June 20, 2024

Specific Diagnostics, LLC
% Katie Hahnemann
Regulatory Affairs Specialist
MDC Associates
180 Cabot Street
Beverly, Massachusetts 01915

Re: K230675
Trade/Device Name: VITEK REVEAL GN AST Assay and VITEK REVEAL AST System
Regulation Number: 21 CFR 866.1650
Regulation Name: A Cellular Analysis System For Multiplexed Antimicrobial Susceptibility Testing
Regulatory Class: Class II
Product Code: SAN, LON
Dated: June 4, 2024
Received: June 4, 2024

Dear Katie Hahnemann:

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

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

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

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

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

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

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

Sincerely,

Natasha Griffin -S

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

Enclosure

Indications for Use

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

510(k) Number *(if known)*
K230675

Device Name
VITEK REVEAL GN AST Assay and VITEK REVEAL AST System

Indications for Use *(Describe)*
The VITEK REVEAL AST System is an automated system for quantitative and qualitative antimicrobial susceptibility testing (AST) of organisms direct from positive blood culture. The VITEK REVEAL AST System does not provide organism identification.

The VITEK REVEAL AST System is an automated system that uses an array of sensors to detect volatile organic compounds emitted by growing bacteria for the in vitro quantitative and qualitative determination of antimicrobial susceptibility. The VITEK REVEAL GN AST Assay is indicated for susceptibility testing direct from positive blood culture samples signaled as positive by a continuous monitoring blood culture system and confirmed to contain gram-negative bacilli by Gram stain. Organism identification is required for AST result interpretation and reporting.

This test is performed by laboratory health professionals in a clinical diagnostic setting. Results may be used as an aid to clinicians in determining appropriate antimicrobial therapy. Test results from the VITEK REVEAL AST System should be interpreted 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. Sub-culturing is necessary to support further testing for: bacteria and antimicrobials not on the VITEK REVEAL GN AST Assay panel, inconclusive results, epidemiologic testing, recovery of organisms present in positive blood cultures samples, and susceptibility testing of bacteria in polymicrobial samples.

The VITEK REVEAL GN AST Assay tests the following antimicrobial agents with the specific target organisms identified below:

Amikacin: Acinetobacter baumannii-calcoaceticus complex, Citrobacter freundii (including Citrobacter freundii complex), Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae group, Proteus mirabilis, Pseudomonas aeruginosa, Serratia marcescens

Amoxicillin/clavulanate: Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae group, Proteus mirabilis

Ampicillin/sulbactam: Escherichia coli, Klebsiella oxytoca, Proteus mirabilis

Aztreonam: Citrobacter freundii (including C. freundii complex), Enterobacter cloacae (including E. cloacae complex), Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae (including K. pneumoniae group), Pseudomonas aeruginosa

Cefepime: Citrobacter koseri (syn. C. diversus), Enterobacter cloacae (including E. cloacae complex), Escherichia coli, Klebsiella species (including K. pneumoniae group and K. aerogenes), Klebsiella oxytoca, Pseudomonas aeruginosa

Cefotaxime: Acinetobacter baumannii-calcoaceticus complex, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae group

Ceftazidime: Acinetobacter baumannii-calcoaceticus complex, Citrobacter koseri, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae group

Ceftazidime/avibactam: Citrobacter freundii complex, Citrobacter koseri, Enterobacter cloacae (including E. cloacae

complex), Escherichia coli, Klebsiella aerogenes, Klebsiella pneumoniae (including K. pneumoniae group), Proteus mirabilis, Pseudomonas aeruginosa

Ceftolozane/tazobactam: Citrobacter koseri, Enterobacter cloacae (including E. cloacae complex), Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa

Ceftriaxone: Enterobacter cloacae (including E. cloacae complex), Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae (including K. pneumoniae group), Proteus mirabilis

Cefuroxime: Citrobacter koseri, Escherichia coli, Klebsiella pneumoniae group, Klebsiella oxytoca, Proteus mirabilis

Ciprofloxacin: Citrobacter freundii (including C. freundii complex), Enterobacter cloacae (including E. cloacae complex), Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae (including K. pneumoniae group), Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens

Ertapenem: Escherichia coli, Klebsiella pneumoniae (including K. pneumoniae group), Proteus mirabilis, Proteus vulgaris

Gentamicin: Citrobacter freundii complex, Citrobacter koseri, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae group, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens

Imipenem: Acinetobacter baumannii-calcoaceticus complex, Citrobacter koseri, Enterobacter cloacae complex, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae group, Pseudomonas aeruginosa, Serratia marcescens

Levofloxacin: Citrobacter koseri, Citrobacter freundii (including C. freundii complex), Enterobacter cloacae (including E. cloacae complex), Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae (including K. pneumoniae group), Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens

Meropenem: Acinetobacter baumannii-calcoaceticus complex, Enterobacter cloacae (including E. cloacae complex), Escherichia coli, Klebsiella pneumoniae (including K. pneumoniae group), Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens

Meropenem/vaborbactam: Citrobacter freundii (incluidng C. freundii complex), Citrobacter koseri, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae (including K. pneumoniae group), Proteus mirabilis

Piperacillin/tazobactam: Citrobacter koseri, Escherichia coli, Klebsiella pneumoniae (including K. pneumoniae group), Proteus vulgaris

Tetracycline: Acinetobacter baumannii-calcoaceticus complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae group

Tobramycin: Citrobacter freundii complex, Citrobacter koseri, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae group, Proteus mirabilis, Pseudomonas aeruginosa, Serratia marcescens

Trimethoprim/sulfamethoxazole: Escherichia coli, Klebsiella aerogenes, Klebsiella pneumoniae group

ESBL Confirmation test: Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae group

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

VITEK® REVEAL™ AST System and VITEK® REVEAL™ GN AST Assay

The summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Contact Details

Sponsor: Specific Diagnostics, LLC
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San Jose, CA 95134

Correspondent: MDC Associates, Inc.
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Beverly, MA 01915
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Date Prepared: June 20, 2024

Device

Device Trade Name: VITEK® REVEAL™ GN AST Assay and VITEK® REVEAL™ AST System

Common Name: VITEK® REVEAL™ GN AST Assay and VITEK® REVEAL™ AST System

Classification Name: A cellular analysis system for multiplexed antimicrobial susceptibility testing in a multiplex qualitative and/or quantitative in vitro device intended for the identification and determination of the antimicrobial susceptibility results of organisms detected in samples from patients with suspected microbial infections. This device is intended to aid in the determination of antimicrobial susceptibility or resistance when used in conjunction with other laboratory findings.

Regulation Number: 866.1650

Product Code: SAN (primary), LON

Predicate Device: Accelerate Pheno System, Accelerate PhenoTest BC Kit, DEN160032, Product Code: PRH, NSU, LON, PEO, PEN, PAM

No reference devices were used in this submission.

Device Description Summary

The VITEK® REVEAL™ AST System is an *in vitro* diagnostic (IVD) automated platform for phenotypic Antimicrobial Susceptibility Testing (AST) of bacterial samples, directly from positive blood cultures. The System utilizes broth microdilution (BMD) principles to quickly and accurately determine Minimum Inhibitory Concentrations (MIC) for the drugs on the VITEK® REVEAL™ GN AST Assay, and in combination with species identification (obtained from an FDA-cleared rapid ID method), will provide a Susceptible / Intermediate / Resistant (SIR) determination, or a Positive/Negative (POS/NEG) determination for the ESBL Confirmation screen test, for the species tested. The VITEK® REVEAL™ AST System is indicated for susceptibility testing of specific Gram-negative bacteria commonly associated with bacteremia (Table 1).

Sample preparation for testing in the VITEK® REVEAL™ AST System is fast, simple, and requires minimal skill. After a blood culture sample is identified as positive by a validated, automated blood culture system, a Gram stain is performed to confirm positivity and to determine whether the sample is Gram-positive, Gram-negative, or yeast. Samples determined by Gram stain to be monomicrobial for Gram-negative bacteria are diluted in Pluronic water and dispensed into VITEK® REVEAL™ Antibiotic Panels, containing serial dilutions of antibiotics and dried media. A VITEK® REVEAL™ Sensor Panel is sealed atop an inoculated VITEK® REVEAL™ Antibiotic Panel using the VITEK® REVEAL™ Sealer in an AST disposable assembly comprising a VITEK® REVEAL™ GN AST Assay.

The VITEK® REVEAL™ AST System detects bacterial growth using an array of proprietary chemical Small Molecule Sensors (SMS), which change color in the presence of various metabolic gases (volatile organic compounds) emitted by growing bacteria during incubation. The SMS arrays, printed onto the VITEK® REVEAL™ Sensor Panel, are positioned atop each well of the VITEK® REVEAL™ Antibiotic Panel. The sealed VITEK® REVEAL™ GN AST Assay is placed in the VITEK® REVEAL™ Instrument, which functions as an incubator for the samples being tested and optically monitors and tracks the change in sensor colors as the bacteria grow. These color changes are monitored by a scan every 10 minutes, allowing a real-time assessment of growth as a function of antibiotic concentration. A real-time algorithm detects sensor array responses indicating the volatile-compound emissions that are associated with bacterial population growth. Each antimicrobial agent-containing well is then compared to the response in control wells (the positive control well containing no antimicrobial agent, and the negative control well containing no growth media). Bacterial growth (indicating resistance) or inhibition of growth (indicating susceptibility) relative to these controls is determined for each antimicrobial agent-concentration pair. The MIC is defined as the lowest concentration of antimicrobial agent that inhibits growth. Categorical interpretation (SIR result) is furnished based on current FDA or FDA-recognized CLSI breakpoints for each antimicrobial. Species identification by an FDA-cleared test method may be entered at any time during the AST run or after the AST run.

The VITEK® REVEAL™ AST System includes a VITEK® REVEAL™ Sealer, a VITEK® REVEAL™ Instrument, and a master controller computer (MCC)/touch screen monitor. The system is scalable, and up to eight (8) VITEK® REVEAL™ Instruments can be controlled by one user-friendly, touchscreen interface. The VITEK® REVEAL™ AST System is also modular, avoiding the risk of a single instrument failure causing an interruption in laboratory testing. Each VITEK® REVEAL™ Instrument has two independently loadable drawers with each drawer able to hold two (2) GN AST Assays. A single VITEK® REVEAL™ Sealer can support multiple VITEK® REVEAL™ instruments since each sealing step takes less than a minute with a one-button operation.

Table 1: Reportable MIC Ranges and Breakpoints for Antimicrobials Included in VITEK® REVEAL™ GN AST Assay

Antimicrobial	Reportable range on VITEK® REVEAL™ (µg/mL)	Breakpoints (FDA STIC ≤S, I, ≥R)		
		Enterobacterales	*P. aeruginosa*	*Acinetobacter*
Amikacin	≤0.5- >128	16, 32, 64	16, 32, 64	16, 32, 64
Amoxicillin/clavulanate	≤2/1- >64/32	8, 16, 32	-	-
Ampicillin/sulbactam	≤2/1- >64/32	8, 16, 32	-	-
Aztreonam	≤0.25- >64	4, 8, 16	8, 16, 32	-
Cefepime	≤0.125- >64	2, 4-8*, 16	8, --, 16	-
Cefotaxime	≤0.25- >128	1, 2, 4	-	1, 2, 4
Ceftazidime	≤0.125- >64	4, 8, 16	-	8, 16, 32
Ceftazidime/avibactam	≤0.0625/4- >32/4	8, --, 16	8, --, 16	-
Ceftolozane/tazobactam	≤0.0625/4- >32/4	2, 4, 8	4, 8, 16	-
Ceftriaxone	≤0.25- >16	1, 2, 4	-	-
Cefuroxime	≤1- >32	8, --, 16	-	-
Ciprofloxacin	≤0.0625- >8	0.25, 0.5, 1	0.5, 1, 2	-
Ertapenem	≤0.125- >16	0.5, 1, 2	-	-
Gentamicin	≤0.25- >32	4, 8, 16	4, 8, 16	-
Imipenem	≤0.25- >16	1, 2, 4	2, 4, 8	2, 4, 8
Levofloxacin	≤0.125- >16	0.5, 1, 2	1, 2, 4	-
Meropenem	≤0.0625- >32	1, 2, 4	2, 4, 8	2, 4, 8
Meropenem/vaborbactam	≤0.0625/8- >32/8	4, 8, 16	-	-
Piperacillin/tazobactam	≤2/4- >256/4	8, 16, 32	-	-
Tetracycline	≤1- >64	4, 8, 16	-	4, 8, 16
Tobramycin	≤0.125- >32	4, 8, 16	4, 8, 16	-
Trimethoprim/sulfamethoxazole	≤0.5/9.5- >64/1216	2, --, 4	-	-
ESBL Confirmation	POS/NEG	-	-	-

NEG=Negative; POS=Positive
*SDD per US FDA STIC website

Intended Use/Indications for Use

The VITEK® REVEAL™ AST System is an automated system for quantitative and qualitative antimicrobial susceptibility testing (AST) of organisms direct from positive blood culture. The VITEK® REVEAL™ AST System does not provide organism identification.

The VITEK® REVEAL™ AST System is an automated system that uses an array of sensors to detect volatile organic compounds emitted by growing bacteria for the *in vitro* diagnostic quantitative and qualitative determination of antimicrobial susceptibility. The VITEK® REVEAL™ GN AST Assay is indicated for susceptibility testing direct from positive blood culture samples signaled positive by a continuous monitoring blood culture system and confirmed to contain gram-negative bacilli by Gram stain. Organism identification is required for the AST result interpretation and reporting.

This test is performed by laboratory health professionals in a clinical diagnostic setting. Results may be used as an aid to clinicians in determining appropriate antimicrobial therapy. Test results from the VITEK® REVEAL™ AST System should be interpreted 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. Subculturing is necessary to support further testing for: bacteria and antimicrobials not on the VITEK® REVEAL™ GN AST Assay panel, inconclusive results, epidemiologic testing, recovery of organisms present in positive blood cultures samples, and susceptibility testing of bacteria in polymicrobial samples.

The VITEK® REVEAL™ GN AST Assay tests the following antimicrobial agents with the specific target organisms identified below:

Amikacin: Acinetobacter baumannii-calcoaceticus complex, Citrobacter freundii (including Citrobacter freundii complex), Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae group, Proteus mirabilis, Pseudomonas aeruginosa, Serratia marcescens

Amoxicillin/clavulanate: Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae group, Proteus mirabilis**:**

Ampicillin/sulbactam: Escherichia coli, Klebsiella oxytoca, Proteus mirabilis

Aztreonam.: Citrobacter freundii (including C. freundii complex), Enterobacter cloacae (including E. cloacae complex), Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae (including K. pneumoniae group), Pseudomonas aeruginosa

Cefepime: Citrobacter koseri (syn. C. diversus), Enterobacter cloacae (including E. cloacae complex), Escherichia coli, Klebsiella species (including K. pneumoniae group and K. aerogenes), Klebsiella oxytoca, Pseudomonas aeruginosa
Cefotaxime: Acinetobacter baumannii-calcoaceticus complex, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae group

Ceftazidime: Acinetobacter baumannii-calcoaceticus complex, Citrobacter koseri, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae group

Ceftazidime/avibactam: Citrobacter freundii complex, Citrobacter koseri, Enterobacter cloacae (including E. cloacae complex), Escherichia coli, Klebsiella aerogenes, Klebsiella pneumoniae (including K. pneumoniae group), Proteus mirabilis, Pseudomonas

Ceftolozane/tazobactam: Citrobacter koseri, Enterobacter cloacae (including E. cloacae complex), Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa
Ceftriaxone: Enterobacter cloacae (including E. cloacae complex), Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae (including K. pneumoniae group), Proteus mirabilis
Cefuroxime: Citrobacter koseri, Escherichia coli, Klebsiella pneumoniae group, Klebsiella oxytoca, Proteus mirabilis

Ciprofloxacin: Citrobacter freundii (including C. freundii complex), Enterobacter cloacae (including E. cloacae complex), Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae (including K. pneumoniae group), Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens
Ertapenem: Escherichia coli, Klebsiella pneumoniae (including K. pneumoniae group), Proteus mirabilis, Proteus vulgaris

Gentamicin: Citrobacter freundii complex, Citrobacter koseri, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae group, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens **Imipenem:** Acinetobacter baumannii-calcoaceticus complex, Citrobacter koseri, Enterobacter cloacae complex, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae group, Pseudomonas aeruginosa, Serratia marcescens

Levofloxacin: Citrobacter koseri, Citrobacter freundii (including C. freundii complex), Enterobacter cloacae (including E. cloacae complex), Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae (including K. pneumoniae group), Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens

Meropenem: Acinetobacter baumannii-calcoaceticus complex, Enterobacter cloacae (including E. cloacae complex), Escherichia coli, Klebsiella pneumoniae (including K. pneumoniae group), Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens

Meropenem/vaborbactam: Citrobacter freundii (incluidng C. freundii complex), Citrobacter koseri, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae (including K. pneumoniae group), Proteus mirabilis

Piperacillin/tazobactam: Citrobacter koseri, Escherichia coli, Klebsiella pneumoniae (including K. pneumoniae group), Proteus vulgaris

Tetracycline: Acinetobacter baumannii-calcoaceticus complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae group

Tobramycin: Citrobacter freundii complex, Citrobacter koseri, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae group, Proteus mirabilis, Pseudomonas aeruginosa, Serratia marcescens

Trimethoprim/sulfamethoxazole: Escherichia coli, Klebsiella aerogenes, Klebsiella pneumoniae group

ESBL Confirmation test: Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae group

Technology Comparison with the Predicate Device

Description	**Specific Diagnostics** **Subject Device** VITEK® REVEAL™ AST System and VITEK® REVEAL™ GN AST Assay	**Accelerate Diagnostics, Inc.** **Predicate Device** Accelerate Pheno System and PhenoTest BC Kit **K192665**
Similarities		
Intended Use	The VITEK® REVEAL™ AST System is an automated system for quantitative and qualitative antimicrobial susceptibility testing (AST) of organisms direct from positive blood culture. The VITEK® REVEAL™ AST System does not provide organism identification.	The Accelerate PhenoTest BC kit is a multiplexed *in vitro* diagnostic test utilizing both qualitative nucleic acid fluorescence in situ hybridization (FISH) identification and quantitative, antimicrobial susceptibility testing (AST) methods and is intended for use with the Accelerate Pheno system. The Accelerate PhenoTest BC kit is capable of simultaneous detection and identification of multiple microbial targets followed by susceptibility testing of the appropriate detected bacterial organisms. The Accelerate PhenoTest BC kit is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system. Results are intended to be interpreted in conjunction with Gram stain results.
Type of Test	Automated incubation and reading	Automated incubation and reading
Indicated Organisms	Gram-negative organisms	Gram-negative organisms
Sample	Dilution from positive blood culture	Aliquot from positive blood culture as identified by a continuous monitoring blood culture system
Inoculum Methods	Manual: Pipetting 25 µL positive blood culture into 25 mL of Pluronic water	Manual: Aliquot of positive blood culture into sample vial
Differences		
AST Panel Preparation	Manual: Pipetting the inoculum into the antibiotic panel and sealing it to the sensor panel using the VITEK® REVEAL™ Sealer	Automated: User loads an aliquot of the positive blood culture into the sample vial, then places the test cassette, reagent cartridge and sample vial into an Accelerate Pheno System module and starts the run. The remaining panel preparation steps are automated
Technology	Automated growth based, using detection of emission of volatiles by colorimetric sensors to detect and monitor organism growth	Morphokinetic cellular analysis (MCA), such as cell morphology and light intensity of a growing clone over time, are used for analysis

Time to AST Result	Approximately 8 hours or less (directly from positive blood cultures)	Approximately 7 hours
Results	Report results as minimum inhibitory concentration (MIC) and categorical interpretation (SIR) for antimicrobials and Positive/Negative (POS/NEG) for the ESBL Confirmation screen test	Report results as minimum inhibitory concentration (MIC) and categorical interpretation (SIR)
Antimicrobial Agents	Amikacin Amoxicillin/clavulanate Ampicillin/sulbactam Aztreonam Cefepime Cefotaxime Cefotaxime/clavulanate Ceftazidime Ceftazidime/avibactam Ceftazidime/clavulanate Ceftolozane/tazobactam Ceftriaxone Cefuroxime Ciprofloxacin Ertapenem Gentamicin Imipenem Levofloxacin Meropenem Meropenem/vaborbactam Piperacillin/tazobactam Tetracycline Tobramycin Trimethoprim/sulfamethoxazole	For use with Gram negative organisms: Amikacin Ampicillin/sulbactam Aztreonam Cefepime Ceftazidime Ceftriaxone Ciprofloxacin Ertapenem Gentamicin Meropenem Piperacillin/tazobactam Tobramycin

Any differences between the subject device and the predicate device shown in the table above do not affect the safety and effectiveness of the subject device.

Performance Characteristics

Reproducibility

The reproducibility study was designed to demonstrate the reproducibility of VITEK® REVEAL™ GN AST Assay results generated on the VITEK® REVEAL™ AST System from positive blood cultures when tested at different sites by different operators and on different days. A set of Gram-negative isolates were selected for reproducibility testing such that there were at least ten (10) on-scale MIC results for each antibiotic on the VITEK® REVEAL™ GN AST Assay. For each panel organism, testing on the VITEK® REVEAL™ AST System was performed at three (3) sites, in triplicate, on three (3) days, for a total of 27 results per sample. Each site utilized at least two (2) operators. Selected isolates were contrived in blood culture bottles with human blood added and incubated until positivity. Blinded positive blood culture aliquots were delivered to each of three testing sites (one internal and two external) on the same day and tested within 16 hours of positivity. Three inoculum dilutions were prepared from each positive blood culture aliquot and used to inoculate three VITEK® REVEAL™ Antibiotic Panels.

Reproducibility was calculated as the percentage of results that fall within one (1) dilution (+/-1) of the mode result. Both best-case (assumes that off-scale results are within one dilution of the mode) and worst-case (assumes that off-scale results are more than one dilution from the mode) reproducibility was calculated for each antibiotic for each site and across all sites.

Overall best-case reproducibility (assumes that off-scale results are within one dilution of the mode) for each antimicrobial was ≥96%, meeting the acceptance criteria of ≥95% (Table 2). Worst-case reproducibility for each antimicrobial was ≥91.7%, meeting the acceptance criteria of ≥89%.

Table 2. VITEK® REVEAL™ Reproducibility Overall Results Summary

Antibiotic	Best case # within +/-1 dilution / Total tests	Best case %	Worst case # within +/-1 dilution/ Total tests	Worst case %
Amikacin	891/891	100.0%	870/891	97.6%
Amoxicillin/clavulanate	324/324	100.0%	323/324	99.7%
Ampicillin/sulbactam*	269/270	99.6%	266/270	98.5%
Aztreonam*	287/296	97.0%	287/296	97.0%
Cefepime	371/377	98.4%	360/377	95.5%
Cefotaxime	342/351	97.4%	342/351	97.4%
Ceftazidime*	395/396	99.7%	395/396	99.7%
Ceftazidime/avibactam*	345/350	98.6%	345/350	98.6%
Ceftolozane/tazobactam*	564/565	99.8%	564/565	99.8%
Ceftriaxone	267/267	100.0%	259/267	97.0%
Cefuroxime	429/429	100.0%	427/429	99.5%

Antibiotic	Best case # within +/-1 dilution / Total tests	Best case %	Worst case # within +/-1 dilution/ Total tests	Worst case %
Ciprofloxacin	319/324	98.5%	319/324	98.5%
Ertapenem*	291/297	98.0%	291/297	98.0%
Gentamicin	538/538	100.0%	523/538	97.2%
Imipenem	397/397	100.0%	364/397	91.7%
Levofloxacin	323/323	100.0%	323/323	100.0%
Meropenem	404/405	99.8%	395/405	97.5%
Meropenem/vaborbactam	285/297	96.0%	285/297	96.0%
Piperacillin/tazobactam	377/377	100.0%	368/377	97.6%
Tetracycline	297/297	100.0%	291/297	98.0%
Tobramycin	808/809	99.9%	807/809	99.8%
Trimethoprim/sulfamethoxazole	269/269	100.0%	263/269	97.8%
ESBL confirmation	529/540	98.0%	N/A	N/A

*This analysis contains non-indicated species.

Blood Culture Bottle Equivalency

The blood culture bottle equivalency study was performed to demonstrate that VITEK® REVEAL™ GN AST Assay results generated on the VITEK® REVEAL™ AST System are consistent across BD BACTEC™ and bioMérieux BACT/ALERT® blood culture monitoring systems and blood culture bottle types. Nine (9) strains representing seven (7) species were contrived and tested on both the BD BACTEC™ FX-40 system and the BACT/ALERT® VIRTUO® system using aerobic and anaerobic blood culture bottles with and without resin (Table 3). Six (6) bottle replicates were tested for each organism and bottle type within 4-8 hours of positivity on the respective instruments. Bottle types that were not tested at 15+ hours of positivity in the sample stability study or the clinical study were also tested at 16+ h of positivity.

The MICs determined by the VITEK® REVEAL™ AST System were compared against the reference (BMD) modal MIC for each antibiotic/strain to determine essential and categorical agreement. Overall, the average EA and CA for each bottle type across all antibiotics tested when compared to the reference MIC was >98% (Table 3), meeting the acceptance criteria of >89.9% and demonstrating the VITEK® REVEAL™ GN AST Assay performs similarly across all bottle types evaluated. For any antibiotic/strain combination that demonstrated <89.9% EA or CA, the discrepancy was observed across multiple bottle types and was determined to be related to strain or system variability and not due to blood culture bottle type. The VITEK® REVEAL™ GN AST Assay and VITEK® REVEAL™ AST System should only be tested with positive blood culture samples from the blood culture media types evaluated.

Table 3. Bottle Equivalency Results Summary

Bottle Type	Overall Performance	
	EA	CA
Aerobic bottles		
bioMérieux BACT/ALERT® SA	98.8% (1872/1895)	99.0% (1899/1918)
bioMérieux BACT/ALERT® FA Plus	99.0% (925/934)	98.8% (934/945)
bioMérieux BACT/ALERT® PF Plus	99.6% (943/947)	99.4% (952/958)
BD BACTEC™ Standard Aerobic	99.1% (1886/1903)	99.1% (1908/1926)
BD BACTEC™ Plus Aerobic	99.1% (956/965)	99.3% (970/977)
BD BACTEC™ Peds Plus™	99.5% (957/962)	99.4% (967/973)
Anaerobic bottles†		
bioMérieux BACT/ALERT® SN	99.9% (741/742)	99.2% (747/753)
bioMérieux BACT/ALERT® FN Plus	99.9% (739/740)	99.2% (745/751)
BD BACTEC™ Standard Anaerobic	99.9% (1507/1509)	99.2% (1519/1532)
BD BACTEC™ Plus Anaerobic	99.6% (1510/1516)	99.2% (1526/1539)
BD BACTEC™ Lytic Anaerobic	99.6% (762/765)	99.1% (770/777)

† Strict aerobic species (i.e., *Acinetobacter baumannii-calcoaceticus* complex members and *Pseudomonas aeruginosa*) were not tested in anaerobic bottles, based on the intended use of the bottles.

Sample Stability

The sample stability study was designed to demonstrate that performance of the VITEK® REVEAL™ GN AST Assay and VITEK® REVEAL™ AST System is consistent when testing positive blood cultures stored at different conditions (incubated on the blood culture monitoring system and room temperature) for up to 16 hours post positivity. The testing was performed using both the BD BACTEC™ FX-40 system (BD BACTEC™ Plus Aerobic bottles) and the BACT/ALERT® VIRTUO® system (BACT/ALERT® FA PLUS bottles). Twenty-five (25) strains representing nine (9) species were selected to provide at least two on-scale MICs for each antibiotic on the VITEK® REVEAL™ GN AST Assay. The timepoints tested were at positivity (0-2 hours), 8-10 hours post positivity, and 16-18 hours post positivity. Positive blood cultures were stored either in the blood culture instrument or removed and held at room temperature until testing. Testing was performed in triplicate for each temperature condition and timepoint.

The MICs determined by the VITEK® REVEAL™ AST System for each temperature condition and timepoint replicate were compared against the reference (BMD) modal MIC to determine essential and categorical agreement. Sample stability of the positive blood culture was evaluated for each antimicrobial and pooled across all organisms for each bottle type.

Across all antibiotics evaluated, the overall EA and CA for each temperature condition and timepoint tested on each instrument was >89.9% when compared to the BMD modal MIC,

meeting the acceptance criteria (Table 4). For antibiotics that showed <89.9% EA or CA, errors could be attributed to the following species and conditions:

- Essential agreement for *E. coli* – cefuroxime at T8 (36-38°C) in BD BACTEC™ Plus Aerobic bottles (Table 4a)
- Essential agreement for *E. coli* – cefuroxime at T0, T8 (RT), and T16 (RT) in BACT/ALERT® FA PLUS bottles (Table 4a-b)
- Categorical agreement for *K. aerogenes* – ceftazidime at T0 and T8 (36-38°C) in BD BACTEC™ Plus Aerobic bottles
- ESBL analysis (categorical agreement) and *E. coli* for all conditions except T8 (RT) in BD BACTEC™ Plus Aerobic bottles
- Categorical agreement for *E. cloacae* – ertapenem at T16 (36-38°C) in BD BACTEC™ Plus Aerobic bottles
- Categorical agreement for *E. cloacae* – ertapenem at T0, T8 (36-38°C), and T8 (36-38°C) in BACT/ALERT® FA PLUS bottles

For cases that resulted in final antibiotic performance of <89.9% EA or CA when compared to reference results, the modal MICs of the triplicate MICs for the specific incubation condition/time point were within ± 1 doubling dilution of the T0 result, indicating these discrepancies were not due to the storage condition or age of the sample. All instances resulted in an EA of 100% based on comparisons between the T0 and other timepoints obtained by the VITEK® REVEAL™ AST System. These results demonstrate that positive blood culture samples may be tested on the VITEK® REVEAL™ GN AST Assay and the VITEK® REVEAL™ AST System when samples are stored for up to 16 hours post positivity if held on the instrument or on the bench.

Table 4a. Sample Stability Results for BD BACTEC™ Plus Aerobic bottles (36-38°C)

BD BACTEC™ Plus Aerobic (36-38°C)						
Antibiotic	**T0**		**T8**		**T16**	
	EA	**CA**	**EA**	**CA**	**EA**	**CA**
Ampicillin/Sulbactam	100.0% (18/18)	100.0% (18/18)	100.0% (16/16)	100.0% (16/16)	100.0% (18/18)	100.0% (18/18)
Cefotaxime	100.0% (27/27)	100.0% (27/27)	100.0% (25/25)	100.0% (25/25)	100.0% (27/27)	100.0% (27/27)
Ceftazidime [a]	96.55% (28/29)	89.66% (26/29)	100.0% (29/29)	89.66% (26/29)	100.0% (30/30)	90.0% (27/30)
Ceftazidime/Avibactam	100.0% (27/27)	100.0% (27/27)	100.0% (26/26)	100.0% (26/26)	100.0% (27/27)	100.0% (27/27)
Ceftolozane/Tazobactam	100.0% (27/27)	100.0% (27/27)	100.0% (26/26)	100.0% (26/26)	100.0% (27/27)	100.0% (27/27)
Ceftriaxone	91.67% (22/24)	100.0% (24/24)	100.0% (23/23)	100.0% (23/23)	100.0% (24/24)	100.0% (24/24)
Cefuroxime [b]	100.0% (15/15)	100.0% (15/15)	85.71% (12/14)	100.0% (14/14)	93.33% (14/15)	100.0% (15/15)
ESBL[c]	N/A	78.57% (11/14)	N/A	85.71% (12/14)	N/A	86.67% (13/15)
Amikacin	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)
Aztreonam	96.67% (29/30)	96.67% (29/30)	96.67% (29/30)	96.67% (29/30)	90.0% (27/30)	100.0% (30/30)
Ertapenem [d]	100.0% (24/24)	91.67% (22/24)	100.0% (24/24)	95.83% (23/24)	100.0% (23/23)	86.96% (20/23)
Gentamicin	100.0% (30/30)	100.0% (30/30)	93.33% (28/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)

BD BACTEC™ Plus Aerobic (36-38°C)						
Antibiotic	T0		T8		T16	
	EA	CA	EA	CA	EA	CA
Imipenem	100.0% (27/27)	100.0% (27/27)	100.0% (26/26)	100.0% (26/26)	100.0% (26/26)	100.0% (26/26)
Meropenem	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)
Meropenem/Vaborbactam	100.0% (24/24)	100.0% (24/24)	95.83% (23/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)
Piperacillin/Tazobactam	93.33% (28/30)	93.33% (28/30)	100.0% (30/30)	96.67% (29/30)	100.0% (30/30)	100.0% (30/30)
Tobramycin	100.0% (30/30)	100.0% (30/30)	90.0% (27/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)
Trimethoprim/Sulfamethoxazole	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)
Amoxicillin/Clavulanate	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)
Cefepime	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (23/23)	100.0% (23/23)
Ciprofloxacin	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)
Levofloxacin	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)
Tetracycline	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)

[a.] Categorical agreement due to *K. aerogenes* – ceftazidime at T0 and T8 (36-38°C) in BD BACTEC™ Plus Aerobic bottles

[b.] Essential agreement due to *E. coli* – cefuroxime at T8 (36-38°C) in BD BACTEC™ Plus Aerobic bottles

[c.] Categorical agreement due to *E. coli* – ESBL for all conditions in BD BACTEC™ Plus Aerobic bottles

[d.] Categorical agreement due to *E. cloacae* – ertapenem at T16 (36-38°C) in BD BACTEC™ Plus Aerobic bottles

All instances (a-d) resulted in an EA of 100% based on comparisons between the T0 and other timepoints obtained by the VITEK® REVEAL™ AST System.

Table 4b. Sample Stability Results for BD BACTEC™ Plus Aerobic bottles (RT)

BD BACTEC™ Plus Aerobic (RT)						
Antibiotic	T0		T8		T16	
	EA	CA	EA	CA	EA	CA
Ampicillin/Sulbactam	100.0% (18/18)	100.0% (18/18)	100.0% (18/18)	100.0% (18/18)	100.0% (18/18)	100.0% (18/18)
Cefotaxime	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)
Ceftazidime [a]	96.55% (28/29)	89.66% (26/29)	100.0% (30/30)	90.0% (27/30)	100.0% (30/30)	90.0% (27/30)
Ceftazidime/Avibactam	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)
Ceftolozane/Tazobactam	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)
Ceftriaxone	91.67% (22/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)
Cefuroxime	100.0% (15/15)	100.0% (15/15)	100.0% (15/15)	100.0% (15/15)	100.0% (15/15)	100.0% (15/15)
ESBL[b]	N/A	78.57% (11/14)	N/A	100.0% (15/15)	N/A	80.0% (12/15)
Amikacin	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)
Aztreonam	96.67% (29/30)	96.67% (29/30)	93.1% (27/29)	100.0% (29/29)	100.0% (30/30)	100.0% (30/30)
Ertapenem	100.0% (24/24)	91.67% (22/24)	100.0% (24/24)	95.83% (23/24)	100.0% (23/23)	100.0% (23/23)
Gentamicin	100.0% (30/30)	100.0% (30/30)	93.33% (28/30)	100.0% (30/30)	96.67% (29/30)	100.0% (30/30)
Imipenem	100.0% (27/27)	100.0% (27/27)	96.15% (25/26)	100.0% (26/26)	100.0% (26/26)	100.0% (26/26)
Meropenem	100.0% (30/30)	100.0% (30/30)	96.67% (29/30)	100.0% (30/30)	100.0% (29/29)	100.0% (29/29)
Meropenem/Vaborbactam	100.0% (24/24)	100.0% (24/24)	95.65% (22/23)	100.0% (23/23)	100.0% (23/23)	100.0% (23/23)
Piperacillin/Tazobactam	93.33% (28/30)	93.33% (28/30)	96.67% (29/30)	93.33% (28/30)	100.0% (30/30)	100.0% (30/30)
Tobramycin	100.0% (30/30)	100.0% (30/30)	96.67% (29/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)
Trimethoprim/Sulfamethoxazole	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)
Amoxicillin/Clavulanate	100.0% (12/12)	100.0% (12/12)	100.0% (11/11)	100.0% (11/11)	100.0% (12/12)	100.0% (12/12)
Cefepime	100.0% (24/24)	100.0% (24/24)	100.0% (23/23)	100.0% (23/23)	100.0% (24/24)	100.0% (24/24)

BD BACTEC™ Plus Aerobic (RT)						
Antibiotic	T0		T8		T16	
	EA	CA	EA	CA	EA	CA
Ciprofloxacin	100.0% (24/24)	100.0% (24/24)	100.0% (23/23)	100.0% (23/23)	100.0% (24/24)	100.0% (24/24)
Levofloxacin	100.0% (24/24)	100.0% (24/24)	100.0% (23/23)	100.0% (23/23)	100.0% (24/24)	100.0% (24/24)
Tetracycline	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)

a. Categorical agreement due to *K. aerogenes* – ceftazidime at T0 in BD BACTEC™ Plus Aerobic bottles

b. Categorical agreement) due to *E. coli* – ESBL for all conditions except T8 (RT) in BD BACTEC™ Plus Aerobic bottles

All instances (a-b) resulted in an EA of 100% based on comparisons between the T0 and other timepoints obtained by the VITEK® REVEAL™ AST System.

Table 4c. Sample Stability Results for BACT/ALERT® FA PLUS Aerobic bottles (36-38°C)

BACT/ALERT® FA PLUS Aerobic (36-38°C)						
Antibiotic	T0		T8		T16	
	EA	CA	EA	CA	EA	CA
Ampicillin/Sulbactam	100.0% (18/18)	100.0% (18/18)	100.0% (18/18)	100.0% (18/18)	100.0% (18/18)	100.0% (18/18)
Cefotaxime	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)
Ceftazidime	100.0% (30/30)	90.0% (27/30)	100.0% (30/30)	90.0% (27/30)	100.0% (30/30)	90.0% (27/30)
Ceftazidime/Avibactam	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	96.3% (26/27)	100.0% (27/27)
Ceftolozane/Tazobactam	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)
Ceftriaxone	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)
Cefuroxime [a]	80.0% (12/15)	100.0% (15/15)	100.0% (15/15)	100.0% (15/15)	93.33% (14/15)	100.0% (15/15)
ESBL	N/A	100.0% (15/15)	N/A	100.0% (15/15)	N/A	93.33% (14/15)
Amikacin	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	90.0% (27/30)	90.0% (27/30)
Aztreonam	90.0% (27/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)
Ertapenem [b]	100.0% (24/24)	87.5% (21/24)	100.0% (24/24)	87.5% (21/24)	100.0% (23/23)	86.96% (20/23)
Gentamicin	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)
Imipenem	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)
Meropenem	100.0% (30/30)	100.0% (30/30)	96.67% (29/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)
Meropenem/Vaborbactam	91.67% (22/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)
Piperacillin/Tazobactam	100.0% (30/30)	90.0% (27/30)	96.67% (29/30)	100.0% (30/30)	90.0% (27/30)	96.67% (29/30)
Tobramycin	100.0% (29/29)	100.0% (29/29)	93.33% (28/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)
Trimethoprim/Sulfamethoxazole	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)
Amoxicillin/Clavulanate	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)
Cefepime	100.0% (24/24)	100.0% (24/24)	100.0% (23/23)	100.0% (23/23)	100.0% (24/24)	100.0% (24/24)
Ciprofloxacin	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)
Levofloxacin	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)
Tetracycline	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)

a. Essential agreement due to *E. coli* – cefuroxime at T0 in BACT/ALERT® FA PLUS bottles

b. Categorical agreement due to *E. cloacae* – ertapenem at T0, T8 (36-38°C), and T16 (36-38°C) in BACT/ALERT® FA PLUS bottles

All instances (a-b) resulted in an EA of 100% based on comparisons between the T0 and other timepoints obtained by the VITEK® REVEAL™ AST System.

Table 4d. Sample Stability Results for BACT/ALERT® FA PLUS Aerobic bottles (RT)

BACT/ALERT® FA PLUS Aerobic (RT)						
Antibiotic	T0		T8		T16	
	EA	CA	EA	CA	EA	CA
Ampicillin/Sulbactam	100.0% (18/18)	100.0% (18/18)	100.0% (18/18)	100.0% (18/18)	100.0% (18/18)	100.0% (18/18)
Cefotaxime	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)
Ceftazidime	100.0% (30/30)	90.0% (27/30)	100.0% (30/30)	90.0% (27/30)	100.0% (30/30)	90.0% (27/30)
Ceftazidime/Avibactam	100.0% (27/27)	100.0% (27/27)	96.3% (26/27)	96.3% (26/27)	100.0% (27/27)	100.0% (27/27)
Ceftolozane/Tazobactam	100.0% (27/27)	100.0% (27/27)	96.3% (26/27)	96.3% (26/27)	100.0% (26/26)	100.0% (26/26)
Ceftriaxone	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)
Cefuroxime [a]	80.0% (12/15)	100.0% (15/15)	86.67% (13/15)	100.0% (15/15)	80.0% (12/15)	100.0% (15/15)
ESBL	N/A	100.0% (15/15)	N/A	100.0% (15/15)	N/A	100.0% (15/15)
Amikacin	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)
Aztreonam	90.0% (27/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (29/29)	100.0% (29/29)
Ertapenem [b]	100.0% (24/24)	87.5% (21/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)
Gentamicin	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)
Imipenem	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)	100.0% (27/27)
Meropenem	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)
Meropenem/Vaborbactam	91.67% (22/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)
Piperacillin/Tazobactam	100.0% (30/30)	90.0% (27/30)	100.0% (30/30)	93.33% (28/30)	90.0% (27/30)	93.33% (28/30)
Tobramycin	100.0% (29/29)	100.0% (29/29)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)
Trimethoprim/Sulfamethoxazole	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)
Amoxicillin/Clavulanate	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)
Cefepime	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (23/23)	100.0% (23/23)
Ciprofloxacin	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)
Levofloxacin	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)	100.0% (24/24)
Tetracycline	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)	100.0% (12/12)

a. Essential agreement due to *E. coli* – cefuroxime at T0, T8 (RT), and T16 (RT) in BACT/ALERT® FA PLUS bottles

b. Categorical agreement due to *E. cloacae* – ertapenem at T0 in BACT/ALERT® FA PLUS bottles

All instances (a-b) resulted in an EA of 100% based on comparisons between the T0 and other timepoints obtained by the VITEK® REVEAL™ AST System.

Interfering Substances

The interfering substances study was performed to evaluate the effects of endogenous and exogenous substances that may be present in positive blood culture bottles on the performance of the VITEK® REVEAL™ GN AST Assay and VITEK® REVEAL™ AST System. Three (3) exogenous substances (anticoagulants) and six (6) endogenous substances were tested on the VITEK® REVEAL™ AST System (Table 5a) at higher concentrations than the concentrations found in a patient blood sample according to CLSI-EP07 and CLSI-EP37. The substances were prepared and added to pooled human blood to achieve the target concentration. Five (5) organisms (*E. coli, P. aeruginosa, K. pneumoniae, E. cloacae, A. baumannii*) were tested in triplicate BD BACTEC™ Aerobic Plus bottles in the presence of each interfering substance. Additionally, triplicate control bottles without the interferent were tested in parallel.

The VITEK® REVEAL™ MIC results for bottles containing interferent were compared to the modal MIC results of the control bottles without interferent. The samples met acceptance

criteria if the EA and CA were ≥95% when comparing the interferent-containing bottles to the control bottles. Overall, the EA and CA for each interferant tested across almost all organisms and antimicrobials were ≥95% when compared to the control samples (Table 5a). Eight antibiotic/interferent combinations did not meet EA acceptance criteria, however, further testing determined these low values were not caused by interference (Table 5b, 5c). These data suggest that the interferents tested do not impact performance of the VITEK® REVEAL™ GN AST Assay tested on the VITEK® REVEAL™ AST System.

Table 5a. Exogenous and Endogenous Interferent Results Summary

Interferent	Normal Concentrations	Concentration Tested	Overall performance	
			EA	CA
Exogenous substances				
Heparin	0.35-1 units/mL	≥3 units/mL	98.8% (255/258)	99.2% (262/264)
Sodium Citrate	3.2-3.8% w/v	>6% w/v	97.6% (244/250)	98.8% (253/256)
Sodium Polyanetholesulfonate	0.03-0.05% w/v	>2% w/v	98.4% (247/251)	99.2% (254/256)
Endogenous substances				
Conjugated bilirubin	0-0.0002 mg/mL	>0.02 mg/mL	100.0% (248/248)	98.8% (251/254)
Gamma-globulin	6-13 mg/mL	>20 mg/mL	100.0% (248/248)	99.6% (253/254)
Triglycerides	1.5-5 mg/mL	>15 mg/mL	99.6% (246/247)	98.0% (248/253)
Hemolysate (Hemoglobin)	100-200 mg/mL	>200 mg/mL	99.2% (247/249)	98.4% (251/255)
WBCs (Mononuclear cells)	$4.5X10^6 – 1.0X10^7$ /mL	>1.2 x 10^7/ mL	100% (245/245)	99.2% (249/251)
Platelets[a]	150,000 – 400,000/µL	>400,000/µL	99.8% (942/944)	98.9% (963/974)

[a] Fifteen-sixteen strains (including *K. oxytoca, K. aerogenes, C. koseri,* and *S. marcescens* strains) per antibiotic were tested for interference with platelets.

[*]Interference has not been established for the following antibiotic/organism combinations for all interferents, except platelets: Amoxicillin-clavulanate/Enterobacterales, Aztreonam/ Enterobacterales, Cefepime/ Enterobacterales, Ceftazidime/ Enterobacterales, Ceftriaxone/Enterobacterales, Ciprofloxacin/*P. aeruginosa,* levofloxacin/*P. aeruginosa,* Ertapenem/Enterobacterales, Imipenem/ Enterobacterales.

Table 5b. Essential and categorical agreement values of VITEK® REVEAL™ AST results for test blood cultures containing potential endogenous interfering substances

Endogenous Interferent	Conjugated bilirubin		Gamma-Globulin		Triglycerides		Hemolysate		Mononuclear Cells	
Antibiotic	EA	CA	EA	CA	EA	CA	EA	CA	EA	CA
Amikacin	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)
Amoxicillin / clavulanate	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)
Ampicillin / sulbactam	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)
Aztreonam	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	91.67% (11/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)
Cefepime	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)
Cefotaxime	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)
Ceftazidime[a]	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	86.67% (13/15)	100% (15/15)	93.33% (14/15)	100% (15/15)	100% (15/15)	100% (15/15)

Ceftazidime / avibactam[b]	100% (11/11)	100% (11/11)	100% (11/11)	100% (11/11)	100% (11/11)	100% (11/11)	91.67% (11/12)	91.67% (11/12)	100% (12/12)	100% (12/12)
Ceftolozane / tazobactam	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)
Ceftriaxone	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (8/8)	100% (8/8)
Cefuroxime	100% (6/6)	100% (6/6)	100% (6/6)	100% (6/6)	100% (6/6)	100% (6/6)	100% (6/6)	100% (6/6)	100% (6/6)	100% (6/6)
Ciprofloxacin	100% (12/12)	91.67% (11/12)	100% (12/12)	91.67% (11/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)
Ertapenem	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (8/8)	100% (8/8)	100% (9/9)	100% (9/9)	100% (8/8)	100% (8/8)
ESBL Confirmation	-	100% (6/6)	-	100% (6/6)	-	100% (6/6)	-	100% (6/6)	-	100% (6/6)
Gentamicin	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)
Imipenem	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)
Levofloxacin	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	75% (9/12)	100% (12/12)	75% (9/12)	100% (12/12)	83.33% (10/12)
Meropenem	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)
Meropenem / vaborbactam[c]	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	88.89% (8/9)	88.89% (8/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)
Piperacillin / tazobactam	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)
Tetracycline	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)
Tobramycin	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)
Trimethoprim / sulfamethoxazole	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)
Overall performance	100.0% (248/248)	98.8% (251/254)	100.0% (248/248)	99.6% (253/254)	99.6% (246/247)	98.0% (248/253)	99.2% (247/249)	98.4% (251/255)	100% (245/245)	99.2% (249/251)

[a.] Ceftazidime in the presence of hemolysate (RBC) and triglycerides (LPD) had an EA < 95% for *K. pneumoniae*. In each instance, one replicate was out of EA yet was within category agreement (CA), and thus is not expected to impact patient care. In addition, variable MIC values were attributed to this strain's growth pattern detection by the system. This is noted in a footnote in the device labeling.
[b.] Ceftazidime/Avibactam in the presence of hemolysate (RBC) had an EA <95% for *P. aeruginosa* due to one replicate being out of EA. However, this result is within category agreement (CA), and thus is not expected to impact patient care. This is noted in a footnote in the device labeling.
[c.] Meropenem/Vaborbactam in the presence of triglycerides (LPD) had an EA <95% for *E. cloacae* due to one replicate being out of EA. Upon repeat testing, the EA was found to be 100% This is noted in a footnote in the device labeling.

Table 5c. Essential and categorical agreement values of VITEK® REVEAL™ AST results for test blood cultures containing potential exogenous interfering substances

Exogenous Interferent	**Heparin**		**Sodium Citrate**		**Sodium Polyanetholesulfonate**	
Antibiotic	**EA**	**CA**	**EA**	**CA**	**EA**	**CA**
Amikacin	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)
Amoxicillin / clavulanate	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (9/9)	100% (9/9)
Ampicillin / sulbactam	100% (9/9)	88.89% (8/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)

Aztreonam	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)
Cefepime	100% (11/11)	100% (11/11)	100% (11/11)	100% (11/11)	100% (12/12)	100% (12/12)
Cefotaxime	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)
Ceftazidime[a]	100% (15/15)	100% (15/15)	80% (12/15)	100% (15/15)	100% (15/15)	100% (15/15)
Ceftazidime / avibactam	100% (11/11)	100% (11/11)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)
Ceftolozane / tazobactam	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)
Ceftriaxone[b]	88.89% (8/9)	88.89% (8/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)
Cefuroxime	100% (6/6)	100% (6/6)	100% (6/6)	100% (6/6)	100% (6/6)	100% (6/6)
Ciprofloxacin	100% (11/11)	100% (11/11)	100% (11/11)	100% (11/11)	100% (12/12)	100% (12/12)
Ertapenem	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)
ESBL Confirmation	-	100% (6/6)	-	100% (6/6)	-	100% (6/6)
Gentamicin	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)
Imipenem	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)
Levofloxacin	100% (12/12)	100% (12/12)	100% (11/11)	72.73% (8/11)	100% (10/10)	80% (8/10)
Meropenem[c]	93.33% (14/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)
Meropenem / vaborbactam[d]	88.89% (8/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)
Piperacillin / tazobactam	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)	100% (15/15)
Tetracycline	100% (8/8)	100% (8/8)	100% (8/8)	100% (8/8)	100% (9/9)	100% (9/9)
Tobramycin	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)	100% (12/12)
Trimethoprim / sulfamethoxazole	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)	100% (9/9)
Overall performance	98.8% (255/258)	99.2% (262/264)	97.6% (244/250)	98.8% (253/256)	98.4% (247/251)	99.2% (254/256)

[a.] Ceftazidime in the presence of, sodium citrate had an EA <95% for *K. pneumoniae*. One replicate was out of EA yet was within category agreement (CA), and thus is not expected to impact patient care. In addition, variable MIC values were attributed to this strain's growth pattern detection by the system. This is noted in a footnote in the device labeling.

[b.] Ceftriaxone in the presence of heparin had an EA <95% for *K. pneumoniae*. The low EA was due to one replicate being out of EA. Upon repeat testing, the EA was found to be 100%. This is noted in a footnote in the device labeling.

[c.] Meropenem in the presence of heparin had an EA <95% for *K. pneumoniae* due to one replicate being out of EA. However, this result is within category agreement (CA), and thus is not expected to impact patient care. This is noted in a footnote in the device labeling.

[d.] Meropenem/Vaborbactam in the presence of heparin had an EA <95% for *K. pneumoniae* due to one replicate being out of EA. However, this result is within category agreement (CA), and thus is not expected to impact patient care. This is noted in a footnote in the device labeling.

Interfering Antibiotics

The interfering antibiotics study was performed to evaluate the effects of antimicrobial substances that may be present in positive blood cultures (from bottles not containing antibiotic-inactivating resin) on the performance of the VITEK® REVEAL™ GN AST Assay and

the VITEK® REVEAL™ AST System. One (1) antibiotic from nine (9) of the main classes of antibiotics that target Gram-negative organisms was tested as the interfering agent. The antibiotics were prepared according to CLSI-M100 and then added to pooled human blood to achieve the target concentration. Antibiotic concentrations for testing were chosen based on antibiotic package insert information for the highest concentrations found in blood during treatment or CLSI-EP37 (three times the highest concentration when a resistant strain was available for testing). A minimum of one (1) Gram-negative strain resistant to each interfering antimicrobial was tested in triplicate in BD BACTEC™ Standard aerobic bottles, which do not contain resins and do not have neutralization capabilities. Triplicate control bottles containing the organism without the antimicrobial interferant were tested in parallel.

The VITEK® REVEAL™ MIC results for bottles containing interferent were compared to the modal MIC results of the control bottles without interferent. Overall, the EA for each interfering antimicrobial tested was ≥97% and the CA was ≥97% when compared to the control samples, meeting the overall acceptance criteria of ≥95% (Table 6). Potential interference was observed with ampicillin/sulbactam with one strain of *E. coli*; however, the interference was not replicated when testing a different strain or a different antimicrobial from the same class. Therefore, it was concluded that the interference was strain specific.

Table 6. Interfering Antibiotic Results Summary

Antimicrobial Class	Interferent	Test Concentration [µg/ml]	Overall performance	
			EA	CA
Penicillins	Ampicillin	75 [a]	100.0% (66/66)	97.1% (67/69)
β-lactam combination agents	Ampicillin/sulbactam	150 Ampicillin / 88 sulbactam [b]	97.0% (255/263)	97.0% (261/269)
Monobactams	Aztreonam	242[c]	100.0% (119/119)	100.0% (121/121)
Cephalosporins	Cefotaxime	176[c]	100.0% (92/92)	100.0% (92/92)
Carbapenems	Meropenem	113 [c]	100.0% (89/89)	100.0% (89/89)
Fluoroquinolones	Ciprofloxacin	12[a]	100.0% (130/130)	100.0% (130/130)
Folate Synthesis Inhibitor	Trimethoprim/ sulfamethoxazole	8.8 Trimethoprim / 106 sulfamethoxazole[b]	100.0% (89/89)	100.0% (89/89)
Tetracyclines	Tetracycline	24 [a]	100.0% (72/72)	97.2% (70/72)
Aminoglycosides	Gentamicin	30[a]	100.0% (47/47)	100.0% (47/47)

[a] Recommended test concentration-3X conc. under therapeutic treatment (CLSI EP37)

[b] Mean peak serum concentration during therapeutic treatment (Drug packet insert)

[c] Highest concentration under therapeutic treatment (CLSI EP37)

Carryover and Cross-talk

The carryover and cross-talk studies were performed to demonstrate the effectiveness of the VITEK® REVEAL™ GN AST Assay seal by evaluating whether volatile organic compounds

(VOCs) are exchanged between individual wells within the VITEK® REVEAL™ GN AST Assay (cross-talk) or from assay to assay run on the same VITEK® REVEAL™ Instrument (carryover).

The cross-talk testing was performed using five (5) species (*E. coli*, *K. pneumoniae*, *P. aeruginosa*, *P. mirabilis*, and *A. baumannii*), contrived in blood culture bottles and grown to positivity. Blank 96-well plates were inoculated in a checkerboard pattern with alternating media-only wells and wells with diluted positive blood culture. Organisms were tested in an alternating pattern over 20 days with four (4) total replicates per organism. The sensor response was evaluated in each media-only well for evidence of growth, indicating cross-talk from organism containing wells. The overall rate of cross-talk as evidenced by growth was 0.1% (1/960), meeting the defined acceptance criteria of <0.3% growth, demonstrating seal effectiveness.

To test system carryover, blank 96-well panels containing media alone were tested on VITEK® REVEAL™ Instruments that had been previously used to test VITEK® REVEAL™ GN AST Assays inoculated with contrived positive blood cultures. Testing was performed with a single replicate of a media-only panel over 20 days on 20 VITEK® REVEAL™ Instruments. The sensor response was evaluated in the media-only wells for evidence of growth, indicating carryover from previous VITEK® REVEAL™ GN AST Assays. The overall rate of carryover as evidenced by growth was 0.1% (1/1920), meeting the defined acceptance criteria of <0.3% growth, demonstrating seal effectiveness.

Initial Inoculum

The initial inoculum study was performed to demonstrate that the concentration of bacteria in a patient blood sample inoculated into a blood culture bottle does not impact the final bacterial concentration of the positive blood culture or VITEK® REVEAL™ GN AST Assay results. Testing was performed using five (5) species inoculated into blood culture bottles at three (3) different starting concentrations spanning five (5) orders of magnitude (75,000, 750, and 7.5 CFU). Testing at each initial inoculum concentration was performed in triplicate blood culture bottles for each species evaluated.

The concentrations (CFU/mL) were calculated for all suspensions at the time of inoculation and within two hours of bottle positivity. The final concentration at positivity met the defined acceptance criteria if the average final concentration for each initial inoculum was within one log of the average final concentrations of the other starting inocula. The results demonstrate that regardless of the concentration of the initial inoculum, the final concentrations of the positive blood culture bottles were comparable (+/- 1 log) (Table 7).

Table 7. Average Initial Inoculum Concentrations and Final Bacterial Concentrations at Bottle Positivity

Organism	Initial Inoculum Dilution	Average Initial CFU	Average Final CFU/mL
A. baumannii	1:2,000	7.44E+04	5.66E+08
	1:20,0000	7.44E+02	1.03E+08
	1:20,000,000	3.76E+00	1.94E+08
P. aeruginosa	1:2,000	3.38E+04	1.00E+09
	1:200,000	5.55E+02	7.72E+08
	1:20,000,000	2.03E+00	2.28E+08
E. cloacae	1:2,000	6.89E+04	1.64E+08
	1:200,000	4.45E+02	1.85E+08
	1:20,000,000	3.48E+00	1.75E+08
K. pneumoniae	1:2,000	5.66E+04	2.77E+08
	1:200,000	5.77E+02	1.36E+08
	1:20,000,000	2.86E+00	1.63E+08
E. coli	1:2,000	7.00E+04	1.47E+08
	1:200,000	6.89E+02	3.50E+08
	1:20,000,000	3.54E+00	2.62E+08

The individual MICs determined by the VITEK® REVEAL™ AST System were compared against the reference (BMD) modal MICs. Both essential and categorical agreement were determined for each antibiotic/strain at each initial inoculum concentration. The EA and CA of each concentration compared against BMD was 100%, meeting the acceptance criteria of > 89.9%. Additionally, the VITEK® REVEAL™ MICs for each replicate were compared against the MICs of the other initial inoculum bottles. All results were within ± 1 doubling dilution of each other for all the initial inoculum concentrations, demonstrating that the initial inoculum concentration does not impact VITEK® REVEAL™ AST results.

Method Comparison Study

The purpose of the method comparison study was to evaluate the clinical performance of the VITEK® REVEAL™ GN AST Assay on the VITEK® REVEAL™ AST System in providing quantitative and qualitative antimicrobial susceptibility testing (AST) results from positive blood cultures containing Gram-negative bacteria. AST results (MICs and categorical interpretations) generated by the VITEK® REVEAL™ AST System were compared to results from reference frozen broth microdilution (BMD), tested according to CLSI M07 (11th Edition) Standard. Samples enrolled in the study included leftover, deidentified clinical positive blood culture samples (fresh prospective) and contrived positive blood culture samples, contrived with either clinical stock or challenge isolates.

Sample enrollment and VITEK® REVEAL™ testing were conducted at seven (7) US clinical sites. Five clinical sites tested prospectively collected, fresh samples defined as leftover, de-identified positive clinical blood culture samples from patients suspected of bacteremia.

Samples were confirmed by Gram stain to contain only Gram-negative bacteria prior to testing on the VITEK® REVEAL™ AST System. Organism identification by an FDA-cleared rapid ID method was required as input into the VITEK® REVEAL™ AST System for AST result generation. Select sites also tested clinical stock isolates from the site's inventory and provided challenge isolates for lower prevalence microorganism-antimicrobial agent combinations. Stock and contrived isolates were contrived in blood culture bottles with human donor blood added and incubated on a continuous monitoring blood culture system until positivity. All positive blood cultures were subcultured to blood agar plates, and the organism identification for all samples was confirmed by an FDA-cleared MALDI ID method.

All reference BMD testing was conducted at a reference testing laboratory. BMD testing was performed in triplicate on custom, 96-well, frozen microdilution plates prepared by the reference testing laboratory. Each isolate was tested in triplicate on BMD panels. Reference BMD testing was performed in accordance with CLSI M07 *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically*.

The performance of the VITEK® REVEAL™ AST System was determined by comparing the modal MIC results of the reference method to the results of the investigational device. Agreement and acceptance criteria were defined based on FDA guidance (Class II Special Controls Document: Antimicrobial Susceptibility Test (AST) Systems) for each antimicrobial agent. For susceptibility, the primary endpoints are Essential Agreement (EA), Categorical Agreement (CA) and error rates for each antimicrobial agent across all organisms in the intended use. Evaluable organisms for EA are those with MIC results that are within the on-scale test range of both the investigational device and the reference method. Essential agreement was determined by comparing MIC as determined by the investigational device to modal MIC as determined by reference BMD testing. Categorial agreement was assessed using FDA-recognized breakpoints (Antimicrobial Susceptibility Test Interpretive Criteria).

A total of 1239 samples were enrolled in the study, including 480 fresh prospective positive blood culture samples, 106 samples from positive blood cultures contrived with clinical stock isolates, and 653 samples contrived with challenge isolates. In total, 124 samples were excluded from final performance analyses due to not meeting inclusion criteria, invalid QC results, or other protocol deviations, as defined below. A total of 1115 samples were included in final performance analyses including 424 fresh prospective positive blood cultures, 101 contrived samples with clinical stock isolates, and 590 contrived samples with challenge isolates.

Table 8 below summarizes the overall AST performance by breakpoint group for all antimicrobials on the VITEK® REVEAL™ GN AST Assay. This summary includes clinical samples (fresh prospective and contrived stock isolates) and contrived challenge isolates. Overall agreement was high; results not in essential or categorical agreement are noted in the

individual antimicrobial summaries below. A trending analysis for all indicated species is provided in Table 9.

Table 8. Summary of VITEK® REVEAL™ Results, All Species

Sample Type	Total	# EA	% EA	Total Eval	# EA Eval	% EA Eval	# CA	% CA	# S	# R	# vmj	# maj	# min
Amikacin													
Enterobacterales													
Clinical	443	434	98.0%	421	412	97.9%	442	99.8%	441	1	0	0	1
Challenge	188	185	98.4%	146	143	97.9%	185	98.4%	147	37	0	0	3
Combined	631	619	98.1%	567	555	97.9%	627	99.4%	588	38	0	0	4
***A. baumannii-calcoaceticus* complex**													
Clinical	13	9	69.2%	12	8	66.7%	12	92.3%	11	2	0	0	1
Challenge	47	45	95.7%	37	35	94.6%	41	87.2%	29	13	0	0	6
Combined	60	54	90.0%	49	43	87.8%	53	88.3%§	40	15	0	0	7
P. aeruginosa													
Clinical	27	26	96.3%	26	25	96.2%	27	100.0%	27	0	0	0	0
Challenge	38	36	94.7%	24	22	91.7%	35	92.1%	11	24	0	0	3
Combined	65	62	95.4%	50	47	94.0%	62	95.4%	38	24	0	0	3
Amoxicillin/clavulanate													
Enterobacterales													
Clinical	370	361	97.6%	156	147	94.2%	338	91.4%	347	8	0	3	29
Challenge	130	114	87.7%	67	51	76.1%	116	89.2%	61	59	0	0	14
Combined	500	475	95.0%	223	198	88.8%	454	90.8%	408	67	0	3	43
Ampicillin/sulbactam													
Enterobacterales													
Clinical	286	280	97.9%	142	136	95.8%	219	76.6%	221	25	0	1	66
Challenge	86	84	97.7%	39	37	94.9%	68	79.1%	31	40	0	2	16
Combined	372	364	97.8%	181	173	95.6%	287	77.2%§	252	**65**	0	3	82
Aztreonam													
Enterobacterales													
Clinical	374	366	97.9%	55	47	85.5%	364	97.3%	314	51	0	2	8
Challenge	156	150	96.2%	38	32	84.2%	145	92.9%	58	90	0	1	10
Combined	530	516	97.4%	93	79	84.9%	543	96.0%	372	141	0	3	18
P. aeruginosa													
Clinical	27	26	96.3%	26	25	96.2%	25	92.6%	23	4	0	0	2
Challenge	38	37	97.4%	25	24	96.0%	31	81.6%	14	18	0	0	7
Combined	65	63	96.9%	51	49	96.1%	56	86.2%§	37	22	0	0	9
Cefepime													
Enterobacterales													
Clinical	397	384	96.7%	52	39	75.0%	384	96.7%	344	42	0	2	11
Challenge	182	172	94.5%	64	54	84.4%	171	94.0%	88	77	0	1	10
Combined	579	556	96.0%	116	93	80.2%	555	95.9%	432	119	0	3	21
P. aeruginosa													
Clinical	28	26	92.9%	28	26	92.9%	27	96.4%	26	2	0	1	0
Challenge	38	38	100.0%	18	18	100.0%	37	97.4%	7	31	0	1	0
Combined	66	64	97.0%	46	44	95.7%	64	97.0%	33	33	0	2	0
Cefotaxime													
Enterobacterales													
Clinical	381	374	98.2%	24	17	70.8%	379	99.5%	313	68	0	0	2
Challenge	173	165	95.4%	42	34	81.0%	170	98.3%	56	115	0	2	1

Sample Type	Total	# EA	% EA	Total Eval	# EA Eval	% EA Eval	# CA	% CA	# S	# R	# vmj	# maj	# min
Combined	554	539	97.3%	66	51	77.3%	549	99.1%	369	183	0	2	3
A. baumannii-calcoaceticus* complex													
Clinical	13	13	100.0%	9	9	100.0%	13	100.0%	0	13	0	0	0
Challenge	25	25	100.0%	5	5	100.0%	25	100.0%	0	25	0	0	0
Combined	38	38	100.0%	14	14	100.0%	38	100.0%	0	38	0	0	0
Ceftazidime													
Enterobacterales													
Clinical	398	381	95.7%	118	101	85.6%	384	96.5%	339	51	0	1	13
Challenge	182	172	94.5%	57	47	82.5%	179	98.4%	74	106	0	0	3
Combined	580	553	95.3%	175	148	84.6%	563	97.1%	413	157	0	1	16
***A. baumannii-calcoaceticus* complex**													
Clinical	13	12	92.3%	9	8	88.9%	12	92.3%	9	4	0	0	1
Challenge	26	26	100.0%	12	12	100.0%	25	96.2%	3	21	0	0	1
Combined	39	38	97.4%	21	20	95.2%	37	94.9%	12	25	0	0	2
Ceftazidime/avibactam													
Enterobacterales													
Clinical	421	408	96.9%	176	163	92.6%	420	99.8%	420	1	0	1	N/A
Challenge	203	189	93.7%	126	112	88.9%	202	99.5%	150	53	1	0	N/A
Combined	624	597	95.7%	302	275	91.1%	692	99.7%	570	54	1	1	N/A
P. aeruginosa													
Clinical	28	28	100.0%	27	27	100.0%	28	100.0%	27	1	0	0	N/A
Challenge	65	63	96.9%	44	42	95.5%	63	96.9%	39	26	0	2	N/A
Combined	93	91	97.8%	71	69	97.2%	91	97.8%	66	27	0	2	N/A
Ceftolozane/tazobactam													
Enterobacterales													
Clinical	346	313	90.5%	321	288	89.7%	339	98.0%	336	8	1	1	5
Challenge	164	161	98.2%	127	124	97.6%	159	97.0%	100	59	0	0	5
Combined	510	474	92.9%	448	412	92.0%	498	97.6%	436	67	1	1	10
P. aeruginosa													
Clinical	28	28	100.0%	28	28	100.0%	27	96.4%	27	0	0	0	1
Challenge	38	38	100.0%	10	10	100.0%	38	100.0%	10	28	0	0	0
Combined	66	66	100.0%	38	38	100.0%	65	98.5%	37	28	0	0	1
Ceftriaxone													
Enterobacterales													
Clinical	394	390	99.0%	10	6	60.0%	392	99.5%	326	65	0	1	1
Challenge	232	218	94.0%	48	34	70.8%	213	91.8%	79	135	0	2	17
Combined	626	608	97.1%	58	40	69.0%	605	96.6%	405	200	0	3	18
Cefuroxime													
Enterobacterales													
Clinical	384	368	95.8%	274	258	94.2%	374	97.4%	316	68	1	9	N/A
Challenge	138	132	95.7%	60	54	90.0%	134	97.1%	57	81	0	4	N/A
Combined	522	500	95.8%	334	312	93.4%	508	97.3%	373	149	1	13	N/A
Ciprofloxacin													
Enterobacterales													
Clinical	464	461	99.4%	60	57	95.0%	448	96.6%	367	92	0	0	16
Challenge	217	213	98.2%	62	58	93.5%	203	93.5%	96	109	1	1	12
Combined	681	674	99.0%	122	115	94.3%	651	95.6%	463	201	1	1	28
P. aeruginosa													
Clinical	28	23	82.1%	14	9	64.3%	26	92.9%	25	2	0	1	1
Challenge	42	42	100.0%	4	4	100.0%	42	100.0%	8	34	0	0	0

Sample Type	Total	# EA	% EA	Total Eval	# EA Eval	% EA Eval	# CA	% CA	# S	# R	# vmj	# maj	# min
Combined	70	65	92.9%	18	13	72.2%	68	97.1%	33	36	0	1	1
Ertapenem													
Enterobacterales													
Clinical	368	363	98.6%	12	7	58.3%	366	99.5%	361	5	0	1	1
Challenge	125	119	95.2%	16	10	62.5%	121	96.8%	61	62	0	0	4
Combined	493	482	97.8%	28	17	60.7%	487	98.8%	422	67	0	1	5
Gentamicin													
Enterobacterales													
Clinical	458	445	97.2%	315	302	95.9%	453	98.9%	419	38	1	1	3
Challenge	226	216	95.6%	123	113	91.9%	219	96.9%	159	61	0	1	6
Combined	684	661	96.6%	438	415	94.7%	672	98.2%	578	99	1	2	9
P. aeruginosa													
Clinical	27	27	100.0%	26	26	100.0%	26	96.3%	25	0	0	0	1
Challenge	38	36	94.7%	14	12	85.7%	36	94.7%	7	27	0	0	2
Combined	65	63	96.9%	40	38	95.0%	62	95.4%	32	27	0	0	3
Imipenem													
Enterobacterales													
Clinical	402	397	98.8%	41	36	87.8%	400	99.5%	395	5	0	0	2
Challenge	170	164	96.5%	55	49	89.1%	159	93.5%	92	68	0	0	11
Combined	572	561	98.1%	96	85	88.5%	559	97.7%	487	73	0	0	13
***A. baumannii-calcoaceticus* complex**													
Clinical	13	12	92.3%	2	1	50.0%	12	92.3%	8	5	0	0	1
Challenge	32	32	100.0%	8	8	100.0%	30	93.8%	7	21	0	0	2
Combined	45	44	97.8%	10	9	90.0%	42	93.3%	15	26	0	0	3
P. aeruginosa													
Clinical	27	24	88.9%	26	23	88.5%	23	85.2%	21	4	2	0	2
Challenge	38	37	97.4%	9	8	88.9%	38	100.0%	1	37	0	0	0
Combined	65	61	93.8%	35	31	88.6%	61	93.8%	22	41	2	0	2
Levofloxacin													
Enterobacterales													
Clinical	481	476	99.0%	105	100	95.2%	469	97.5%	385	88	1	0	11
Challenge	243	242	99.6%	93	92	98.9%	228	93.8%	115	109	0	0	15
Combined	724	718	99.2%	198	192	97.0%	697	96.3%	500	197	1	0	26
P. aeruginosa													
Clinical	28	27	96.4%	25	24	96.0%	26	92.9%	24	2	0	1	1
Challenge	46	45	97.8%	14	13	92.9%	44	95.7%	10	35	0	0	2
Combined	74	72	97.3%	39	37	94.9%	70	94.6%	34	37	0	1	3
Meropenem													
Enterobacterales													
Clinical	406	399	98.3%	19	12	63.2%	403	99.3%	402	4	0	2	1
Challenge	206	196	95.1%	72	62	86.1%	200	97.1%	132	71	0	1	5
Combined	612	595	97.2%	91	74	81.3%	603	98.5%	534	75	0	3	6
***A. baumannii-calcoaceticus* complex**													
Clinical	13	12	92.3%	10	9	90.0%	13	100.0%	8	5	0	0	0
Challenge	48	43	89.6%	31	26	83.9%	46	95.8%	21	25	0	0	2
Combined	61	55	90.2%	41	35	85.4%	59	96.7%	29	30	0	0	2
P. aeruginosa													
Clinical	27	26	96.3%	26	25	96.2%	25	92.6%	24	1	0	0	2
Challenge	38	37	97.4%	16	15	93.8%	35	92.1%	3	30	0	0	3
Combined	65	63	96.9%	42	40	95.2%	60	92.3%	27	31	0	0	5
Meropenem/vaborbactam													

Sample Type	Total	# EA	% EA	Total Eval	# EA Eval	% EA Eval	# CA	% CA	# S	# R	# vmj	# maj	# min
Enterobacterales													
Clinical	437	432	98.9%	10	5	50.0%	436	99.8%	436	1	0	0	1
Challenge	255	240	94.1%	80	65	81.2%	242	94.9%	199	52	0	0	13
Combined	692	672	97.1%	90	70	77.8%	678	98.0%	635	53	0	0	14
Piperacillin/tazobactam													
Enterobacterales													
Clinical	358	336	93.9%	46	24	52.2%	344	96.1%	338	13	1	3	10
Challenge	131	127	97.0%	28	24	85.7%	120	91.6%	63	59	0	1	10
Combined	489	463	94.7%	74	48	64.9%	464	94.9%	401	72	1	4	20
Tetracycline													
Enterobacterales													
Clinical	365	359	98.4%	112	106	94.6%	359	98.4%	281	81	0	3	3
Challenge	148	146	98.6%	77	75	97.4%	139	93.9%	75	69	0	0	9
Combined	513	505	98.4%	189	181	95.8%	498	97.1%	356	150	0	3	12
***A. baumannii-calcoaceticus* complex**													
Clinical	13	13	100.0%	6	6	100.0%	13	100.0%	6	5	0	0	0
Challenge	26	26	100.0%	4	4	100.0%	26	100.0%	1	25	0	0	0
Combined	39	39	100.0%	10	10	100.0%	39	100.0%	7	30	0	0	0
Tobramycin													
Enterobacterales													
Clinical	462	445	96.3%	458	441	96.3%	437	94.6%	420	31	2	1	22
Challenge	195	189	96.9%	150	144	96.0%	186	95.4%	112	78	1	0	8
Combined	657	634	96.5%	608	585	96.2%	623	94.8%	532	109	3	1	30
P. aeruginosa													
Clinical	27	27	100.0%	27	27	100.0%	27	100.0%	27	0	0	0	0
Challenge	38	38	100.0%	8	8	100.0%	38	100.0%	7	31	0	0	0
Combined	65	65	100.0%	35	35	100.0%	65	100.0%	34	31	0	0	0
Trimethoprim/sulfamethoxazole													
Enterobacterales													
Clinical	338	326	96.4%	15	3	20.0%	331	97.9%	258	80	2	5	N/A
Challenge	142	130	91.5%	23	11	47.8%	132	93.0%	67	75	1	9	N/A
Combined	480	456	95.0%	38	14	36.8%	463	96.5%	325	155	3	14	N/A
ESBL Confirmation													
Enterobacterales													
Clinical	340	N/A	N/A	N/A	N/A	N/A	338	99.4%	287	53	1	1	N/A
Challenge	68	N/A	N/A	N/A	N/A	N/A	64	94.1%	49	19	0	4	N/A
Combined	408	N/A	N/A	N/A	N/A	N/A	402	98.5%	336	72	1	5	N/A

§ Low category agreement was due to the occurrence of a high number of minor errors.

* No cefotaxime susceptible strains were evaluated for *A. baumannii-calcoaceticus* complex. Cefotaxime susceptibility is rare in *A. baumannii-calcoaceticus* complex

Amikacin

A total of 756 samples were evaluated with amikacin including 631 Enterobacterales species (299 *E. coli*, 123 *K. pneumoniae* group, 40 *K. oxytoca*, 48 *K. aerogenes*, 39 *E. cloacae* complex, 23 *C. freundii* complex, 31 *P. mirabilis*, 28 *S. marcescens*), 60 *A. baumannii-calcoaceticus* complex strains, and 65 *P. aeruginosa* strains.

The overall performance for Enterobacterales species met defined acceptance criteria with EA of 98.1% and CA of 99.4%, with no very major or major errors.

The overall performance for *A. baumannii-calcoaceticus* complex resulted in EA of 90.0% and CA of 88.3%, due to all minor errors. Low CA is addressed by the following limitation in product labeling:

For Amikacin, perform an alternative method of testing prior to reporting of results for A. baumannii-calcoaceticus complex when the MIC is 32 µg/mL due to the occurrence of minor errors that were in essential agreement, resulting in a category agreement below 90%.

The overall performance for *P. aeruginosa* met defined acceptance criteria, with EA of 95.4% and CA of 95.4%. There were no very major or major errors.

The following statements are added to the AST performance table in product labeling to address trending:

VITEK® REVEAL™ amikacin MIC values for C. freundii complex, K. oxytoca, and P. aeruginosa tended to be exact match or at least one doubling dilution lower than the reference method.

VITEK® REVEAL™ amikacin MIC values for S. marcescens tended to be exact match or at least one doubling dilution higher than the reference method.

Amoxicillin/clavulanate

A total of 500 samples were evaluated with amoxicillin/clavulanate, all Enterobacterales species (302 *E. coli*, 124 *K. pneumoniae* group, 41 *K. oxytoca*, and 33 *P. mirabilis*).

The overall performance for Enterobacterales species met defined acceptance criteria with EA of 95.0% and CA of 90.8%. There were no very major errors and three major errors. CA for *E. coli* was 88.1% due to a majority of minor errors. Low CA is addressed by the following limitation in product labeling:

For Amoxicillin/Clavulanate, perform an alternative method of testing prior to reporting of results for E. coli when the MIC is 16 µg/mL due to the occurrence of minor errors that were in essential agreement, resulting in a category agreement below 90%.

The following statement is added to the AST performance table in product labeling to address trending:

VITEK® REVEAL™ amoxicillin/clavulanate MIC values for E. coli, K. pneumoniae group, and P. mirabilis tended to be exact match or at least one doubling dilution higher than the reference method.

Ampicillin/sulbactam

A total of 372 samples were evaluated with ampicillin/sulbactam, all Enterobacterales species (300 *E. coli*, 40 *K. oxytoca*, and 32 *P. mirabilis*).

The overall performance for Enterobacterales species resulted in EA of 97.8% and CA of 77.2%. There were no very major errors and three major errors. CA for *E. coli* was 77.1% due to primarily minor errors, and CA for *K. oxytoca* was 65.0% due to all minor errors. As the evaluable EA was high (94.3% and 100.0%, respectively), performance for *E. coli* and *K. oxytoca* is considered acceptable.

The following statement is added to the AST performance table in product labeling to address trending:

VITEK® REVEAL™ ampicillin/sulbactam MIC values for E. coli tended to be exact match or at least one doubling dilution higher than the reference method.

Aztreonam

A total of 595 samples were evaluated with aztreonam, including 530 Enterobacterales species (295 *E. coli*, 127 *K. pneumoniae* group, 43 *K. oxytoca*, 39 *E. cloacae* complex, 26 *C. freundii* complex) and 65 *P. aeruginosa* strains.

The overall performance for Enterobacterales species met defined acceptance criteria with EA of 97.4% and CA of 96.0%. There were no very major errors and three major errors.

The overall performance for *P. aeruginosa* met defined acceptance criteria for EA, with EA of 96.9%. CA was 86.2% due to all minor errors. As the evaluable EA was high (96.1%), performance for *P. aeruginosa* is considered acceptable.

The following statements are added to the AST performance table in product labeling to address trending:

VITEK® REVEAL™ aztreonam MIC values for E. coli, K. oxytoca and *P. aeruginosa tended to be exact match or at least one doubling dilution lower than the reference method.*

Cefepime

A total of 645 samples were evaluated with cefepime, including 579 Enterobacterales species (301 *E. coli*, 121 *K. pneumoniae* group, 40 *K. oxytoca*, 46 *K. aerogenes*, 35 *E. cloacae* complex, 36 *C. koseri*) and 66 *P. aeruginosa* strains.

The overall performance for Enterobacterales species met defined acceptance criteria with EA of 96.0% and CA of 95.9%. There were no very major errors and three major errors. CA for *E. cloacae* complex was 88.6% due to all minor errors. As the evaluable EA was high (94.4%), performance for *E. cloacae* complex is considered acceptable.

The overall performance for *P. aeruginosa* resulted in EA of 97.0% and CA of 97.0%. There were no very major errors and two major errors. Since there is no intermediate category for *P. aeruginosa*, and both major errors were within essential agreement, this resulted in an acceptable adjusted major error rate.

The following statements are added to the AST performance table in product labeling to address trending:

VITEK® REVEAL™ cefepime MIC values for E. cloacae complex tended to be exact match or at least one doubling dilution higher than the reference method.

Cefotaxime

A total of 592 samples were evaluated with cefotaxime, including 554 Enterobacterales species (303 *E. coli*, 123 *K. pneumoniae* group, 42 *K. oxytoca*, 47 *K. aerogenes*, 39 *E. cloacae* complex) and 38 *A. baumannii-calcoaceticus* complex strains.

The overall performance for Enterobacterales species met defined acceptance criteria with EA of 97.3% and CA of 99.1%. There were no very major errors and two major errors.

The overall performance for *A. baumannii-calcoaceticus* complex met defined acceptance criteria with EA of 100.0% and CA of 100.0%. No cefotaxime susceptible strains were evaluated. Cefotaxime susceptibility is rare in *A. baumannii-calcoaceticus* complex.

The following statements are added to the AST performance table in product labeling to address trending:

VITEK® REVEAL™ cefotaxime MIC values for K. aerogenes and A. baumannii-calcoaceticus complex tended to be exact match or at least one doubling dilution lower than the reference method.

VITEK® REVEAL™ cefotaxime MIC values for E. coli and K. pneumoniae group tended to be exact match or at least one doubling dilution higher than the reference method.

No cefotaxime susceptible strains were evaluated for A. baumannii-calcoaceticus complex. Cefotaxime susceptibility is rare in A. baumannii-calcoaceticus complex.

Ceftazidime

A total of 619 samples were evaluated with ceftazidime, including 580 Enterobacterales species (302 *E. coli*, 123 *K. pneumoniae* group, 40 *K. oxytoca*, 47 *K. aerogenes*, 38 *E. cloacae* complex, 30 *C. koseri*) and 39 *A. baumannii-calcoaceticus* complex strains.

The overall performance for Enterobacterales species met defined acceptance criteria with EA of 95.3% and CA of 97.1%. There were no very major errors and one major error.

The overall performance for *A. baumannii-calcoaceticus* complex met defined acceptance criteria with EA of 97.4% and CA of 94.9%. There were no very major errors and no major errors.

The following statements are added to the AST performance table in product labeling to address trending:

VITEK® REVEAL™ ceftazidime MIC values for E. coli, K. pneumoniae group, K. oxytoca, K. aerogenes, and C. koseri tended to be exact match or at least one doubling dilution lower than the reference method.

VITEK® REVEAL™ ceftazidime MIC values for A. baumannii-calcoaceticus complex *tended to be exact match or at least one doubling dilution higher than the reference method.*

Ceftazidime/avibactam

A total of 717 samples were evaluated with ceftazidime/avibactam, including 624 Enterobacterales species (301 *E. coli*, 124 *K. pneumoniae* group, 67 *K. aerogenes*, 39 *E. cloacae* complex, 24 *C. freundii* complex, 30 *C. koseri*, 39 *P. mirabilis*) and 93 *P. aeruginosa* strains.

The overall performance for Enterobacterales species met defined acceptance criteria with EA of 95.7% and CA of 99.7%. There was one very major error and one major error. The single very major error was for *K. aerogenes*, but because there is no intermediate category, and the error was within essential agreement, it resulted in an acceptable adjusted very major error rate of 0.0%.

The overall performance for *P. aeruginosa* resulted in EA of 97.8% and CA of 97.8%. There were two major errors, with an acceptable major error rate of 3.0%.

The following statement is added to the AST performance table in product labeling to address trending:

VITEK® REVEAL™ ceftazidime/avibactam MIC values for Enterobacterales tended to be exact match or at least one doubling dilution lower than the reference method.

Ceftolozane/Tazobactam

A total of 576 samples were evaluated with ceftolozane/tazobactam, including 510 Enterobacterales species (293 *E. coli*, 40 *K. oxytoca*, 45 *K. aerogenes*, 37 *E. cloacae* complex, 42 *C. koseri*, 31 *P. mirabilis*, 22 *P. vulgaris*) and 66 *P. aeruginosa* strains.

The overall performance for Enterobacterales species met defined acceptance criteria with EA of 92.9% and CA of 97.6%. There was one very major error and one major error. The one (1) very major error was considered a random error due to the limited number of resistant isolates tested.

CA for *K. aerogenes* was 88.9% due to all minor errors. As the evaluable EA is high (92.3%), *K. aerogenes* performance is considered acceptable.

The overall performance for *P. aeruginosa* met defined acceptance criteria with EA of 100.0% and CA of 98.5%. There were no very major errors and no major errors.

The following statement is added to the AST performance table in product labeling to address trending:

VITEK® REVEAL™ ceftolozane/tazobactam MIC values for E. coli, K. aerogenes, K. oxytoca, and P. aeruginosa tended to be exact match or at least one doubling dilution lower than the reference method.

Ceftriaxone

A total of 626 samples were evaluated with ceftriaxone, all Enterobacterales species (294 *E. coli*, 132 *K. pneumoniae* group, 47 *K. oxytoca*, 52 *K. aerogenes*, 46 *E. cloacae* complex, and 55 *P. mirabilis*).

The overall performance for Enterobacterales species met defined acceptance criteria with EA of 97.1% and CA of 96.6%. There were no very major errors and three major errors.

The following statements are added to the AST performance table in product labeling to address trending:

VITEK® REVEAL™ ceftriaxone MIC values for K. pneumoniae group tended to be at least one doubling dilution higher than the reference method.

Cefuroxime

A total of 522 samples were evaluated with cefuroxime, all Enterobacterales species (300 *E. coli*, 119 *K. pneumoniae* group, 40 *K. oxytoca*, 27 *C. koseri*, and 36 *P. mirabilis*).

The overall performance for Enterobacterales species resulted in EA of 95.8% and CA of 97.3%. There was one very major error and thirteen major errors. Since there is no intermediate category for cefuroxime, the major error rate is 2.4% when adjusted for EA, which is acceptable. The major error rates for *K. pneumoniae* group (five major errors), *K. oxytoca* (four major errors), and *C. koseri* (one major error) are addressed by the following limitations in product labeling:

Due to the occurrence of major errors with cefuroxime, isolates of K. pneumoniae group that provide an MIC of 16 μg/mL should be retested by an alternate method, if critical to patient care.

Due to the occurrence of major errors with cefuroxime, isolates of K. oxytoca that provide an MIC of 32 μg/mL should be retested by an alternate method, if critical to patient care.

Due to the occurrence of major errors with cefuroxime, isolates of C. koseri that provide an MIC of >32 mg/mL should be retested by an alternate method, if critical to patient care.

The following statements are added to the AST performance table in product labeling to address trending:

VITEK® REVEAL™ cefuroxime MIC values for C. koseri, E. coli, and P. mirabilis tended to be exact match or at least one doubling dilution lower than the reference method.

VITEK® REVEAL™ cefuroxime MIC values for K. pneumoniae group tended to be exact match or at least one doubling dilution higher than the reference method.

Ciprofloxacin

A total of 751 samples were evaluated with ciprofloxacin, including 681 Enterobacterales species (303 *E. coli*, 123 *K. pneumoniae* group, 46 *K. oxytoca*, 47 *K. aerogenes*, 39 *E. cloacae* complex, 26 *C. freundii* complex, 38 *P. mirabilis*, 33 *P. vulgaris*, 26 *S. marcescens*) and 70 *P. aeruginosa* strains.

The overall performance for Enterobacterales species met defined acceptance criteria with EA of 99.0% and CA of 95.6%. There was one very major error and one major error. The single very major error was observed for *P. mirabilis* and is addressed by the following limitation in product labeling:

> *Due to the occurrence of a very major error with ciprofloxacin, isolates of P. mirabilis that provide an MIC of 0.25 µg/mL should be retested by an alternate method.*

The overall performance for *P. aeruginosa* resulted in EA of 92.9% and CA of 97.1%. There were no very major errors and one major error, with an acceptable major error rate of 3.0%.

The following statement is added to the AST performance table in product labeling to address trending:

> *VITEK® REVEAL™ ciprofloxacin MIC values for E. coli, K. pneumoniae group, E. cloacae complex, and C. freundii complex tended to be exact match or at least one doubling dilution higher than the reference method.*

Ertapenem

A total of 493 samples were evaluated with ertapenem, all Enterobacterales species (301 *E. coli*, 126 *K. pneumoniae* group, 40 *P. mirabilis*, and 26 *P. vulgaris*).

The overall performance for Enterobacterales species met defined acceptance criteria with EA of 97.8% and CA of 98.8%. There were no very major errors and one major error.

The following statement is added to the AST performance table in product labeling to address trending:

> *VITEK® REVEAL™ ertapenem MIC values for E. coli tended to be exact match or at least one doubling dilution lower than the reference method.*

Gentamicin

A total of 749 samples were evaluated with gentamicin, including 684 Enterobacterales species (299 *E. coli*, 123 *K. pneumoniae* group, 40 *K. oxytoca*, 46 *K. aerogenes*, 30 *C. freundii* complex, 35 *C. koseri*, 30 *P. mirabilis*, 55 *P. vulgaris*, and 26 *S. marcescens*) and 65 *P. aeruginosa* strains.

The overall performance for Enterobacterales species met defined acceptance criteria with EA of 96.6% and CA of 98.2%. There was one very major error and two major errors. The very major error for *E. coli* is addressed by the following limitation in product labeling:

Due to the occurrence of a very major error with gentamicin, isolates of E. coli that provide an MIC of 4 μg/mL should be retested by an alternate method.

The overall performance for *P. aeruginosa* met defined acceptance criteria with EA of 96.9% and CA of 95.4%. There were no very major errors and no major errors.

The following statement is added to the AST performance table in product labeling to address trending:

VITEK® REVEAL™ gentamicin MIC values for E. coli, K. aerogenes, K. pneumoniae group, C. freundii complex, and S. marcescens tended to be exact match or at least one doubling dilution higher than the reference method.

Imipenem

A total of 682 samples were evaluated with imipenem, including 572 Enterobacterales species (301 *E. coli*, 124 *K. pneumoniae* group, 44 *K. oxytoca*, 39 *E. cloacae* complex, 38 *C. koseri*, and 26 *S. marcescens*), 45 *A. baumannii-calcoaceticus* complex strains, and 65 *P. aeruginosa* strains.

The overall performance for Enterobacterales species met defined acceptance criteria with EA of 98.1% and CA of 97.7%. There were no very major errors and no major errors.

The overall performance for *A. baumannii-calcoaceticus* complex strains met defined acceptance criteria with EA of 97.8% and CA of 93.3%. There were no very major errors and no major errors.

The overall performance for *P. aeruginosa* resulted in EA of 93.8% and CA of 93.8%. There were two very major errors, which is addressed by the following limitation in product labeling:

Due to the occurrence of very major errors with imipenem, isolates of P. aeruginosa that provide an MIC of 2 μg/mL should be retested by an alternate method.

The following statements are added to the AST performance table in product labeling to address trending:

VITEK® REVEAL™ imipenem MIC values for E. cloacae complex, A. baumannii-calcoaceticus complex, and P. aeruginosa tended to be exact match or at least one doubling dilution lower than the reference method.

VITEK® REVEAL™ imipenem MIC values for E. coli and K. pneumoniae group tended to be exact match or at least one doubling dilution higher than the reference method.

Levofloxacin

A total of 798 samples were evaluated with levofloxacin, including 724 Enterobacterales species (300 *E. coli*, 124 *K. pneumoniae* group, 44 *K. oxytoca*, 47 *K. aerogenes*, 39 *E. cloacae* complex, 31 *C. freundii* complex, 37 *C. koseri*, 31 *P. mirabilis*, 36 *P. vulgaris*, and 35 *S. marcescens*) and 74 *P. aeruginosa* strains.

The overall performance for Enterobacterales species met defined acceptance criteria with EA of 99.2% and CA of 96.3%. There was one very major error and no major errors. The single very major error was observed with *P. mirabilis* and is addressed by the following limitation in product labeling:

Due to the occurrence of a very major error with levofloxacin, isolates of P. mirabilis that provide an MIC of 0.5 µg/mL should be retested by an alternate method.

The overall performance for *P. aeruginosa* resulted in EA of 97.3% and CA of 94.6%. There were no very major errors and one major error, with an acceptable major error rate of 2.9%.

The following statements are added to the AST performance table in product labeling to address trending:

VITEK® REVEAL™ levofloxacin MIC values for K. pneumoniae group, K. aerogenes, E. cloacae complex, C. freundii complex, and P. mirabilis tended to be exact match or at least one doubling dilution lower than the reference method.

VITEK® REVEAL™ levofloxacin MIC values for P. aeruginosa tended to be exact match or at least one doubling dilution higher than the reference method.

Meropenem

A total of 738 samples were evaluated with meropenem, including 612 Enterobacterales species (301 *E. coli*, 123 *K. pneumoniae* group, 39 *E. cloacae* complex, 50 *P. mirabilis*, 59 *P. vulgaris*, and 40 *S. marcescens*), 61 *A. baumannii-calcoaceticus* complex strains, and 65 *P. aeruginosa* strains.

The overall performance for Enterobacterales species met defined acceptance criteria with EA of 97.2% and CA of 98.5%. There were no very major errors and three major errors.

The overall performance for *A. baumannii-calcoaceticus* complex strains resulted in EA of 90.2% and CA of 96.7%. There were no very major or major errors.

The overall performance for *P. aeruginosa* met defined acceptance criteria with EA of 96.9% and CA of 92.3%. There were no very major errors and no major errors.

The following statements are added to the AST performance table in product labeling to address trending:

VITEK® REVEAL™ meropenem MIC values for A. baumannii-calcoaceticus complex, P. aeruginosa, and S. marcescens tended to be exact match or at least one doubling dilution lower than the reference method.

VITEK® REVEAL™ meropenem MIC values for P. mirabilis tended to be at least one doubling dilution higher than the reference method.

Meropenem/vaborbactam

A total of 692 samples were evaluated with meropenem/vaborbactam, all Enterobacterales species (298 *E. coli*, 123 *K. pneumoniae* group, 45 *K. oxytoca*, 47 *K. aerogenes*, 43 *E. cloacae* complex, 36 *C. freundii* complex, 61 *C. koseri*, and 39 *P. mirabilis*).

The overall performance for Enterobacterales species met defined acceptance criteria with EA of 97.1% and CA of 98.0%. There were no very major errors and no major errors.

The following statements are added to the AST performance table in product labeling to address trending:

VITEK® REVEAL™ meropenem/vaborbactam MIC values for C. freundii complex, K. pneumoniae group, and K. aerogenes tended to be exact match or at least one doubling dilution lower than the reference method.

VITEK® REVEAL™ meropenem/vaborbactam MIC values for C. koseri and P. mirabilis tended to be exact match or at least one doubling dilution higher than the reference method.

Piperacillin/tazobactam

A total of 489 samples were evaluated with piperacillin/tazobactam, all Enterobacterales species (299 *E. coli*, 122 *K. pneumoniae* group, 33 *C. koseri*, and 35 *P. vulgaris*).

The overall performance for Enterobacterales species met defined acceptance criteria with EA of 94.7% and CA of 94.9%. There was one very major error and four major errors. CA for

C. koseri was 87.9% due to all minor errors. As the evaluable EA was high (90.9%), performance for *C. koseri* is considered acceptable. The very major error for *E. coli* is addressed by the following limitation in product labeling:

Due to the occurrence of a very major error with piperacillin/tazobactam, isolates of E. coli that provide an MIC of 8 μg/mL should be retested by an alternate method.

The following statement is added to the AST performance table in product labeling to address trending:

VITEK® REVEAL™ piperacillin/tazobactam MIC values for E. coli, K. pneumoniae group, and C. koseri tended to be exact match or at least one doubling dilution lower than the reference method.

Tetracycline

A total of 552 samples were evaluated with tetracycline, including 513 Enterobacterales species (301 *E. coli*, 123 *K. pneumoniae* group, 42 *K. oxytoca*, 47 *K. aerogenes*) and 39 *A. baumannii-calcoaceticus* complex strains.

The overall performance for Enterobacterales species met defined acceptance criteria with EA of 98.4% and CA of 97.1%. There were no very major errors and three major errors. CA for *K. aerogenes* was 87.2% due to all minor errors. As the evaluable EA was high (96.2%), performance for *K. aerogenes* is considered acceptable.

The overall performance for *A. baumannii-calcoaceticus* complex met defined acceptance criteria with EA of 100.0% and CA of 100.0%.

The following statement is added to the AST performance table in product labeling to address trending:

VITEK® REVEAL™ tetracycline MIC values for K. aerogenes tended to be exact match or at least one doubling dilution lower than the reference method.

Tobramycin

A total of 722 samples were evaluated with tobramycin, including 657 Enterobacterales species (300 *E. coli*, 124 *K. pneumoniae* group, 40 *K. oxytoca*, 46 *K. aerogenes*, 39 *E. cloacae* complex, 22 *C. freundii* complex, 29 *C. koseri*, 31 *P. mirabilis*, and 26 *S. marcescens*) and 65 *P. aeruginosa* strains.

The overall performance for Enterobacterales species met defined acceptance criteria with EA of 96.5% and CA of 94.8%. There were three very major errors and one major error. The

one (1) very major error for *K. oxytoca* was considered a random error due to the limited number of resistant isolates tested. The very major errors for *E. coli* are addressed by the following limitation in product labeling:

Due to the occurrence of very major errors with tobramycin, isolates of E. coli that provide an MIC of 4 µg/mL should be retested by an alternate method.

The major error for *S. marcescens* is addressed by the following limitation in product labeling:

Tobramycin with S. marcescens may produce a resistant result that can be found susceptible by the reference method. If critical to patient care, confirm these results with an alternate method.

The overall performance for *P. aeruginosa* met defined acceptance criteria with EA of 100.0% and CA of 100.0%.

The following statements are added to the AST performance table in product labeling to address trending:

VITEK® REVEAL™ tobramycin MIC values for P. mirabilis tended to be exact match or at least one doubling dilution lower than the reference method.

VITEK® REVEAL™ tobramycin MIC values for E. cloacae complex and C. freundii complex tended to be exact match or at least one doubling dilution higher than the reference method.

Trimethoprim/sulfamethoxazole

A total of 482 samples were evaluated with trimethoprim/sulfamethoxazole, all Enterobacterales species (303 *E. coli*, 130 *K. pneumoniae* group, and 47 *K. aerogenes*).

The overall performance for Enterobacterales species met defined acceptance criteria with EA of 95.0% and CA of 96.5%. There were three very major errors and 14 major errors. The major error rate for *E. coli* is addressed by the following limitation in product labeling:

Due to the occurrence of major errors with trimethoprim/sulfamethoxazole, isolates of E. coli that provide an MIC of 4-64 µg/ml should be retested by an alternate method.

The following statement is added to the AST performance table in product labeling to address trending:

VITEK® REVEAL™ trimethoprim/sulfamethoxazole MIC values for E. coli and K. pneumoniae group tended to be at least one doubling dilution higher than the reference method.

Confirmatory ESBL Test

A total of 408 samples were evaluated with the confirmatory ESBL test, including 408 Enterobacterales species (279 *E. coli*, 90 *K. pneumoniae* group, and 39 *K. oxytoca*).

The overall performance for Enterobacterales species met defined acceptance criteria with CA of 98.5%. The ESBL screen is for the detection of organisms that produce extended spectrum beta lactamase and generates a "Positive" or "Negative" result; therefore, EA is not calculated. There was one very major error and five major errors. The two major errors for *K. oxytoca* are addressed by the following limitation in product labeling:

Isolates of K. oxytoca that test as ESBL positive by VITEK® REVEAL™ should be retested by an alternate method to confirm the presence of ESBL.

Table 9. Trending Analysis Summary

Species group	Total Evaluable for Trending	≥ 1 Dilution lower # (%)	Exact # (%)	≥ 1 Dilution Higher # (%)	Percent Difference (95% CI)	Trending Noted
Amikacin						
Enterobacterales	589	160 (27.2)	348 (59.1)	81 (13.8)	-13.4% (-17.9%, -8.8%)	No
A. baumannii-calcoaceticus complex	52	23 (44.2)	19 (36.5)	10 (19.2)	-25.0% (-40.9%, -7.1%)	No
P. aeruginosa	57	25 (43.9)	26 (45.6)	6 (10.5)	-33.3% (-47.4%, -17.3%)	Yes
Amoxicillin/clavulanate						
Enterobacterales	296	5 (1.7)	78 (26.4)	213 (72.0)	70.3% (64.5%, 75.2%)	Yes
Ampicillin/sulbactam						
Enterobacterales	200	38 (19.0)	60 (30.0)	102 (51.0)	32.0% (22.9%, 40.4%)	Yes
Aztreonam						
Enterobacterales	113	33 (29.2)	35 (31.0)	45 (39.8)	10.6% (-1.8%, 22.6%)	No
P. aeruginosa	53	21 (39.6)	30 (56.6)	2 (3.8)	-35.8% (-49.6%, -20.8%)	Yes
Cefepime						
Enterobacterales	138	40 (29.0)	45 (32.6)	53 (38.4)	9.4% (-1.7%, 20.2%)	No
P. aeruginosa	46	10 (21.7)	27 (58.7)	9 (19.6)	-2.2% (-18.6%, 14.4%)	No
Cefotaxime						
Enterobacterales	86	264 (30.2)	28 (32.6)	32 (37.2)	7.0% (-7.1%, 20.7%)	No
A. baumannii-calcoaceticus complex	21	10 (47.6)	11 (52.4)	0 (0.0)	-47.6% (-67.6%, -22.9%)	Yes
Ceftazidime						

Species group	Total Evaluable for Trending	≥ 1 Dilution lower # (%)	Exact # (%)	≥ 1 Dilution Higher # (%)	Percent Difference (95% CI)	Trending Noted
Enterobacterales	331	195 (58.9)	79 (23.9)	57 (17.2)	-41.7% (-48.0%, -34.7%)	Yes
A. baumannii-calcoaceticus complex	22	1 (4.5)	11 (50.0)	10 (45.5)	40.9% (15.6%, 61.1%)	Yes
Ceftazidime/avibactam						
Enterobacterales	444	266 (59.9)	154 (34.7)	24 (5.4)	-54.5% (-59.3%, -49.2%)	Yes
P. aeruginosa	76	22 (28.9)	45 (59.2)	9 (11.8)	-17.1% (-29.4%, -4.3%)	No
Ceftolozane/tazobactam						
Enterobacterales	478	255 (53.3)	186 (38.9)	37 (7.7)	-45.6% (-50.5%, -40.4%)	Yes
P. aeruginosa	39	21 (53.8)	18 (46.2)	0 (0.0)	-53.8% (-68.4%, -36.1%)	Yes
Ceftriaxone						
Enterobacterales	84	31 (36.9)	20 (23.8)	33 (39.3)	2.4% (-12.1%, 16.7%)	No
Cefuroxime						
Enterobacterales	365	166 (45.5)	125 (34.2)	74 (20.3)	-25.2% (-31.6%, -18.5%)	No
Ciprofloxacin						
Enterobacterales	148	10 (6.8)	61 (41.2)	77 (52.0)	45.3% (35.7%, 53.7%)	Yes
P. aeruginosa	34	18 (52.9)	5 (14.7)	11 (32.4)	-20.6% (-41.0%, 2.8%)	No
Ertapenem						
Enterobacterales	40	21 (52.5)	11 (27.5)	8 (20.0)	-32.5% (-49.9%, -11.5%)	Yes
Gentamicin						
Enterobacterales	554	77 (13.9)	198 (35.7)	279 (50.4)	36.5% (31.3%, 41.4%)	Yes
P. aeruginosa	42	10 (23.8)	25 (59.5)	7 (16.7)	-7.1% (-24.1%, 10.2%)	No
Imipenem						
Enterobacterales	161	47 (29.2)	47 (29.2)	67 (41.6)	12.4% (2.0%, 22.5%)	No
A. baumannii-calcoaceticus complex	15	12 (80.0)	3 (20.0)	0 (0.0)	-80.0% (-93.0%, -47.6%)	Yes
P. aeruginosa	39	20 (51.3)	17 (43.6)	2 (5.1)	-46.2% (-61.5%, -27.0%)	Yes
Levofloxacin						
Enterobacterales	225	77 (34.2)	123 (54.7)	25 (11.1)	-23.1% (-30.4%, -15.5%)	No
P. aeruginosa	43	4 (9.3)	21 (48.8)	18 (41.9)	32.6% (14.3%, 48.4%)	Yes
Meropenem						
Enterobacterales	137	50 (36.5)	33 (24.1)	54 (39.4)	2.9% (-8.5%, 14.2%)	No
A. baumannii-calcoaceticus complex	50	33 (66.0)	17 (34.0)	0 (0.0)	-66.0% (-77.6%, -50.4%)	Yes
P. aeruginosa	45	20 (44.4)	23 (51.1)	2 (4.4)	-40.0% (-54.7%, -23.0%)	Yes
Meropenem/vaborbactam						
Enterobacterales	106	35 (33.0)	30 (28.3)	41 (38.7)	5.7% (-7.2%, 18.2%)	No
Piperacillin/tazobactam						
Enterobacterales	148	107 (72.3)	21 (14.2)	20 (13.5)	-58.8% (-66.8%, -48.7%)	Yes
Tetracycline						

Species group	Total Evaluable for Trending	≥ 1 Dilution lower # (%)	Exact # (%)	≥ 1 Dilution Higher # (%)	Percent Difference (95% CI)	Trending Noted
Enterobacterales	346	150 (43.4)	129 (37.3)	67 (19.4)	-24.0% (-30.5%, -17.2%)	No
A. baumannii-calcoaceticus complex	12	4 (33.3)	6 (50.0)	2 (16.7)	-16.7% (-46.8%, 17.6%)	No
Tobramycin						
Enterobacterales	620	120 (19.4)	341 (55.0)	159 (25.6)	6.2% (1.6%, 10.9%)	No
P. aeruginosa	37	8 (21.6)	27 (73.0)	2 (5.4)	-16.2% (-32.3%, -0.2%)	No
Trimethoprim/sulfamethoxazole						
Enterobacterales	57	9 (15.8)	7 (12.3)	41 (71.9)	56.1% (38.9%, 68.5%)	Yes

Conclusion

The conclusions drawn from the analytical and clinical tests demonstrate that the device is substantially equivalent to the predicate device.