* and *Enterococcus*.
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	Ampicillin – ≤0.25 to ≥128 µg/mL Clindamycin – ≤0.03 to ≥16 µg/mL Ceftaroline – ≤0.06 to ≥32 µg/mL Daptomycin – ≤0.06 to ≥32 µg/mL Delafloxacin – ≤0.008 to ≥8 µg/mL Eravacycline – ≤0.002 to ≥0.5 µg/mL Erythromycin – ≤0.06 to ≥32 µg/mL Levofloxacin – ≤0.06 to ≥32 µg/mL Linezolid – ≤0.25 to ≥32 µg/mL Minocycline – ≤0.12 to ≥64 µg/mL Oxacillin – ≤0.03 to ≥32 µg/mL Penicillin – ≤0.03 to ≥64 µg/mL Trimethoprim – ≤0.25 to ≥64 µg/mL Vancomycin – ≤0.12 to ≥128 µg/mL	Vancomycin ≤0.5 to ≥64 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

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 from three separate inoculums on three separate days for a total of 45 results per antimicrobial. Best-case intra-site reproducibility was ≥95% and worst-case intra-site reproducibility was ≥89% (see following table). Please note the best-case intra-site reproducibility for erythromycin is 93.6%, which is <95%; however, reproducibility testing at two other sites were 100%.

Selux AST System Intra-site Reproducibility				
	All organisms (combined)		Indicated organisms only	
Antimicrobial	Best-case (%)	Worst case (%)	Best-case (%)	Worst case (%)
Ampicillin	45/45 (100%)	45/45 (100%)	45/45 (100%)	45/45 (100%)
Cefoxitin screen	47/47 (100%)	47/47 (100%)	47/47 (100%)	47/47 (100%)
Ceftaroline	48/49 (98.0%)	48/49 (98.0%)	48/49 (98.0%)	48/49 (98.0%)
Clindamycin	54/54 (100%)	54/54 (100%)	36/36 (100%)	36/36 (100%)
Daptomycin	74/74 (100%)	74/74 (100%)	65/65 (100%)	65/65 (100%)
Eravacycline	103/103 (100%)	99/103 (96.1%)	103/103 (100%)	99/103 (96.1%)
Erythromycin	44/47 (93.6%)	42/47 (89.4%)	44/47 (93.6%)	42/47 (89.4%)
Linezolid	62/63 (98.4%)	62/63 (98.4%)	53/54 (98.1%)	53/54 (98.1%)
Oxacillin	62/65 (95.4%)	62/65 (95.4%)	62/65 (95.4%)	62/65 (95.4%)
Vancomycin	83/83 (100%)	79/83 (95.2%)	83/83 (100%)	79/83 (95.2%)

Inter-site reproducibility was evaluated by testing a minimum of 25 isolates for each of the 14 antimicrobials plus one screening test 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 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 (%)
Ampicillin	72/75 (96%)	72/75 (96%)	68/69 (98.6%)	68/69 (98.6%)
Cefoxitin screen	74/75 (98.7%)	74/75 (98.7%)	74/75 (98.7%)	74/75 (98.7%)
Ceftaroline	74/75 (98.7%)	74/75 (98.7%)	74/75 (98.7%)	74/75 (98.7%)
Clindamycin	78/81 (96.3%)	78/81 (96.3%)	63/66 (95.5%)	63/66 (95.5%)
Daptomycin	77/78 (98.7%)	77/78 (98.7%)	77/78 (98.6%)	77/78 (98.6%)
Delafloxacin	144/144 (100%)	144/144 (100%)	144/144 (100%)	144/144 (100%)
Eravacycline	78/78 (100%)	78/78 (100%)	78/78 (100%)	78/78 (100%)
Erythromycin	141/144 (97.9%)	136/144 (94.4%)	141/144 (97.9%)	136/144 (94.4%)
Levofloxacin	76/78 (97.4%)	76/78 (97.4%)	76/78 (97.4%)	76/78 (97.4%)
Linezolid	77/78 (98.7%)	77/78 (98.7%)	56/57 (98.2%)	56/57 (98.2%)
Minocycline	73/75 (97.3%)	73/75 (97.3%)	64/66 (97.0%)	64/66 (97.0%)
Oxacillin	76/78 (97.4%)	75/78 (96.2%)	76/78 (97.4%)	75/78 (96.2%)
Penicillin	74/78 (94.9%)	70/78 (89.7%)	74/78 (94.9%)	70/78 (89.7%)
Trimethoprim	77/81 (95.1%)	74/81 (91.4%)	77/81 (95.1%)	74/81 (91.4%)
Vancomycin	79/80 (98.8%)	75/80 (93.8%)	79/80 (98.8%)	75/80 (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
Ampicillin	AMP	*Enterococcus faecium* *Enterococcus faecalis*	≤0.25 to ≥128 µg/mL	≤8 / ≥16
Clindamycin	CLI	*Staphylococcus aureus* *Staphylococcus epidermidis*	≤0.03 to ≥16 µg/mL	≤0.5 / 1-2 / ≥4
Ceftaroline	CPT	*Staphylococcus aureus*	≤0.06 to ≥32 µg/mL	≤1 / 2 / ≥4
Daptomycin	DAP	*Enterococcus faecalis* *Staphylococcus aureus*	≤0.06 to ≥32 µg/mL	*E. faecalis*: ≤2 / 4 / ≥8 *S. aureus*: ≤1 (≥2 NS)
Delafloxacin	DFX	*Enterococcus faecalis* *Staphylococcus aureus* *Staphylococcus haemolyticus*	≤0.008 to ≥8 µg/mL	*Enterococcus* spp.: ≤0.12 / 0.25 / ≥0.5 *Staphylococcus* spp.: ≤0.25 / 0.5 / ≥1
Eravacycline	ERV	*Enterococcus faecalis* *Staphylococcus aureus*	≤0.002 to ≥0.5 µg/mL	≤0.06 / ≥0.12
Erythromycin	ERY	*Staphylococcus aureus*	≤0.06 to ≥32 µg/mL	≤0.5 / 1-4 / ≥8
Levofloxacin	LVX	*Enterococcus faecium* *Enterococcus faecalis* Methicillin-susceptible *Staphylococcus aureus*	≤0.06 to ≥32 µg/mL	≤2 / 4 / ≥8
Linezolid	LNZ	*Enterococcus faecium* *Enterococcus faecalis* *Staphylococcus aureus* *Staphylococcus epidermidis* *Staphylococcus haemolyticus*	≤0.25 to ≥32 µg/mL	*Enterococcus* spp.: ≤2 / 4 / ≥8 *Staphylococcus* spp.: ≤4 / ≥8
Minocycline	MIN	*Staphylococcus aureus*	≤0.12 to ≥64 µg/mL	≤4 / 8 / ≥16
Oxacillin	OXA	*Staphylococcus aureus* *Staphylococcus lugdunensis*	≤0.03 to ≥32 µg/mL	≤2 / ≥4
Penicillin	PEN	*Enterococcus faecium* *Enterococcus faecalis* *Staphylococcus aureus*	≤0.03 to ≥64 µg/mL	*Enterococcus* spp.: ≤8 / ≥16 *S. aureus*: ≤0.12 / ≥0.25

Antimicrobial	Abbreviation	Targeted Organism	Reporting Range	Breakpoints
Trimethoprim	TMP	*Staphylococcus aureus* Coagulase-Negative *Staphylococci (CoNS)* (including *S. capitis, S. haemolyticus, S. saprophyticus, S. simulans*)	≤0.25 to ≥64 µg/mL	≤8 / ≥16
Vancomycin	VAN	*Enterococcus faecium* *Enterococcus faecalis* *Staphylococcus aureus* Coagulase-Negative *Staphylococci (CoNS)* (including *S. capitis, S. cohnii, S. epidermidis, S. haemolyticus, S. hominis, S. intermedius* group, *S. lugdunensis, S. saprophyticus, S. schleiferi, S. simulans*)	≤0.12 to ≥128 µg/mL	*Enterococcus* spp.: ≤4 / 8-16 / ≥32 *S. aureus*: ≤2 / 4-8 / ≥16 CoNS: ≤4 / 8-16 / ≥32
Cefoxitin Screen to predict *mecA*-mediated oxacillin resistance	FOX SCN	*Staphylococcus aureus* *Staphylococcus lugdunensis*	SN or SP	N/A

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 well as stock (frozen/banked) challenge isolates, which were selected for their rare resistance profiles. A total of 706 clinical (193 contemporary and 513 stock) and 159 challenge samples from 11 Staphylococci and 2 Enterococci species were tested to evaluate the Selux AST System performance for 14 antimicrobials and one screening test, the Cefoxitin Screen. 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 39 (e.g. *S. lugdunensis*/Oxacillin) to 311 (e.g. *Staphylococcus*/Clindamycin).

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 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
Ampicillin	*Enterococcus* spp.	299	294	98.3	299	100	163	0	0	0
Clindamycin	*Staphylococcus* spp.	311	298	95.8	302	97.1	73	1	3	5
Ceftaroline	*Staphylococcus spp.*	138	136	98.6	136	98.6	1	0	1	1
Daptomycin	*Enterococcus* spp.	116	109	94	116	100	0	0	0	0
	Staphylococcus spp.	134	132	98.5	133	99.3	1	1	0	0
Delafloxacin	*Enterococcus* spp.	180	175	97.2	164	91.1	38	0	2	14
	Staphylococcus spp.	229	227	99.1	216	94.3	14	0	0	13
Eravacycline	*Enterococcus* spp.[1]	287	248	86.4	280	97.6	6	2	5	0
	Staphylococcus spp.	118	118	100	118	100	2	0	0	0
Erythromycin	*Staphylococcus spp.*	220	204	92.7	208	94.5	123	0	5	7
Linezolid	*Enterococcus* spp.	299	287	96	294	98.3	1	0	3	2
	Staphylococcus spp.	228	223	97.8	227	99.6	3	0	1	0
Levofloxacin	*Enterococcus* spp.	281	272	96.8	272	96.8	129	2	2	5
	Staphylococcus spp.	135	132	97.8	130	96.3	43	0	1	4
Minocycline	*Staphylococcus* spp.	217	210	96.8	214	98.6	2	1	0	2
Oxacillin	*Staphylococcus aureus*[1]	122	104	85.2	121	99.2	49	1	0	0
	Staphylococcus lugdunensis[1]	39	35	89.7	37	94.9	3	0	2	0
Penicillin	*Enterococcus* spp.	238	223	93.7	234	98.3	105	0	4	0
	Staphylococcus spp.[1]	204	172	84.3	200	98	163	4	0	0
Trimethoprim	*Staphylococcus spp.*	215	196	91.2	211	98.1	33	2	2	0
Vancomycin	*Enterococcus* spp.	199	187	94	195	98	64	0	2	2
	Staphylcoccus aureus	238	236	99.2	236	99.2	0	0	1	1
	Coagulase-negative Staphylococci	111	109	98.2	111	100	0	0	0	0

Screening Test	Organism Group	Total Tested	# Agree	% Agree	# R	# VMJ	# MAJ
Cefoxitin Screen	*Staphylococcus aureus, Staphylococcus lugdunensis*	175	172	98.3	81	1	2

Conclusion

Based on our studies and testing, the Selux AST System was determined to be substantially equivalent to the predicate device (K131331).

[1] EA performance (<90%) is addressed in limitation statements in the device labeling.