



September 24, 2026

QIAGEN GmbH
% Pamela Nge
Senior Manager, Regulatory Affairs
Qiagen
19300 Germantown Rd.
Germantown, Maryland 20874

Re: K262168

Trade/Device Name: QIAstat-Dx BCID GN Plus AMR Panel
Regulation Number: 21 CFR 866.3365
Regulation Name: Multiplex Nucleic Acid Assay For Identification Of Microorganisms And Resistance
Markers From Positive Blood Cultures
Regulatory Class: Class II
Product Code: PEN
Dated: June 26, 2026
Received: June 26, 2026

Dear Pamela Nge:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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,

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Bryan Grabias, Ph.D.

Acting Branch Chief

Bacterial Respiratory and Medical Countermeasures 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

510(k) Number (*if known*)

K262168

Device Name

QIAstat-Dx BCID GN Plus AMR Panel

Indications for Use (*Describe*)

The QIAstat-Dx BCID GN Plus AMR Panel is an automated qualitative multiplexed real-time PCR-based in vitro diagnostic test intended for use with the QIAstat-Dx Analyzer 2.0. The QIAstat-Dx BCID GN Plus AMR Panel is capable of simultaneous detection and identification of multiple gram-negative bacterial targets and selected genetic determinants associated with antimicrobial resistance.

The following gram-negative bacteria are identified and differentiated using the QIAstat-Dx BCID GN Plus AMR Panel:

- Acinetobacter calcoaceticus-baumannii complex
- Bacteroides fragilis
- Enterobacter spp.
- Escherichia coli
- Haemophilus influenzae
- Klebsiella spp.
- Neisseria meningitidis (encapsulated)
- Proteus spp.
- Pseudomonas aeruginosa
- Salmonella spp.
- Serratia spp.
- Stenotrophomonas maltophilia
- Pan Enterobacterales

The QIAstat-Dx BCID GN Plus AMR Panel contains assays for the detection of the following genetic determinants of resistance:

- aac(6')-Ib
- ampC (CMY/LAT/DHA/FOX)
- armA
- CTX-M
- GES
- IMP
- KPC
- NDM
- OXA-23
- OXA-24/40
- OXA-48-like
- OXA-58
- PER
- SHV
- SPM
- TEM
- VEB
- VIM

The QIAstat-Dx BCID GN Plus AMR Panel contains assays for the detection of genetic determinants associated with resistance to aminoglycosides (aac(6')-Ib and armA), penicillins and cephalosporins (ampC [CMY/LAT/DHA/FOX],

CTX-M, GES, PER, SHV, TEM, and VEB), and carbapenems (GES, IMP, KPC, NDM, OXA-23, OXA-24/40, OXA-48-like, OXA-58, SPM, and VIM). The antimicrobial resistance gene detected may or may not be associated with the agent responsible for disease. Negative results for certain antimicrobial resistance assays do not indicate susceptibility, as multiple mechanisms of resistance exist.

The QIAstat-Dx BCID GN Plus AMR Panel is intended for use in patients suspected of having bacterial infections identified as gram-negative via Gram stain in positive blood culture samples. The test is performed on blood culture samples identified as positive by a continuous monitoring blood culture system that demonstrates the presence of gram-negative bacteria via Gram stain. The QIAstat-Dx BCID GN Plus AMR Panel is intended to aid in the diagnosis of specific pathogens of bloodstream infection and select determinants of antimicrobial-resistance. Results should be used in conjunction with additional laboratory testing, e.g. sub-culturing of positive blood cultures for identification of organisms not detected by QIAstat-Dx BCID GN Plus AMR Panel and susceptibility testing and clinical presentation must be taken into consideration for patient management decisions.

Negative results do not preclude the presence of pathogens that are not detected by this test. Positive QIAstat-Dx BCID GN Plus AMR Panel results do not rule out infection or co-infection with organisms not included in the QIAstat-Dx BCID GN Plus AMR Panel.

Negative AMR results do not preclude the presence of other antimicrobial resistance mechanisms, and the absence of a resistance gene does not necessarily predict susceptibility to a particular drug nor predict therapeutic failure.

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

General Information

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Date Prepared: September 24, 2026

Device Name: QIAstat-Dx BCID GN Plus AMR Panel

Classification: 21 CFR 866.3365 - Multiplex nucleic acid assay for identification of microorganisms and resistance markers from positive blood cultures.

Product Code: PEN

Predicate Device

Product Name	510(k) No.
ePlex Blood Culture Identification Gram Negative (BCID-GN) Panel	K182619

Device Description

The QIAstat-Dx BCID GN Plus AMR Panel is part of a system consisting of the QIAstat-Dx Cartridge, the QIAstat-Dx Analyzer 2.0, and the QIAstat-Dx Software (the QIAstat-Dx Analyzer's Software and a panel-specific software known as the Assay Definition File (ADF)).

The QIAstat-Dx BCID GN Plus AMR Panel is intended to be used on blood culture samples identified as positive by a continuous monitoring blood culture system that demonstrates the presence of gram-negative bacteria via Gram stain.

The QIAstat-Dx BCID GN Plus AMR Panel consists of single-test cartridges with pre-packaged reagents including both wet and dry chemistry necessary to perform the sample preparation, nucleic acid amplification and detection. Samples grown in BACT/ALERT bioMérieux and BACTEC Becton Dickinson bottles are diluted in saline prior to loading in the QIAstat-Dx BCID GN Plus AMR cartridge, while samples grown in VersaTrek™ bottles do not require dilution. Following the pre-dilution step the user needs to load the sample into the Lysis Chamber of the Cartridge with a Transfer Pipette provided in the kit and then insert the Cartridge in the Analytical Module of the QIAstat-Dx Analyzer. The user does not need to come in contact with or manipulate any reagents other than the pre-dilution step with saline (for bioMérieux and Becton Dickinson bottles).

Within the cartridge, multiple steps are automatically performed in sequence by using pneumatic pressure and a multiport valve to transfer sample and fluids via the Transfer Chamber (TC) to their intended destinations. Following the introduction of the sample from a disposable Transfer Pipette, the following assay steps occur automatically and sequentially:

- Resuspension of Internal Control and Proteinase K enzyme
- Cell lysis using mechanical, enzymatic, and chemical means
- Membrane-based nucleic acid purification
- Mixing of the purified nucleic acid with lyophilized Master Mix reagents
- Transfer of defined aliquots of eluate/Master Mix to different Reaction Chambers
- Performance of multiplex real-time PCR testing within each Reaction Chamber.

Once the cartridge has been inserted into the instrument, the test starts automatically, and results are generated in approximately 75 minutes. When the test is finished, the cartridge is removed by the user and discarded. The QIAstat-Dx BCID GN Plus AMR Panel ADF automatically interprets test results and displays a summary on the instrument display screen. The results can be printed using a connected printer if needed. The detected analytes are displayed in red. For other analytes tested, they are displayed in green if not detected, or in gray if not applicable or invalid. The analyzer will report if an error occurs during processing, in which case the test will fail, and no results will be provided (the screen will show "FAIL").

Intended Use

The QIAstat-Dx BCID GN Plus AMR Panel is an automated qualitative multiplexed real-time PCR-based *in vitro* diagnostic test intended for use with the QIAstat-Dx Analyzer 2.0. The QIAstat-Dx BCID GN Plus AMR Panel is capable of simultaneous detection and identification of multiple gram-negative bacterial targets and selected genetic determinants associated with antimicrobial resistance.

The following gram-negative bacteria are identified and differentiated using the QIAstat-Dx BCID GN Plus AMR Panel:

- *Acinetobacter calcoaceticus-baumannii* complex
- *Bacteroides fragilis*
- *Enterobacter* spp.
- *Escherichia coli*
- *Haemophilus influenzae*
- *Klebsiella* spp.
- *Neisseria meningitidis* (encapsulated)
- *Proteus* spp.
- *Pseudomonas aeruginosa*
- *Salmonella* spp.
- *Serratia* spp.
- *Stenotrophomonas maltophilia*
- Pan Enterobacterales

The QIAstat-Dx BCID GN Plus AMR Panel contains assays for the detection of the following genetic determinants of resistance:

- *aac(6')-Ib*
- *ampC* (CMY/LAT/DHA/FOX)
- *armA*
- CTX-M
- GES
- IMP
- KPC
- NDM
- OXA-23
- OXA-24/40
- OXA-48-like
- OXA-58
- PER
- SHV
- SPM

- TEM
- VEB
- VIM

The QIAstat-Dx BCID GN Plus AMR Panel contains assays for the detection of genetic determinants associated with resistance to aminoglycosides (*aac(6')-lb* and *armA*), penicillins and cephalosporins (*ampC* [CMY/LAT/DHA/FOX], CTX-M, GES, PER, SHV, TEM, and VEB), and carbapenems (GES, IMP, KPC, NDM, OXA-23, OXA-24/40, OXA-48-like, OXA-58, SPM, and VIM). The antimicrobial resistance gene detected may or may not be associated with the agent responsible for disease. Negative results for certain antimicrobial resistance assays do not indicate susceptibility, as multiple mechanisms of resistance exist.

The QIAstat-Dx BCID GN Plus AMR Panel is intended for use in patients suspected of having bacterial infections identified as gram-negative via Gram stain in positive blood culture samples. The test is performed on blood culture samples identified as positive by a continuous monitoring blood culture system that demonstrates the presence of gram-negative bacteria via Gram stain. The QIAstat-Dx BCID GN Plus AMR Panel is intended to aid in the diagnosis of specific pathogens of bloodstream infection and select determinants of antimicrobial-resistance. Results should be used in conjunction with additional laboratory testing, e.g. sub-culturing of positive blood cultures for identification of organisms not detected by QIAstat-Dx BCID GN Plus AMR Panel and susceptibility testing and clinical presentation must be taken into consideration for patient management decisions.

Negative results do not preclude the presence of pathogens that are not detected by this test. Positive QIAstat-Dx BCID GN Plus AMR Panel results do not rule out infection or co-infection with organisms not included in the QIAstat-Dx BCID GN Plus AMR Panel.

Negative AMR results do not preclude the presence of other antimicrobial resistance mechanisms, and the absence of a resistance gene does not necessarily predict susceptibility to a particular drug nor predict therapeutic failure.

Comparison of the QIAstat-Dx BCID GN Plus AMR Panel and the Predicate Device

Similarities and differences between the QIAstat-Dx BCID GN Plus AMR Panel and the predicate device are shown in [Table 1](#).

Table 1: Comparison of Similarities and Differences of the QIAstat-Dx BCID GN Plus AMR Panel and the Predicate Device

Characteristic	Subject Device	Predicate Device
Name	QIAstat-Dx BCID GN Plus AMR Panel	ePlex Blood Culture Identification Gram Negative (BCID-GN) Panel
510(k) No.	K262168	K182619
Regulation	21 CFR 866.3365	21 CFR 866.3365
Product Code(s)	PEN	PEN, PAM, PEO
Device Class	Class II	Class II

Characteristic	Subject Device	Predicate Device
Similarities		
Intended Use	The QIAstat-Dx BCID GN Plus AMR Panel is an automated qualitative multiplexed real-time PCR-based <i>in vitro</i> diagnostic test intended for use with the QIAstat-Dx Analyzer 2.0. The QIAstat-Dx BCID GN Plus AMR Panel is capable of simultaneous detection and identification of multiple gram-negative bacterial targets and selected genetic determinants associated with antimicrobial resistance. The following gram-negative bacteria are identified and differentiated using the QIAstat-Dx BCID GN Plus AMR Panel: • <i>Acinetobacter calcoaceticus-baumannii</i> complex • <i>Bacteroides fragilis</i> • <i>Enterobacter</i> spp. • <i>Escherichia coli</i> • <i>Haemophilus influenzae</i> • <i>Klebsiella</i> spp. • <i>Neisseria meningitidis</i> (encapsulated) • <i>Proteus</i> spp. • <i>Pseudomonas aeruginosa</i> • <i>Salmonella</i> spp. • <i>Serratia</i> spp. • <i>Stenotrophomonas maltophilia</i> • Pan Enterobacterales The QIAstat-Dx BCID GN Plus AMR Panel contains assays for the detection of the following genetic determinants of resistance: • <i>aac(6')-Ib</i> • <i>ampC</i> (CMY/LAT/DHA/FOX)	The GenMark ePlex Blood Culture Identification Gram-Negative (BCID-GN) Panel is a qualitative nucleic acid multiplex <i>in vitro</i> diagnostic test intended for use on GenMark's ePlex Instrument for simultaneous qualitative detection and identification of multiple potentially pathogenic gram-negative bacterial organisms and select determinants associated with antimicrobial resistance in positive blood culture. In addition, the ePlex BCID-GN Panel is capable of detecting several gram-positive bacteria (Pan Gram-Positive assay) and several <i>Candida</i> species (Pan <i>Candida</i> assay). The ePlex BCID-GN Panel is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system and which contain gram-negative organism. The following bacterial organisms and genes associated with antibiotic resistance are identified using the ePlex BCID-GN Panel: <i>Acinetobacter baumannii</i>, <i>Bacteroides fragilis</i>, <i>Citrobacter</i>, <i>Cronobacter sakazakii</i>, <i>Enterobacter cloacae</i> complex, <i>Enterobacter</i> (non-cloacae complex), <i>Escherichia coli</i>, <i>Fusobacterium necrophorum</i>, <i>Fusobacterium nucleatum</i>, <i>Haemophilus influenzae</i>, <i>Klebsiella oxytoca</i>, <i>Klebsiella pneumoniae</i> group, <i>Morganella morganii</i>, <i>Neisseria meningitidis</i>, <i>Proteus</i>, <i>Proteus mirabilis</i>, <i>Pseudomonas aeruginosa</i>, <i>Salmonella</i>, <i>Serratia</i>, <i>Serratia marcescens</i>, <i>Stenotrophomonas maltophilia</i>, CTX-M (<i>bla</i>_{CTX-M}), IMP (<i>bla</i>_{IMP}), KPC (<i>bla</i>_{KPC}), NDM (<i>bla</i>_{NDM}), OXA (<i>bla</i>_{OXA}) (OXA-23 and OXA-48 groups only), and VIM (<i>bla</i>_{VIM}). The ePlex BCID-GN Panel contains assays for the detection of genetic determinants associated with resistance to antimicrobial agents including CTX-M(<i>bla</i>_{CTX-M}), which is associated with resistance to extended spectrum beta-lactamase (ESBL)-mediated resistance to penicillins, cephalosporins and monobactams, as well as OXA (<i>bla</i>_{OXA}) (OXA-23 and OXA-48 groups only), KPC (<i>bla</i>_{KPC}), and metallo-beta-lactamases IMP (<i>bla</i>_{IMP}), VIM (<i>bla</i>_{VIM}), and NDM (<i>bla</i>_{NDM}), which is associated with carbapenemase-mediated resistance. The antimicrobial resistance gene detected may or may not be associated with the agent responsible for disease. Negative results for these select

Characteristic	Subject Device	Predicate Device
	• <i>armA</i> • CTX-M • GES • IMP • KPC • NDM • OXA-23 • OXA-24/40 • OXA-48-like • OXA-58 • PER • SHV • SPM • TEM • VEB • VIM The QIAstat-Dx BCID GN Plus AMR Panel contains assays for the detection of genetic determinants associated with resistance to aminoglycosides (<i>aac(6')-Ib</i> and <i>armA</i>), penicillins and cephalosporins (<i>ampC</i> [CMY/LAT/DHA/FOX], CTX-M, GES, PER, SHV, TEM, and VEB), and carbapenems (GES, IMP, KPC, NDM, OXA-23, OXA-24/40, OXA-48-like, OXA-58, SPM, and VIM). The antimicrobial resistance gene detected may or may not be associated with the agent responsible for disease. Negative results for certain antimicrobial resistance assays do not indicate susceptibility, as multiple mechanisms of resistance exist. The QIAstat-Dx BCID GN Plus AMR Panel is intended for use in patients suspected of having bacterial infections identified as gram-negative via Gram stain in positive	antimicrobial resistance assays do not indicate susceptibility, as there are multiple mechanisms of resistance in gram-negative bacteria. The ePlex BCID-GN Panel also contains targets designed to detect a broad range of organisms with a potentially misleading Gram stain result or organisms that may be missed by Gram staining altogether, for example in the case of co-infections. These include a broad Pan Gram-Positive assay (which is designed to detect <i>Bacillus cereus</i> group, <i>Bacillus subtilis</i> group, <i>Enterococcus</i>, <i>Staphylococcus</i>, and <i>Streptococcus</i>), as well as a Pan <i>Candida</i> assay, which is designed to detect four <i>Candida</i> species: <i>Candida albicans</i>, <i>Candida glabrata</i>, <i>Candida krusei</i>, and <i>Candida parapsilosis</i>. The detection and identification of specific bacterial and fungal nucleic acids from individuals exhibiting signs and/or symptoms of bloodstream infection aids in the diagnosis of bloodstream infection when used in conjunction with other clinical information. The results from the ePlex BCID-GN Panel are intended to be interpreted in conjunction with Gram stain results and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Negative results in the setting of a suspected bloodstream infection may be due to infection with pathogens that are not detected by this test. Positive results do not rule out co-infection with other organisms; the organism(s) detected by the ePlex BCID-GN Panel may not be the definite cause of disease. Additional laboratory testing (e.g. sub-culturing of positive blood cultures for identification of organisms not detected by ePlex BCID-GN Panel and for susceptibility testing, differentiation of mixed growth, and association of antimicrobial resistance marker genes to a specific organism) and clinical presentation must be taken into consideration in the final diagnosis of bloodstream infection.

Characteristic	Subject Device	Predicate Device
	blood culture samples. The test is performed on blood culture samples identified as positive by a continuous monitoring blood culture system that demonstrates the presence of gram-negative bacteria via Gram stain. The QIAstat-Dx BCID GN Plus AMR Panel is intended to aid in the diagnosis of specific pathogens of bloodstream infection and select determinants of antimicrobial-resistance. Results should be used in conjunction with additional laboratory testing, e.g. sub-culturing of positive blood cultures for identification of organisms not detected by QIAstat-Dx BCID GN Plus AMR Panel and susceptibility testing and clinical presentation must be taken into consideration for patient management decisions. Negative results do not preclude the presence of pathogens that are not detected by this test. Positive QIAstat-Dx BCID GN Plus AMR Panel results do not rule out infection or co-infection with organisms not included in the QIAstat-Dx BCID GN Plus AMR Panel. Negative AMR results do not preclude the presence of other antimicrobial resistance mechanisms, and the absence of a resistance gene does not necessarily predict susceptibility to a particular drug nor predict therapeutic failure.	

Characteristic	Subject Device	Predicate Device
Pathogens Detected	Gram-negative Bacteria: <i>Bacteroides fragilis</i> <i>Escherichia coli</i> <i>Haemophilus influenzae</i> <i>Neisseria meningitidis</i> (encapsulated) <i>Proteus</i> spp. <i>Pseudomonas aeruginosa</i> <i>Salmonella</i> spp. <i>Serratia</i> spp. <i>Stenotrophomonas maltophilia</i>	Gram-negative Bacteria: <i>Bacteroides fragilis</i> <i>Escherichia coli</i> <i>Haemophilus influenzae</i> <i>Neisseria meningitidis</i> (Encapsulated) <i>Proteus</i> <i>Pseudomonas aeruginosa</i> <i>Salmonella</i> <i>Serratia</i> <i>Stenotrophomonas maltophilia</i>
Antimicrobial Resistance Genes Detected	CTX-M IMP KPC NDM OXA-23 OXA-48-like VIM	CTX-M IMP KPC NDM OXA (OXA-23 and OXA-48 groups only) VIM
Specimen Type	Blood culture samples identified as positive by a continuous monitoring blood culture system that demonstrates the presence of gram-negative bacteria via Gram stain.	Blood culture samples identified as positive by a continuous monitoring blood culture system that demonstrates the presence of organisms as confirmed by Gram stain.
Blood Culture Bottles	BACTEC Plus Aerobic BACTEC Plus Anaerobic BACTEC Standard Aerobic BACTEC Standard Anaerobic BACTEC Peds Plus BACTEC Lytic Anaerobic BACT/ALERT SA Standard Aerobic BACT/ALERT SN Standard Anaerobic BACT/ALERT FA PLUS Aerobic BACT/ALERT FN PLUS Anaerobic BACT/ALERT PF PLUS Aerobic Versatrek Redox 1 EZ Draw Aerobic Versatrek Redox 2 EZ Draw Anaerobic	BACTEC Plus Aerobic BACTEC Plus Anaerobic BACTEC Standard Aerobic BACTEC Standard Anaerobic BACTEC Peds Plus BACTEC Lytic Anaerobic BACT/ALERT SA Standard Aerobic BACT/ALERT SN Standard Anaerobic BACT/ALERT FA Plus BACT/ALERT FN Plus BACT/ALERT PF Plus VersaTREK REDOX 1 EZ Draw Aerobic VersaTREK REDOX 2 EZ Draw Anaerobic
Analyte Detected	DNA	DNA
Technological Principles	Multiplex nucleic acid amplification test (NAAT)	Multiplex nucleic acid amplification test (NAAT)
Differences		
Pathogens Detected	Gram-negative Bacteria: <i>Acinetobacter calcoaceticus-baumannii</i> complex <i>Enterobacter</i> spp. <i>Klebsiella</i> spp. Pan Enterobacterales	Gram-negative Bacteria: <i>Acinetobacter baumannii</i> <i>Citrobacter</i> <i>Cronobacter sakazakii</i> <i>Enterobacter cloacae</i> complex, <i>Enterobacter</i> (non-cloacae complex) <i>Fusobacterium necrophorum</i> <i>Fusobacterium nucleatum</i> <i>Klebsiella oxytoca</i> <i>Klebsiella pneumoniae</i> group <i>Morganella morganii</i> <i>Proteus mirabilis</i> <i>Serratia marcescens</i>

Characteristic	Subject Device	Predicate Device
	Gram-positive Bacteria: N/A	Gram-positive Bacteria: Pan Gram-Positive
	Fungi: N/A	Fungi: Pan <i>Candida</i>
Antimicrobial Resistance Genes Detected	<i>aac(6')-lb</i> <i>ampC</i> (CMY/LAT/DHA/FOX) <i>armA</i> GES OXA-24/40 OXA-58 PER SHV SPM TEM VEB	N/A
Test Principles	All reagents required for the complete execution of a test run are pre-loaded and self-contained in the QIAstat-Dx BCID GN Plus AMR Panel Cartridge. Samples grown in BACT/ALERT and BACTEC bottles must be diluted in saline prior to loading in the QIAstat-Dx BCID GN Plus AMR Panel Cartridge. Samples grown in VersaTrek bottles do not require this predilution step. The following assay steps occur automatically: cell lysis, nucleic acid extraction using silica membrane, rehydration of master mix, PCR, and fluorescence detection.	Reagents on cartridge include: Sample lysis and nucleic acid extraction (capture onto magnetic beads), PCR amplification, and hybridization-based electrochemical detection reagents.
Assay Controls	One (1) internal control is included which controls for both the sample processing and PCR stages.	Each cartridge includes two types of internal controls that together monitor performance of each step of the testing process, including extraction, amplification and detection processes.
Instrumentation	QIAstat-Dx Analyzer 2.0	GenMark ePlex Instrument
Software Interface Result Reporting	- QIAstat-Dx Analyzer's Software - The QIAstat-Dx BCID GN Plus AMR Panel Assay Definition File ("ADF")	- GenMark ePlex System Software - GenMark ePlex BCID-GN Panel Software

Performance Characteristics - Non-clinical Studies

Limit of Detection

The Limit of Detection (LoD) is defined as the lowest concentration at which $\geq 95\%$ of the tested samples generate a positive call.

The LoD for each of the QIAstat-Dx BCID GN Plus AMR Panel targets was assessed, using a total of 37 pathogen strains, by analyzing serial dilutions of analytical samples prepared from culture isolates from commercial suppliers (e.g., ATCC, NCTC, CCUG) spiked into blood culture matrix.

The confirmed LoD was established by testing 20 replicates at the concentration determined from the preliminary LoD for each strain. The LoD for each strain was confirmed if $\geq 95\%$ of the replicates were positive. To further confirm the LoD, at least one dilution below the LoD was tested for each strain and was also tested and was required to result in less than 95% positivity.

Individual LoD values for each QIAstat-Dx BCID GN Plus AMR Panel target are shown in [Table 2](#).

Table 2: Limit of Detection Results Summary

Target	Organism	Source ID	LoD concentration PBCM (CFU/mL)
Microorganism			
<i>Acinetobacter calcoaceticus-baumannii</i> complex	<i>Acinetobacter baumannii</i>	NCTC 13305	3.50E+04
	<i>Acinetobacter baumannii</i>	ATCC BAA-2803	1.78E+04
	<i>Acinetobacter baumannii</i>	CCUG 57249	1.78E+04
	<i>Acinetobacter baumannii</i>	ATCC BAA-2801	4.14E+04
	<i>Acinetobacter baumannii</i>	ATCC BAA-2890	3.50E+03
<i>Bacteroides fragilis</i>	<i>Bacteroides fragilis</i>	NCTC 11625	1.30E+04
	<i>Bacteroides fragilis</i>	NCTC 8560	1.30E+04
<i>Enterobacter</i> spp.	<i>Enterobacter asburiae</i>	ATCC 35955	3.40E+05
	<i>Enterobacter cloacae</i>	NCTC 14326	2.70E+06
<i>Escherichia coli</i>	<i>Escherichia coli</i>	CCUG 67180	3.14E+05
	<i>Escherichia coli</i>	NCTC 14325	1.35E+05
	<i>Escherichia coli</i>	NCTC 14321	2.30E+05
<i>Haemophilus influenzae</i>	<i>Haemophilus influenzae</i>	CCUG 23946	9.00E+03 (9.05E+04 copies/mL)
	<i>Haemophilus influenzae</i>	CCUG 33775	1.87E+04 (copies/mL)
<i>Klebsiella</i> spp.	<i>Klebsiella pneumoniae</i>	ATCC BAA-3077	3.00E+04
	<i>Klebsiella pneumoniae</i>	NCTC 14334	3.00E+04
	<i>Klebsiella pneumoniae</i>	ATCC BAA-1705	3.00E+05
	<i>Klebsiella pneumoniae</i>	CCUG 68728	3.38E+04
<i>Neisseria meningitidis</i> (Encapsulated)	<i>Neisseria meningitidis</i>	ATCC 13090	1.00E+03
	<i>Neisseria meningitidis</i>	ATCC 13077	1.00E+04
Pan Enterobacterales	<i>Hafnia paralvei</i>	CCUG 59411	1.26E+07
	<i>Citrobacter freundii</i>	CCUG 418T	1.60E+05
<i>Proteus</i> spp.	<i>Proteus vulgaris</i>	ATCC 6380	3.00E+05
	<i>Proteus mirabilis</i>	ATCC BAA-2792	3.00E+04
<i>Pseudomonas aeruginosa</i>	<i>Pseudomonas aeruginosa</i>	MRSN 12914	3.22E+07
	<i>Pseudomonas aeruginosa</i>	NCTC 13437	1.00E+06
	<i>Pseudomonas aeruginosa</i>	JMI 378769	9.60E+05
	<i>Pseudomonas aeruginosa</i>	NCTC 13921	8.40E+05

Target	Organism	Source ID	LoD concentration PBCM (CFU/mL)
	<i>Pseudomonas aeruginosa</i>	ATCC BAA-2794	1.00E+06
Salmonella spp.	<i>Salmonella enterica</i>	ATCC 6962	1.00E+04
	<i>Salmonella enterica</i>	NCTC 13954	5.00E+03
Serratia spp.	<i>Serratia marcescens</i>	ATCC 14041	7.00E+06
	<i>Serratia liquefaciens</i>	ATCC 27592	7.50E+04
Stenotrophomonas maltophilia	<i>Stenotrophomonas maltophilia</i>	NCTC 10499	1.63E+08
	<i>Stenotrophomonas maltophilia</i>	NCTC 10258	6.50E+06
AMR			
aac(6')-Ib	<i>Klebsiella pneumoniae</i>	ATCC BAA-3077	3.00E+04
	<i>Pseudomonas aeruginosa</i>	ATCC BAA-2799	1.00E+05
	<i>Escherichia coli</i>	NCTC 14325	1.35E+04
	<i>Klebsiella pneumoniae</i>	CCUG 68728	3.38E+04
	<i>Pseudomonas aeruginosa</i>	NCTC 13921	8.40E+05
	<i>Pseudomonas aeruginosa</i>	ATCC BAA-2794	1.00E+05
	<i>Proteus mirabilis</i>	ATCC BAA-2792	3.00E+05
	<i>Klebsiella pneumoniae</i>	NCTC 14334	3.00E+04
	<i>Klebsiella pneumoniae</i>	ATCC BAA-1705	3.00E+05
ampC (CMY/LAT/DHA/FOX)	<i>Klebsiella pneumoniae</i>	CCUG 68728	3.38E+05
	<i>Proteus mirabilis</i>	ATCC BAA-2792	3.00E+05
	<i>Citrobacter freundii</i>	CCUG 418T	1.60E+05
armA	<i>Acinetobacter baumannii</i>	ATCC BAA-2803	1.78E+04
	<i>Klebsiella pneumoniae</i>	CCUG 68728	3.38E+04
CTX-M	<i>Klebsiella pneumoniae</i>	ATCC BAA-3077	3.00E+04
	<i>Escherichia coli</i>	NCTC 14325	1.35E+05
	<i>Klebsiella pneumoniae</i>	CCUG 68728	3.38E+04
GES	<i>Klebsiella pneumoniae</i>	ATCC BAA-3077	3.00E+04
	<i>Pseudomonas aeruginosa</i>	ATCC BAA-2794	1.00E+06
IMP	<i>Escherichia coli</i>	CCUG 67180	3.14E+05
	<i>Klebsiella pneumoniae</i>	NCTC 14334	3.00E+04
KPC	<i>Escherichia coli</i>	NCTC 14321	2.30E+05
	<i>Klebsiella pneumoniae</i>	ATCC BAA-1705	3.00E+05
NDM	<i>Escherichia coli</i>	NCTC 14325	1.35E+05
	<i>Klebsiella pneumoniae</i>	CCUG 68728	3.38E+06
OXA-23	<i>Acinetobacter baumannii</i>	ATCC BAA-2803	1.78E+04
	<i>Acinetobacter baumannii</i>	ATCC BAA-2801	4.14E+04
OXA-24/40	<i>Acinetobacter baumannii</i>	CCUG 57249	1.78E+04

Target	Organism	Source ID	LoD concentration PBCM (CFU/mL)
	<i>Acinetobacter baumannii</i>	ATCC BAA-2881	5.73E+04
OXA-48-like	<i>Escherichia coli</i>	NCTC 14321	2.30E+05
	<i>Salmonella enterica</i>	NCTC 13954	5.00E+03
OXA-58	<i>Acinetobacter baumannii</i>	NCTC 13305	3.50E+04
	<i>Acinetobacter baumannii</i>	ATCC BAA-2890	3.50E+03
PER	<i>Acinetobacter baumannii</i>	ATCC BAA-2801	4.14E+05
	<i>Pseudomonas aeruginosa</i>	ATCC BAA-2799	1.00E+05
SHV	<i>Klebsiella pneumoniae</i>	ATCC BAA-3077	3.00E+04
	<i>Klebsiella pneumoniae</i>	ATCC BAA-1705	3.00E+05
	<i>Klebsiella pneumoniae</i>	CCUG 68728	3.38E+04
	<i>Klebsiella pneumoniae</i>	NCTC 14334	3.00E+05
SPM	<i>Pseudomonas aeruginosa</i>	JMI 378769	9.60E+06
	<i>Pseudomonas aeruginosa</i>	NCTC 13921	8.40E+05
TEM	<i>Klebsiella pneumoniae</i>	ATCC BAA-3077	3.00E+05
	<i>Escherichia coli</i>	CCUG 67180	3.14E+05
	<i>Klebsiella pneumoniae</i>	CCUG 68728	3.38E+06
	<i>Proteus mirabilis</i>	ATCC BAA-2792	3.00E+06
VEB	<i>Pseudomonas aeruginosa</i>	MRSN 12914	3.22E+07
	<i>Pseudomonas aeruginosa</i>	NCTC 13437	1.00E+06
VIM	<i>Pseudomonas aeruginosa</i>	NCTC 13437	1.00E+06
	<i>Pseudomonas aeruginosa</i>	ATCC BAA-2799	1.00E+05
	<i>Enterobacter cloacae</i>	NCTC 14326	2.70E+05
	<i>Proteus mirabilis</i>	ATCC BAA-2792	3.00E+04

Analytical Reactivity (Inclusivity)

The inclusivity study was performed to evaluate the detection of all clinically relevant organism subtypes, strains, genotypes, serotypes, species, and AMR gene variants representing the genetic, temporal and geographic diversity for each analyte of the QIAstat-Dx BCID GN Plus AMR Panel on the QIAstat-Dx Analyzer 2.0. To further demonstrate the inclusivity of the assays, a deeper *in silico* analysis was performed for every single PCR assay included in the QIAstat-Dx BCID GN Plus AMR Panel.

In vitro testing

For the laboratory testing, a minimum of 5 strains were tested for every On-Panel target analyte. For those targets including more than one species (*Acinetobacter calcoaceticus-baumannii* complex, *Enterobacter* spp., *Klebsiella* spp., *Proteus* spp., *Salmonella* spp., *Serratia* spp., and Pan Enterobacterales assay), at least 5 strains were tested in total. As an exception, AMR genes OXA-

58 and SPM were tested in less than 5 strains because of samples availability. First, all assays included in the QIAstat-Dx BCID GN Plus AMR Panel, intended to detect the presence of organisms, were evaluated. All strains shown in Table 3 were tested in triplicate at the initial concentration near LoD, for the majority of the targets. In cases where results were not positive for all the tested replicates, higher concentrations (e.g., 30x LoD, 300x LoD) were tested to assess the assay's inclusivity.

A summary of the results obtained is shown in Table 3 for pathogens and Table 4 for AMR genes.

Table 3: Summary of Pathogen Inclusivity Results

Target	Species	Source ID	Strain name/ Designation	Result
<i>Acinetobacter calcoaceticus-baumannii</i> complex	<i>Acinetobacter baumannii</i>	PA212222	N/A	Detected
	<i>Acinetobacter calcoaceticus</i>	CCUG 57816	(Beijerinck 1911) Baumann et al. 1968 (Approved Lists 1980), RUH2202	
	<i>Acinetobacter nosocomialis</i>	CCUG 74064	Nemec et al. 2011 in [Validation List No. 140 (2011)], NIPH 2119; CCM 7791; LMG 10619; RUH 2376	
	<i>Acinetobacter baumannii</i>	ATCC BAA-2801*	1103521	
	<i>Acinetobacter baumannii</i>	ATCC BAA-2803*	1125209	
	<i>Acinetobacter baumannii</i>	ATCC BAA-2881	Bouvet and Grimont, 1173844	
	<i>Acinetobacter baumannii</i>	ATCC BAA-2901	Bouvet and Grimont, 157075	
	<i>Acinetobacter baumannii</i>	ATCC BAA-2890*	Bouvet and Grimont, 177579	
	<i>Acinetobacter baumannii</i>	ATCC BAA-2895	N/A	
	<i>Acinetobacter baumannii</i>	ATCC BAA-2873	1081925	
	<i>Acinetobacter baumannii</i>	CCUG 57249*	Bouvet and Grimont 1986	
	<i>Acinetobacter baumannii</i>	CCUG 68164	Bouvet and Grimont 1986	
	<i>Acinetobacter baumannii</i>	NCTC 13302	OXA-25, 327009	
	<i>Acinetobacter baumannii</i>	NCTC 13305*	A-15	
	<i>Acinetobacter baumannii</i>	NCTC 13424	UK 20	
	<i>Acinetobacter pittii</i>	CCUG 72793	EQUA 2018:03/B	
<i>Bacteroides fragilis</i>	<i>Bacteroides fragilis</i>	CCUG 4856T	(Veillon and Zuber 1898) Castellani and Chalmers 1919 (Approved Lists 1980), EN-2, Onslow/VPI 2553 [EN-2; NCTC 9343]	Detected
	<i>Bacteroides fragilis</i>	CCUG 25931	Bergan and Hovig 1968, LRA 048 07 85/ [ICPB 3498, NCTC 10581]	
	<i>Bacteroides fragilis</i>	NCTC 11295	(Veillon and Zuber 1898) Castellani and Chalmers 1919 (AL), 83008	

Target	Species	Source ID	Strain name/ Designation	Result
	<i>Bacteroides fragilis</i>	NCTC 11625*	(Veillon and Zuber 1898) Castellani and Chalmers 1919 (AL)	
	<i>Bacteroides fragilis</i>	NCTC 8560*	(Veillon and Zuber 1898) Castellani and Chalmers 1919 (AL), WPMH 1	
Enterobacter spp.	<i>Enterobacter amnigenus</i>	ATCC 33072	(Izard et al. 1981) Brady et al. 2013, CUETM 77-118	Detected
	<i>Lelliottia nimipressuralis</i>	CCUG 69901	(Carter 1945) Brady et al. 2013	
	<i>Enterobacter ludwigii</i>	CCUG 26899	(Jordan 1890) Hormaeche and Edwards 1960 (Approved Lists 1980)	
	<i>Enterobacter ludwigii</i>	CCUG 51323T	Hoffmann et al. 2005, EN-119	
	<i>Enterobacter asburiae</i>	ATCC 35955*	Brenner et al., CDC 14-81	
	<i>Enterobacter cancerogenus</i>	CCUG 48556	(Urosevic 1966) Dickey and Zumoff 1988, strain RSTN 68352/03	
	<i>Enterobacter cloacae</i>	NCTC 14326*	(Jordan 1890) Hormaeche and Edwards 1960, 29	
	<i>Enterobacter hormaechei subsp. Xiangfangensis</i>	CCUG 63474	N/A	
	<i>Enterobacter kobei</i>	CCUG 59627	(Jordan 1890) Hormaeche and Edwards 1960 (Approved Lists 1980)	
	<i>Enterobacter bugandensis</i>	CCUG 75194T	N/A, EB-247, 247BMC, DSM 29888, NCCB 100573	
	<i>Enterobacter hormaechei subsp. Oharae</i>	CCUG 53905T	Hoffmann et al. 2016, EN-314	
	<i>Enterobacter hormaechei subsp. Steigerwaltii</i>	CCUG 60271	O'Hara et al. 1990	
	<i>E. roggenkampii</i>	CCUG 75192T	N/A, EN-117; DSM 16690; LMG 30172	
	<i>E. hormaechei subsp. Hoffmannii</i>	NCTC 13870	O'Hara et al. 1990, sp. nov., LBM 93.03.067, CCM 7804, CCUG 60038, 2.5, R26	
	<i>Enterobacter cloacae</i>	NCTC 14328	(Jordan 1890) Hormaeche and Edwards 1960	
	<i>Enterobacter cloacae</i>	NCTC 14322	(Jordan 1890) Hormaeche and Edwards 1960, 42E	
	<i>Enterobacter cloacae subsp. dissolvens</i>	CCUG 25230T	(Rosen 1922) Hoffmann et al. 2005, W-4, 8122-8	
	<i>Enterobacter gergoviae</i>	CCUG 33719†‡	(Brenner et al. 1980) Brady et al. 2013	
Escherichia coli	<i>Escherichia coli</i>	ATCC BAA-2774	(Migula) Castellani and Chalmers, 1093925	Detected
	<i>Escherichia coli</i>	ATCC BAA-2775	1099675	
	<i>Escherichia coli</i>	NCTC 13919	(Migula 1895) Castellani and Chalmers 1919 (AL), NCTC13919, H162440763	

Target	Species	Source ID	Strain name/ Designation	Result
	<i>Escherichia coli</i>	NCTC 14320	(Migula 1895) Castellani and Chalmers 1919	
	<i>Escherichia coli</i>	CCUG 67180*	(Migula 1895) Castellani and Chalmers 1919 (Approved Lists 1980)	
	<i>Escherichia coli</i>	NCTC 14321*	(Migula 1895) Castellani and Chalmers 1919, 7	
	<i>Escherichia coli</i>	NCTC 14325*	(Migula 1895) Castellani and Chalmers 1919	
	<i>Escherichia coli</i>	NCTC 14333	(Migula 1895) Castellani and Chalmers 1919, MLST: 167	
	<i>Escherichia coli</i>	NCTC 14339	(Migula 1895) Castellani and Chalmers 1919, MLST: 361	
	<i>Escherichia coli</i>	NCTC 13351	N/A	
	<i>Escherichia coli</i>	NCTC 13462	N/A	
	<i>Escherichia coli</i>	NCTC 13352	N/A	
<i>Haemophilus influenzae</i>	<i>Haemophilus influenzae</i>	NCTC 4560	<i>Haemophilus influenzae</i> corrig. (Lehmann and Neumann 1896) Winslow et al. 1917 (Approved Lists 1980), NCTC 4560 [18]	Detected
	<i>Haemophilus influenzae</i>	CCUG 23946*	(Lehmann and Neumann 1896) Winslow et al. 1917 (Approved Lists 1980), Kilian HK 394, Pittman 576, 576, HK 394	
	<i>Haemophilus influenzae</i>	CCUG 29539	<i>Haemophilus influenzae</i> corrig. (Lehmann and Neumann 1896) Winslow et al. 1917 (Approved Lists 1980), L-378	
	<i>Haemophilus influenzae</i>	CCUG 33775*	<i>Haemophilus influenzae</i> corrig. (Lehmann and Neumann 1896) Winslow et al. 1917 (Approved Lists 1980), 572, LRA 026 05 90/AMC 36-A-1 [572]	
	<i>Haemophilus influenzae</i>	CCUG 7317	<i>Haemophilus influenzae</i> corrig. (Lehmann and Neumann 1896) Winslow et al. 1917 (Approved Lists 1980), 641/AMC 36-A-4 [641, NCTC 8467]	
<i>Klebsiella</i> spp.	<i>Klebsiella aerogenes</i>	ATCC 13048	(Hormaeche and Edwards 1960) Tindall et al. 2017, NCDC 819-56	Detected
	<i>Klebsiella pneumoniae</i>	ATCC BAA-3072	(Schroeter) Trevisan, 979620	
	<i>Klebsiella pneumoniae</i>	ATCC BAA-1705*	(Schroeter) Trevisan, ART 2008133 [D-05, 1338]	
	<i>Klebsiella pneumoniae</i>	ATCC BAA-2783	972863	
	<i>Klebsiella pneumoniae</i>	ATCC BAA-3060	(Schroeter) Trevisan, 1150539	
	<i>Klebsiella pneumoniae</i>	ATCC BAA-3063§	1121740	
	<i>Klebsiella pneumoniae</i>	ATCC BAA-3068	1104762	
	<i>Klebsiella pneumoniae</i>	ATCC BAA-3077*	875638	
	<i>Klebsiella pneumoniae</i>	CCUG 68727	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13442	

Target	Species	Source ID	Strain name/ Designation	Result
	<i>Klebsiella pneumoniae</i>	CCUG 68728*	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13443	
	<i>Klebsiella pneumoniae</i>	NCTC 14334*	(Schroeter 1886) Trevisan 1887, 47C	
	<i>Klebsiella pneumoniae</i>	NCTC 14337	(Schroeter 1886) Trevisan 1887, 54	
	<i>Klebsiella pneumoniae</i>	JMI Strain 1238756	N/A	
	<i>Klebsiella variicola</i>	ATCC BAA-830	Rosenblueth et al., F2R9 [CFNE 2004, DSM 15968]	
	<i>Klebsiella oxytoca</i>	ATCC BAA-3059	(Flugge) Lautrop, 957532	
	<i>Klebsiella pneumoniae</i>	NCTC 13438	Isolate 1, Hospital A	
	<i>Klebsiella pneumoniae</i>	ATCC 700603	N/A, K6 [CCUG 45421, LMG 20218, MCV37]	
	<i>Klebsiella pneumoniae</i>	ATCC 700603	N/A, K6 [CCUG 45421, LMG 20218, MCV37]	
<i>Neisseria meningitidis</i> (Encapsulated)	<i>Neisseria meningitidis</i>	ATCC 13077*	(Albrecht and Ghon 1901) Murray 1929 (Approved Lists 1980), M1027	Detected
	<i>Neisseria meningitidis</i>	ATCC 13090*	(Albrecht and Ghon 1901) Murray 1929 (Approved Lists 1980), M2092	
	<i>Neisseria meningitidis</i>	CCUG 27650	(Albrecht and Ghon 1901) Murray 1929 (Approved Lists 1980), LNP 638	
	<i>Neisseria meningitidis</i>	CCUG 55208	EQUALIS 07-040/2	
	<i>Neisseria meningitidis</i>	NCTC 8556	(Albrecht and Ghon 1901) Murray 1929 (AL), 60	
Pan Enterobacterales	<i>Cedecea davisae</i>	NCTC 13724	Grimont et al. 1981, 005, 3278-77	Detected
	<i>Citrobacter braakii</i>	ATCC 51113	Brenner et al. 1993, CDC 80-58	
	<i>Citrobacter freundii</i>	CCUG 418T*	(Braak 1928) Werkman and Gillen 1932 (Approved Lists 1980), [ATCC 13316, NCTC 9750]	
	<i>Citrobacter koseri</i>	ATCC 27156	Frederiksen 1970 (Approved Lists 1980), CDC 3613-63	
	<i>Cronobacter sakazakii</i>	ATCC 29004	(Farmer et al.) Iversen et al., CDC 3225-73	
	<i>Edwardsiella tarda</i>	NCTC 10396	Ewing and McWhorter 1965 (Approved Lists 1980), K 349, K349, 4-78, 1483-59	
	<i>Kluyvera cryocrescens</i>	NCTC 10483	Farmer et al. 1981, 2367, No.4	
	<i>Kosakonia quasiacchari</i>	NCTC 14272	Wang et al. 2019, GDMCC1.1570, WCHEs120001	
	<i>Leclercia adecarboxylata</i>	NCTC 13032	(Leclerc 1962) Tamura et al. 1987, 1783	
	<i>Morganella morganii</i>	ATCC 25829	(Winslow et al. 1919) Jensen et al. 1992, M4	
	<i>Providencia stuartii</i>	CCUG 74678	N/A	
	<i>Rahnella aquatilis</i>	CCUG 52909	Izard et al. 1981	
	<i>Raoultella terrigena</i>	NCTC 13038	Izard et al. 1981, 84, L84/CUETM 77-176 [CIP 80-07, DSM 2687]	
	<i>Shigella sonnei</i>	CCUG 68726	(Levine 1920) Weldin 1927 (Approved Lists 1980), I virulent	

Target	Species	Source ID	Strain name/ Designation	Result
	<i>Serratia rubidaea</i>	CCUG 35289	(Stapp 1940) Ewing et al. 1973 (Approved Lists 1980)	
	<i>Tatumella ptyseos</i>	NCTC 11468	Hollis et al. 1982, H36	
	<i>Yersinia enterocolitica</i> subsp <i>enterocolitica</i>	NCTC 12982	(Schleifstein and Coleman 1939) Neubauer et al. 2000, 33114	
	<i>Yokenella regensburgei</i>	NCTC 12131	Kosako et al. 1985, 3349-72	
	<i>Citrobacter freundii</i>	ATCC 6879	Werkman and Gillen 1932 (Approved Lists 1980), NCTC 4143 [104, IFO 13539]	
	<i>Hafnia alvei</i>	CCUG 59411	Møller 1954 (Approved Lists 1980), SMI Oth047	
	<i>Citrobacter amalonaticus</i>	CCUG 4860	(Young et al. 1971) Brenner and Farmer 1982, 9823 [NCTC 10805]	
	<i>Escherichia fergusonii</i>	CCUG 18766T	Farmer et al. 1985, CDC 0568-73 [DSM 13698]	
	<i>Morganella Morganii SS siboni</i>	ATCC 51206	Jensen et al., CDC 3522-75	
	<i>Providencia rettgeri</i>	CCUG 14804	(Hadley et al. 1918) Brenner et al. 1978 (Approved Lists 1980), 1163 [CCUG 14804, CIP 103182, DSM 4542, JCM 1675, LMG 3259, NCTC 11801]	
	<i>Raoultella ornithinolytica</i>	NCTC 13096	N/A	
	<i>Shigella boydii</i>	CCUG 49022	Ewing 1949 (Approved Lists 1980), P288/NCTC 12985	
	<i>Escherichia hermannii</i>	CCUG 15714T	Brenner et al. 1983, CDC 980-72	Pan Enterobac terales not detected
	<i>Kosakonia cowanii</i>	CCUG 45998	(Inoue et al. 2001) Brady et al. 2013, 888-76, KSK 246, UM-79, KSK246, U11-79	
<i>Proteus</i> spp.	<i>Proteus mirabilis</i>	ATCC 43071	Hauser, CDC S-17	Detected
	<i>Proteus mirabilis</i>	ATCC BAA-2792*	Hauser, 1104843	
	<i>Proteus penneri</i>	NCTC 12737	Hickman et al. 1983, 1808-73	
	<i>Proteus vulgaris</i>	ATCC 6380*	Hauser emend. Judicial Commission	
	<i>Proteus vulgaris</i>	NCTC 13145	Hauser emend. Judicial Commission, CDC PR1	
	<i>Proteus terrae/cibarius</i>	CCUG 35385	Hauser 1885 (Approved Lists 1980), HSCT 3586 T1, CDC 1404-81	
	<i>Proteus hauseri</i>	CCUG 63603	N/A	
<i>Pseudomonas aeruginosa</i>	<i>Pseudomonas aeruginosa</i>	ATCC BAA-2794*	(Schroeter) Migula, 1079232	Detected
	<i>Pseudomonas aeruginosa</i>	NCTC 13437*	N/A	
	<i>Pseudomonas aeruginosa</i>	MRSN 12914*	Snesrud,E. and Mcgann,P., NR-51575	
	<i>Pseudomonas aeruginosa</i>	NCTC 13921*	(Schroeter 1872) Migula 1900 (AL), NCTC 13921	
	<i>Pseudomonas aeruginosa</i>	ATCC BAA-3099	1079205	

Target	Species	Source ID	Strain name/ Designation	Result
	<i>Pseudomonas aeruginosa</i>	ATCC BAA-3108	Strain: 835930, 853930	
	<i>Pseudomonas aeruginosa</i>	ATCC BAA-2796	1106434	
	<i>Pseudomonas aeruginosa</i>	JMI Strain 378769*	N/A	
	<i>Pseudomonas aeruginosa</i>	JMI Strain 338718	N/A	
	<i>Pseudomonas aeruginosa</i>	JMI Strain JMI-147	N/A	
	<i>Pseudomonas aeruginosa</i>	JMI Strain 1227781	N/A	
	<i>Pseudomonas aeruginosa</i>	MRSN 6241	Strain MRSN 6241, NR-51550	
	<i>Pseudomonas aeruginosa</i>	MRSN 8141	Strain MRSN 8141, NR-51558	
	<i>Pseudomonas aeruginosa</i>	NCTC 14383	(Schroeter 1872) Migula 1900 (Approved Lists 1980)	
Salmonella spp.	<i>Salmonella bongori</i>	CCUG 63587	(Le Minor et al. 1985) Reeves et al. 1989	Detected
	<i>Salmonella enterica</i>	ATCC 6962*	(ex Kauffmann and Edwards) Le Minor and Popoff serovar Newport, NCTC 129	
	<i>Salmonella enterica subsp. gallinarum</i>	ATCC 700623	(Kauffmann and Edwards) Le Minor and Popoff, X-142	
	<i>Salmonella enterica subsp. seftenberg</i>	NCTC 13953	(ex Kauffmann and Edwards 1952) Le Minor and Popoff 1987	
	<i>Salmonella typhimurium</i>	NCTC 13954*	(ex Kauffmann and Edwards 1952) Le Minor and Popoff 1987	
	<i>Salmonella enterica subsp. enterica serotype Westhampton</i>	NCTC 8549	(LE MINOR et al. 1982) LE MINOR and POPOFF 1987, 1314-52	
Serratia spp.	<i>Serratia ficaria</i>	CCUG 20935	Grimont et al. 1981, F.Grimont G 5779	Detected
	<i>Serratia fonticola</i>	CCUG 14186	N/A, CUETM 77-165; CIP 78.64; ATCC 29844; LMG 7882; CCM 3407; IAM 1242;	
	<i>Serratia liquefaciens</i>	ATCC 27592*	(Grimes and Hennerty 1931) Bascomb et al. 1971 (Approved Lists 1980), CDC 1284-57	
	<i>Serratia marcescens</i>	ATCC 14041*	Bizio 1823 (Approved Lists 1980), NRRL B-1481	
	<i>Serratia plymuthica</i>	ATCC 7462	(Lehmann and Neumann 1896) Breed et al. 1948 (Approved Lists 1980)/(Dyar) Bergey et al., [Grimont 502]	
	<i>Serratia marcescens</i>	NCTC 13382	Bizio, NRS 116-175 [CIP 104221]	
	<i>Serratia odorifera</i>	CCUG 14508	N/A	
Stenotrophomonas maltophilia	<i>Stenotrophomonas maltophilia</i>	ATCC 13637	(Hugh 1981 ex Hugh and Ryschenkow 1961) Palleroni and Bradbury 1993, 810-2	Detected
	<i>Stenotrophomonas maltophilia</i>	CCUG 72210	N/A	
	<i>Stenotrophomonas maltophilia</i>	NCTC 10258*	(Hugh 1981 ex Hugh and Ryschenkow 1961) Palleroni and Bradbury 1993, 560	

Target	Species	Source ID	Strain name/ Designation	Result
			[CDC3903, group I, MDB strain BS 1639, NCTC 10258]	
	<i>Stenotrophomonas maltophilia</i>	NCTC 10259	(Hugh) Palleroni and Bradbury, 611 [NCTC 10259]	
	<i>Stenotrophomonas maltophilia</i>	NCTC 10498	(Hugh 1981) Palleroni and Bradbury 1993, RH 661-1	
	<i>Stenotrophomonas maltophilia</i>	NCTC 10499*	(Hugh 1981) Palleroni and Bradbury 1993, RH 873-3 (NRC 730, NCIB 9204)	

N/A: Information not available.

* These strains were evaluated during the LoD study.

† Detected with reduced sensitivity below the mean bottle positive concentration.

‡ Lower concentrations of these strains were not tested in the original dataset, and it is not known whether this strain would be detected closer to the LoD determined for *Enterobacter* spp.

§ ATCC BAA-3063 detected at bottle positive concentration as observed in the contrived samples during the clinical study. Lower pathogen concentrations could not be evaluated in this study because *E. amnigenus* was also included in the mix, which has been shown to cross-react with the *Klebsiella* spp. assay.

Table 4: Summary of AMR Markers Inclusivity Results

Target	AMR variant	Species	Catalog number	Strain designation	Result
aac(6')-Ib	aac(6')-Ib	<i>Pseudomonas aeruginosa</i>	JMI Strain 378769	N/A	Detected
	aac(6')-Ib	<i>Pseudomonas aeruginosa</i>	JMI Strain 338718	N/A	
	aac(6')-Ib	<i>Pseudomonas aeruginosa</i>	JMI Strain JMI-147	N/A	
	aac(6')-Ib3	<i>Klebsiella pneumoniae</i>	ATCC BAA-3068	1104762	
	aac(6')-Ib-cr	<i>Escherichia coli</i>	ATCC BAA-2774	(Migula) Castellani and Chalmers, 1093925	
	aac(6')-Ib	<i>Escherichia coli</i>	NCTC 14320	(Migula 1895) Castellani and Chalmers 1919	
	aac(6')-Ib4	<i>Klebsiella pneumoniae</i>	ATCC BAA-3077*	875638	
	aac(6')-Ib7	<i>Proteus mirabilis</i>	ATCC BAA-2792*	Hauser, 1104843	
	aac(6')-Ib	<i>Pseudomonas aeruginosa</i>	ATCC BAA-2799*	1145009	
	aac(6')-Ib	<i>Escherichia coli</i>	NCTC 13919	(Migula 1895) Castellani and Chalmers 1919 (AL), NCTC13919, H162440763	
	aac(6')-Ib3	<i>Acinetobacter baumannii</i>	ATCC BAA-2901	Bouvet and Grimont, 157075	
	aac(6')-Ib	<i>Pseudomonas aeruginosa</i>	ATCC BAA-2794*	(Schroeter) Migula, 1079232	
	aac(6')-Ib	<i>Klebsiella pneumoniae</i>	CCUG 68728*	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13443	
	aac(6')-Ib	<i>Pseudomonas aeruginosa</i>	NCTC 13921*	(Schroeter 1872) Migula 1900 (AL), NCTC 13921	
	aac(6')-Ib	<i>Klebsiella pneumoniae</i>	NCTC 14334*	(Schroeter 1886) Trevisan 1887, 47C	
	aac(6')-Ib	<i>Klebsiella pneumoniae</i>	ATCC BAA-1705*	(Schroeter) Trevisan, ART 2008133 [D-05, 1338]	

Target	AMR variant	Species	Catalog number	Strain designation	Result
	<i>aac(6')-Ib</i>	<i>Escherichia coli</i>	NCTC 14325*	(Migula 1895) Castellani and Chalmers 1919, N/A	
	<i>aac(6')-Ib3, aac(6')-Ib-cr5</i>	<i>Klebsiella pneumoniae</i>	ATCC BAA-2783	972863	
	<i>aac(6')-Ib</i>	<i>Pseudomonas aeruginosa</i>	ATCC BAA-3108	853930, Strain: 835930	
	<i>aac6-Ib-cr</i>	<i>Klebsiella pneumoniae</i>	ATCC BAA-3072	(Schroeter) Trevisan, 979620	
	<i>aac(6')-Ib3, aac(6')-Ib-cr, aac(6')-IIc</i>	<i>Klebsiella pneumoniae</i>	ATCC BAA-3060	(Schroeter) Trevisan, 1150539	
	<i>aac(6')-Ib-cr</i>	<i>Klebsiella pneumoniae</i>	ATCC BAA-3063§	1121740	
	<i>aac(6')-Ib</i>	<i>Klebsiella oxytoca</i>	ATCC BAA-3059	(Flugge) Lautrop, 957532	
	<i>aac(6')-Ib-cr5</i>	<i>Enterobacter bugandensis</i>	CCUG 75194T	N/A, EB-247, 247BMC, DSM 29888, NCCB 100573	
	<i>aac(6')-Ib</i>	<i>Pseudomonas aeruginosa</i>	NCTC 14383	(Schroeter 1872) Migula 1900 (Approved Lists 1980)	
	<i>aac(6')-Ib</i>	<i>Acinetobacter baumannii</i>	NCTC 13424	UK 20	
	<i>aac(6')-Ib</i>	<i>Pseudomonas aeruginosa</i>	MRSN 6241	N/A	
	<i>aac(6')-Ib</i>	<i>Pseudomonas aeruginosa</i>	MRSN 8141	N/A	
	<i>aac(6')-Ib</i>	<i>Klebsiella pneumoniae</i>	NCTC 14337	54, (Schroeter 1886) Trevisan 1887	
	<i>aac(6')-Ib</i>	<i>Escherichia coli</i>	NCTC 13351	N/A	
	<i>aac(6')-Ib</i>	<i>Klebsiella pneumoniae</i>	NCTC 13438	Isolate 1, Hospital A,	
	<i>aac(6')-Ib</i>	<i>Acinetobacter baumannii</i>	CCUG 68164	Bouvet and Grimont 1986	<i>aac(6')-Ib</i> Detected with reduced sensitivity (2.31E+06 CFU/mL)†
<i>ampC</i> (CMY/DHA/FOX/LAT)	<i>ampC</i> (DHA-D7)	<i>Klebsiella pneumoniae</i>	ATCC BAA-3060	(Schroeter) Trevisan, 1150539	Detected
	<i>ampC</i> (FOX)	**gBlock <i>ampC FOX-X77455.1</i>	**gBlock <i>ampC FOX-X77455.1</i>	N/A	
	<i>ampC</i> (CMY-16)	<i>Proteus mirabilis</i>	ATCC BAA-2792*	Hauser, 1104843	
	<i>ampC</i> (CMY-LAT)	<i>Citrobacter freundii</i>	ATCC 6879	Werkman and Gillen 1932 (Approved Lists 1980), NCTC 4143 [104, IFO 13539]	
	<i>ampC</i> (CMY-2)	<i>Citrobacter brakkii</i>	ATCC 51113	Brenner et al. 1993, CDC 80-58	
	<i>ampC</i> -(CMY-LAT)	<i>Salmonella enterica</i>	NCTC 13953	(ex Kauffmann and Edwards 1952) Le Minor and Popoff 1987	
	<i>ampC</i> (CMY-LAT) <i>ampC</i> (DHA)	<i>Klebsiella pneumoniae</i>	CCUG 68728*	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13443	

Target	AMR variant	Species	Catalog number	Strain designation	Result
	<i>ampC</i> (CMY-72)	<i>Citrobacter freundii</i>	CCUG 418*	(Braak 1928) Werkman and Gillen 1932 (Approved Lists 1980), [ATCC 13316, NCTC 9750]	
	<i>ampC</i> (DHA-4)	<i>Morganella morganii</i> SS <i>siboni</i>	ATCC 51206	<i>Morganella morganii</i> subsp. <i>siboni</i> Jensen et al., CDC 3522-75 [RB 2405]	
	<i>ampC</i> (DHA)	<i>Morganella morganii</i>	ATCC 25829	(Winslow et al. 1919) Jensen et al. 1992, M4	
	<i>ampC</i> (FOX-5)	<i>Klebsiella pneumoniae</i>	JMI Strain 1238756	N/A	
	<i>ampC</i> (CMY-LAT)	<i>Escherichia coli</i>	NCTC 14333	(Migula 1895) Castellani and Chalmers 1919, MLST: 167	
	<i>ampC</i> (CMY-LAT)	<i>Escherichia coli</i>	NCTC 14339	(Migula 1895) Castellani and Chalmers 1919, MLST: 361	
<i>armA</i>	<i>armA</i>	<i>Acinetobacter baumannii</i>	ATCC BAA-2803*	1125209	Detected
	<i>armA</i>	<i>Acinetobacter baumannii</i>	NCTC 13424	UK 20	
	<i>armA</i>	<i>Klebsiella pneumoniae</i>	ATCC BAA-3072	(Schroeter) Trevisan, 979620	
	<i>armA</i>	<i>Acinetobacter baumannii</i>	ATCC BAA-2873	1081925	
	<i>armA</i>	<i>Klebsiella pneumoniae</i>	ATCC BAA-2783	972863	
	<i>armA</i>	<i>Klebsiella pneumoniae</i>	CCUG 68728*	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13443	
	<i>armA</i>	<i>Klebsiella oxytoca</i>	ATCC BAA-3059	(Flugge) Lautrop, 957532	
CTX-M	CTX-M-15 (Group 1)	<i>Escherichia coli</i>	ATCC BAA-2774	(Migula) Castellani and Chalmers, 1093925	Detected
	CTX-M-14 (Group 9)	<i>Escherichia coli</i>	ATCC BAA-2775	1099675	
	CTX-M-2, CTX-M-15 (Group 1 and Group 2)	<i>Klebsiella pneumoniae</i>	ATCC BAA-2783	972863	
	CTX-M-15 (Group 1)	<i>Klebsiella pneumoniae</i>	ATCC BAA-3077*	875638	
	CTX-M-26 (Group 25)	**gBlock_CTX-M (group 25)_AY157676.1 <i>Klebsiella pneumoniae</i> CTX-M-26 beta-lactamase (<i>bla</i> CTX-M-26) gene, complete <i>cds</i>	**gBlock_CTX-M (group 25)_AY157676.1	N/A	
	CTX-M-15 (Group 1)	<i>Klebsiella pneumoniae</i>	ATCC BAA-3063§	1121740	
	CTX-M-15 (Group 1)	<i>Klebsiella pneumoniae</i>	CCUG 68728*	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13443	
	CTX-M	<i>Escherichia coli</i>	NCTC 14325*	(Migula 1895) Castellani and Chalmers 1919	
	CTX-M-15 (Group 1)	<i>Escherichia coli</i>	NCTC 13919	(Migula 1895) Castellani and Chalmers 1919 (AL), NCTC13919, H162440763	

Target	AMR variant	Species	Catalog number	Strain designation	Result
	CTX-M-3 (Group 1)	<i>Klebsiella oxytoca</i>	ATCC BAA-3059	(Flugge) Lautrop, 957532	
	CTX-M-2 (Group 2)	<i>Escherichia coli</i>	NCTC 13462	N/A	
	CTX-M-15 (Group 1)	<i>Enterobacter bugandensis</i>	CCUG 75194T	EB-247, 247BMC, DSM 29888, NCCB 100573	
	CTX-M-14 (Group 9)	<i>Enterobacter cloacae</i>	NCTC 14328	(Jordan 1890) Hormaeche and Edwards 1960	
GES	GES-5	<i>Escherichia coli</i>	NCTC 13919	(Migula 1895) Castellani and Chalmers 1919 (AL), NCTC13919, H162440763	Detected
	GES-6	<i>Klebsiella pneumoniae</i>	ATCC BAA-3068	1104762	
	GES-1	<i>Klebsiella pneumoniae</i>	ATCC BAA-3077*	875638	
	GES-19, GES-26	<i>Pseudomonas aeruginosa</i>	ATCC BAA-3108	Strain: 835930, 853930	
	GES-11	<i>Acinetobacter baumannii</i>	CCUG 68164	Bouvet and Grimont 1986	
	GES-5	<i>Pseudomonas aeruginosa</i>	ATCC BAA-2794*	(Schroeter) Migula, 1079232	
IMP	IMP-1	<i>Escherichia coli</i>	CCUG 67180*	(Migula 1895) Castellani and Chalmers 1919 (Approved Lists 1980)	Detected
	IMP-21	**gBlock_IMP 21_AB204557.1 <i>Pseudomonas aeruginosa blaIMP-21 gene for metallo-beta-lactamase IMP-21, complete cds</i>	gBlock_IMP 21_AB204557.1	N/A	
	IMP-14	**gBlock_IMP 14_AY553332.1:114-854 <i>Pseudomonas aeruginosa class I integron IMP-14 (blaIMP-14) and aminoglycoside 6'-N-acetyltransferase (aac(6')) genes, complete cds</i>	gBlock_IMP 14_AY553332.1:114-854	N/A	
	IMP	<i>Escherichia coli</i>	NCTC 14320	(Migula 1895) Castellani and Chalmers 1919	
	IMP-4	<i>Klebsiella pneumoniae</i>	NCTC 14334*	(Schroeter 1886) Trevisan 1887, 47C	
	IMP-1	<i>Klebsiella pneumoniae</i>	NCTC 14337	54, (Schroeter 1886) Trevisan 1887	
KPC	KPC-2	<i>Escherichia coli</i>	ATCC BAA-2774	(Migula 1895) Castellani and Chalmers, 1093925	Detected
	KPC	<i>Escherichia coli</i>	NCTC 14320	(Migula 1895) Castellani and Chalmers 1919	
	KPC	<i>Escherichia coli</i>	NCTC 14321*	(Migula 1895) Castellani and Chalmers 1919, 7	
	KPC-2	<i>Klebsiella pneumoniae</i>	ATCC BAA-1705*	(Schroeter) Trevisan, ART 2008133 [D-05, 1338]	
	KPC-2	<i>Klebsiella pneumoniae</i>	ATCC BAA-3068	1104762	

Target	AMR variant	Species	Catalog number	Strain designation	Result
	KPC-3	<i>Klebsiella pneumoniae</i>	NCTC 13438	Isolate 1, Hospital A	
	KPC-4	<i>Enterobacter cloacae</i>	NCTC 14322	(Jordan 1890) Hormaeche and Edwards 1960, 42E	
NDM	NDM-16	<i>Klebsiella pneumoniae</i>	ATCC BAA-3063§	1121740	Detected
	NDM-1	<i>Klebsiella pneumoniae</i>	CCUG 68728*	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13443	
	NDM-1	<i>Pseudomonas aeruginosa</i>	ATCC BAA-2796	1106434	
	NDM-1	<i>Salmonella enterica seftenberg</i>	NCTC 13953	(ex Kauffmann and Edwards 1952) Le Minor and Popoff 1987	
	NDM-1	<i>Pseudomonas aeruginosa</i>	JMI Strain 1227781	N/A	
	NDM-7	<i>Escherichia coli</i>	NCTC 14325*	(Migula 1895) Castellani and Chalmers 1919	
	NDM-4	<i>Escherichia coli</i>	NCTC 14333	(Migula 1895) Castellani and Chalmers 1919, MLST: 167	
	NDM-5	<i>Escherichia coli</i>	NCTC 14339	(Migula 1895) Castellani and Chalmers 1919, MLST: 361	
	NDM-1	<i>Klebsiella pneumoniae</i>	ATCC BAA-3072	(Schroeter) Trevisan, 979620	NDM detected with reduced sensitivity (4.37E+06CFU/mL) †
OXA-23	OXA-23	<i>Acinetobacter baumannii</i>	ATCC BAA-2801*	1103521	Detected
	OXA-23	<i>Acinetobacter baumannii</i>	ATCC BAA-2873	1081925	
	OXA-23	<i>Acinetobacter baumannii</i>	ATCC BAA-2803*	1125209	
	OXA-23	<i>Acinetobacter baumannii</i>	CCUG 68164	Bouvet and Grimont 1986	
	OXA-23	<i>Acinetobacter baumannii</i>	NCTC 13424	UK 20	
OXA-24/40	OXA-24	<i>Acinetobacter baumannii</i>	ATCC BAA-2881*	Bouvet and Grimont, 1173844	Detected
	OXA-24	<i>Acinetobacter baumannii</i>	CCUG 57249*	Bouvet and Grimont 1986	
	OXA-25	<i>Acinetobacter baumannii</i>	NCTC 13302	OXA-25, 327009	
	OXA-24	<i>Acinetobacter baumannii</i>	PA212222	N/A	
	OXA-40	**gBlock OXA 24/40_AF509241.1 <i>Acinetobacter baumannii</i> carbapenem-hydrolyzing beta-lactamase OXA-40 (bla-OXA-40) gene, complete cds	**gBlock OXA 24/40_AF509241.1	N/A	

Target	AMR variant	Species	Catalog number	Strain designation	Result
OXA-48-like	OXA-48-like	<i>Escherichia coli</i>	NCTC 14320	(Migula 1895) Castellani and Chalmers 1919	Detected
	OXA-48-like	<i>Escherichia coli</i>	NCTC 14321*	(Migula 1895) Castellani and Chalmers 1919, 7	
	OXA-48	<i>Klebsiella pneumoniae</i>	CCUG 68727	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13442	
	OXA-48	<i>Salmonella typhimurium</i>	NCTC 13954*	(ex Kauffmann and Edwards 1952) Le Minor and Popoff 1987	
	OXA-48	<i>Klebsiella pneumoniae</i>	ATCC BAA-3072	(Schroeter) Trevisan, 979620	
OXA-58	OXA-58	<i>Acinetobacter baumannii</i>	ATCC BAA-2890*	Bouvet and Grimont, 177579	Detected
	OXA 58	<i>Acinetobacter baumannii</i>	ATCC BAA-2901	Bouvet and Grimont, 157075	
	OXA-58	<i>Acinetobacter baumannii</i>	ATCC BAA-2895	N/A	
	OXA-58	<i>Acinetobacter baumannii</i>	NCTC 13305*	A-15	
PER	PER-1	<i>Acinetobacter baumannii</i>	ATCC BAA-2801*	1103521	Detected
	PER-1	<i>Pseudomonas aeruginosa</i>	MRSN 6241	Strain MRSN 6241, NR-51550	
	PER-1	<i>Pseudomonas aeruginosa</i>	MRSN 8141	Strain MRSN 8141, NR-51558	
	PER-14	**gBlock PER 14_MN715315.1 <i>Raoultella ornithinolytica</i> strain 1256861 class A extended-spectrum beta-lactamase PER-2 and PER-14 (blaPER) gene, blaPER-14 allele, complete cds	**gBlock PER-2_PER-14_MN715315.1	N/A	
	PER-1	<i>Pseudomonas aeruginosa</i>	ATCC BAA-2799*	1145009	
	PER	<i>Pseudomonas aeruginosa</i>	NCTC 14383	(Schroeter 1872) Migula 1900 (Approved Lists 1980)	
SHV	SHV	<i>Klebsiella pneumoniae</i>	NCTC 14337	54, (Schroeter 1886) Trevisan 1887	Detected
	SHV-11	<i>Klebsiella pneumoniae</i>	ATCC BAA-1705*	(Schroeter) Trevisan, ART 2008133 [D-05, 1338]	
	SHV-11	<i>Klebsiella pneumoniae</i>	ATCC BAA-3060	(Schroeter) Trevisan, 1150539	
	SHV-27	<i>Klebsiella pneumoniae</i>	ATCC BAA-3068	N/A, 1104762	
	SHV-1	<i>Klebsiella pneumoniae</i>	ATCC BAA-3077*	N/A, 875638	
	SHV-11	<i>Klebsiella pneumoniae</i>	CCUG 68727	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13442	
	SHV	<i>Klebsiella pneumoniae</i>	CCUG 68728*	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13443	

Target	AMR variant	Species	Catalog number	Strain designation	Result
	SHV-12	<i>Salmonella enterica seftenberg</i>	NCTC 13953	ex Kauffmann and Edwards 1952) Le Minor and Popoff 1987, N/A	
	SHV	<i>Klebsiella pneumoniae</i>	NCTC 14334*	(Schroeter 1886) Trevisan 1887, 47C	
	SHV-187	<i>Klebsiella pneumoniae</i>	JMI 1238756	N/A, NA	
	SHV-11	<i>Klebsiella pneumoniae</i>	NCTC 13438	Isolate 1, Hospital A, N/A	
	SHV	<i>Enterobacter cloacae</i>	NCTC 14328	(Jordan 1890) Hormaeche and Edwards 1960, N/A	
	SHV-18	<i>Klebsiella pneumoniae</i>	ATCC 700603	N/A, K6 [CCUG 45421, LMG 20218, MCV37]	
	SHV-28	<i>Klebsiella pneumoniae</i>	ATCC BAA-3063	N/A, 1121740	
	SHV-28	<i>Klebsiella pneumoniae</i>	ATCC BAA-3072	(Schroeter) Trevisan, 979620	SHV Detected with reduced sensitivity (4.37E+06 CFU/mL)†
	SHV-1	<i>Klebsiella pneumoniae</i>	ATCC BAA-2783	N/A, 972863	SHV Detected with reduced sensitivity (4.37E+07 CFU/mL)†
	SHV	<i>Escherichia coli</i>	NCTC 14325	(Migula 1895) Castellani and Chalmers 1919, N/A	SHV Not detected
SPM	SPM-1	<i>Pseudomonas aeruginosa</i>	NCTC 13921*	(Schroeter 1872) Migula 1900 (AL), NCTC 13921	Detected
	SPM-1	<i>Pseudomonas aeruginosa</i>	JMI Strain 378769*	N/A	
	SPM-1	<i>Pseudomonas aeruginosa</i>	JMI Strain 338718	N/A	
	SPM-1	<i>Pseudomonas aeruginosa</i>	JMI Strain JMI-147	N/A	
TEM	TEM-1	<i>Escherichia coli</i>	ATCC BAA-2775	1099675	Detected
	TEM-1	<i>Klebsiella pneumoniae</i>	ATCC BAA-3060	(Schroeter) Trevisan, 1150539	
	TEM-1	<i>Klebsiella pneumoniae</i>	ATCC BAA-3077*	875638	
	TEM-1	<i>Klebsiella pneumoniae</i>	CCUG 68727	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13442	
	TEM-1	<i>Klebsiella pneumoniae</i>	CCUG 68728*	(Schroeter 1886) Trevisan 1887 (Approved Lists 1980), NCTC 13443	
	TEM-2	<i>Proteus mirabilis</i>	ATCC BAA-2792*	Hauser, 1104843	
	TEM	<i>Escherichia coli</i>	NCTC 14320	(Migula 1895) Castellani and Chalmers 1919	
	TEM	<i>Escherichia coli</i>	CCUG 67180*	(Migula 1895) Castellani and Chalmers 1919 (Approved Lists 1980)	
	TEM-1	<i>Klebsiella oxytoca</i>	ATCC BAA-3059*	(Flugge) Lautrop, 957532	
	TEM-1	<i>Enterobacter bugandensis</i>	CCUG 75194T	EB-247, 247BMC, DSM 29888, NCCB 100573	

Target	AMR variant	Species	Catalog number	Strain designation	Result
	TEM	<i>Escherichia coli</i>	NCTC 14333	(Migula 1895) Castellani and Chalmers 1919, MLST: 167	
	TEM-3	<i>Escherichia coli</i>	NCTC 13351	N/A	
	TEM-10	<i>Escherichia coli</i>	NCTC 13352	N/A	
	TEM	<i>Enterobacter cloacae</i>	NCTC 14328	(Jordan 1890) Hormaeche and Edwards 1960	
	TEM	<i>Escherichia fergusonii</i>	CCUG 18766T	Farmer et al. 1985, CDC 0568-73 [DSM 13698]	
	TEM-1	<i>Klebsiella pneumoniae</i>	ATCC BAA-3063 [¶]	1121740	
	TEM-1	<i>Klebsiella pneumoniae</i>	ATCC BAA-3068	1104762	TEM Detected with reduced sensitivity (4.37E+06 CFU/ml) [†]
	TEM-1	<i>Klebsiella pneumoniae</i>	ATCC BAA-2783	972863	
	TEM-1	<i>Acinetobacter baumannii</i>	ATCC BAA-2881	Bouvet and Grimont, 1173844	TEM Detected with reduced sensitivity (2.31E+06 CFU/mL) [†]
	TEM-1	<i>Acinetobacter baumannii</i>	ATCC BAA-2873	1081925	
	TEM	<i>Salmonella enterica seftenberg</i>	NCTC 13953	ex Kauffmann and Edwards 1952) Le Minor and Popoff 1987	TEM Detected with reduced sensitivity (2.25E+05 CFU/mL) [†]
	TEM-1	<i>Acinetobacter baumannii</i>	ATCC BAA-2801	1103521	TEM Detected with reduced sensitivity (2.31E+08 CFU/mL) [‡]
	TEM-1	<i>Escherichia coli</i>	NCTC 13462	N/A	TEM Detected with reduced sensitivity (6.78E+07 CFU/mL) [†]
	TEM	<i>Escherichia coli</i>	NCTC 14321	(Migula 1895) Castellani and Chalmers 1919, 7	TEM Detected with reduced sensitivity (1.71E+09 CFU/mL) ^{‡#}
	TEM	<i>Klebsiella pneumoniae</i>	ATCC BAA-1705	(Schroeter) Trevisan, ART 2008133 [D-05, 1338]	TEM Detected with reduced sensitivity (6.25E+09 CFU/mL) [‡] **
VEB	VEB-14	<i>Pseudomonas aeruginosa</i>	ATCC BAA-3099	1079205	Detected
	VEB	<i>Pseudomonas aeruginosa</i>	MRSN 12914*	Snesrud,E. and McGann,P., NR-51575	
	VEB-22	**gBlock VEB_MN201581.1 <i>Pseudomonas aeruginosa</i> strain 1879174 class A extended-spectrum beta-lactamase VEB-22 (<i>bla</i> VEB) gene, <i>bla</i> VEB-22 allele, complete <i>cds</i>	**gBlock VEB_MN201581.1	N/A	
	VEB-14	<i>Pseudomonas aeruginosa</i>	JMI Strain 1227781	N/A	

Target	AMR variant	Species	Catalog number	Strain designation	Result
	VEB-9	<i>Pseudomonas aeruginosa</i>	ATCC BAA-2796	1106434	
	VEB-1	<i>Pseudomonas aeruginosa</i>	NCTC 13437*	N/A	
VIM	VIM-1	<i>Enterobacter cloacae</i>	NCTC 14326*	(Jordan 1890) Hormaeche and Edwards 1960, 29	Detected
	VIM-1	<i>Proteus mirabilis</i>	ATCC BAA-2792*	Hauser, 1104843	
	VIM-5	<i>Pseudomonas aeruginosa</i>	ATCC BAA-3099	1079205	
	VIM-10	<i>Pseudomonas aeruginosa</i>	NCTC 13437*	N/A	
	VIM-5	<i>Pseudomonas aeruginosa</i>	ATCC BAA-2799*	1145009	
	VIM-4	<i>Enterobacter cloacae</i>	NCTC 14328	(Jordan 1890) Hormaeche and Edwards 1960	

N/A: Information not available.

* These AMRs were evaluated during the LoD study.

† Detected with reduced sensitivity below the mean bottle positive concentration determined for the pathogen.

‡ Detected with reduced sensitivity above the mean bottle positive concentration determined for the pathogen.

§ This AMR was detected in ATCC BAA-3063 at bottle positive concentration as observed in the contrived samples during the clinical study. Lower pathogen concentrations could not be evaluated in this study because *E. amnigenus* was also included in the mix which has been shown to cross react with the *Klebsiella* spp. assay. It is not known whether this AMR in this strain would be detected near the combined LoD determined for *Klebsiella* spp.

¶ This AMR was detected in ATCC BAA-3063 at bottle positive concentration as observed in the contrived samples during the clinical study. In this study, it was not detected at concentrations below (4.37E+06 CFU/mL (44.4x the combined LoD determined for *Klebsiella* spp)). Because the root cause was dropout of the AMR target, the AMR is reported as detected with reduced sensitivity for this strain.

** Concentrations between Limit of Detection study test concentrations and stock not tested. It is not known if TEM would be detected at a lower concentration.

In silico analysis

In silico prediction of the reactivity of all primers-probe oligonucleotide sequences included in the QIAstat-Dx BCID GN Plus AMR Panel was performed against sequences publicly available in databases.

All the organism-PCR assays (Table 5) are expected to detect the complete list of sequences analyzed, with a small portion of sequences predicted undetected. No additional analyses were performed. The overall inclusivity level for each of the PCR assays included in the QIAstat-Dx BCID GN Plus AMR Panel was close to 100% for all the relevant species.

The AMR-PCR assays (Table 5) showed perfect inclusivity levels for all the AMR genes targeted by the panel with few observations.

Table 5: Summary and Observations Found in the in silico Prediction of the QIAstat-Dx BCID GN plus AMR Panel.

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
Organism-PCR assays	<i>Acinetobacter calcoaceticus-baumannii</i> complex	1403 (100.00%)	Species detected list includes at least <i>A. baumannii</i> , <i>A. calcoaceticus</i> , <i>A. pittii</i> , <i>A. nosocomialis</i> , <i>A. lactucae</i> , <i>A. seifertii</i>
	<i>Bacteroides fragilis</i>	79 (100%)	Inclusivity determined for <i>B. fragilis</i>
	<i>Enterobacter</i> spp.	959 (100.00%)	<i>Enterobacter</i> species detected includes at least <i>E. adalaidae</i> , <i>E. asburiae</i> , <i>E. bugandensis</i> , <i>E. cancerogenus</i> , <i>E. chengduensis</i> , <i>E. chuandaensis</i> , <i>E. cloacae</i> (<i>E. cloacae</i> spp., <i>E. cloacae</i> subsp. <i>Cloacae</i> , <i>E. cloacae</i> subsp. <i>dissolvens</i>), <i>E. dykesii</i> , <i>E. hormaechei</i> (<i>E. hormaechei</i> sp., <i>E. hormaechei</i> subsp. <i>Hoffmannii</i> , <i>E. hormaechei</i> subsp. <i>Hormaechei</i> , <i>E. hormaechei</i> subsp. <i>Oharae</i> , <i>E. hormaechei</i> subsp. <i>Steigerwaltii</i> , <i>E. hormaechei</i> subsp. <i>xiangfangensis</i>), <i>E. huaxiensis</i> , <i>E. intestinhominis</i> , <i>E. kobei</i> , <i>E. ludwigii</i> , <i>E. mori</i> , <i>E. oligotrophicus</i> , <i>E. pasteurii</i> , <i>E. pseudoroggenkampii</i> , <i>E. quasiroggenkampii</i> , <i>E. roggenkampii</i> , <i>E. sichuanensis</i> , <i>E. soli</i> , <i>E. vonholyi</i> , <i>E. wuhouensis</i> . In addition, the following species are also detected: <i>Lelliottia amnigena</i> (<i>E. amnigenus</i>), <i>Lelliottia nimipressuralis</i> (<i>E. nimipressuralis</i>), <i>Pluralibacter gergoviae</i> (<i>E. gergoviae</i>).
	<i>Escherichia coli</i>	2845 (100%)	Inclusivity determined for <i>E. coli</i>
	<i>Haemophilus influenzae</i>	416 (100.00%)	<i>H. influenzae</i> sequences detected include all encapsulated serotypes (a, b, c, d, e, f) and unencapsulated strains (nontypable, NTHi) including var. <i>H. aegyptius</i> .
	<i>Klebsiella</i> spp.	4742 (100.00%)	<i>Klebsiella</i> detected species list includes at least <i>K. oxytoca</i> , <i>K. pneumoniae</i> , <i>K. aerogenes</i> , <i>K. variicola</i> , <i>K. quasipneumoniae</i> , <i>K. quasivariicola</i> , <i>K. Africana</i> .
	<i>Neisseria meningitidis</i> (Encapsulated)	227 (100%)	<i>N. meningitidis</i> species detected correspond to encapsulated serotypes (A, B, C, D, E, H, I, K, L, NG, W, W135, X, Y, Z, 29E).
	<i>Pan Enterobacterales</i> †	3294 (100.00%)	List of species detected includes at least <i>Atlantibacter</i> (<i>A. hermannii</i>), <i>Brenneria</i> (<i>B. rubrifaciens</i>), <i>Cedecea</i> (<i>C. lapagei</i>), <i>Chania</i> (<i>C. multitudinisentens</i>), <i>Chimaeribacter</i> (<i>C. arupi</i>), <i>Citrobacter</i> (<i>C. braakii</i> , <i>C. cronae</i> , <i>C. europaeus</i> , <i>C. freundii</i> , <i>C. koseri</i> , <i>C. meridianamericanus</i> , <i>C. portucalensis</i> , <i>C. werkmanii</i>), <i>Cronobacter</i> (<i>C. condiment</i> , <i>C. malonaticus</i> , <i>C. sakazakii</i>), <i>Dickeya</i> (<i>D. oryzae</i> , <i>D. zeae</i>), <i>Dryocola</i> (<i>Dryocola</i> sp.), <i>Edwardsiella</i> (<i>E. ictalurid</i> , <i>E. tarda</i>), <i>Enterobacter</i> (<i>E. bugandensis</i> , <i>E. cancerogenus</i> , <i>E. cloacae</i> , <i>E. hormaechei</i> , <i>E. kobei</i> , <i>E. ludwigii</i> , <i>E. mori</i> , <i>E. pasteurii</i> , <i>E. roggenkampii</i>), <i>Erwinia</i> (<i>E. amylovora</i> , <i>E. aphidicola</i> , <i>E. billingiae</i> , <i>E. persicina</i> , <i>E. rhapontici</i> , <i>E. tracheiphila</i>), <i>Escherichia</i> (<i>E. albertii</i> , <i>E. coli</i> , <i>E. fergusonii</i> , <i>E. marmotae</i> , <i>E. ruisyae</i>), <i>Ewingella</i> (<i>E. americana</i>), <i>Gibbsiella</i> (<i>G. quercinecans</i>), <i>Hafnia</i> (<i>H. alvei</i> , <i>H. paralvei</i>), <i>Klebsiella</i> (<i>K. aerogenes</i> , <i>K. africana</i> , <i>K. electrica</i> , <i>K. grimontii</i> , <i>K. michiganensis</i> , <i>K. oxytoca</i> , <i>K. pasteurii</i> , <i>K. pneumoniae</i> , <i>K. quasipneumoniae</i> , <i>K. quasivariicola</i> , <i>K. variicola</i>), <i>Khuyvera</i> (<i>K. genomospecies</i> , <i>K. intermedia</i> , <i>K. ascorbata</i>), <i>Kosakonia</i> (<i>K. cowanii</i> , <i>K. pseudosacchari</i> , <i>K. radicincitans</i>), <i>Leclercia</i> (<i>L. adecarboxylata</i> , <i>L. pneumoniae</i>), <i>Lelliottia</i> (<i>Lelliottia</i> sp.), <i>Limnobaculum</i> (<i>L. parvum</i> , <i>L. zhutongyuii</i>), <i>Lonsdalea</i> (<i>L. populi</i>), <i>Morganella</i> (<i>M. morganii</i>),

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
			<i>Obesumbacterium</i> (<i>O. proteus</i>), <i>Pectobacterium</i> (<i>P. aroidearum</i> , <i>P. brasiliense</i> , <i>P. peruvienne</i> , <i>P. versatile</i>), <i>Photobacterium</i> (<i>P. asymbiotica</i> , <i>P. luminescens</i>), <i>Phytobacter</i> (<i>P. diazotrophicus</i> , <i>P. ursingii</i>), <i>Pluralibacter</i> (<i>P. gergoviae</i>), <i>Pragia</i> (<i>P. fontium</i>), <i>Proteus</i> (<i>P. columbae</i> , <i>P. hauseri</i> , <i>P. mirabilis</i> , <i>P. terrae</i> , <i>P. vulgaris</i>), <i>Providencia</i> (<i>P. alcalifaciens</i> , <i>P. hangzhouensis</i> , <i>P. heimbachae</i> , <i>P. huaxiensis</i> , <i>P. manganooxydans</i> , <i>P. rettgeri</i> , <i>P. rustigianii</i> , <i>P. stuartii</i> , <i>P. vermicola</i>), <i>Pseudoscherichia</i> (<i>P. vulneris</i>), <i>Rahnella</i> (<i>R. bonasera</i>), <i>Raoultella</i> (<i>R. ornithinolytica</i> , <i>R. planticola</i> , <i>R. terrigena</i>), <i>Salmonella</i> (<i>S. bongori</i> , <i>S. enterica</i>), <i>Scandinavium</i> (<i>S. goeteborgense</i>), <i>Serratia</i> (<i>S. aquatilis</i> , <i>S. bockelmannii</i> , <i>S. entomophila</i> , <i>S. ficaria</i> , <i>S. fonticola</i> , <i>S. grimesii</i> , <i>S. inhibens</i> , <i>S. liquefaciens</i> , <i>S. marcescens</i> , <i>S. myotis</i> , <i>S. nematodiphila</i> , <i>S. nevei</i> , <i>S. odorifera</i> , <i>S. plymuthica</i> , <i>S. proteamaculans</i> , <i>S. quinivorans</i> , <i>S. rhizosphaerae</i> , <i>S. rubidaea</i> , <i>S. sarumani</i> , <i>S. ureilytica</i>), <i>Shigella</i> (<i>S. boydii</i> , <i>S. dysenteriae</i> , <i>S. flexneri</i> , <i>S. sonnei</i>), <i>Shimwellia</i> (<i>S. blattae</i>), <i>Sodalis</i> (<i>S. glossinidius</i> , <i>S. ligni</i> , <i>S. praecaptivus</i>), <i>Tatumella</i> (<i>T. citrea</i> , <i>T. ptyseos</i>), <i>Xenorhabdus</i> (<i>X. budapestensis</i> , <i>X. griffiniae</i> , <i>X. stockiae</i>), <i>Yersinia</i> (<i>Y. enterocolitica</i> , <i>Y. frederiksenii</i> , <i>Y. intermedia</i> , <i>Y. massiliensis</i> , <i>Y. mollaretii</i> , <i>Y. pestis</i> , <i>Y. pseudotuberculosis</i> , <i>Y. ruckeri</i>), <i>Yokenella</i> (<i>Y. regensburgi</i>).
	<i>Proteus</i> spp.	300 (100.00%)	<i>Proteus</i> detected species list includes at least <i>P. alimentorum</i> , <i>P. appendicitidis</i> , <i>P. cibi</i> , <i>P. columbae</i> , <i>P. faecis</i> , <i>P. mirabilis</i> , <i>P. penneri</i> , <i>P. terrae</i> (including <i>cibarius</i>), <i>P. vulgaris</i> , <i>P. hauseri</i> .
	<i>Pseudomonas aeruginosa</i>	1595 (99.94%) [‡]	Inclusivity determined for <i>P. aeruginosa</i> . Two <i>P. aeruginosa</i> chromosome sequences (CP047066 & CP104695) not detected
	<i>Salmonella</i> spp.	3114 (100%)	Species detected list includes at least <i>S. bongori</i> and <i>S. enterica</i> (including serovars 42:r,1, 4, 43:a:1, Abaetetuba, Abeokuta, Aberdeen, Abony, Abortusequi, Abortusovis, Adelaide, Adjame, Agona, Alachua, Albany, Albert, Anatum, Antsalova, Apapa, Bardo, Bareilly, Bergen, Berta, Birkenhead, Bispebjerg, Blegdam, Blockley, Borreze, Bovismorbificans, Braenderup, Brancaster, Brandenburg, Bredeney, Buzu, California, Cerro, Chester, Choleraesuis, Concord, Corvallis, Crossness, Cubana, Daytona, Derby, Dessau, Djakarta, Dublin, Eastbourne, Enteritidis, Fresno, Gallinarum, Gallinarum/Pullorum, Gaminara, Give, Gloucester, Goldcoast, Gombe, Hadar, Hartford, Havana, Hayindogo, Heidelberg, Hillingdon, Hissar, Hvittingfoss, India, Indiana, Infantis, Inverness, Irumu, Isangi, Itami, Java, Javiana, Johannesburg, Karamoja, Kedougou, Kentucky, Kiambu, Koessen, Kottbus, Krefeld, Kunzendorf, Litchfield, Livingstone, London, Lubbock, Macclesfield, Manchester, Manhattan, Mbandaka, Meleagridis, Miami, Mikawasima, Milwaukee, Minnesota, Moero, Montevideo, Moscow, Muenchen, Muenster, Nchanga, Newlands, Newport, Nitra, Ohio, Onderstepoort, Oranienburg, Othmarschen, Ouakam, Panama, Paratyphi, Pomona, Poona, Potsdam, Pullorum, Quebec, Reading, Rissen, Rough, Rubislaw, Saintpaul, San Diego, San Juan, Schwarzengrund, Senftenberg, Shamba, Singapore, Sloterdijk, Soerenga, Stanley, Stanleyville, Strathcona, Tennessee, Thompson, Typhi, Typhimurium, Uganda, Virchow, Wandsworth, Waycross, Weltevreden, Westhampton, Wien, Worthington, Yovokome).
	<i>Serratia</i> spp.	347 (100%)	<i>Serratia</i> species list detected includes at least <i>S. marcescens</i> , <i>S. ficaria</i> , <i>S. fonticola</i> , <i>S. liquefaciens</i> , <i>S. plymuthica</i> , <i>S. bockelmannii</i> , <i>S. nevei</i> , <i>S. rubidaea</i> , <i>S. sarumani</i> , <i>S. surfactantfaciens</i> , <i>S. ureilytica</i> , <i>S. inhibens</i> , <i>S. nematodiphila</i> , <i>S. proteamaculans</i> , <i>S. quinivorans</i> .

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
	<i>Stenotrophomonas maltophilia</i>	135 (99.26%)	1 sequence (CP133415) of <i>S. maltophilia</i> not detected.
AMR-PCR assays	<i>aac(6')-Ib</i>	957 (99.79%)	All available <i>aac(6')-Ib</i> sequences detected (Including AAC(6')-Ib; AAC(6')-Ib'; AAC(6')-Ib10; AAC(6')-Ib11; AAC(6')-Ib3; AAC(6')-Ib4; AAC(6')-Ib7; AAC(6')-Ib8; AAC(6')-Ib9; AAC(6')-Ib-cr1; <i>aac(6')-Ib-cr10</i> ; <i>aac(6')-Ib-cr11</i> ; AAC(6')-Ib-cr3; AAC(6')-Ib-cr4; AAC(6')-Ib-cr5; AAC(6')-Ib-cr6; AAC(6')-Ib-cr7; AAC(6')-Ib-cr8; AAC(6')-Ib-cr9; AAC6_IB_HZ; AAC_6_IB_Su; AAC6_30_AAC6_Ib; AAC_3Ib_AAC_6Ib), with the exception of AAC(6')-Ib-SK, specific for <i>Streptomyces kanamyceticus</i> . §
	<i>ampC</i> (CMY/LAT) ¶	702 (98.45%)	All available CMY and LAT sequences detected (Including CMY-2; CMY-4 to CMY-7; CMY-12 to CMY-18; CMY-20 to CMY-51; CMY-53 to CMY-87; CMY-89 to CMY-90; CMY-93 to CMY-97; CMY-99 to CMY-119; CMY-121 to CMY-122; CMY-124 to CMY-125; CMY-127 to CMY-186; CMY-188 to CMY-189; CMY-191 to CMY-192; CMY-194 to CMY-199; and LAT-1), with the exception of CMY-1; CMY-8 to CMY-11; CMY-19; CMY-98; CMY-190; CMY-8b.)
	<i>ampC</i> (DHA)	272 (100.00%)	All available DHA sequences detected, including DHA-1 to DHA-7; DHA-9 to DHA-10; DHA-12 to DHA-34.
	<i>ampC</i> (FOX)	25 (100.00%)	All available FOX sequences detected, including FOX-1 to FOX-10; FOX-12 to FOX-21.
	<i>armA</i>	436 (100.00%).	All available <i>armA</i> sequences detected.
	CTX-M	2659 (99.36%)	All available CTX-M sequences detected (including CTX-M-1 to CTX-M-17; CTX-M-19 to CTX-M-56; CTX-M-58 to CTX-M-69; CTX-M-71 to CTX-M-73; CTX-M-76 to CTX-M-117; CTX-M-121 to CTX-M-122; CTX-M-124 to CTX-M-127; CTX-M-129 to CTX-M-131; CTX-M-133 to CTX-M-134; CTX-M-136 to CTX-M-144; CTX-M-146 to CTX-M-148; CTX-M-150; CTX-M-152; CTX-M-154 to CTX-M-233; CTX-M-235 to CTX-M-249; CTX-M-251 to CTX-M-278), with the exception of CTX-M-74, CTX-M-75, CTX-M-123, CTX-M-132, CTX-M-151, CTX-M-153, CTX-M-234.
	GES	117 (99.15%)	All available GES sequences detected (including GES-1 to GES-22; GES-24 to GES-62; GES-65 to GES-66), with the exception of GES-23.
	IMP	280 (100.00%)	All available IMP sequences detected, including IMP-1 to IMP-35; IMP-37 to IMP-49; IMP-51 to IMP-56; IMP-58 to IMP-71; IMP-73 to IMP-102; IMP-104 to IMP-105.
	KPC	1052 (100.00%)	All available KPC sequences detected, including KPC-1 to KPC-19; KPC-21 to KPC-197; KPC-201 to KPC-209; KPC-211 to KPC-218; KPC-223 to KPC-228; KPC-230 to KPC-234; KPC-236 to KPC-242.
	NDM	655 (100.00%)	All available NDM sequences detected, including NDM-1 to NDM-15; NDM-16a; NDM-16b; NDM-17 to NDM-31; NDM-33 to NDM-58; NDM-60 to NDM-61; NDM-64 to NDM-74.
	OXA-23**	384 (100.00%)	OXA alleles detected: OXA-23; OXA-27; OXA-49; OXA-73; OXA-103; OXA-105; OXA-133; OXA-146; OXA-165 to OXA-171; OXA-225; OXA-239; OXA-366; OXA-398; OXA-422 to OXA-423; OXA-435; OXA-440; OXA-481 to OXA-483; OXA-565; OXA-657; OXA-806 to OXA-818; OXA-893; OXA-911; OXA-966 to OXA-969; OXA-1216; OXA-1221; OXA-1223; OXA-1236; OXA-1241. OXA alleles not detected: OXA-1 to OXA-5; OXA-7; OXA-9 to OXA-

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
			22; OXA-24 to OXA-26; OXA-28 to OXA-37; OXA-40; OXA-42 to OXA-43; OXA-45 to OXA-48; OXA-50 to OXA-51; OXA-53 to OXA-72; OXA-74 to OXA-101; OXA-104; OXA-106 to OXA-113; OXA-114a to OXA-114n; OXA114p to OXA114x; OXA-115 to OXA-132; OXA-134; OXA-136 to OXA-145; OXA-147 to OXA-164; OXA-172 to OXA-185; OXA-192 to OXA-217; OXA-219; OXA-223 to OXA-224; OXA-226; OXA-228 to OXA-237; OXA-240 to OXA-309; OXA-312 to OXA-317; OXA-320; OXA-322 to OXA-365; OXA-368; OXA-370 to OXA-392; OXA-395 to OXA-397; OXA-400 to OXA-418; OXA-420 to OXA-421; OXA-424 to OXA-427; OXA-429 to OXA-433; OXA-436 to OXA-439; OXA-441 to OXA-444; OXA-446 to OXA-455; OXA-457 to OXA-461; OXA-464 to OXA-466; OXA-470 to OXA-480; OXA-484 to OXA-486; OXA-488 to OXA-489; OXA-491; OXA-493 to OXA-494; OXA-496 to OXA-564; OXA-566 to OXA656; OXA-658 to OXA791; OXA-793 to OXA-805; OXA-819 to OXA-892; OXA-894 to OXA-910; OXA-912 to OXA-965; OXA-970 to OXA-1053; OXA-1055 to OXA-1094; OXA-1096 to OXA-1178; OXA-1181 to OXA-1191; OXA-1193 to OXA-1194; OXA-1198 to OXA-1208; OXA-1211 to OXA-1215; OXA-1217 to OXA-1220; OXA-1222; OXA-1224 to OXA-1235; OXA-1237 to OXA-1240; OXA-1242 to OXA-1309.
	OXA-48-like**	473 (100.00%)	OXA alleles detected: OXA-48; OXA-162 to OXA-163; OXA-181; OXA-199; OXA-204; OXA-232; OXA-244 to OXA-245; OXA-247; OXA-252; OXA-370; OXA-405; OXA-416; OXA-438 to OXA-439; OXA-484; OXA-505; OXA-514 to OXA-515; OXA-517; OXA-519; OXA-538; OXA-546 to OXA-547; OXA-566 to OXA-567; OXA-788; OXA-793; OXA-833; OXA-894; OXA-918; OXA-920; OXA-922 to OXA-924; OXA-929; OXA-933 to OXA-934; OXA-1012; OXA-1038 to OXA-1039; OXA-1055; OXA-1119; OXA-1146; OXA-1167; OXA-1181; OXA-1200 to OXA-1201; OXA-1205; OXA-1207; OXA-1211 to OXA-1213; OXA-1226; OXA-1240; OXA-1242; OXA-1304 to OXA-1309. OXA alleles not detected: OXA-1 to OXA-5; OXA-7; OXA-9 to OXA-37; OXA-40; OXA-42 to OXA-43; OXA-45 to OXA-47; OXA-49 to OXA-51; OXA-53 to OXA-101; OXA-103 to OXA-113; OXA-114a to OXA-114n; OXA-114p to OXA-114x; OXA-115 to OXA-134; OXA-136 to OXA-161; OXA-164 to OXA-180; OXA-182 to OXA-185; OXA-192 to OXA-198; OXA-200 to OXA-203; OXA-205 to OXA-217; OXA-219; OXA-223 to OXA-226; OXA-228 to OXA-231; OXA-233 to OXA-237; OXA-239 to OXA-243; OXA-246; OXA-248 to OXA-251; OXA-253 to OXA-309; OXA-312 to OXA-317; OXA-320; OXA-322 to OXA-366; OXA-368; OXA-371 to OXA-392; OXA-395 to OXA-398; OXA-400 to OXA-404; OXA-406 to OXA-415; OXA-417 to OXA-418; OXA-420 to OXA-427; OXA-429 to OXA-433; OXA-435 to OXA-437; OXA-440 to OXA-444; OXA-446 to OXA-455; OXA-457 to OXA-461; OXA-464 to OXA-466; OXA-470 to OXA-483; OXA-485 to OXA-486; OXA-488 to OXA-489; OXA-491; OXA-493 to OXA-494; OXA-496 to OXA-504; OXA-506 to OXA-513; OXA-516; OXA-518; OXA-520 to OXA-537; OXA-539 to OXA-545; OXA-548 to OXA-565; OXA-568 to OXA-787; OXA-789 to OXA-791; OXA-794 to OXA-832; OXA-834 to OXA-893; OXA-895 to OXA-917; OXA-919; OXA-921; OXA-925 to OXA-932; OXA-935 to OXA-1011; OXA-1013 to OXA-1037; OXA-1040 to OXA-1053; OXA-1056 to OXA-1118; OXA-1120 to OXA-1145; OXA-1147 to OXA-1166; OXA-1168 to OXA-1178; OXA-1182 to OXA-1191; OXA-1193 to OXA-1194; OXA-1198 to OXA-1199; OXA-1202 to

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
			OXA-1204; OXA-1206; OXA-1208; OXA-1214 to OXA-1225; OXA-1227 to OXA-1239; OXA-1241; OXA-1243 to OXA-1303.
	OXA-24/40**	59 (100.00%)	OXA alleles detected: OXA-24 to OXA-26; OXA-40; OXA-72; OXA-139; OXA-160; OXA-207; OXA-437; OXA-653; OXA-897; OXA-1040; OXA-1081; OXA-1225; OXA-1303. OXA alleles not detected: OXA-1 to OXA-5; OXA-7; OXA-9 to OXA-23; OXA-27 to OXA-37; OXA-42 to OXA-43; OXA-45 to OXA-51; OXA-53 to OXA-71; OXA-73 to OXA-101; OXA-103 to OXA-113; OXA-114a to OXA-114n; OXA-114p to OXA-114x; OXA-115 to OXA-134; OXA-136 to OXA-138; OXA-140 to OXA-159; OXA-161 to OXA-185; OXA-192 to OXA-206; OXA-208 to OXA-217; OXA-219; OXA-223 to OXA-226; OXA-228 to OXA-237; OXA-239 to OXA-309; OXA-312 to OXA-317; OXA-320; OXA-322 to OXA-366; OXA-368; OXA-370 to OXA-392; OXA-395 to OXA-398; OXA-400 to OXA-418; OXA-420 to OXA-427; OXA-429 to OXA-433; OXA-435 to OXA-436; OXA-438 to OXA-444; OXA-446 to OXA-455; OXA-457 to OXA-461; OXA-464 to OXA-466; OXA-470 to OXA-486; OXA-488 to OXA-499; OXA-491; OXA-493 to OXA-494; OXA-496 to OXA-652; OXA-654 to OXA-791; OXA-793 to OXA-896; OXA-898 to OXA-1039; OXA-1041 to OXA-1053; OXA-1055 to OXA-1080; OXA-1082 to OXA-1178; OXA-1181 to OXA-1191; OXA-1193 to OXA-1194; OXA-1198 to OXA-1208; OXA-1211 to OXA-1224; OXA-1226 to OXA-1302; OXA-1304 to OXA-1309
	OXA-58**	80 (100.00%)	OXA alleles detected: OXA-58; OXA-96 to OXA-97; OXA-164; OXA-397; OXA-420; OXA-512; OXA-1178. OXA alleles not detected: OXA-1 to OXA-5; OXA-7; OXA-9 to OXA-37; OXA-40; OXA-42 to OXA-43; OXA-45 to OXA-51; OXA-53 to OXA-57; OXA-59 to OXA-95; OXA-98 to OXA-101; OXA-103 to OXA-113; OXA-114a to OXA-114n; OXA-114p to OXA-114x; OXA-115 to OXA-134; OXA-136 to OXA-163; OXA-165 to OXA-185; OXA-192 to OXA-217; OXA-219; OXA-223 to OXA-226; OXA-228 to OXA-237; OXA-239 to OXA-309; OXA-312 to OXA-317; OXA-320; OXA-322 to OXA-366; OXA-368; OXA-370 to OXA-392; OXA-395 to OXA-396; OXA-398; OXA-400 to OXA-418; OXA-421 to OXA-427; OXA-429 to OXA-433; OXA-435 to OXA-444; OXA-446 to OXA-455; OXA-457 to OXA-461; OXA-464 to OXA-466; OXA-470 to OXA-486; OXA-488 to OXA-489; OXA-491; OXA-493 to OXA-494; OXA-496 to OXA-511; OXA-513 to OXA-791; OXA-793 to OXA-1053; OXA-1055 to OXA-1177; OXA-1181 to OXA-1191; OXA-1193 to OXA-1194; OXA-1198 to OXA-1208; OXA-1211 to OXA-1309.
	PER††	88 (100.00%)	All available PER sequences detected(including PER-1 to PER-5; PER-7 to PER-18), with the exception of PER-6
	SHV	2296 (100.00%)	All available SHV sequences detected, including SHV-1 to SHV-9; SHV-11 to SHV-16; SHV-18 to SHV-38; SHV-40 to SHV-46; SHV-48 to SHV-53; SHV-55 to SHV-57; SHV-59 to SHV-67; SHV-69 to SHV-86; SHV-89; SHV-92 to SHV-111; SHV-115 to SHV-116; SHV-119 to SHV-129; SHV-132 to SHV-135; SHV-137; SHV-140 to SHV-165; SHV-167 to SHV-168; SHV-171 to SHV-173; SHV-178 to SHV-180; SHV-182 to SHV-183; SHV-185 to SHV-191; SHV-193 to SHV-245; SHV-1b-b; SHV-2A; SHV-5a; SHV-1-2a; SHV-5-2a; SHV-136; SHV-122b.

PCR assay type	Target	Sequences analyzed* (inclusivity level)	Final inclusivity assessment
	SPM	9 (100.00%)	All available SPM sequences detected, including SPM-1.
	TEM	3371 (100.00%)	All available TEM sequences detected, including TEM-1; TEM-1b; TEM-2 to TEM-12; TEM-14 to TEM-17; TEM-19 to TEM-22 to TEM-24; TEM-26; TEM-26b; TEM-28 to TEM-37; TEM-39 to TEM-40; TEM-42 to TEM-43; TEM-45; TEM-47 to TEM-49; TEM-52 to TEM-55; TEM-57; TEM-59 to TEM-61; TEM-63 to TEM-64; TEM-67 to TEM-68; TEM-70 to TEM-73; TEM-75 to TEM-76; TEM-78 to TEM-99; TEM-101 to TEM-118; TEM-120 to TEM-139; TEM-141 to TEM-160; TEM-162 to TEM-164; TEM-166 to TEM-169; TEM-171; TEM-176 to TEM-178; TEM-181 to TEM-199; TEM-201; TEM-205 to TEM-217; TEM-219 to TEM-220; TEM-224 to TEM-258; RTE-1; TEM-1B; TEM-E2; TEM-HM.
	VEB	88 (100.00%)	All available VEB sequences detected, including VEB-1 to VEB-39; VEB-1a; VEB-1b.
	VIM	218 (100.00%).	All available VEB sequences detected, including VIM-1 to VIM-20; VIM-23 to VIM-91.

* Number of sequences analyzed from the total of sequences included in the analysis after removing preliminary sequences and artificial sequences.

† In silico analyses could not be performed for *Izhakiella* as no sequences were available. This is deemed low to no risk given that this genus has not been found to be implicated in human disease.

‡ *Pseudomonas aeruginosa* Accession Number CP104695 was not detected during primer mapping. This Accession Number corresponds to *P. aeruginosa* strain 2021CK-01281, which also carries a plasmid (Accession Number CP104696) where the target gene of the QIAstat-Dx BCID GN Plus AMR Panel is placed. The primers and probe mapped with 100% homology with this genetic region of the plasmid, thus confirming full inclusivity for this *P. aeruginosa* strain.

§ The AAC(6')-Ib-SK is a chromosomal-encoded aminoglycoside acetyltransferase specific for *Streptomyces kanamyceticus*. Based on the big amount of sequences described for this allele, percentages were calculated excluding this allele to homogenize the data. In addition, 2 out of 305 AAC(6')-Ib-9 sequences were predicted not to be detected because of the presence of mismatches.

¶ One out of 6 (1/6) sequences of the CMY-136 allele was predicted not to be detected because of the presence of mismatches.

** In case of OXA family PCR assays (OXA-23, OXA-58, OXA-48, OXA-24/40), analysis was performed using the entire list of OXA genes and alleles. Therefore, all percentages correspond to the sequences detected into the detected OXA alleles.

†† PER-6 has not been included in the analyzed sequences assessment.

Analytical Specificity (Cross-Reactivity and Exclusivity)

The analytical specificity study was carried out by in vitro testing and in silico analysis to assess the potential cross-reactivity and exclusivity of the QIAstat-Dx BCID GN Plus AMR Panel.

In vitro testing

On-panel organisms were tested to assess the potential for intra-panel cross-reactivity, and off-panel organisms were tested to evaluate cross-reactivity with organisms not covered by the panel content. Each off-panel organism was tested in triplicate with bacteria tested at a concentration of $>1.5E+08$ CFU/mL and fungi tested at a concentration of $>1.5E+06$ CFU/mL. Six organisms were tested below the intended starting concentration due to limitations in achievable growth in positive blood culture matrix: *Corynebacterium jeikeium* ($1.92E+07$ CFU/mL), *Fusarium solani*

(3.70E+03 CFU/mL), *Mucor velutinosus* (1.00E+05 CFU/mL), *Staphylococcus capitis* (7.70E+07 CFU/mL), *Staphylococcus lugdunensis* (9.00E+07 CFU/mL), and *Trichosporon asteroides* (2.08E+05 CFU/mL). No cross-reactivity was predicted for these organisms in the in silico analysis.

Several off-panel microorganisms showed cross-reactivity with the *Acinetobacter calcoaceticus-baumannii* complex, *Enterobacter* spp., *Pseudomonas aeruginosa*, *Stenotrophomonas maltophilia*, *Klebsiella* spp., and *Escherichia coli* assays. The off-panel organisms tested are shown in [Table 6](#).

Table 6: List of Off-Panel Targets Tested for Cross-Reactivity in-vitro Analysis

Pathogen	Source ID	Pathogen	Source ID
<i>Acinetobacter haemolyticus</i>	CCUG 888	<i>Haemophilus haemolyticus</i>	CCUG 12834
<i>Acinetobacter junii</i> *	CCUG 889	<i>Haemophilus parainfluenzae</i>	CCUG 12836T
<i>Acinetobacter lwoffii</i>	NCTC 5866	<i>Lactobacillus acidophilus</i>	CCUG 5917
<i>Acinetobacter nosocomialis</i> (<i>genomospecies anitratus</i>)	CCUG 26488	<i>Lactobacillus casei</i>	CCUG 21451
<i>Acremonium kiliense</i>	NCPF 2901	<i>Lactobacillus crispatus</i>	LMG 12004
<i>Aeromonas hydrophila</i>	CCUG 67305	<i>Lactobacillus paracasei</i>	CCUG 34678
<i>Aeromonas salmonicida</i>	LMG 3780	<i>Lactobacillus rhamnosus</i>	CCUG 18011
<i>Aeromonas sobria</i>	CCUG 14550	<i>Legionella pneumophila</i>	CCUG 9568
<i>Aggregatibacter aphrophilus</i>	NCTC 5906	<i>Listeria monocytogenes</i>	CCUG 74245
<i>Bacillus cereus</i>	NCTC 8035	<i>Listeria innocua</i>	CCUG 15531
<i>Bacteroides ovatus</i>	CCUG 4943	<i>Malassezia furfur</i>	CBS 7019
<i>Bacteroides caccae</i>	CCUG 38735	<i>Micrococcus luteus</i>	NCTC 7011
<i>Bacteroides distasonis</i>	CCUG 4941	<i>Mucor velutinosus</i>	CBS 204.68
<i>Bacteroides eggerthii</i>	CCUG 9559	<i>Neisseria flavescens</i>	CCUG 17913
<i>Bacteroides merdae</i>	CCUG 38734	<i>Neisseria gonorrhoeae</i>	CCUG 26876
<i>Bacteroides thetaiotaomicron</i>	CCUG 10774	<i>Neisseria sicca</i>	CCUG 23929
<i>Bacteroides ureolyticus</i>	CCUG 7319T	<i>Neisseria perflava</i>	CCUG 66328
<i>Bacteroides vulgatus</i>	CCUG 4940	<i>Pasteurella aerogenes</i>	CCUG 12761
<i>Burkholderia cepacia</i>	NCTC 10743	<i>Pasteurella multocida subsp. Multocide</i>	NCTC 10322
<i>Burkholderia glumae</i>	CCUG 20835T	<i>Penicillium marneffeii</i> (gDNA ONLY HG3)	CBS 549.77
<i>Candida albicans</i>	NCPF 8672	<i>Prevotella corporis</i>	CCUG 15404
<i>Candida auris</i>	NCPF 8971	<i>Prevotella intermedia</i>	CCUG 24041
<i>Candida glabrata</i>	NCPF 8018	<i>Prevotella nigrescens</i>	CCUG 9560
<i>Candida tropicalis</i>	NCPF 8760	<i>Propionibacterium/Cutibacterium acnes</i>	NCTC 737
<i>Candida dublinensis</i>	CCUG 69485	<i>Pseudomonas alcaligenes</i>	CCUG 1425
<i>Candida famata</i>	NCPF 8744	<i>Pseudomonas fluorescens</i>	NCTC 10038
<i>Candida guilliermondii</i>	NCPF 3896	<i>Pseudomonas putida</i>	NCTC 10936
<i>Candida kefyr</i>	NCPF 8343	<i>Pseudomonas mendocina</i> [†]	CCUG 1781
<i>Candida krusei</i>	CCUG 35869	<i>Pseudomonas stutzeri</i>	CCUG 58289
<i>Candida lusitanae</i>	CCUG 37495	<i>Ralstonia insidiosa</i>	CCUG 46789

Pathogen	Source ID	Pathogen	Source ID
<i>Candida metapsilosis</i>	NCPF 8791	<i>Ralstonia pickettii</i>	CCUG 3318
<i>Candida norvegensis</i>	CBS 1922	<i>Rhizobium pusense</i> †	LMG 25623
<i>Candida orthopsilosis</i>	NCPF 8804	<i>Rhodotorula minuta</i>	NCPF 8736
<i>Candida parapsilosis</i>	NCPF 3207	<i>Staphylococcus aureus</i>	CCUG 67181
<i>Corynebacterium diphtheriae</i>	CCUG 33629	<i>Staphylococcus capitis</i>	CCUG 42761
<i>Corynebacterium striatum</i>	ATCC 43735	<i>Staphylococcus epidermidis</i>	ATCC 35984
<i>Corynebacterium jeikeium</i>	ATCC BAA-949	<i>Staphylococcus lugdunensis</i>	CCUG 74993
<i>Corynebacterium ulcerans</i>	ATCC 51799	<i>Stenotrophomonas acidaminiphila</i> §	CCUG 46887T
<i>Corynebacterium urealyticum</i>	ATCC 43044	<i>Streptococcus agalactiae</i>	CCUG 4208
<i>Cryptococcus neoformans</i>	CCUG 23479	<i>Streptococcus pneumoniae</i>	CCUG 70149
<i>Cryptococcus gattii</i>	ATCC MYA-4071	<i>Streptococcus pyogenes</i>	NCTC 12696
<i>Eikenella corrodens</i>	CCUG 2138	<i>Streptococcus anginosus</i>	CCUG 27298
<i>Enterococcus faecalis</i>	CCUG 19916	<i>Streptococcus galloyticus</i>	NCTC 13784
<i>Enterococcus faecium</i>	CCUG 68933	<i>Trichosporon asahii</i>	CCUG 57655
<i>Fusarium solani</i>	NCPF 7483	<i>Trichosporon asteroides</i>	NCPF 3856
<i>Fusobacterium gonidiaformans</i>	CCUG 16790	<i>Trichosporon dermatitis</i>	CBS 2043
<i>Fusobacterium necrophorum</i>	ATCC 27852	<i>Trichosporon mucoides</i>	CBS 8667
<i>Fusobacterium nucleatum</i>	ATCC 25586	<i>Vibrio alginolyticus</i>	NCTC 10675
<i>Fusobacterium varium</i>	NCTC 10560	<i>Vibrio furnissii</i>	CCUG 37458
<i>Haemophilus parahaemolyticus</i>	CCUG 3716		

* Cross-reaction observed with the *Acinetobacter calcoaceticus-baumannii* complex assay at $\geq 1.50 \times 10^6$ CFU/mL and predicted in silico with several sequence mismatches.

† Cross-reaction observed with the *Pseudomonas aeruginosa* assay at $\geq 2.88 \times 10^6$ CFU/mL and predicted in silico with several sequence mismatches.

‡ Cross-reaction predicted in silico with the *Escherichia coli* assay but not confirmed in vitro.

§ Cross-reaction observed with the *Stenotrophomonas maltophilia* assay at $\geq 1.5 \times 10^6$ CFU/mL and predicted in silico.

Cross-reactivity with the on-panel targets was observed for microorganisms shown in [Table 7](#). The on-panel organisms tested are shown in [Table 3](#) (tested as part of the Growth and Detection study) and [Table 9](#) (Analytical Reactivity), or observed during the execution of the clinical study.

Table 7: Summary of Cross-Reactivities Observed for On-Panel Targets

On-Panel Pathogen	Source ID	Target in the QIAstat-Dx BCID GN Plus AMR Panel
<i>Enterobacter ludwigii</i>	CCUG 26899	<i>Klebsiella</i> spp.
<i>Enterobacter ludwigii</i>	CCUG 26899	<i>Proteus</i> spp.
<i>Citrobacter braaki</i> *	ATCC 51113	<i>Serratia</i> spp.
<i>Hafnia paralvei</i> *	CCUG 59411	<i>Proteus</i> spp.
<i>Lelliottia amnigena</i>	ATCC 33072	<i>Klebsiella</i> spp.
<i>Leclercia adecarboxylata</i>	NCTC 13032	<i>Enterobacter</i> spp.
<i>Shigella sonnei</i>	CCUG 68726	<i>Escherichia coli</i>
<i>Shigella boydii</i>	CCUG 49022	<i>Escherichia coli</i>
<i>Providentia stuartii</i>	CCUG 74678	<i>Proteus</i> spp.
<i>Yersinia enterocolitica</i>	NCTC 12982	<i>Serratia</i> spp.
<i>Haemophilus influenzae</i> †	Clinical study	Pan Enterobacterales
<i>Pasteurella multocida</i> †	Clinical study	Pan Enterobacterales

* Cross-reaction not predicted by *in silico* analysis.

† Cross-reaction observed during clinical study.

In silico analysis

In silico analysis was performed for every primer and probe included in the QIAstat-Dx BCID GN Plus AMR Panel to detect possible unexpected cross-reactions.

Apart from the cross-reactions detected in vitro, in silico predictions (Table 8) showed that the following cross-reactions may occur (organisms or AMRs not tested in vitro).

Table 8: Potential Cross-Reactions Based on in silico Analysis

Potential cross-reactive organisms/AMRs	Target in the QIAstat-Dx BCID GN Plus AMR Panel
<i>Bacteroides hominis</i> *	<i>Bacteroides fragillis</i>
<i>Citrobacter</i> spp. (on-panel)	<i>Enterobacter</i> spp.
<i>Enterobacter</i> spp. (on-panel)	<i>Klebsiella</i> spp.
<i>Escherichia ruysiae</i> (on-panel)	<i>Escherichia coli</i>
<i>Kosakonia cowanii</i> and <i>Kosakonia radicincitans</i> (on-panel)†	<i>Enterobacter</i> spp.
<i>Pantoea agglomerans</i> (on-panel)	<i>Proteus</i> spp.
<i>Pseudomonas denitrificans</i>	<i>Pseudomonas aeruginosa</i>
<i>Shigella flexneri</i> and <i>Shigella dysenteriae</i> (on-panel)	<i>Escherichia coli</i>
<i>Stenotrophomonas muris</i> ‡, <i>Stenotrophomonas riyadhensis</i> and <i>Stenotrophomonas tuberculopleuritidis</i>	<i>Stenotrophomonas maltophilia</i>
AFM b-lactamases family	NDM
ANT(3'')-II-AAC(6')-IId	<i>aac(6')-Ib</i> (<i>aacA4</i>)
<i>bla</i> _{AAK-1}	SHV
<i>bla</i> _{OKP-c-1}	SHV
LEN b-lactamases family	SHV
MOX-9	<i>ampC</i> (FOX)

* *Bacteroides fragilis* Division II now represents a distinct species, which is recognized as *Bacteroides hominis*.

† Organisms currently classified as *Kosakonia cowanii* and *Kosakonia radicincitans* were previously described as *Enterobacter radicincitans*, and have been associated with human disease, Cross-reaction with *Kosakonia cowanii* and *Enterobacter* spp. not confirmed in vitro.

‡ This species is classified into the *S. maltophilia* complex; therefore, a potential cross-reaction is expected.

Growth and Detection

The expected organism concentration in incubated blood cultures at bottle positivity was determined for each organism on the QIAstat-Dx BCID GN Plus AMR Panel. Each bacterium in the QIAstat-Dx BCID GN Plus AMR Panel was represented by at least one strain, which was mixed with negative human whole blood and directly seeded into a blood culture bottle, typically at ≤300 CFU/bottle. The bottle was then incubated in a continuous monitoring blood culture system until it was indicated as positive for growth (also known as the “bottle ring”) and 27 hours after the “bottle ring”. At this point, the bottles were removed, and the organism concentration was determined in CFU/mL using a standard plate count procedure.

The system was then used to test the blood culture sample following the QIAstat-Dx BCID GN Plus AMR Panel procedure.

Each representative strain was grown in at least 3 independent blood culture bottles, and each bottle was tested on the QIAstat-Dx system in triplicate, at least.

Mean CFU/mL across the 3 bottles for each condition and pathogen, and results for the detection of the organism at the bottle-positive concentration and plus 27 hours are reported in [Table 9](#). The concentrations listed below indicate approximate levels that may typically occur in a clinical setting.

Table 9: Growth and Detection Results Summary

Organism	Source ID	Organism target [AMR target]	Concentration at bottle positivity (CFU/mL)	Concentration at bottle positivity + 27h (CFU/mL)
<i>Acinetobacter baumannii</i>	ATCC BAA-2801	<i>Acinetobacter calcoaceticus-baumannii</i> complex [OXA-23, PER, TEM]	1.65E+08	2.54E+08
<i>Klebsiella pneumoniae</i>	CCUG 68728	<i>Klebsiella spp.</i> , Pan Enterobacterales [CTX-M, <i>armA</i> , <i>ampC</i> (CMY/LAT/DHA/FOX), SHV, NDM, TEM, <i>aac(6')-Ib</i>]	7.70E+07	2.70E+09
<i>Proteus mirabilis</i>	ATCC BAA-2792	<i>Proteus spp.</i> , Pan Enterobacterales [VIM, <i>aac(6')-Ib</i> , <i>ampC</i> (CMY/LAT/DHA/FOX), TEM]	1.91E+08	6.39E+09
<i>Salmonella enterica</i>	ATCC 6962	<i>Salmonella spp.</i> , Pan Enterobacterales	4.32E+08	3.69E+09
<i>Stenotrophomonas maltophilia</i>	NCTC 10259	<i>Stenotrophomonas maltophilia</i>	1.57E+07	3.13E+08
<i>Serratia marcescens</i>	ATCC 14041	<i>Serratia spp.</i> , Pan Enterobacterales	3.83E+08	4.79E+08
<i>Acinetobacter baumannii</i>	ATCC BAA-2890	<i>Acinetobacter calcoaceticus-baumannii</i> complex [OXA-58]	4.03E+07	9.18E+07
<i>Escherichia coli</i>	NCTC 14320	<i>Escherichia coli</i> , Pan Enterobacterales, [IMP, <i>aac(6')-Ib</i> , KPC, TEM, OXA-48-like]	1.36E+08	4.30E+09
<i>Acinetobacter baumannii</i>	CCUG 57249	<i>Acinetobacter calcoaceticus-baumannii</i> complex [OXA-24/40]	6.47E+07	1.71E+09
<i>Enterobacter asburiae</i>	ATCC 35955	<i>Enterobacter spp.</i> , Pan Enterobacterales	3.25E+08	2.66E+09
<i>Escherichia coli</i>	NCTC 13919	<i>Escherichia coli</i> , Pan Enterobacterales [CTX-M, GES, <i>aac(6')-Ib</i>]	9.23E+07	2.75E+09
<i>Pseudomonas aeruginosa</i>	MRSN 12914	<i>Pseudomonas aeruginosa</i> [VEB]	2.21E+08	2.18E+09
<i>Citrobacter freundii</i>	CCUG 418T	Pan Enterobacterales [<i>ampC</i> (CMY/LAT/DHA/FOX)]	4.79E+07	4.16E+09
<i>Acinetobacter baumannii</i>	NCTC 13302	<i>Acinetobacter calcoaceticus-baumannii</i> complex, [OXA-24/40]	2.11E+08	2.21E+08
<i>Pseudomonas aeruginosa</i>	NCTC 13921	<i>Pseudomonas aeruginosa</i> , [<i>aac(6')-Ib</i> , SPM]	3.46E+07	3.78E+09

Organism	Source ID	Organism target [AMR target]	Concentration at bottle positivity (CFU/mL)	Concentration at bottle positivity + 27h (CFU/mL)
<i>Neisseria meningitidis</i>	ATCC 13077	<i>Neisseria meningitidis</i>	1.94E+08	8.50E+07
<i>Bacteroides fragilis</i>	CCUG 4856T	<i>Bacteroides fragilis</i>	5.78E+08	1.53E+10
<i>Haemophilus influenzae</i>	CCUG 33775	<i>Haemophilus influenzae</i>	7.68E+07	1.00E+09

Interfering Substances

The effect of potentially interfering substances on the detectability of the QIAstat-Dx BCID GN Plus AMR Panel organisms was evaluated. Thirty-two (32) potentially interfering substances were spiked into the sample mixes at a level predicted to be above the concentration of the substance likely to be found in positive blood culture media specimens. Endogenous substances such as bilirubin, human genomic DNA, and hemoglobin were tested alongside exogenous substances like antibiotics, other sepsis-related medications, and different technique-specific substances.

Testing included samples containing negative blood culture media with and without the addition of each potentially interfering substance. Samples containing organism mixes with one strain for 3 representative organisms also harboring a total of 5 AMR were tested at 3x LoD or lower. The positive mix covered all reaction chambers of the QIAstat-Dx BCID GN Plus AMR Panel. Testing was performed in triplicate. Additionally, negative blood culture media were spiked with only the test substance to evaluate the potential for false positive results due to the test substance itself.

The only interference that was observed for the substances tested was Amoxicillin at 0.075 mg/mL; however, inhibitory effect was not observed when tested at 0.038 mg/mL. Results from the 32 interfering substances that could be present or introduced in a positive blood culture specimen are provided in [Table 10](#).

Table 10: Final Highest Concentration without Observable Inhibitory Effect

Substance name	Concentration in blood culture matrix (units/mL)	Result
Exogenous Substances		
Acetaminophen	0.156 mg/mL	No Interference
Amoxicillin	0.038 mg/mL	No Interference
Amoxicillin trihydrate: Potassium clavulanate (4:1)	0.075 mg/mL	No Interference
Amphotericin B	0.002 mg/mL	No Interference
Ara-C Triphosphate	2.64 µg/mL	No Interference
Biotin (Vitamin B7)	0.00351 mg/mL	No Interference
Sodium hypochlorite solution (Bleach)	5% (v/v) (6 mg/mL)	No Interference
Caspofungin Diacetate	0.005 mg/mL	No Interference
Ceftriaxone Disodium Hemiheptahydrate	0.966 mg/mL	No Interference

Substance name	Concentration in blood culture matrix (units/mL)	Result
Ciprofloxacin	0.01 mg/mL	No Interference
Ethanol	5% (v/v) (39.4 mg/mL)	No Interference
Fluconazole	0.075 mg/mL	No Interference
5-Fluorocytosine	0.09 mg/mL	No Interference
Gentamicin sulphate	0.03 mg/mL	No Interference
Heparin Sodium	3 U/mL	No Interference
Ibuprofen	0.219 mg/mL	No Interference
Imipenem Monohydrate	0.5 mg/mL	No Interference
Povidone (iodinated)	5 mg/mL	No Interference
Salicylic Acid	0.0286 mg/mL	No Interference
Sodium Polyanethol Sulfonate (SPS)	0.0025 mg/mL	No Interference
Tetracycline Hydrochloride	0.015 mg/mL	No Interference
Vancomycin (hydrochloride)	0.12 mg/mL	No Interference
Endogenous Substances		
Bilirubin	0.25 mg/mL	No Interference
Cholesterol	0.5 mg/mL	No Interference
D-Glucose	5 mg/mL	No Interference
Fibrinogen	0.5 mg/mL	No Interference
Haemoglobin	5 mg/mL	No Interference
Magnesium Sulphate (MgSO ₄)	0.1 mg/mL	No Interference
hgDNA	10.55 µg/mL	No Interference
Human Serum Albumin	25 mg/mL	No Interference
Triglycerides mixtures (Lipid standards)	15 mg/mL	No Interference
γ-globulin	60 mg/mL	No Interference

Competitive Inhibition

The QIAstat-Dx BCID GN Plus AMR Panel was evaluated for its ability to simultaneously detect multiple analytes within a single sample under conditions of differential pathogen concentrations where one pathogen is present at a high level (approximately bottle positivity + 24 hours) and another at a lower level (approximately 3×LoD). The study focused on clinically relevant and prevalent analyte combinations observed in polymicrobial blood cultures. Testing included a mixture of panel targets and mixtures of target analytes with non-target organisms, including common skin contaminants. If fewer than 3 replicates (<3/3) were detected for the pathogen (or associated AMR) when tested at 3xLoD in a sample mix, then repeat testing was performed with the pathogen tested at a higher concentration (i.e., >3xLoD) until 100% hit rate was observed. If the pathogen was still not detected when the concentration was increased close to that typical of a

“bottle positive” sample, the concentration of the other pathogen in the mix was reduced to determine the concentration at which co-detection was achieved.

Details of the organisms assessed and their respective concentrations are summarized in [Table 11](#).

Table 11: Summary of Competitive Inhibition Results

Co-infection pathogens	Organism target [AMR target]	High positive concentration tested* (CFU/mL)	Low positive concentration detected for all targets* (CFU/mL)
<i>Escherichia coli</i> (CCUG 70662)	<i>Escherichia coli</i> , Pan Enterobacterales	6.08E+08	1.24E+06 (5.5xLoD)
<i>Klebsiella pneumoniae</i> (CCUG 68728)	<i>Klebsiella</i> spp., Pan Enterobacterales	1.40E+09	9.00E+06 (266.3xLoD)
	[<i>aac</i> (6')-Ib, <i>armA</i> , <i>ampC</i> (CMY/LAT/DHA/FOX), CTX-M, NDM, SHV, TEM]		
<i>Escherichia coli</i> (NCTC 14320)	<i>Escherichia coli</i> , Pan Enterobacterales	2.01E+09	1.24E+07 (54.7xLoD)
	[<i>aac</i> (6')-Ib, IMP, KPC, OXA-48-like, TEM]		
<i>Proteus mirabilis</i> (ATCC BAA 2792)	<i>Proteus</i> spp., Pan Enterobacterales	3.17E+09	9.75E+06 (BP stock)
	[<i>aac</i> (6')-Ib, <i>ampC</i> (CMY/LAT/DHA/FOX), VIM, TEM]		
<i>Klebsiella pneumoniae</i> (CCUG 68728)	<i>Klebsiella</i> spp., Pan Enterobacterales	1.40E+09	3.53E+06 (BP stock)
	[<i>aac</i> (6')-Ib, <i>armA</i> , <i>ampC</i> (CMY/LAT/DHA/FOX), CTX-M, NDM, SHV, TEM]		
<i>Enterobacter cloacae</i> (NCTC 14326)	<i>Enterobacter</i> spp., Pan Enterobacterales	8.10E+06	8.10E+06 (3xLoD)
	[<i>aac</i> (6')-Ib, VIM]		
<i>Escherichia coli</i> (NCTC 14320)	<i>Escherichia coli</i> , Pan Enterobacterales	2.01E+09	1.24E+07 (54.7xLoD)
	[<i>aac</i> (6')-Ib, IMP, KPC, OXA-48-like, TEM]		
<i>Enterobacter cloacae</i> (NCTC 14326)	<i>Enterobacter</i> spp.	9.56E+08	8.10E+06 (3xLoD)
	[<i>aac</i> (6')-Ib, VIM]		
<i>Pseudomonas aeruginosa</i> (NCTC 13921)	<i>Pseudomonas aeruginosa</i>	1.41E+09	2.52E+07 (30xLoD)
	[<i>aac</i> (6')-Ib, SPM]		
<i>Proteus mirabilis</i> (ATCC BAA 2792)	<i>Proteus</i> spp., Pan Enterobacterales	3.17E+09	9.00E+06 (300xLoD)
	[<i>aac</i> (6')-Ib, <i>ampC</i> (CMY/LAT/DHA/FOX), VIM, TEM]		
<i>Acinetobacter baumannii</i> (ATCC BAA 2801)	<i>Acinetobacter calcoaceticus-baumannii</i> complex	4.81E+06	5.34E+05 (12.9xLoD)
	[OXA-23, PER, TEM]		
<i>Klebsiella pneumoniae</i> (CCUG 68728)	<i>Klebsiella</i> spp., Pan Enterobacterales	1.40E+09	3.53E+06 (BP stock)
	[<i>aac</i> (6')-Ib, <i>armA</i> , <i>ampC</i> (CMY/LAT/DHA/FOX), CTX-M, NDM, SHV, TEM]		
	<i>Klebsiella</i> spp., Pan Enterobacterales	1.40E+09	

Co-infection pathogens	Organism target [AMR target]	High positive concentration tested* (CFU/mL)	Low positive concentration detected for all targets* (CFU/mL)
<i>Klebsiella pneumoniae</i> (CCUG 68728)	[<i>aac(6')-Ib</i> , <i>armA</i> , <i>ampC</i> (CMY/LAT/DHA/FOX), CTX-M, NDM, SHV, TEM]		3.53E+06 (BP stock)
<i>Proteus mirabilis</i> (ATCC BAA 2792)	<i>Proteus spp.</i> , Pan Enterobacterales	8.10E+07	9.75E+06 (BP stock)
	[<i>ampC</i> (CMY/LAT/DHA/FOX), VIM, TEM]		
<i>Pseudomonas aeruginosa</i> (NCTC 13921)	<i>Pseudomonas aeruginosa</i>	1.41E+09	1.29E+06 (BP stock)
	[<i>aac(6')-Ib</i> , SPM]		
<i>Acinetobacter baumannii</i> (NCTC 13302)	<i>Acinetobacter calcoaceticus-baumannii</i> complex	4.97E+05	5520 (0.24xLoD)
	[OXA-24/40]		
<i>Escherichia coli</i> (NCTC 14320)	<i>Escherichia coli</i> , Pan Enterobacterales	1.11E+08	1.24E+08 (546.9xLoD)
	[<i>aac(6')-Ib</i> , IMP, KPC, OXA-48-like, TEM]		
<i>Bacteroides fragilis</i> (CCUG 4856T)	<i>Bacteroides fragilis</i>	8.19E+09	3.38E+07 (BP stock)
<i>Pseudomonas aeruginosa</i> (NCTC 2799)	<i>Pseudomonas aeruginosa</i>	8.28E+06	8.28E+06 (3xLoD)
	[<i>aac(6')-Ib</i> , PER, VIM]		
<i>Stenotrophomonas maltophilia</i> (NCTC 10259)	<i>Stenotrophomonas maltophilia</i>	2.05E+09	2.54E+08 (3xLoD)
<i>Pseudomonas aeruginosa</i> (NCTC 13921)	<i>Pseudomonas aeruginosa</i>	1.25E+09	N/A
	[<i>aac(6')-Ib</i> , SPM]		
<i>Stenotrophomonas maltophilia</i> (NCTC 10259)	<i>Stenotrophomonas maltophilia</i>	N/A	2.54E+08 (3xLoD)
<i>Klebsiella pneumoniae</i> (CCUG 68728)	<i>Klebsiella spp.</i> , Pan Enterobacterales	8.10E+06	9.00E+06 (266.3xLoD)
	[<i>aac(6')-Ib</i> , <i>armA</i> , <i>ampC</i> (CMY/LAT/DHA/FOX), CTX-M, NDM, SHV, TEM]		
<i>Serratia marcescens</i> (ATCC 14041)	<i>Serratia spp.</i> , Pan Enterobacterales	4.82E+08	2.10E+07 (BP stock)
<i>Enterobacter cloacae</i> (NCTC 14326)	<i>Enterobacter spp.</i>	9.56E+08	8.10E+06 (3xLoD)
	[<i>aac(6')-Ib</i> , VIM]		
<i>Acinetobacter baumannii</i> (ATCC BAA 2801)	<i>Acinetobacter calcoaceticus-baumannii</i> complex	1.38E+08	5.34E+06 (129xLoD)
	[OXA-23, PER, TEM]		
<i>Cutibacterium acnes</i> (NCTC 737)	N/A - Off Panel target	1.71E+08	N/A
<i>Escherichia coli</i> (NCTC 14320)	<i>Escherichia coli</i> , Pan Enterobacterales	N/A	1.24E+07 (54.7xLoD)
	[<i>aac(6')-Ib</i> , IMP, KPC, OXA-48-like, TEM]		
<i>Enterococcus faecium</i> (ATCC-BAA 2316)	N/A - Off Panel target	8.96E+08	N/A

Co-infection pathogens	Organism target [AMR target]	High positive concentration tested* (CFU/mL)	Low positive concentration detected for all targets* (CFU/mL)
<i>Klebsiella pneumoniae</i> (CCUG 68728)	<i>Klebsiella spp.</i> , Pan Enterobacterales	N/A	9.00E+05 (26.6xLoD)
	[<i>aac(6')-Ib</i> , <i>armA</i> , <i>ampC</i> (CMY/LAT/DHA/FOX), CTX-M, NDM, SHV, TEM]		
<i>Bacillus cereus</i> (ATCC 21769)	N/A - Off Panel target	1.87E+06	N/A
<i>Pseudomonas aeruginosa</i> (ATCC 2799)	<i>Pseudomonas aeruginosa</i>	N/A	8.28E+06(3xLoD)
	[<i>aac(6')-Ib</i> , PER, VIM]		
<i>Corynebacterium striatum</i> (ATCC 43735)	N/A - Off Panel target	9.54E+08	N/A
<i>Acinetobacter baumannii</i> (NCTC 13302)	<i>Acinetobacter calcoaceticus-baumannii</i> complex	N/A	5.52E+04 (2.4xLoD)
	[OXA-24/40]		
<i>Candida albicans</i> (ATCC 10231)	N/A - Off Panel target	1.83E+07	N/A
<i>Enterobacter cloacae</i> (NCTC 14326)	<i>Enterobacter spp.</i> , Pan Enterobacterales	N/A	8.10E+06 (3xLoD)
	[<i>aac(6')-Ib</i> , VIM]		
<i>Micrococcus luteus</i> (NCTC 7011)	N/A - Off Panel target	2.13E+08	N/A
<i>Serratia marcescens</i> (ATCC 14041)	<i>Serratia spp.</i> , Pan Enterobacterales	N/A	1.89E+08 (3xLoD)
<i>Staphylococcus aureus</i> (ATCC BAA 2313)	N/A - Off Panel target	2.09E+08	N/A
<i>Proteus mirabilis</i> (ATCC BAA 2792)	<i>Proteus spp.</i>	N/A	9.75E+06 (300xLoD)
	[<i>ampC</i> (CMY/LAT/DHA/FOX), VIM, TEM]		
<i>Staphylococcus epidermidis</i> (ATCC 35984)	N/A - Off Panel target	7.29E+08	N/A
<i>Bacteroides fragilis</i> (CCUG 4856T)	<i>Bacteroides fragilis</i>	N/A	3.90E+04 (3xLoD)
<i>Enterococcus faecalis</i> (ATCC 51299)	N/A - Off Panel target	7.25E+08	N/A
<i>Stenotrophomonas maltophilia</i> (NCTC 10259)	<i>Stenotrophomonas maltophilia</i>	N/A	2.54E+08 (3xLoD)

* The high positive concentration tested corresponds to the highest concentration at which no dropout was observed for any target associated with the co-infecting organism. The low positive concentration detected corresponds to the lowest concentration tested at which a 100% hit rate was achieved for all the targets within the low concentration microorganism.

Carryover

A carry-over study was performed to evaluate the potential occurrence of cross-contamination between consecutive runs when using the QIAstat-Dx BCID GN Plus AMR Panel on a QIAstat-Dx Analyzer. Pathogen samples, alternating high-positive (at least 1.00 E+09 CFU/mL) and negative blood culture media, respectively, were tested on 2 QIAstat-Dx Analyzer instruments. No carryover between samples was observed in the QIAstat-Dx BCID GN Plus AMR Panel, demonstrating that the system design and recommended sample handling and testing practices are effective at preventing false positive results from carryover or cross-contamination.

Specimen Stability

Specimen stability testing demonstrated that the QIAstat-Dx BCID GN Plus AMR Panel assay can process blood culture samples that are stored at different temperatures without affecting the performance.

Results from specimen stability testing demonstrated that positive blood culture samples may be stored at the following conditions:

- Room temperature (15–25°C) up to 24 hours, after initial blood culture bottle positivity.
- In the blood culture system for up to 24 hours after positivity.

Bottle Equivalency (Matrix Equivalency)

The performance of various blood culture media bottle types was assessed using the QIAstat-Dx BCID GN Plus AMR Panel to demonstrate that it can detect targets at positive bottle concentrations across different bottle types.

Thirteen blood culture bottles, both aerobic and anaerobic, were included in this study. Samples containing a representative organism for each target were prepared at the point of bottle positivity for BD BACTEC and BioMérieux BACT/ALERT blood culture media bottles by incubating them in a continuous monitoring blood culture system (CMBCS). For VersaTREK bottles, which lacked an appropriate CMBCS, samples were prepared at a similar concentration to bottle positivity by spiking them with representative target microorganisms. Additionally, one negative blood culture matrix (NBCM) sample was generated and tested on the QIAstat-Dx BCID GN Plus AMR Panel for each bottle type.

A summary of the bottle types assessed, including the proportion of positive calls by bottle type, is found in [Table 12](#).

Table 12: Bottle Equivalency Results Summary

Blood culture bottle information	Proportion of positive calls			Study outcome (%)
	Hits	N	Percentage (%) (Two-sided 95% Confidence Interval)	
BACTEC Plus Aerobic	480	480	100.0	100.0 correct calls
			(99.2-100)	

Blood culture bottle information	Proportion of positive calls			Study outcome (%)
	Hits	N	Percentage (%) (Two-sided 95% Confidence Interval)	
BACTEC Plus Anaerobic	129	129	100.0 (97.2-100)	100.0 correct calls
BACTEC Standard Aerobic	153	153	100.0 (97.6-100)	100.0 correct calls
BACTEC Standard Anaerobic	119	119	100.0 (96.9-100)	100.0 correct calls
BACTEC Peds Plus	162	162	100.0 (97.8-100)	100.0 correct calls
BACTEC Lytic Anaerobic	119	121	98.3 (94.2-99.8)	98.3 correct calls False negative results observed for TEM (in <i>Acinetobacter baumannii</i>) (2)
BACT/ALERT SA Standard Aerobic	150	150	100.0 (97.6-100)	100.0 correct calls
BACT/ALERT SN Standard Anaerobic	151	151	100.0 (97.6-100)	100.0 correct calls
BACT/ALERT FA PLUS Aerobic	153	153	100.0 (97.6-100)	100.0 correct calls
BACT/ALERT FN PLUS Anaerobic	107	107	100.0 (96.6-100)	100.0 correct calls
BACT/ALERT PF PLUS Peds	149	149	100.0 (97.6-100)	100.0 correct calls
Thermo Scientific Versatrek Redox 1 EZ Draw Aerobic	156	156	100.0 (97.7-100)	100.0 correct calls
Versatrek Redox 2 EZ Draw Anaerobic	158	158	100.0 (97.7-100)	100.0 correct calls
Overall	2186	2188	99.9	
Overall BACTEC	1162	1164	99.8	
Overall BACT/ALERT	710	710	100.0	
Overall Versatrek	314	314	100.0	

Precision (Repeatability and Reproducibility)

Reproducibility

Reproducibility testing of contrived samples was performed at 3 test sites including 1 internal site (Site A) and 2 external sites (Site B and Site C). The study incorporated a range of potential variation introduced by sites, days, replicates, operators, and QIAstat-Dx Analyzers.

For each site, testing was performed across 6 non-consecutive days with 3 replicates per day by each of the 2 operators (leading to a total of 36 replicates per target, concentration, and site), 6–7 QIAstat-Dx Analyzers (at least 2 QIAstat-Dx Analyzer per operator and per site), and at least 2 operators on each testing day.

Three sample mixes were prepared. Two combined samples were prepared from pathogens grown independently and collected at different incubation stages: one at the time of bottle positivity and one following an additional 24 hours of incubation after bottle positivity. The third sample was a negative control containing an off-panel organism (*Cutibacterium acnes*, NCTC 737) incubated to bottle positivity.

Table 13 shows the detection rate per target and concentration for each site of the Reproducibility study. In addition, data obtained at all 3 sites have been compiled to calculate the exact two-sided 95% CI by target and concentration.

Table 13: Reproducibility Hit Rate Results and Confidence Intervals Established for all Targets

Pathogen	Target	Sample (Concentration tested)	Expected	Agreement with expected results			
				Site A	Site B	Site C	All Sites (95% Confidence Interval)
<i>Acinetobacter baumannii</i> (NCTC 13302)	<i>Acinetobacter calcoaceticus-baumannii</i> complex	Positive (Bottle Positive)	Positive	36/36	36/36	36/36	108/108 (96.6-100.0%)
		High Positive (Bottle Positive + 24 hours)	Positive	37/37	36/36	36/36	109/109 (96.7-100.0%)
		Negative	Negative	0/36	0/36	0/36	0/108 (0.0-3.4%)
	OXA-24/40	Positive (Bottle Positive)	Positive	36/36	36/36	36/36	108/108 (96.6-100.0%)
		High Positive (Bottle Positive + 24 hours)	Positive	37/37	36/36	36/36	109/109 (96.7-100.0%)
		Negative	Negative	0/36	0/36	0/36	0/108 (0.0-3.4%)
<i>Salmonella enterica</i> (NCTC 13954)	<i>Salmonella</i> spp.	Positive (Bottle Positive)	Positive	36/36	36/36	36/36	108/108 (96.6-100.0%)
		High Positive (Bottle Positive + 24 hours)	Positive	37/37	36/36	36/36	109/109 (96.7-100.0%)
		Negative	Negative	0/36	0/36	0/36	0/108 (0.0-3.4%)
	OXA-48-like	Positive (Bottle Positive)	Positive	36/36	36/36	36/36	108/108 (96.6-100.0%)
		High Positive (Bottle Positive + 24 hours)	Positive	37/37	36/36	36/36	109/109 (96.7-100.0%)
		Negative	Negative	0/36	0/36	0/36	0/108 (0.0-3.4%)
<i>Pseudomonas aeruginosa</i> (MRSN 12914)	<i>Pseudomonas aeruginosa</i>	Positive (Bottle Positive)	Positive	36/36	36/36	36/36	108/108 (96.6-100.0%)
		High Positive (Bottle Positive + 24 hours)	Positive	37/37	36/36	36/36	109/109 (96.7-100.0%)
		Negative	Negative	0/36	0/36	0/36	0/108 (0.0-3.4%)
	VEB	Positive (Bottle Positive)	Positive	36/36	36/36	36/36	108/108 (96.6-100.0%)
		High Positive (Bottle Positive + 24 hours)	Positive	37/37	36/36	36/36	109/109 (96.7-100.0%)
		Negative	Negative	0/36	0/36	0/36	0/108 (0.0-3.4%)
<i>Proteus vulgaris</i> (ATCC 6380)	<i>Proteus</i> spp.	Positive (Bottle Positive)	Positive	36/36	36/36	36/36	108/108 (96.6-100.0%)
		High Positive (Bottle Positive + 24 hours)	Positive	37/37	36/36	36/36	109/109 (96.7-100.0%)
		Negative	Negative	0/36	0/36	0/36	0/108 (0.0-3.4%)

Pathogen	Target	Sample (Concentration tested)	Expected	Agreement with expected results			
				Site A	Site B	Site C	All Sites (95% Confidence Interval)
<i>Stenotrophomonas maltophilia</i> (NCTC 10499)	<i>Stenotrophomonas maltophilia</i>	Positive (Bottle Positive)	Positive	36/36	36/36	36/36	108/108 (96.6-100.0%)
		High Positive (Bottle Positive + 24 hours)	Positive	37/37	36/36	36/36	109/109 (96.7-100.0%)
		Negative	Negative	0/36	0/36	0/36	0/108 (0.0-3.4%)
<i>Proteus vulgaris</i> (CCUG 6380)/ <i>Salmonella enterica</i> (NCTC 13954)	Pan Enterobacterales	Positive (Bottle Positive)	Positive	36/36	36/36	36/36	108/108 (96.6-100.0%)
		High Positive (Bottle Positive + 24 hours)	Positive	37/37	36/36	36/36	109/109 (96.7-100.0%)
		Negative	Negative	0/36	0/36	0/36	0/108 (0.0-3.4%)

Repeatability

A repeatability study was conducted for both sample types on a QIAstat-Dx Analyzer. Positive test samples were combined from individually grown pathogens, which were contrived by inoculating blood culture bottles with whole blood and the pathogenic material. Pathogens were incubated in a blood culture instrument until positive ring to obtain positive samples and negative sample containing an off-panel organism (*Cutibacterium acnes*, NCTC 737) incubated at bottle positivity. In addition, cultures were allowed to incubate for an additional 24 hours after positive ring to obtain the high positive sample. The QIAstat-Dx BCID GN Plus AMR Panel detected pathogens included in the positive samples *Acinetobacter baumannii*, OXA-24/40 (NCTC 13302), *Salmonella enterica*, OXA-48-like (NCTC 13954), *Pseudomonas aeruginosa*, VEB (MRSN 12914), *Proteus vulgaris* (ATCC 6380) and *Stenotrophomonas maltophilia* (NCTC 10499). Negative samples included *Cutibacterium acnes* (NCTC 737). All samples were tested on 3 instruments per day over 16 days on 3 cartridge lots. In total, 90 replicates of positive and 90 replicates of high positive per each of the tested targets and 90 replicates of negative samples were run per cartridge lot. For all positive samples, 100% detection was obtained for all expected targets (90/90 detected positive hits). Negative samples showed 100% negative calls for all panel analytes.

Performance Characteristics - Clinical Studies

Expected values

The performance characteristics of the QIAstat-Dx BCID GN Plus AMR Panel were assessed by a multi-centre, observational, prospective and retrospective, clinical performance study, on Positive Blood Culture Media (PBCM) from subjects with signs and symptoms of bloodstream infection. The study was conducted at 10 geographically diverse study sites: 8 US sites and 2 European sites.

The number and percentage of positive cases, as determined by the QIAstat-Dx BCID GN Plus AMR Panel, during the clinical performance evaluation were stratified by age group (Table 14). Overall, 661 prospective specimens were included in the prevalence assessment and the QIAstat-

Dx BCID GN Plus AMR Panel detected at least one organism in a total of 618 prospective specimens (93.5% positivity rate).

Table 14: QIAstat-Dx BCID GN Plus AMR Panel Prospective Prevalence For Each and Overall Age Group for PBCM Samples

Pathogen	Overall (n=661)	<1 year (n=6)	1-17 years (n=18)	18-44 years (n=79)	45-64 years (n=172)	65-89 years (n=361)	90+ years (n=25)
<i>Enterobacter spp.</i>	45 (6.8%)	2 (33.3%)	1 (5.6%)	5 (6.3%)	14 (8.1%)	23 (6.4%)	0 (0.0%)
<i>Escherichia coli</i>	290 (43.9%)	2 (33.3%)	2 (11.1%)	34 (43.0%)	77 (44.8%)	162 (44.9%)	13 (52.0%)
<i>Klebsiella spp.</i>	145 (21.9%)	0 (0.0%)	1 (5.6%)	18 (22.8%)	43 (25.0%)	79 (21.9%)	4 (16.0%)
<i>Proteus spp.</i>	39 (5.9%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	10 (5.8%)	25 (6.9%)	3 (12.0%)
<i>Salmonella spp.</i>	12 (1.8%)	0 (0.0%)	6 (33.3%)	4 (5.1%)	2 (1.2%)	0 (0.0%)	0 (0.0%)
<i>Serratia spp.</i>	21 (3.2%)	0 (0.0%)	1 (5.6%)	2 (2.5%)	8 (4.7%)	9 (2.5%)	1 (4.0%)
<i>Pseudomonas aeruginosa</i>	39 (5.9%)	0 (0.0%)	3 (16.7%)	8 (10.1%)	8 (4.7%)	20 (5.5%)	0 (0.0%)
<i>Neisseria meningitidis</i> (encapsulated)	1 (0.2%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
<i>Haemophilus influenzae</i>	3 (0.5%)	0 (0.0%)	1 (5.6%)	1 (1.3%)	0 (0.0%)	1 (0.3%)	0 (0.0%)
<i>Acinetobacter calcoaceticus- baumannii</i> complex	5 (0.8%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	2 (1.2%)	2 (0.6%)	0 (0.0%)
<i>Bacteroides fragilis</i>	12 (1.8%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	2 (1.2%)	8 (2.2%)	1 (4.0%)
<i>Stenotrophomonas maltophilia</i>	3 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	2 (0.6%)	0 (0.0%)
Pan Enterobacterales	559 (84.6%)	4 (66.7%)	12 (66.7%)	63 (79.7%)	154 (89.5%)	303 (83.9%)	23 (92.0%)
AmpC (CMY/LAT/DHA/F OX)	16 (2.4%)	0 (0.0%)	1 (5.6%)	1 (1.3%)	4 (2.3%)	10 (2.8%)	0 (0.0%)
CTX-M	77 (11.6%)	0 (0.0%)	1 (5.6%)	7 (8.9%)	21 (12.2%)	43 (11.9%)	5 (20.0%)
IMP	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
KPC	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
NDM	3 (0.5%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	0 (0.0%)	2 (0.6%)	0 (0.0%)
OXA-23	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)
OXA-48-like	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)
OXA-24/40	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
OXA-58	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Pathogen	Overall (n=661)	<1 year (n=6)	1-17 years (n=18)	18-44 years (n=79)	45-64 years (n=172)	65-89 years (n=361)	90+ years (n=25)
SHV	97 (14.7%)	0 (0.0%)	0 (0.0%)	12 (15.2%)	28 (16.3%)	54 (15.0%)	3 (12.0%)
TEM	150 (22.7%)	2 (33.3%)	1 (5.6%)	24 (30.4%)	40 (23.3%)	72 (19.9%)	11 (44.0%)
VIM	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)
PER	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)
<i>armA</i>	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)
<i>aac(6')-Ib</i>	40 (6.1%)	0 (0.0%)	0 (0.0%)	3 (3.8%)	12 (7.0%)	22 (6.1%)	3 (12.0%)
VEB	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
GES	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SPM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Clinical Performance

Between November 2023 and May 2025, a total of 2142 PBCM samples were enrolled comprising of 1711 prospective and 431 archived samples. After Gram stain 694 prospective and 145 retrospective specimens were enrolled for the QIAstat-Dx BCID GN Plus AMR Panel testing. Of those 694 prospective specimens, 33 were withdrawn giving a final number of 661 prospectively collected specimens. The most common reason for specimen withdrawal was that the sample did not meet eligibility criteria. The final dataset for the clinical performance evaluation study of the QIAstat-Dx BCID GN Plus AMR Panel consisted of 661 prospective specimens of which 31 (3%) were frozen before any testing and 630 (97%) were tested fresh.

The demographic information for the 661 prospective specimens stratified by Gram stain and evaluated with the QIAstat-Dx BCID GN Plus AMR Panel is summarized in [Table 15](#).

Table 15: Demographic Summary for Prospective Samples for QIAstat-Dx BCID GN Plus AMR Panel clinical evaluation

Sample Type	Variable	Subgroup	US Sites		Non-US Sites	
			N	%	N	%
Prospective Fresh	Age group	< 1 year	5	1.0	0	0.0
		1-17 years	17	3.4	1	0.8
		18-44 years	64	12.8	11	8.4
		45-64 years	145	29.1	22	16.8
		65-89 years	249	49.9	91	69.5
		90+ years	19	3.8	6	4.6
	Sex	Female	250	50.1	65	49.6
		Male	249	49.9	66	50.4
Prospective Frozen	Age group	< 1 year	1	3.2	0	0.0
		1-17 years	0	0.0	0	0.0
		18-44 years	4	12.9	0	0.0

Sample Type	Variable	Subgroup	US Sites		Non-US Sites	
			N	%	N	%
		45-64 years	5	16.1	0	0.0
		65-89 years	21	67.7	0	0.0
		90+ years	0	0.0	0	0.0
	Sex	Female	13	41.9	0	0.0
		Male	18	58.1	0	0.0
Prospective Total	Age group	< 1 year	6	1.1	0	0.0
		1-17 years	17	3.2	1	0.8
		18-44 years	68	12.8	11	8.4
		45-64 years	150	28.3	22	16.8
		65-89 years	270	50.9	91	69.5
		90+ years	19	3.6	6	4.6
	Sex	Female	263	49.6	65	49.6
		Male	267	50.4	66	50.4

Residual PBCM specimens were tested with the QIAstat-Dx BCID GN Plus AMR Panel and Standard of Care (SoC) following the study sites' respective local procedures as comparator method. Additional reflex testing was performed if SoC results did not provide sufficient species-level identification.

For all AMR targets on the QIAstat-Dx BCID GN Plus AMR Panel, the reference method was a lab developed qPCR, followed by confirmatory single PCR assays and Bidirectional sequencing (BDS) for selected targets (Table 16).

Phenotypic AST results were also collected, if performed as part of the SoC procedure. Correlation of the QIAstat-Dx BCID GN Plus AMR Panel genotypic AMR target results to available phenotypic AST results was performed as a secondary endpoint.

Table 16: Testing overview including comparator method used for each pathogen

Target	Comparator Method(s)	Discordant Method(s)
<i>Acinetobacter calcoaceticus-baumannii</i> complex <i>Bacteroides fragilis</i> <i>Enterobacter</i> spp. <i>Escherichia coli</i> <i>Haemophilus influenzae</i> <i>Klebsiella</i> spp. <i>Neisseria meningitidis</i> (Encapsulated) <i>Proteus</i> spp. <i>Pseudomonas aeruginosa</i> <i>Salmonella</i> spp. <i>Serratia</i> spp. <i>Stenotrophomonas maltophilia</i> Pan Enterobacterales	Comparator method was based on Standard of Care at each site.	Roche cobas eplex; BioFire BCID 2 or MALDI-TOF MS
<i>aac(6')-Ib</i> <i>ampC</i> (CMY/LAT/DHA/FOX) <i>armA</i>	PCR-BDS from the positive blood culture specimen	N/A

CTX-M		
GES		
IMP		
KPC		
NDM		
OXA-23		
OXA-24/40		
OXA-48-like		
OXA-58		
PER		
SHV		
SPM		
TEM		
VEB		
VIM		

The Positive Percentage Agreement (PPA) and the Negative Percentage Agreement (NPA) were calculated for the prospective samples.

Clinical sensitivity or Positive Percent Agreement (PPA) was calculated as $100\% \times (TP / (TP + FN))$. True positive (TP) indicates that both QIAstat-Dx BCID GN Plus AMR Panel and comparator method have a positive result for the specific pathogen. False negative (FN) indicates that the QIAstat-Dx result is negative while the comparator result is positive for the specific pathogen. Specificity or Negative Percent Agreement (NPA) was calculated as $100\% \times (TN / (TN + FP))$. True negative (TN) indicates that both the QIAstat-Dx BCID GN Plus AMR Panel and the comparator method have negative results for the specific pathogen. False positive (FP) indicates that the QIAstat-Dx BCID GN Plus AMR Panel result is positive for the specific pathogen, but the comparator result is negative. The two-sided 95% Confidence Intervals were calculated.

Prospective Specimens Testing

The QIAstat-Dx BCID GN Plus AMR Panel prospective data for Positive Percent Agreement and Negative Percent Agreement against the comparator methods are presented by analyte in [Table 17](#) and [Table 18](#) for pathogens and AMRs, respectively.

Table 17: QIAstat-Dx BCID GN Plus AMR Panel Prospective Clinical Performance Summary for Pathogen Identification on PBCM Samples

Pathogen	Sample	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
<i>Enterobacter</i> spp. *	Prospective Fresh	40 / 42	95.2	84.2–98.7	584 / 586	99.7	98.8–99.9
	Prospective Frozen	3 / 3	100.0	43.9–100.0	28 / 28	100.0	87.9–100.0
	Total	43 / 45	95.6	85.2–98.8	612 / 614	99.7	98.8–99.9
<i>Escherichia coli</i> †	Prospective Fresh	272 / 277	98.2	95.8–99.2	348 / 352	98.9	97.1–99.6
	Prospective Frozen	14 / 14	100.0	78.5–100.0	17 / 17	100.0	81.6–100.0

Pathogen	Sample	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
	Total	286 / 291	98.3	96.0–99.3	365 / 369	98.9	97.2–99.6
<i>Klebsiella</i> spp. ‡	Prospective Fresh	129 / 132	97.7	93.5–99.2	489 / 496	98.6	97.1–99.3
	Prospective Frozen	9 / 9	100.0	70.1–100.0	22 / 22	100.0	85.1–100.0
	Total	138 / 141	97.9	93.9–99.3	511 / 518	98.6	97.2–99.3
<i>Proteus</i> spp. §	Prospective Fresh	32 / 32	100.0	89.3–100.0	589 / 596	98.8	97.6–99.4
	Prospective Frozen	0 / 1	0.0	0.0–79.3	30 / 30	100.0	88.6–100.0
	Total	32 / 33	97.0	84.7–99.5	619 / 626	98.9	97.7–99.5
<i>Salmonella</i> spp.	Prospective Fresh	12 / 12	100.0		616 / 616	100.0	75.8–100.0
	Prospective Frozen	0 / 0	0 / 0	N/A	31 / 31	100.0	99.4–100.0
	Total	12 / 12	100.0	75.8–100.0	647 / 647	100.0	99.4–100
<i>Serratia</i> spp.	Prospective Fresh	20 / 20	100.0	83.9–100.0	608 / 608	100.0	99.4–100.0
	Prospective Frozen	1 / 1	100.0	20.7–100.0	30 / 30	100.0	88.6–100.0
	Total	21 / 21	100.0	84.5–100.0	638 / 638	100.0	99.4–100.0
<i>Pseudomonas aeruginosa</i> ¶	Prospective Fresh	36 / 37	97.3	86.2–99.5	591 / 591	100.0	99.4–100.0
	Prospective Frozen	3 / 3	100.0	43.9–100.0	28 / 28	100.0	87.9–100.0
	Total	39 / 40	97.5	87.1–99.6	619 / 619	100.0	99.4–100.0
<i>Neisseria meningitidis</i> (encapsulated)	Prospective Fresh	1 / 1	100.0	20.7–100.0	627 / 627	100.0	99.4–100.0
	Prospective Frozen	0 / 0	N/A	N/A	31 / 31	100.0	89.0–100.0
	Total	1 / 1	100.0	20.7–100.0	658 / 658	100.0	99.4–100.0
<i>Haemophilus influenzae</i> ††	Prospective Fresh	2 / 2	100.0	34.2–100.0	625 / 626	99.8	99.1–100.0
	Prospective Frozen	0 / 0	N/A	N/A	31 / 31	100.0	89.0–100.0
	Total	2 / 2	100.0	34.2–100.0	656 / 657	99.8	99.1–100.0
<i>Acinetobacter calcoaceticus-baumannii</i> complex	Prospective Fresh	5 / 5	100.0	56.6–100.0	623 / 623	100.0	99.4–100.0
	Prospective Frozen	0 / 0	N/A	N/A	31 / 31	100.0%	89.0–100.0
	Total	5 / 5	100.0	56.6–100.0	654 / 654	100.0	99.4–100.0
<i>Bacteroides fragilis</i> ‡‡	Prospective Fresh	10 / 12	83.3	55.2–95.3	614 / 616	99.7	98.8–99.9
	Prospective Frozen	0 / 0	N/A	N/A	31 / 31	100.0	89.0–100.0
	Total	10 / 12	83.3	55.2–95.3	614 / 616	99.7	98.8–99.9
<i>Stenotrophomonas maltophilia</i>	Prospective Fresh	3 / 3	100.0	43.9–100.0	625 / 625	100.0	99.4–100.0
	Prospective Frozen	0 / 0	N/A	N/A	31 / 31	100.0	89.0–100.0
	Total	3 / 3	100.0	43.9–100.0	656 / 656	100.0	99.4–100.0
Pan Enterobacterales§§	Prospective Fresh	529 / 531	99.6	98.6–99.9	95 / 99	96.0	90.1–98.4
	Prospective Frozen	26 / 27	96.3	81.7–99.3	4 / 4	100.0	51.0–100.0
	Total	555 / 558	99.5	98.4–99.8	99 / 103	96.1	90.4–98.5

* *Enterobacter* spp. was detected in 1/2 FP prospective specimens using an additional molecular method. For the other FP prospective specimen, cross-reactivity of the QIAstat-Dx BCID GN Plus AMR Panel *Enterobacter* spp. with *Leclercia adecarboxylata* was identified. *Enterobacter* spp. was not detected in 1/2 FN prospective specimens using an additional molecular method.

† *Escherichia coli* was detected in 3/4 FP prospective specimens and not detected in the remaining specimen using an additional molecular method. *Escherichia coli* was detected in all FN specimens using an additional molecular method.

‡ Of the 7 *Klebsiella* spp. FP prospective samples, *Klebsiella* spp. was detected in 1/7 FP specimens, and was not detected in the remaining FP specimens using an additional molecular method. Cross-reactivity of the QIAstat-Dx BCID GN Plus AMR Panel for *Klebsiella* spp. and *Proteus* spp. was observed with 4 *Enterobacter* spp. specimens. Additional speciation was completed by 23S sequencing and/or MALDI-TOF and all 4 specimens were identified as *E. ludwigii*. In addition, in silico cross-reactivity was predicted between the QIAstat-Dx BCID GN Plus AMR Panel *Klebsiella* spp. and *Enterobacter* species. Of the 3 FN samples, *Klebsiella* spp. was detected in one specimen and not detected in 2 specimens using an additional molecular method.

§ *Proteus* spp. was detected in 3 FP specimens and not detected in the remaining 4 FP specimens using an additional molecular method. Cross-reactivity of the QIAstat-Dx BCID GN Plus AMR Panel for *Klebsiella* spp. and *Proteus* spp. was observed with 4 *Enterobacter* spp. specimens. Additional speciation was completed by 23S sequencing and MALDI-TOF and all 4 specimens were identified as *E. ludwigii*. No additional testing was performed for the single FN *Proteus* spp. prospective specimen.

¶ *Pseudomonas aeruginosa* was detected in the single FN prospective specimen using an alternative molecular method.

†† *Haemophilus influenzae* was detected in the single FP prospective specimen using an additional molecular method.

‡‡ *Bacteroides fragilis* was detected in the 2 FP and not detected in the 2 FN prospective specimens using an alternative molecular method.

§§ Cross-reactivity of the QIAstat-Dx BCID GN Plus AMR Panel *Pan* Enterobacterales was predicted by in silico analysis with *Pantoea septica* and observed in 2 FP prospective specimens. Of the remaining 2 *Pan* Enterobacterales FP prospective specimens, an additional molecular method was performed in one specimen where *Pan* Enterobacterales was detected. Of the 3 FN *Pan* Enterobacterales prospective specimens, *Pan* Enterobacterales was not detected in one FN sample using additional molecular method, no additional testing was performed for the remaining 2 FN specimens.

Table 18: QIAstat-Dx BCID GN Plus AMR Panel Prospective Clinical Performance Summary for AMR Identification on PBCM samples

AMR	Sample	PPA			NPA		
		TP/(TP+FN)	%	95% CI (%)	TN/(TN+FP)	%	95% CI (%)
AmpC (CMY/LAT/DHA/ FOX)	Prospective Fresh	15 / 20	75.0	53.1–88.8	545 / 546	99.8	99.0–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	15 / 20	75.0	53.1–88.8	574 / 575	99.8	99.0–100.0
CTX-M	Prospective Fresh	73 / 75	97.3	90.8–99.3	489 / 491	99.6	98.5–99.9
	Prospective Frozen	2 / 2	100.0	34.2–100.0	27 / 27	100.0	87.5–100.0
	Total	75 / 77	97.4	91.0–99.3	516 / 518	99.6	98.6–99.9
IMP	Prospective Fresh	0 / 0	N/A	N/A	543 / 543	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	0 / 0	N/A	N/A	572 / 572	100.0	99.3–100.0
KPC	Prospective Fresh	0 / 0	N/A	N/A	567 / 567	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	0 / 0	N/A	N/A	596 / 596	100.0	99.4–100.0
NDM	Prospective Fresh	3 / 3	100.0	43.9–100.0	564 / 564	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	3 / 3	100.0	43.9–100.0	593 / 593	100.0	99.4–100.0
OXA-23	Prospective Fresh	1 / 1	100.0	20.7–100.0	566 / 566	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	1 / 1	100.0	20.7–100.0	595 / 595	100.0	99.4–100.0
OXA-48-like	Prospective Fresh	1 / 1	100.0	20.7–100.0	562 / 562	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	1 / 1	100.0	20.7–100.0	591 / 591	100.0	99.4–100.0

AMR	Sample	PPA			NPA		
		TP/(TP+FN)	%	95% CI (%)	TN/(TN+FP)	%	95% CI (%)
OXA-24/40	Prospective Fresh	0 / 0	N/A	N/A	567 / 567	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	0 / 0	N/A	N/A	596 / 596	100.0	99.4–100.0
OXA-58	Prospective Fresh	0 / 0	N/A	N/A	567 / 567	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	0 / 0	N/A	N/A	596 / 596	100.0	99.4–100.0
SHV	Prospective Fresh	89 / 90	98.9	94.0–99.8	473 / 477	99.2	97.9–99.7
	Prospective Frozen	4 / 4	100.0	51.0–100.0	25 / 25	100.0	86.7–100.0
	Total	93 / 94	98.9	94.2–99.8	498 / 502	99.2	98.0–99.7
TEM	Prospective Fresh	134 / 141	95.0	90.1–97.6	435 / 438	99.3	98.0–99.8
	Prospective Frozen	9 / 9	100.0	70.1–100.0	19 / 20	95.0	76.4–99.1
	Total	143 / 150	95.3	90.7–97.7	454 / 458	99.1	97.8–99.7
VIM	Prospective Fresh	1 / 2	50.0	9.5–90.5	565 / 565	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	1 / 2	50.0	9.5–90.5	594 / 594	100.0	99.4–100.0
PER	Prospective Fresh	1 / 1	100.0	20.7–100.0	566 / 566	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	1 / 1	100.0	20.7–100.0	595 / 595	100.0	99.4–100.0
armA	Prospective Fresh	1 / 1	100.0	20.7–100.0	566 / 566	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	1 / 1	100.0	20.7–100.0	595 / 595	100.0	99.4–100.0
aac(6')-Ib	Prospective Fresh	37 / 40	92.5	80.1–97.4	525 / 527	99.6	98.6–99.9
	Prospective Frozen	1 / 1	100.0	20.7–100.0	28 / 28	100.0	87.9–100.0
	Total	38 / 41	92.7	80.6–97.5	553 / 555	99.6	98.7–99.9
VEB	Prospective Fresh	0 / 0	N/A	N/A	567 / 567	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	0 / 0	N/A	N/A	596 / 596	100.0	99.4–100.0
GES	Prospective Fresh	0 / 0	N/A	N/A	566 / 566	100.0	99.3–100.0
	Prospective Frozen	0 / 0	N/A	N/A	29 / 29	100.0	88.3–100.0
	Total	0 / 0	N/A	N/A	595 / 595	100.0	99.4–100.0
SPM	Prospective Fresh	0 / 0	N/A	N/A	40 / 40	100.0	91.2–100.0
	Prospective Frozen	0 / 0	N/A	N/A	3 / 3	100.0	43.9–100.0
	Total	0 / 0	N/A	N/A	43 / 43	100.0	91.8–100.0

Co-Infections

The QIAstat-Dx BCID GN Plus AMR Panel reported multiple organism detections (i.e., co-infections) for a total of 22/661 (3.3%) prospective specimens (Table 19). Most multiple detections in prospective specimens (18/22; 81.8%) contained 2 organisms, while (4/22; 18.2%) contained 3 organisms.

Table 19: Detection Summary Combinations Determined by the QIAstat-Dx BCID GN Plus AMR Panel in the Prospective Clinical Study

Detection summary	
Detected pathogens on QIAstat-Dx BCID GN Plus AMR Panel	No. of specimens with multi-detections
Total co-infection detections	22
Double detections	18
Triple detections	4

The most common multiple infections (>3 instances) are shown in Table 20.

Table 20: Most Prevalent Multiple Detection Combinations (>3 instances) as Determined by the QIAstat-Dx BCID GN Plus AMR Panel in the Prospective Clinical Study

Detected pathogens on QIAstat-Dx BCID GN Plus AMR Panel	No. of specimens with multi-detections
Detection summary	
<i>Escherichia coli</i> + <i>Klebsiella</i> spp.	6
<i>Escherichia coli</i> + <i>Enterobacter</i> spp.	3
<i>Haemophilus influenzae</i> + <i>Pseudomonas aeruginosa</i>	3
<i>Enterobacter</i> spp. + <i>Klebsiella</i> spp. + <i>Proteus</i> spp.	4

Archived Specimens Testing

Several analytes were either not encountered or had a low prevalence in the prospective arm of the study; an effort was made to collect and test as many archived samples (positive targeted archived specimens) as possible for all targets within the panel.

The demographic information for the 145 evaluable archived specimens evaluated with the QIAstat-Dx BCID GN Plus AMR Panel is summarized in Table 21.

Table 21: Demographic summary of evaluable archived specimens for QIAstat-Dx BCID GN Plus AMR Panel clinical evaluation

Sample type	Variable	Subgroup	N	%
Retrospective Archived	Age group	< 1 year	5	3.4
		1-17 years	8	5.5
		18-44 years	29	20.0
		45-64 years	28	19.3

Sample type	Variable	Subgroup	N	%
		65-89 years	71	49.0
		90+ years	4	2.8
	Sex	Female	61	42.1
		Male	83	57.2
		Not reported	1	0.7

A summary of the performance agreement for archived specimens is presented [Table 22](#) and [Table 23](#), for pathogen and AMR respectively.

Table 22: QIAstat-Dx BCID GN Plus AMR Panel Clinical Performance Summary for Pathogen Identification on Archived PBCM Samples

Pathogen	Sensitivity/PPA			Specificity/NPA		
	TP/(TP+FN)	%	95% CI (%)	TN/(TN+FP)	%	95% CI (%)
<i>Enterobacter</i> spp.	0 / 0	N/A	N/A	145 / 145	100.0	97.4–100.0
<i>Escherichia coli</i>	1 / 1	100.0	20.7–100.0	144 / 144	100.0	97.4–100.0
<i>Klebsiella</i> spp.	1 / 1	100.0	20.7–100.0	144 / 144	100.0	97.4–100.0
<i>Proteus</i> spp.	29 / 29	100.0	88.3–100.0	116 / 116	100.0	96.8–100.0
<i>Salmonella</i> spp.	22 / 22	100.0	85.1–100.0	123 / 123	100.0	97.0–100.0
<i>Serratia</i> spp.	24 / 24	100.0	86.2–100.0	121 / 121	100.0	96.9–100.0
<i>Pseudomonas aeruginosa</i> *	1 / 1	100.0	20.7–100.0	139 / 144	96.5	92.1–98.5
<i>Neisseria meningitidis</i> (encapsulated) †	6 / 7	85.7	48.7–97.4	138 / 138	100.0	97.3–100.0
<i>Haemophilus influenzae</i> ‡	20 / 20	100.0	83.9–100.0	124 / 125	99.2	95.6–99.9
<i>Acinetobacter calcoaceticus-baumannii</i> complex	8 / 8	100.0	67.6–100.0	137 / 137	100.0	97.3–100.0
<i>Bacteroides fragilis</i> §	28 / 28	100.0	87.9–100.0	116 / 117	99.1	95.3–99.8
<i>Stenotrophomonas maltophilia</i>	6 / 6	100.0	61.0–100.0	139 / 139	100.0	97.3–100.0
Pan Enterobacterales**	76 / 76	100.0	95.2–100.0	68 / 69	98.6	92.2–99.7

* *Pseudomonas aeruginosa* was detected in all 5 FP retrospective specimens using an additional molecular method.

† The single *Neisseria meningitidis* FN retrospective specimen was further investigated by an additional test specific to encapsulated *Neisseria meningitidis* and not detected. Note that the QIAstat-Dx BCID GN Plus AMR Panel only detects encapsulated *Neisseria meningitidis*.

‡ *Haemophilus influenzae* was not detected in the single FP retrospective specimen using an additional molecular method.

§ The single *Bacteroides fragilis* FP retrospective specimen, was detected using an additional molecular method.

** Cross-reactivity of the QIAstat-Dx BCID GN Plus AMR Panel Pan Enterobacterales was predicted by in silico analysis with *Haemophilus influenzae* and observed in the retrospective FP specimen.

Table 23: QIAstat-Dx BCID GN Plus AMR Panel Archived Clinical Performance Summary for AMRs Identification on Archived PBCM Samples

AMR	PPA			NPA		
	TP/(TP+FN)	%	95% CI (%)	TN/(TN+FP)	%	95% CI (%)
AmpC (CMY/LAT/DHA/FOX)	0 / 0	N/A	N/A	88 / 89	98.9	93.9–99.8
CTX-M	1 / 1	100.0	20.7–100.0	87 / 87	100.0	95.8–100.0
IMP	0 / 0	N/A	N/A	74 / 74	100.0	95.1–100.0
KPC	0 / 0	N/A	N/A	89 / 89	100.0	95.9–100.0
NDM	0 / 0	N/A	N/A	89 / 89	100.0	95.9–100.0
OXA-23	1 / 1	100.0	20.7–100.0	88 / 88	100.0	95.8–100.0
OXA-48-like	0 / 0	N/A	N/A	81 / 81	100.0	95.5–100.0
OXA-24/40	0 / 0	N/A	N/A	89 / 89	100.0	95.9–100.0
OXA-58	0 / 0	N/A	N/A	89 / 89	100.0	95.9–100.0
SHV	1 / 1	100.0	20.7–100.0	88 / 88	100.0	95.8–100.0
TEM	8 / 8	100.0	67.6–100.0	129 / 129	100.0	97.1–100.0
VIM	0 / 0	N/A	N/A	89 / 89	100.0	95.9–100.0
PER	0 / 0	N/A	N/A	89 / 89	100.0	95.9–100.0
<i>armA</i>	1 / 1	100.0	20.7–100.0	88 / 88	100.0	95.8–100.0
<i>aac(6')-Ib</i>	2 / 2	100.0	34.2–100.0	87 / 87	100.0	95.8–100.0
VEB	0 / 0	N/A	N/A	89 / 89	100.0	95.9–100.0
GES	0 / 0	N/A	N/A	89 / 89	100.0	95.9–100.0
SPM	0 / 0	N/A	N/A	14 / 14	100.0	78.5–100.0

Resistance Gene Assay Species Stratification according to host organism

Clinical performance data (prospective, retrospective archived) of resistance gene targets according to host organism are presented in [Table 24](#) to [Table 41](#). Test results for resistance genes are only reported when an associated organism assay is positive in the same sample.

Table 24: Clinical performance (prospective, retrospective) of AMR target with associated host organism – *ampC* (CMY/LAT/DHA/FOX)

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
Prospective	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	4 / 4	100.0%	51.0% - 100.0%
	Pan Enterobacterales	5 / 5	100.0%	56.6% - 100.0%	29 / 29	100.0%	88.3% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 2	0.0%	0.0% - 65.8%	37 / 37	100.0%	90.6% - 100.0%

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
	Pan Enterobacterales, <i>Escherichia coli</i>	6 / 6	100.0%	61.0% - 100.0%	275 / 275	100.0%	98.6% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp.	1 / 3	33.3%	6.1% - 79.2%	37 / 37	100.0%	90.6% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	133 / 133	100.0%	97.2% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 1	0.0%	0.0% - 79.3%	29 / 29	100.0%	88.3% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	19 / 19	100.0%	83.2% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Enterobacter</i> spp.	1 / 1	100.0%	20.7% - 100.0%	2 / 2	100.0%	34.2% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	1 / 1	100.0%	20.7% - 100.0%	5 / 5	100.0%	56.6% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp., <i>Pseudomonas aeruginosa</i>	1 / 1	100.0%	20.7% - 100.0%	0 / 0	N/A	N/A
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	0 / 1	0.0%	0.0% - 79.3%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Klebsiella</i> spp., <i>Serratia</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Retrospective Archived	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	8 / 8	100.0%	67.6% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	21 / 21	100.0%	84.5% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	5 / 5	100.0%	56.6% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	28 / 29	96.6%	82.8% - 99.4%
	Pan Enterobacterales, <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	24 / 24	100.0%	86.2% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Table 25: Clinical performance (prospective, retrospective) of AMR target with associated host organism – CTX-M

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
Prospective	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	4 / 4	100.0%	51.0% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	22 / 22	100.0%	85.1% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	39 / 39	100.0%	91.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i>	54 / 55	98.2%	90.4% - 99.7%	224 / 226	99.1%	96.8% - 99.8%
	Pan Enterobacterales, <i>Enterobacter</i> spp.	2 / 2	100.0%	34.2% - 100.0%	38 / 38	100.0%	90.8% - 100.0%

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
	Pan Enterobacterales, <i>Klebsiella</i> spp.	17 / 18	94.4%	74.2% - 99.0%	114 / 114	100.0%	96.7% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	30 / 30	100.0%	88.6% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	12 / 12	100.0%	75.8% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	20 / 20	100.0%	83.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	3 / 3	100.0%	43.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	1 / 1	100.0%	20.7% - 100.0%	5 / 5	100.0%	56.6% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Proteus</i> spp.	1 / 1	100.0%	20.7% - 100.0%	0 / 0	N/A	N/A
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp., <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Klebsiella</i> spp., <i>Serratia</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Retrospective Archived	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	8 / 8	100.0%	67.6% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	5 / 5	100.0%	56.6% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	29 / 29	100.0%	88.3% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	20 / 20	100.0%	83.9% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	24 / 24	100.0%	86.2% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	1 / 1	100.0%	20.7% - 100.0%	0 / 0	N/A	N/A
	Pan Enterobacterales, <i>Pseudomonas aeruginosa</i> , <i>Salmonella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Table 26: Clinical performance (prospective, retrospective) of AMR target with associated host organism – IMP

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
Prospective	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	4 / 4	100.0%	51.0% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	20 / 20	100.0%	83.9% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	39 / 39	100.0%	91.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i>	0 / 0	N/A	N/A	266 / 266	100.0%	98.6% - 100.0%

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
	Pan Enterobacterales, <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	38 / 38	100.0%	90.8% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	129 / 129	100.0%	97.1% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	30 / 30	100.0%	88.6% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	11 / 11	100.0%	74.1% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	20 / 20	100.0%	83.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	3 / 3	100.0%	43.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	6 / 6	100.0%	61.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp., <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Klebsiella</i> spp., <i>Serratia</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Retrospective Archived	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	8 / 8	100.0%	67.6% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	5 / 5	100.0%	56.6% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	25 / 25	100.0%	86.7% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	17 / 17	100.0%	81.6% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	18 / 18	100.0%	82.4% - 100.0%
	Pan Enterobacterales, <i>Pseudomonas aeruginosa</i> , <i>Salmonella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Table 27: Clinical performance (prospective, retrospective) of AMR target with associated host organism – KPC

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
Prospective	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	4 / 4	100.0%	51.0% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	22 / 22	100.0%	85.1% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	39 / 39	100.0%	91.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i>	0 / 0	N/A	N/A	281 / 281	100.0%	98.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	40 / 40	100.0%	91.2% - 100.0%

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
	Pan Enterobacterales, <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	133 / 133	100.0%	97.2% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	30 / 30	100.0%	88.6% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	12 / 12	100.0%	75.8% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	20 / 20	100.0%	83.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	3 / 3	100.0%	43.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	6 / 6	100.0%	61.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp., <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Klebsiella</i> spp., <i>Serratia</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Retrospective Archived	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	8 / 8	100.0%	67.6% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	5 / 5	100.0%	56.6% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	29 / 29	100.0%	88.3% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	21 / 21	100.0%	84.5% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	24 / 24	100.0%	86.2% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Pseudomonas aeruginosa</i> , <i>Salmonella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Table 28: Clinical performance (prospective, retrospective) of AMR target with associated host organism – NDM

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
Prospective	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	4 / 4	100.0%	51.0% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	22 / 22	100.0%	85.1% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	39 / 39	100.0%	91.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i>	1 / 1	100.0%	20.7% - 100.0%	280 / 280	100.0%	98.6% - 100.0%

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
	Pan Enterobacterales, <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	40 / 40	100.0%	91.2% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	1 / 1	100.0%	20.7% - 100.0%	132 / 132	100.0%	97.2% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	1 / 1	100.0%	20.7% - 100.0%	29 / 29	100.0%	88.3% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	12 / 12	100.0%	75.8% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	20 / 20	100.0%	83.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	3 / 3	100.0%	43.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	6 / 6	100.0%	61.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp., <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Klebsiella</i> spp., <i>Serratia</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Retrospective Archived	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	8 / 8	100.0%	67.6% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	5 / 5	100.0%	56.6% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	29 / 29	100.0%	88.3% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	21 / 21	100.0%	84.5% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	24 / 24	100.0%	86.2% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Pseudomonas aeruginosa</i> , <i>Salmonella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Table 29: Clinical performance (prospective, retrospective) of AMR target with associated host organism – OXA-23

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
Prospective	<i>Acinetobacter calcoaceticus-baumannii</i> complex	1 / 1	100.0%	20.7% - 100.0%	3 / 3	100.0%	43.9% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	378 / 378	100.0%	99.0% - 100.0%

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	39 / 39	100.0%	91.0% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	140 / 140	100.0%	97.3% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	32 / 32	100.0%	89.3% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	2 / 2	100.0%	34.2% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp., <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Retrospective Archived	<i>Acinetobacter calcoaceticus-baumannii</i> complex	1 / 1	100.0%	20.7% - 100.0%	7 / 7	100.0%	64.6% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	45 / 45	100.0%	92.1% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	5 / 5	100.0%	56.6% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	29 / 29	100.0%	88.3% - 100.0%
	Pan Enterobacterales, <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Table 30: Clinical performance (prospective, retrospective) of AMR target with associated host organism – OXA-48-like

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
Prospective	Pan Enterobacterales	0 / 0	N/A	N/A	22 / 22	100.0%	85.1% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	39 / 39	100.0%	91.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i>	1 / 1	100.0%	20.7% - 100.0%	280 / 280	100.0%	98.6% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	40 / 40	100.0%	91.2% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	133 / 133	100.0%	97.2% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	30 / 30	100.0%	88.6% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	12 / 12	100.0%	75.8% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	20 / 20	100.0%	83.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	3 / 3	100.0%	43.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	6 / 6	100.0%	61.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
	Pan Enterobacterales, <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp., <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Klebsiella</i> spp., <i>Serratia</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Retrospective Archived	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	5 / 5	100.0%	56.6% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	29 / 29	100.0%	88.3% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	21 / 21	100.0%	84.5% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	24 / 24	100.0%	86.2% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Pseudomonas aeruginosa</i> , <i>Salmonella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Table 31: Clinical performance (prospective, retrospective) of AMR target with associated host organism – OXA-24/40

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
Prospective	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	4 / 4	100.0%	51.0% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	378 / 378	100.0%	99.0% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	39 / 39	100.0%	91.0% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	140 / 140	100.0%	97.3% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	32 / 32	100.0%	89.3% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	2 / 2	100.0%	34.2% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp., <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Retrospective Archived	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	8 / 8	100.0%	67.6% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	45 / 45	100.0%	92.1% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	5 / 5	100.0%	56.6% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	29 / 29	100.0%	88.3% - 100.0%

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
	Pan Enterobacterales, <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Table 32: Clinical performance (prospective, retrospective) of AMR target with associated host organism – OXA-58

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
Prospective	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	4 / 4	100.0%	51.0% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	54 / 54	100.0%	93.4% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	39 / 39	100.0%	91.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i>	0 / 0	N/A	N/A	281 / 281	100.0%	98.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	40 / 40	100.0%	91.2% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	133 / 133	100.0%	97.2% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	30 / 30	100.0%	88.6% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	3 / 3	100.0%	43.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	6 / 6	100.0%	61.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp., <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Retrospective Archived	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	8 / 8	100.0%	67.6% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	45 / 45	100.0%	92.1% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	5 / 5	100.0%	56.6% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	29 / 29	100.0%	88.3% - 100.0%
	Pan Enterobacterales, <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Table 33: Clinical performance (prospective, retrospective) of AMR target with associated host organism – SHV

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
Prospective	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	4 / 4	100.0%	51.0% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	22 / 22	100.0%	85.1% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	39 / 39	100.0%	91.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i>	10 / 10	100.0%	72.2% - 100.0%	270 / 271	99.6%	97.9% - 99.9%
	Pan Enterobacterales, <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	40 / 40	100.0%	91.2% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	81 / 81	100.0%	95.5% - 100.0%	49 / 52	94.2%	84.4% - 98.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	30 / 30	100.0%	88.6% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 1	0.0%	0.0% - 79.3%	11 / 11	100.0%	74.1% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	20 / 20	100.0%	83.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	3 / 3	100.0%	43.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	6 / 6	100.0%	61.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp., <i>Proteus</i> spp.	1 / 1	100.0%	20.7% - 100.0%	0 / 0	N/A	N/A
	Pan Enterobacterales, <i>Proteus</i> spp., <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Klebsiella</i> spp., <i>Serratia</i> spp.	1 / 1	100.0%	20.7% - 100.0%	0 / 0	N/A	N/A
Retrospective Archived	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	8 / 8	100.0%	67.6% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	5 / 5	100.0%	56.6% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	29 / 29	100.0%	88.3% - 100.0%

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	21 / 21	100.0%	84.5% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	24 / 24	100.0%	86.2% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	1 / 1	100.0%	20.7% - 100.0%	0 / 0	N/A	N/A
	Pan Enterobacterales, <i>Pseudomonas aeruginosa</i> , <i>Salmonella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Table 34: Clinical performance (prospective, retrospective) of AMR target with associated host organism – TEM

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
Prospective	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	4 / 4	100.0%	51.0% - 100.0%
	<i>Bacteroides fragilis</i>	0 / 0	N/A	N/A	9 / 9	100.0%	70.1% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	22 / 22	100.0%	85.1% - 100.0%
	<i>Haemophilus influenzae</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>Neisseria meningitidis</i> (encapsulated)	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 1	0.0%	0.0% - 79.3%	37 / 37	100.0%	90.6% - 100.0%
	<i>Bacteroides fragilis</i> , <i>Haemophilus influenzae</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i>	118 / 120	98.3%	94.1% - 99.5%	154 / 158	97.5%	93.7% - 99.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp.	2 / 3	66.7%	20.8% - 93.9%	37 / 37	100.0%	90.6% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	15 / 17	88.2%	65.7% - 96.7%	116 / 116	100.0%	96.8% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	1 / 2	50.0%	9.5% - 90.5%	27 / 27	100.0%	87.5% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	12 / 12	100.0%	75.8% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	20 / 20	100.0%	83.9% - 100.0%
	<i>Haemophilus influenzae</i> , <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>Bacteroides fragilis</i> , Pan Enterobacterales, <i>Escherichia coli</i>	2 / 2	100.0%	34.2% - 100.0%	1 / 1	100.0%	20.7% - 100.0%
	<i>Bacteroides fragilis</i> , Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Enterobacter</i> spp.	2 / 2	100.0%	34.2% - 100.0%	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	3 / 3	100.0%	43.9% - 100.0%	3 / 3	100.0%	43.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp., <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Klebsiella</i> spp., <i>Serratia</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Retrospective Archived	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	8 / 8	100.0%	67.6% - 100.0%
	<i>Bacteroides fragilis</i>	0 / 0	N/A	N/A	26 / 26	100.0%	87.1% - 100.0%
	<i>Haemophilus influenzae</i>	4 / 4	100.0%	51.0% - 100.0%	14 / 14	100.0%	78.5% - 100.0%
	<i>Neisseria meningitidis</i> (encapsulated)	0 / 0	N/A	N/A	4 / 4	100.0%	51.0% - 100.0%
	<i>Bacteroides fragilis</i> , <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	2 / 2	100.0%	34.2% - 100.0%

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(T P+FN)	%	95% CI	TN/(TN +FP)	%	95% CI
	Pan Enterobacterales, <i>Proteus</i> spp.	2 / 2	100.0%	34.2% - 100.0%	26 / 26	100.0%	87.1% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	1 / 1	100.0%	20.7% - 100.0%	20 / 20	100.0%	83.9% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	24 / 24	100.0%	86.2% - 100.0%
	<i>Haemophilus influenzae</i> , <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	2 / 2	100.0%	34.2% - 100.0%
	<i>Neisseria meningitidis</i> (encapsulated), <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>Bacteroides fragilis</i> , Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	1 / 1	100.0%	20.7% - 100.0%	0 / 0	N/A	N/A
	Pan Enterobacterales, <i>Pseudomonas aeruginosa</i> , <i>Salmonella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Table 35: Clinical performance (prospective, retrospective) of AMR target with associated host organism – VIM

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP +FN)	%	95% CI	TN/(TN+ FP)	%	95% CI
Prospective	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	4 / 4	100.0%	51.0% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	22 / 22	100.0%	85.1% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 1	0.0%	0.0% - 79.3%	38 / 38	100.0%	90.8% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i>	1 / 1	100.0%	20.7% - 100.0%	280 / 280	100.0%	98.6% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	40 / 40	100.0%	91.2% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	133 / 133	100.0%	97.2% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	30 / 30	100.0%	88.6% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	12 / 12	100.0%	75.8% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	20 / 20	100.0%	83.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	3 / 3	100.0%	43.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	6 / 6	100.0%	61.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp., <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Klebsiella</i> spp., <i>Serratia</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
Retrospective Archived	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	8 / 8	100.0%	67.6% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	5 / 5	100.0%	56.6% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	29 / 29	100.0%	88.3% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	21 / 21	100.0%	84.5% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	24 / 24	100.0%	86.2% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Pseudomonas aeruginosa</i> , <i>Salmonella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Table 36: Clinical performance (prospective, retrospective) of AMR target with associated host organism – PER

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
Prospective	<i>Acinetobacter calcoaceticus-baumannii</i> complex	1 / 1	100.0%	20.7% - 100.0%	3 / 3	100.0%	43.9% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	42 / 42	100.0%	91.6% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	39 / 39	100.0%	91.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i>	0 / 0	N/A	N/A	281 / 281	100.0%	98.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	40 / 40	100.0%	91.2% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	133 / 133	100.0%	97.2% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	30 / 30	100.0%	88.6% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	12 / 12	100.0%	75.8% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	3 / 3	100.0%	43.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	6 / 6	100.0%	61.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp., <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
Retrospective Archived	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	8 / 8	100.0%	67.6% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	24 / 24	100.0%	86.2% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	5 / 5	100.0%	56.6% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	29 / 29	100.0%	88.3% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	21 / 21	100.0%	84.5% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Pseudomonas aeruginosa</i> , <i>Salmonella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Table 37: Clinical performance (prospective, retrospective) of AMR target with associated host organism – *armA*

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
Prospective	<i>Acinetobacter calcoaceticus-baumannii</i> complex	1 / 1	100.0%	20.7% - 100.0%	3 / 3	100.0%	43.9% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	22 / 22	100.0%	85.1% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	39 / 39	100.0%	91.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i>	0 / 0	N/A	N/A	281 / 281	100.0%	98.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	40 / 40	100.0%	91.2% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	133 / 133	100.0%	97.2% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	30 / 30	100.0%	88.6% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	12 / 12	100.0%	75.8% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	20 / 20	100.0%	83.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	3 / 3	100.0%	43.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	6 / 6	100.0%	61.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp., <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Klebsiella</i> spp., <i>Serratia</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Retrospective Archived	<i>Acinetobacter calcoaceticus-baumannii</i> complex	1 / 1	100.0%	20.7% - 100.0%	7 / 7	100.0%	64.6% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	5 / 5	100.0%	56.6% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	29 / 29	100.0%	88.3% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	21 / 21	100.0%	84.5% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	24 / 24	100.0%	86.2% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Pseudomonas aeruginosa</i> , <i>Salmonella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Table 38: Clinical performance (prospective, retrospective) of AMR target with associated host organism – *aac(6')-Ib*

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
Prospective	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	4 / 4	100.0%	51.0% - 100.0%
	Pan Enterobacterales	1 / 1	100.0%	20.7% - 100.0%	21 / 21	100.0%	84.5% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 1	0.0%	0.0% - 79.3%	38 / 38	100.0%	90.8% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i>	23 / 24	95.8%	79.8% - 99.3%	255 / 257	99.2%	97.2% - 99.8%
	Pan Enterobacterales, <i>Enterobacter</i> spp.	1 / 1	100.0%	20.7% - 100.0%	39 / 39	100.0%	91.0% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	12 / 13	92.3%	66.7% - 98.6%	120 / 120	100.0%	96.9% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	1 / 1	100.0%	20.7% - 100.0%	29 / 29	100.0%	88.3% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	12 / 12	100.0%	75.8% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	20 / 20	100.0%	83.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	3 / 3	100.0%	43.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	6 / 6	100.0%	61.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp., <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Klebsiella</i> spp., <i>Serratia</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Retrospective Archived	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	8 / 8	100.0%	67.6% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	5 / 5	100.0%	56.6% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	1 / 1	100.0%	20.7% - 100.0%	28 / 28	100.0%	87.9% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	21 / 21	100.0%	84.5% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	24 / 24	100.0%	86.2% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	1 / 1	100.0%	20.7% - 100.0%	0 / 0	N/A	N/A
	Pan Enterobacterales, <i>Pseudomonas aeruginosa</i> , <i>Salmonella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Table 39: Clinical performance (prospective, retrospective) of AMR target with associated host organism – VEB

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
Prospective	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	4 / 4	100.0%	51.0% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	42 / 42	100.0%	91.6% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	39 / 39	100.0%	91.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i>	0 / 0	N/A	N/A	281 / 281	100.0%	98.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	40 / 40	100.0%	91.2% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	133 / 133	100.0%	97.2% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	30 / 30	100.0%	88.6% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	12 / 12	100.0%	75.8% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	3 / 3	100.0%	43.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	6 / 6	100.0%	61.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp., <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp., <i>Proteus</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Retrospective Archived	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	8 / 8	100.0%	67.6% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	24 / 24	100.0%	86.2% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	5 / 5	100.0%	56.6% - 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0 / 0	N/A	N/A	29 / 29	100.0%	88.3% - 100.0%
	Pan Enterobacterales, <i>Salmonella</i> spp.	0 / 0	N/A	N/A	21 / 21	100.0%	84.5% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Pseudomonas aeruginosa</i> , <i>Salmonella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Table 40: Clinical performance (prospective, retrospective) of AMR target with associated host organism – GES

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
Prospective	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	4 / 4	100.0%	51.0% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	63 / 63	100.0%	94.3% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	39 / 39	100.0%	91.0% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i>	0 / 0	N/A	N/A	282 / 282	100.0%	98.7% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	41 / 41	100.0%	91.4% - 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	134 / 134	100.0%	97.2% - 100.0%
	Pan Enterobacterales, <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	20 / 20	100.0%	83.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Enterobacter</i> spp.	0 / 0	N/A	N/A	3 / 3	100.0%	43.9% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	7 / 7	100.0%	64.6% - 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp., <i>Klebsiella</i> spp., <i>Serratia</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Retrospective Archived	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	8 / 8	100.0%	67.6% - 100.0%
	Pan Enterobacterales	0 / 0	N/A	N/A	50 / 50	100.0%	92.9% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	5 / 5	100.0%	56.6% - 100.0%

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
	Pan Enterobacterales, <i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	Pan Enterobacterales, <i>Serratia</i> spp.	0 / 0	N/A	N/A	24 / 24	100.0%	86.2% - 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Table 41: Clinical performance (prospective, retrospective) of AMR target with associated host organism – SPM

Enrolment	Pathogen(s) Detected	PPA			NPA		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
Prospective	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	4 / 4	100.0%	51.0% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	39 / 39	100.0%	91.0% - 100.0%
Retrospective Archived	<i>Acinetobacter calcoaceticus-baumannii</i> complex	0 / 0	N/A	N/A	8 / 8	100.0%	67.6% - 100.0%
	<i>Pseudomonas aeruginosa</i>	0 / 0	N/A	N/A	6 / 6	100.0%	61.0% - 100.0%

Validity of Results in Clinical Specimens

The proportion of failed runs in clinical specimens (prospective and retrospective archived samples) on initial attempt was 1.6% (13/808) and following repeats it was reduced to 0.5% (4/808), resulting in an overall success rate of 98.4% (795/808) before retesting, and 99.5% (804/808) after retesting.

Contrived Specimens Testing

Contrived specimen testing was required for all targets on the panel as there were insufficient positive specimens obtained from both prospective and archived collection efforts. Contrived specimens were prepared by spiking different strains representative of the genetic diversity of each pathogen. Contrived specimens were tested alongside negative specimens in a blinded manner. The results are summarized in [Table 42](#) for both pathogens and AMRs.

Table 42: Summary of Performance for the Contrived Samples Tested with the QIAstat-Dx BCID GN Plus AMR Panel

Target	TP/(TP+FN)	%	95% CI
<i>Enterobacter</i> spp.*	10 / 10	100.0%	72.2% - 100.0%
<i>Escherichia coli</i> *	60 / 60	100.0%	94.0% - 100.0%
<i>Klebsiella</i> spp.*	99 / 99	100.0%	96.3% - 100.0%
<i>Salmonella</i> spp.	50 / 50	100.0%	92.9% - 100.0%
<i>Serratia</i> spp.*	30 / 30	100.0%	88.6% - 100.0%
<i>Pseudomonas aeruginosa</i> *	212 / 212	100.0%	98.2% - 100.0%

Target	TP/(TP+FN)	%	95% CI
<i>Neisseria meningitidis</i> (encapsulated)	50 / 50	100.0%	92.9% - 100.0%
<i>Haemophilus influenzae</i>	50 / 50	100.0%	92.9% - 100.0%
<i>Acinetobacter calcoaceticus-baumannii</i> complex	150 / 150	100.0%	97.5% - 100.0%
<i>Stenotrophomonas maltophilia</i>	50 / 50	100.0%	92.9% - 100.0%
Pan Enterobacterales*	259 / 259	100.0%	98.5% - 100.0%
AmpC (CMY/LAT/DHA/FOX)	50 / 50	100.0%	92.9% - 100.0%
CTX-M*	50 / 50	100.0%	92.9% - 100.0%
IMP	33 / 33	100.0%	89.6% - 100.0%
KPC	50 / 50	100.0%	92.9% - 100.0%
NDM	82 / 84	97.6%	91.7% - 99.3%
OXA-23	60 / 60	100.0%	94.0% - 100.0%
OXA-48-like	50 / 50	100.0%	92.9% - 100.0%
OXA-24/40	60 / 60	100.0%	94.0% - 100.0%
OXA-58	50 / 50	100.0%	92.9% - 100.0%
SHV*	110 / 110	100.0%	96.6% - 100.0%
TEM*	227 / 229	99.1%	96.9% - 99.8%
VIM	68 / 68	100.0%	94.7% - 100.0%
PER	47 / 49	95.9%	86.3% - 98.9%
<i>armA</i>	60 / 60	100.0%	94.0% - 100.0%
<i>aac(6')-Ib</i>	417 / 419	99.5%	98.3% - 99.9%
VEB	62 / 62	100.0%	94.2% - 100.0%
GES	50 / 50	100.0%	92.9% - 100.0%
SPM	76 / 80	95.0%	87.8% - 98.0%

* Targets co-detected with the target of interest but not intended to be contrived based on prevalence.

The proportion of positive results was $\geq 95\%$ for all prepared contrived samples for pathogen in all tested analytes.

The proportion of positive results was $\geq 95\%$ for all prepared contrived samples for AMRs in all tested analytes.

Genus and Group Assay Stratification by Species

The QIAstat-Dx BCID GN Plus AMR Panel includes genus level targets for *Enterobacter* spp., *Klebsiella* spp., *Proteus* spp., *Salmonella* spp., *Serratia* spp., *Acinetobacter calcoaceticus-baumannii* complex, and Pan Enterobacterales. Summary results (positive percent agreement (PPA)) for these genus level and group targets, stratified by the species level, are presented in [Table 43](#).

Table 43 Clinical Performance for Genus Level and Pan Targets Stratified by Species

Species	Prospective			Retrospective Archived			Contrived			Total		
	TP/(TP+FN)	%	95% CI	TP/(TP+FN)	%	95% CI	TP/(TP+FN)	%	95% CI	TP/(TP+FN)	%	95% CI
<i>Enterobacter spp.*</i>	43 / 45	95.6%	85.2% - 98.8%	0 / 0	N/A	N/A	10 / 10	100.0%	72.2% - 100.0%	53 / 55	96.4%	87.7% - 99.0%
<i>Enterobacter cloacae</i>	29 / 31	93.5%	79.3% - 98.2%	0/0	N/A	N/A	10 / 10	100.0%	72.2% - 100.0%	39 / 41	95.1%	83.9% - 98.7%
<i>Enterobacter hormacheii</i>	1 / 1	100.0%	20.7% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
<i>Morganella morganii</i>	1 / 1	100.0%	20.7% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Not Specified	12 / 12	100.0%	75.8% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	12 / 12	100.0%	75.8% - 100.0%
<i>Pluralibacter gergoviae</i>	1 / 1	100.0%	20.7% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
<i>Klebsiella spp.</i>	138 / 141	97.9%	93.9% - 99.3%	1 / 1	100.0%	20.7% - 100.0%	99 / 99	100.0%	96.3% - 100.0%	238 / 241	98.8%	96.4% - 99.6%
<i>Klebsiella aerogenes</i>	14 / 15	93.3%	70.2% - 98.8%	0/0	N/A	N/A	0/0	N/A	N/A	14 / 15	93.3%	70.2% - 98.8%
<i>Klebsiella oxytoca</i>	19 / 20	95.0%	76.4% - 99.1%	0/0	N/A	N/A	0/0	N/A	N/A	19 / 20	95.0%	76.4% - 99.1%
<i>Klebsiella pneumoniae</i>	99 / 100	99.0%	94.6% - 99.8%	1 / 1	100.0%	20.7% - 100.0%	99 / 99	100.0%	96.3% - 100.0%	199 / 200	99.5%	97.2% - 99.9%
<i>Klebsiella pneumoniae/oxytoca</i>	1 / 1	100.0%	20.7% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
<i>Klebsiella pneumoniae/variicola</i>	1 / 1	100.0%	20.7% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
<i>Klebsiella variicola</i>	4 / 4	100.0%	51.0% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	4 / 4	100.0%	51.0% - 100.0%
<i>Proteus spp.</i>	32 / 33	97.0%	84.7% - 99.5%	29 / 29	100.0%	88.3% - 100.0%	0/0	N/A	N/A	61 / 62	98.4%	91.4% - 99.7%
<i>Proteus mirabilis</i>	30 / 31	96.8%	83.8% - 99.4%	24 / 24	100.0%	86.2% - 100.0%	0/0	N/A	N/A	54 / 55	98.2%	90.4% - 99.7%
<i>Proteus vulgaris</i>	2 / 2	100.0%	34.2% - 100.0%	5 / 5	100.0%	56.6% - 100.0%	0/0	N/A	N/A	7 / 7	100.0%	64.6% - 100.0%
<i>Salmonella spp.</i>	12 / 12	100.0%	75.8% - 100.0%	22 / 22	100.0%	85.1% - 100.0%	50 / 50	100.0%	92.9% - 100.0%	84 / 84	100.0%	95.6% - 100.0%
Not Specified	7 / 7	100.0%	64.6% - 100.0%	21 / 21	100.0%	84.5% - 100.0%	0/0	N/A	N/A	28 / 28	100.0%	87.9% - 100.0%
<i>Salmonella bongori</i>	0/0	N/A	N/A	0/0	N/A	N/A	10 / 10	100.0%	72.2% - 100.0%	10 / 10	100.0%	72.2% - 100.0%
<i>Salmonella enterica</i>	5 / 5	100.0%	56.6% - 100.0%	1 / 1	100.0%	20.7% - 100.0%	40 / 40	100.0%	91.2% - 100.0%	46 / 46	100.0%	92.3% - 100.0%
<i>Serratia spp.</i>	21 / 21	100.0%	84.5% - 100.0%	24 / 24	100.0%	86.2% - 100.0%	30 / 30	100.0%	88.6% - 100.0%	75 / 75	100.0%	95.1% - 100.0%
<i>Serratia liquefaciens</i>	2 / 2	100.0%	34.2% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	2 / 2	100.0%	34.2% - 100.0%
<i>Serratia marcescens</i>	19 / 19	100.0%	83.2% - 100.0%	24 / 24	100.0%	86.2% - 100.0%	30 / 30	100.0%	88.6% - 100.0%	73 / 73	100.0%	95.0% - 100.0%
<i>Acinetobacter calcoaceticus-baumannii</i> complex	5 / 5	100.0%	56.6% - 100.0%	8 / 8	100.0%	67.6% - 100.0%	150 / 150	100.0%	97.5% - 100.0%	163 / 163	100.0%	97.7% - 100.0%
<i>Acinetobacter baumannii</i>	3 / 3	100.0%	43.9% - 100.0%	7 / 7	100.0%	64.6% - 100.0%	150 / 150	100.0%	97.5% - 100.0%	160 / 160	100.0%	97.7% - 100.0%

Species	Prospective			Retrospective Archived			Contrived			Total		
	TP/(TP+FN)	%	95% CI	TP/(TP+FN)	%	95% CI	TP/(TP+FN)	%	95% CI	TP/(TP+FN)	%	95% CI
Acinetobacter calcoaceticus	1 / 1	100.0%	20.7% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Not Specified	1 / 1	100.0%	20.7% - 100.0%	1 / 1	100.0%	20.7% - 100.0%	0/0	N/A	N/A	2 / 2	100.0%	34.2% - 100.0%
Pan <i>Enterobacterales</i> *	555 / 558	99.5%	98.4% - 99.8%	76 / 76	100.0%	95.2% - 100.0%	259 / 259	100.0%	98.5% - 100.0%	890 / 893	99.7%	99.0% - 99.9%
Citrobacter amalonaticus	2 / 2	100.0%	34.2% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	2 / 2	100.0%	34.2% - 100.0%
Citrobacter freundii	4 / 4	100.0%	51.0% - 100.0%	1 / 1	100.0%	20.7% - 100.0%	10 / 10	100.0%	72.2% - 100.0%	15 / 15	100.0%	79.6% - 100.0%
Citrobacter koseri	8 / 8	100.0%	67.6% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	8 / 8	100.0%	67.6% - 100.0%
Cronobacter spp.	0 / 1	0.0%	0.0% - 79.3%	0/0	N/A	N/A	0/0	N/A	N/A	0 / 1	0.0%	0.0% - 79.3%
Enterobacter cloacae	14 / 14	100.0%	78.5% - 100.0%	0/0	N/A	N/A	10 / 10	100.0%	72.2% - 100.0%	24 / 24	100.0%	86.2% - 100.0%
Enterobacter cloacae complex	28 / 29	96.6%	82.8% - 99.4%	0/0	N/A	N/A	0/0	N/A	N/A	28 / 29	96.6%	82.8% - 99.4%
Enterobacter hormaechei	1 / 1	100.0%	20.7% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Escherichia coli	292 / 292	100.0%	98.7% - 100.0%	1 / 1	100.0%	20.7% - 100.0%	60 / 60	100.0%	94.0% - 100.0%	353 / 353	100.0%	98.9% - 100.0%
Hafnia alvei	2 / 2	100.0%	34.2% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	2 / 2	100.0%	34.2% - 100.0%
Klebsiella aerogenes	15 / 15	100.0%	79.6% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	15 / 15	100.0%	79.6% - 100.0%
Klebsiella oxytoca	20 / 20	100.0%	83.9% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	20 / 20	100.0%	83.9% - 100.0%
Klebsiella pneumoniae	100 / 100	100.0%	96.3% - 100.0%	1 / 1	100.0%	20.7% - 100.0%	99 / 99	100.0%	96.3% - 100.0%	200 / 200	100.0%	98.1% - 100.0%
Klebsiella pneumoniae/oxytoca	1 / 1	100.0%	20.7% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Klebsiella pneumoniae/variicola	1 / 1	100.0%	20.7% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Klebsiella variicola	4 / 4	100.0%	51.0% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	4 / 4	100.0%	51.0% - 100.0%
Leclercia adecarboxylata	1 / 1	100.0%	20.7% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Morganella morganii	5 / 5	100.0%	56.6% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	5 / 5	100.0%	56.6% - 100.0%
Pluralibacter gergoviae	1 / 1	100.0%	20.7% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Proteus mirabilis	30 / 31	96.8%	83.8% - 99.4%	24 / 24	100.0%	86.2% - 100.0%	0/0	N/A	N/A	54 / 55	98.2%	90.4% - 99.7%
Proteus vulgaris	2 / 2	100.0%	34.2% - 100.0%	5 / 5	100.0%	56.6% - 100.0%	0/0	N/A	N/A	7 / 7	100.0%	64.6% - 100.0%
Providencia rettgeri	2 / 2	100.0%	34.2% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	2 / 2	100.0%	34.2% - 100.0%
Providencia stuartii	3 / 3	100.0%	43.9% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	3 / 3	100.0%	43.9% - 100.0%
Raoultella ornithinolytica	1 / 1	100.0%	20.7% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%

Species	Prospective			Retrospective Archived			Contrived			Total		
	TP/(TP+FN)	%	95% CI	TP/(TP+FN)	%	95% CI	TP/(TP+FN)	%	95% CI	TP/(TP+FN)	%	95% CI
Raoultella planticola	1 / 1	100.0%	20.7% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
Salmonella bongori	0/0	N/A	N/A	0/0	N/A	N/A	10 / 10	100.0%	72.2% - 100.0%	10 / 10	100.0%	72.2% - 100.0%
Salmonella enterica	0/0	N/A	N/A	0/0	N/A	N/A	40 / 40	100.0%	91.2% - 100.0%	40 / 40	100.0%	91.2% - 100.0%
Salmonella spp.	12 / 12	100.0%	75.8% - 100.0%	22 / 22	100.0%	85.1% - 100.0%	0/0	N/A	N/A	34 / 34	100.0%	89.8% - 100.0%
Serratia liquefaciens	2 / 2	100.0%	34.2% - 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	2 / 2	100.0%	34.2% - 100.0%
Serratia marcescens	19 / 19	100.0%	83.2% - 100.0%	24 / 24	100.0%	86.2% - 100.0%	30 / 30	100.0%	88.6% - 100.0%	73 / 73	100.0%	95.0% - 100.0%

*Sample count between individual species and overall cumulative differ due to coinfections with species of the same group in one or more samples.

Resistance Markers Comparison to Antimicrobial Susceptibility Testing

For the clinical specimens (prospective and retrospective archived specimens), a supplemental analysis was performed to determine the correlation between the QIAstat-Dx BCID GN Plus AMR Panel resistance marker detection and phenotypic antimicrobial susceptibility testing (AST) results. For the low prevalent AMRs, contrived samples were tested and the combined results (prospective, retrospective archived, and contrived specimens) are presented in addition to stratified results. All the results are provided in [Table 44](#) to [Table 65](#).

Positive Percentage Agreement (PPA) was calculated as the proportion of resistant specimens by AST where the corresponding AMR was detected by the QIAstat-Dx BCID GN Plus AMR Panel. Negative Percentage Agreement (NPA) was calculated as the proportion of susceptible specimens by AST where the corresponding AMR was not detected by the QIAstat-Dx BCID GN Plus AMR Panel. For analysis across all AMRs, the combined PPA was calculated as the proportion of resistant specimens where at least one of the AMRs under consideration was detected by the QIAstat-Dx BCID GN Plus AMR Panel. The combined NPA was calculated as the proportion of susceptible specimens where none of the AMRs under consideration are detected by the QIAstat-Dx BCID GN Plus AMR Panel.

The performance of *armA* and *aac(6')-lb* resistance markers compared to phenotypic AST results for aminoglycosides-class antibiotics by relevant organisms is presented in [Table 44](#), [Table 45](#) and [Table 46](#). In addition, phenotypic correlations for *armA* was also performed with contrived samples by comparing to the AST results for the aminoglycoside reported on the certificate of analysis of the strains of relevant organisms. Since either or both *aac(6')-lb* and *armA* may be present in an aminoglycoside resistant isolate, the overall genotypic/phenotypic pattern correlation is a combination of *aac(6')-lb* and *armA* results. Note that antimicrobial resistance is known to occur via mechanisms other than presence of *armA* and *aac(6')-lb* genes, therefore absence does not infer phenotypic susceptibility. The combined results for clinical specimens and contrived samples are provided in [Table 44](#) while the breakdown is shown in [Table 45](#) for clinical specimens and [Table 46](#) for contrived specimens.

Table 44 Performance of *aac(6')-lb* and *armA* Compared to Phenotypic AST Results for Amikacin, Gentamicin and Tobramycin in Clinical Specimens and Contrived Samples Combined

Pathogen	<i>aac(6')-lb</i>		<i>armA</i>		Combined (<i>aac(6')-lb</i> , <i>armA</i>)	
	PPA	NPA	PPA	NPA	PPA	NPA
Amikacin susceptibility testing						
<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/1) 0.0% - 79.3%	100.0% (3/3) 43.9% - 100.0%	100.0% (61/61) 94.1% - 100.0%	100.0% (3/3) 43.9% - 100.0%	100.0% (61/61) 94.1% - 100.0%	100.0% (3/3) 43.9% - 100.0%
<i>Enterobacter</i> spp.	0/0	94.7% (18/19) 75.4% - 99.1%	0/0	100.0% (19/19) 83.2% - 100.0%	0/0	94.7% (18/19) 75.4% - 99.1%
<i>Escherichia coli</i>	100.0% (3/3) 43.9% - 100.0%	89.0% (138/155) 83.1% - 93.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (155/155) 97.6% - 100.0%	100.0% (3/3) 43.9% - 100.0%	89.0% (138/155) 83.1% - 93.0%
<i>Klebsiella</i> spp.	100.0% (1/1) 20.7% - 100.0%	91.9% (68/74) 83.4% - 96.2%	0.0% (0/1) 0.0% - 79.3%	100.0% (74/74) 95.1% - 100.0%	100.0% (1/1) 20.7% - 100.0%	91.9% (68/74) 83.4% - 96.2%

Pathogen	<i>aac(6')-lb</i>		<i>armA</i>		Combined (<i>aac(6')-lb, armA</i>)	
	PPA	NPA	PPA	NPA	PPA	NPA
<i>Proteus</i> spp.	0/0	100.0% (21/21) 84.5% - 100.0%	0/0	100.0% (21/21) 84.5% - 100.0%	0/0	100.0% (21/21) 84.5% - 100.0%
<i>Pseudomonas aeruginosa</i>	0/0	100.0% (22/22) 85.1% - 100.0%	0/0	100.0% (22/22) 85.1% - 100.0%	0/0	100.0% (22/22) 85.1% - 100.0%
<i>Serratia</i> spp.	0/0	100.0% (16/16) 80.6% - 100.0%	0/0	100.0% (16/16) 80.6% - 100.0%	0/0	100.0% (16/16) 80.6% - 100.0%
Gentamicin susceptibility testing						
<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (11/11) 74.1% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (11/11) 74.1% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/2) 0.0% - 65.8%	97.3% (36/37) 86.2% - 99.5%	0.0% (0/2) 0.0% - 65.8%	100.0% (37/37) 90.6% - 100.0%	0.0% (0/2) 0.0% - 65.8%	97.3% (36/37) 86.2% - 99.5%
<i>Escherichia coli</i>	34.3% (12/35) 20.8% - 50.8%	94.0% (221/235) 90.2% - 96.4%	0.0% (0/35) 0.0% - 9.9%	100.0% (235/235) 98.4% - 100.0%	34.3% (12/35) 20.8% - 50.8%	94.0% (221/235) 90.2% - 96.4%
<i>Klebsiella</i> spp.	88.9% (8/9) 56.5% - 98.0%	96.9% (126/130) 92.4% - 98.8%	0.0% (0/9) 0.0% - 29.9%	100.0% (130/130) 97.1% - 100.0%	88.9% (8/9) 56.5% - 98.0%	96.9% (126/130) 92.4% - 98.8%
<i>Proteus</i> spp.	0.0% (0/5) 0.0% - 43.4%	97.5% (39/40) 87.1% - 99.6%	0.0% (0/5) 0.0% - 43.4%	100.0% (40/40) 91.2% - 100.0%	0.0% (0/5) 0.0% - 43.4%	97.5% (39/40) 87.1% - 99.6%
<i>Pseudomonas aeruginosa</i>	0.0% (0/7) 0.0% - 35.4%	100.0% (18/18) 82.4% - 100.0%	0.0% (0/7) 0.0% - 35.4%	100.0% (18/18) 82.4% - 100.0%	0.0% (0/7) 0.0% - 35.4%	100.0% (18/18) 82.4% - 100.0%
<i>Salmonella</i> spp.	0/0	100.0% (20/20) 83.9% - 100.0%	0/0	100.0% (20/20) 83.9% - 100.0%	0/0	100.0% (20/20) 83.9% - 100.0%
<i>Serratia</i> spp.	0/0	100.0% (30/30) 88.6% - 100.0%	0/0	100.0% (30/30) 88.6% - 100.0%	0/0	100.0% (30/30) 88.6% - 100.0%
Tobramycin susceptibility testing						
<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/1) 0.0% - 79.3%	100.0% (3/3) 43.9% - 100.0%	100.0% (41/41) 91.4% - 100.0%	100.0% (3/3) 43.9% - 100.0%	100.0% (41/41) 91.4% - 100.0%	100.0% (3/3) 43.9% - 100.0%
<i>Enterobacter</i> spp.	0/0	95.2% (20/21) 77.3% - 99.2%	0/0	100.0% (21/21) 84.5% - 100.0%	0/0	95.2% (20/21) 77.3% - 99.2%
<i>Escherichia coli</i>	54.5% (18/33) 38.0% - 70.2%	98.5% (128/130) 94.6% - 99.6%	0.0% (0/33) 0.0% - 10.4%	100.0% (130/130) 97.1% - 100.0%	54.5% (18/33) 38.0% - 70.2%	98.5% (128/130) 94.6% - 99.6%
<i>Klebsiella</i> spp.	88.9% (8/9) 56.5% - 98.0%	100.0% (75/75) 95.1% - 100.0%	0.0% (0/9) 0.0% - 29.9%	100.0% (75/75) 95.1% - 100.0%	88.9% (8/9) 56.5% - 98.0%	100.0% (75/75) 95.1% - 100.0%
<i>Proteus</i> spp.	0.0% (0/2) 0.0% - 65.8%	100.0% (21/21) 84.5% - 100.0%	0.0% (0/2) 0.0% - 65.8%	100.0% (21/21) 84.5% - 100.0%	0.0% (0/2) 0.0% - 65.8%	100.0% (21/21) 84.5% - 100.0%
<i>Pseudomonas aeruginosa</i>	0.0% (0/3) 0.0% - 56.1%	100.0% (26/26) 87.1% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (26/26) 87.1% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (26/26) 87.1% - 100.0%
<i>Serratia</i> spp.	0.0% (0/3) 0.0% - 56.1%	100.0% (14/14) 78.5% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (14/14) 78.5% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (14/14) 78.5% - 100.0%

Table 45 Performance of *aac(6')-lb* and *armA* Compared to Phenotypic AST Results for Amikacin, Gentamicin and Tobramycin in Clinical Specimens

Pathogen	<i>aac(6')-lb</i>		<i>armA</i>		Combined (<i>aac(6')-lb, armA</i>)	
	PPA	NPA	PPA	NPA	PPA	NPA
Amikacin susceptibility testing						
<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/1) 0.0% - 79.3%	100.0% (3/3) 43.9% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (3/3) 43.9% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (3/3) 43.9% - 100.0%
<i>Enterobacter</i> spp.	0/0	94.7% (18/19) 75.4% - 99.1%	0/0	100.0% (19/19) 83.2% - 100.0%	0/0	94.7% (18/19) 75.4% - 99.1%
<i>Escherichia coli</i>	100.0% (3/3) 43.9% - 100.0%	89.0% (138/155) 83.1% - 93.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (155/155) 97.6% - 100.0%	100.0% (3/3) 43.9% - 100.0%	89.0% (138/155) 83.1% - 93.0%

Pathogen	<i>aac(6')-lb</i>		<i>armA</i>		Combined (<i>aac(6')-lb</i> , <i>armA</i>)	
	PPA	NPA	PPA	NPA	PPA	NPA
<i>Klebsiella</i> spp.	100.0% (1/1) 20.7% - 100.0%	91.9% (68/74) 83.4% - 96.2%	0.0% (0/1) 0.0% - 79.3%	100.0% (74/74) 95.1% - 100.0%	100.0% (1/1) 20.7% - 100.0%	91.9% (68/74) 83.4% - 96.2%
<i>Proteus</i> spp.	0/0	100.0% (21/21) 84.5% - 100.0%	0/0	100.0% (21/21) 84.5% - 100.0%	0/0	100.0% (21/21) 84.5% - 100.0%
<i>Pseudomonas aeruginosa</i>	0/0	100.0% (22/22) 85.1% - 100.0%	0/0	100.0% (22/22) 85.1% - 100.0%	0/0	100.0% (22/22) 85.1% - 100.0%
<i>Serratia</i> spp.	0/0	100.0% (16/16) 80.6% - 100.0%	0/0	100.0% (16/16) 80.6% - 100.0%	0/0	100.0% (16/16) 80.6% - 100.0%
Gentamicin susceptibility testing						
<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (11/11) 74.1% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (11/11) 74.1% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/2) 0.0% - 65.8%	97.3% (36/37) 86.2% - 99.5%	0.0% (0/2) 0.0% - 65.8%	100.0% (37/37) 90.6% - 100.0%	0.0% (0/2) 0.0% - 65.8%	97.3% (36/37) 86.2% - 99.5%
<i>Escherichia coli</i>	34.3% (12/35) 20.8% - 50.8%	94.0% (221/235) 90.2% - 96.4%	0.0% (0/35) 0.0% - 9.9%	100.0% (235/235) 98.4% - 100.0%	34.3% (12/35) 20.8% - 50.8%	94.0% (221/235) 90.2% - 96.4%
<i>Klebsiella</i> spp.	88.9% (8/9) 56.5% - 98.0%	96.9% (126/130) 92.4% - 98.8%	0.0% (0/9) 0.0% - 29.9%	100.0% (130/130) 97.1% - 100.0%	88.9% (8/9) 56.5% - 98.0%	96.9% (126/130) 92.4% - 98.8%
<i>Proteus</i> spp.	0.0% (0/5) 0.0% - 43.4%	97.5% (39/40) 87.1% - 99.6%	0.0% (0/5) 0.0% - 43.4%	100.0% (40/40) 91.2% - 100.0%	0.0% (0/5) 0.0% - 43.4%	97.5% (39/40) 87.1% - 99.6%
<i>Pseudomonas aeruginosa</i>	0.0% (0/7) 0.0% - 35.4%	100.0% (18/18) 82.4% - 100.0%	0.0% (0/7) 0.0% - 35.4%	100.0% (18/18) 82.4% - 100.0%	0.0% (0/7) 0.0% - 35.4%	100.0% (18/18) 82.4% - 100.0%
<i>Salmonella</i> spp.	0/0	100.0% (20/20) 83.9% - 100.0%	0/0	100.0% (20/20) 83.9% - 100.0%	0/0	100.0% (20/20) 83.9% - 100.0%
<i>Serratia</i> spp.	0/0	100.0% (30/30) 88.6% - 100.0%	0/0	100.0% (30/30) 88.6% - 100.0%	0/0	100.0% (30/30) 88.6% - 100.0%
Tobramycin susceptibility testing						
<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/1) 0.0% - 79.3%	100.0% (3/3) 43.9% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (3/3) 43.9% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (3/3) 43.9% - 100.0%
<i>Enterobacter</i> spp.	0/0	95.2% (20/21) 77.3% - 99.2%	0/0	100.0% (21/21) 84.5% - 100.0%	0/0	95.2% (20/21) 77.3% - 99.2%
<i>Escherichia coli</i>	54.5% (18/33) 38.0% - 70.2%	98.5% (128/130) 94.6% - 99.6%	0.0% (0/33) 0.0% - 10.4%	100.0% (130/130) 97.1% - 100.0%	54.5% (18/33) 38.0% - 70.2%	98.5% (128/130) 94.6% - 99.6%
<i>Klebsiella</i> spp.	88.9% (8/9) 56.5% - 98.0%	100.0% (75/75) 95.1% - 100.0%	0.0% (0/9) 0.0% - 29.9%	100.0% (75/75) 95.1% - 100.0%	88.9% (8/9) 56.5% - 98.0%	100.0% (75/75) 95.1% - 100.0%
<i>Proteus</i> spp.	0.0% (0/2) 0.0% - 65.8%	100.0% (21/21) 84.5% - 100.0%	0.0% (0/2) 0.0% - 65.8%	100.0% (21/21) 84.5% - 100.0%	0.0% (0/2) 0.0% - 65.8%	100.0% (21/21) 84.5% - 100.0%
<i>Pseudomonas aeruginosa</i>	0.0% (0/3) 0.0% - 56.1%	100.0% (26/26) 87.1% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (26/26) 87.1% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (26/26) 87.1% - 100.0%
<i>Serratia</i> spp.	0.0% (0/3) 0.0% - 56.1%	100.0% (14/14) 78.5% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (14/14) 78.5% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (14/14) 78.5% - 100.0%

Table 46 Performance of *armA* Compared to Phenotypic AST Results for Amikacin and Tobramycin in Contrived Samples

Pathogen	<i>armA</i>	
	PPA	NPA
Amikacin susceptibility testing		
<i>A. calcoaceticus-baumannii</i> complex	100.0% (60/60) 94.0% - 100.0%	0/0
Tobramycin susceptibility testing		
<i>A. calcoaceticus-baumannii</i> complex	100.0% (40/40) 91.2% - 100.0%	0/0

The performance of SHV and TEM resistance markers compared to phenotypic AST results for penicillin-class antibiotics by relevant organisms is presented in [Table 47](#). Since either or both SHV and TEM may be present in an ampicillin or penicillin resistant isolate, the overall genotypic/phenotypic pattern correlation is a combination of SHV and TEM results. Note that antimicrobial resistance is known to occur via mechanisms other than presence of TEM and SHV genes, therefore absence does not infer phenotypic susceptibility.

Table 47: Performance of SHV and TEM Compared to Phenotypic AST Results for Ampicillin and Penicillin in Clinical Specimens

Pathogen	SHV		TEM		Combined (SHV, TEM)	
	PPA	NPA	PPA	NPA	PPA	NPA
Ampicillin susceptibility testing						
<i>Enterobacter</i> spp.	6.3% (1/16) 1.1% - 28.3%	0/0	0.0% (0/16) 0.0% - 19.4%	0/0	6.3% (1/16) 1.1% - 28.3%	0/0
<i>Escherichia coli</i>	6.5% (11/168) 3.7% - 11.3%	99.0% (95/96) 94.3% - 99.8%	70.6% (120/170) 63.3% - 76.9%	97.9% (94/96) 92.7% - 99.4%	74.7% (127/170) 67.7% - 80.6%	96.9% (93/96) 91.2% - 98.9%
<i>Haemophilus influenzae</i>	N/A	N/A	27.3% (3/11) 9.7% - 56.6%	100.0% (6/6) 61.0% - 100.0%	27.3% (3/11) 9.7% - 56.6%	100.0% (6/6) 61.0% - 100.0%
<i>Klebsiella</i> spp.	73.3% (55/75) 62.4% - 82.0%	66.7% (2/3) 20.8% - 93.9%	17.3% (13/75) 10.4% - 27.4%	100.0% (3/3) 43.9% - 100.0%	73.3% (55/75) 62.4% - 82.0%	66.7% (2/3) 20.8% - 93.9%
<i>Proteus</i> spp.	0.0% (0/10) 0.0% - 27.8%	100.0% (32/32) 89.3% - 100.0%	30.0% (3/10) 10.8% - 60.3%	100.0% (32/32) 89.3% - 100.0%	30.0% (3/10) 10.8% - 60.3%	100.0% (32/32) 89.3% - 100.0%
<i>Salmonella</i> spp.	0.0% (0/1) 0.0% - 79.3%	100.0% (27/27) 87.5% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (27/27) 87.5% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (27/27) 87.5% - 100.0%
<i>Serratia</i> spp.	14.3% (1/7) 2.6% - 51.3%	100.0% (1/1) 20.7% - 100.0%	0.0% (0/7) 0.0% - 35.4%	100.0% (1/1) 20.7% - 100.0%	14.3% (1/7) 2.6% - 51.3%	100.0% (1/1) 20.7% - 100.0%
Penicillin susceptibility testing						
<i>Bacteroides fragilis</i>	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	0/0	0.0% (0/1) 0.0% - 79.3%	0/0
<i>Neisseria meningitidis</i>	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (2/2) 34.2% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (2/2) 34.2% - 100.0%

The performance of TEM, SHV, PER, CTX-M, VEB and GES resistance markers compared to phenotypic AST results for extended spectrum cephalosporin-class antibiotics by relevant organisms is presented in [Table 48](#), [Table 49](#), and [Table 50](#). Note: TEM and SHV variants have varying substrate spectrums (i.e. their effect on cephalosporins depends on whether they are the narrow-spectrum parent enzymes or ESBL variants) which are not differentiated by the assay. Therefore, their detection does not necessarily denote resistance to extended spectrum

cephalosporins. Since one or more of the resistance markers may be present in an extended spectrum cephalosporin resistant isolate, the overall genotypic/phenotypic pattern correlation is a combination of TEM, SHV, PER, CTX-M, VEB and GES results. Note that antimicrobial resistance is known to occur via mechanisms other than presence of TEM, SHV, PER, CTX-M, VEB and GES genes therefore absence does not infer phenotypic susceptibility. In addition, phenotypic correlations for PER, VEB and GES was also performed with contrived samples by comparing to the AST results for extended spectrum cephalosporin reported on the certificate of analysis of the strains of relevant organisms. The combined results for clinical specimens and contrived samples are provided in [Table 48](#) while the breakdown is shown in [Table 49](#) for clinical specimens and [Table 50](#) for contrived specimens.

Table 48: Performance of TEM, SHV, PER, CTX-M, VEB and GES Compared to Phenotypic AST Results for Cefotaxime, Ceftazidime and Ceftriaxone in Clinical Specimens and Contrived Samples Combined

Pathogen	TEM		SHV		PER		CTX-M		VEB		GES		Combined (TEM, SHV, PER, CTX-M, VEB, GES)	
	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
Cefotaxime susceptibility testing														
<i>A. calcoaceticus-baumannii</i> complex	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/5) 0.0% - 43.4%	100.0% (4/4) 51.0% - 100.0%	0.0% (0/5) 0.0% - 43.4%	100.0% (4/4) 51.0% - 100.0%	0.0% (0/5) 0.0% - 43.4%	100.0% (4/4) 51.0% - 100.0%	0.0% (0/5) 0.0% - 43.4%	100.0% (4/4) 51.0% - 100.0%	0.0% (0/5) 0.0% - 43.4%	100.0% (4/4) 51.0% - 100.0%	0.0% (0/5) 0.0% - 43.4%	100.0% (4/4) 51.0% - 100.0%	0.0% (0/5) 0.0% - 43.4%	100.0% (4/4) 51.0% - 100.0%
<i>Escherichia coli</i>	71.4% (5/7) 35.9% - 91.8%	37.5% (9/24) 21.2% - 57.3%	28.6% (2/7) 8.2% - 64.1%	95.8% (23/24) 79.8% - 99.3%	0.0% (0/7) 0.0% - 35.4%	100.0% (24/24) 86.2% - 100.0%	71.4% (5/7) 35.9% - 91.8%	100.0% (24/24) 86.2% - 100.0%	0.0% (0/7) 0.0% - 35.4%	100.0% (24/24) 86.2% - 100.0%	0.0% (0/7) 0.0% - 35.4%	100.0% (24/24) 86.2% - 100.0%	100.0% (7/7) 64.6% - 100.0%	33.3% (8/24) 18.0% - 53.3%
<i>Klebsiella</i> spp.	66.7% (2/3) 20.8% - 93.9%	100.0% (10/10) 72.2% - 100.0%	100.0% (3/3) 43.9% - 100.0%	40.0% (4/10) 16.8% - 68.7%	0.0% (0/3) 0.0% - 56.1%	100.0% (10/10) 72.2% - 100.0%	100.0% (3/3) 43.9% - 100.0%	100.0% (10/10) 72.2% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (10/10) 72.2% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (10/10) 72.2% - 100.0%	100.0% (3/3) 43.9% - 100.0%	40.0% (4/10) 16.8% - 68.7%
<i>Proteus</i> spp.	0.0% (0/1) 0.0% - 79.3%	83.3% (5/6) 43.6% - 97.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (6/6) 61.0% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (6/6) 61.0% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (6/6) 61.0% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (6/6) 61.0% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	83.3% (5/6) 43.6% - 97.0%
<i>Salmonella</i> spp.	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	N/A	N/A	0/0	100.0% (1/1) 20.7% - 100.0%
Ceftazidime susceptibility testing														
<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/3) 0.0% - 56.1%	100.0% (7/7) 64.6% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (7/7) 64.6% - 100.0%	33.3% (1/3) 6.1% - 79.2%	100.0% (7/7) 64.6% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (7/7) 64.6% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (7/7) 64.6% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (7/7) 64.6% - 100.0%	33.3% (1/3) 6.1% - 79.2%	100.0% (7/7) 64.6% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/9) 0.0% - 29.9%	100.0% (13/13) 77.2% - 100.0%	0.0% (0/9) 0.0% - 29.9%	92.3% (12/13) 66.7% - 98.6%	0.0% (0/9) 0.0% - 29.9%	100.0% (13/13) 77.2% - 100.0%	0.0% (0/9) 0.0% - 29.9%	100.0% (13/13) 77.2% - 100.0%	0.0% (0/9) 0.0% - 29.9%	100.0% (13/13) 77.2% - 100.0%	0.0% (0/9) 0.0% - 29.9%	100.0% (13/13) 77.2% - 100.0%	0.0% (0/9) 0.0% - 29.9%	92.3% (12/13) 66.7% - 98.6%
<i>Escherichia coli</i>	52.2% (12/23) 33.0% - 70.8%	54.8% (57/104) 45.2% - 64.0%	17.4% (4/23) 7.0% - 37.1%	97.1% (101/104) 91.9% - 99.0%	24.2% (8/33) 12.8% - 41.0%	100.0% (104/104) 96.4% - 100.0%	60.9% (14/23) 40.8% - 77.8%	98.1% (102/104) 93.3% - 99.5%	0.0% (0/23) 0.0% - 14.3%	100.0% (104/104) 96.4% - 100.0%	0.0% (0/23) 0.0% - 14.3%	100.0% (104/104) 96.4% - 100.0%	84.8% (28/33) 69.1% - 93.3%	51.0% (53/104) 41.5% - 60.4%

Pathogen	TEM		SHV		PER		CTX-M		VEB		GES		Combined (TEM, SHV, PER, CTX-M, VEB, GES)	
	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
<i>Klebsiella</i> spp.	71.4% (5/7) 35.9% - 91.8%	94.8% (55/58) 85.9% - 98.2%	100.0% (7/7) 64.6% - 100.0%	34.5% (20/58) 23.6% - 47.3%	56.3% (9/16) 33.2% - 76.9%	100.0% (58/58) 93.8% - 100.0%	100.0% (7/7) 64.6% - 100.0%	96.6% (56/58) 88.3% - 99.0%	58.8% (10/17) 36.0% - 78.4%	100.0% (58/58) 93.8% - 100.0%	58.8% (10/17) 36.0% - 78.4%	100.0% (58/58) 93.8% - 100.0%	100.0% (36/36) 90.4% - 100.0%	32.8% (19/58) 22.1% - 45.6%
<i>Proteus</i> spp.	0.0% (0/2) 0.0% - 65.8%	90.3% (28/31) 75.1% - 96.7%	0.0% (0/2) 0.0% - 65.8%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/2) 0.0% - 65.8%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/2) 0.0% - 65.8%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/2) 0.0% - 65.8%	100.0% (31/31) 89.0% - 100.0%	N/A	N/A	0.0% (0/2) 0.0% - 65.8%	90.3% (28/31) 75.1% - 96.7%
<i>Pseudomonas aeruginosa</i>	0.0% (0/4) 0.0% - 49.0%	100.0% (22/22) 85.1% - 100.0%	0.0% (0/4) 0.0% - 49.0%	100.0% (22/22) 85.1% - 100.0%	83.3% (20/24) 64.1% - 93.3%	100.0% (22/22) 85.1% - 100.0%	0.0% (0/4) 0.0% - 49.0%	100.0% (22/22) 85.1% - 100.0%	90.5% (38/42) 77.9% - 96.2%	100.0% (22/22) 85.1% - 100.0%	83.3% (20/24) 64.1% - 93.3%	100.0% (22/22) 85.1% - 100.0%	95.1% (78/82) 88.1% - 98.1%	100.0% (22/22) 85.1% - 100.0%
<i>Salmonella</i> spp.	0.0% (0/1) 0.0% - 79.3%	94.7% (18/19) 75.4% - 99.1%	0.0% (0/1) 0.0% - 79.3%	100.0% (19/19) 83.2% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (19/19) 83.2% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (19/19) 83.2% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (19/19) 83.2% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	94.7% (18/19) 75.4% - 99.1%
<i>Serratia</i> spp.	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	0.0% (0/1) 0.0% - 79.3%	90.9% (10/11) 62.3% - 98.4%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	0.0% (0/1) 0.0% - 79.3%	90.9% (10/11) 62.3% - 98.4%
Ceftriaxone susceptibility testing														
<i>A. calcoaceticus-baumannii</i> complex	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/3) 0.0% - 56.1%	100.0% (2/2) 34.2% - 100.0%	0.0% (0/3) 0.0% - 56.1%	50.0% (1/2) 9.5% - 90.5%	0.0% (0/3) 0.0% - 56.1%	100.0% (2/2) 34.2% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (2/2) 34.2% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (2/2) 34.2% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (2/2) 34.2% - 100.0%	0.0% (0/3) 0.0% - 56.1%	50.0% (1/2) 9.5% - 90.5%
<i>Escherichia coli</i>	20.0% (6/30) 9.5% - 37.3%	50.9% (85/167) 43.4% - 58.4%	3.3% (1/30) 0.6% - 16.7%	97.0% (160/165) 93.1% - 98.7%	20.0% (8/40) 10.5% - 34.8%	100.0% (165/165) 97.7% - 100.0%	93.3% (28/30) 78.7% - 98.2%	98.8% (163/165) 95.7% - 99.7%	0.0% (0/30) 0.0% - 11.4%	100.0% (165/165) 97.7% - 100.0%	0.0% (0/30) 0.0% - 11.4%	100.0% (165/165) 97.7% - 100.0%	95.0% (38/40) 83.5% - 98.6%	48.5% (81/167) 41.0% - 56.0%
<i>Haemophilus influenzae</i>	0/0	100.0% (2/2) 34.2% - 100.0%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0/0	100.0% (2/2) 34.2% - 100.0%
<i>Klebsiella</i> spp.	76.9% (10/13) 49.7% - 91.8%	96.4% (80/83) 89.9% - 98.8%	100.0% (13/13) 77.2% - 100.0%	32.5% (27/83) 23.4% - 43.2%	40.9% (9/22) 23.3% - 61.3%	100.0% (83/83) 95.6% - 100.0%	100.0% (13/13) 77.2% - 100.0%	98.8% (82/83) 93.5% - 99.8%	43.5% (10/23) 25.6% - 63.2%	100.0% (83/83) 95.6% - 100.0%	43.5% (10/23) 25.6% - 63.2%	100.0% (83/83) 95.6% - 100.0%	100.0% (42/42) 91.6% - 100.0%	31.3% (26/83) 22.4% - 41.9%
<i>Neisseria meningitidis</i>	0/0	100.0% (6/6) 61.0% - 100.0%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0/0	100.0% (6/6) 61.0% - 100.0%

Pathogen	TEM		SHV		PER		CTX-M		VEB		GES		Combined (TEM, SHV, PER, CTX-M, VEB, GES)	
	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
<i>Proteus</i> spp.	0/0	95.7% (22/23) 79.0% - 99.2%	0/0	100.0% (23/23) 85.7% - 100.0%	0/0	100.0% (23/23) 85.7% - 100.0%	0/0	100.0% (23/23) 85.7% - 100.0%	0/0	100.0% (23/23) 85.7% - 100.0%	N/A	N/A	0/0	95.7% (22/23) 79.0% - 99.2%
<i>Salmonella</i> spp.	0/0	93.8% (15/16) 71.7% - 98.9%	0/0	100.0% (16/16) 80.6% - 100.0%	0/0	100.0% (16/16) 80.6% - 100.0%	0/0	100.0% (16/16) 80.6% - 100.0%	0/0	100.0% (16/16) 80.6% - 100.0%	N/A	N/A	0/0	93.8% (15/16) 71.7% - 98.9%
<i>Serratia</i> spp.	0.0% (0/1) 0.0% - 79.3%	100.0% (9/9) 70.1% - 100.0%	0.0% (0/1) 0.0% - 79.3%	88.9% (8/9) 56.5% - 98.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (9/9) 70.1% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (9/9) 70.1% - 100.0%	0.0% (0/1) 0.0% - 79.3%	88.9% (8/9) 56.5% - 98.0%

Table 49: Performance of TEM, SHV, PER, CTX-M, VEB and GES Compared to Phenotypic AST Results for Cefotaxime, Ceftazidime and Ceftriaxone in Clinical Specimens

Pathogen	TEM		SHV		PER		CTX-M		VEB		GES		Combined (TEM, SHV, PER, CTX-M, VEB, GES)	
	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
Cefotaxime susceptibility testing														
<i>A. calcoaceticus-baumannii</i> complex	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/5) 0.0% - 43.4%	100.0% (4/4) 51.0% - 100.0%	0.0% (0/5) 0.0% - 43.4%	100.0% (4/4) 51.0% - 100.0%	0.0% (0/5) 0.0% - 43.4%	100.0% (4/4) 51.0% - 100.0%	0.0% (0/5) 0.0% - 43.4%	100.0% (4/4) 51.0% - 100.0%	0.0% (0/5) 0.0% - 43.4%	100.0% (4/4) 51.0% - 100.0%	0.0% (0/5) 0.0% - 43.4%	100.0% (4/4) 51.0% - 100.0%	0.0% (0/5) 0.0% - 43.4%	100.0% (4/4) 51.0% - 100.0%
<i>Escherichia coli</i>	71.4% (5/7) 35.9% - 91.8%	37.5% (9/24) 21.2% - 57.3%	28.6% (2/7) 8.2% - 64.1%	95.8% (23/24) 79.8% - 99.3%	0.0% (0/7) 0.0% - 35.4%	100.0% (24/24) 86.2% - 100.0%	71.4% (5/7) 35.9% - 91.8%	100.0% (24/24) 86.2% - 100.0%	0.0% (0/7) 0.0% - 35.4%	100.0% (24/24) 86.2% - 100.0%	0.0% (0/7) 0.0% - 35.4%	100.0% (24/24) 86.2% - 100.0%	100.0% (7/7) 64.6% - 100.0%	33.3% (8/24) 18.0% - 53.3%
<i>Klebsiella</i> spp.	66.7% (2/3) 20.8% - 93.9%	100.0% (10/10) 72.2% - 100.0%	100.0% (3/3) 43.9% - 100.0%	40.0% (4/10) 16.8% - 68.7%	0.0% (0/3) 0.0% - 56.1%	100.0% (10/10) 72.2% - 100.0%	100.0% (3/3) 43.9% - 100.0%	100.0% (10/10) 72.2% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (10/10) 72.2% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (10/10) 72.2% - 100.0%	100.0% (3/3) 43.9% - 100.0%	40.0% (4/10) 16.8% - 68.7%
<i>Proteus</i> spp.	0.0% (0/1) 0.0% - 79.3%	83.3% (5/6) 43.6% - 97.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (6/6) 61.0% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (6/6) 61.0% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (6/6) 61.0% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (6/6) 61.0% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	83.3% (5/6) 43.6% - 97.0%

Pathogen	TEM		SHV		PER		CTX-M		VEB		GES		Combined (TEM, SHV, PER, CTX-M, VEB, GES)	
	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
<i>Salmonella</i> spp.	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	N/A	N/A	0/0	100.0% (1/1) 20.7% - 100.0%
Ceftazidime susceptibility testing														
<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/3) 0.0% - 56.1%	100.0% (7/7) 64.6% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (7/7) 64.6% - 100.0%	33.3% (1/3) 6.1% - 79.2%	100.0% (7/7) 64.6% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (7/7) 64.6% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (7/7) 64.6% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (7/7) 64.6% - 100.0%	33.3% (1/3) 6.1% - 79.2%	100.0% (7/7) 64.6% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/9) 0.0% - 29.9%	100.0% (13/13) 77.2% - 100.0%	0.0% (0/9) 0.0% - 29.9%	92.3% (12/13) 66.7% - 98.6%	0.0% (0/9) 0.0% - 29.9%	100.0% (13/13) 77.2% - 100.0%	0.0% (0/9) 0.0% - 29.9%	100.0% (13/13) 77.2% - 100.0%	0.0% (0/9) 0.0% - 29.9%	100.0% (13/13) 77.2% - 100.0%	0.0% (0/9) 0.0% - 29.9%	100.0% (13/13) 77.2% - 100.0%	0.0% (0/9) 0.0% - 29.9%	92.3% (12/13) 66.7% - 98.6%
<i>Escherichia coli</i>	52.2% (12/23) 33.0% - 70.8%	54.8% (57/104) 45.2% - 64.0%	17.4% (4/23) 7.0% - 37.1%	97.1% (101/104) 91.9% - 99.0%	0.0% (0/23) 0.0% - 14.3%	100.0% (104/104) 96.4% - 100.0%	60.9% (14/23) 40.8% - 77.8%	98.1% (102/104) 93.3% - 99.5%	0.0% (0/23) 0.0% - 14.3%	100.0% (104/104) 96.4% - 100.0%	0.0% (0/23) 0.0% - 14.3%	100.0% (104/104) 96.4% - 100.0%	87.0% (20/23) 67.9% - 95.5%	51.0% (53/104) 41.5% - 60.4%
<i>Klebsiella</i> spp.	71.4% (5/7) 35.9% - 91.8%	94.8% (55/58) 85.9% - 98.2%	100.0% (7/7) 64.6% - 100.0%	34.5% (20/58) 23.6% - 47.3%	0.0% (0/7) 0.0% - 35.4%	100.0% (58/58) 93.8% - 100.0%	100.0% (7/7) 64.6% - 100.0%	96.6% (56/58) 88.3% - 99.0%	0.0% (0/7) 0.0% - 35.4%	100.0% (58/58) 93.8% - 100.0%	0.0% (0/7) 0.0% - 35.4%	100.0% (58/58) 93.8% - 100.0%	100.0% (7/7) 64.6% - 100.0%	32.8% (19/58) 22.1% - 45.6%
<i>Proteus</i> spp.	0.0% (0/2) 0.0% - 65.8%	90.3% (28/31) 75.1% - 96.7%	0.0% (0/2) 0.0% - 65.8%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/2) 0.0% - 65.8%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/2) 0.0% - 65.8%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/2) 0.0% - 65.8%	100.0% (31/31) 89.0% - 100.0%	N/A	N/A	0.0% (0/2) 0.0% - 65.8%	90.3% (28/31) 75.1% - 96.7%
<i>Pseudomonas aeruginosa</i>	0.0% (0/4) 0.0% - 49.0%	100.0% (22/22) 85.1% - 100.0%	0.0% (0/4) 0.0% - 49.0%	100.0% (22/22) 85.1% - 100.0%	0.0% (0/4) 0.0% - 49.0%	100.0% (22/22) 85.1% - 100.0%	0.0% (0/4) 0.0% - 49.0%	100.0% (22/22) 85.1% - 100.0%	0.0% (0/4) 0.0% - 49.0%	100.0% (22/22) 85.1% - 100.0%	0.0% (0/4) 0.0% - 49.0%	100.0% (22/22) 85.1% - 100.0%	0.0% (0/4) 0.0% - 49.0%	100.0% (22/22) 85.1% - 100.0%
<i>Salmonella</i> spp.	0.0% (0/1) 0.0% - 79.3%	94.7% (18/19) 75.4% - 99.1%	0.0% (0/1) 0.0% - 79.3%	100.0% (19/19) 83.2% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (19/19) 83.2% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (19/19) 83.2% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (19/19) 83.2% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	94.7% (18/19) 75.4% - 99.1%
<i>Serratia</i> spp.	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	0.0% (0/1) 0.0% - 79.3%	90.9% (10/11) 62.3% - 98.4%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	0.0% (0/1) 0.0% - 79.3%	90.9% (10/11) 62.3% - 98.4%
Ceftriaxone susceptibility testing														
<i>A. calcoaceticus-baumannii</i> complex	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%

Pathogen	TEM		SHV		PER		CTX-M		VEB		GES		Combined (TEM, SHV, PER, CTX-M, VEB, GES)	
	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
<i>Enterobacter</i> spp.	0.0% (0/3) 0.0% - 56.1%	100.0% (2/2) 34.2% - 100.0%	0.0% (0/3) 0.0% - 56.1%	50.0% (1/2) 9.5% - 90.5%	0.0% (0/3) 0.0% - 56.1%	100.0% (2/2) 34.2% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (2/2) 34.2% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (2/2) 34.2% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (2/2) 34.2% - 100.0%	0.0% (0/3) 0.0% - 56.1%	50.0% (1/2) 9.5% - 90.5%
<i>Escherichia coli</i>	20.0% (6/30) 9.5% - 37.3%	50.9% (85/167) 43.4% - 58.4%	3.3% (1/30) 0.6% - 16.7%	97.0% (160/165) 93.1% - 98.7%	0.0% (0/30) 0.0% - 11.4%	100.0% (165/165) 97.7% - 100.0%	93.3% (28/30) 78.7% - 98.2%	98.8% (163/165) 95.7% - 99.7%	0.0% (0/30) 0.0% - 11.4%	100.0% (165/165) 97.7% - 100.0%	0.0% (0/30) 0.0% - 11.4%	100.0% (165/165) 97.7% - 100.0%	100.0% (30/30) 88.6% - 100.0%	48.5% (81/167) 41.0% - 56.0%
<i>Haemophilus influenzae</i>	0/0	100.0% (2/2) 34.2% - 100.0%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0/0	100.0% (2/2) 34.2% - 100.0%
<i>Klebsiella</i> spp.	76.9% (10/13) 49.7% - 91.8%	96.4% (80/83) 89.9% - 98.8%	100.0% (13/13) 77.2% - 100.0%	32.5% (27/83) 23.4% - 43.2%	0.0% (0/13) 0.0% - 22.8%	100.0% (83/83) 95.6% - 100.0%	100.0% (13/13) 77.2% - 100.0%	98.8% (82/83) 93.5% - 99.8%	0.0% (0/13) 0.0% - 22.8%	100.0% (83/83) 95.6% - 100.0%	0.0% (0/13) 0.0% - 22.8%	100.0% (83/83) 95.6% - 100.0%	100.0% (13/13) 77.2% - 100.0%	31.3% (26/83) 22.4% - 41.9%
<i>Neisseria meningitidis</i>	0/0	100.0% (6/6) 61.0% - 100.0%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0/0	100.0% (6/6) 61.0% - 100.0%
<i>Proteus</i> spp.	0/0	95.7% (22/23) 79.0% - 99.2%	0/0	100.0% (23/23) 85.7% - 100.0%	0/0	100.0% (23/23) 85.7% - 100.0%	0/0	100.0% (23/23) 85.7% - 100.0%	0/0	100.0% (23/23) 85.7% - 100.0%	N/A	N/A	0/0	95.7% (22/23) 79.0% - 99.2%
<i>Salmonella</i> spp.	0/0	93.8% (15/16) 71.7% - 98.9%	0/0	100.0% (16/16) 80.6% - 100.0%	0/0	100.0% (16/16) 80.6% - 100.0%	0/0	100.0% (16/16) 80.6% - 100.0%	0/0	100.0% (16/16) 80.6% - 100.0%	N/A	N/A	0/0	93.8% (15/16) 71.7% - 98.9%
<i>Serratia</i> spp.	0.0% (0/1) 0.0% - 79.3%	100.0% (9/9) 70.1% - 100.0%	0.0% (0/1) 0.0% - 79.3%	88.9% (8/9) 56.5% - 98.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (9/9) 70.1% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (9/9) 70.1% - 100.0%	0.0% (0/1) 0.0% - 79.3%	88.9% (8/9) 56.5% - 98.0%

Table 50: Performance of PER, VEB and GES Compared to Phenotypic AST Results for Ceftazidime and Ceftriaxone in Contrived samples

Pathogen	PER		VEB		GES		All Combined (PER, VEB, GES)	
	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
Ceftazidime susceptibility testing								
<i>Escherichia coli</i>	80.0% (8/10) 49.0% - 94.3%	0/0	N/A	N/A	N/A	N/A	80.0% (8/10) 49.0% - 94.3%	0/0
<i>Klebsiella</i> spp.	100.0% (9/9) 70.1% - 100.0%	0/0	100.0% (10/10) 72.2% - 100.0%	0/0	100.0% (10/10) 72.2% - 100.0%	0/0	100.0% (29/29) 88.3% - 100.0%	0/0
<i>Pseudomonas aeruginosa</i>	100.0% (20/20) 83.9% - 100.0%	0/0	100.0% (38/38) 90.8% - 100.0%	0/0	100.0% (20/20) 83.9% - 100.0%	0/0	100.0% (78/78) 95.3% - 100.0%	0/0
Ceftriaxone susceptibility testing								
<i>Escherichia coli</i>	80.0% (8/10) 49.0% - 94.3%	0/0	N/A	N/A	N/A	N/A	80.0% (8/10) 49.0% - 94.3%	0/0
<i>Klebsiella</i> spp.	100.0% (9/9) 70.1% - 100.0%	0/0	100.0% (10/10) 72.2% - 100.0%	0/0	100.0% (10/10) 72.2% - 100.0%	0/0	100.0% (29/29) 88.3% - 100.0%	0/0

The performance of VEB, *ampC*, CTX-M and KPC resistance markers compared to phenotypic AST results for monobactam-class antibiotic (aztreonam) by relevant organisms is presented [Table 51](#), [Table 52](#), and [Table 53](#). Since one or more of the resistance markers may be present in an aztreonam resistant isolate, the overall genotypic/phenotypic pattern correlation is a combination of VEB, *ampC*, CTX-M and KPC results. Note that antimicrobial resistance is known to occur via mechanisms other than presence of VEB, *ampC*, CTX-M and KPC genes therefore absence does not infer phenotypic susceptibility. In addition, phenotypic correlations for VEB was also performed with contrived samples by comparing to the AST results for monobactam reported on the certificate of analysis of the strains of relevant organisms. The combined results for clinical specimens and contrived samples are provided in [Table 51](#) while the breakdown is shown in [Table 52](#) for clinical specimens and [Table 53](#) and for contrived specimens.

Table 51: Performance of VEB, *ampC*, CTX-M and KPC Compared to Phenotypic AST Results for Aztreonam in Clinical Specimens and Contrived Samples Combined

Pathogen	VEB		<i>ampC</i>		CTX-M		KPC		Combined (VEB, <i>ampC</i> , CTX-M, KPC)	
	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
Aztreonam susceptibility testing										
<i>Enterobacter</i> spp.	0.0% (0/3) 0.0% - 56.1%	100.0% (5/5) 56.6% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (5/5) 56.6% - 100.0%	0.0% (0/3) 0.0% - 56.1%	80.0% (4/5) 37.6% - 96.4%	0.0% (0/3) 0.0% - 56.1%	100.0% (5/5) 56.6% - 100.0%	0.0% (0/3) 0.0% - 56.1%	80.0% (4/5) 37.6% - 96.4%
<i>Escherichia coli</i>	0.0% (0/9) 0.0% - 29.9%	100.0% (53/53) 93.2% - 100.0%	0.0% (0/9) 0.0% - 29.9%	98.1% (52/53) 90.1% - 99.7%	88.9% (8/9) 56.5% - 98.0%	98.1% (52/53) 90.1% - 99.7%	0.0% (0/9) 0.0% - 29.9%	100.0% (53/53) 93.2% - 100.0%	94.7% (18/19) 75.4% - 99.1%	96.2% (51/53) 87.2% - 99.0%
<i>Klebsiella</i> spp.	76.9% (10/13) 49.7% - 91.8%	100.0% (36/36) 90.4% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (36/36) 90.4% - 100.0%	100.0% (3/3) 43.9% - 100.0%	97.2% (35/36) 85.8% - 99.5%	0.0% (0/3) 0.0% - 56.1%	100.0% (36/36) 90.4% - 100.0%	100.0% (13/13) 77.2% - 100.0%	97.2% (35/36) 85.8% - 99.5%
<i>Proteus</i> spp.	0/0	100.0% (12/12) 75.8% - 100.0%	0/0	91.7% (11/12) 64.6% - 98.5%	0/0	100.0% (12/12) 75.8% - 100.0%	0/0	100.0% (12/12) 75.8% - 100.0%	0/0	91.7% (11/12) 64.6% - 98.5%
<i>Pseudomonas aeruginosa</i>	88.4% (38/43) 75.5% - 94.9%	100.0% (12/12) 75.8% - 100.0%	0.0% (0/5) 0.0% - 43.4%	91.7% (11/12) 64.6% - 98.5%	0.0% (0/5) 0.0% - 43.4%	100.0% (12/12) 75.8% - 100.0%	0.0% (0/5) 0.0% - 43.4%	100.0% (12/12) 75.8% - 100.0%	90.6% (48/53) 79.7% - 95.9%	91.7% (11/12) 64.6% - 98.5%
<i>Serratia</i> spp.	N/A	N/A	0/0	100.0% (6/6) 61.0% - 100.0%	0/0	100.0% (6/6) 61.0% - 100.0%	0/0	100.0% (6/6) 61.0% - 100.0%	0/0	23.1% (6/26) 11.0% - 42.1%

Table 52: Performance of VEB, *ampC*, CTX-M and KPC Compared to Phenotypic AST Results for Aztreonam in Clinical Specimens

Pathogen	VEB		<i>ampC</i>		CTX-M		KPC		Combined (VEB, <i>ampC</i> , CTX-M, KPC)	
	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
Aztreonam susceptibility testing										
<i>Enterobacter</i> spp.	0.0% (0/3) 0.0% - 56.1%	100.0% (5/5) 56.6% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (5/5) 56.6% - 100.0%	0.0% (0/3) 0.0% - 56.1%	80.0% (4/5) 37.6% - 96.4%	0.0% (0/3) 0.0% - 56.1%	100.0% (5/5) 56.6% - 100.0%	0.0% (0/3) 0.0% - 56.1%	80.0% (4/5) 37.6% - 96.4%
<i>Escherichia coli</i>	0.0% (0/9) 0.0% - 29.9%	100.0% (53/53) 93.2% - 100.0%	0.0% (0/9) 0.0% - 29.9%	98.1% (52/53) 90.1% - 99.7%	88.9% (8/9) 56.5% - 98.0%	98.1% (52/53) 90.1% - 99.7%	0.0% (0/9) 0.0% - 29.9%	100.0% (53/53) 93.2% - 100.0%	88.9% (8/9) 56.5% - 98.0%	96.2% (51/53) 87.2% - 99.0%
<i>Klebsiella</i> spp.	0.0% (0/3) 0.0% - 56.1%	100.0% (36/36) 90.4% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (36/36) 90.4% - 100.0%	100.0% (3/3) 43.9% - 100.0%	97.2% (35/36) 85.8% - 99.5%	0.0% (0/3) 0.0% - 56.1%	100.0% (36/36) 90.4% - 100.0%	100.0% (3/3) 43.9% - 100.0%	97.2% (35/36) 85.8% - 99.5%
<i>Proteus</i> spp.	0/0	100.0% (12/12) 75.8% - 100.0%	0/0	91.7% (11/12) 64.6% - 98.5%	0/0	100.0% (12/12) 75.8% - 100.0%	0/0	100.0% (12/12) 75.8% - 100.0%	0/0	91.7% (11/12) 64.6% - 98.5%
<i>Pseudomonas aeruginosa</i>	0.0% (0/5) 0.0% - 43.4%	100.0% (12/12) 75.8% - 100.0%	0.0% (0/5) 0.0% - 43.4%	91.7% (11/12) 64.6% - 98.5%	0.0% (0/5) 0.0% - 43.4%	100.0% (12/12) 75.8% - 100.0%	0.0% (0/5) 0.0% - 43.4%	100.0% (12/12) 75.8% - 100.0%	0.0% (0/5) 0.0% - 43.4%	91.7% (11/12) 64.6% - 98.5%
<i>Serratia</i> spp.	N/A	N/A	0/0	100.0% (6/6) 61.0% - 100.0%	0/0	100.0% (6/6) 61.0% - 100.0%	0/0	100.0% (6/6) 61.0% - 100.0%	0/0	100.0% (6/6) 61.0% - 100.0%

Table 53: Performance of VEB to Phenotypic AST Results for Aztreonam in Contrived samples

Pathogen	VEB	
	PPA	NPA
Aztreonam susceptibility testing		
<i>Escherichia coli</i>	N/A	N/A
<i>Klebsiella</i> spp.	100.0% (10/10) 72.2% - 100.0%	0/0
<i>Pseudomonas aeruginosa</i>	100.0% (38/38) 90.8% - 100.0%	0/0
<i>Serratia</i> spp.	N/A	N/A

The performance of KPC, NDM, IMP, SPM, GES, VIM, OXA-23, OXA-48-like, OXA24/40 and OXA-58 resistance markers compared to phenotypic AST results for carbapenem-class antibiotic by relevant organisms is presented in [Table 54](#), [Table 55](#), and [Table 56](#). Since one or more of the resistance markers may be present in carbapenem resistant isolates, the overall genotypic/phenotypic pattern correlation is a combination of KPC, NDM, IMP, SPM, GES, VIM, OXA-23, OXA-48-like, OXA24/40 and OXA-58 results. Some variants of GES may be extended spectrum beta-lactamases and some may be carbapenemases. The assay does not distinguish those variants. Note that antimicrobial resistance is known to occur via mechanisms other than presence of KPC, NDM, IMP, SPM, GES, VIM, OXA-23, OXA-48-like, OXA24/40 and OXA-58 genes therefore absence does not infer phenotypic susceptibility. In addition, phenotypic correlations for KPC, NDM, IMP, SPM, GES, VIM, OXA-23, OXA-48-like, OXA24/40 and OXA-58 was also performed with contrived samples by comparing to the AST results for Carbapenem reported on the certificate of analysis of the strains of relevant organisms. The combined results for clinical specimens and contrived samples are provided in [Table 54](#) while the breakdown is shown in [Table 55](#) for clinical specimens and [Table 56](#) for contrived specimens.

Table 54: Performance of KPC, NDM, IMP, SPM, GES, VIM, OXA-23, OXA-48-like, OXA24/40 and OXA-58 Compared to Phenotypic AST Results for Carbapenem in Clinical Specimens and Contrived Samples Combined

Pathogen	KPC		NDM		IMP		SPM		GES		VIM		OXA-23		OXA-48-like		OXA-24/40		OXA-58		Combined (KPC, NDM, IMP, SPM, GES,VIM, OXA- 23, OXA-48-like, OXA-24/40, OXA-58)	
	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
Ertapenem susceptibility testing																						
<i>Enterobacter</i> <i>r</i> spp.	71.4% (10/14) 45.4% - 88.3%	100.0% (13/13) 77.2% - 100.0%	0.0% (0/4) 0.0% - 49.0%	100.0% (13/13) 77.2% - 100.0%	0.0% (0/4) 0.0% - 49.0%	100.0% (13/13) 77.2% - 100.0%	N/A	N/A	0.0% (0/4) 0.0% - 49.0%	100.0% (13/13) 77.2% - 100.0%	0.0% (0/4) 0.0% - 49.0%	100.0% (13/13) 77.2% - 100.0%	N/A	N/A	0.0% (0/4) 0.0% - 49.0%	100.0% (13/13) 77.2% - 100.0%	N/A	N/A	0.0% (0/4) 0.0% - 49.0%	100.0% (13/13) 77.2% - 100.0%	71.4% (10/14) 45.4% - 88.3%	100.0% (13/13) 77.2% - 100.0%
<i>Escherichia</i> <i>coli</i>	0.0% (0/6) 0.0% - 39.0%	100.0% (106/10 6) 96.5% - 100.0%	16.7% (1/6) 3.0% - 56.4%	100.0% (106/10 6) 96.5% - 100.0%	0.0% (0/6) 0.0% - 39.0%	100.0% (105/10 5) 96.5% - 100.0%	N/A	N/A	0.0% (0/6) 0.0% - 39.0%	100.0% (106/10 6) 96.5% - 100.0%	16.7% (1/6) 3.0% - 56.4%	91.4% (106/11 6) 84.9% - 95.3%	N/A	N/A	0.0% (0/6) 0.0% - 39.0%	100.0% (106/10 6) 96.5% - 100.0%	N/A	N/A	0.0% (0/6) 0.0% - 39.0%	100.0% (106/10 6) 96.5% - 100.0%	33.3% (2/6) 9.7% - 70.0%	91.4% (106/116) 84.9% - 95.3%
<i>Klebsiella</i> spp.	90.9% (10/11) 62.3% - 98.4%	100.0% (64/64) 94.3% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (64/64) 94.3% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (64/64) 94.3% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (64/64) 94.3% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (64/64) 94.3% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (64/64) 94.3% - 100.0%	95.2% (20/21) 77.3% - 99.2%	100.0% (64/64) 94.3% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (64/64) 94.3% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (64/64) 94.3% - 100.0%	100.0% (31/31) 89.0% - 100.0%	100.0% (64/64) 94.3% - 100.0%
<i>Proteus</i> spp.	0.0% (0/1) 0.0% - 79.3%	100.0% (18/18) 82.4% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (18/18) 82.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (18/18) 82.4% - 100.0%	N/A	N/A	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (18/18) 82.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (18/18) 82.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (18/18) 82.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (18/18) 82.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (18/18) 82.4% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (18/18) 82.4% - 100.0%
<i>Salmonella</i> spp.	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	N/A	N/A	N/A	N/A	0/0	100.0% (1/1) 20.7% - 100.0%	N/A	N/A	0/0	100.0% (1/1) 20.7% - 100.0%	N/A	N/A	N/A	N/A	0/0	100.0% (1/1) 20.7% - 100.0%
<i>Serratia</i> spp.	0/0	100.0% (7/7) 64.6% - 100.0%	0/0	100.0% (7/7) 64.6% - 100.0%	0/0	100.0% (7/7) 64.6% - 100.0%	N/A	N/A	0/0	100.0% (7/7) 64.6% - 100.0%	100.0% (10/10) 72.2% - 100.0%	41.2% (7/17) 21.6% - 64.0%	N/A	N/A	0/0	100.0% (7/7) 64.6% - 100.0%	N/A	N/A	N/A	N/A	100.0% (10/10) 72.2% - 100.0%	41.2% (7/17) 21.6% - 64.0%
Imipenem susceptibility testing																						
<i>A. calcoaceticu</i> <i>s-baumannii</i> complex	0/0	100.0% (1/1) 20.7% - 100.0%	100.0% (10/10) 72.2% - 100.0%	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	100.0% (60/60) 94.0% - 100.0%	100.0% (1/1) 20.7% - 100.0%	N/A	N/A	100.0% (40/40) 91.2% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (50/50) 92.9% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (130/130) 97.1% - 100.0%	100.0% (1/1) 20.7% - 100.0%
<i>Enterobacter</i> <i>r</i> spp.	100.0% (10/10) 72.2% - 100.0%	100.0% (12/12) 75.8% - 100.0%	0/0	100.0% (12/12) 75.8% - 100.0%	0/0	100.0% (12/12) 75.8% - 100.0%	N/A	N/A	0/0	100.0% (12/12) 75.8% - 100.0%	0/0	100.0% (12/12) 75.8% - 100.0%	N/A	N/A	0/0	100.0% (12/12) 75.8% - 100.0%	N/A	N/A	0/0	100.0% (12/12) 75.8% - 100.0%	100.0% (10/10) 72.2% - 100.0%	100.0% (12/12) 75.8% - 100.0%
<i>Escherichia</i> <i>coli</i>	90.9% (10/11) 62.3% - 98.4%	100.0% (53/53) 93.2% - 100.0%	72.7% (8/11) 43.4% - 90.3%	100.0% (53/53) 93.2% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (52/52) 93.1% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (53/53) 93.2% - 100.0%	100.0% (11/11) 74.1% - 100.0%	100.0% (53/53) 93.2% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (53/53) 93.2% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (53/53) 93.2% - 100.0%	93.5% (29/31) 79.3% - 98.2%	100.0% (53/53) 93.2% - 100.0%

Pathogen	KPC		NDM		IMP		SPM		GES		VIM		OXA-23		OXA-48-like		OXA-24/40		OXA-58		Combined (KPC, NDM, IMP, SPM, GES,VIM, OXA- 23, OXA-48-like, OXA-24/40, OXA-58)	
	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
<i>Klebsiella</i> spp.	100.0% (20/20) 83.9% - 100.0%	100.0% (28/28) 87.9% - 100.0%	100.0% (10/10) 72.2% - 100.0%	100.0% (28/28) 87.9% - 100.0%	0/0	100.0% (28/28) 87.9% - 100.0%	N/A	N/A	100.0% (10/10) 72.2% - 100.0%	100.0% (28/28) 87.9% - 100.0%	0/0	100.0% (28/28) 87.9% - 100.0%	0/0	100.0% (28/28) 87.9% - 100.0%	100.0% (20/20) 83.9% - 100.0%	100.0% (28/28) 87.9% - 100.0%	0/0	100.0% (28/28) 87.9% - 100.0%	0/0	100.0% (28/28) 87.9% - 100.0%	100.0% (50/50) 92.9% - 100.0%	100.0% (28/28) 87.9% - 100.0%
<i>Proteus</i> spp.	0.0% (0/7) 0.0% - 35.4%	0/0	14.3% (1/7) 2.6% - 51.3%	0/0	0.0% (0/7) 0.0% - 35.4%	0/0	N/A	N/A	N/A	N/A	0.0% (0/7) 0.0% - 35.4%	0/0	0.0% (0/7) 0.0% - 35.4%	0/0	0.0% (0/7) 0.0% - 35.4%	0/0	0.0% (0/7) 0.0% - 35.4%	0/0	0.0% (0/7) 0.0% - 35.4%	0/0	14.3% (1/7) 2.6% - 51.3%	0/0
<i>Pseudomonas aeruginosa</i>	0/0	100.0% (5/5) 56.6% - 100.0%	100.0% (44/44) 92.0% - 100.0%	100.0% (5/5) 56.6% - 100.0%	100.0% (11/11) 74.1% - 100.0%	100.0% (5/5) 56.6% - 100.0%	80.0% (16/20) 58.4% - 91.9%	100.0% (5/5) 56.6% - 100.0%	0/0	20.0% (5/25) 8.9% - 39.1%	0/0	33.3% (5/15) 15.2% - 58.3%	0/0	100.0% (5/5) 56.6% - 100.0%	0/0	100.0% (5/5) 56.6% - 100.0%	0/0	100.0% (5/5) 56.6% - 100.0%	0/0	100.0% (5/5) 56.6% - 100.0%	93.8% (60/64) 85.0% - 97.5%	20.0% (5/25) 8.9% - 39.1%
<i>Salmonella</i> spp.	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	N/A	N/A	N/A	N/A	0/0	100.0% (1/1) 20.7% - 100.0%	N/A	N/A	0/0	100.0% (1/1) 20.7% - 100.0%	N/A	N/A	N/A	N/A	0/0	100.0% (1/1) 20.7% - 100.0%
<i>Serratia</i> spp.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100.0% (20/20) 83.9% - 100.0%	0/0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100.0% (20/20) 83.9% - 100.0%	0/0
Meropenem susceptibility testing																						
<i>A. calcoaceticus</i> <i>s-baumannii</i> complex	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	90.9% (10/11) 62.3% - 98.4%	100.0% (11/11) 74.1% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	100.0% (61/61) 94.1% - 100.0%	100.0% (11/11) 74.1% - 100.0%	N/A	N/A	97.6% (40/41) 87.4% - 99.6%	100.0% (11/11) 74.1% - 100.0%	98.0% (50/51) 89.7% - 99.7%	100.0% (11/11) 74.1% - 100.0%	100.0% (131/131) 97.2% - 100.0%	100.0% (11/11) 74.1% - 100.0%
<i>Enterobacter</i> spp.	90.9% (10/11) 62.3% - 98.4%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (29/29) 88.3% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (31/31) 89.0% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (31/31) 89.0% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (31/31) 89.0% - 100.0%	90.9% (10/11) 62.3% - 98.4%	100.0% (31/31) 89.0% - 100.0%
<i>Escherichia coli</i>	58.8% (10/17) 36.0% - 78.4%	100.0% (233/233) 98.4% - 100.0%	52.9% (9/17) 31.0% - 73.8%	100.0% (233/233) 98.4% - 100.0%	0.0% (0/7) 0.0% - 35.4%	100.0% (217/217) 98.3% - 100.0%	N/A	N/A	0.0% (0/7) 0.0% - 35.4%	100.0% (233/233) 98.4% - 100.0%	64.7% (11/17) 41.3% - 82.7%	100.0% (233/233) 98.4% - 100.0%	N/A	N/A	0.0% (0/7) 0.0% - 35.4%	99.6% (232/233) 97.6% - 99.9%	N/A	N/A	0.0% (0/7) 0.0% - 35.4%	100.0% (233/233) 98.4% - 100.0%	81.1% (30/37) 65.8% - 90.5%	99.6% (232/233) 97.6% - 99.9%
<i>Klebsiella</i> spp.	95.2% (20/21) 77.3% - 99.2%	100.0% (103/103) 96.4% - 100.0%	100.0% (11/11) 74.1% - 100.0%	100.0% (103/103) 96.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (98/98) 96.2% - 100.0%	N/A	N/A	90.9% (10/11) 62.3% - 98.4%	100.0% (103/103) 96.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (103/103) 96.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (103/103) 96.4% - 100.0%	95.2% (20/21) 77.3% - 99.2%	100.0% (103/103) 96.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (103/103) 96.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (103/103) 96.4% - 100.0%	100.0% (51/51) 93.0% - 100.0%	100.0% (103/103) 96.4% - 100.0%
<i>Proteus</i> spp.	0.0% (0/1) 0.0% - 79.3%	100.0% (33/33) 89.6% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (33/33) 89.6% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (33/33) 89.6% - 100.0%	N/A	N/A	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (33/33) 89.6% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (33/33) 89.6% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (33/33) 89.6% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (33/33) 89.6% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (33/33) 89.6% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (33/33) 89.6% - 100.0%

Pathogen	KPC		NDM		IMP		SPM		GES		VIM		OXA-23		OXA-48-like		OXA-24/40		OXA-58		Combined (KPC, NDM, IMP, SPM, GES,VIM, OXA- 23, OXA-48-like, OXA-24/40, OXA-58)	
	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
<i>Pseudomonas aeruginosa</i>	0.0% (0/3) 0.0% - 56.1%	100.0% (31/31) 89.0% - 100.0%	93.6% (44/47) 82.8% - 97.8%	100.0% (31/31) 89.0% - 100.0%	78.6% (11/14) 52.4% - 92.4%	100.0% (31/31) 89.0% - 100.0%	69.6% (16/23) 49.1% - 84.4%	100.0% (30/30) 88.6% - 100.0%	76.9% (10/13) 49.7% - 91.8%	75.6% (31/41) 60.7% - 86.2%	88.9% (24/27) 71.9% - 96.1%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (31/31) 89.0% - 100.0%	92.3% (84/91) 85.0% - 96.2%	75.6% (31/41) 60.7% - 86.2%
<i>Salmonella</i> spp.	0.0% (0/2) 0.0% - 65.8%	100.0% (20/20) 83.9% - 100.0%	0.0% (0/2) 0.0% - 65.8%	100.0% (20/20) 83.9% - 100.0%	0.0% (0/2) 0.0% - 65.8%	100.0% (15/15) 79.6% - 100.0%	N/A	N/A	N/A	N/A	0.0% (0/2) 0.0% - 65.8%	100.0% (20/20) 83.9% - 100.0%	N/A	N/A	0.0% (0/2) 0.0% - 65.8%	100.0% (20/20) 83.9% - 100.0%	N/A	N/A	N/A	N/A	0.0% (0/2) 0.0% - 65.8%	100.0% (20/20) 83.9% - 100.0%
<i>Serratia</i> spp.	0/0	100.0% (22/22) 85.1% - 100.0%	0/0	100.0% (22/22) 85.1% - 100.0%	0/0	100.0% (22/22) 85.1% - 100.0%	N/A	N/A	0/0	100.0% (22/22) 85.1% - 100.0%	100.0% (20/20) 83.9% - 100.0%	100.0% (22/22) 85.1% - 100.0%	N/A	N/A	0/0	100.0% (22/22) 85.1% - 100.0%	N/A	N/A	N/A	N/A	100.0% (20/20) 83.9% - 100.0%	100.0% (22/22) 85.1% - 100.0%

Table 55: Performance of KPC, NDM, IMP, SPM, GES, VIM, OXA-23, OXA-48-like, OXA-24/40 and OXA-58 Compared to Phenotypic AST Results for Carbapenem in Clinical Specimens

Pathogen	KPC		NDM		IMP		SPM		GES		VIM		OXA-23		OXA-48-like		OXA-24/40		OXA-58		Combined (KPC, NDM, IMP, SPM, GES, VIM, OXA-23, OXA-48- like, OXA-24/40, OXA-58)	
	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
Ertapenem susceptibility testing																						
<i>Enterobacter</i> spp.	0.0% (0/4) 0.0% - 49.0%	100.0% (13/13) 77.2% - 100.0%	0.0% (0/4) 0.0% - 49.0%	100.0% (13/13) 77.2% - 100.0%	0.0% (0/4) 0.0% - 49.0%	100.0% (13/13) 77.2% - 100.0%	N/A	N/A	0.0% (0/4) 0.0% - 49.0%	100.0% (13/13) 77.2% - 100.0%	0.0% (0/4) 0.0% - 49.0%	100.0% (13/13) 77.2% - 100.0%	N/A	N/A	0.0% (0/4) 0.0% - 49.0%	100.0% (13/13) 77.2% - 100.0%	N/A	N/A	0.0% (0/4) 0.0% - 49.0%	100.0% (13/13) 77.2% - 100.0%	0.0% (0/4) 0.0% - 49.0%	100.0% (13/13) 77.2% - 100.0%
<i>Escherichia coli</i>	0.0% (0/6) 0.0% - 39.0%	100.0% (106/106) 96.5% - 100.0%	16.7% (1/6) 3.0% - 56.4%	100.0% (106/106) 96.5% - 100.0%	0.0% (0/6) 0.0% - 39.0%	100.0% (105/105) 96.5% - 100.0%	N/A	N/A	0.0% (0/6) 0.0% - 39.0%	100.0% (106/106) 96.5% - 100.0%	16.7% (1/6) 3.0% - 56.4%	100.0% (106/106) 96.5% - 100.0%	N/A	N/A	0.0% (0/6) 0.0% - 39.0%	100.0% (106/106) 96.5% - 100.0%	N/A	N/A	0.0% (0/6) 0.0% - 39.0%	100.0% (106/106) 96.5% - 100.0%	33.3% (2/6) 9.7% - 70.0%	100.0% (106/106) 96.5% - 100.0%
<i>Klebsiella</i> spp.	0.0% (0/1) 0.0% - 79.3%	100.0% (64/64) 94.3% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (64/64) 94.3% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (64/64) 94.3% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (64/64) 94.3% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (64/64) 94.3% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (64/64) 94.3% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (64/64) 94.3% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (64/64) 94.3% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (64/64) 94.3% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (64/64) 94.3% - 100.0%

Pathogen	KPC		NDM		IMP		SPM		GES		VIM		OXA-23		OXA-48-like		OXA-24/40		OXA-58		Combined (KPC, NDM, IMP, SPM, GES, VIM, OXA-23, OXA-48- like, OXA-24/40, OXA-58)	
	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
<i>Proteus</i> spp.	0.0% (0/1) 0.0% - 79.3%	100.0% (18/18) 82.4% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (18/18) 82.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (18/18) 82.4% - 100.0%	N/A	N/A	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (18/18) 82.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (18/18) 82.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (18/18) 82.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (18/18) 82.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (18/18) 82.4% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (18/18) 82.4% - 100.0%
<i>Salmonella</i> spp.	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	N/A	N/A	N/A	N/A	0/0	100.0% (1/1) 20.7% - 100.0%	N/A	N/A	0/0	100.0% (1/1) 20.7% - 100.0%	N/A	N/A	N/A	N/A	0/0	100.0% (1/1) 20.7% - 100.0%
<i>Serratia</i> spp.	0/0	100.0% (7/7) 64.6% - 100.0%	0/0	100.0% (7/7) 64.6% - 100.0%	0/0	100.0% (7/7) 64.6% - 100.0%	N/A	N/A	0/0	100.0% (7/7) 64.6% - 100.0%	0/0	100.0% (7/7) 64.6% - 100.0%	N/A	N/A	0/0	100.0% (7/7) 64.6% - 100.0%	N/A	N/A	N/A	N/A	0/0	100.0% (7/7) 64.6% - 100.0%
Imipenem susceptibility testing																						
<i>A. calcoaceticu</i> <i>s-baumannii</i> complex	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	N/A	N/A	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%
<i>Enterobacte</i> <i>r</i> spp.	0/0	100.0% (12/12) 75.8% - 100.0%	0/0	100.0% (12/12) 75.8% - 100.0%	0/0	100.0% (12/12) 75.8% - 100.0%	N/A	N/A	0/0	100.0% (12/12) 75.8% - 100.0%	0/0	100.0% (12/12) 75.8% - 100.0%	N/A	N/A	0/0	100.0% (12/12) 75.8% - 100.0%	N/A	N/A	0/0	100.0% (12/12) 75.8% - 100.0%	0/0	100.0% (12/12) 75.8% - 100.0%
<i>Escherichia</i> <i>coli</i>	0.0% (0/1) 0.0% - 79.3%	100.0% (53/53) 93.2% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (53/53) 93.2% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (52/52) 93.1% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (53/53) 93.2% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (53/53) 93.2% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (53/53) 93.2% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (53/53) 93.2% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (53/53) 93.2% - 100.0%
<i>Klebsiella</i> spp.	0/0	100.0% (28/28) 87.9% - 100.0%	0/0	100.0% (28/28) 87.9% - 100.0%	0/0	100.0% (28/28) 87.9% - 100.0%	N/A	N/A	0/0	100.0% (28/28) 87.9% - 100.0%	0/0	100.0% (28/28) 87.9% - 100.0%	0/0	100.0% (28/28) 87.9% - 100.0%	0/0	100.0% (28/28) 87.9% - 100.0%	0/0	100.0% (28/28) 87.9% - 100.0%	0/0	100.0% (28/28) 87.9% - 100.0%	0/0	100.0% (28/28) 87.9% - 100.0%
<i>Proteus</i> spp.	0.0% (0/7) 0.0% - 35.4%	0/0	14.3% (1/7) 2.6% - 51.3%	0/0	0.0% (0/7) 0.0% - 35.4%	0/0	N/A	N/A	N/A	N/A	0.0% (0/7) 0.0% - 35.4%	0/0	0.0% (0/7) 0.0% - 35.4%	0/0	0.0% (0/7) 0.0% - 35.4%	0/0	0.0% (0/7) 0.0% - 35.4%	0/0	0.0% (0/7) 0.0% - 35.4%	0/0	14.3% (1/7) 2.6% - 51.3%	0/0

Pathogen	KPC		NDM		IMP		SPM		GES		VIM		OXA-23		OXA-48-like		OXA-24/40		OXA-58		Combined (KPC, NDM, IMP, SPM, GES, VIM, OXA-23, OXA-48- like, OXA-24/40, OXA-58)	
	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
<i>Pseudomonas aeruginosa</i>	0/0	100.0% (5/5) 56.6% - 100.0%	0/0	100.0% (5/5) 56.6% - 100.0%	0/0	100.0% (5/5) 56.6% - 100.0%	0/0	100.0% (5/5) 56.6% - 100.0%	0/0	100.0% (5/5) 56.6% - 100.0%	0/0	100.0% (5/5) 56.6% - 100.0%	0/0	100.0% (5/5) 56.6% - 100.0%	0/0	100.0% (5/5) 56.6% - 100.0%	0/0	100.0% (5/5) 56.6% - 100.0%	0/0	100.0% (5/5) 56.6% - 100.0%	0/0	100.0% (5/5) 56.6% - 100.0%
<i>Salmonella</i> spp.	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	0/0	100.0% (1/1) 20.7% - 100.0%	N/A	N/A	N/A	N/A	0/0	100.0% (1/1) 20.7% - 100.0%	N/A	N/A	0/0	100.0% (1/1) 20.7% - 100.0%	N/A	N/A	N/A	N/A	0/0	100.0% (1/1) 20.7% - 100.0%
Meropenem susceptibility testing																						
<i>A. calcoaceticus</i> complex	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (11/11) 74.1% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (11/11) 74.1% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/1) 0.0% - 79.3%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (29/29) 88.3% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (31/31) 89.0% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (31/31) 89.0% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (31/31) 89.0% - 100.0%
<i>Escherichia coli</i>	0.0% (0/7) 0.0% - 35.4%	100.0% (233/233) 98.4% - 100.0%	14.3% (1/7) 2.6% - 51.3%	100.0% (233/233) 98.4% - 100.0%	0.0% (0/7) 0.0% - 35.4%	100.0% (217/217) 98.3% - 100.0%	N/A	N/A	0.0% (0/7) 0.0% - 35.4%	100.0% (233/233) 98.4% - 100.0%	14.3% (1/7) 2.6% - 51.3%	100.0% (233/233) 98.4% - 100.0%	N/A	N/A	0.0% (0/7) 0.0% - 35.4%	99.6% (232/233) 97.6% - 99.9%	N/A	N/A	0.0% (0/7) 0.0% - 35.4%	100.0% (233/233) 98.4% - 100.0%	28.6% (2/7) 8.2% - 64.1%	99.6% (232/233) 97.6% - 99.9%
<i>Klebsiella</i> spp.	0.0% (0/1) 0.0% - 79.3%	100.0% (103/103) 96.4% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (103/103) 96.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (98/98) 96.2% - 100.0%	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (103/103) 96.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (103/103) 96.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (103/103) 96.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (103/103) 96.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (103/103) 96.4% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (103/103) 96.4% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (103/103) 96.4% - 100.0%
<i>Proteus</i> spp.	0.0% (0/1) 0.0% - 79.3%	100.0% (33/33) 89.6% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (33/33) 89.6% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (33/33) 89.6% - 100.0%	N/A	N/A	N/A	N/A	0.0% (0/1) 0.0% - 79.3%	100.0% (33/33) 89.6% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (33/33) 89.6% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (33/33) 89.6% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (33/33) 89.6% - 100.0%	0.0% (0/1) 0.0% - 79.3%	100.0% (33/33) 89.6% - 100.0%	100.0% (1/1) 20.7% - 100.0%	100.0% (33/33) 89.6% - 100.0%
<i>Pseudomonas aeruginosa</i>	0.0% (0/3) 0.0% - 56.1%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (30/30) 88.6% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (31/31) 89.0% - 100.0%	0.0% (0/3) 0.0% - 56.1%	100.0% (31/31) 89.0% - 100.0%

Pathogen	KPC		NDM		IMP		SPM		GES		VIM		OXA-23		OXA-48-like		OXA-24/40		OXA-58		Combined (KPC, NDM, IMP, SPM, GES, VIM, OXA-23, OXA-48-like, OXA-24/40, OXA-58)	
	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
<i>Salmonella spp.</i>	0.0% (0/2) 0.0% - 65.8%	100.0% (20/20) 83.9% - 100.0%	0.0% (0/2) 0.0% - 65.8%	100.0% (20/20) 83.9% - 100.0%	0.0% (0/2) 0.0% - 65.8%	100.0% (15/15) 79.6% - 100.0%	N/A	N/A	N/A	N/A	0.0% (0/2) 0.0% - 65.8%	100.0% (20/20) 83.9% - 100.0%	N/A	N/A	0.0% (0/2) 0.0% - 65.8%	100.0% (20/20) 83.9% - 100.0%	N/A	N/A	N/A	N/A	0.0% (0/2) 0.0% - 65.8%	100.0% (20/20) 83.9% - 100.0%
<i>Serratia spp.</i>	0/0	100.0% (22/22) 85.1% - 100.0%	0/0	100.0% (22/22) 85.1% - 100.0%	0/0	100.0% (22/22) 85.1% - 100.0%	N/A	N/A	0/0	100.0% (22/22) 85.1% - 100.0%	0/0	100.0% (22/22) 85.1% - 100.0%	N/A	N/A	0/0	100.0% (22/22) 85.1% - 100.0%	N/A	N/A	N/A	N/A	0/0	100.0% (22/22) 85.1% - 100.0%

Table 56: Performance of KPC, NDM, IMP, GES, VIM, SPM, OXA-23, OXA-48-like, OXA-24/40 and OXA-58 , Compared to Phenotypic AST Results for Carbapenem in Contrived Samples

Pathogen	KPC		NDM		IMP		GES		VIM		SPM		OXA-23		OXA-48-like		OXA-24/40		OXA-58		Combined (KPC, NDM, IMP, SPM, GES, VIM, OXA-23, OXA-48-like, OXA-24/40, OXA-58)	
	PPA	NP A	PPA	NP A	PPA	NP A	PPA	NPA	PPA	NPA	PPA	NP A	PPA	NP A	PPA	NPA	PPA	NP A	PPA	NP A	PPA	NPA
Ertapenem susceptibility testing																						
<i>Enterobacter spp.</i>	100.0% (10/10) 72.2% - 100.0%	0/0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100.0% (10/10) 72.2% - 100.0%	0/0
<i>Escherichia coli</i>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0/0	0.0% (0/10) 0.0% - 27.8%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0/0	0.0% (0/10) 0.0% - 27.8%
<i>Klebsiella spp.</i>	100.0% (10/10) 72.2% - 100.0%	0/0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100.0% (20/20) 83.9% - 100.0%	0/0	N/A	N/A	N/A	N/A	100.0% (30/30) 88.6% - 100.0%	0/0
<i>Serratia spp.</i>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100.0% (10/10) 72.2% - 100.0%	0.0% (0/10) 0.0% - 27.8%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100.0% (10/10) 72.2% - 100.0%	0.0% (0/10) 0.0% - 27.8%
Imipenem susceptibility testing																						

Pathogen	KPC		NDM		IMP		GES		VIM		SPM		OXA-23		OXA-48-like		OXA-24/40		OXA-58		Combined (KPC, NDM, IMP, SPM, GES, VIM, OXA-23, OXA-48- like, OXA-24/40, OXA-58)	
	PPA	NP A	PPA	NP A	PPA	NP A	PPA	NPA	PPA	NPA	PPA	NP A	PPA	NP A	PPA	NPA	PPA	NP A	PPA	NP A	PPA	NPA
<i>A. calcoaceticus- baumannii</i> complex	N/A	N/ A	100.0% (10/10) 72.2% - 100.0%	0/0	N/A	N/ A	N/A	N/A	N/A	N/A	N/A	N/ A	100.0% (60/60) 94.0% - 100.0%	0/0	N/A	N/A	100.0% (40/40) 91.2% - 100.0%	0/0	100.0% (50/50) 92.9% - 100.0%	0/0	100.0% (130/130) 97.1% - 100.0%	0/0
<i>Enterobacter</i> spp.	100.0% (10/10) 72.2% - 100.0%	0/0	N/A	N/ A	N/A	N/ A	N/A	N/A	N/A	N/A	N/A	N/ A	N/A	N/ A	N/A	N/A	N/A	N/A	N/A	N/ A	100.0% (10/10) 72.2% - 100.0%	0/0
<i>Escherichia coli</i>	100.0% (10/10) 72.2% - 100.0%	0/0	80.0% (8/10) 49.0% - 94.3%	0/0	N/A	N/ A	N/A	N/A	100.0% (10/10) 72.2% - 100.0%	0/0	N/A	N/ A	N/A	N/ A	N/A	N/A	N/A	N/A	N/A	N/ A	93.3% (28/30) 78.7% - 98.2%	0/0
<i>Klebsiella</i> spp.	100.0% (20/20) 83.9% - 100.0%	0/0	100.0% (10/10) 72.2% - 100.0%	0/0	N/A	N/ A	100.0% (10/10) 72.2% - 100.0%	0/0	N/A	N/A	N/A	N/ A	N/A	N/ A	100.0% (20/20) 83.9% - 100.0%	0/0	N/A	N/A	N/A	N/ A	100.0% (50/50) 92.9% - 100.0%	0/0
<i>Pseudomonas aeruginosa</i>	N/A	N/ A	100.0% (44/44) 92.0% - 100.0%	0/0	100.0% (11/11) 74.1% - 100.0%	0/0	0/0	0.0% (0/20) 0.0% - 16.1%	0/0	0.0% (0/10) 0.0% - 27.8%	80.0% (16/20) 58.4% - 91.9%	0/0	N/A	N/ A	N/A	N/A	N/A	N/A	N/A	N/ A	93.8% (60/64) 85.0% - 97.5%	0.0% (0/20) 0.0% - 16.1%
<i>Serratia</i> spp.	N/A	N/ A	N/A	N/ A	N/A	N/ A	N/A	N/A	100.0% (20/20) 83.9% - 100.0%	0/0	N/A	N/ A	N/A	N/ A	N/A	N/A	N/A	N/A	N/A	N/ A	100.0% (20/20) 83.9% - 100.0%	0/0
Meropenem susceptibility testing																						
<i>A. calcoaceticus- baumannii</i> complex	N/A	N/ A	100.0% (10/10) 72.2% - 100.0%	0/0	N/A	N/ A	N/A	N/A	N/A	N/A	N/A	N/ A	100.0% (60/60) 94.0% - 100.0%	0/0	N/A	N/A	100.0% (40/40) 91.2% - 100.0%	0/0	100.0% (50/50) 92.9% - 100.0%	0/0	100.0% (130/130) 97.1% - 100.0%	0/0
<i>Enterobacter</i> spp.	100.0% (10/10) 72.2% - 100.0%	0/0	N/A	N/ A	N/A	N/ A	N/A	N/A	N/A	N/A	N/A	N/ A	N/A	N/ A	N/A	N/A	N/A	N/A	N/A	N/ A	100.0% (10/10) 72.2% - 100.0%	0/0
<i>Escherichia coli</i>	100.0% (10/10) 72.2% - 100.0%	0/0	80.0% (8/10) 49.0% - 94.3%	0/0	N/A	N/ A	N/A	N/A	100.0% (10/10) 72.2% - 100.0%	0/0	N/A	N/ A	N/A	N/ A	N/A	N/A	N/A	N/A	N/A	N/ A	93.3% (28/30) 78.7% - 98.2%	0/0
<i>Klebsiella</i> spp.	100.0% (20/20) 83.9% - 100.0%	0/0	100.0% (10/10) 72.2% - 100.0%	0/0	N/A	N/ A	100.0% (10/10) 72.2% - 100.0%	0/0	N/A	N/A	N/A	N/ A	N/A	N/ A	100.0% (20/20) 83.9% - 100.0%	0/0	N/A	N/A	N/A	N/ A	100.0% (50/50) 92.9% - 100.0%	0/0

Pathogen	KPC		NDM		IMP		GES		VIM		SPM		OXA-23		OXA-48-like		OXA-24/40		OXA-58		Combined (KPC, NDM, IMP, SPM, GES, VIM, OXA-23, OXA-48- like, OXA-24/40, OXA-58)	
	PPA	NP A	PPA	NP A	PPA	NP A	PPA	NPA	PPA	NPA	PPA	NP A	PPA	NP A	PPA	NPA	PPA	NP A	PPA	NP A	PPA	NPA
<i>Pseudomonas aeruginosa</i>	N/A	N/ A	100.0% (44/44) 92.0% - 100.0%	0/0	100.0% (11/11) 74.1% - 100.0%	0/0	100.0% (10/10) 72.2% - 100.0%	0.0% (0/10) 0.0% - 27.8%	100.0% (24/24) 86.2% - 100.0%	0/0	80.0% (16/20) 58.4% - 91.9%	0/0	N/A	N/ A	N/A	N/A	N/A	N/A	N/A	N/ A	95.5% (84/88) 88.9% - 98.2%	0.0% (0/10) 0.0% - 27.8%
<i>Serratia spp.</i>	N/A	N/ A	N/A	N/ A	N/A	N/ A	N/A	N/A	100.0% (20/20) 83.9% - 100.0%	0/0	N/A	N/ A	N/A	N/ A	N/A	N/A	N/A	N/A	N/A	N/ A	100.0% (20/20) 83.9% - 100.0%	0/0

The performance of plasmid *ampC* resistance markers compared to phenotypic AST results for beta-lactam-class antibiotics by relevant organisms is presented from Table 57 to Table 65. Note that antimicrobial resistance is known to occur via mechanisms other than the presence of plasmid *ampC* therefore absence does not infer phenotypic susceptibility. In addition, phenotypic correlations for plasmid *ampC* was also performed with contrived samples by comparing to the AST results for corresponding antibiotic reported on the certificate of analysis of the strains of relevant organisms. The combined results for clinical specimens and contrived samples are provided in Table 57, Table 60 and Table 63 while the breakdown is shown in Table 58, Table 61, and Table 64 for clinical specimens and Table 59, Table 62, and Table 65 for contrived specimens.

Table 57: Performance of plasmid *ampC* Compared to Phenotypic AST Results for Ampicillin in Clinical Specimens and Contrived Samples Combined

Pathogen	<i>ampC</i>	
	PPA	NPA
Ampicillin susceptibility testing		
<i>Enterobacter</i> spp.	38.5% (10/26) 22.4% - 57.5%	0/0
<i>Escherichia coli</i>	4.2% (7/168) 2.0% - 8.3%	100.0% (96/96) 96.2% - 100.0%
<i>Klebsiella</i> spp.	1.3% (1/75) 0.2% - 7.2%	100.0% (3/3) 43.9% - 100.0%
<i>Proteus</i> spp.	10.0% (1/10) 1.8% - 40.4%	93.8% (30/32) 79.9% - 98.3%
<i>Serratia</i> spp.	58.8% (10/17) 36.0% - 78.4%	100.0% (1/1) 20.7% - 100.0%

Table 58: Performance of plasmid *ampC* Compared to Phenotypic AST Results for Ampicillin in Clinical Specimens

Pathogen	<i>ampC</i>	
	PPA	NPA
Ampicillin susceptibility testing		
<i>Enterobacter</i> spp.	0.0% (0/16) 0.0% - 19.4%	0/0
<i>Escherichia coli</i>	4.2% (7/168) 2.0% - 8.3%	100.0% (96/96) 96.2% - 100.0%
<i>Klebsiella</i> spp.	1.3% (1/75) 0.2% - 7.2%	100.0% (3/3) 43.9% - 100.0%
<i>Proteus</i> spp.	10.0% (1/10) 1.8% - 40.4%	93.8% (30/32) 79.9% - 98.3%
<i>Serratia</i> spp.	0.0% (0/7) 0.0% - 35.4%	100.0% (1/1) 20.7% - 100.0%

Table 59: Performance of plasmid *ampC* Compared to Phenotypic AST Results for Ampicillin in Contrived Samples

Pathogen	AmpC	
	PPA	NPA
Ampicillin susceptibility testing		
<i>Enterobacter</i> spp.	100.0% (10/10) 72.2% - 100.0%	0/0
<i>Serratia</i> spp.	100.0% (10/10) 72.2% - 100.0%	0/0

Table 60 Performance of plasmid *ampC* Compared to Phenotypic AST Results for 1st generation cephalosporin in Clinical Specimens and Contrived Samples Combined

Pathogen	<i>ampC</i>	
	PPA	NPA
Cefazolin susceptibility testing		
<i>Enterobacter</i> spp.	43.5% (10/23) 25.6% - 63.2%	0/0
<i>Escherichia coli</i>	6.2% (5/81) 2.7% - 13.6%	100.0% (95/95) 96.1% - 100.0%
<i>Klebsiella</i> spp.	0.0% (0/34) 0.0% - 10.2%	98.3% (58/59) 91.0% - 99.7%
<i>Proteus</i> spp.	11.8% (2/17) 3.3% - 34.3%	100.0% (7/7) 64.6% - 100.0%
<i>Serratia</i> spp.	38.5% (10/26) 22.4% - 57.5%	0/0

Table 61 Performance of plasmid *ampC* Compared to Phenotypic AST Results for 1st generation cephalosporin in Clinical Specimens

Pathogen	<i>ampC</i>	
	PPA	NPA
Cefazolin susceptibility testing		
<i>Enterobacter</i> spp.	0.0% (0/13) 0.0% - 22.8%	0/0
<i>Escherichia coli</i>	6.2% (5/81) 2.7% - 13.6%	100.0% (95/95) 96.1% - 100.0%
<i>Klebsiella</i> spp.	0.0% (0/34) 0.0% - 10.2%	98.3% (58/59) 91.0% - 99.7%
<i>Proteus</i> spp.	11.8% (2/17) 3.3% - 34.3%	100.0% (7/7) 64.6% - 100.0%
<i>Serratia</i> spp.	0.0% (0/16) 0.0% - 19.4%	0/0

Table 62 Performance of plasmid *ampC* Compared to Phenotypic AST Results for 1st generation cephalosporin in Contrived Samples

Pathogen	<i>ampC</i>	
	PPA	NPA
Cefazolin susceptibility testing		
<i>Enterobacter</i> spp.	100.0% (10/10) 72.2% - 100.0%	0/0
<i>Serratia</i> spp.	100.0% (10/10) 72.2% - 100.0%	0/0

Table 63 Performance of plasmid *ampC* Compared to Phenotypic AST Results for third generation cephalosporins (cefotaxime, ceftazidime, ceftriaxone) and a cephamycin (cefoxitin) in Clinical Specimens and Contrived Samples Combined

Pathogen	<i>ampC</i>	
	PPA	NPA
Cefotaxime susceptibility testing		
<i>A. calcoaceticus-baumannii</i> complex	0/0	100.0% (1/1) 20.7% - 100.0%
<i>Enterobacter</i> spp.	66.7% (10/15) 41.7% - 84.8%	100.0% (4/4) 51.0% - 100.0%
<i>Escherichia coli</i>	0.0% (0/7) 0.0% - 35.4%	95.8% (23/24) 79.8% - 99.3%
<i>Klebsiella</i> spp.	0.0% (0/3) 0.0% - 56.1%	100.0% (10/10) 72.2% - 100.0%
<i>Proteus</i> spp.	0.0% (0/1) 0.0% - 79.3%	100.0% (6/6) 61.0% - 100.0%
<i>Serratia</i> spp.	100.0% (10/10) 72.2% - 100.0%	0/0
Ceftazidime susceptibility testing		
<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/3) 0.0% - 56.1%	100.0% (7/7) 64.6% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/9) 0.0% - 29.9%	100.0% (13/13) 77.2% - 100.0%
<i>Escherichia coli</i>	13.0% (3/23) 4.5% - 32.1%	100.0% (104/104) 96.4% - 100.0%
<i>Klebsiella</i> spp.	0.0% (0/7) 0.0% - 35.4%	100.0% (58/58) 93.8% - 100.0%
<i>Proteus</i> spp.	50.0% (1/2) 9.5% - 90.5%	96.8% (30/31) 83.8% - 99.4%
<i>Pseudomonas aeruginosa</i>	0.0% (0/4) 0.0% - 49.0%	95.5% (21/22) 78.2% - 99.2%
<i>Serratia</i> spp.	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%
Ceftriaxone susceptibility testing		
<i>A. calcoaceticus-baumannii</i> complex	0/0	100.0% (1/1) 20.7% - 100.0%
<i>Enterobacter</i> spp.	76.9% (10/13) 49.7% - 91.8%	100.0% (2/2) 34.2% - 100.0%
<i>Escherichia coli</i>	6.7% (2/30) 1.8% - 21.3%	98.2% (162/165) 94.8% - 99.4%
<i>Klebsiella</i> spp.	43.5% (10/23) 25.6% - 63.2%	98.8% (82/83) 93.5% - 99.8%

Pathogen	<i>ampC</i>	
	PPA	NPA
<i>Proteus</i> spp.	0/0	95.7% (22/23) 79.0% - 99.2%
<i>Serratia</i> spp.	90.9% (10/11) 62.3% - 98.4%	100.0% (9/9) 70.1% - 100.0%
Cefoxitin susceptibility testing		
<i>Enterobacter</i> spp.	41.7% (10/24) 24.5% - 61.2%	0/0
<i>Escherichia coli</i>	16.7% (2/12) 4.7% - 44.8%	99.1% (109/110) 95.0% - 99.8%
<i>Klebsiella</i> spp.	0.0% (0/12) 0.0% - 24.2%	100.0% (49/49) 92.7% - 100.0%
<i>Proteus</i> spp.	0.0% (0/1) 0.0% - 79.3%	92.9% (13/14) 68.5% - 98.7%
<i>Serratia</i> spp.	37.0% (10/27) 21.5% - 55.8%	0/0

Table 64 Performance of plasmid *ampC* Compared to Phenotypic AST Results for third generation cephalosporins (cefotaxime, ceftazidime, ceftriaxone) and a cephamycin (cefoxitin) in Clinical Specimens

Pathogen	<i>ampC</i>	
	PPA	NPA
Cefotaxime susceptibility testing		
<i>A. calcoaceticus-baumannii</i> complex	0/0	100.0% (1/1) 20.7% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/5) 0.0% - 43.4%	100.0% (4/4) 51.0% - 100.0%
<i>Escherichia coli</i>	0.0% (0/7) 0.0% - 35.4%	95.8% (23/24) 79.8% - 99.3%
<i>Klebsiella</i> spp.	0.0% (0/3) 0.0% - 56.1%	100.0% (10/10) 72.2% - 100.0%
<i>Proteus</i> spp.	0.0% (0/1) 0.0% - 79.3%	100.0% (6/6) 61.0% - 100.0%
Ceftazidime susceptibility testing		
<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/3) 0.0% - 56.1%	100.0% (7/7) 64.6% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/9) 0.0% - 29.9%	100.0% (13/13) 77.2% - 100.0%
<i>Escherichia coli</i>	13.0% (3/23) 4.5% - 32.1%	100.0% (104/104) 96.4% - 100.0%
<i>Klebsiella</i> spp.	0.0% (0/7) 0.0% - 35.4%	100.0% (58/58) 93.8% - 100.0%
<i>Proteus</i> spp.	50.0% (1/2) 9.5% - 90.5%	96.8% (30/31) 83.8% - 99.4%
<i>Pseudomonas aeruginosa</i>	0.0% (0/4) 0.0% - 49.0%	95.5% (21/22) 78.2% - 99.2%
<i>Serratia</i> spp.	0.0% (0/1) 0.0% - 79.3%	100.0% (11/11) 74.1% - 100.0%
Ceftriaxone susceptibility testing		
<i>A. calcoaceticus-baumannii</i> complex	0/0	100.0% (1/1) 20.7% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/3) 0.0% - 56.1%	100.0% (2/2) 34.2% - 100.0%

Pathogen	<i>ampC</i>	
	PPA	NPA
<i>Escherichia coli</i>	6.7% (2/30) 1.8% - 21.3%	98.2% (162/165) 94.8% - 99.4%
<i>Klebsiella</i> spp.	0.0% (0/13) 0.0% - 22.8%	98.8% (82/83) 93.5% - 99.8%
<i>Proteus</i> spp.	0/0	95.7% (22/23) 79.0% - 99.2%
<i>Serratia</i> spp.	0.0% (0/1) 0.0% - 79.3%	100.0% (9/9) 70.1% - 100.0%
Cefoxitin susceptibility testing		
<i>Enterobacter</i> spp.	0.0% (0/14) 0.0% - 21.5%	0/0
<i>Escherichia coli</i>	16.7% (2/12) 4.7% - 44.8%	99.1% (109/110) 95.0% - 99.8%
<i>Klebsiella</i> spp.	0.0% (0/12) 0.0% - 24.2%	100.0% (49/49) 92.7% - 100.0%
<i>Proteus</i> spp.	0.0% (0/1) 0.0% - 79.3%	92.9% (13/14) 68.5% - 98.7%
<i>Serratia</i> spp.	0.0% (0/17) 0.0% - 18.4%	0/0

Table 65 Performance of plasmid *ampC* Compared to Phenotypic AST Results for third generation cephalosporins (cefotaxime, ceftriaxone) and a cephamycin (cefoxitin) in Contrived Samples

Pathogen	<i>ampC</i>	
	PPA	NPA
Cefotaxime susceptibility testing		
<i>Enterobacter</i> spp.	100.0% (10/10) 72.2% - 100.0%	0/0
<i>Serratia</i> spp.	100.0% (10/10) 72.2% - 100.0%	0/0
Ceftriaxone susceptibility testing		
<i>Enterobacter</i> spp.	100.0% (10/10) 72.2% - 100.0%	0/0
<i>Klebsiella</i> spp.	100.0% (10/10) 72.2% - 100.0%	0/0
<i>Serratia</i> spp.	100.0% (10/10) 72.2% - 100.0%	0/0
Cefoxitin susceptibility testing		
<i>Enterobacter</i> spp.	100.0% (10/10) 72.2% - 100.0%	0/0
<i>Serratia</i> spp.	100.0% (10/10) 72.2% - 100.0%	0/0

Conclusion

The QIAstat-Dx BCID GN Plus AMR Panel is substantially equivalent to its legally marketed predicated device the ePlex Blood Culture Identification Gram Negative (BCID-GN) Panel.