510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K260160

B Applicant

bioMérieux, Inc.

C Proprietary and Established Names

VITEK REVEAL GN AST Assay and VITEK REVEAL AST System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
SAN	Class II	21 CFR 866.1650 A cellular analysis System for multiplexed antimicrobial susceptibility	MI – Microbiology
LON	Class II	21 CFR 866.1645 System, test, automated, antimicrobial susceptibility, short incubation	MI – Microbiology

II Submission/Device Overview:

A Purpose for Submission:

1. To obtain substantial equivalence determination for use of the VITEK REVEAL GN AST Assay for testing *Pseudomonas aeruginosa* with ceftazidime on the VITEK REVEAL AST System.
2. To update labeling to remove testing for *Pseudomonas aeruginosa* with amikacin and gentamicin and *Acinetobacter* spp. with tetracycline due to updates to FDA Susceptibility Test Interpretive Criteria (STIC).
3. To update labeling for performance of the VITEK REVEAL GN AST Assay for testing *Pseudomonas aeruginosa* with cefepime on the VITEK REVEAL AST System, per the breakpoint change protocol predetermined change control plan (PCCP) cleared with K230675.

B Measurand:

Ceftazidime ≤0.125 - >64 µg/mL

C Type of Test:

Quantitative and qualitative antimicrobial susceptibility test (AST) System that utilizes sensors to detect metabolic byproducts of microbial growth from positive blood culture samples to determine the minimum inhibitory concentration (MIC) of specific antimicrobial-organism combinations.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use.

B Indication(s) for Use:

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. Interpretive results (Susceptible/Intermediate/Susceptible-dose dependent/Resistant) are provided for specific drug/organism combinations. Results are intended to be used in conjunction with other clinical and laboratory findings. Standard laboratory protocols for processing positive blood cultures should be followed to ensure availability of isolates for supplemental testing as needed. Additionally, subculture of positive blood culture is necessary for the susceptibility testing of organisms present in polymicrobial samples, for testing antimicrobial agents and species not indicated for testing with the device and for epidemiologic testing and for recovery of organisms present in microbial samples.

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. 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. The VITEK REVEAL AST system does not provide organism identification and is not indicated for use with polymicrobial samples. Testing is indicated for *Acinetobacter* spp., Enterobacterales, and *Pseudomonas aeruginosa* as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC). The VITEK REVEAL GN AST Assay with VITEK REVEAL AST system has demonstrated acceptable performance with the following organisms:

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

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

Ampicillin/sulbactam: Enterobacterales (*Escherichia coli*, *Klebsiella oxytoca*, *Proteus mirabilis*)

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

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

Cefotaxime: *Acinetobacter* spp. (*Acinetobacter baumannii-calcoaceticus* complex) and Enterobacterales (*Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae* group)

Ceftazidime: *Acinetobacter* spp. (*Acinetobacter baumannii-calcoaceticus* complex), Enterobacterales (*Citrobacter koseri*, *Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae* group), and *Pseudomonas aeruginosa*

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

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

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

Cefuroxime: Enterobacterales (*Citrobacter koseri*, *Escherichia coli*, *Klebsiella pneumoniae* group, *Klebsiella oxytoca*, and *Proteus mirabilis*)

Ciprofloxacin: Enterobacterales (*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*, *Serratia marcescens*) and *Pseudomonas aeruginosa*

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

Gentamicin: Enterobacterales (*Citrobacter freundii* complex, *Citrobacter koseri*, *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae* group, *Proteus mirabilis*, *Proteus vulgaris*, *Serratia marcescens*)

Imipenem: *Acinetobacter* spp. (*Acinetobacter baumannii-calcoaceticus* complex), Enterobacterales (*Citrobacter koseri*, *Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae* group, *Serratia marcescens*) and *Pseudomonas aeruginosa*

Levofloxacin: Enterobacterales (*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*, *Serratia marcescens*) and *Pseudomonas aeruginosa*

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

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

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

Tetracycline: Enterobacterales (*Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae* group)

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

Trimethoprim/sulfamethoxazole: Enterobacterales (*Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella pneumoniae* group)

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

C Special Conditions for Use Statement(s):

Rx – For prescription use only

D Special Instrument Requirements:

VITEK REVEAL GN AST Assay must be used with the VITEK REVEAL AST System, Software Version 1.3 or higher.

IV Device/System Characteristics:

A Device Description:

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 growth-based broth microdilution (BMD) principles to rapidly determine Minimum Inhibitory Concentrations (MIC) for the drugs on the VITEK REVEAL GN AST Assay. In combination with species identification (obtained from an FDA-cleared rapid bacterial identification method), the System will provide a Susceptible / Intermediate / Resistant ("SIR") and/or extended-spectrum β-lactamase (ESBL) determination for the species tested. The VITEK REVEAL AST System and the VITEK REVEAL GN AST Assay are indicated for susceptibility testing of specific pathogenic bacteria commonly associated with bacteremia.

The VITEK REVEAL AST System and the VITEK REVEAL GN AST Assay detect bacterial growth using an array of chemical Small Molecule Sensors (SMS), which change color in the presence of various metabolic gases (VOC; volatile organic compounds) emitted by growing bacteria during incubation. The SMS arrays, printed onto a VITEK REVEAL Sensor Panel, are positioned atop each well of an inoculated VITEK REVEAL Antibiotic Panel in an AST disposable assembly comprising a VITEK REVEAL GN AST Assay.

There are four key components unique to the VITEK REVEAL AST System: 1) VITEK REVEAL Antibiotic Panels; 2) VITEK REVEAL Sensor Panel; 3) VITEK REVEAL Sealer; 4) VITEK REVEAL Instrument. In addition, the provided inoculator is required for inoculation of the VITEK REVEAL Antibiotic Panels.

B Principle of Operation:

The VITEK REVEAL sensor technology is based on novel, proprietary chemical Small Molecule Sensors (SMS) that sensitively register a "fingerprint" of complex volatile compound mixtures. The sensors comprising the array have distinct chemical reactivity with volatiles and changes color upon exposure to low concentrations of volatile organic compounds (VOCs) emitted by populations of microorganisms during growth.

The VITEK REVEAL AST System leverages this sensitive capability to detect growth, using an array of seven sensors positioned over each well of the VITEK REVEAL GN AST Assay plate. Thus, the VITEK REVEAL Sensor Panels consist of a sheet of 96, 7-sensor arrays heat-sealed to a 96-well antibiotic panel so that when inoculated with bacteria, each array individually responds to the volatiles emitted in that well to sensitively register growth.

Bacterial growth or inhibition in each antimicrobial-containing well of the VITEK REVEAL GN AST Assay is determined by the VITEK REVEAL AST System based on the change in color intensity of the corresponding SMS array compared to the sensor responses in the positive control (no antimicrobials) and negative control (no growth media) wells. An algorithm detects the divergence between the compared SMS responses and rapidly determines growth (indicating resistance) or inhibition (indicating susceptibility) for each two-fold doubling dilution of each antimicrobial thereby enabling a quantitative MIC determination directly analogous to BMD. Once the identification (ID) using a result of an FDA-cleared method is furnished to the system, the MIC result enables the System to generate an interpretation (SIR/ESBL result) based on the FDA-recognized breakpoints. MICs and interpretations are displayed only after the species ID has been entered into the system.

C Instrument Description Information:

1. Instrument Name:

   VITEK REVEAL AST System

2. Specimen Identification:

   The user enters sample information into the user interface or sample information is transferred to the VITEK REVEAL AST System via an LIS connection. To ensure sample traceability, the user prints a sample barcode label and places the barcode label on the area of the Sensor Panel where indicated. The sample barcode encodes the sample ID and associated information. There is a separate sensor barcode which encodes the sensor/array information.

3. Specimen Sampling and Handling:

   The workflow requires an aliquot from a positive blood culture sample that has been confirmed to be Gram-negative and monomicrobial by a Gram stain. The aliquot is diluted into a tube of Pluronic water and the Pluronic suspension is poured into the Renok inoculator tray. The Renok inoculator is used to dispense the suspension into each well of the 96-well VITEK REVEAL Antibiotic Panel. A VITEK REVEAL Sensor Panel is then placed onto the Antibiotic Panel, and the VITEK REVEAL Sealer seals the Sensor Panel onto the Antibiotic Panel such that an array of seven (7) sensors is positioned over each well. The sealed GN AST Assay is then loaded on the VITEK REVEAL Instrument. The VITEK REVEAL Instrument will automatically begin the run. Any time after the run has started, the species ID may be entered into the System. The MIC determinations and SIR/ESBL interpretations are visible on the user interface in real-time.

4. Calibration:

   The VITEK REVEAL Instrument and software have the following internal Quality Control (QC) checks:

   - VITEK REVEAL Instrument drawer incubation temperature has low and high limits that, when exceeded, will display alarms on the user interface.
   - Should either the sensor barcode or sample barcode be unreadable, a default artificial barcode would be assigned, using the instrument ID, plate location, and the current timestamp. An alert will be displayed on the user interface, and the user will have the option to enter the information manually.
   - If the instrument does not identify or cannot locate the 96 well plate, an alert is provided to the user to examine the plate to confirm it is placed correctly in the instrument.
   - If the initial intensity of a sensor is above a certain threshold, it suggests poor quality of the sensor and the user is alerted to retest the sample using a sensor from a new lot. If sensor quality is affected only in certain wells, then the result for the affected antibiotic alone will be suppressed.

- If there is insufficient growth in the positive control well, then no results are reported, the user is alerted to the possibility of insufficient inoculum or a slow growing organism, and the user is advised to retest the sample.
- If there is growth detected in the negative control well, then a warning message is displayed on the user interface to alert the user.
- Each VOC sensor has a QC check to ensure that the sensor quality is acceptable. If a particular sensor fails this check in any well, then that sensor is not used.

5. Quality Control:

In addition to the above controls, QC testing of the VITEK REVEAL Instrument and the Sealer should be performed as dictated by the laboratory's protocols. The purpose of external Quality Control (QC) testing is to monitor performance of the VITEK REVEAL AST System (including the Sensor Panels and Antibiotic Panels) and the VITEK REVEAL Sealer, as well as the proficiency of the laboratory personnel who use the System.

VITEK REVEAL AST System QC is performed by testing the manufacturer recommended QC strains. The QC workflow follows the same steps as the sample workflow, with the exception that provided QC sample barcodes are placed on the GN AST assay plate, which automatically instructs the instrument to operate in QC mode. The QC results are generated and displayed on the user interface indicating the expected QC MIC range, the VITEK REVEAL MIC call, and whether the relevant antimicrobials for the organism have passed or failed. See more details about quality control in section VII.A. below.

V Substantial Equivalence Information:

A Predicate Device Name(s):

VITEK REVEAL GN AST Assay and VITEK REVEAL AST System

B Predicate 510(k) Number(s):

K230675

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device: K260160	Predicate: K230675
Device Trade Name	VITEK REVEAL GN AST Assay and VITEK REVEAL AST System	VITEK REVEAL GN AST Assay and VITEK REVEAL AST System
General Device Characteristic Similarities		
Intended Use	The VITEK REVEAL AST System is an *in vitro* diagnostic (IVD) automated System for quantitative and qualitative	Same

Device & Predicate Device(s):	Device: K260160	Predicate: K230675
	antimicrobial susceptibility testing (AST) of organisms direct from positive blood culture. The VITEK REVEAL AST System does not provide organism identification.	
Indicated Organisms	Gram-negative organisms	Same
Sample Type	Dilution from positive blood culture as identified by a continuous monitoring blood culture System	Same
Inoculum Method	Manual	Same
Read Method	Automated	Same
Technology	Automated and growth based, using detection of emission of volatiles by colorimetric sensors to detect and monitor organism growth	Same
Results	Report results as minimum inhibitory concentration (MIC) and categorical interpretation.	Same
Antimicrobial Panel	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	Same
General Device Characteristic Differences		
Tested Species with Ceftazidime	*Pseudomonas aeruginosa* *Acinetobacter baumannii-calcoaceticus* complex	*Acinetobacter baumannii-calcoaceticus* complex

Device & Predicate Device(s):	Device: K260160	Predicate: K230675
	Citrobacter koseri *Enterobacter cloacae* complex *Escherichia coli* *Klebsiella aerogenes* *Klebsiella oxytoca* *Klebsiella pneumoniae* group	*Citrobacter koseri* *Enterobacter cloacae* complex *Escherichia coli* *Klebsiella aerogenes* *Klebsiella oxytoca* *Klebsiella pneumoniae* group

Predetermined Change Control Plan (PCCP):

To support the implementation of changes to FDA-recognized susceptibility test interpretive criteria (i.e., breakpoints), this submission included a predetermined change control plan (PCCP) with a breakpoint change protocol that was reviewed and accepted by FDA in submission K250274 cleared on April 30, 2025. This protocol addresses future revisions to device labeling in response to breakpoint changes that are recognized on the FDA STIC webpage (FDA-Recognized Antimicrobial Susceptibility Test Interpretive Criteria). The protocol outlined the specific procedures and acceptance criteria that bioMérieux, Inc. intends to use to evaluate the VITEK REVEAL AST System and the VITEK REVEAL GN AST Assay when revised breakpoints for indicated drugs are published on the FDA STIC webpage. The breakpoint change protocol included with the submission indicated that if specific criteria are met, bioMérieux, Inc. will update the VITEK REVEAL AST System and the VITEK REVEAL GN AST Assay label to include (1) the new breakpoints, (2) an updated performance section after re-evaluation of data in this premarket notification with the new breakpoints, and (3) any new limitations as determined by their evaluation.

VI Standards/Guidance Documents Referenced:

- FDA Class II Special Controls Guidance Document: Antimicrobial Susceptibility (AST) Systems; Guidance for Industry and FDA (Issued August 28, 2009). General Principles of Software Validation; Final Guidance for Industry and FDA Staff
- CLSI Standard M07 11th Ed. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically
- CLSI supplement M100 35th Ed. Performance Standards for Antimicrobial Susceptibility Testing

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   The reproducibility of the VITEK REVEAL GN AST Assay, including ceftazidime, with the VITEK REVEAL AST System was previously demonstrated in K230675. This submission does not include the addition of new antimicrobials and *Pseudomonas aeruginosa* was part of the original reproducibility study assessed in K230675. Refer to the K230675 Decision Summary for additional details.

2. Linearity:

   N/A

3. Analytical Specificity/Interference:

   The potential impact of interfering substances on the results of the VITEK REVEAL GN AST Assay, including ceftazidime, with the VITEK REVEAL AST System was previously assessed in K230675. Refer to the K230675 Decision Summary for additional details.

4. Detection Limit and Assay Reportable Range:

   N/A

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Quality Control Testing
   Quality control testing was performed each day that testing was conducted. CLSI recommended QC strains for ceftazidime (*E. coli* ATCC 25922, *P. aeruginosa* ATCC 27853, and *K. pneumoniae* ATCC 700603) were tested a sufficient number of times (i.e., at least 20 times/site) at each testing site using the VITEK REVEAL AST System and at the reference site using the broth microdilution reference method.

   Please refer to K230675 which demonstrated that greater than 95% of results were within the expected range for ceftazidime, which is acceptable.

   Purity Check
   Purity plates were prepared from the positive blood cultures of every sample tested. AST results were only reported for pure isolates; data generated from plates that generated multiple colony morphologies were excluded from analyses.

   Specimen Stability
   Specimen stability for the VITEK REVEAL GN AST Assay, including ceftazidime, with the VITEK REVEAL AST System was previously assessed in K230675. Refer to the K230675 Decision Summary for additional details.

6. Assay Cut-Off:

N/A

B Comparison Studies:

1. Method Comparison with Predicate Device:

Clinical performance testing on the VITEK REVEAL AST System using the VITEK REVEAL GN AST Assay with ceftazidime was performed at five external, geographically diverse, U.S. clinical test sites. The broth microdilution (BMD) reference testing was performed at a single reference site. Challenge isolate testing was performed at two internal sites. Performance was evaluated using fresh (prospective) positive blood cultures, as well as positive blood culture samples contrived with clinical stock isolates and challenge isolates. The challenge isolates were selected for their resistance profiles. Positive blood cultures confirmed by Gram stain to contain only gram-negative rods were enrolled into the study.

Organism identification was obtained from an FDA-cleared molecular bacterial identification method and/or FDA-cleared MALDI TOF method for input into the VITEK REVEAL AST System. The species identification provided by the clinical site was confirmed at the reference site using an FDA-cleared MALDI identification method. Any samples with a species identification at the reference site not matching the expected ID or found to be polymicrobial did not proceed to BMD testing.

A total of 101 positive blood cultures with *P. aeruginosa* (28 prospective clinical and 73 challenge strains) were tested to evaluate the VITEK REVEAL AST System performance using the VITEK REVEAL GN AST Assay with ceftazidime. VITEK REVEAL results were compared to the modal value of triplicate broth microdilution reference results performed at an independent reference laboratory.

Performance was determined generally based on criteria outlined in the Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems including essential agreement (EA), category agreement (CA), and categorical errors (minor, major and very major errors). EA was calculated as the percentage of VITEK REVEAL MIC results that were within plus or minus one serial two-fold dilution of the reference result. CA was calculated as the percentage of VITEK REVEAL interpretive results (S/I/R) that were identical to the interpretive results of the reference result. EA of evaluable results (on-scale VITEK REVEAL and reference results or results in which an off-scale result was at least two doubling dilutions from the on-scale result) were also calculated. Performance was considered acceptable if the EA and CA were ≥90%, major error rate was ≤3%, and very major error rate was ≤2%.

Performance of the VITEK REVEAL GN AST Assay for ceftazidime with *P. aeruginosa* from clinical and challenge testing demonstrated an EA of 95.1% and CA of 95.1%. There were three (3) minor errors, two (2) major errors (2.9%) and no very major errors (**Table 1**). Overall, performance is acceptable.

Table 1. Performance of VITEK REVEAL GN AST Assay with Ceftazidime/*P. aeruginosa*

Sample Type	Total	No.EA	EA %	Eval EA Tot	No. Eval EA	Eval EA %	No. CA	CA %	No. R	No. S	min	maj	vmj
***P. aeruginosa* [Breakpoints (µg/mL): 8 (S), 16 (I), 32 (R)]**													
Clinical	28	26	92.9	27	25	92.6	26	92.9	2	25	2	0	0
Challenge	73	70	95.9	56	53	94.6	70	95.9	29	43	1	2	0
Combined	101	96	95.0	83	78	94.0	96	95.0	31	68	3	2	0

EA – Essential Agreement
CA – Category Agreement
EVAL – Evaluable isolates
R – Resistant isolates
S – Susceptible isolates
min – Minor Discrepancy
maj – Major Discrepancy
vmj – Very Major Discrepancy

Essential Agreement (EA) occurs when there the result of the reference method and that of the VITEK REVEAL MIC panel are within plus or minus one serial two-fold dilution of the antibiotic. Evaluable results are those that are on-scale for both the VITEK REVEAL panel and the reference method or results in which an off-scale result is at least two doubling dilutions from the on-scale result. Category Agreement (CA) occurs when the interpretation of the result of the reference method agrees exactly with the interpretation of the VITEK REVEAL panel.

Trending Analysis

A trending analysis using combined clinical and challenge isolate results was also conducted to evaluate antimicrobial/organism combinations for which VITEK REVEAL MIC results were determined to be one or more doubling dilutions lower or higher than the reference result. MIC results that were off scale for both the reference and VITEK REVEAL were not considered in the trending analysis. Antimicrobial/organism combinations for which the difference between the percentage of isolates with higher or lower MIC values was ≥30% with a statistically significant confidence interval were considered to have evidence of trending (**Table 2**).

Analysis of trending for ceftazidime/*P. aeruginosa* indicated that VITEK REVEAL MIC values demonstrated no trending.

Table 2. Trending for *P. aeruginosa* with Ceftazidime and the VITEK REVEAL AST System

Organism Name	Total Evaluable for Trending	≥ 1 Dilution lower No. (%)	Exact No.	≥ 1 Dilution Higher No. (%)	Percent Difference (CI)	Trending Noted
Pseudomonas aeruginosa	85	30 (35.3%)	48	7 (8.2%)	-27% (-38%, -15%)	No

Testing/Reporting MICs for Species Not Listed in the Indications for Use

For this review, the interpretive criteria are applied to the organisms/organism groups according to the FDA STIC website. As required under 511A(2)(2)(B) of the Federal Food, Drug and Cosmetic Act, the following statement is included in the Warnings and Precautions section of the device labeling to address testing and reporting of species not listed in the device Indications for Use:

The safety and efficacy of antimicrobial drugs, for which antimicrobial susceptibility is tested by this AST device, may or may not have been established in adequate and well controlled clinical trials for treating clinical infections due to microorganisms outside of those found in the indications and usage in the drug label. The clinical significance of susceptibility information in those instances is unknown. The approved labeling for specific antimicrobial drugs provides the uses for which the antimicrobial drug is approved.

2. Matrix Comparison:

Blood Bottle Equivalency for the VITEK REVEAL GN AST Assay, including ceftazidime, with the VITEK REVEAL AST System was previously assessed in K230675. Refer to the K230675 Decision Summary for additional details.

C Clinical Studies:

1. Clinical Sensitivity:

N/A

2. Clinical Specificity:

N/A

3. Clinical Cut-Off

N/A

4. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

N/A

D Expected Values/Reference Range:

The FDA-recognized/approved susceptibility interpretive criteria for ceftazidime evaluated with the VITEK REVEAL GN AST Assay are listed in **Table 3** below:

Table 3. FDA-Approved or Recognized Interpretive Criteria[a]

Antimicrobial	Organism	Minimum Inhibitory Concentration (µg/mL)		
		S	I	R
Ceftazidime	*Pseudomonas aeruginosa*	≤8	16	≥32

S = Susceptible, I = Intermediate, R = Resistant

[a]According to the FDA STIC Webpage, FDA-Recognized Antimicrobial Susceptibility Test Interpretive Criteria

E Other Supportive Instrument Performance Characteristics Data:

Cross Contamination/Carry-Over for the VITEK REVEAL GN AST Assay, including ceftazidime, with the VITEK REVEAL AST System were previously assessed in K230675. Refer to the K230675 Decision Summary for additional details.

Electrical safety and electromagnetic compatibility (EMC) testing were performed and previously assessed in K230675. Refer to the K230675 Decision Summary for additional details.

Software and cybersecurity documentation was assessed and found to be acceptable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.