July 8, 2026

bioMerieux, Inc.
Joshua Lay
Regulatory affairs specialist
595 Anglum Rd.
Hazelwood, Missouri 63042

Re: K260160/S002
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 3, 2026
Received: June 4, 2026

Dear Joshua Lay:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not

required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

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

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

Sincerely,

Ribhi Shawar -S

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

Enclosure

Indications for Use

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

510(k) Number *(if known)*
K260160

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 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 (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: 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

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™ GN AST Assay and VITEK® REVEAL™ AST System

A. 510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Joshua Lay Regulatory Affairs Specialist
Phone Number: Fax Number:	314-795-5946 314-731-8689
Date of Preparation:	January 20, 2026
Submission type:	Traditional 510(k)

B. Device Name:

Formal/Trade Name:	VITEK® REVEAL™ GN AST Assay and VITEK® REVEAL™ AST System
Classification Name:	21CFR 866.1650 Automated Antimicrobial Susceptibility Test System For Positive Blood Culture Samples Product Code SAN Secondary Code LON
Common Name:	VITEK® REVEAL™ GN AST Assay, VITEK® REVEAL™ AST System

C. Predicate Device: VITEK® REVEAL™ GN AST Assay and VITEK® REVEAL™ AST System (K230675)

D. Device Description:

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 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 two key components unique to the VITEK® REVEAL™ GN AST Assay:

1. VITEK® REVEAL™ ANTIBIOTIC PANEL– A plastic 96-well microtiter plate with each well containing a serial dilution of antibiotics and dried media (cation-adjusted Mueller-Hinton broth) at specific concentrations. The user pipettes a pre-defined amount of liquid sample inoculum into each well using an inoculator. The VITEK® REVEAL™ Antibiotic Panels are custom manufactured by Beckman Coulter and are released with VITEK® REVEAL™ branding.

2. VITEK® REVEAL™ SENSOR PANEL – An assembly comprised of a frame, a clear plastic film, and a membrane sheet with 96 sensor arrays (12 x 8), each of which consists of seven chemically responsive sensors, which detect growth in each well based on a change in color produced by emission of volatiles that are byproducts of the growth of microorganisms. The sensor is hermetically sealed on top of the VITEK® REVEAL™ Antibiotic Panel after inoculation to form the VITEK® REVEAL™ GN AST Assay. The VITEK® REVEAL™ Sensor Panel also contains a seal quality sensor located between each SMS array.

The VITEK® REVEAL™ AST results are intended to be used in conjunction with Gram stain, organism identification and other clinical laboratory findings. The VITEK® REVEAL™ AST System generates MIC values for the drugs tested on the Antibiotic Panels. Reporting of MIC values and the determination of the SIR interpretation of the bacterial strain tested requires a species identification, which can be obtained by any of several common FDA-cleared test methods, including MALDI-TOF mass spectrometry or PCR molecular testing.

After clinical samples are 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 Panel(s). Each Antibiotic Panel is sealed to a Sensor Panel, considered the VITEK® REVEAL™ GN AST Assay, with each well becoming a closed system for the assessment of microbial growth in the presence of an antibiotic at a given concentration.

Inoculated and sealed GN AST Assays are loaded into the VITEK® REVEAL™ AST System, where they are scanned, rocked, and incubated at 36.5±1°C. A real-time algorithm detects

sensor array responses indicating the volatile-compound emissions that are associated with bacterial population growth.

E. Substantial Equivalence:

The similarities and differences of the VITEK® REVEAL™ GN AST Assay and VITEK® REVEAL™ AST System when compared to the predicate device, VITEK® REVEAL™ GN AST Assay and VITEK® REVEAL™ AST System (K230675) are described in the following table.

Table 1: Substantial Equivalence

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 antimicrobial susceptibility testing (AST) of organisms direct from positive blood culture. The VITEK REVEAL AST System does not provide organism identification.	Same
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,	Same

Device & Predicate Device(s):	Device: K260160	Predicate: K230675
	Ceftazidime, Ceftazidime/avibactam, Ceftazidime/clavulanate, Ceftolozane/tazobactam, Ceftriaxone, Cefuroxime, Ciprofloxacin, Ertapenem, Gentamicin, Imipenem, Levofloxacin, Meropenem, Meropenem/vaborbactam, Piperacillin/tazobactam, Tetracycline, Tobramycin, Trimethoprim/sulfamethoxazole	
General Device Characteristic Differences		
Tested Species with Ceftazidime	*Pseudomonas aeruginosa* *Acinetobacter baumannii-calcoaceticus* complex *Citrobacter koseri* *Enterobacter cloacae* complex *Escherichia coli* *Klebsiella aerogenes* *Klebsiella oxytoca* *Klebsiella pneumoniae* group	*Acinetobacter baumannii-calcoaceticus* complex *Citrobacter koseri* *Enterobacter cloacae* complex *Escherichia coli* *Klebsiella aerogenes* *Klebsiella oxytoca* *Klebsiella pneumoniae* group

F. Indications 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), Proteus mirabilis)

Cefuroxime: Enterobacterales (Citrobacter koseri, Escherichia coli, Klebsiella pneumoniae group, Klebsiella oxytoca, 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, 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 (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: 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

G. Performance Overview

The VITEK® REVEAL™ GN AST Assay has identical technological characteristics to the VITEK® REVEAL™ GN AST Assay (K230675). In this submission, data from a previously conducted study was analyzed using 2025 FDA STIC breakpoints to add *Pseudomonas aeruginosa* to the tested species with ceftazidime. The performance of cefepime/*Pseudomonas aeruginosa* was updated using FDA STIC breakpoints as of September 2025 per the breakpoint change protocol Predetermined Change Control Plan (PCCP) cleared within K230675. No new data were collected. In addition, amikacin and gentamicin/*Pseudomonas aeruginosa* and tetracycline/*Acinetobacter* spp. combinations were removed from the Indications for Use and labeling to conform with latest breakpoint recognition updates on the FDA STIC website.

The VITEK® REVEAL™ GN AST Assay demonstrated acceptable performance for *P. aeruginosa*/ceftazidime of 95.0% Essential Agreement and 95.0% Category Agreement with the reference method. Quality Control can also be seen in Table 2 below with a summary of *P. aeruginosa* Clinical Performance and Challenge performance in Table 3.

Table 2: VITEK® REVEAL™ GN AST Assay Performance of Ceftazidime

Performance	
Clinical & Challenge Performance Data	Enterobacterales EA = 95.3% CA = 97.1%
	A. baumannii – calcoaceticus complex EA = 97.4% CA = 94.9%
	P. aeruginosa EA = 95.0% CA = 95.0%
Quality Control	*E. coli* ATCC® 25922 97.6% within range
	P. aeruginosa ATCC® 27853 99.1% within range
	K. pneumoniae ATCC® 700603 99.1% within range

Table 3: Summary of Ceftazidime Results for P. aeruginosa

Sample Set	Total	#EA	%EA	Total Eval	#EA Eval	%EA Eval	#CA	%CA	#S	#I	#R	#vmj	#maj	#min
Clinical	28	26	92.9%	27	25	92.6%	26	92.9%	25	1	2	0	0	2
Challenge	73	70	95.9%	56	53	94.6%	70	95.9%	43	1	29	0	2	1
Combined	**101**	**96**	**95.0%**	**83**	**78**	**94.0%**	**96**	**95.0%**	**68**	**2**	**31**	**0**	**2**	**3**

H. Conclusion:

The clinical performance data and cybersecurity documentation presented in this submission support a substantial equivalence decision for the addition of the claim for *P. aeruginosa* as an indicated species for testing ceftazidime and the revision of the VITEK® REVEAL™ GN AST Assay indications for use. VITEK® REVEAL™ GN AST Assay and VITEK® REVEAL™ AST System K260160 devices are substantially equivalent to VITEK® REVEAL™ GN AST Assay and VITEK® REVEAL™ AST System predicate devices (K230675).