June 26, 2026

Phast Corp.
% Katie Hahnemann
Regulatory Affairs Specialist
MDC Associates
48 Dunham Ridge Rd.
Suite 4000
Beverly, Massachusetts 01915

Re: K253316
Trade/Device Name: PhAST instrument and PhAST Blood Culture Gram-negative Panel
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: May 20, 2026
Received: May 20, 2026

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP) for Removal of Resistant-Isolate Labeling Limitations, version 04. 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253316

Device Name
PhAST instrument and PhAST Blood Culture Gram-negative Panel

Indications for Use *(Describe)*
The PhAST Blood Culture Gram-negative Panel (PhAST BC GN Panel) is an in vitro diagnostic assay for qualitative (breakpoint) determination of antimicrobial susceptibility testing (AST) of pathogenic gram-negative bacteria from positive blood cultures (BC) and is intended to be used with the PhAST instrument. The PhAST BC GN Panel is a phenotypic test that utilizes video microscopy and analysis of single-cell phenotypes to determine susceptibility based on categorical interpretation. The PhAST BC GN Panel does not provide organism identification. The PhAST BC GN Panel is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system and reported as monomicrobial gram-negative specimens by gram staining. Organism identity must be entered into the PhAST instrument or PhAST web application before categorical interpretation (Susceptible, Susceptible Dose-Dependent, Intermediate, Resistant, S/SDD/I/R) of antimicrobial susceptibility is reported. The PhAST BC GN Panel contains 15 antimicrobials.

The PhAST BC GN Panel is intended to aid in the diagnosis and treatment of individuals suspected of bloodstream infection by a healthcare provider. Results should not be used as the sole basis for patient management decisions.

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 PhAST BC GN Panel 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 PhAST BC GN Panel, inconclusive results, epidemiologic testing, recovery of organisms present in positive blood cultures samples, and susceptibility testing of bacteria in polymicrobial samples.

Testing is indicated for Acinetobacter spp., Enterobacterales, and Pseudomonas aeruginosa, as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC). The PhAST BC GN Panel with the PhAST instrument has demonstrated acceptable performance with the following organisms:

Amikacin: Enterobacterales (Citrobacter freundii complex, Citrobacter koseri, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Serratia marcescens)

Ampicillin/sulbactam: Acinetobacter spp. (Acinetobacter baumannii complex)

Aztreonam: Enterobacterales (Citrobacter freundii complex, Citrobacter koseri, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus vulgaris group)

Cefepime: Enterobacterales (Citrobacter freundii complex, Citrobacter koseri, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Serratia marcescens) and Pseudomonas aeruginosa

Ceftazidime: Acinetobacter spp. (Acinetobacter baumannii complex), Enterobacterales (Enterobacter cloacae complex, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Serratia marcescens) and Pseudomonas aeruginosa

Ceftazidime/avibactam: Enterobacterales (Citrobacter freundii complex, Citrobacter koseri, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus

vulgaris group, Serratia marcescens) and Pseudomonas aeruginosa

Ceftriaxone: Enterobacterales (Citrobacter freundii complex, Citrobacter koseri, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis)

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

Ertapenem: Enterobacterales (Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis)

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

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

Meropenem: Acinetobacter spp. (Acinetobacter baumannii complex), Enterobacterales (Citrobacter freundii complex, Citrobacter koseri, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis) and Pseudomonas aeruginosa

Piperacillin/tazobactam: Acinetobacter spp. (Acinetobacter baumannii complex), Enterobacterales (Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae) and Pseudomonas aeruginosa

Tobramycin: Enterobacterales (Citrobacter freundii complex, Citrobacter koseri, Enterobacter cloacae complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Proteus vulgaris group) and Pseudomonas aeruginosa

Trimethoprim/sulfamethoxazole: Enterobacterales (Citrobacter koseri, Escherichia coli, Klebsiella aerogenes, Klebsiella pneumoniae, Serratia marcescens)

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

PhAST instrument and PhAST Blood Culture Gram-negative Panel

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: PhAST Corp.
Roman Stocker
38 Wareham St. Fl 2
Boston, MA 02118
submissions@phast.ai

Correspondent: MDC Associates, Inc.
Katie Hahnemann
48 Dunham Ridge Road
Beverly, MA 01915
phastdx@MDCassoc.com

Device

Device Trade Name: PhAST instrument and PhAST Blood Culture Gram-negative Panel

Common Name: PhAST instrument and PhAST BC GN Panel

Classification Name: A cellular analysis system for multiplexed antimicrobial susceptibility testing

Regulation Number: 21 CFR 866.1650

Regulatory Class: Class II

Product Code: SAN, LON

Predicate Device: Accelerate Pheno System, Accelerate PhenoTest BC Kit, DEN160032

Device Description Summary

The PhAST Blood Culture Gram-negative Panel (PhAST BC GN Panel) is an *in vitro* diagnostic assay for antimicrobial susceptibility testing (AST) of pathogenic gram-negative bacteria from positive blood cultures (BC) and is intended to be used with the PhAST instrument. The PhAST BC GN Panel is a phenotypic test that utilizes video microscopy and analysis of single-cell phenotypes to determine susceptibility. The PhAST BC GN Panel is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system and reported as monomicrobial gram-negative specimens by gram staining. The PhAST BC GN Panel does not provide organism identification. Organism identity, using an FDA-cleared method, must be entered into the PhAST instrument or PhAST web application before categorical interpretation (Susceptible, Susceptible Dose-Dependent, Intermediate, Resistant, S/SDD/I/R) of antimicrobial susceptibility is reported. The PhAST BC GN Panel contains 15 antimicrobials. The workflow is simple, from a direct positive blood culture specimen, and requires less than 1 minute of hands-on time. PhAST BC GN Panel cartridges are run on-demand utilizing one of four independent, random-access bays on the PhAST instrument, with a 99 +/- 6 minute time to result (TTR) for Enterobacterales and *Acinetobacter* spp. and a 141 +/- 6 minute TTR for *Pseudomonas aeruginosa* (mean +/- std. dev.).

For each organism/antimicrobial combination, the PhAST BC GN Panel reports a categorical interpretation (Susceptible [S], Susceptible-dose dependent [SDD], Intermediate [I] or Resistant [R]) in accordance with the FDA interpretive criteria in the table below.

Table 1. FDA Susceptibility Test Interpretive Criteria (STIC)/"Breakpoints" in the PhAST BC GN Panel.

Antimicrobial	Enterobacterales			*P. aeruginosa*			*Acinetobacter* spp.		
	S	I/SDD	R	S	I	R	S	I	R
Amikacin	≤4	8	≥16	-	-	-	-	-	-
Ampicillin/sulbactam	-	-	-	-	-	-	≤8	16	≥32
Aztreonam	≤4	8	≥16	-	-	-	-	-	-
Cefepime	≤2	4-8 (SDD)	≥16	≤8	16	≥32	-	-	-
Ceftazidime	≤4	8	≥16	≤8	16	≥32	≤8	16	≥32
Ceftazidime/avibactam	≤8	-	≥16	≤8	-	≥16	-	-	-
Ceftriaxone	≤1	2	≥4	-	-	-	-	-	-
Ciprofloxacin	≤0.25	0.5	≥1	≤0.5	1	≥2	-	-	-
Ertapenem	≤0.5	1	≥2	-	-	-	-	-	-
Gentamicin	≤2	4	≥8	-	-	-	-	-	-
Levofloxacin	≤0.5	1	≥2	≤1	2	≥4	-	-	-
Meropenem	≤1	2	≥4	≤2	4	≥8	≤2	4	≥8
Piperacillin/tazobactam	≤8	16	≥32	≤16	32	≥64	≤16	32-64	≥128
Tobramycin	≤2	4	≥8	≤1	2	≥4	-	-	-
Trimethoprim/sulfamethoxazole	≤2	-	≥4	-	-	-	-	-	-

Intended Use/Indications for Use

The PhAST Blood Culture Gram-negative Panel (PhAST BC GN Panel) is an *in vitro* diagnostic assay for qualitative (breakpoint) determination of antimicrobial susceptibility testing (AST) of pathogenic gram-negative bacteria from positive blood cultures (BC) and is intended to be used with the PhAST instrument. The PhAST BC GN Panel is a phenotypic test that utilizes video microscopy and analysis of single-cell phenotypes to determine susceptibility based on categorical interpretation. The PhAST BC GN Panel does not provide organism identification. The PhAST BC GN Panel is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system and reported as monomicrobial gram-negative specimens by gram staining. Organism identity must be entered into the PhAST instrument or PhAST web application before categorical interpretation (Susceptible, Susceptible Dose-Dependent, Intermediate, Resistant, S/SDD/I/R) of antimicrobial susceptibility is reported. The PhAST BC GN Panel contains 15 antimicrobials.

The PhAST BC GN Panel is intended to aid in the diagnosis and treatment of individuals suspected of bloodstream infection by a healthcare provider. Results should not be used as the sole basis for patient management decisions.

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 PhAST BC GN Panel 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 PhAST BC GN Panel, inconclusive results, epidemiologic testing, recovery of organisms present in positive blood cultures samples, and susceptibility testing of bacteria in polymicrobial samples.

Testing is indicated for *Acinetobacter* spp., Enterobacterales, and *Pseudomonas aeruginosa*, as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC). The PhAST BC GN Panel with the PhAST instrument has demonstrated acceptable performance with the following organisms:

Amikacin: Enterobacterales (*Citrobacter freundii* complex, *Citrobacter koseri*, *Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Serratia marcescens*)

Ampicillin/sulbactam: *Acinetobacter* spp. (*Acinetobacter baumannii* complex)

Aztreonam: Enterobacterales (*Citrobacter freundii* complex, *Citrobacter koseri*, *Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus vulgaris* group)

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

Ceftazidime: *Acinetobacter* spp. (*Acinetobacter baumannii* complex), Enterobacterales (*Enterobacter cloacae* complex, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Serratia marcescens*) and *Pseudomonas aeruginosa*

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

Ceftriaxone: Enterobacterales (*Citrobacter freundii* complex, *Citrobacter koseri*, *Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus mirabilis*)

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

Ertapenem: Enterobacterales (*Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus mirabilis*)

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

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

Meropenem: *Acinetobacter* spp. (*Acinetobacter baumannii* complex), Enterobacterales (*Citrobacter freundii* complex, *Citrobacter koseri*, *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus mirabilis*) and *Pseudomonas aeruginosa*

Piperacillin/tazobactam: *Acinetobacter* spp. (*Acinetobacter baumannii* complex), Enterobacterales (*Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*) and *Pseudomonas aeruginosa*

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

Trimethoprim/sulfamethoxazole: Enterobacterales (*Citrobacter koseri*, *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella pneumoniae*, *Serratia marcescens*)

Comparison with the Predicate Device

Table 2. Comparison with the predicate device.

Device & Predicate Device	**Device** PhAST BC GN Panel and PhAST instrument	**Predicate Device** Accelerate PhenoTest BC Kit and Accelerate Pheno System (DEN160032)
General Device Characteristic Similarities		
Intended Use	The PhAST Blood Culture Gram-negative Panel (PhAST BC GN Panel) is an *in vitro* diagnostic assay for qualitative (breakpoint) determination of antimicrobial susceptibility testing (AST) of pathogenic gram-negative bacteria from positive blood cultures (BC) and is intended to be used with the PhAST instrument. The PhAST BC GN Panel is a phenotypic test that utilizes video microscopy and analysis of single-cell phenotypes to determine susceptibility based on categorical interpretation. The PhAST BC GN Panel does not provide organism identification. The PhAST BC GN Panel is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system and reported as monomicrobial gram-negative specimens by gram staining. Organism identity must be entered into the PhAST instrument or PhAST web application before categorical interpretation (Susceptible, Susceptible Dose-Dependent, Intermediate, Resistant, S/SDD/I/R) of antimicrobial susceptibility is reported. The PhAST BC GN Panel contains 15 antimicrobials. The PhAST BC GN Panel is intended to aid in the diagnosis and treatment of individuals suspected of bloodstream infection by a healthcare provider. Results should not be used as the sole basis for patient management decisions.	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 by a continuous monitoring blood culture system. Results are intended to be interpreted in conjunction with gram stain results.

	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 PhAST BC GN Panel 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 PhAST BC GN Panel, inconclusive results, epidemiologic testing, recovery of organisms present in positive blood cultures samples, and susceptibility testing of bacteria in polymicrobial samples.	
Sample Type	Positive blood culture	Same
Inoculation Method	Automated	Same
Detection Technology	Single-cell, time-lapse microscopy	Similar
AST Read Method	Automated	Same
General Device Characteristic Differences		
Indicated Antimicrobials	Amikacin Ampicillin/sulbactam Aztreonam Cefepime Ceftazidime Ceftazidime/avibactam Ceftriaxone Ciprofloxacin Ertapenem Gentamicin Levofloxacin Meropenem Piperacillin/tazobactam Tobramycin Trimethoprim/sulfamethoxazole	Amikacin Ampicillin/sulbactam Aztreonam Cefepime Ceftazidime Ceftriaxone Ciprofloxacin Ertapenem Gentamicin Meropenem Piperacillin/tazobactam Tobramycin Additional gram-positive antimicrobials are also included on the Accelerate PhenoTest BC kit
Tested Organisms	Enterobacterales, *Pseudomonas aeruginosa*, *Acinetobacter* spp.	Enterobacterales, *Pseudomonas aeruginosa*, *Acinetobacter* spp.,

		Enterococcus spp., *Staphylococcus* spp.
Sample Preparation	Short (<1 min) pre-processing step for red blood cell lysis	Automated
Sample Runtime to AST	Approximately 100 minutes for Enterobacterales and *Acinetobacter* spp. and approximately 140 minutes for *Pseudomonas aeruginosa*	Approximately 7 hours
Results	Report results as categorical interpretation	Report results as minimum inhibitory concentration (MIC) with categorical interpretation
Samples per Instrument	4	1

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 evaluate the performance of the PhAST BC GN Panel run on the PhAST instrument when testing the same isolate on different PhAST instruments, at different sites, across multiple days of testing by different operators. Three sites were chosen for the study and testing was performed in triplicate across three days of testing at each site to demonstrate reproducibility. For each day of testing, aliquots from the same contrived positive blood culture bottle were distributed to the three sites and tested on the PhAST BC GN Panel in triplicate at each site. Testing was performed across three days at all sites for each of the 16 representative organisms used in this study, by at least two operators per site. Performance was quantified for each organism/antimicrobial combination as the Categorical Agreement between each result and the categorical mode across all tests for that organism/antimicrobial combination. Both inter-site and intra-site reproducibility were computed for each antimicrobial on the PhAST BC GN Panel.

Reproducibility results are summarized in the table below as the Categorical Agreement for each antimicrobial across all organisms on the testing panel and all sites. Testing demonstrated that results from the PhAST BC GN Panel are highly reproducible, with a reproducibility of ≥95% for each antimicrobial and of 99.3% overall.

Table 3. PhAST BC GN Panel reproducibility for each antimicrobial.

Antimicrobial	# of Total Tests	Categorical Agreement
Amikacin	309	97.1%
Ampicillin/sulbactam	307	99.0%
Aztreonam	339	100.0%
Cefepime	393	99.7%
Ceftazidime	475	99.6%
Ceftazidime/avibactam	382	100.0%
Ceftriaxone	333	100.0%
Ciprofloxacin	394	100.0%
Ertapenem	284	97.5%
Gentamicin	335	100.0%
Levofloxacin	396	99.7%
Meropenem	467	99.8%
Piperacillin/tazobactam	473	97.3%
Tobramycin	382	98.7%
Trimethoprim/sulfamethoxazole	336	100%

Blood Culture Bottle Equivalency

The Blood Culture Bottle Equivalency Study was designed to evaluate the performance of the PhAST BC GN Panel run on the PhAST instrument when tested with different blood culture bottle types, given in the table below. For each bottle type, the corresponding continuous blood culturing system was used: BacT/ALERT 3D (bioMérieux) and BACTEC (Becton Dickinson, BD). Similar bottle types were aggregated across the two manufacturers based on function (see table below).

To evaluate whether different aggregate bottle types affect PhAST BC GN Panel performance, a panel of 17 representative organisms, spanning all three claimed organism groups, was tested on aerobic bottle types, and a reduced, 12-organism panel (only the Enterobacterales from the 17-organism panel) was tested on anaerobic bottle types. Blood culture bottles were inoculated and incubated until positivity in their respective blood culturing systems. Bottles from each bottle type were tested on the PhAST BC GN Panel as biological replicates. Each of the 15 antimicrobials on the panel was evaluated for each bottle type. Performance was quantified for each aggregated bottle type, organism and antimicrobial as the Categorical Agreement between the PhAST BC GN Panel results and the categorical mode of results obtained from triplicate broth microdilution. Blood culture bottles containing charcoal were not tested.

Results are summarized in the table below as the Categorical Agreement for each bottle type, across all organisms and antimicrobials. Overall Categorical Agreement was >90% for each bottle type tested.

The overall No Call: Inconclusive + Technical Error rate across all organisms and antimicrobials was <10% for each bottle type tested.

Specific bottle/organism/antimicrobial observations relevant to interpretation of the study are summarized below.

- *Discordant ertapenem results were observed for E. coli tested from BD BACTEC Plus Anaerobic/F blood culture bottles, primarily associated with one strain.*
- *A No Call: Inconclusive + Technical Error rate of 25.8% was observed for tobramycin in BD BACTEC Lytic Anaerobic/F bottles, with the observed events occurring in E. coli and S. marcescens.*

Table 4. PhAST BC GN Panel bottle equivalency results summary.

Aggregate Bottle Type	Bottle Type	# of Tests	Categorical Agreement
Aerobic with resin	BD BACTEC Plus Aerobic/F	385	97.9%
	bioMérieux BacT/ALERT FA Plus Aerobic	555	99.3%
Aerobic without resin	BD BACTEC Standard/10 Aerobic/F	379	99.2%
	bioMérieux BacT/ALERT SA Standard Aerobic	586	99.1%
Pediatric with resin	BD BACTEC PEDS PLUS/F	380	94.5%

(aerobic)	bioMérieux BacT/ALERT PF Plus	585	98.8%
Anaerobic with resin	BD BACTEC Plus Anaerobic/F	492	93.9%[a]
	bioMérieux BacT/ALERT FN Plus Anaerobic	473	98.3%
Anaerobic without resin	BD BACTEC Standard/10 Anaerobic/F	475	99.2%
	bioMérieux BacT/ALERT SN Standard Anaerobic	504	99.2%
Lytic anaerobic	BD BACTEC Lytic Anaerobic/F	932	98.5%[b]

[a] ETP did not meet ≥90% Categorical Agreement when tested from BD BACTEC Plus Anaerobic/F blood culture bottles. Discordance was observed in *E. coli* and was primarily associated with one strain.

[b] TOB: The combined No Call: Inconclusive + Technical Error rates were >10% when tested from BD BACTEC Lytic Anaerobic/F blood culture bottles. Observed events occurred with *E. coli* and *S. marcescens*.

The following statement is included in the device labeling:

- The performance of this test has only been evaluated using the following blood culture bottles:
  - BD BACTEC Standard/10 Aerobic/F
  - BD BACTEC Standard/10 Anaerobic/F
  - BD BACTEC PEDS PLUS/F
  - BD BACTEC Plus Aerobic/F
  - BD BACTEC Plus Anaerobic/F
  - BD BACTEC Lytic Anaerobic/F
  - bioMérieux BacT/ALERT SA Standard Aerobic
  - bioMérieux BacT/ALERT SN Standard Anaerobic
  - bioMérieux BacT/ALERT FA Plus Aerobic
  - bioMérieux BacT/ALERT FN Plus Anaerobic
  - bioMérieux BacT/ALERT PF Plus

Sample Stability

The Sample Stability Study was designed to evaluate the performance of the PhAST BC GN Panel on positive blood culture bottles tested after storage under conditions representative of clinical laboratory workflows. The study evaluated positive blood culture bottles that were either maintained in a blood culture incubator after positivity or removed from the incubator and stored at ambient room temperature before testing on the PhAST instrument. Storage conditions were evaluated using a panel of 16 organisms. The tested conditions included: (i) storage for 14 hours in a blood culture incubator at 35°C after positivity ("14 h 35C" in the table), and (ii) storage for 5 hours in a blood culture incubator at 35°C after positivity, followed by an additional 14 hours at ambient room temperature after bottle removal ("5 h 35C + 14 h RT"). Results obtained after each storage condition were compared to the mode result from samples tested in triplicate within one hour after bottle positivity. Each of the 15 antimicrobials on the panel was evaluated under each storage condition.

Results are summarized in the table below across all organisms and antimicrobials for each storage condition and the Categorical Agreement was >99.5% for both the 14 h at 35°C condition and the 5 h at

35°C + 14 h room temperature condition. These results support testing positive blood culture bottles that are removed from the blood culture incubator up to 5 hours after positivity and then stored at ambient room temperature for up to 12 hours after bottle removal before testing on the PhAST BC GN Panel.

The following statement is included in the device labeling:

- Positive blood cultures should be tested immediately after a positive flag, where possible. In the case of unavoidable delays or if the need for re-testing arises, testing on the PhAST BC GN Panel may be performed on positive blood cultures removed from the continuous monitoring blood culture system within 5 hours of bottle ring and subsequently kept at room temperature for up to 12 hours after removal.

Table 5. Performance of the PhAST BC GN Panel for two storage conditions, supporting a 12-hour stability claim.

Storage Condition	Categorical Agreement
14 h 35C	99.7%
5 h 35C + 14 h RT	99.8%

Interfering Substances

The Interfering Substances Study was designed to evaluate the performance of the PhAST BC GN Panel run on the PhAST instrument for positive blood culture samples that contain high, clinically-relevant levels of endogenous and exogenous substances. The PhAST BC GN Panel was tested on blood culture samples that contained concentrations of such substances at elevated, clinically-relevant concentrations by spiking the substances directly into blood.

To evaluate whether the presence of elevated concentrations of endogenous and exogenous substances affects PhAST BC GN Panel performance, a panel of 17 organisms was tested. Whole human blood was spiked with each of 9 potentially interfering substances at high, clinically-relevant concentrations, inoculated with the test organisms and cultured in a blood culture bottle until positivity. Each of the 15 antimicrobials on the panel was evaluated for each potential interfering substance. Performance was quantified for each interfering substance, organism and antimicrobial as the Categorical Agreement between the PhAST BC GN Panel results and the categorical mode obtained from negative control bottles, prepared with the same test organisms but without interfering substances.

Results are summarized in the table below as the Categorical Agreement for each potential interfering substance, across all organisms and antimicrobials. Overall Categorical Agreement was >97% for each potential interfering substance at high, clinically-relevant concentrations.

Specific organism/antimicrobial/interferent observations relevant to interpretation of the study are summarized below.

- Discordant results were observed when testing ertapenem, ampicillin/sulbactam, piperacillin/tazobactam and tobramycin with tested Enterobacterales with the addition of triglycerides at 5 mg/mL. Discordance was not observed with an addition of 1.67 mg/mL triglycerides for the affected claimed combinations.
- Discordant tobramycin results were observed for *Pseudomonas aeruginosa* with the addition of conjugated bilirubin at 400 mg/L. Discordance was not observed with the addition of 133 mg/L conjugated bilirubin.

Table 6. Performance of the PhAST BC GN Panel in the presence of potential interfering substances.

Endogenous Substances	**Test Concentration Added to Blood ***	**Categorical Agreement**
Conjugated bilirubin	400 mg/L	99.1% [a]
Unconjugated bilirubin	400 mg/L	99.5%
Gamma-globulin	50 g/L	99.9%
Triglycerides	5 mg/mL	97.8% [b]
Red blood cells (Hematocrit/Hemoglobin)	20 g/dL	99.7%
White blood cells (buffy coat)	12,000 WBC/µL	99.7%
Platelets	400,000 platelets/µL	99.5%
Exogenous Substances		
Heparin	3,000 Units/L	99.6%
Sodium Polyanetholesulfonate (SPS)	0.1% w/v (in bottle with blood)	99.6%

* From CLSI EP37 (2018).

[a] TOB demonstrated <95% Categorical Agreement at the tested concentration due to one *P. aeruginosa* strain. When retested with 133 mg/L conjugated bilirubin, performance was acceptable.

[b] ETP, SAM, TOB and TZP demonstrated <95% Categorical Agreement at the tested concentration due to Enterobacterales strains. When retested with 1.67 mg/mL triglycerides, performance was acceptable.

Interfering Antimicrobials

The Interfering Antimicrobials Study was designed to evaluate the performance of the PhAST BC GN Panel run on the PhAST instrument for positive blood culture samples that contain therapeutic levels of antimicrobials. One representative antimicrobial for each of four major classes of antimicrobials was tested as the interfering antimicrobial in non-resin bottles (see table below), to mimic a blood sample from a patient that was already dosed with antimicrobials prior to blood draw. The PhAST BC GN Panel

was tested on blood culture samples that contained concentrations of such potential interfering antimicrobials at therapeutic concentrations by spiking the potential interfering antimicrobials directly into blood.

To evaluate whether the presence of antimicrobials in blood affects PhAST BC GN Panel performance when performed on blood collected in standard (non-resin) bottles, a panel of 10 organisms was tested. The test organisms were seeded into blood containing therapeutic concentrations of the potential interfering antimicrobial (see table below) and cultured until positivity in non-resin bottles. The PhAST BC GN Panel was tested on these positive blood culture samples containing the potential interfering antimicrobials and compared against negative controls prepared without interfering antimicrobials. Each of the 15 antimicrobials on the panel was evaluated for each potential interfering antimicrobial. Performance was quantified for each interfering antimicrobial, organism and antimicrobial as the Categorical Agreement between the PhAST BC GN Panel results and the categorical mode obtained from negative control bottles, prepared with the same test organisms but without interfering antimicrobials.

Results are summarized in the table below as the Categorical Agreement for each potential interfering antimicrobial, across all organisms and antimicrobials. Overall Categorical Agreement was >97% for each potential interfering antimicrobial at therapeutic concentrations.
Specific organism/antimicrobial/interferent observations relevant to interpretation of the study are summarized below.

- One *Klebsiella oxytoca* strain tested from a non-resin blood culture bottle had discordant amikacin results in the presence of ciprofloxacin at 0.4 mg/dL or ampicillin/sulbactam at 2.5/1.25 mg/dL. Discordance was also observed when the strain was retested at 0.13 mg/dL ciprofloxacin and 0.83/0.42 mg/dL ampicillin/sulbactam.
- One *Klebsiella pneumoniae* strain tested from a non-resin blood culture bottle had a discordant tobramycin result in the presence of ciprofloxacin at 0.4 mg/dL. Discordance was not observed when the strain was retested at 0.13 mg/dL ciprofloxacin.

Table 7. Performance of the PhAST BC GN Panel in the presence of potential interfering antimicrobials.

Antimicrobial Class	Potential Interfering Antimicrobial	Test Concentration in Blood*	Categorical Agreement
Fluoroquinolones	Ciprofloxacin	0.4 mg/dL	97.3% [a, b]
Cephalosporins	Ceftriaxone	28 mg/dL	99.6% [c]
β-lactam / β-lactamase inhibitor	Ampicillin/sulbactam	2.5/1.25 mg/dL	99.0% [b]
Aminoglycosides	Amikacin	4.8 mg/dL	98.5% [d, e]

* Drug concentration values from CLSI EP37 (2018).

[a] TOB in the presence of ciprofloxacin had a CA <95% due to minor errors with one *P. aeruginosa* strain and one *K. pneumoniae* strain. Supplemental testing of two additional *P. aeruginosa* strains at therapeutic ciprofloxacin

concentration (0.4 mg/dL) and one *K. pneumoniae* strain at three-fold lower ciprofloxacin concentration (0.13 mg/dL) demonstrated acceptable performance.

[b] AMK in the presence of ciprofloxacin or ampicillin/sulbactam had a CA <95% due to one *K. oxytoca* strain. Repeat testing with three-fold lower concentrations of ciprofloxacin (0.13 mg/dL) or ampicillin/sulbactam (0.83/0.42 mg/dL), demonstrated CA <95% due to minor errors of the same *K. oxytoca* strain.

[c] TZP in the presence of ceftriaxone had a CA <95% due to a single minor error with one replicate of a single *K. pneumoniae* strain.

[d] TOB in the presence of amikacin had a CA <95% due to three minor errors with one *P. aeruginosa* strain. Supplemental testing of two additional *P. aeruginosa* strains demonstrated acceptable performance.

[e] CZA in the presence of amikacin had a CA <95% due to a single very major error, which was determined to be a technical error.

Carryover/Cross-Contamination

The Carryover/Cross-Contamination Study was designed to evaluate the possibility of sample carryover on the PhAST BC GN Panel across samples run at different times within the same bay or of cross-contamination between the instrument's four bays.

To evaluate whether carryover or cross-contamination occurred, blood culture bottles were seeded with complementary pairs of organisms with opposite S/R profiles for indicated antimicrobials. Samples were then tested on the PhAST BC GN Panel in alternating patterns to detect carryover or cross-contamination. Categorical Agreement was used as the metric to detect the presence of carryover or cross-contamination.

The results demonstrate that the PhAST BC GN Panel cartridges, run on the PhAST instrument, are sufficiently self-contained to prevent contamination of results from different cartridges run either on different bays or on the same bay at a different time.

Method Comparison Study

The purpose of the method comparison study was to evaluate the clinical performance of the PhAST BC GN Panel for use on the PhAST instrument in providing phenotypic, qualitative antimicrobial susceptibility testing (AST) results from positive blood cultures containing gram-negative bacteria. PhAST BC GN Panel results (categorical interpretations, S/SDD/I/R) were compared to results from reference frozen broth microdilution (BMD) in triplicate, tested according to CLSI M07 (12th Edition) Standard and performed at a single reference site.

Clinical performance testing using the PhAST BC GN Panel was conducted at 4 sites (3 US clinical sites and 1 internal site). Performance was evaluated using prospectively collected, fresh leftover positive blood culture samples from patients with suspected bacteremia. Samples were confirmed by gram stain to contain only gram-negative bacteria prior to testing on the PhAST BC GN Panel. Additionally, blood culture bottles containing fresh human donor blood were contrived with clinical stock isolates and challenge isolates to supplement the fresh prospective blood cultures for lower prevalence species and

resistance profiles. Subcultures of all positive blood cultures onto appropriate media (Tryptic Soy Agar with 5% sheep blood) were used to check for purity prior to preparing a frozen stock for shipment to the central reference laboratory. Polymicrobial samples were excluded from analysis. Organism identification was obtained from an FDA-cleared MALDI-TOF method for input into the PhAST web application to generate AST results.

Performance was determined by comparing the modal S/SDD/I/R results of the reference method as assessed using FDA-recognized breakpoints (Antimicrobial Susceptibility Test Interpretive Criteria) to the results of the investigational device. Performance was generally based on criteria outlined in the Class II Special Controls Document: Antimicrobial Susceptibility Test (AST) Systems including Categorical Agreement (CA) and categorical errors (minor, major, and very major errors) for each antimicrobial agent. CA was calculated as the percentage of PhAST results that were identical to the categorical interpretation of the reference results. Performance was considered acceptable if the CA was ≥90%, major error rate was ≤3%, and very major error rate was ≤2%.

In addition, the combined rate of Technical Errors (TE) and No Call: Inconclusive (NC) result rate was also evaluated for each antimicrobial/organism group combination, and all were ≤10%.

A total of 1,028 samples were enrolled in the study, of which 890 samples were included in the performance analysis (256 fresh prospective positive blood culture samples, 121 samples contrived with clinical stock isolates, 513 samples contrived with challenge isolates). In total, 138 samples were excluded from final performance analyses due to not meeting inclusion criteria, invalid QC results, or other protocol deviations. A high-level summary of the PhAST BC GN panel performance is provided below for each antimicrobial and indicated species. Complete details and results including CA and error rate analyses by organism group and antimicrobial are summarized in the table below. Overall Categorical Agreement was high. Antimicrobial/organism combinations not meeting acceptance criteria are discussed in the individual antimicrobial summaries below.

Table 8. PhAST BC GN Panel overall results summary for each antimicrobial.

Antimicrobial	Organism Group	Total #	CA #	S #	I or SDD #	R #	min #	maj #	vmj #	CA %	min %	maj %	vmj %
Amikacin	Enterobacterales	463	441	420	12	31	16	6	0	95.2	3.5	1.4	0.0
Ampicillin/ sulbactam	*Acinetobacter* spp.	62	57	35	3	24	4	1	0	91.9	6.5	2.9	0.0
Aztreonam	Enterobacterales	409	397	278	9	122	11	1	0	97.1	2.7	0.4	0.0
Cefepime	Enterobacterales	477	455	382	21	74	19	3	0	95.4	4.0	0.8	0.0
	P. aeruginosa	54	52	25	1	28	2	0	0	96.3	3.7	0.0	0.0
Ceftazidime	*Acinetobacter* spp.	44	44	15	0	29	0	0	0	100.0	0.0	0.0	0.0
	Enterobacterales	319	306	201	3	115	10	2	1	95.9	3.1	1.0	0.9
	P. aeruginosa	55	54	26	1	28	1	0	0	98.2	1.8	0.0	0.0

Ceftazidime/ avibactam	Enterobacterales	516	515	484	n/a	32	n/a	1	0	99.8	n/a	0.2	0.0
	P. aeruginosa	55	55	26	n/a	29	n/a	0	0	100.0	n/a	0.0	0.0
Ceftriaxone	Enterobacterales	452	452	294	0	158	0	0	0	100.0	0.0	0.0	0.0
Ciprofloxacin	Enterobacterales	517	504	327	4	186	12	1	0	97.5	2.3	0.3	0.0
	P. aeruginosa	51	51	22	0	29	0	0	0	100.0	0.0	0.0	0.0
Ertapenem	Enterobacterales	383	370	348	1	34	4	9	0	96.6	1.0	2.6	0.0
Gentamicin	Enterobacterales	570	555	418	2	150	13	0	2	97.4	2.3	0.0	1.3
Levofloxacin	Enterobacterales	493	478	361	7	125	15	0	0	97.0	3.0	0.0	0.0
	P. aeruginosa	51	50	22	0	29	1	0	0	98.0	2.0	0.0	0.0
Meropenem	*Acinetobacter* spp.	42	41	15	1	26	1	0	0	97.6	2.4	0.0	0.0
	Enterobacterales	447	439	410	0	37	1	7	0	98.2	0.2	1.7	0.0
	P. aeruginosa	52	52	24	0	28	0	0	0	100.0	0.0	0.0	0.0
Piperacillin/ tazobactam	*Acinetobacter* spp.	44	44	15	0	29	0	0	0	100.0	0.0	0.0	0.0
	Enterobacterales	378	359	273	8	97	18	1	0	95.0	4.8	0.4	0.0
	P. aeruginosa	52	48	25	2	25	4	0	0	92.3	7.7	0.0	0.0
Tobramycin	Enterobacterales	370	361	276	5	89	5	3	1	97.6	1.4	1.1	1.1
	P. aeruginosa	53	52	25	0	28	1	0	0	98.1	1.9	0.0	0.0
Trimethoprim/ sulfamethoxazole	Enterobacterales	404	396	315	n/a	89	n/a	8	0	98.0	n/a	2.5	0.0

Amikacin

A total of 463 Enterobacterales isolates (27 *C. freundii* complex, 37 *C. koseri*, 39 *E. cloacae* complex, 164 *E. coli,* 40 *K. aerogenes,* 37 *K. oxytoca,* 81 *K. pneumoniae*, and 38 *S. marcescens*) were evaluated with amikacin. The combined results from clinical and challenge testing demonstrated a CA of 95.2%. There were 16 minor (3.5%), 6 major (1.4%), and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

Amikacin was evaluated for *P. mirabilis* and *P. vulgaris* group but did not meet acceptance criteria. The following limitation is included in the device labeling:

- Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combinations:
  - Amikacin: *P. mirabilis*, *P. vulgaris* group

To address the lack of resistant isolates, the following limitation is included in the device labeling:

- The ability of the PhAST BC GN Panel to detect amikacin resistance in *C. koseri, K. aerogenes* and *K. oxytoca* is unknown because an insufficient number of resistant isolates were tested.

Ampicillin/sulbactam

A total of 62 *A. baumannii* complex samples were evaluated with ampicillin/sulbactam. The combined results from clinical and challenge testing demonstrated a CA of 91.9%. There were 4 minor errors (6.5%), 1 major error (2.9%), and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

Ampicillin/sulbactam was evaluated for Enterobacterales but did not meet acceptance criteria. The following limitation is included in the device labeling:

- Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combinations:
  - Ampicillin/sulbactam: Enterobacterales

Aztreonam

A total of 409 Enterobacterales isolates (25 *C. freundii* complex, 18 *C. koseri,* 43 *E. cloacae* complex, 170 *E. coli,* 31 *K. aerogenes,* 26 *K. oxytoca,* 82 *K. pneumoniae and* 14 *P. vulgaris* group) were evaluated with aztreonam. The combined results from clinical and challenge testing demonstrated a CA of 97.1%. There were 11 minor (2.7%), 1 major (0.4%), and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

Aztreonam was evaluated for *P. mirabilis* and *S. marcescens* but did not meet acceptance criteria. The following limitation is included in the device labeling:

- Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combinations:
  - Aztreonam: *P. mirabilis*, *S. marcescens*

To address the lack of resistant isolates, the following limitation is included in the device labeling:

- The ability of the PhAST BC GN Panel to detect aztreonam resistance in *C. koseri* and *P. vulgaris* group is unknown because an insufficient number of resistant isolates were tested.

Aztreonam was evaluated for *P. aeruginosa* but did not meet acceptance criteria. The following limitation is included in the device labeling:

- Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combination:
  - Aztreonam: *P. aeruginosa*

Cefepime

A total of 477 Enterobacterales isolates (46 *C. freundii* complex, 36 *C. koseri,* 173 *E. coli,* 32 *K. aerogenes,* 27 *K. oxytoca,* 80 *K. pneumoniae,* 41 *P. mirabilis,* and 42 *S. marcescens*) were evaluated with cefepime. The combined results from clinical and challenge testing demonstrated a CA of 95.4%. There were 19 minor (4.0%), 3 major (0.8%), and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

Cefepime was evaluated for *E. cloacae* complex and *P. vulgaris* group but did not meet acceptance criteria. The following limitation is included in the device labeling:

- Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combinations:
  - Cefepime: *E. cloacae* complex, *P. vulgaris* group

To address the lack of resistant isolates, the following limitation is included in the device labeling:

- The ability of the PhAST BC GN Panel to detect cefepime resistance in *C. koseri* is unknown because an insufficient number of resistant isolates were tested.

A total of 54 *P. aeruginosa* isolates were evaluated with cefepime. The combined results from clinical and challenge testing demonstrated a CA of 96.3%. There were 2 minor (3.7%), 0 major (0.0%), and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

Ceftazidime

A total of 319 Enterobacterales isolates (59 *E. cloacae* complex*,* 70 *K. aerogenes,* 28 *K. oxytoca,* 80 *K. pneumoniae,* 40 *P. mirabilis* and 42 *S. marcescens*) were evaluated with ceftazidime. The combined results from clinical and challenge testing demonstrated a CA of 95.9%. There were 10 minor (3.1%), 2 major (1.0%), and 1 very major (0.9%) errors. Overall, performance met defined acceptance criteria.

Ceftazidime was evaluated for *C. freundii* complex, *C. koseri*, *E. coli* and *P. vulgaris* group but did not meet acceptance criteria. The following limitation is included in the device labeling:

- Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combinations:
  - Ceftazidime: *C. freundii* complex, *C. koseri*, *E. coli*, *P. vulgaris* group

To address the lack of resistant isolates, the following limitation is included in the device labeling:

- The ability of the PhAST BC GN Panel to detect ceftazidime resistance in *P. mirabilis* is unknown because an insufficient number of resistant isolates were tested.

A total of 55 *P. aeruginosa* isolates were evaluated with ceftazidime. The combined results from clinical and challenge testing demonstrated a CA of 98.2%. There were 1 minor (1.8%), 0 major (0.0%), and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

A total of 44 *A. baumannii* complex samples were evaluated with ceftazidime. The combined results from clinical and challenge testing demonstrated a CA of 100.0%. There were 0 minor (0.0%), 0 major (0.0%), and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

Ceftazidime/avibactam

A total of 516 Enterobacterales isolates (24 *C. freundii* complex, 19 *C. koseri,* 43 *E. cloacae* complex*,* 180 *E. coli,* 47 *K. aerogenes,* 28 *K. oxytoca,* 80 *K. pneumoniae,* 42 *P. mirabilis,* 11 *P. vulgaris* group and 42 *S. marcescens*) were evaluated with ceftazidime/avibactam. The combined results from clinical and challenge testing demonstrated a CA of 99.8%. There were 1 major (0.2%) and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

To address the lack of resistant isolates, the following limitation is included in the device labeling:

- The ability of the PhAST BC GN Panel to detect ceftazidime/avibactam resistance in *C. freundii* complex*, C. koseri*, *K. aerogenes*, *P. mirabilis* and *P. vulgaris* group is unknown because an insufficient number of resistant isolates were tested.

A total of 55 *P. aeruginosa* isolates were evaluated with ceftazidime/avibactam. The combined results from clinical and challenge testing demonstrated a CA of 100.0%. There were 0 major (0.0%) and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

Ceftriaxone

A total of 452 Enterobacterales isolates (26 *C. freundii* complex, 28 *C. koseri*, 43 *E. cloacae* complex*,* 176 *E. coli,* 32 *K. aerogenes,* 26 *K. oxytoca,* 81 *K. pneumoniae,* and 40 *P. mirabilis*) were evaluated with ceftriaxone. The combined results from clinical and challenge testing demonstrated a CA of 100.0%. There were 0 minor (0.0%), 0 major (0.0%), and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

Ceftriaxone was evaluated for *P. vulgaris* group and *S. marcescens* but did not meet acceptance criteria. The following limitation is included in the device labeling:

- Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combinations:
  - Ceftriaxone: *P. vulgaris* group, *S. marcescens*

Ciprofloxacin

A total of 517 Enterobacterales isolates (26 *C. freundii* complex, 40 *E. cloacae* complex, 217 *E. coli*, 46 *K. aerogenes*, 27 *K. oxytoca*, 78 *K. pneumoniae*, 44 *P. mirabilis* and 39 *S. marcescens*) were evaluated with ciprofloxacin. The combined results from clinical and challenge testing demonstrated a CA of 97.5%. There were 12 minor (2.3%), 1 major (0.3%), and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

Ciprofloxacin was evaluated for *C. koseri* and *P. vulgaris* group but did not meet acceptance criteria. The following limitation is included in the device labeling:

- Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combinations:
  - Ciprofloxacin: *C. koseri*, *P. vulgaris* group

A total of 51 *P. aeruginosa* isolates were evaluated with ciprofloxacin. The combined results from clinical and challenge testing demonstrated a CA of 100.0%. There were 0 minor (0.0%), 0 major (0.0%), and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

Ertapenem

A total of 383 Enterobacterales isolates (192 *E. coli,* 41 *K. aerogenes,* 27 *K. oxytoca,* 81 *K. pneumoniae,* and 42 *P. mirabilis*) were evaluated with ertapenem. The combined original results from clinical and challenge testing demonstrated a CA of 96.6%. There were 4 minor (1.0%), 9 major (2.6%), and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

Ertapenem was evaluated for *C. freundii* complex, *C. koseri, E. cloacae* complex, *P. vulgaris* group, and *S. marcescens* but did not meet acceptance criteria. The following limitation is included in the device labeling:

- Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combinations:
  - Ertapenem: *C. freundii* complex, *C. koseri*, *E. cloacae* complex, *P. vulgaris* group, *S. marcescens*

To address the lack of resistant isolates, the following limitation is included in the device labeling:

- The ability of the PhAST BC GN Panel to detect ertapenem resistance in *P. mirabilis* is unknown because an insufficient number of resistant isolates were tested.

Gentamicin

A total of 570 Enterobacterales isolates (27 *C. freundii* complex, 18 *C. koseri,* 42 *E. cloacae* complex, 249 *E. coli,* 33 *K. aerogenes,* 28 *K. oxytoca,* 81 *K. pneumoniae,* 43 *P. mirabilis*, 11 *P. vulgaris* group, and 38 *S. marcescens*) were evaluated with gentamicin. The combined results from clinical and challenge testing demonstrated a CA of 97.4%. There were 13 minor (2.3%), 0 major (0.0%), and 2 very major (1.3%) errors. Overall, performance met defined acceptance criteria.

When evaluating results by individual species, for *E. coli* the CA was 97.2%. There were 5 minor (2.0%), 0 major (0.0%) and two (2) very major (2.1%) errors. Under the AST Special Controls, the observed very major error rate is acceptable based on the high number of resistant *E. coli* isolates tested (2/95).

To address the lack of resistant isolates, the following limitation is included in the device labeling:

- The ability of the PhAST BC GN Panel to detect gentamicin resistance in *C. koseri*, *P. vulgaris* group and *S. marcescens* is unknown because an insufficient number of resistant isolates were tested.

Levofloxacin

A total of 493 Enterobacterales isolates (27 *C. freundii* complex, 19 *C. koseri,* 43 *E. cloacae* complex, 168 *E. coli,* 31 *K. aerogenes,* 27 *K. oxytoca,* 78 *K. pneumoniae,* 44 *P. mirabilis*, 14 *P. vulgaris* group, and 42 *S. marcescens*) were evaluated with levofloxacin. The combined results from clinical and challenge testing demonstrated a CA of 97.0%. There were 15 minor (3.0%), 0 major (0.0%), and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

To address the lack of resistant isolates, the following limitation is included in the device labeling:

- The ability of the PhAST BC GN Panel to detect levofloxacin resistance in *C. koseri* and *P. vulgaris* group is unknown because an insufficient number of resistant isolates were tested.

A total of 51 *P. aeruginosa* isolates were evaluated with levofloxacin. The combined results from clinical and challenge testing demonstrated a CA of 98.0%. There were 1 minor (2.0%), 0 major (0.0%), and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

Meropenem

A total of 447 Enterobacterales isolates (39 *C. freundii* complex, 36 *C. koseri,* 173 *E. coli,* 31 *K. aerogenes,* 43 *K. oxytoca,* 82 *K. pneumoniae,* and 43 *P. mirabilis*) were evaluated with meropenem. The combined results from clinical and challenge testing demonstrated a CA of 98.2%. There was 1 minor (0.2%), 7 major (1.7%), and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

Meropenem was evaluated for *E. cloacae* complex, *P. vulgaris* group, and *S. marcescens* but did not meet acceptance criteria. The following limitation is included in the device labeling:

- Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combinations:
  - Meropenem: *E. cloacae* complex, *P. vulgaris* group, *S. marcescens*

To address the lack of resistant isolates, the following limitation is included in the device labeling:

- The ability of the PhAST BC GN Panel to detect meropenem resistance in *C. koseri* and *P. mirabilis* is unknown because an insufficient number of resistant isolates were tested.

A total of 52 *P. aeruginosa* isolates were evaluated with meropenem. The combined results from clinical and challenge testing demonstrated a CA of 100.0%. There were 0 minor (0.0%), 0 major (0.0%), and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

A total of 42 *A. baumannii* complex samples were evaluated with meropenem. The combined results from clinical and challenge testing demonstrated a CA of 97.6%. There were 1 minor (2.4%), 0 major (0.0%), and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

Piperacillin/tazobactam

A total of 378 Enterobacterales isolates (51 *E. cloacae* complex, 175 *E. coli,* 32 *K. aerogenes,* 28 *K. oxytoca* and 92 *K. pneumoniae*) were evaluated with piperacillin/tazobactam. The combined results from clinical and challenge testing demonstrated a CA of 95.0%. There were 18 minor (4.8%), 1 major (0.4%), and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

Piperacillin/tazobactam was evaluated for *C. freundii, C. koseri*, *P. mirabilis*, *P. vulgaris* group, and *S. marcescens* but did not meet acceptance criteria. The following limitation is included in the device labeling:

- Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combinations:
  - Piperacillin/tazobactam: *C. freundii* complex, *C. koseri*, *P. mirabilis*, *P. vulgaris* group, *S. marcescens*

A total of 52 *P. aeruginosa* isolates were evaluated with piperacillin/tazobactam. The combined results from clinical and challenge testing demonstrated a CA of 92.3%. There were 4 minor (7.7%), 0 major (0.0%), and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

A total of 44 *A. baumannii* complex samples were evaluated with piperacillin/tazobactam. The combined results from clinical and challenge testing demonstrated a CA of 100.0%. There were 0 minor (0.0%) errors, 0 major (0.0%) errors, and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

Tobramycin

A total of 370 Enterobacterales isolates (26 *C. freundii* complex, 34 *C. koseri,* 40 *E. cloacae* complex, 201 *E. coli,* 32 *K. aerogenes,* 28 *K. oxytoca*, and 9 *P. vulgaris* group) were evaluated with tobramycin. The combined results from clinical and challenge testing demonstrated a CA of 97.6%. There were 5 minor (1.4%), 3 major (1.1%), and 1 very major (1.1%) errors. Overall, performance met defined acceptance criteria.

Tobramycin was evaluated for *K. pneumoniae*, *P. mirabilis* and *S. marcescens* but did not meet acceptance criteria. The following limitation is included in the device labeling:

- Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combinations:
  - Tobramycin: *K. pneumoniae*, *P. mirabilis*, *S. marcescens*

To address the lack of resistant isolates, the following limitation is included in the device labeling:

- The ability of the PhAST BC GN Panel to detect tobramycin resistance in *C. koseri* and *P. vulgaris* group is unknown because an insufficient number of resistant isolates were tested.

A total of 53 *P. aeruginosa* isolates were evaluated with tobramycin. The combined results from clinical and challenge testing demonstrated a CA of 98.1%. There were 1 minor (1.9%), 0 major (0.0%), and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

Trimethoprim/sulfamethoxazole

A total of 404 Enterobacterales isolates (16 *C. koseri*, 230 *E. coli,* 33 *K. aerogenes,* 87 *K. pneumoniae* and 38 *S. marcescens*) were evaluated with trimethoprim/sulfamethoxazole. The combined results from clinical and challenge testing demonstrated a CA of 98.0%. There were 8 major (2.5%) and 0 very major (0.0%) errors. Overall, performance met defined acceptance criteria.

When evaluating results by individual species, for *E. coli* the CA was 97.4%. There were 6 major (3.5%) and 0 very major (0.0%) errors. One major error was associated with an isolated, sample-specific cartridge fluidics anomaly that did not meet predefined Technical Error criteria.

Trimethoprim/sulfamethoxazole was evaluated for *C. freundii, E. cloacae* complex, *K. oxytoca*, *P. mirabilis*, and *P. vulgaris* group but did not meet acceptance criteria. The following limitation is included in the device labeling:

- Perform an alternative method of testing prior to reporting results for the following antibiotic/organism combinations:
  - Trimethoprim/sulfamethoxazole: *C. freundii* complex, *E. cloacae* complex, *K. oxytoca*, *P. mirabilis*, *P. vulgaris* group

To address the lack of resistant isolates, the following limitation is included in the device labeling:

- The ability of the PhAST BC GN Panel to detect trimethoprim/sulfamethoxazole resistance in *C. koseri* is unknown because an insufficient number of resistant isolates were tested.

Conclusion

The conclusions drawn from the analytical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device 807.92(b)(3).