



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY**

I Background Information:

A 510(k) Number

K262168

B Applicant

QIAGEN GmbH

C Proprietary and Established Names

QIAstat-Dx BCID GN Plus AMR Panel

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PEN	Class II	21 CFR 866.3365 - Multiplex Nucleic Acid Assay For Identification Of Microorganisms And Resistance Markers From Positive Blood Cultures	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain substantial equivalence determination for the QIAstat-Dx BCID GN Plus AMR Panel

B Measurand:

Nucleic acid sequences from the following gram-negative bacteria and fungi, and antimicrobial resistance markers:

- *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
- *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

C Type of Test:

A multiplexed nucleic acid test intended for use with the QIAstat-Dx Analyzer 2.0 for the qualitative *in vitro* detection and identification of nucleic acids from gram-negative bacteria and fungi in a positive blood culture media sample

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for 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')-lb*
- *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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

For *in vitro* Diagnostic Use Only

D Special Instrument Requirements:

QIAstat-Dx Analyzer 2.0

IV Device/System Characteristics:

A Device Description:

The QIAstat-Dx BCID GN Plus AMR Panel is an automated, qualitative, multiplex real-time PCR-based in vitro diagnostic (IVD) test used with the QIAstat-Dx Analyzer 2.0. It is designed for the simultaneous detection and identification of 13 gram-negative bacterial targets and 18 genetic determinants of antimicrobial resistance (AMR) directly from positive blood culture samples confirmed gram-negative by Gram stain.

The QIAstat-Dx BCID GN Plus AMR Panel test system consist of:

- The QIAstat-Dx BCID GN Plus AMR Panel cartridge kit contains six individually packed, single-use disposable cartridge, which are pre-packaged with wet and dry chemistry reagents necessary to perform sample preparation, nucleic acid amplification, and assay specific PCR detection (buffers, lyophilized master mix, air-dried primers and probes, and an internal process control using *Schizosaccharomyces pombe*) and six individually packed, single use transfer pipettes.
- QIAstat-Dx Analyzer 2.0, consisting of one Operational Module PRO and up to four Analytical Modules with software v1.6 or higher. The QIAstat-Dx Application Software is embedded in the QIAstat-Dx Analyzer 2.0.

Calibrators and Controls: Negative and positive external controls are recommended but not provided with the QIAstat-Dx BCID GN Plus AMR Panel. An internal control (“IC”) within the cartridge which provides a full process control covering lysis, nucleic acid purification, and DNA amplification. The IC is *Schizosaccharomyces pombe* and is in the IC cavity and mixed with the sample during sample preparation (See “**Principle of Operation**”). The QIAstat-Dx Analyzer 2.0 is provided factory calibrated and does not require user calibration. The QIAstat-

Dx Analyzer 2.0 includes self-check controls to verify the performance of all sensors and actuators and alert the user in case of failure

B Principle of Operation:

The QIAstat-Dx BCID GN Plus AMR Panel operates as a fully automated, closed-system molecular assay designed to detect Gram-negative bacteria and antimicrobial resistance markers from positive blood culture samples. Once a blood culture sample is loaded into the disposable cartridge and inserted into the QIAstat-Dx Analyzer 2.0, the following steps occur automatically:

1. Internal Control & Proteinase K Resuspension — Following insertion of the cartridge, the IC and Proteinase K is resuspended with the buffer located in Reservoir 1. The buffer is added to the interconnected IC cavity and Proteinase K cavity and transferred repeatedly between the transfer chamber and the cavities to ensure resuspension.
2. Cell Lysis — Lysis of the sample and IC occur by a combination of mechanical (rotor + silica beads), enzymatic (Proteinase K), and chemical (guanidine-based buffers) methods.
3. Nucleic Acid Purification — DNA binds to a silica membrane, is washed to remove contaminants, and is then eluted.
4. Master Mix Rehydration — The purified eluate rehydrates the lyophilized Master Mix (containing DNA polymerase, reverse transcriptase, and dNTPs).
5. Multiplex Real-Time PCR — ~15 µL aliquots are distributed into each of 8 Reaction Chambers containing target-specific primers and probes. Within each Reaction Chamber, multiplex, real-time PCR is performed (forty PCR cycles). Increase in fluorescence (indicative of detection of each target analyte) is detected directly within each Reaction Chamber after each cycle .

Results are automatically interpreted by the analyzer software and displayed as Detected / Not Detected for each target, in approximately 75 minutes. The results screen displays a message indicating that the IC “Passed” when the test is run successfully, and a message of “Failed” indicates that the internal control was not amplified. If the IC fails, detected targets are reported as “Positive with Warning” (“POSITIVE*”), and negative results are reported as “Invalid”, and testing should be repeated.

V Substantial Equivalence Information:

A Predicate Device Name(s):

ePlex Blood Culture Identification Gram Negative (BCID-GN) Panel

B Predicate 510(k) Number(s):

K182619

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K262168</u>	<u>K182619</u>
Device Trade Name	QIAstat-Dx BCID GN Plus AMR Panel	ePlex Blood Culture Identification Gram Negative (BCID-GN) Panel
General Device Characteristic Similarities		

Intended Use/Indications For 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) • <i>armA</i> • CTX-M • GES • IMP • KPC • NDM	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 (blaCTX-M), IMP (blaIMP), KPC (blaKPC), NDM (blaNDM), OXA (blaOXA) (OXA-23 and OXA-48 groups only), and VIM (blaVIM). The ePlex BCID-GN Panel contains assays for the detection of genetic determinants associated with resistance to antimicrobial agents including CTX-M(blaCTX-M), which is associated with resistance to extended spectrum beta-lactamase (ESBL)-
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	• 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 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	mediated resistance to penicillins, cephalosporins and monobactams, as well as OXA (blaOXA) (OXA-23 and OXA-48 groups only), KPC (blaKPC), and metallo-beta-lactamases IMP (blaIMP), VIM (blaVIM), and NDM (blaNDM), 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 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 Candida 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
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	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.	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.
Specimen Type	Same	Blood culture samples identified as positive by a continuous monitoring blood culture system
Blood Culture Bottles	Same	BD BACTEC Plus Aerobic BD BACTEC Plus Anaerobic BD BACTEC Standard Aerobic BD BACTEC Standard Anaerobic BD BACTEC Peds Plus BD BACTEC Lytic Anaerobic bioMérieux BACT/ALERT SA Standard Aerobic bioMérieux BACT/ALERT SN Standard Anaerobic bioMérieux BACT/ALERT FA Plus bioMérieux BACT/ALERT FN Plus bioMérieux BACT/ALERT PF Plus Thermo Scientific VersaTREK REDOX 1 EZ Draw Aerobic Thermo Scientific VersaTREK REDOX 2 EZ Draw Anaerobic

Analyte Detected	Same	DNA
Technological Principles	Same	Multiplex nucleic acid amplification test (NAAT)
General Device Characteristic Differences		
Pathogens Detected	Gram-negative Bacteria: <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	Gram-negative Bacteria: <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> (encapsulated) <i>Proteus mirabilis</i> <i>Proteus</i> spp. <i>Pseudomonas aeruginosa</i> <i>Salmonella</i> spp. <i>Serratia marcescens</i> <i>Serratia</i> spp. <i>Stenotrophomonas maltophilia</i> Gram-positive Bacteria: Pan Gram-Positive
Antimicrobial Resistance Genes Detected	<i>aac(6')-Ib</i> <i>ampC</i> (CMY/LAT/DHA/FOX) <i>armA</i> CTX-M GES IMP KPC NDM OXA-23 OXA-24/40 OXA-48-like	CTX-M IMP KPC NDM OXA-23 OXA-48-like VIM

	OXA-58 PER SHV SPM TEM VEB VIM	
Assay Controls	One internal control is included that monitors performance of 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

VI Standards/Guidance Documents Referenced:

ISO Standards:

- ISO 14971, Third Edition (2019-12) — *Medical devices – Application of risk management to medical devices*. Listed as General Use (Recognition No. 5-125). This is the foundational risk management standard applied across the submission.

IEC Standards:

- IEC 62304, Edition 1.1 (2015-06) Consolidated Version — *Medical device software – Software life cycle processes*. Listed as Declaration of Conformity (Recognition No. 13-79). A formal Declaration of Conformity (DoC) was issued by QIAGEN GmbH for the ADF software, covering subclauses 5.1, clause 6, and clause 8, with a Class C software safety classification.
- IEC 81001-5-1, Edition 1.0 (2021-12) — *Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle*. Listed as General Use (Recognition No. 13-122).
- IEC 61010-1, Edition 3.1 (2017-01) Consolidated Version — *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements*. Listed as General Use (Recognition No. 19-34).
- IEC 60601-1-2, Edition 4.1 (2020-09) Consolidated Version — *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances*. Listed as General Use (Recognition No. 19-36).
- IEC 62366-1, Edition 1.1 (2020-06) Consolidated Version — *Medical devices – Part 1: Application of usability engineering to medical devices*. Listed as General Use (Recognition No. 5-129).

CLSI Guidelines (Referenced in Analytical Testing):

- CLSI EP17-A2 — Referenced in the context of the linearity justification; defines linearity as the ability to provide measured quantity values proportional to the measurand (cited to explain inapplicability to this qualitative assay).
- CLSI EP06-A — Referenced to justify that reportable range does not apply to qualitative clinical assays.

Clinical Practice Standards (Referenced in Statements of Compliance):

- Declaration of Helsinki — Ethical principles governing clinical research; cited in both US and OUS Statements of Compliance.
- ICH E6(R2) Good Clinical Practice — International standard for clinical trial conduct; cited in both Statements of Compliance.
- EN ISO/DIS 20916:2019 — *Good study practice* for in vitro diagnostic medical devices; cited in both Statements of Compliance for clinical performance study conduct.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

A precision/reproducibility study was conducted to assess the performance of the QIAstat-Dx BCID GN Plus AMR Panel. Two positive samples (1 low "bottle positive," 1 high "bottle positive" + 24 hours) and one negative sample were prepared. Positive samples were prepared by combining representative, on-panel isolates covering six of the 13 microorganism detected by the device. Organisms were selected for gram-negative taxonomic diversity and analytical worst-case characteristics, including coverage of different bacterial families and both fermenting and non-fermenting species (*Acinetobacter baumannii*, *Salmonella enterica*, *Pseudomonas aeruginosa*, *Proteus vulgaris*, *Stenotrophomonas maltophilia*), as well as AMR gene targets (OXA-24/40, OXA-48-like, VEB) and Pan Enterobacterales. Stock isolates were inoculated with whole blood into blood culture bottles and incubated in a blood culture monitoring system until "positive ring" (plus 24 hours for high positive samples). The negative sample was prepared by inoculating a blood culture bottle with whole blood and an off-panel organism (*Cutibacterium acnes*) and incubating until "positive ring." Studies were conducted in BD BACTEC Plus Aerobic and BD BACTEC Anaerobic Lytic medium bottles. **Table 1** shows the sample composition and testing strategy for the precision/reproducibility studies.

Table 1: Sample Composition and Test Strategy for Reproducibility Studies

Sample	Intended Target	Organism	Source ID
Positive or High Positive	<i>Acinetobacter calcoaceticus-baumannii</i> complex OXA-24/40	<i>Acinetobacter baumannii</i>	NCTC 13302
	<i>Salmonella</i> spp. OXA-48-like	<i>Salmonella enterica</i>	NCTC 13954
	<i>Pseudomonas aeruginosa</i> VEB	<i>Pseudomonas aeruginosa</i>	MRSN 12914
	<i>Proteus</i> spp.	<i>Proteus vulgaris</i>	ATCC 6380

	<i>Stenotrophomonas maltophilia</i>	<i>Stenotrophomonas maltophilia</i>	NCTC 10499
	Pan Enterobacterales	<i>Proteus vulgaris</i> / <i>Salmonella enterica</i>	ATCC 6380 / NCTC 13954
Negative	N/A	<i>Cutibacterium acnes</i>	NCTC 737

Site-to-Site Variability

A site-to-site study was conducted at three external sites using six to seven QIAstat-Dx Analyzers per site. Runs were performed at each site over the course of six consecutive days, with two operators performing three replicates per sample each day, resulting in 36 replicates per sample per site (3 replicates × 2 operators × 6 days × 3 sites = 108 replicates at each concentration). A single lot of QIAstat-Dx BCID GN Plus AMR Panel was used for all runs in this study. A run was considered valid if no error code was detected by the software. Any run that caused an error code was repeated to obtain a valid result. Results where there was a failed internal control and at least one positive target in another reaction chamber ("Positive with warning") were considered invalid for analytical performance studies and were repeated to obtain valid results. Acceptance criteria were ≥95% detection for positive and high-positive samples and 100% negative calls for negative samples.

Overall, 325 valid runs were included in the analysis. For all positive samples tested at all three sites, 100% detection was obtained for all expected targets (108/108 detected positive hits) (**Table 2**). No false positives were reported for any positive sample, and 100% negative calls were obtained for the negative samples.

Table 2: Results of Site-to-Site Reproducibility Study

Organism	Target Type	Agreement with Expected Results				95% C.I.	
		Site 1	Site 2	Site 3	Overall	Lower	Upper
<i>Acinetobacter calcoaceticus-baumannii</i> complex	Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100.0%
	High Positive	100% (37/37)	100% (36/36)	100% (36/36)	100% (109/109)	96.7%	100.0%
Pan Enterobacterales	Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100.0%
	High Positive	100% (37/37)	100% (36/36)	100% (36/36)	100% (109/109)	96.7%	100.0%
		(37/37)	(36/36)	(36/36)	(109/109)		
<i>Proteus</i> spp.	Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100.0%
	High Positive	100% (37/37)	100% (36/36)	100% (36/36)	100% (109/109)	96.7%	100.0%
<i>Pseudomonas aeruginosa</i>	Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100.0%
		(36/36)	(36/36)	(36/36)	(108/108)		
	High Positive	100% (37/37)	100% (36/36)	100% (36/36)	100% (109/109)	96.7%	100.0%
<i>Salmonella</i> spp.	Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100.0%

	High Positive	100% (37/37)	100% (36/36)	100% (36/36)	100% (109/109)	96.7%	100.0%
<i>Stenotrophomonas maltophilia</i>	Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100.0%
	High Positive	100% (37/37)	100% (36/36)	100% (36/36)	100% (109/109)	96.7%	100.0%
Resistance Markers							
OXA-24/40	Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100.0%
	High Positive	100% (37/37)	100% (36/36)	100% (36/36)	100% (109/109)	96.7%	100.0%
OXA-48-like	Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100.0%
	High Positive	100% (37/37)	100% (36/36)	100% (36/36)	100% (109/109)	96.7%	100.0%
VEB	Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100.0%
	High Positive	100% (37/37)	100% (36/36)	100% (36/36)	100% (109/109)	96.7%	100.0%

Lot-to-Lot Variability

A lot-to-lot study was conducted at one site using one operator on three QIAstat-Dx Analyzers per day over the course of 16 consecutive days. Three cartridge lots were used in the study, generating a total of 90 replicates per sample per lot (270 total valid runs). Acceptance criteria were $\geq 95\%$ detection for positive and high-positive samples and 100% negative calls for negative samples.

For all positive samples, 100% detection was obtained for all expected targets (90/90 detected positive hits across all three lots) (**Table 3**), and 100% negative calls were observed for the negative samples.

Table 3: Results of Lot-to-Lot Repeatability Study

Target	Sample	Agreement with Expected Results				95% C.I.	
		Lot 1	Lot 2	Lot 3	Overall	Lower	Upper
Organisms							
<i>Acinetobacter calcoaceticus-baumannii</i> complex	Positive	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (90/90)	96.0%	100.0%
	High Positive	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (90/90)	96.0%	100.0%
Pan Enterobacterales	Positive	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (90/90)	96.0%	100.0%
	High Positive	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (90/90)	96.0%	100.0%
<i>Proteus</i> spp.	Positive	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (90/90)	96.0%	100.0%
		100.0%	100.0%	100.0%	100.0%	96.0%	100.0%

	High Positive	(30/30)	(30/30)	(30/30)	(90/90)		
<i>Pseudomonas aeruginosa</i>	Positive	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (90/90)	96.0%	100.0%
	High Positive	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (90/90)	96.0%	100.0%
<i>Salmonella spp.</i>	Positive	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (90/90)	96.0%	100.0%
	High Positive	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (90/90)	96.0%	100.0%
<i>Stenotrophomonas maltophilia</i>	Positive	100.0%	100.0%	100.0%	100.0%	96.0%	100.0%
		(30/30)	(30/30)	(30/30)	(90/90)		
	High Positive	100.0%	100.0%	100.0%	100.0%	96.0%	100.0%
		(30/30)	(30/30)	(30/30)	(90/90)		
Resistance Markers							
OXA-24/40	Positive	100.0%	100.0%	100.0%	100.0%	96.0%	100.0%
		(30/30)	(30/30)	(30/30)	(90/90)		
	High Positive	100.0%	100.0%	100.0%	100.0%	96.0%	100.0%
		(30/30)	(30/30)	(30/30)	(90/90)		
OXA-48-like	Positive	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (90/90)	96.0%	100.0%
		100.0%	100.0%	100.0%	100.0%		
	High Positive	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (90/90)	96.0%	100.0%
		100.0%	100.0%	100.0%	100.0%		
VEB	Positive	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (90/90)	96.0%	100.0%
		100.0%	100.0%	100.0%	100.0%		
	High Positive	100.0% (30/30)	100.0% (30/30)	100.0% (30/30)	100.0% (90/90)	96.0%	100.0%
		100.0%	100.0%	100.0%	100.0%		

2. Linearity:

Not applicable, qualitative assay.

3. Analytical Specificity/Interference:

The QIAstat-Dx BCID GN Plus AMR Panel was evaluated for analytical specificity/cross-reactivity and interference.

Cross-Reactivity

A total of 107 organisms, including those phylogenetically related to on-panel organisms and organisms likely to be present in positive blood culture specimens (e.g., skin flora, environmental contaminants), were tested to verify the absence of cross-reactivity with the candidate device (**Table 4**). All bacterial samples were initially prepared by spiking organisms at high concentration into Negative Blood Culture Matrix (NBCM) at a minimum concentration of $\geq 1.5 \times 10^8$ CFU/mL; all fungi were tested at $\geq 1.50 \times 10^6$ CFU/mL. All samples were tested in triplicate. Where cross-reactivity was observed at the initial concentration, samples were serially diluted until a concentration was reached at which no cross-reactivity was detected. Studies were conducted in BD BACTEC Plus Aerobic bottles.

Table 5 lists the organisms for which cross-reactivity was observed, the targets detected by the candidate device, and the concentration at which the organism was no longer cross-reactive on the candidate device.

Table 4: List of Microorganisms Evaluated for Cross-Reactivity

Organism	Concentration Tested (CFU/mL)	Organism	Concentration Tested (CFU/mL)
<i>Acinetobacter haemolyticus</i>	1.50E+08	<i>Staphylococcus epidermidis</i>	1.50E+08
<i>Acinetobacter junii</i>	1.50E+08	<i>Streptococcus agalactiae</i>	1.50E+08
<i>Acinetobacter lwoffii</i>	1.50E+08	<i>Streptococcus anginosus</i>	1.50E+08
<i>Aeromonas hydrophila</i>	1.50E+08	<i>Streptococcus pyogenes</i>	1.50E+08
<i>Aeromonas salmonicida</i>	1.50E+08	<i>Acremonium kiliense</i>	1.74E+06
<i>Aeromonas sobria</i>	1.50E+08	<i>Candida albicans</i>	1.53E+06
<i>Eikenella corrodens</i>	1.50E+08	<i>Candida auris</i>	5.00E+06
<i>Haemophilus haemolyticus</i>	1.50E+08	<i>Candida glabrata</i>	1.14E+07
<i>Haemophilus parahaemolyticus</i>	1.50E+08	<i>Candida guilliermondii</i>	3.80E+07
<i>Legionella pneumophila</i>	1.50E+08	<i>Candida kefyr</i>	4.72E+07
<i>Neisseria flavescens</i>	1.50E+08	<i>Candida tropicalis</i>	1.66E+06
<i>Neisseria gonorrhoeae</i>	1.50E+08	<i>Corynebacterium jeikeium</i>	1.92E+07 ^b
<i>Neisseria sicca</i>	1.50E+08	<i>Corynebacterium striatum</i>	1.69E+08
<i>Pasteurella aerogenes</i>	1.50E+08	<i>Cryptococcus gattii</i>	3.10E+06
<i>Pasteurella multocida</i> subsp. <i>multocida</i>	1.50E+08	<i>Cryptococcus neoformans</i>	5.30E+06
<i>Pseudomonas fluorescens</i>	1.50E+08	<i>Propionibacterium/Cutibacterium acnes</i>	2.13E+08
<i>Pseudomonas mendocina</i>	1.50E+08	<i>Fusarium solani</i>	3.70E+03 ^b
<i>Pseudomonas putida</i>	1.50E+08	<i>Mucor velutinosus</i>	1.00E+05 ^b
<i>Pseudomonas stutzeri</i>	1.50E+08	<i>Staphylococcus capitis</i>	7.70E+07 ^b
<i>Ralstonia insidiosa</i>	1.50E+08	<i>Staphylococcus lugdunensis</i>	9.00E+07 ^b
<i>Ralstonia pickettii</i>	1.50E+08	<i>Trichosporon asahii</i>	8.00E+06
<i>Vibrio alginolyticus</i>	1.50E+08	<i>Trichosporon asteroides</i>	2.08E+05 ^b
<i>Vibrio furnissii</i>	1.50E+08	<i>Trichosporon mucoides</i>	4.00E+07
<i>Bacteroides caccae</i>	1.50E+08	<i>Penicillium marneffei</i> (gDNA ONLY HG3)	2.35E+07 ^a
<i>Bacteroides distasonis</i>	1.50E+08	<i>Trichosporon dermatis</i>	5.00E+06
<i>Bacteroides eggerthii</i>	1.50E+08	<i>Acinetobacter nosocomialis</i>	1.50E+08
<i>Bacteroides merdae</i>	1.50E+08	<i>Bacteroides ureolyticus</i>	1.50E+08
<i>Bacteroides ovatus</i>	1.50E+08	<i>Burkholderia cepacia</i>	1.50E+08
<i>Bacteroides thetaiotaomicron</i>	1.50E+08	<i>Corynebacterium diphtheriae</i>	6.30E+08
<i>Bacteroides vulgatus</i>	1.50E+08	<i>Lactobacillus acidophilus</i>	1.50E+08
<i>Fusobacterium gonidiaformans</i>	1.50E+08	<i>Malassezia furfur</i>	5.00E+06
<i>Fusobacterium necrophorum</i>	1.50E+08	<i>Rhodotorula minuta</i>	5.00E+06
<i>Fusobacterium nucleatum</i>	1.50E+08	<i>Neisseria perflava</i>	1.50E+08
<i>Fusobacterium varium</i>	1.50E+08	<i>Candida norvegensis</i>	5.00E+06
<i>Bacillus cereus</i>	1.50E+08	<i>Corynebacterium urealyticum</i>	1.50E+08
<i>Candida dublinensis</i>	5.00E+06	<i>Escherichia fergusonii</i> ^c	1.50E+08
<i>Candida famata</i>	5.00E+06	<i>Streptococcus pneumoniae</i>	1.50E+08
<i>Candida krusei</i>	5.00E+06	<i>Prevotella corporis</i>	1.50E+08
<i>Candida lusitanae</i>	5.00E+06	<i>Prevotella intermedia</i>	1.50E+08

<i>Candida metapsilosis</i>	5.00E+06	<i>Prevotella nigrescens</i>	1.50E+08
<i>Candida orthopsilosis</i>	5.00E+06	<i>Pseudomonas alcaligenes</i>	1.50E+08
<i>Candida parapsilosis</i>	5.00E+06	<i>Haemophilus aegyptius</i>	1.50E+08
<i>Corynebacterium ulcerans</i>	1.50E+08	<i>Leclercia adecarboxylata</i> °	1.50E+08
<i>Enterococcus faecalis</i>	1.50E+08	<i>Rhizobium pusense</i>	1.50E+08
<i>Enterococcus faecium</i>	1.50E+08	<i>Streptococcus galloyticus</i>	1.50E+08
<i>Lactobacillus casei</i>	1.50E+08	<i>Aggregatibacter aphrophilus</i>	1.50E+08
<i>Lactobacillus crispatus</i>	1.50E+08	<i>Kluyvera ascorbata</i> °	1.50E+08
<i>Lactobacillus paracasei</i>	1.50E+08	<i>Phytobacter diazotrophicus</i> °	1.50E+08
<i>Lactobacillus rhamnosus</i>	1.50E+08	<i>Phytobacter ursingii</i> °	1.50E+08
<i>Listeria innocua</i>	1.50E+08	<i>Burkholderia glumae</i>	1.50E+08
<i>Listeria monocytogenes</i>	1.50E+08	<i>Kluyvera intermedia</i> °	1.50E+08
<i>Micrococcus luteus</i>	1.50E+08	<i>Stenotrophomonas acidaminiphila</i>	1.50E+08
<i>Staphylococcus aureus</i>	1.50E+08	<i>Haemophilus parainfluenzae</i>	1.50E+08

^aD0 concentration reported in copies/ml because these samples were derived from gDNA stocks spiked into Negative Blood Culture Matrix.

^bSamples were not targeted to the intended starting test concentration of $\geq 1.50E+08$ CFU/mL for bacteria and $\geq 1.50E+06$ CFU/mL for fungal targets. The affected samples had a lower stock titre after growth than required for this study. All samples were derived from inoculating pre-cultured pathogen into blood culture bottles. The bottles were incubated in a blood culture instrument until 'positive ring' to obtain the 'positive' samples.

^cThese pathogens are part of the Enterobacterales order and a positive signal for Pan Enterobacterales is expected as confirmed by the *in silico* assessment as part of the "Inclusivity" Study. For six pathogens tested (*Leclercia adecarboxylata* EP100, *Phytobacter diazotrophicus* EP238, *Kluyvera intermedia* EP241, *Kluyvera ascorbate* EP237, *Phytobacter ursingi* EP239 and *Escherichia fergusonii* EP091) positive results were obtained for Pan Enterobacterales. All noted pathogens belong to the Enterobacterales order. *In silico* analysis as part of the "Inclusivity" Study was conducted and confirmed the assay to be inclusive of these pathogens for the Pan Enterobacterales target. Therefore, the signal cannot be considered a cross-reaction for the QIAstat-Dx BCID GN Plus AMR Panel as expected. Runs were valid and data were included in the line data.

Three runs obtained for EP080, *Acinetobacter nosocomialis*, were excluded from the analysis because it is an on-panel pathogen and was measured in error as the scope of the work was to assess cross-reactivity using off-panel pathogens.

Table 5: List of Microorganisms Where Cross-Reactivity Observed

Organism	Target Detected	Concentration (CFU/mL)
<i>Acinetobacter junii</i>	<i>Acinetobacter calcoaceticus-baumannii</i> complex	3.27E+04
<i>Leclercia adecarboxylata</i>	<i>Enterobacter</i> spp.	3.16E+05
<i>Pseudomonas mendocina</i>	<i>Pseudomonas aeruginosa</i>	2.88E+05
<i>Stenotrophomonas acidaminiphila</i>	<i>Stenotrophomonas maltophilia</i>	7.50E+05

NOTE: Cross-reactivity was confirmed by *in vitro* testing at the initial concentration and serial dilution. Concentration shown is the lowest tested concentration at which all three replicates were negative (no cross-reactivity). Three additional organisms (*Kluyvera ascorbata* / CTX-M; *Escherichia fergusonii* / TEM; *Haemophilus aegyptius* / *H. influenzae*) produced unexpected signals but cross-reactivity was discarded upon investigation (on-panel gene carriers or expected subgroup targets).

In silico Analysis

Primers and probes included in the QIAstat-Dx BCID GN Plus AMR Panel were analyzed to evaluate their specificity using BLAST homology analysis run against the Core nucleotide database from The National Center for Biotechnology Information (NCBI) database. A dedicated analysis was performed to determine the specificity of the PCR assays detecting AMR genes. Results of the *in silico* analysis are shown in **Table 6** below. Target organisms for which sequences predicted potential cross-reactivity are listed.

Table 6: Summary Results of *In silico* Cross-Reactivity Analysis

Target	In Silico Prediction
<i>Bacteroides fragilis</i>	Cross-reaction with <i>Bacteroides hominis</i> (<i>B. fragilis</i> Division II now recognized as <i>B. hominis</i> ; cross-reaction expected based on assay design).
<i>Enterobacter</i> spp.	Cross-reaction with some <i>Citrobacter</i> species (<i>C. braakii</i> , <i>C. cronae</i> , <i>C. europaeus</i> , <i>C. freundii</i> , <i>C. portucalensis</i> , <i>C. youngae</i>), <i>Kosakonia cowanii</i> , <i>Kosakonia radicincitans</i> , and <i>Leclercia adecarboxylata</i> .
<i>Klebsiella</i> spp.	Cross-reaction with <i>Lelliottia amnigena</i> (all 9 available genomes predicted to be detected; confirmed by in vitro Inclusivity Study).
<i>Proteus</i> spp.	Cross-reaction with <i>Pantoea agglomerans</i> (52/53 complete genomes predicted to be detected).
<i>Escherichia coli</i>	Cross-reaction with <i>Escherichia ruysiae</i> and <i>Shigella</i> spp. (<i>S. boydii</i> , <i>S. flexneri</i> , <i>S. dysenteriae</i> , <i>S. sonnei</i>). <i>Rhizobium pusense</i> predicted in silico but not confirmed in vitro.
<i>Stenotrophomonas maltophilia</i>	Cross-reaction with <i>S. muris</i> (within <i>S. maltophilia</i> complex), <i>S. acidaminiphila</i> , <i>S. riyadhensis</i> , and <i>S. tuberculopleuritidis</i> .
<i>Pseudomonas aeruginosa</i>	Cross-reaction with <i>Pseudomonas denitrificans</i> (<i>in silico</i>). <i>P. fluorescens</i> and <i>P. triclosanedens</i> discarded as cross-reactants.
<i>aac(6')-Ib</i>	Cross-reaction with ANT(3'')-II-AAC(6')-IId (rare fused mechanism; originally described in a single <i>S. marcescens</i> clinical isolate; no evidence of widespread clinical distribution).
<i>ampC</i> (FOX)	Cross-reaction with MOX-9 (plasmid-mediated class C β -lactamase; identified in a single clinical/hospital instance; no human BSI reports).
SHV	Cross-reaction with blaOKP-c-1, blaAAK-1, and LEN β -lactamase family (chromosomal β -lactamases in <i>K. quasipneumoniae</i> and <i>K. variicola</i> ; confer low-level intrinsic resistance only).
NDM	Cross-reaction with AFM β -lactamase family (rare class B MBL; BSIs involving AFM producers are exceptionally rare and limited to isolated case reports).

Competitive Inhibition (Microbial Interference)

A competitive inhibition study was conducted to evaluate the capability of the QIAstat-Dx BCID GN Plus AMR Panel to detect multiple analytes in one sample when one pathogen is present at a high concentration and another pathogen is present at a lower concentration.

Twenty-one organism strains from commercial suppliers were used to create representative combinations of on-panel and off-panel organisms commonly found in polymicrobial positive blood cultures. Samples were prepared by spiking one organism at high concentration (bottle positive + 24 hours of incubation) into Negative Blood Culture Matrix (NBCM), and the second organism at a lower concentration targeted at approximately 3 $\times$ LoD for that pathogen (**Table 7**). Studies were conducted in BD BACTEC Plus Aerobic and BD BACTEC Plus Anaerobic bottles.

Table 7: List of Tested Organism Mixtures in Competitive Inhibition Study

Mix	High Positive		Low Positive	
	Organism	Concentration (CFU/mL)	Organism	Concentration (CFU/mL)
1	<i>Escherichia coli</i> (CCUG 70662)	6.08E+08	<i>Klebsiella pneumoniae</i> (CCUG 68728)	9.00E+04
1	<i>Klebsiella pneumoniae</i> (CCUG 68728)	1.40E+09	<i>Escherichia coli</i> (CCUG 70662)	1.24E+06
2	<i>Escherichia coli</i> (NCTC 14320)	2.01E+09	<i>Proteus mirabilis</i> (ATCC BAA-2792)	9.00E+04
2	<i>Proteus mirabilis</i> (ATCC BAA-2792)	3.17E+09	<i>Escherichia coli</i> (NCTC 14320)	1.24E+06
3	<i>Klebsiella pneumoniae</i> (CCUG 68728)	1.40E+09	<i>Enterobacter cloacae</i> (NCTC 14326)	8.10E+06
3	<i>Enterobacter cloacae</i> (NCTC 14326)	9.56E+08	<i>Klebsiella pneumoniae</i> (CCUG 68728)	9.00E+04
4	<i>Escherichia coli</i> (NCTC 14320)	2.01E+09	<i>Enterobacter cloacae</i> (NCTC 14326)	8.10E+06
4	<i>Enterobacter cloacae</i> (NCTC 14326)	9.56E+08	<i>Escherichia coli</i> (NCTC 14320)	1.24E+06
5	<i>Pseudomonas aeruginosa</i> (NCTC 13921)	1.41E+09	<i>Proteus mirabilis</i> (ATCC BAA-2792)	9.00E+04
5	<i>Proteus mirabilis</i> (ATCC BAA-2792)	3.17E+09	<i>Pseudomonas aeruginosa</i> (NCTC 13921)	2.52E+06
6	<i>Acinetobacter baumannii</i> (ATCC BAA-2801)	1.38E+08	<i>Klebsiella pneumoniae</i> (CCUG 68728)	9.00E+04
6	<i>Klebsiella pneumoniae</i> (CCUG 68728)	1.40E+09	<i>Acinetobacter baumannii</i> (ATCC BAA-2801)	5.34E+04
7	<i>Proteus mirabilis</i> (ATCC BAA-2792)	3.17E+09	<i>Klebsiella pneumoniae</i> (CCUG 68728)	9.00E+04
7	<i>Klebsiella pneumoniae</i> (CCUG 68728)	1.40E+09	<i>Proteus mirabilis</i> (ATCC BAA-2792)	9.00E+04
8	<i>Acinetobacter baumannii</i> (NCTC 13302)	2.72E+08	<i>Pseudomonas aeruginosa</i> (NCTC 13921)	2.52E+06
8	<i>Pseudomonas aeruginosa</i> (NCTC 13921)	1.41E+09	<i>Acinetobacter baumannii</i> (NCTC 13302)	5.52E+02
9	<i>Bacteroides fragilis</i> (CCUG 4856T)	8.19E+09	<i>Escherichia coli</i> (NCTC 14320)	1.24E+06
9	<i>Escherichia coli</i> (NCTC 14320)	2.01E+09	<i>Bacteroides fragilis</i> (CCUG 4856T)	3.90E+04
10	<i>Pseudomonas aeruginosa</i> (ATCC BAA-2799)	6.62E+07	<i>Stenotrophomonas maltophilia</i> (NCTC 10259)	2.54E+08
10	<i>Stenotrophomonas maltophilia</i> (NCTC 10259)	2.05E+09	<i>Pseudomonas aeruginosa</i> (ATCC BAA-2799)	8.28E+06
10	<i>Pseudomonas aeruginosa</i> (NCTC 13921)	1.25E+09	<i>Stenotrophomonas maltophilia</i> (NCTC 10259)	2.54E+08
11	<i>Klebsiella pneumoniae</i> (CCUG 68728)	1.40E+09	<i>Serratia marcescens</i> (ATCC 14041)	1.89E+08
11	<i>Serratia marcescens</i> (ATCC 14041)	4.82E+08	<i>Klebsiella pneumoniae</i> (CCUG 68728)	9.00E+04
12	<i>Acinetobacter baumannii</i> (ATCC BAA-2801)	1.38E+08	<i>Enterobacter cloacae</i> (NCTC 14326)	8.10E+06
12	<i>Enterobacter cloacae</i> (NCTC 14326)	9.56E+08	<i>Acinetobacter baumannii</i> (ATCC BAA-2801)	5.34E+04
13	<i>Cutibacterium acnes</i> (NCTC 737)	1.71E+08	<i>Escherichia coli</i> (NCTC 14320)	1.24E+06
14	<i>Enterococcus faecium</i> (ATCC BAA-2316)	8.96E+08	<i>Klebsiella pneumoniae</i> (CCUG 68728)	9.00E+04
15	<i>Bacillus cereus</i> (ATCC 21769)	1.87E+06	<i>Pseudomonas aeruginosa</i> (ATCC BAA-2799)	8.28E+06
16	<i>Corynebacterium striatum</i> (ATCC 43735)	9.54E+08	<i>Acinetobacter baumannii</i> (NCTC 13302)	5.52E+02
17	<i>Candida albicans</i> (ATCC 10231)	1.83E+07	<i>Enterobacter cloacae</i> (NCTC 14326)	8.10E+06
18	<i>Micrococcus luteus</i> (NCTC 7011)	2.13E+08	<i>Serratia marcescens</i> (ATCC 14041)	1.89E+08

19	<i>Staphylococcus aureus</i> (ATCC BAA-2313)	2.09E+08	<i>Proteus mirabilis</i> (ATCC BAA-2792)	9.00E+04
20	<i>Staphylococcus epidermidis</i> (ATCC 35984)	7.29E+08	<i>Bacteroides fragilis</i> (CCUG 4856T)	3.90E+04
21	<i>Enterococcus faecalis</i> (ATCC 51299)	7.25E+08	<i>Stenotrophomonas maltophilia</i> (NCTC 10259)	2.54E+08

Endogenous/Exogenous Interference

An interfering substances study was conducted to evaluate whether potentially interfering endogenous or exogenous substances that may be present in positive blood culture specimens impact the performance of the QIAstat-Dx BCID GN Plus AMR Panel. A single positive sample mix was prepared by combining three (3) representative on-panel isolates *Escherichia coli* (NCTC 14325), *Acinetobacter baumannii* (CCUG 57249), and *Pseudomonas aeruginosa* (MRSN 12914) at approximately 3×LoD for each pathogen in Negative Blood Culture Matrix (NBCM), covering all eight Reaction Chambers of the QIAstat-Dx BCID GN Plus AMR Panel cartridge (**Table 8**). A negative sample was prepared by inoculating blood culture bottles with whole human blood without any pathogenic material and incubating until a negative ring was confirmed. Studies were conducted in BD BACTEC Plus Aerobic bottles.

Table 8: Positive Sample Mix Composition

Pathogen	Test Concentration (CFU/mL)
<i>Escherichia coli</i>	4.05E+05
<i>Acinetobacter baumannii</i>	5.34E+04
<i>Pseudomonas aeruginosa</i>	3.00E+07

Interfering substances were individually spiked into the positive and negative sample mixes to achieve the test concentrations listed in **Table 9** below.

All targets were detected in the positive sample mix and no false positives were observed in the negative sample mix for all substances tested, with one exception: Amoxicillin at 0.075 mg/mL caused inhibition of the *Acinetobacter calcoaceticus-baumannii* complex target (2/3 replicates detected). Upon retesting at the lower concentration of 0.038 mg/mL, full detection (3/3) was restored with no interference observed.

Table 9: List of Potentially Interfering Substances

Substance	Concentration in Blood Culture Bottle	Solvent
Acetaminophen	0.156 mg/mL	Water
Amoxicillin	0.075 mg/mL ^a	Water
Amoxicillin trihydrate: potassium clavulanate (4:1)	0.075 mg/mL	Water
Amphotericin B	0.002 mg/mL	DMSO
Ara-C Triphosphate	2.64 µg/mL	Water
Biotin (Vitamin B7)	0.00351 mg/mL	DMSO

Sodium hypochlorite solution (Bleach)	5% (v/v) / 6 mg/mL	N/A
Caspofungin Diacetate	0.005 mg/mL	DMSO
Ceftriaxone Disodium Hemiheptahydrate	0.966 mg/mL	Water
Ciprofloxacin	0.01 mg/mL	DMSO
Ethanol	5% (v/v) / 39.4 mg/mL	N/A
Fluconazole	0.075 mg/mL	Ethanol
5-Fluorocytosine	0.09 mg/mL	Water
Gentamicin sulfate	0.03 mg/mL	Water
Heparin Sodium	3 Units/mL	Water
Ibuprofen	0.219 mg/mL	DMSO
Imipenem Monohydrate	0.5 mg/mL	Water
Povidone (iodinated)	5 mg/mL	Water
Salicylic Acid	0.0286 mg/mL	Water
Sodium Polyanethol Sulfonate (SPS)	0.0025 mg/mL	Water
Tetracycline Hydrochloride	0.015 mg/mL	Water
Vancomycin (hydrochloride)	0.12 mg/mL	Water
Bilirubin (unconjugated)	0.25 mg/mL	Chloroform
Cholesterol	0.5 mg/mL	Ethanol
D-Glucose	5 mg/mL	Water
γ -globulin	60 mg/mL	Saline
Haemoglobin	5 mg/mL	Water
Magnesium Sulphate (MgSO ₄)	0.1 mg/mL	Water
Human genomic DNA (hgDNA)	10.55 μ g/mL	N/A
Human Serum Albumin	25 mg/mL	Water
Triglycerides (Lipid standards)	15 mg/mL	Chloroform
Fibrinogen	0.5 mg/mL	Saline

4. Detection Limit and Assay Reportable Range:

Limit of Detection Studies

Limit of detection (LoD) studies were conducted to determine the LoD for the QIAstat-Dx BCID GN Plus AMR Panel, defined as the lowest concentration of organism detected in positive blood culture samples at least 95% of the time. The LoD was determined in combined isolate mixtures and verified in single-spiked samples.

Combined LoD Study

Seventeen combined sample mixtures were prepared, with up to three organisms per mix, covering a minimum of two isolates for each of the 31 targets on the panel. Samples were prepared using two methods: (1) pre-cultured pathogenic material was inoculated into blood culture bottles (BD BACTEC Plus Aerobic or Anaerobic media) and incubated until

"positive ring," and (2) for seven isolates where high-titer material was insufficient, 5.0 McFarland suspensions were generated and spiked into negative blood culture matrix (NBCM). All samples were enumerated to determine CFU/mL concentration and serially diluted in NBCM to concentrations ranging from 10× to 0.01× the estimated LoD.

The LoD was established at the lowest concentration yielding a detection rate of ≥95% (≥19/20 replicates), with at least two dropouts observed at the 10-fold lower concentration.

For all 31 intended targets, the LoD was successfully established in at least two isolates.

Table 10 summarized the LoD results.

Table 10: Summary of Established LoD Equivalency

Target	Organism	LoD (CFU/mL)	Combined LoD (CFU/mL)
Organisms			
<i>Acinetobacter calcoaceticus-baumannii</i> complex	<i>Acinetobacter baumannii</i>	3.50E+04	2.31E+04
	<i>Acinetobacter baumannii</i>	1.78E+04	
	<i>Acinetobacter baumannii</i>	1.78E+04	
	<i>Acinetobacter baumannii</i>	4.14E+04	
	<i>Acinetobacter baumannii</i>	3.50E+03	
<i>Bacteroides fragilis</i>	<i>B. fragilis</i>	1.30E+04	1.30E+04
	<i>B. fragilis</i>	1.30E+04	
<i>Enterobacter</i> spp.	<i>E. asburiae</i>	3.40E+05	1.52E+06
	<i>E. cloacae</i>	2.70E+06	
<i>Escherichia coli</i>	<i>E. coli</i>	3.14E+05	2.26E+05
	<i>E. coli</i>	1.35E+05	
	<i>E. coli</i>	2.30E+05	
<i>Haemophilus influenzae</i>	<i>H. influenzae</i>	9.05E+04 copies/ml ^b (9.00E+03 CFU/ml)	5.46E+04 copies/mL ^b
	<i>H. influenzae</i>	1.87E+04 copies/ml ^b	
<i>Klebsiella</i> spp.	<i>K. pneumoniae</i>	3.00E+04	9.84E+04
	<i>K. pneumoniae</i>	3.00E+04	
	<i>K. pneumoniae</i>	3.00E+05	
	<i>K. pneumoniae</i>	3.38E+04	
<i>Neisseria meningitidis</i> (encapsulated)	<i>Neisseria meningitidis</i> (encapsulated)	1.00E+03	5.50E+03
	<i>Neisseria meningitidis</i> (encapsulated)	1.00E+04	
Pan Enterobacterales	<i>H. parveii</i>	1.26E+07	6.38E+06
	<i>C. freundii</i>	1.60E+05	
<i>Proteus</i> spp.	<i>P. vulgaris</i>	3.00E+05	1.65E+05
	<i>P. mirabilis</i>	3.00E+04	

<i>Pseudomonas aeruginosa</i>	<i>P. aeruginosa</i>	1.00E+07	2.76E+06
	<i>P. aeruginosa</i>	1.00E+06	
	<i>P. aeruginosa</i>	9.60E+05	
	<i>P. aeruginosa</i>	8.40E+05	
	<i>P. aeruginosa</i>	1.00E+06	
<i>Salmonella</i> spp.	<i>S. enterica</i> ^a	1.00E+04	7.50E+03
	<i>S. enterica</i>	5.00E+03	
<i>Serratia</i> spp.	<i>S. marcescens</i>	7.00E+06	3.54E+06
	<i>S. liquefaciens</i>	7.50E+04	
<i>Stenotrophomonas maltophilia</i>	<i>S. maltophilia</i>	1.63E+08	8.48E+07
	<i>S. maltophilia</i>	6.50E+06	
Resistance Markers			
<i>aac(6')-Ib</i>	<i>K. pneumoniae</i>	3.00E+04	1.94E+05
	<i>P. aeruginosa</i>	1.00E+05	
	<i>E. coli</i>	1.35E+04	
	<i>K. pneumoniae</i>	3.38E+04	
	<i>P. aeruginosa</i>	8.40E+05	
	<i>P. aeruginosa</i>	1.00E+05	
	<i>P. mirabilis</i>	3.00E+05	
	<i>K. pneumoniae</i>	3.00E+04	
	<i>K. pneumoniae</i>	3.00E+05	
<i>ampC</i> (CMY/LAT/DHA/F OX)	<i>K. pneumoniae</i>	3.38E+05	2.66E+05
	<i>P. mirabilis</i>	3.00E+05	
	<i>C. freundii</i>	1.60E+05	
<i>armA</i>	<i>Acinetobacter baumannii</i>	1.78E+04	2.58E+04
	<i>K. pneumoniae</i>	3.38E+04	
CTX-M	<i>K. pneumoniae</i>	3.00E+04	2.58E+04
	<i>E. coli</i>	1.35E+04	
	<i>K. pneumoniae</i>	3.38E+04	
GES	<i>K. pneumoniae</i>	3.00E+04	6.50E+04
	<i>P. aeruginosa</i>	1.00E+05	
IMP	<i>E. coli</i>	3.14E+05	1.72E+05
	<i>K. pneumoniae</i>	3.00E+04	
KPC	<i>E. coli</i>	2.30E+05	2.65E+05
	<i>K. pneumoniae</i>	3.00E+05	
NDM	<i>E. coli</i>	1.35E+05	1.76E+06
	<i>K. pneumoniae</i>	3.38E+06	
OXA-23	<i>Acinetobacter baumannii</i>	1.78E+04	2.96E+04
	<i>Acinetobacter baumannii</i> ^a	4.14E+04	
OXA-24/40	<i>Acinetobacter baumannii</i>	1.78E+04	3.76E+04

	<i>Acinetobacter baumannii</i>	5.73E+04	
OXA-48 like	<i>E. coli</i>	2.30E+05	1.17E+05
	<i>S. enterica</i>	5.00E+03	
OXA-58	<i>Acinetobacter baumannii</i>	3.50E+04	1.93E+04
	<i>Acinetobacter baumannii</i>	3.50E+03	
PER	<i>Acinetobacter baumannii</i> ^a	4.14E+05	2.57E+05
	<i>P. aeruginosa</i>	1.00E+05	
SHV	<i>K. pneumoniae</i>	3.00E+04	1.66E+05
	<i>K. pneumoniae</i>	3.00E+05	
	<i>K. pneumoniae</i>	3.38E+04	
	<i>K. pneumoniae</i>	3.00E+05	
SPM	<i>P. aeruginosa</i>	9.60E+06	5.22E+06
	<i>P. aeruginosa</i>	8.40E+05	
TEM	<i>K. pneumoniae</i>	3.00E+05	1.75E+06
	<i>E. coli</i>	3.14E+05	
	<i>K. pneumoniae</i>	3.38E+06	
	<i>P. mirabilis</i>	3.00E+06	
VEB	<i>P. aeruginosa</i>	1.00E+07	5.50E+06
	<i>P. aeruginosa</i>	1.00E+06	
VIM	<i>P. aeruginosa</i>	1.00E+06	3.50E+05
	<i>P. aeruginosa</i>	1.00E+05	
	<i>E. cloacae</i>	2.70E+05	
	<i>P. mirabilis</i>	3.00E+04	

^a An error caused additional replicate to be included in the dataset but did not have an influence on LoD determination as all (21/21) or none (0/21) of the replicates for the individual targets in this mix were positive.

^b Isolate Stock specific LoD and average LoD for *H. influenzae* isolates are shown in copies/ml instead of CFU/ml. LoD for *H. influenzae* isolate CCUG 23946 was determined to be at 9.00E+03 CFU/ml.

Single-Spiked LoD Verification Study

A separate single-spiked LoD study was conducted using 18 single-isolate samples detecting 22 intended targets to verify that LoD performance in combined multi-isolate mixes is equivalent to that in single-isolate samples. The same sample preparation methods and serial dilution scheme were used, with testing at 1× and 0.1× the expected LoD (derived from the combined LoD study). A semi-log concentration (3.16× expected LoD) was used if ≥95% detection was not achieved at 1× LoD. For 18 out of 22 intended targets, LoD equivalency between single-spiked and combined samples was confirmed.

Results were compared to the Growth and Detection Study to ensure that LoDs were at or below the concentration in positive blood culture specimens.

Growth and Detection

A growth and detection study was conducted to establish the range of expected organism concentrations present in positive blood culture samples at bottle positivity ("positive ring") and to verify that the QIAstat-Dx BCID GN Plus AMR Panel can detect all panel targets in Positive Blood Culture Media.

Eighteen contrived single-spiked blood culture samples were prepared, with one representative isolate per organism, covering all pathogens and AMR genes on the panel. In some cases, additional isolates of the same pathogen were included to represent different AMR genes. Each pathogen was inoculated into three individual BD BACTEC Plus Aerobic blood culture bottles (BD BACTEC Plus Anaerobic bottles were used for *Bacteroides fragilis*). Bottles were incubated in a blood culture instrument until "positive ring," removed within two hours of positive detection, and tested within two hours of removal. Each bottle replicate was enumerated to determine CFU/mL concentration. **Table 11** below summarizes the results from the growth and detection study.

Table 11: Results for Growth and Detection Study

Target	Organism	Established LoD (CFU/mL)	Bottle Positive Concentration (CFU/mL)
Organisms			
<i>Acinetobacter calcoaceticus-baumannii</i> complex	<i>A. baumannii</i> (NCTC 13305)	3.50E+04	2.11E+08
	<i>A. baumannii</i> (ATCC BAA-2803)	1.78E+04	1.65E+08
	<i>A. baumannii</i> (CCUG 57249)	1.78E+04	6.47E+07
	<i>A. baumannii</i> (ATCC BAA-2801)	4.14E+04	1.65E+08
	<i>A. baumannii</i> (ATCC BAA-2890)	3.50E+03	4.03E+07
<i>Bacteroides fragilis</i>	<i>B. fragilis</i> (NCTC 11625)	1.30E+04	5.78E+08
	<i>B. fragilis</i> (NCTC 8560)	1.30E+04	5.78E+08
<i>Enterobacter</i> spp.	<i>E. asburiae</i> (ATCC 35955)	3.40E+05	3.25E+08
	<i>E. cloacae</i> (NCTC 14326)	2.70E+06	3.25E+08
<i>Escherichia coli</i>	<i>E. coli</i> (CCUG 67180)	3.14E+05	1.36E+08
	<i>E. coli</i> (NCTC 14325)	1.35E+05	9.23E+07
	<i>E. coli</i> (NCTC 14321)	2.30E+05	1.36E+08
<i>Haemophilus influenzae</i>	<i>H. influenzae</i> (CCUG 23946)	9.05E+04 copies/mL ^b	7.68E+07
	<i>H. influenzae</i> (CCUG 33775)	1.87E+04 copies/mL ^b	7.68E+07
<i>Klebsiella</i> spp.	<i>K. pneumoniae</i> (ATCC BAA-3077)	3.00E+04	7.70E+07
	<i>K. pneumoniae</i> (NCTC 14334)	3.00E+04	7.70E+07
	<i>K. pneumoniae</i> (ATCC BAA-1705)	3.00E+05	7.70E+07
	<i>K. pneumoniae</i> (CCUG 68728)	3.38E+04	7.70E+07
<i>Neisseria meningitidis</i> (encapsulated)	<i>N. meningitidis</i> (ATCC 13090)	1.00E+03	1.94E+08
	<i>N. meningitidis</i> (ATCC 13077)	1.00E+04	1.94E+08
Pan Enterobacterales	<i>H. parveii</i> (CCUG 59411)	1.26E+07	3.25E+08
	<i>C. freundii</i> (CCUG 418T)	1.60E+05	4.79E+07
<i>Proteus</i> spp.	<i>P. vulgaris</i> (ATCC 6380)	3.00E+05	1.91E+08
	<i>P. mirabilis</i> (ATCC BAA-2792)	3.00E+04	1.91E+08
<i>Pseudomonas aeruginosa</i>	<i>P. aeruginosa</i> (MRSN 12914)	1.00E+07	2.21E+08
	<i>P. aeruginosa</i> (NCTC 13437)	1.00E+06	3.46E+07
	<i>P. aeruginosa</i> (JMI 378769)	9.60E+06	3.46E+07

	<i>P. aeruginosa</i> (NCTC 13921)	8.40E+05	3.46E+07
	<i>P. aeruginosa</i> (ATCC BAA-2794)	1.00E+06	2.21E+08
<i>Salmonella</i> spp.	<i>S. enterica</i> (ATCC 6962)	1.00E+04	4.32E+08
	<i>S. enterica</i> (NCTC 13954)	5.00E+03	4.32E+08
<i>Serratia</i> spp.	<i>S. marcescens</i> (ATCC 14041)	7.00E+06	3.83E+08
	<i>S. liquefaciens</i> (ATCC 27592)	7.50E+04	3.83E+08
<i>Stenotrophomonas maltophilia</i>	<i>S. maltophilia</i> (NCTC 10499)	1.63E+08	1.57E+07 ^c
	<i>S. maltophilia</i> (NCTC 10258)	6.50E+06	1.57E+07 ^c
<i>ampC</i> (CMY/LAT/DHA/FOX)	<i>K. pneumoniae</i> (CCUG 68728)	3.38E+05	7.70E+07
	<i>P. mirabilis</i> (ATCC BAA-2792)	3.00E+05	1.91E+08
	<i>C. freundii</i> (CCUG 418T)	1.60E+05	4.79E+07
Resistance Markers			
<i>aac(6')-Ib</i>	<i>K. pneumoniae</i> (ATCC BAA-3077)	3.00E+04	7.70E+07
	<i>P. aeruginosa</i> (ATCC BAA-2799)	1.00E+05	2.21E+08
	<i>E. coli</i> (NCTC 14325)	1.35E+04	1.36E+08
	<i>K. pneumoniae</i> (CCUG 68728)	3.38E+04	7.70E+07
	<i>P. aeruginosa</i> (NCTC 13921)	8.40E+05	3.46E+07
	<i>P. aeruginosa</i> (ATCC BAA-2794)	1.00E+05	2.21E+08
	<i>P. mirabilis</i> (ATCC BAA-2792)	3.00E+05	1.91E+08
	<i>K. pneumoniae</i> (NCTC 14334)	3.00E+04	7.70E+07
	<i>K. pneumoniae</i> (ATCC BAA-1705)	3.00E+05	7.70E+07
<i>armA</i>	<i>A. baumannii</i> (ATCC BAA-2803)	1.78E+04	1.65E+08
	<i>K. pneumoniae</i> (CCUG 68728)	3.38E+04	7.70E+07
CTX-M	<i>K. pneumoniae</i> (ATCC BAA-3077)	3.00E+04	7.70E+07
	<i>E. coli</i> (NCTC 14325)	1.35E+04	9.23E+07
	<i>K. pneumoniae</i> (CCUG 68728)	3.38E+04	7.70E+07
GES	<i>K. pneumoniae</i> (ATCC BAA-3077)	3.00E+04	7.70E+07
	<i>P. aeruginosa</i> (ATCC BAA-2794)	1.00E+06 ^a	2.21E+08
IMP	<i>E. coli</i> (CCUG 67180)	3.14E+05	1.36E+08
	<i>K. pneumoniae</i> (NCTC 14334)	3.00E+04	7.70E+07
KPC	<i>E. coli</i> (NCTC 14321)	2.30E+05	1.36E+08
	<i>K. pneumoniae</i> (ATCC BAA-1705)	3.00E+05	7.70E+07
NDM	<i>E. coli</i> (NCTC 14325)	1.35E+05	9.23E+07
	<i>K. pneumoniae</i> (CCUG 68728)	3.38E+06	7.70E+07
OXA-23	<i>A. baumannii</i> (ATCC BAA-2803)	1.78E+04	1.65E+08
	<i>A. baumannii</i> (ATCC BAA-2801)	4.14E+04	1.65E+08

OXA-24/40	<i>A. baumannii</i> (CCUG 57249)	1.78E+04	6.47E+07
	<i>A. baumannii</i> (ATCC BAA-2881)	5.73E+04	2.11E+08
OXA-48-like	<i>E. coli</i> (NCTC 14321)	2.30E+05	1.36E+08
	<i>S. enterica</i> (NCTC 13954)	5.00E+03	4.32E+08
OXA-58	<i>A. baumannii</i> (NCTC 13305)	3.50E+04	2.11E+08
	<i>A. baumannii</i> (ATCC BAA-2890)	3.50E+03	4.03E+07
PER	<i>A. baumannii</i> (ATCC BAA-2801)	4.14E+05	1.65E+08
	<i>P. aeruginosa</i> (ATCC BAA-2799)	1.00E+05	2.21E+08
SHV	<i>K. pneumoniae</i> (ATCC BAA-3077)	3.00E+04	7.70E+07
	<i>K. pneumoniae</i> (ATCC BAA-1705)	3.00E+05	7.70E+07
	<i>K. pneumoniae</i> (CCUG 68728)	3.38E+04	7.70E+07
	<i>K. pneumoniae</i> (NCTC 14334)	3.00E+05	7.70E+07
SPM	<i>P. aeruginosa</i> (JMI 378769)	9.60E+06	3.46E+07
	<i>P. aeruginosa</i> (NCTC 13921)	8.40E+05	3.46E+07
TEM	<i>K. pneumoniae</i> (ATCC BAA-3077)	3.00E+05	7.70E+07
	<i>E. coli</i> (CCUG 67180)	3.14E+05	1.36E+08
	<i>K. pneumoniae</i> (CCUG 68728)	3.38E+06	7.70E+07
	<i>P. mirabilis</i> (ATCC BAA-2792)	3.00E+06	1.91E+08
VEB	<i>P. aeruginosa</i> (MRSN 12914)	1.00E+07	2.21E+08
	<i>P. aeruginosa</i> (NCTC 13437)	1.00E+06	3.46E+07
VIM	<i>P. aeruginosa</i> (NCTC 13437)	1.00E+06	3.46E+07
	<i>P. aeruginosa</i> (ATCC BAA-2799)	1.00E+05	2.21E+08
	<i>E. cloacae</i> (NCTC 14326)	2.70E+05	3.25E+08
	<i>P. mirabilis</i> (ATCC BAA-2792)	3.00E+04	1.91E+08

^a GES LoD: the established single-spiked LoD (1.00E+06 CFU/mL) is reported, as it is higher (less sensitive) than the combined LoD and represents the claimed IFU value.

^b *H. influenzae* LoD is expressed in copies/mL because a valid CFU/mL titre could not be determined for isolate CCUG 33775; the LoD for isolate CCUG 23946 was established at 9.00×10^3 CFU/mL.

^c The LoD for *S. maltophilia* isolate NCTC 10499 (1.63E+08 CFU/mL) exceeds the initial mean bottle positive concentration (1.57 E+07 CFU/mL). An expanded analysis incorporating data from multiple verification studies yielded a revised mean BP concentration of 8.76E+08 CFU/mL, which exceeds the LoD for both isolates.

A detection rate of 100% (9/9) was achieved for all 31 panel targets across all 18 isolates tested, meeting the $\geq 95\%$ acceptance criterion. No false-positive signals for on-panel targets were observed in any replicate, demonstrating the absence of on-panel cross-reactivity in this study.

Analytical Reactivity/Inclusivity

An analytical reactivity/inclusivity study was conducted to evaluate the inclusivity of the QIAstat-Dx BCID GN Plus AMR Panel through testing of clinically relevant organism subtypes, strains, genotypes, serotypes, species, and AMR gene variants representing the genetic, temporal, and geographic diversity for each on-panel reportable target (**Table 12**).

Strains that did not achieve 100% detection and their corresponding test results are shown in Table 13. The study comprised both an *in silico* and an *in vitro* component, as well as an assessment of on-panel cross-reactivity.

Table 12: List of Wet Tested Organism for Inclusivity

Target	Species	Catalogue No.	Strain Designation / Strain Name	Result
Organisms				
<i>Acinetobacter calcoaceticus-baumannii</i> complex	<i>A. baumannii</i>	PA212222	N/A	Detected
	<i>A. calcoaceticus</i>	CCUG 57816	RUH2202	Detected
	<i>A. nosocomialis</i>	CCUG 74064	NIPH 2119	Detected
	<i>A. baumannii</i>	ATCC BAA-2801	1103521	Detected
	<i>A. baumannii</i>	ATCC BAA-2803	1125209	Detected
	<i>A. baumannii</i>	ATCC BAA-2881	1173844	Detected
	<i>A. baumannii</i>	ATCC BAA-2901	157075	Detected
	<i>A. baumannii</i>	ATCC BAA-2890	177579	Detected
	<i>A. baumannii</i>	ATCC BAA-2895	N/A	Detected
	<i>A. baumannii</i>	ATCC BAA-2873	1081925	Detected
	<i>A. baumannii</i>	CCUG 57249	N/A	Detected
	<i>A. baumannii</i>	CCUG 68164	N/A	Detected
	<i>A. baumannii</i>	NCTC 13302	OXA-25, 327009	Detected
	<i>A. baumannii</i>	NCTC 13305	A-15	Detected
	<i>A. baumannii</i>	NCTC 13424	UK 20	Detected
	<i>A. pittii</i>	CCUG 72793	EQUA 2018:03/B	Detected
<i>Bacteroides fragilis</i>	<i>B. fragilis</i>	CCUG 4856T	EN-2, Onslow/VPI 2553	Detected
	<i>B. fragilis</i>	CCUG 25931	LRA 048 07 85	Detected
	<i>B. fragilis</i>	NCTC 11295	83008	Detected
	<i>B. fragilis</i>	NCTC 11625	N/A	Detected
	<i>B. fragilis</i>	NCTC 8560	WPMH 1	Detected
<i>Enterobacter</i> spp.	<i>E. amnigenus</i> (<i>Lelliottia amnigena</i>)	ATCC 33072	CUETM 77-118	Detected
	<i>L. nimipressuralis</i>	CCUG 69901	N/A	Detected
	<i>E. ludwigii</i>	CCUG 26899	N/A	Detected
	<i>E. ludwigii</i>	CCUG 51323T	EN-119	Detected
	<i>E. asburiae</i>	ATCC 35955	CDC 14-81	Detected
	<i>E. cancerogenus</i>	CCUG 48556	strain RSTN 68352/03	Detected
	<i>E. cloacae</i>	NCTC 14326	29	Detected
	<i>E. hormaechei</i> subsp. <i>xiangfangensis</i>	CCUG 63474	N/A	Detected
	<i>E. kobei</i>	CCUG 59627	N/A	Detected
	<i>E. bugandensis</i>	CCUG 75194T	EB-247	Detected
	<i>E. hormaechei</i> subsp. <i>oharae</i>	CCUG 53905T	EN-314	Detected

	<i>E. hormaechei</i> subsp. <i>steigerwaltii</i>	CCUG 60271	N/A	Detected
	<i>E. roggkampii</i>	CCUG 75192T	EN-117	Detected
	<i>E. hormaechei</i> subsp. <i>hoffmannii</i>	NCTC 13870	LBM 93.03.067	Detected
	<i>E. cloacae</i>	NCTC 14328	N/A	Detected
	<i>E. cloacae</i>	NCTC 14322	42E	Detected
	<i>E. cloacae</i> subsp. <i>dissolvens</i>	CCUG 25230T	W-4, 8122-8	Detected
	<i>E. gergoviae</i>	CCUG 33719	N/A	Detected
<i>Escherichia coli</i>	<i>E. coli</i>	ATCC BAA-2774	1093925	Detected
	<i>E. coli</i>	ATCC BAA-2775	1099675	Detected
	<i>E. coli</i>	NCTC 13919	NCTC13919, H162440763	Detected
	<i>E. coli</i>	NCTC 14320	N/A	Detected
	<i>E. coli</i>	CCUG 67180	N/A	Detected
	<i>E. coli</i>	NCTC 14321	7	Detected
	<i>E. coli</i>	NCTC 14325	N/A	Detected
	<i>E. coli</i>	NCTC 14333	MLST: 167	Detected
	<i>E. coli</i>	NCTC 13462	N/A	Detected
	<i>E. coli</i>	NCTC 14339	MLST: 361	Detected
	<i>E. coli</i>	NCTC 13351	N/A	Detected
	<i>E. coli</i>	NCTC 13352	N/A	Detected
<i>Haemophilus influenzae</i>	<i>H. influenzae</i>	NCTC 4560	NCTC 4560 [18]	Detected
	<i>H. influenzae</i>	CCUG 23946	Kilian HK 394	Detected
	<i>H. influenzae</i>	CCUG 29539	L-378	Detected
	<i>H. influenzae</i>	CCUG 33775	572	Detected
	<i>H. influenzae</i>	CCUG 7317	641	Detected
<i>Klebsiella</i> spp.	<i>K. aerogenes</i>	ATCC 13048	NCDC 819-56	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3072	979620	Detected
	<i>K. pneumoniae</i>	ATCC BAA-1705	ART 2008133	Detected
	<i>K. pneumoniae</i>	ATCC BAA-2783	972863	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3060	1150539	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3063	1121740	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3068	1104762	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3077	875638	Detected
	<i>K. pneumoniae</i>	CCUG 68727	NCTC 13442	Detected
	<i>K. pneumoniae</i>	CCUG 68728	NCTC 13443	Detected
	<i>K. pneumoniae</i>	NCTC 14334	47C	Detected
	<i>K. pneumoniae</i>	NCTC 14337	54	Detected
	<i>K. pneumoniae</i>	JMI Strain 1238756	N/A	Detected
	<i>K. variicola</i>	ATCC BAA-830	F2R9	Detected
	<i>K. oxytoca</i>	ATCC BAA-3059	957532	Detected

	<i>K. pneumoniae</i>	NCTC 13438	N/A	Detected
	<i>K. pneumoniae</i>	ATCC 700603	K6	Detected
<i>Neisseria meningitidis</i> (Encapsulated)	<i>N. meningitidis</i>	ATCC 13077	M1027	Detected
	<i>N. meningitidis</i>	ATCC 13090	M2092	Detected
	<i>N. meningitidis</i>	CCUG 27650	LNP 638	Detected
	<i>N. meningitidis</i>	CCUG 55208	EQUALIS 07-040/2	Detected
	<i>N. meningitidis</i>	NCTC 8556	60	Detected
	<i>N. meningitidis</i>	NCTC 8556	60	Detected
Pan Enterobacterales	<i>Cedecea davisae</i>	NCTC 13724	005, 3278-77	Detected
	<i>Citrobacter braakii</i>	ATCC 51113	CDC 80-58	Detected
	<i>Citrobacter freundii</i>	CCUG 418T	[ATCC 13316, NCTC 9750]	Detected
	<i>Citrobacter koseri</i>	ATCC 27156	CDC 3613-63	Detected
	<i>Cronobacter sakazakii</i>	ATCC 29004	CDC 3225-73	Detected
	<i>Edwardsiella tarda</i>	NCTC 10396	K 349	Detected
	<i>Kluyvera cryocrescens</i>	NCTC 10483	2367, No.4	Detected
	<i>Kosakonia quasisacchari</i>	NCTC 14272	GDMCC1.1570	Detected
	<i>Leclercia adecarboxylata</i>	NCTC 13032	1783	Detected
	<i>Morganella morganii</i>	ATCC 25829	M4	Detected
	<i>Providencia stuartii</i>	CCUG 74678	N/A	Detected
	<i>Rahnella aquatilis</i>	CCUG 52909	N/A	Detected
	<i>Raoultella terrigena</i>	NCTC 13038	84, L84/CUETM 77-176	Detected
	<i>Shigella sonnei</i>	CCUG 68726	I virulent	Detected
	<i>Serratia rubidaea</i>	CCUG 35289	N/A	Detected
	<i>Tatumella ptyseos</i>	NCTC 11468	H36	Detected
	<i>Yersinia enterocolitica</i> subsp. <i>enterocolitica</i>	NCTC 12982	33114	Detected
	<i>Yokenella regensburgei</i>	NCTC 12131	3349-72	Detected
	<i>Citrobacter freundii</i>	ATCC 6879	NCTC 4143	Detected
	<i>Hafnia paralvei</i>	CCUG 59411	SMI Oth047	Detected
	<i>Citrobacter amalonaticus</i>	CCUG 4860	9823	Detected
	<i>Escherichia fergusonii</i>	CCUG 18766T	CDC 0568-73	Detected
	<i>Morganella morganii</i> subsp. <i>siboni</i>	ATCC 51206	CDC 3522-75	Detected

	<i>Providencia rettgeri</i>	CCUG 14804	1163	Detected
	<i>Raoultella ornithinolytica</i>	NCTC 13096	N/A	Detected
	<i>Shigella boydii</i>	CCUG 49022	P288/NCTC 12985	Detected
	<i>Escherichia hermannii</i> (<i>Atlantibacter hermannii</i>)	CCUG 15714T	CDC 980-72	Not Detected
	<i>Kosakonia cowanii</i>	CCUG 45998	888-76, KSK 246	Not Detected
<i>Proteus</i> spp.	<i>P. mirabilis</i>	ATCC 43071	CDC S-17	Detected
	<i>P. mirabilis</i>	ATCC BAA-2792	1104843	Detected
	<i>P. penneri</i>	NCTC 12737	1808-73	Detected
	<i>P. vulgaris</i>	ATCC 6380	N/A	Detected
	<i>P. vulgaris</i>	NCTC 13145	CDC PR1	Detected
	<i>P. terrae/cibarius</i>	CCUG 35385	HSCT 3586 T1	Detected
	<i>P. hauseri</i>	CCUG 63603	N/A	Detected
<i>Pseudomonas aeruginosa</i>	<i>P. aeruginosa</i>	ATCC BAA-2794	1079232	Detected
	<i>P. aeruginosa</i>	NCTC 13437	N/A	Detected
	<i>P. aeruginosa</i>	MRSN 12914	NR-51575	Detected
	<i>P. aeruginosa</i>	NCTC 13921	NCTC 13921	Detected
	<i>P. aeruginosa</i>	ATCC BAA-3099	1079205	Detected
	<i>P. aeruginosa</i>	ATCC BAA-3108	853930	Detected
	<i>P. aeruginosa</i>	ATCC BAA-2796	1106434	Detected
	<i>P. aeruginosa</i>	JMI Strain 378769	N/A	Detected
	<i>P. aeruginosa</i>	JMI Strain 338718	N/A	Detected
	<i>P. aeruginosa</i>	JMI Strain JMI-147	N/A	Detected
	<i>P. aeruginosa</i>	JMI Strain 1227781	N/A	Detected
	<i>P. aeruginosa</i>	MRSN 6241	NR-51550	Detected
	<i>P. aeruginosa</i>	MRSN 8141	NR-51558	Detected
	<i>P. aeruginosa</i>	NCTC 14383	N/A	Detected
<i>Salmonella</i> spp.	<i>S. bongori</i>	CCUG 63587	N/A	Detected
	<i>S. enterica</i> (serovar Newport)	ATCC 6962	NCTC 129	Detected
	<i>S. enterica</i> subsp. <i>enterica</i> serotype Gallinarum	ATCC 700623	X-142	Detected
	<i>S. enterica</i> subsp. <i>enterica</i> serotype Seftenberg	NCTC 13953	N/A	Detected
	<i>S. enterica</i> subsp. <i>enterica</i>	NCTC 13954	N/A	Detected

	serotype Typhimurium			
	<i>S. enterica</i> subsp. <i>enterica</i> serotype Westhampton	NCTC 8549	1314-52	Detected
<i>Serratia</i> spp.	<i>S. ficaria</i>	CCUG 20935	F.Grimont G 5779	Detected
	<i>S. fonticola</i>	CCUG 14186	CUETM 77-165	Detected
	<i>S. liquefaciens</i>	ATCC 27592	CDC 1284-57	Detected
	<i>S. marcescens</i>	ATCC 14041	NRRL B-1481	Detected
	<i>S. plymuthica</i>	ATCC 7462	[Grimont 502]	Detected
	<i>S. marcescens</i>	NCTC 13382	NRS 116-175	Detected
	<i>S. odorifera</i>	CCUG 14508	N/A	Detected
<i>Stenotrophomonas maltophilia</i>	<i>S. maltophilia</i>	ATCC 13637	810-2	Detected
	<i>S. maltophilia</i>	CCUG 72210	N/A	Detected
	<i>S. maltophilia</i>	NCTC 10258	560	Detected
	<i>S. maltophilia</i>	NCTC 10259	611	Detected
	<i>S. maltophilia</i>	NCTC 10498	RH 661-1	Detected
	<i>S. maltophilia</i>	NCTC 10499	RH 873-3	Detected
Resistane Markers				
<i>aac(6')-Ib</i>	<i>P. aeruginosa</i>	JMI Strain 378769	aac(6')-Ib / N/A	Detected
	<i>P. aeruginosa</i>	JMI Strain 338718	aac(6')-Ib / N/A	Detected
	<i>P. aeruginosa</i>	JMI Strain JMI- 147	aac(6')-Ib / N/A	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3068	aac(6')-Ib3 / 1104762	Detected
	<i>E. coli</i>	ATCC BAA-2774	aac(6')-Ib-cr / 1093925	Detected
	<i>E. coli</i>	NCTC 14320	aac(6')-Ib / N/A	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3077	aac(6')-Ib4 / 875638	Detected
	<i>P. mirabilis</i>	ATCC BAA-2792	aac(6')-Ib7 / 1104843	Detected
	<i>P. aeruginosa</i>	ATCC BAA-2799	aac(6')-Ib / 1145009	Detected
	<i>E. coli</i>	NCTC 13919	aac(6')-Ib / NCTC13919	Detected
	<i>A. baumannii</i>	ATCC BAA-2901	aac(6')-Ib3 / 157075	Detected
	<i>P. aeruginosa</i>	ATCC BAA-2794	aac(6')-Ib / 1079232	Detected
	<i>K. pneumoniae</i>	CCUG 68728	aac(6')-Ib / NCTC 13443	Detected
	<i>P. aeruginosa</i>	NCTC 13921	aac(6')-Ib / NCTC 13921	Detected
	<i>K. pneumoniae</i>	NCTC 14334	aac(6')-Ib / 47C	Detected

	<i>K. pneumoniae</i>	ATCC BAA-1705	aac(6')-Ib / ART 2008133	Detected
	<i>E. coli</i>	NCTC 14325	aac(6')-Ib / N/A	Detected
	<i>K. pneumoniae</i>	ATCC BAA-2783	aac(6')-Ib3, aac(6')-Ib-cr5 / 972863	Detected
	<i>P. aeruginosa</i>	ATCC BAA-3108	aac(6')-Ib / 853930	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3072	aac(6')-Ib-cr / 979620	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3060	aac(6')-Ib3, aac(6')-Ib-cr, aac(6')-IIc / 1150539	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3063	aac(6')-Ib-cr / 1121740	Detected
	<i>K. oxytoca</i>	ATCC BAA-3059	aac(6')-Ib / 957532	Detected
	<i>E. bugandensis</i>	CCUG 75194T	aac(6')-Ib-cr5 / EB-247	Detected
	<i>P. aeruginosa</i>	NCTC 14383	aac(6')-Ib / N/A	Detected
	<i>A. baumannii</i>	NCTC 13424	aac(6')-Ib / UK 20	Detected
	<i>P. aeruginosa</i>	MRSN 6241	aac(6')-Ib / N/A	Detected
	<i>P. aeruginosa</i>	MRSN 8141	aac(6')-Ib / N/A	Detected
	<i>K. pneumoniae</i>	NCTC 14337	aac(6')-Ib / 54	Detected
	<i>E. coli</i>	NCTC 13351	aac(6')-Ib / N/A	Detected
	<i>K. pneumoniae</i>	NCTC 13438	aac(6')-Ib / N/A	Detected
	<i>A. baumannii</i>	CCUG 68164	aac(6')-Ib / N/A	Detected with reduced sensitivity
<i>ampC</i> (CMY/DHA/FOX/LAT)	<i>K. pneumoniae</i>	ATCC BAA-3060	<i>ampC</i> (DHA-7) / 1150539	Detected
	gBlock	<i>ampC</i> FOX-X77455.1	<i>ampC</i> (FOX) gBlock	Detected
	<i>P. mirabilis</i>	ATCC BAA-2792	<i>ampC</i> (CMY-16) / 1104843	Detected
	<i>Citrobacter freundii</i>	ATCC 6879	<i>ampC</i> (CMY-LAT) / NCTC 4143	Detected
	<i>Citrobacter braakii</i>	ATCC 51113	<i>ampC</i> (CMY-2) / CDC 80-58	Detected
	<i>S. enterica</i> subsp. <i>enterica</i> serotype Seftenberg	NCTC 13953	<i>ampC</i> (CMY-LAT)	Detected
	<i>K. pneumoniae</i>	CCUG 68728	<i>ampC</i> (CMY-LAT), <i>ampC</i> (DHA) / NCTC 13443	Detected
	<i>Citrobacter freundii</i>	CCUG 418T	<i>ampC</i> (CMY-72)	Detected
	<i>Morganella morganii</i> subsp. <i>siboni</i>	ATCC 51206	<i>ampC</i> (DHA-4) / CDC 3522-75	Detected
	<i>Morganella morganii</i>	ATCC 25829	<i>ampC</i> (DHA) / M4	Detected

	<i>K. pneumoniae</i>	JMI Strain 1238756	<i>ampC</i> (FOX-5) / N/A	Detected
	<i>E. coli</i>	NCTC 14333	<i>ampC</i> (CMY-LAT) / MLST: 167	Detected
	<i>E. coli</i>	NCTC 14339	<i>ampC</i> (CMY-LAT) / MLST: 361	Detected
<i>armA</i>	<i>A. baumannii</i>	ATCC BAA-2803	<i>armA</i> / 1125209	Detected
	<i>A. baumannii</i>	NCTC 13424	<i>armA</i> / UK 20	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3072	<i>armA</i> / 979620	Detected
	<i>A. baumannii</i>	ATCC BAA-2873	<i>armA</i> / 1081925	Detected
	<i>K. pneumoniae</i>	ATCC BAA-2783	<i>armA</i> / 972863	Detected
	<i>K. pneumoniae</i>	CCUG 68728	<i>armA</i> / NCTC 13443	Detected
	<i>K. oxytoca</i>	ATCC BAA-3059	<i>armA</i> / 957532	Detected
CTX-M	<i>E. coli</i>	ATCC BAA-2774	CTX-M-15 (Group 1)	Detected
	<i>E. coli</i>	ATCC BAA-2775	CTX-M-14 (Group 9)	Detected
	<i>K. pneumoniae</i>	ATCC BAA-2783	CTX-M-15 (Group 1)	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3077	CTX-M-15 (Group 1)	Detected
	gBlock	gBlock CTX-M-26 (AY157676.1)	CTX-M-26 (Group 25)	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3063	CTX-M-15 (Group 1)	Detected
	<i>K. pneumoniae</i>	CCUG 68728	CTX-M-15 (Group 1)	Detected
	<i>E. coli</i>	NCTC 14325	CTX-M / N/A	Detected
	<i>E. coli</i>	NCTC 13919	CTX-M-15 (Group 1)	Detected
	<i>K. oxytoca</i>	ATCC BAA-3059	CTX-M-3 (Group 1)	Detected
	<i>E. coli</i>	NCTC 13462	CTX-M-2 (Group 2)	Detected
	<i>E. bugandensis</i>	CCUG 75194T	CTX-M-15 (Group 1)	Detected
	<i>E. cloacae</i>	NCTC 14328	CTX-M-14 (Group 9)	Detected
GES	<i>E. coli</i>	NCTC 13919	GES-5	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3068	GES-6	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3077	GES-1	Detected
	<i>P. aeruginosa</i>	ATCC BAA-3108	GES-19, GES-26	Detected
	<i>A. baumannii</i>	CCUG 68164	GES-11	Detected
	<i>P. aeruginosa</i>	ATCC BAA-2794	GES-5	Detected
IMP	<i>E. coli</i>	CCUG 67180	IMP-1	Detected
	gBlock	gBlock IMP-21 (AB204557.1)	IMP-21	Detected
	gBlock	gBlock IMP-14 (AY553332.1)	IMP-14	Detected

	<i>E. coli</i>	NCTC 14320	IMP / N/A	Detected
	<i>K. pneumoniae</i>	NCTC 14334	IMP-4	Detected
	<i>K. pneumoniae</i>	NCTC 14337	IMP-1	Detected
KPC	<i>E. coli</i>	ATCC BAA-2774	KPC-2	Detected
	<i>E. coli</i>	NCTC 14320	KPC / N/A	Detected
	<i>E. coli</i>	NCTC 14321	KPC / 7	Detected
	<i>K. pneumoniae</i>	ATCC BAA-1705	KPC-2	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3068	KPC-2	Detected
	<i>K. pneumoniae</i>	NCTC 13438	KPC-3	Detected
	<i>E. cloacae</i>	NCTC 14322	KPC-4	Detected
NDM	<i>K. pneumoniae</i>	ATCC BAA-3063	NDM-16	Detected
	<i>K. pneumoniae</i>	CCUG 68728	NDM-1	Detected
	<i>P. aeruginosa</i>	ATCC BAA-2796	NDM-1	Detected
	<i>S. enterica</i> subsp. <i>enterica</i> serotype Seftenberg	NCTC 13953	NDM-1	Detected
	<i>P. aeruginosa</i>	JMI Strain 1227781	NDM-1	Detected
	<i>E. coli</i>	NCTC 14325	NDM-7	Detected
	<i>E. coli</i>	NCTC 14333	NDM-4	Detected
	<i>E. coli</i>	NCTC 14339	NDM-5	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3072	NDM-1	Detected with reduced sensitivity
OXA-23	<i>A. baumannii</i>	ATCC BAA-2801	OXA-23	Detected
	<i>A. baumannii</i>	ATCC BAA-2873	OXA-23	Detected
	<i>A. baumannii</i>	ATCC BAA-2803	OXA-23	Detected
	<i>A. baumannii</i>	CCUG 68164	OXA-23	Detected
	<i>A. baumannii</i>	NCTC 13424	OXA-23	Detected
OXA-24/40	<i>A. baumannii</i>	ATCC BAA-2881	OXA-24	Detected
	<i>A. baumannii</i>	CCUG 57249	OXA-24	Detected
	<i>A. baumannii</i>	NCTC 13302	OXA-25	Detected
	<i>A. baumannii</i>	PA212222	OXA-24	Detected
	gBlock	gBlock OXA-40 (AF509241.1)	OXA-40	Detected
OXA-48-like	<i>E. coli</i>	NCTC 14320	OXA-48-like	Detected
	<i>E. coli</i>	NCTC 14321	OXA-48-like	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3072	OXA-48-like	Detected
	<i>K. pneumoniae</i>	CCUG 68727	OXA-48	Detected
	<i>S. enterica</i> subsp. <i>enterica</i> serotype Seftenberg	NCTC 13954	OXA-48	Detected
OXA-58	<i>A. baumannii</i>	ATCC BAA-2890	OXA-58	Detected
	<i>A. baumannii</i>	ATCC BAA-2901	OXA-58	Detected
	<i>A. baumannii</i>	ATCC BAA-2895	OXA-58	Detected
	<i>A. baumannii</i>	NCTC 13305	OXA-58	Detected

PER	<i>A. baumannii</i>	ATCC BAA-2801	PER-1	Detected
	<i>P. aeruginosa</i>	MRSN 6241	PER-1	Detected
	<i>P. aeruginosa</i>	MRSN 8141	PER-1	Detected
	gBlock	gBlock PER-14 (MN715315.1)	PER-14	Detected
	<i>P. aeruginosa</i>	ATCC BAA-2799	PER-1	Detected
	<i>P. aeruginosa</i>	NCTC 14383	PER / N/A	Detected
SHV	<i>K. pneumoniae</i>	NCTC 14337	SHV	Detected
	<i>K. pneumoniae</i>	ATCC BAA-1705	SHV-11	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3060	SHV-11	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3068	SHV-27	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3077	SHV-1	Detected
	<i>K. pneumoniae</i>	CCUG 68727	SHV-11	Detected
	<i>S. enterica</i> subsp. <i>enterica</i> serotype Seftenberg	NCTC 13953	SHV-12	Detected
	<i>K. pneumoniae</i>	NCTC 14334	SHV	Detected
	<i>K. pneumoniae</i>	JMI Strain 1238756	SHV-187	Detected
	<i>K. pneumoniae</i>	NCTC 13438	SHV-11	Detected
	<i>E. cloacae</i>	NCTC 14328	SHV	Detected
	<i>K. pneumoniae</i>	ATCC 700603	SHV-18	Detected
	<i>K. pneumoniae</i>	CCUG 68728	SHV	Detected
	<i>K. pneumoniae</i>	NCTC 14334	SHV	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3063	SHV-28	Detected with reduced sensitivity
	<i>K. pneumoniae</i>	ATCC BAA-3072	SHV-28	Detected with reduced sensitivity
	<i>K. pneumoniae</i>	ATCC BAA-2783	SHV-1	Detected with reduced sensitivity
	<i>E. coli</i>	NCTC 14325	SHV / N/A	Not Detected
SPM	<i>P. aeruginosa</i>	NCTC 13921	SPM-1	Detected
	<i>P. aeruginosa</i>	JMI Strain 378769	SPM-1	Detected
	<i>P. aeruginosa</i>	JMI Strain 338718	SPM-1	Detected
	<i>P. aeruginosa</i>	JMI Strain JMI- 147	SPM-1	Detected
TEM	<i>E. coli</i>	ATCC BAA-2775	TEM-1	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3060	TEM-1	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3077	TEM-1	Detected
	<i>K. pneumoniae</i>	CCUG 68727	TEM-1	Detected
	<i>K. pneumoniae</i>	CCUG 68728	TEM-1	Detected
	<i>P. mirabilis</i>	ATCC BAA-2792	TEM-2	Detected
	<i>E. coli</i>	NCTC 14320	TEM	Detected
	<i>E. coli</i>	CCUG 67180	TEM	Detected
	<i>K. oxytoca</i>	ATCC BAA-3059	TEM-1	Detected

	<i>E. bugandensis</i>	CCUG 75194T	TEM-1	Detected
	<i>E. coli</i>	NCTC 14333	TEM	Detected
	<i>E. cloacae</i>	NCTC 14328	TEM	Detected
	<i>Escherichia fergusonii</i>	CCUG 18766T	TEM	Detected
	<i>E. coli</i>	NCTC 13462	TEM-1	Detected
	<i>S. enterica</i> subsp. <i>enterica</i> serotype Seftenberg	NCTC 13953	TEM	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3068	TEM-1	Detected
	<i>K. pneumoniae</i>	ATCC BAA-3063	TEM-1	Detected
	<i>E. coli</i>	NCTC 13351	TEM-3	Detected
	<i>E. coli</i>	NCTC 13352	TEM-10	Detected
	<i>K. pneumoniae</i>	ATCC BAA-2783	TEM-1	Detected with reduced sensitivity
	<i>K. pneumoniae</i>	ATCC BAA-3068	TEM-1	Detected with reduced sensitivity
	<i>A. baumannii</i>	ATCC BAA-2881	TEM-1	Detected with reduced sensitivity
	<i>A. baumannii</i>	ATCC BAA-2873	TEM-1	Detected with reduced sensitivity
	<i>S. enterica</i> subsp. <i>enterica</i> serotype Seftenberg	NCTC 13953	TEM	Detected with reduced sensitivity
	<i>A. baumannii</i>	ATCC BAA-2801	TEM-1	Detected with reduced sensitivity (above mean bottle positive)
	<i>E. coli</i>	NCTC 14321	TEM	Detected with reduced sensitivity (above mean bottle positive)
	<i>K. pneumoniae</i>	ATCC BAA-1705	TEM	Detected with reduced sensitivity (above mean bottle positive)
VEB	<i>P. aeruginosa</i>	ATCC BAA-3099	VEB-14	Detected
	<i>P. aeruginosa</i>	MRSN 12914	VEB / NR-51575	Detected
	<i>gBlock</i>	gBlock VEB-22 (MN201581.1)	VEB-22	Detected
	<i>P. aeruginosa</i>	JMI Strain 1227781	VEB-14	Detected
	<i>P. aeruginosa</i>	ATCC BAA-2796	VEB-9	Detected
	<i>P. aeruginosa</i>	NCTC 13437	VEB-1	Detected
	<i>E. cloacae</i>	NCTC 14326	VIM-1	Detected
	<i>P. mirabilis</i>	ATCC BAA-2792	VIM-1	Detected
	<i>P. aeruginosa</i>	ATCC BAA-3099	VIM-5	Detected
	<i>P. aeruginosa</i>	NCTC 13437	VIM-10	Detected
	<i>P. aeruginosa</i>	ATCC BAA-2799	VIM-5	Detected

	<i>E. cloacae</i>	NCTC 14328	VIM-4	Detected
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Table 13: Summary Results of Strains Tested at Higher Concentrations

Target	Organism	Result	Concentration Tested (CFU/mL)
Organism			
Pan Enterobacterales	<i>Escherichia hermannii</i>	Not Detected	NA
	<i>Kosakonia cowanii</i>	Not Detected	NA
	<i>Kosakonia cowanii</i>	Not Detected	NA
Resistance Markers			
<i>aac(6')-Ib</i>	<i>A. baumannii</i>	Detected with reduced sensitivity	2.31E+06
NDM	<i>K. pneumoniae</i>	Detected with reduced sensitivity	4.37E+06
SHV	<i>E. coli</i>	Not Detected	NA
	<i>K. pneumoniae</i>	Detected with reduced sensitivity	4.37E+06
	<i>K. pneumoniae</i>	Detected with reduced sensitivity	4.37E+06
	<i>K. pneumoniae</i>	Detected with reduced sensitivity	4.37E+06
	<i>K. pneumoniae</i>	Detected with reduced sensitivity	4.37E+07
	<i>K. pneumoniae</i>	Detected with reduced sensitivity	4.37E+07
TEM	<i>A. baumannii</i>	Detected with reduced sensitivity	2.31E+05
	<i>A. baumannii</i>	Detected with reduced sensitivity	2.31E+06
	<i>A. baumannii</i>	Detected with reduced sensitivity	2.31E+05
	<i>A. baumannii</i>	Detected with reduced sensitivity	2.31E+06
	<i>A. baumannii</i>	Detected with reduced sensitivity	2.31E+05
	<i>A. baumannii</i>	Detected with reduced sensitivity	2.31E+06
	<i>A. baumannii</i>	Detected with reduced sensitivity	2.31E+07
	<i>A. baumannii</i>	Detected with reduced sensitivity (above mean bottle positive)	2.31E+08
	<i>E. coli</i>	Detected with reduced sensitivity (above mean bottle positive)	1.71E+09
	<i>E. coli</i>	Detected with reduced sensitivity	2.03E+06
	<i>E. coli</i>	Detected with reduced sensitivity	6.78E+06
	<i>E. coli</i>	Detected with reduced sensitivity	6.78E+07
	<i>K. pneumoniae</i>	Detected with reduced sensitivity	4.37E+06
	<i>K. pneumoniae</i>	Detected with reduced sensitivity	4.37E+06
	<i>K. pneumoniae</i>	Detected with reduced sensitivity	4.37E+07
	<i>K. pneumoniae</i>	Detected with reduced sensitivity	4.37E+07
	<i>K. pneumoniae</i>	Detected with reduced sensitivity (above mean bottle positive)	6.25E+09
	<i>S. enterica</i> subsp. <i>enterica</i> serotype Seftenberg	Detected with reduced sensitivity	2.25E+05

An *in silico* inclusivity assessment was performed for all organism-PCR and AMR-PCR assays included in the panel. For organism assays, all complete genomes available for each target organism in the NCBI Taxonomy Browser were analyzed using Geneious software (v10.2 or later). For complex assays (e.g., Pan Enterobacterales), BLAST homology analysis was performed against the NCBI Core nucleotide database. For AMR assays, all available

sequences in the Comprehensive Antibiotic Resistance Database (CARD) were analyzed..
Results are shown in **Table 14**.

Table 14. Predicted (*in silico*) Inclusivity Results

Target	Sequences Analyzed	% Predicted to Detect	Detection Prediction
Organisms			
<i>Bacteroides fragilis</i>	79	100.00%	Inclusivity determined for <i>B. fragilis</i> .
<i>Salmonella</i> spp.	3,187	100.00%	Species detected list includes at least <i>S. bongori</i> and <i>S. enterica</i> (subspecies <i>enterica</i> , <i>salamae</i> , <i>arizonae</i> , <i>diarizonae</i> , <i>houtenae</i> and <i>indica</i>). The following <i>Salmonella enterica</i> subsp. <i>enterica</i> serovars are detected: serovar 42:r,1; serovar 4,[5],12:i:-; serovar 43:a:1; serovar 1,4,[5],12:i:-; 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>Acinetobacter calcoaceticus-baumannii</i> complex	1,403	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>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>Enterobacter</i> spp. & <i>Pluralibacter gergoviae</i>	972	100.00%	<i>Enterobacter</i> species detected includes at least <i>E. adelaidei</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> sp., <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. roggkampii</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>Klebsiella</i> spp.	4,742	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>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>Escherichia coli</i>	2,845	100.00%	Inclusivity determined for <i>E. coli</i> .
<i>Stenotrophomonas maltophilia</i>	136	99.26%	Inclusivity determined for <i>S. maltophilia</i> . Note: only one (1) sequence (ID CP133415) was not detected.
<i>Pseudomonas aeruginosa</i>	1,596	99.94%	Inclusivity determined for <i>P. aeruginosa</i> . Note: only one (1) genome sequence (ID CP047066) was not detected. Note: as an exception, the targeted gene of the strain corresponding to accession number CP104695 is present in the plasmid instead of the chromosome (CP104696).

Pan Enterobacterales	3,294	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. ictaluri</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. ruysiae</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>Kluyvera</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. zhutongyui</i>), <i>Lonsdalea</i> (<i>L. populi</i>), <i>Morganella</i> (<i>M. morganii</i>), <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>Photobacter</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. manganoxydans</i>, <i>P. rettgeri</i>, <i>P. rustigianii</i>, <i>P. stuartii</i>, <i>P. vermicola</i>), <i>Pseudoescherichia</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. sarumanii</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. regensburgei</i>).
<i>Serratia</i> spp.	347	100.00%	<i>Serratia</i> detected species list 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. sarumanii</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>.
<i>Neisseria meningitidis</i> (Encapsulated)	227	100.00%	<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).
Resistance Markers			

CTX-M	2,676	99.36%	Available CTX-M sequences detected: 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. Note: Only 17 sequences corresponding to CTX-M-74, CTX-M-75, CTX-M-123, CTX-M-132, CTX-M-151, CTX-M-153, CTX-M-234 were not detected.
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.
VIM	218	100.00%	All available VIM sequences detected, including VIM-1 to VIM-20; VIM-23 to VIM-91.
<i>armA</i>	436	100.00%	All available <i>armA</i> sequences detected.
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.
VEB	88	100.00%	All available VEB sequences detected, including VEB-1 to VEB-39; VEB-1a; VEB-1b.
GES	118	99.15%	Available GES sequences detected: GES-1 to GES-22; GES-24 to GES-62; GES-65 to GES-66. Note: Only one (1) sequence corresponding to GES-23 was not detected.
<i>aac(6')-Ib (aacA4)</i>	959	99.79%	Available <i>aac(6')-Ib</i> sequences detected: <i>aac(6')-Ib</i> ; <i>aac(6')-Ib'</i> ; <i>aac(6')-Ib10</i> ; <i>aac(6')-Ib11</i> ; <i>aac(6')-Ib3</i> ; <i>aac(6')-Ib4</i> ; <i>aac(6')-Ib7</i> ; <i>aac(6')-Ib8</i> ; <i>aac(6')-Ib9</i> ; <i>aac(6')-Ib-cr1</i> to <i>aac(6')-Ib-cr11</i> ; <i>aac(6')-Ib-Hangzhou</i> ; <i>aac(6')-Ib-Suzhou</i> ; <i>aac(6')-30/aac(6')-Ib</i> ; <i>aac(3)-Ib/aac(6')-Ib3</i> . Note: Two (2) out of 305 <i>aac(6')-Ib9</i> sequences were predicted not to be detected due to mismatches. Note: This PCR assay does not detect the <i>aac(6')-Ib-SK</i> allele, a chromosomally-encoded aminoglycoside acetyltransferase specific for <i>Streptomyces kanamyceticus</i> .
<i>ampC</i> (CMY/LAT/DHA/FOX)	1,010	98.91%	Available CMY/LAT alleles detected: 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. Available DHA alleles detected: DHA-1 to DHA-7; DHA-9 to DHA-10; DHA-12 to DHA-34. Available FOX alleles detected: FOX-1 to FOX-10; FOX-12 to FOX-21. Note: Sequences CMY-1; CMY-8 to CMY-11; CMY-19; CMY-98; CMY-190; CMY-8b were not detected. Note: One out of six (1/6) sequences of the CMY-136 allele was predicted not to be detected due to mismatches.
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.

PER	88	N/A *	Available PER sequences detected: PER-1 to PER-5; PER-7 to PER-18. Note: PER-6 is not detected by the assay and is excluded from the intended use of the device. *Percentage not calculated as PER-6 is excluded from scope per intended use.
SHV	2,296	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.
KPC	1,052	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.
TEM	3,371	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-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; RTEM-1; TEM-1B; TEM-E2; TEM-HM.
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-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.
SPM	9	100.00%	All available SPM sequences detected, including SPM-1.

1. Number of sequences analyzed reflects the total after removing preliminary (NZ-prefixed), artificial, and vector sequences from NCBI.

2. AMR-PCR assays were characterized including alleles detected and not detected based on the available CARD database list. Alleles not included correspond to alleles with no information in CARD and therefore could not be analyzed. For OXA family assays (OXA-23, OXA-58, OXA-48-like, OXA-24/40), analysis was performed using the entire OXA gene/allele list; percentages reflect detection within the specific intended OXA sub-family only.

3. The *aac(6')-Ib* percentage (99.79%) was calculated excluding the 1,028 *aac(6')-Ib-SK* allele sequences to homogenize the data.
4. The *ampC* assay is a combination of three PCR assays detecting CMY/LAT, DHA, and FOX variants.
5. For the PER assay, PER-6 is not within the intended scope of the device per its intended use; percentage was therefore not calculated including PER-6 sequences.
6. Organism-PCR assays used NCBI complete genome sequences analyzed in Geneious v10.2 or later (allowing ≤ 3 mismatches) and/or BLAST (core_nt database; blastn; $\geq 70\%$ query cover). AMR-PCR assays used CARD database sequences analyzed in Geneious v10.2 or later (allowing ≤ 3 mismatches).

On-Panel Cross-Reactivity

An on-panel cross-reactivity assessment was conducted concurrently with the *in vitro* inclusivity testing to verify the absence of cross-reactivity between on-panel targets. The following cross-reactivity was observed:

- *Shigella* spp. (*S. sonnei* and *S. boydii*) with the *Escherichia coli* assay
- *Enterobacter ludwigii* with the *Proteus* spp. assay
- *Enterobacter ludwigii* with the *Klebsiella* spp. assay
- *Lelliottia amnigena* (formerly *E. amnigenus*) with the *Klebsiella* spp. assay
- *Providencia stuartii* with the *Proteus* spp. assay
- *Leclercia adecarboxylata* with the *Enterobacter* spp. assay
- *Citrobacter braakii* with the *Serratia* spp. assay
- *Yersinia enterocolitica* with the *Serratia* spp. assay
- *Hafnia paralvei* with the *Proteus* spp. Assay

All cross-reactivity limitations are documented in the QIAstat-Dx BCID GN Plus AMR Panel Instructions for Use.

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

The QIAstat-Dx BCID GN Plus AMR Panel is a qualitative nucleic acid amplification test (NAAT) that reports binary (detected/not detected) results for bacterial pathogens and antimicrobial resistance (AMR) genes from positive blood culture media. Because the device does not produce quantitative analyte measurements, conventional metrological traceability to a reference standard or certified reference material is not applicable in the traditional sense.

In-Use Stability

An In-Use Stability study was conducted to determine the maximum time a QIAstat-Dx BCID GN Plus AMR Panel cartridge can be opened and loaded with a sample before initiating a run, without adversely affecting device performance.

A single positive sample mix was prepared containing eight analytes spiked into Negative Blood Culture Matrix (NBCM) at approximately $3 \times$ LoD, as established in the combined LoD study. The in-use condition tested the worst-case scenario in which a cartridge is removed from its sealed primary packaging, held open for 30 minutes prior to sample loading, and the sample-loaded cartridge is then held for an additional 100 minutes before instrument insertion — corresponding to approximately 130 minutes total elapsed time from cartridge opening to run start. Eight replicates of the positive sample mix were tested per timepoint per condition. All positive sample mixes generated positive results for all included panel targets at every tested timepoint under both conditions, and all timepoints passed the acceptance criterion.

Specimen Stability

Specimen stability was evaluated to determine the maximum storage time for positive blood culture media samples following blood culture positivity. Eighteen contrived single-spiked positive blood culture media samples covering all panel targets were tested under three storage conditions (**Table 15**).

Table 15: Specimen Stability Storage Conditions

Condition	Storage
t0	Reference (immediate testing)
t1a	Blood culture system ($35 \pm 1.5^{\circ}\text{C}$) for up to 24 hours
t1b	Ambient ($15 \pm 3^{\circ}\text{C}$) for up to 24 hour

A 100% detection rate was achieved for all panel targets across all three timepoints .

Fresh vs. Frozen Study

A fresh vs. frozen study was conducted to demonstrate that storage of Positive Blood Culture Matrix (PBCM) specimens at -90°C to -60°C for an extended period, with up to three freeze-thaw cycles, does not impact the performance of the QIAstat-Dx BCID GN Plus AMR Panel relative to freshly tested samples. Twenty representative organisms covering all panel pathogens and AMR targets were tested, each prepared as three individual single-spiked blood culture bottles (60 samples total). **Table 16** summarizes the conditions tested in the study.

Table 16: Analytical Fresh vs. Frozen Testing Conditions

Condition	Freeze-Thaw Cycles	Timeframe from T0
T0 (Reference)	0 (fresh)	Immediate
FT1	1	~30 days
FT2	2	~60 days
FT3	3	≥ 121 days
FT1a	1	≥ 121 days
FT2a	2	$\geq 1,054$ days

Nine replicates were tested per organism at T0; three replicates per organism were tested at all subsequent timepoints.

Storage of positive blood culture media samples at -90°C to -60°C for up to 121 days with up to 3 freeze-thaw cycles, and for up to 1,054 days with 2 freeze-thaw cycles, does not affect the performance of the QIAstat-Dx BCID GN Plus AMR Panel compared to freshly tested samples.

A separate fresh vs. frozen study was conducted using clinical positive blood culture media specimens to support the validity of frozen sample testing within the Clinical Performance Study (CPS). This study was not intended to establish a product claim for frozen sample use by end-users. Sixty prospective positive blood culture specimens (29 from Clinical Site 1 -

Medical College of Wisconsin; 31 from Clinical Site 2 - Labor Berlin) were each tested once fresh and once after a single freeze-thaw cycle, following storage at -100°C to -50°C for 113 to 194 days (average 135 days). Testing was performed at the two clinical sites. All analytes detected in the fresh condition were also detected in the corresponding frozen condition, yielding a 100% positive agreement for all targets present at relevant concentrations.

Expected Values (Controls)

Each QIAstat-Dx BCID GN Plus AMR Panel cartridge includes an internal processing control (*Schizosaccharomyces pombe*) that monitors performance of the complete test process, including cell lysis, nucleic acid purification, and PCR amplification. External controls are not provided with the QIAstat-Dx BCID GN Plus AMR Panel. The package insert states that regular testing of external controls are not necessary.

6. Assay Cut-Off:

Configuration of the Results Call Algorithm (RCA) parameters are established for the Assay Definition File (ADF) during product development.

7. Carry-Over:

Carryover of the QIAstat-Dx BCID GN Plus AMR Panel on the QIAstat-Dx Analyzer was evaluated for the potential of cross-contamination between consecutive runs using the checkerboard approach. Samples of blood culture media with alternating high-positive (ranging from 1.92×10^9 to 1.62×10^{10} CFU/mL) and negative samples were tested on two instruments during 23 runs over two days. No carryover between samples was observed.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Not applicable. Refer to the Clinical Studies section.

2. Matrix Comparison:

A bottle equivalency study was conducted to evaluate the performance of the QIAstat-Dx BCID GN Plus AMR Panel across 13 commercially available blood culture bottle

- 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

Contrived positive blood culture samples were prepared by inoculating sterile whole human blood with representative gram-negative bacterial pathogens and AMR gene-carrying organisms at concentrations up to 25 CFU/mL, then incubating in a continuous monitoring blood culture system (CMBCS) until bottle positivity. For VersaTREK bottles, where an appropriate CMBCS was unavailable, samples were spiked at bottle-positive concentrations (1.5×10^8 CFU/mL for bacteria).

Sixteen pathogen strains were tested (**Table 17**) across all 13 bottle types, with each pathogen tested in triplicate per bottle type. Across all bottle types, the pathogen-level hit rate was 99.9% (2186/2188 total target hits). The two dropouts were AMR-level (TEM in *Acinetobacter baumannii*, ATCC BAA-2801, in the BD BACTEC Lytic Anaerobic bottle [b06]), attributed to suboptimal anaerobic growth conditions for a strictly aerobic organism; all pathogen targets were detected at 100%. Cartridge reliability across all bottle types was 97.67% (755/773; 95% CI: 96.34%–98.61%), meeting the pre-specified acceptance criterion of >95%. No false positives were observed in negative blood culture matrix (NBCM) samples tested for each bottle type. **Table 18** summarizes the study results.

Table 17: List of Tested Organisms for Bottle Equivalency Study

Organism	Target(s)	Strain ID
<i>Acinetobacter baumannii</i>	<i>Acinetobacter calcoaceticus-baumannii</i> complex; PER; TEM; OXA-23	ATCC BAA-2801
<i>Klebsiella pneumoniae</i>	Pan Enterobacterales; <i>Klebsiella</i> spp.; CTX-M; <i>armA</i> ; <i>ampC</i> (CMY/LAT/DHA/FOX); SHV; NDM; TEM; <i>aac(6')-Ib</i>	CCUG 68728
<i>Proteus mirabilis</i>	Pan Enterobacterales; <i>Proteus</i> spp.; VIM; <i>ampC</i> (CMY/LAT/DHA/FOX); TEM; <i>aac(6')-Ib</i>	ATCC BAA-2792
<i>Salmonella enterica</i>	<i>Salmonella</i> spp.; Pan Enterobacterales	ATCC 6962
<i>Stenotrophomonas maltophilia</i>	<i>Stenotrophomonas maltophilia</i>	NCTC 10259
<i>Serratia marcescens</i>	<i>Serratia</i> spp.	ATCC 14041
<i>Acinetobacter baumannii</i>	<i>Acinetobacter calcoaceticus-baumannii</i> complex; OXA-58	ATCC BAA-2890
<i>Escherichia coli</i>	Pan Enterobacterales; IMP; <i>aac(6')-Ib</i> ; KPC; OXA-48-like; TEM	NCTC 14320
<i>Acinetobacter baumannii</i>	<i>Acinetobacter calcoaceticus-baumannii</i> complex; OXA-24/40	CCUG 57249
<i>Enterobacter cloacae</i>	<i>Enterobacter</i> spp.; Pan Enterobacterales	CCUG 25230
<i>Escherichia coli</i>	CTX-M; GES; <i>aac(6')-Ib</i> ; Pan Enterobacterales	NCTC 13919
<i>Pseudomonas aeruginosa</i>	<i>Pseudomonas aeruginosa</i> ; VEB	MRSN 12914
<i>Citrobacter freundii</i>	Pan Enterobacterales; <i>ampC</i> (CMY/LAT/DHA/FOX)	CCUG 418T
<i>Pseudomonas aeruginosa</i>	<i>Pseudomonas aeruginosa</i> ; SPM; <i>aac(6')-Ib</i>	NCTC 13921
<i>Neisseria meningitidis</i>	<i>Neisseria meningitidis</i> (Encapsulated)	ATCC 13077
<i>Bacteroides fragilis</i>	<i>Bacteroides fragilis</i>	CCUG 4856T
<i>Haemophilus influenzae</i>	<i>Haemophilus influenzae</i>	CCUG 33775

Table 18. Summary Results of Bottle Equivalency Study by Bottle Type

Blood Culture Bottle	Hits	N	% Agreement (Two-sided 95% CI)
BD BACTEC Plus Aerobic (b01)	480	480	100.0% (99.2–100.0%)
BD BACTEC Plus Anaerobic (b02)	129	129	100.0% (97.2–100.0%)
BD BACTEC Standard Aerobic (b03)	153	153	100.0% (97.6–100.0%)
BD BACTEC Standard Anaerobic (b04)	119	119	100.0% (97.0–100.0%)
BD BACTEC Peds Plus (b05)	162	162	100.0% (97.8–100.0%)
BD BACTEC Lytic Anaerobic (b06)	119	121	98.4% (94.2–99.8%) ^a
BACT/ALERT SA Standard Aerobic (b07)	150	150	100.0% (97.6–100.0%)
BACT/ALERT SN Standard Anaerobic (b08)	151	151	100.0% (97.6–100.0%)
BACT/ALERT FA Plus Aerobic (b09)	153	153	100.0% (97.6–100.0%)
BACT/ALERT FN Plus Anaerobic (b10)	107	107	100.0% (96.6–100.0%)
BACT/ALERT PF Plus Peds Aerobic (b11)	149	149	100.0% (97.6–100.0%)
VersaTREK Redox 1 EZ Draw Aerobic (b12)	156	156	100.0% (97.7–100.0%)
VersaTREK Redox 2 EZ Draw Anaerobic (b13)	158	158	100.0% (97.7–100.0%)

^a TEM AMR not detected in 2 replicates for *A. baumannii* (ATCC BAA-2801); all pathogens detected.

C Clinical Evidence:

1. Clinical Study:

Clinical performance of the QIAstat-Dx BCID GN Plus AMR Panel was established through a multi-center, prospective study conducted between November 2023 and May 2025. The study was conducted at eight U.S. and two European clinical testing sites, two central laboratories, and one discordant testing site, using residual positive blood culture media (PBCM) specimens. Each study location was representative of the intended use setting, and testing was performed by trained clinical laboratory personnel.

A total of 2,142 positive blood culture media specimens were enrolled: 1,711 prospective and 431 retrospective archived. Of these, 661 prospective and 145 retrospective archived specimens were evaluated for the QIAstat-Dx BCID GN Plus AMR Panel specimens were allocated following Gram stain, with only those showing gram-negative organisms eligible for this panel. For analytes with low expected prevalence, 772 contrived specimens were prepared and tested blinded across 4 clinical sites. **Table 19** lists site information for collected specimens. **Tables 20-21** show demographic information for prospectively collected samples. **Table 22** shows demographic information for retrospectively collected samples.

Table 19: List of Enrollment and Exclusions of Clinical Specimens by Site

Site	Prospective Fresh		Prospective Frozen		Retrospective		Total	
	Eligible	Evaluable	Eligible	Evaluable	Eligible	Evaluable	Eligible	Evaluable

Site 1 (IU)	22	21	0	0	0	0	22	21
Site 2 (MCW)	47	46	15	15	0	0	62	61
Site 3 (GMC)	61	56	9	9	0	0	70	65
Site 4 (VUMC)	66	66	0	0	83	83	149	149
Site 5 (JHU)	118	117	3	3	24	24	145	144
Site 6 (CCF)	87	84	1	1	27	27	115	112
Site 7 (CHR)	77	65	0	0	0	0	77	65
Site 9 (LB)	43	43	0	0	5	5	48	48
Site 10 (HVI)	71	71	0	0	0	0	71	71
Site 11 (QD)	74	64	0	0	6	6	80	70
Total	666	633	28	28	145	145	839	806

Table 20. Demographic Data for Evaluable Prospective Specimens

Sample Type	Variable	Subgroup	PBCM Specimens N	PBCM Specimens %
Prospective Fresh	Age group	< 1 year	5	0.80%
		1-17 years	18	2.90%
		18-44 years	75	11.90%
		45-64 years	167	26.50%
		65-89 years	340	54.00%
		90+ years	25	4.00%
	Sex	Female	315	50.00%
		Male	315	50.00%
Prospective Frozen	Age group	< 1 year	1	3.20%
		18-44 years	4	12.90%
		45-64 years	5	16.10%
		65-89 years	21	67.70%
	Sex	Female	13	41.90%
		Male	18	58.10%
Prospective Total	Age group	< 1 year	6	0.90%
		1-17 years	18	2.70%
		18-44 years	79	12.00%
		45-64 years	172	26.00%
		65-89 years	361	54.60%

		90+ years	25	3.80%
	Sex	Female	328	49.60%
		Male	333	50.40%

Table 21. Summary of Blood Culture Bottle Types for Evaluable Prospective Specimens

Sample Type	Bottle Type	N	%
Prospective Fresh	BD BACTEC Lytic Anaerobic	210	33.30%
	BD BACTEC PedPlus TM	15	2.40%
	BD BACTEC Plus Aerobic	193	30.60%
	BD BACTEC Plus Anaerobic	21	3.30%
	BD BACTEC Standard Anaerobic	1	0.20%
	BioMerieux BACT/ALERT FA Plus	64	10.20%
	BioMerieux BACT/ALERT FN Plus	65	10.30%
	BioMerieux BACT/ALERT PF Plus	19	3.00%
	VersaTREK TM REDOX1 TM EZ Draw TM	36	5.70%
	VersaTREK TM REDOX2 TM EZ Draw TM	6	1.00%
Prospective Frozen	BD BACTEC Lytic Anaerobic	9	29.00%
	BD BACTEC Plus Aerobic	5	16.10%
	BioMerieux BACT/ALERT FA Plus	10	32.30%
	BioMerieux BACT/ALERT FN Plus	1	3.20%
	BioMerieux BACT/ALERT PF Plus	5	16.10%
	VersaTREK TM REDOX1 TM EZ Draw TM	1	3.20%
Prospective Total	BD BACTEC Lytic Anaerobic	219	33.10%
	BD BACTEC PedPlus TM	15	2.30%
	BD BACTEC Plus Aerobic	198	30.00%
	BD BACTEC Plus Anaerobic	21	3.20%
	BD BACTEC Standard Anaerobic	1	0.20%
	BioMerieux BACT/ALERT FA Plus	74	11.20%
	BioMerieux BACT/ALERT FN Plus	66	10.00%
	BioMerieux BACT/ALERT PF Plus	24	3.60%
	VersaTREK TM REDOX1 TM EZ Draw TM	37	5.60%
	VersaTREK TM REDOX2 TM EZ Draw TM	6	0.90%

Table 22. Demographic Data for Evaluable Retrospective Specimens

Sample Type	Variable	Subgroup	PBCM Specimens N	PBCM Specimens %
Retrospective Archived	Age group	< 1 year	500.00%	3.40%
		1-17 years	800.00%	5.50%
		18-44 years	2900.00%	20.00%
		45-64 years	2800.00%	19.30%
		65-89 years	7100.00%	49.00%

	90+ years	400.00%	2.80%
Sex	Female	6100.00%	42.10%
	Male	8300.00%	57.20%
	Not Reported	100.00%	0.70%

QIAstat-Dx BCID GN Plus AMR Panel results were compared to Standard Laboratory Techniques (SLT), including culture and MALDI-TOF MS, for pathogen identification, and validated PCR followed by bi-directional sequencing (PCR-BDS) for AMR targets. Specimens yielding discordant results between the candidate device and the comparator method were investigated using an alternate method, when remaining sample volume was available. The comparator methods for each target are summarized in **Table 23**.

Table 23. List of Comparator Method(s) by Panel Target

Target(s)	Comparator Method(s)	Discordant Method(s)
<i>Acinetobacter calcoaceticus-baumannii</i> complex	Comparator method was based on Standard of Care at each site.	Roche cobas eplex; BioFire BCID2 or MALDI-TOF
<i>Bacteroides fragilis</i>		
<i>Enterobacter</i> spp.		
<i>Escherichia coli</i>		
<i>Haemophilus influenzae</i>		
<i>Klebsiella</i> spp.		
<i>Neisseria meningitidis</i>		
<i>Proteus</i> spp.		
<i>Pseudomonas aeruginosa</i>		
<i>Salmonella</i> spp.		
<i>Serratia</i> spp.		
<i>Stenotrophomonas maltophilia</i>		
Pan Enterobacterales		
<i>aac(6')-Ib</i>	PCR-BDS from the positive blood culture specimen	N/A
<i>ampC</i> (CMY/LAT/DHA/FOX)		
<i>armA</i>		
CTX-M		
GES		
IMP		
KPC		
NDM		
OXA-23		
OXA-24/40		
OXA-48-like		
OXA-58		
PER		
SHV		
SPM		
TEM		
VEB		

Performance was measured as Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) with 95% confidence intervals (Wilson score method). Repeat testing of invalid hits was performed to obtain valid results per the device instruction. Results of performance for prospectively collected PBCM specimens are presented in **Tables 24-26** according to target organism and resistance marker. Results of performance for retrospective, archived PBCM specimens are presented in **Tables 27-29**.

Table 24. Clinical Performance for Prospective Samples by Target Organism

Organism	Sample	TP/(TP+FN)	PPA (%)	95% CI	TN/(TN+FP)	NPA (%)	95% CI
<i>Enterobacter spp.</i> ^a	Prospective Fresh	40/42	95.20%	84.2%-98.7%	584/586	99.70%	98.8%-99.9%
	Prospective Frozen	3/3	100.00%	43.9%-100.0%	28/28	100.00%	87.9%-100.0%
	Total	43/45	95.60%	85.2%-98.8%	612/614	99.70%	98.8%-99.9%
<i>Escherichia coli</i> ^b	Prospective Fresh	272/277	98.20%	95.8%-99.2%	348/352	98.90%	97.1%-99.6%
	Prospective Frozen	14/14	100.00%	78.5%-100.0%	17/17	100.00%	81.6%-100.0%
	Total	286/291	98.30%	96.0%-99.3%	365/369	98.90%	97.2%-99.6%
<i>Klebsiella spp.</i> ^c	Prospective Fresh	129/132	97.70%	93.5%-99.2%	489/496	98.60%	97.1%-99.3%
	Prospective Frozen	9/9	100.00%	70.1%-100.0%	22/22	100.00%	85.1%-100.0%
	Total	138/141	97.90%	93.9%-99.3%	511/518	98.60%	97.2%-99.3%
<i>Proteus spp.</i> ^d	Prospective Fresh	32/32	100.00%	89.3%-100.0%	589/596	98.80%	97.6%-99.4%
	Prospective Frozen	0/1	0.00%	0.0%-79.3%	30/30	100.00%	88.6%-100.0%
	Total	32/33	97.00%	84.7%-99.5%	619/626	98.90%	97.7%-99.5%
<i>Salmonella spp.</i>	Prospective Fresh	12/12	100.00%	75.8%-100.0%	616/616	100.00%	99.4%-100.0%
	Prospective Frozen	0/0	N/A	N/A	31/31	100.00%	89.0%-100.0%
	Total	12/12	100.00%	75.8%-100.0%	647/647	100.00%	99.4%-100.0%
<i>Serratia spp.</i>	Prospective Fresh	20/20	100.00%	83.9%-100.0%	608/608	100.00%	99.4%-100.0%
	Prospective Frozen	1/1	100.00%	20.7%-100.0%	30/30	100.00%	88.6%-100.0%
	Total	21/21	100.00%	84.5%-100.0%	638/638	100.00%	99.4%-100.0%

<i>Pseudomonas aeruginosae</i>	Prospective Fresh	36/37	97.30%	86.2%-99.5%	591/591	100.00%	99.4%-100.0%
	Prospective Frozen	3/3	100.00%	43.9%-100.0%	28/28	100.00%	87.9%-100.0%
	Total	39/40	97.50%	87.1%-99.6%	619/619	100.00%	99.4%-100.0%
<i>Neisseria meningitidis</i> (Encapsulated)	Prospective Fresh	1/1	100.00%	20.7%-100.0%	627/627	100.00%	99.4%-100.0%
	Prospective Frozen	0/0	N/A	N/A	31/31	100.00%	89.0%-100.0%
	Total	1/1	100.00%	20.7%-100.0%	658/658	100.00%	99.4%-100.0%
<i>Haemophilus influenzae</i> ^f	Prospective Fresh	2/2	100.00%	34.2%-100.0%	625/626	99.80%	99.1%-100.0%
	Prospective Frozen	0/0	N/A	N/A	31/31	100.00%	89.0%-100.0%
	Total	2/2	100.00%	34.2%-100.0%	656/657	99.80%	99.1%-100.0%
<i>Acinetobacter calcoaceticus-baumannii</i> complex	Prospective Fresh	5/5	100.00%	56.6%-100.0%	623/623	100.00%	99.4%-100.0%
	Prospective Frozen	0/0	N/A	N/A	31/31	100.00%	89.0%-100.0%
	Total	5/5	100.00%	56.6%-100.0%	654/654	100.00%	99.4%-100.0%
<i>Bacteroides fragilis</i> ^g	Prospective Fresh	10/12	83.30%	55.2%-95.3%	614/616	99.70%	98.8%-99.9%
	Prospective Frozen	0/0	N/A	N/A	31/31	100.00%	89.0%-100.0%
	Total	10/12	83.30%	55.2%-95.3%	645/647	99.70%	98.9%-99.9%
<i>Stenotrophomonas maltophilia</i>	Prospective Fresh	3/3	100.00%	43.9%-100.0%	625/625	100.00%	99.4%-100.0%
	Prospective Frozen	0/0	N/A	N/A	31/31	100.00%	89.0%-100.0%
	Total	3/3	100.00%	43.9%-100.0%	656/656	100.00%	99.4%-100.0%
Pan Enterobacterales ^h	Prospective Fresh	529/531	99.60%	98.6%-99.9%	95/99	96.00%	90.1%-98.4%
	Prospective Frozen	26/27	96.30%	81.7%-99.3%	4-Apr	100.00%	51.0%-100.0%
	Total	555/558	99.50%	98.4%-99.8%	99/103	96.10%	90.4%-98.5%

^a *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.

^b *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.

^c 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.

^d *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.

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

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

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

^h 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 25. Clinical Performance for Prospective Samples by Target Resistance Marker

Target	Sample	TP/ (TP+FN)	PPA (%)	95% CI	TP/ (TP+FP)	NPA (%)	95% CI
<i>ampC</i> (CMY/LAT/DHA/FOX)	Prospective Fresh	15/20	75.00%	53.1%- 88.8%	545/546	99.80%	99.0%- 100.0%
	Prospective Frozen	0/0	N/A	N/A	29/29	100.00%	88.3%- 100.0%
	Total	15/20	75.00%	53.1%- 88.8%	574/575	99.80%	99.0%- 100.0%
CTX-M	Prospective Fresh	73/75	97.30%	90.8%- 99.3%	489/491	99.60%	98.5%- 99.9%
	Prospective Frozen	2/2	100.00%	34.2%- 100.0%	27/27	100.00%	87.5%- 100.0%
	Total	75/77	97.40%	91.0%- 99.3%	516/518	99.60%	98.6%- 99.9%
IMP	Prospective Fresh	0/0	N/A	N/A	543/543	100.00%	99.3%- 100.0%
	Prospective Frozen	0/0	N/A	N/A	29/29	100.00%	88.3%- 100.0%
	Total	0/0	N/A	N/A	572/572	100.00%	99.3%- 100.0%
KPC	Prospective Fresh	0/0	N/A	N/A	567/567	100.00%	99.3%- 100.0%
	Prospective Frozen	0/0	N/A	N/A	29/29	100.00%	88.3%- 100.0%
	Total	0/0	N/A	N/A	596/596	100.00%	99.4%- 100.0%
NDM	Prospective Fresh	3/3	100.00%	43.9%- 100.0%	564/564	100.00%	99.3%- 100.0%
	Prospective Frozen	0/0	N/A	N/A	29/29	100.00%	88.3%- 100.0%

	Total	3/3	100.00%	43.9%-100.0%	593/593	100.00%	99.4%-100.0%
OXA-23	Prospective Fresh	1/1	100.00%	20.7%-100.0%	566/566	100.00%	99.3%-100.0%
	Prospective Frozen	0/0	N/A	N/A	29/29	100.00%	88.3%-100.0%
	Total	1/1	100.00%	20.7%-100.0%	595/595	100.00%	99.4%-100.0%
OXA-48-like	Prospective Fresh	1/1	100.00%	20.7%-100.0%	562/562	100.00%	99.3%-100.0%
	Prospective Frozen	0/0	N/A	N/A	29/29	100.00%	88.3%-100.0%
	Total	1/1	100.00%	20.7%-100.0%	591/591	100.00%	99.4%-100.0%
OXA-24/40	Prospective Fresh	0/0	N/A	N/A	567/567	100.00%	99.3%-100.0%
	Prospective Frozen	0/0	N/A	N/A	29/29	100.00%	88.3%-100.0%
	Total	0/0	N/A	N/A	596/596	100.00%	99.4%-100.0%
OXA-58	Prospective Fresh	0/0	N/A	N/A	567/567	100.00%	99.3%-100.0%
	Prospective Frozen	0/0	N/A	N/A	29/29	100.00%	88.3%-100.0%
	Total	0/0	N/A	N/A	596/596	100.00%	99.4%-100.0%
SHV	Prospective Fresh	89/90	98.90%	94.0%-99.8%	473/477	99.20%	97.9%-99.7%
	Prospective Frozen	4/4	100.00%	51.0%-100.0%	25/25	100.00%	86.7%-100.0%
	Total	93/94	98.90%	94.2%-99.8%	498/502	99.20%	98.0%-99.7%
TEM	Prospective Fresh	134/141	95.00%	90.1%-97.6%	435/438	99.30%	98.0%-99.8%
	Prospective Frozen	9/9	100.00%	70.1%-100.0%	19/20	95.00%	76.4%-99.1%
	Total	143/150	95.30%	90.7%-97.7%	454/458	99.10%	97.8%-99.7%
VIM	Prospective Fresh	1/2	50.00%	9.5%-90.5%	568/568	100.00%	99.3%-100.0%
	Prospective Frozen	0/0	N/A	N/A	29/29	100.00%	88.3%-100.0%

	Total	1/2	50.00%	9.5%- 90.5%	597/597	100.00%	99.4%- 100.0%
PER	Prospective Fresh	1/1	100.00%	20.7%- 100.0%	566/566	100.00%	99.3%- 100.0%
	Prospective Frozen	0/0	N/A	N/A	29/29	100.00%	88.3%- 100.0%
	Total	1/1	100.00%	20.7%- 100.0%	595/595	100.00%	99.4%- 100.0%
<i>armA</i>	Prospective Fresh	1/1	100.00%	20.7%- 100.0%	566/566	100.00%	99.3%- 100.0%
	Prospective Frozen	0/0	N/A	N/A	29/29	100.00%	88.3%- 100.0%
	Total	1/1	100.00%	20.7%- 100.0%	595/595	100.00%	99.4%- 100.0%
<i>aac(6')-lb</i>	Prospective Fresh	37/40	92.50%	80.1%- 97.4%	525/527	99.60%	98.6%- 99.9%
	Prospective Frozen	1/1	100.00%	20.7%- 100.0%	28/28	100.00%	87.9%- 100.0%
	Total	38/41	92.70%	80.6%- 97.5%	553/555	99.60%	98.7%- 99.9%
VEB	Prospective Fresh	0/0	N/A	N/A	567/567	100.00%	99.3%- 100.0%
	Prospective Frozen	0/0	N/A	N/A	29/29	100.00%	88.3%- 100.0%
	Total	0/0	N/A	N/A	596/596	100.00%	99.4%- 100.0%
GES	Prospective Fresh	0/0	N/A	N/A	566/566	100.00%	99.3%- 100.0%
	Prospective Frozen	0/0	N/A	N/A	29/29	100.00%	88.3%- 100.0%
	Total	0/0	N/A	N/A	595/595	100.00%	99.4%- 100.0%
SPM	Prospective Fresh	0/0	N/A	N/A	40/40	100.00%	91.2%- 100.0%
	Prospective Frozen	0/0	N/A	N/A	3/3	100.00%	43.9%- 100.0%
	Total	0/0	N/A	N/A	43/43	100.00%	91.8%- 100.0%

Table 26. Clinical Performance for Prospective Samples by Target Resistance Marker and Associated Organism(s)

Target	Organism(s) Detected	TP/ (TP+FN)	PPA (%)	95% CI	TN/ (TN+FP)	NPA (%)	95% CI
ampC (CMY/LAT/DHA/FOX)	Pan Enterobacterales	46147	100.00%	56.6%- 100.0%	29/29	100.00%	88.3%- 100.0%
	<i>Pseudomonas aeruginosa</i>	0/2	0.00%	0.0%- 65.8%	37/37	100.00%	90.6%- 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i>	46179	100.00%	61.0%- 100.0%	275/275	100.00%	98.6%- 100.0%
	Pan Enterobacterales, <i>Enterobacter</i> spp.	46025	33.30%	6.1%- 79.2%	37/37	100.00%	90.6%- 100.0%
	Pan Enterobacterales, <i>Proteus</i> spp.	0/1	0.00%	0.0%- 79.3%	29/29	100.00%	88.3%- 100.0%
CTX-M	Pan Enterobacterales, <i>Escherichia coli</i>	54/55	98.20%	90.4%- 99.7%	224/226	99.10%	96.8%- 99.8%
	Pan Enterobacterales, <i>Enterobacter</i> spp.	46055	100.00%	34.2%- 100.0%	38/38	100.00%	90.8%- 100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	17/18	94.40%	74.2%- 99.0%	114/114	100.00%	96.7%- 100.0%
	Pan Enterobacterales, <i>Escherichia coli</i> , <i>Klebsiella</i> spp.	46023	100.00%	20.7%- 100.0%	46147	100.00%	56.6%- 100.0%
SHV	Pan Enterobacterales, <i>Escherichia coli</i>	46305	100.00%	72.2%- 100.0%	270/271	99.60%	97.9%- 99.9%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	81/81	100.00%	95.5%- 100.0%	49/52	94.20%	84.4%- 98.0%
TEM	Pan Enterobacterales, <i>Escherichia coli</i>	118/120	98.30%	94.1%- 99.5%	154/158	97.50%	93.7%- 99.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	15/17	88.20%	65.7%- 96.7%	116/116	100.00%	96.8%- 100.0%
	<i>Pseudomonas aeruginosa</i>	0/1	0.00%	0.0%- 79.3%	37/37	100.00%	90.6%- 100.0%
aac(6')-Ib	Pan Enterobacterales, <i>Escherichia coli</i>	23/24	95.80%	79.8%- 99.3%	255/257	99.20%	97.2%- 99.8%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	46369	92.30%	66.7%- 98.6%	120/120	100.00%	96.9%- 100.0%

	<i>Pseudomonas aeruginosa</i>	0/1	0.00%	0.0%-79.3%	38/38	100.00%	90.8%-100.0%
VIM	Pan Enterobacterales, <i>Escherichia coli</i>	46023	100.00%	20.7%-100.0%	280/280	100.00%	98.6%-100.0%
	<i>Pseudomonas aeruginosa</i>	0/1	0.00%	0.0%-79.3%	38/38	100.00%	90.8%-100.0%
NDM	Pan Enterobacterales, <i>Escherichia coli</i>	46023	100.00%	20.7%-100.0%	280/280	100.00%	98.6%-100.0%
	Pan Enterobacterales, <i>Klebsiella</i> spp.	46023	100.00%	20.7%-100.0%	132/132	100.00%	97.2%-100.0%
OXA-23	<i>Acinetobacter calcoaceticus-baumannii</i> complex	46023	100.00%	20.7%-100.0%	46084	100.00%	43.9%-100.0%
OXA-48-like	Pan Enterobacterales, <i>Escherichia coli</i>	46023	100.00%	20.7%-100.0%	280/280	100.00%	98.6%-100.0%
<i>armA</i>	<i>Acinetobacter calcoaceticus-baumannii</i> complex	46023	100.00%	20.7%-100.0%	46084	100.00%	43.9%-100.0%
PER	<i>Acinetobacter calcoaceticus-baumannii</i> complex	46023	100.00%	20.7%-100.0%	46084	100.00%	43.9%-100.0%

Table 27. Clinical Performance for Archived Samples by Target Organism

Organism	TP/(TP+FN)	PPA (%)	95% CI	TN/(TN+FP)	NPA (%)	95% CI
<i>Enterobacter</i> spp.	0/0	N/A	N/A	1	100.0%	97.4%-100.0%
<i>Escherichia coli</i>	1/1	100.0%	20.7%-100.0%	1	100.0%	97.4%-100.0%
<i>Klebsiella</i> spp.	1/1	100.0%	20.7%-100.0%	1	100.0%	97.4%-100.0%
<i>Proteus</i> spp.	29/29	100.0%	88.3%-100.0%	1	100.0%	96.8%-100.0%
<i>Salmonella</i> spp.	22/22	100.0%	85.1%-100.0%	1	100.0%	97.0%-100.0%
<i>Serratia</i> spp.	24/24	100.0%	86.2%-100.0%	1	100.0%	96.9%-100.0%
<i>Pseudomonas aeruginosa</i>	1/1	100.0%	20.7%-100.0%	28/29	96.5%	92.1%-98.5%
<i>Neisseria meningitidis</i> (encapsulated)	6/7	85.7%	48.7%-97.4%	1	100.0%	97.3%-100.0%

<i>Haemophilus influenzae</i>	20/20	100.0%	83.9%-100.0%	1	99.2%	95.6%-99.9%
<i>Acinetobacter calcoaceticus-baumannii</i> complex	8/8	100.0%	67.6%-100.0%	1	100.0%	97.3%-100.0%
<i>Bacteroides fragilis</i>	28/28	100.0%	87.9%-100.0%	1	99.1%	95.3%-99.8%
<i>Stenotrophomonas maltophilia</i>	6/6	100.0%	61.0%-100.0%	1	100.0%	97.3%-100.0%
Pan Enterobacterales	76/76	100.0%	95.2%-100.0%	68/69	98.6%	92.2%-99.7%

Table 28. Clinical Performance for Archived Samples by Target Resistance Marker

Target	TP/(TP+FN)	PPA (%)	95% CI	TN/(TN+FP)	NPA (%)	95% CI
<i>ampC</i> (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%	1	100.0%	95.8%-100.0%
IMP	0/0	N/A	N/A	1	100.0%	95.1%-100.0%
KPC	0/0	N/A	N/A	1	100.0%	95.9%-100.0%
NDM	0/0	N/A	N/A	1	100.0%	95.9%-100.0%
OXA-23	1/1	100.0%	20.7%-100.0%	1	100.0%	95.8%-100.0%
OXA-48-like	0/0	N/A	N/A	1	100.0%	95.5%-100.0%
OXA-24/40	0/0	N/A	N/A	1	100.0%	95.9%-100.0%
OXA-58	0/0	N/A	N/A	1	100.0%	95.9%-100.0%
SHV	1/1	100.0%	20.7%-100.0%	1	100.0%	95.8%-100.0%
TEM	8/8	100.0%	67.6%-100.0%	1	100.0%	97.1%-100.0%
VIM	0/0	N/A	N/A	1	100.0%	96.1%-100.0%
PER	0/0	N/A	N/A	1	100.0%	95.9%-100.0%

<i>armA</i>	1/1	100.0%	20.7%-100.0%	1	100.0%	95.8%-100.0%
<i>aac(6')-lb</i>	2/2	100.0%	34.2%-100.0%	1	100.0%	95.8%-100.0%
VEB	0/0	N/A	N/A	1	100.0%	95.9%-100.0%
GES	0/0	N/A	N/A	1	100.0%	95.9%-100.0%
SPM	0/0	N/A	N/A	1	100.0%	78.5%-100.0%

Table 29. Clinical Performance for Retrospective Samples by Target Resistance Marker and Associated Organism(s)

AMR Target	Organism(s) Detected	TP/ (TP+FN)	PPA (%)	95% CI	TN/ (TN+FP)	NPA (%)	95% CI
ampC (CMY/LAT/DHA/FOX)	Pan Enterobacterales + <i>Proteus</i> spp.	0/0	N/A	N/A	28/29	96.60%	82.8%-99.4%
	Pan Enterobacterales + <i>Serratia</i> spp.	0/0	N/A	N/A	24/24	100.00%	86.2%-100.0%
CTX-M	Pan Enterobacterales + <i>Escherichia coli</i> + <i>Klebsiella</i> spp.	1/1	100.00%	20.7%-100.0%	0/0	N/A	N/A
OXA-23	<i>Acinetobacter calcoaceticus-baumannii</i> complex	1/1	100.00%	20.7%-100.0%	7/7	100.00%	64.6%-100.0%
SHV	Pan Enterobacterales + <i>Escherichia coli</i> + <i>Klebsiella</i> spp.	1/1	100.00%	20.7%-100.0%	0/0	N/A	N/A
TEM	<i>Haemophilus influenzae</i>	4/4	100.00%	51.0%-100.0%	14/14	100.00%	78.5%-100.0%
	Pan Enterobacterales + <i>Proteus</i> spp.	2/2	100.00%	34.2%-100.0%	26/26	100.00%	87.1%-100.0%
	Pan Enterobacterales + <i>Salmonella</i> spp.	1/1	100.00%	20.7%-100.0%	20/20	100.00%	83.9%-100.0%
armA	<i>Acinetobacter calcoaceticus-baumannii</i> complex	1/1	100.00%	20.7%-100.0%	7/7	100.00%	64.6%-100.0%
aac(6')-lb	Pan Enterobacterales + <i>Proteus</i> spp.	1/1	100.00%	20.7%-100.0%	28/28	100.00%	87.9%-100.0%
	Pan Enterobacterales + <i>Escherichia coli</i> + <i>Klebsiella</i> spp.	1/1	100.00%	20.7%-100.0%	0/0	N/A	N/A

2. Contrived Evaluation:

Contrived samples were prepared and tested for targets for which low prevalence was observed for both prospective and retrospective testing. Results are summarized in **Table 30**.

Table 30. Clinical Performance for Contrived Samples

Target	TP/(TP+FN)	PPA (%)	95% CI
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Organisms			
<i>Escherichia coli</i>	60/60	100.0%	94.0%-100.0%
<i>Klebsiella</i> spp.	100/100	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%
<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%
Resistance Markers			
<i>ampC</i> (CMY/LAT/DHA/FOX)	50/50	100.0%	92.9%-100.0%
CTX-M	50/50	100.0%	92.9%-100.0%
IMP	50/50	100.0%	92.9%-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	228/230	99.1%	96.9%-99.8%
VIM	68/68	100.0%	94.7%-100.0%
PER	48/50	96.0%	86.5%-98.9%
<i>armA</i>	60/60	100.0%	94.0%-100.0%
<i>aac(6')</i> -Ib	418/420	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%

3. Combined Performance:

The combined prospective, retrospective and contrived performance is shown in **Tables 31-32**.

Table 31. Combined Clinical Performance by Target Organism

Organism	Sample	TP/(TP+FN)	PPA (%)	95% CI	TN/(TN+FP)	NPA (%)	95% CI
<i>Enterobacter</i> spp.	Archived Frozen	0/0	N/A	N/A	145/145	100.00%	97.4%-100.0%
	Prospective Fresh	40/42	95.20%	84.2%-98.7%	584/586	99.70%	98.8%-99.9%
	Prospective Frozen	3/3	100.00%	43.9%-100.0%	28/28	100.00%	87.9%-100.0%

	Total	43/45	95.60%	85.2%-98.8%	757/759	99.70%	99.0%-99.9%
<i>Escherichia coli</i>	Archived Frozen	1/1	100.00%	20.7%-100.0%	144/144	100.00%	97.4%-100.0%
	Prospective Fresh	272/277	98.20%	95.8%-99.2%	348/352	98.90%	97.1%-99.6%
	Prospective Frozen	14/14	100.00%	78.5%-100.0%	17/17	100.00%	81.6%-100.0%
	Total	287/292	98.30%	96.1%-99.3%	509/513	99.20%	98.0%-99.7%
<i>Klebsiella spp.</i>	Archived Frozen	1/1	100.00%	20.7%-100.0%	144/144	100.00%	97.4%-100.0%
	Prospective Fresh	129/132	97.70%	93.5%-99.2%	489/496	98.60%	97.1%-99.3%
	Prospective Frozen	9/9	100.00%	70.1%-100.0%	22/22	100.00%	85.1%-100.0%
	Total	139/142	97.90%	94.0%-99.3%	655/662	98.90%	97.8%-99.5%
<i>Proteus spp.</i>	Archived Frozen	29/29	100.00%	88.3%-100.0%	116/116	100.00%	96.8%-100.0%
	Prospective Fresh	32/32	100.00%	89.3%-100.0%	589/596	98.80%	97.6%-99.4%
	Prospective Frozen	0/1	0.00%	0.0%-79.3%	30/30	100.00%	88.6%-100.0%
	Total	61/62	98.40%	91.4%-99.7%	735/742	99.10%	98.1%-99.5%
<i>Salmonella spp.</i>	Archived Frozen	22/22	100.00%	85.1%-100.0%	123/123	100.00%	97.0%-100.0%
	Prospective Fresh	12/12	100.00%	75.8%-100.0%	616/616	100.00%	99.4%-100.0%
	Prospective Frozen	0/0	N/A	N/A	31/31	100.00%	89.0%-100.0%
	Total	34/34	100.00%	89.8%-100.0%	770/770	100.00%	99.5%-100.0%
<i>Serratia spp.</i>	Archived Frozen	24/24	100.00%	86.2%-100.0%	121/121	100.00%	96.9%-100.0%
	Prospective Fresh	20/20	100.00%	83.9%-100.0%	608/608	100.00%	99.4%-100.0%
	Prospective Frozen	1/1	100.00%	20.7%-100.0%	30/30	100.00%	88.6%-100.0%
	Total	45/45	100.00%	92.1%-100.0%	759/759	100.00%	99.5%-100.0%
<i>Pseudomonas aeruginosa</i>	Archived Frozen	1/1	100.00%	20.7%-100.0%	139/144	96.50%	92.1%-98.5%
	Contrived	212/212	100.00%	98.2%-100.0%	N/A	N/A	N/A
	Prospective Fresh	36/37	97.30%	86.2%-99.5%	591/591	100.00%	99.4%-100.0%
	Prospective Frozen	3/3	100.00%	43.9%-100.0%	28/28	100.00%	87.9%-100.0%
	Total	252/253	99.60%	97.8%-99.9%	758/763	99.30%	98.5%-99.7%
Pan Enterobacterales	Archived Frozen	76/76	100.00%	95.2%-100.0%	68/69	98.60%	92.2%-99.7%
	Prospective Fresh	529/531	99.60%	98.6%-99.9%	95/99	96.00%	90.1%-98.4%

	Prospective Frozen	26/27	96.30%	81.7%-99.3%	4/4	100.00%	51.0%-100.0%
	Total	631/634	99.50%	98.6%-99.8%	167/172	97.10%	93.4%-98.8%

Table 32. Combined Clinical Performance by Target Resistance Marker

Target	Sample	TP/(TP+FN)	PPA (%)	95% CI	TN/(TN+FP)	NPA (%)	95% CI
<i>ampC</i> (CMY/LAT/DHA/FOX)	Archived Frozen	0/0	N/A	N/A	88/89	98.90%	93.9%-99.8%
	Contrived	50/50	100.00%	92.9%-100.0%	N/A	N/A	N/A
	Prospective Fresh	15/20	75.00%	53.1%-88.8%	545/546	99.80%	99.0%-100.0%
	Prospective Frozen	0/0	N/A	N/A	29/29	100.00%	88.3%-100.0%
	Total	65/70	92.90%	84.3%-96.9%	662/664	99.70%	98.9%-99.9%
CTX-M	Archived Frozen	1/1	100.00%	20.7%-100.0%	87/87	100.00%	95.8%-100.0%
	Contrived	50/50	100.00%	92.9%-100.0%	N/A	N/A	N/A
	Prospective Fresh	73/75	97.30%	90.8%-99.3%	489/491	99.60%	98.5%-99.9%
	Prospective Frozen	2/2	100.00%	34.2%-100.0%	27/27	100.00%	87.5%-100.0%
	Total	126/128	98.40%	94.5%-99.6%	603/605	99.70%	98.8%-99.9%
NDM	Contrived	82/84	97.60%	91.7%-99.3%	N/A	N/A	N/A
	Prospective Fresh	3/3	100.00%	43.9%-100.0%	564/564	100.00%	99.3%-100.0%
	Total	85/87	97.70%	92.0%-99.4%	682/682	100.00%	99.4%-100.0%
SHV	Archived Frozen	1/1	100.00%	20.7%-100.0%	88/88	100.00%	95.8%-100.0%
	Contrived	110/110	100.00%	96.6%-100.0%	N/A	N/A	N/A
	Prospective Fresh	89/90	98.90%	94.0%-99.8%	473/477	99.20%	97.9%-99.7%
	Prospective Frozen	4/4	100.00%	51.0%-100.0%	25/25	100.00%	86.7%-100.0%
	Total	204/205	99.50%	97.3%-99.9%	586/590	99.30%	98.3%-99.7%
TEM	Archived Frozen	8/8	100.00%	67.6%-100.0%	129/129	100.00%	97.1%-100.0%
	Contrived	227/229	99.10%	96.9%-99.8%	N/A	N/A	N/A
	Prospective Fresh	134/141	95.00%	90.1%-97.6%	435/438	99.30%	98.0%-99.8%
	Prospective Frozen	9/9	100.00%	70.1%-100.0%	19/20	95.00%	76.4%-99.1%
	Total	378/387	97.70%	95.6%-98.8%	583/587	99.30%	98.3%-99.7%
aac(6')-lb	Archived Frozen	2/2	100.00%	34.2%-100.0%	87/87	100.00%	95.8%-100.0%

	Contrived	417/419	99.50%	98.3%-99.9%	N/A	N/A	N/A
	Prospective Fresh	37/40	92.50%	80.1%-97.4%	525/527	99.60%	98.6%-99.9%
	Prospective Frozen	1/1	100.00%	20.7%-100.0%	28/28	100.00%	87.9%-100.0%
	Total	457/462	98.90%	97.5%-99.5%	640/642	99.70%	98.9%-99.9%
VIM	Contrived	68/68	100.00%	94.7%-100.0%	N/A	N/A	N/A
	Prospective Fresh	1/2	50.00%	9.5%-90.5%	568/568	100.00%	99.3%-100.0%
	Total	69/70	98.60%	92.3%-99.7%	692/692	100.00%	99.4%-100.0%

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 for these genus level and group targets, stratified by the species level, are presented in **Table 33**.

Table 33: Clinical Performance for Genus Level and Pan Targets Stratified by Species

Target	Prospective			Retrospective Archived			Contrived			Total (All Sample Types)		
	TP/ (TP+FN)	PPA %	95% CI	TP/ (TP+FN)	PPA %	95% CI	TP/ (TP+FN)	PPA %	95% CI	TP/ (TP+FN)	PPA %	95% CI
Organisms												
Enterobacter spp.	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>E. cloacae</i> (<i>Enterobacter cloacae</i> complex)	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>E. hormaechei</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> (cross-reactive)	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>Enterobacter</i> spp. (unspciated)	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%
Klebsiella spp.	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>K. 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>K. oxytoca</i>	25/27	92.6%	76.6%–97.9%	0/0	N/A	N/A	0/0	N/A	N/A	25/27	92.6%	76.6%–97.9%
<i>K. pneumoniae</i>	100/101	99.0%	94.6%–99.8%	1/1	100.0%	20.7%–100.0%	99/99	100.0%	96.3%–100.0%	200/201	99.5%	97.2%–99.9%
<i>K. pneumoniae/variicola</i> (indeterminate)	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>K. 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%
Proteus spp.	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>P. 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>P. 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%
Salmonella spp.	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%
<i>Salmonella</i> spp. (unspeciated)	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>S. 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>S. 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%
Serratia spp.	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>S. 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>S. 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%
Acinetobacter calcoaceticus- baumannii 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>A. 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%
<i>A. calcoaceticus</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>Acinetobacter</i> spp. (unspeciated)	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 Enterobacterales												
Pan Enterobacterales	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%
<i>Citrobacter amalonaticus</i>	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%
<i>Citrobacter freundii</i>	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%
<i>Citrobacter koseri</i>	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%
<i>Cronobacter</i> 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%
<i>Enterobacter cloacae</i>	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%
<i>Enterobacter cloacae</i> 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%
<i>Enterobacter hormaechei</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>Escherichia coli</i>	293/293	100.0%	98.7%– 100.0%	1/1	100.0%	20.7%– 100.0%	60/60	100.0%	94.0%– 100.0%	354/354	100.0%	98.9%– 100.0%
<i>Hafnia alvei</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>Klebsiella aerogenes</i>	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%
<i>Klebsiella oxytoca</i>	21/21	100.0%	84.5%– 100.0%	0/0	N/A	N/A	0/0	N/A	N/A	21/21	100.0%	84.5%– 100.0%
<i>Klebsiella pneumoniae</i>	101/101	100.0%	96.3%– 100.0%	1/1	100.0%	20.7%– 100.0%	99/99	100.0%	96.3%– 100.0%	201/201	100.0%	98.1%– 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>Leclercia adecarboxylata</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>	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%
<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>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>Providencia rettgeri</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>Providencia stuartii</i>	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%
<i>Raoultella ornithinolytica</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>Raoultella planticola</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>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>	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%
<i>Salmonella spp. (unspciated)</i>	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%
<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%

NOTE: 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 clinical specimens (prospective and retrospective 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.

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.

Performance of *armA* and *aac(6')-Ib* resistance markers compared to phenotypic AST results for aminoglycosides-class antibiotics by relevant organisms is presented in **Tables 34-36**. In

addition, phenotypic correlations for *armA* was also performed with contrived samples by comparing to the AST results for 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 34** while the breakdown is shown in **Table 35** for clinical specimens and **Table 36** for contrived specimens.

Table 14: 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, armA)</i>					
	PPA	NPA	PPA	NPA	PPA	NPA
Amikacin susceptibility testing						
<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/1)	100.0% (3/3)	100.0% (61/61)	100.0% (3/3)	100.0% (61/61)	100.0% (3/3)
	0.0% - 79.3%	43.9% - 100.0%	94.1% - 100.0%	43.9% - 100.0%	94.1% - 100.0%	43.9% - 100.0%
<i>Enterobacter</i> spp.	0/0	94.7% (18/19)	0/0	100.0% (19/19)	0/0	94.7% (18/19)
		75.4% - 99.1%		83.2% - 100.0%		75.4% - 99.1%
<i>Escherichia coli</i>	100.0% (3/3)	89.0% (138/155)	0.0% (0/3)	100.0% (155/155)	100.0% (3/3)	89.0% (138/155)
	43.9% - 100.0%	83.1% - 93.0%	0.0% - 56.1%	97.6% - 100.0%	43.9% - 100.0%	83.1% - 93.0%
<i>Klebsiella</i> spp.	100.0% (1/1)	91.9% (68/74)	0.0% (0/1)	100.0% (74/74)	100.0% (1/1)	91.9% (68/74)
	20.7% - 100.0%	83.4% - 96.2%	0.0% - 79.3%	95.1% - 100.0%	20.7% - 100.0%	83.4% - 96.2%
<i>Proteus</i> spp.	0/0	100.0% (21/21)	0/0	100.0% (21/21)	0/0	100.0% (21/21)
		84.5% - 100.0%		84.5% - 100.0%		84.5% - 100.0%
<i>Pseudomonas aeruginosa</i>	0/0	100.0% (22/22)	0/0	100.0% (22/22)	0/0	100.0% (22/22)
		85.1% - 100.0%		85.1% - 100.0%		85.1% - 100.0%
<i>Serratia</i> spp.	0/0	100.0% (16/16)	0/0	100.0% (16/16)	0/0	100.0% (16/16)
		80.6% - 100.0%		80.6% - 100.0%		80.6% - 100.0%
Gentamicin susceptibility testing						
<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/1)	100.0% (11/11)	100.0% (1/1)	100.0% (11/11)	100.0% (1/1)	100.0% (11/11)
	0.0% - 79.3%	74.1% - 100.0%	20.7% - 100.0%	74.1% - 100.0%	20.7% - 100.0%	74.1% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/2)	97.3% (36/37)	0.0% (0/2)	100.0% (37/37)	0.0% (0/2)	97.3% (36/37)
	0.0% - 65.8%	86.2% - 99.5%	0.0% - 65.8%	90.6% - 100.0%	0.0% - 65.8%	86.2% - 99.5%
<i>Escherichia coli</i>	34.3% (12/35)	94.0% (221/235)	0.0% (0/35)	100.0% (235/235)	34.3% (12/35)	94.0% (221/235)
	20.8% - 50.8%	90.2% - 96.4%	0.0% - 9.9%	98.4% - 100.0%	20.8% - 50.8%	90.2% - 96.4%

<i>Klebsiella</i> spp.	88.9% (8/9)	96.9% (126/130)	0.0% (0/9)	100.0% (130/130)	88.9% (8/9)	96.9% (126/130)
	56.5% - 98.0%	92.4% - 98.8%	0.0% - 29.9%	97.1% - 100.0%	56.5% - 98.0%	92.4% - 98.8%
<i>Proteus</i> spp.	0.0% (0/5)	97.5% (39/40)	0.0% (0/5)	100.0% (40/40)	0.0% (0/5)	97.5% (39/40)
	0.0% - 43.4%	87.1% - 99.6%	0.0% - 43.4%	91.2% - 100.0%	0.0% - 43.4%	87.1% - 99.6%
<i>Pseudomonas aeruginosa</i>	0.0% (0/7)	100.0% (18/18)	0.0% (0/7)	100.0% (18/18)	0.0% (0/7)	100.0% (18/18)
	0.0% - 35.4%	82.4% - 100.0%	0.0% - 35.4%	82.4% - 100.0%	0.0% - 35.4%	82.4% - 100.0%
<i>Salmonella</i> spp.	0/0	100.0% (20/20)	0/0	100.0% (20/20)	0/0	100.0% (20/20)
		83.9% - 100.0%		83.9% - 100.0%		83.9% - 100.0%
<i>Serratia</i> spp.	0/0	100.0% (30/30)	0/0	100.0% (30/30)	0/0	100.0% (30/30)
		88.6% - 100.0%		88.6% - 100.0%		88.6% - 100.0%
Tobramycin susceptibility testing						
<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/1)	100.0% (3/3)	100.0% (41/41)	100.0% (3/3)	100.0% (41/41)	100.0% (3/3)
	0.0% - 79.3%	43.9% - 100.0%	91.4% - 100.0%	43.9% - 100.0%	91.4% - 100.0%	43.9% - 100.0%
<i>Enterobacter</i> spp.	0/0	95.2% (20/21)	0/0	100.0% (21/21)	0/0	95.2% (20/21)
		77.3% - 99.2%		84.5% - 100.0%		77.3% - 99.2%
<i>Escherichia coli</i>	54.5% (18/33)	98.5% (128/130)	0.0% (0/33)	100.0% (130/130)	54.5% (18/33)	98.5% (128/130)
	38.0% - 70.2%	94.6% - 99.6%	0.0% - 10.4%	97.1% - 100.0%	38.0% - 70.2%	94.6% - 99.6%
<i>Klebsiella</i> spp.	88.9% (8/9)	100.0% (75/75)	0.0% (0/9)	100.0% (75/75)	88.9% (8/9)	100.0% (75/75)
	56.5% - 98.0%	95.1% - 100.0%	0.0% - 29.9%	95.1% - 100.0%	56.5% - 98.0%	95.1% - 100.0%
<i>Proteus</i> spp.	0.0% (0/2)	100.0% (21/21)	0.0% (0/2)	100.0% (21/21)	0.0% (0/2)	100.0% (21/21)
	0.0% - 65.8%	84.5% - 100.0%	0.0% - 65.8%	84.5% - 100.0%	0.0% - 65.8%	84.5% - 100.0%
<i>Pseudomonas aeruginosa</i>	0.0% (0/3)	100.0% (26/26)	0.0% (0/3)	100.0% (26/26)	0.0% (0/3)	100.0% (26/26)
	0.0% - 56.1%	87.1% - 100.0%	0.0% - 56.1%	87.1% - 100.0%	0.0% - 56.1%	87.1% - 100.0%
<i>Serratia</i> spp.	0.0% (0/3)	100.0% (14/14)	0.0% (0/3)	100.0% (14/14)	0.0% (0/3)	100.0% (14/14)
	0.0% - 56.1%	78.5% - 100.0%	0.0% - 56.1%	78.5% - 100.0%	0.0% - 56.1%	78.5% - 100.0%

Table 35: Performance of *aac(6')*-lb and *armA* Compared to Phenotypic AST Results for Amikacin, Gentamicin and Tobramycin in Clinical Specimens

Pathogen	<i>aac(6')</i> -lb		<i>armA</i>		Combined (<i>aac(6')</i> -lb, <i>armA</i>)	
	PPA	NPA	PPA	NPA	PPA	NPA
Amikacin susceptibility testing						
<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/1)	100.0% (3/3)	100.0% (1/1)	100.0% (3/3)	100.0% (1/1)	100.0% (3/3)
	0.0% - 79.3%	43.9% - 100.0%	20.7% - 100.0%	43.9% - 100.0%	20.7% - 100.0%	43.9% - 100.0%
<i>Enterobacter</i> spp.	0/0	94.7% (18/19)	0/0	100.0% (19/19)	0/0	94.7% (18/19)

		75.4% - 99.1%		83.2% - 100.0%		75.4% - 99.1%
<i>Escherichia coli</i>	100.0% (3/3)	89.0% (138/155)	0.0% (0/3)	100.0% (155/155)	100.0% (3/3)	89.0% (138/155)
	43.9% - 100.0%	83.1% - 93.0%	0.0% - 56.1%	97.6% - 100.0%	43.9% - 100.0%	83.1% - 93.0%
<i>Klebsiella</i> spp.	100.0% (1/1)	91.9% (68/74)	0.0% (0/1)	100.0% (74/74)	100.0% (1/1)	91.9% (68/74)
	20.7% - 100.0%	83.4% - 96.2%	0.0% - 79.3%	95.1% - 100.0%	20.7% - 100.0%	83.4% - 96.2%
<i>Proteus</i> spp.	0/0	100.0% (21/21)	0/0	100.0% (21/21)	0/0	100.0% (21/21)
		84.5% - 100.0%		84.5% - 100.0%		84.5% - 100.0%
<i>Pseudomonas aeruginosa</i>	0/0	100.0% (22/22)	0/0	100.0% (22/22)	0/0	100.0% (22/22)
		85.1% - 100.0%		85.1% - 100.0%		85.1% - 100.0%
<i>Serratia</i> spp.	0/0	100.0% (16/16)	0/0	100.0% (16/16)	0/0	100.0% (16/16)
		80.6% - 100.0%		80.6% - 100.0%		80.6% - 100.0%
Gentamicin susceptibility testing						
<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/1)	100.0% (11/11)	100.0% (1/1)	100.0% (11/11)	100.0% (1/1)	100.0% (11/11)
	0.0% - 79.3%	74.1% - 100.0%	20.7% - 100.0%	74.1% - 100.0%	20.7% - 100.0%	74.1% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/2)	97.3% (36/37)	0.0% (0/2)	100.0% (37/37)	0.0% (0/2)	97.3% (36/37)
	0.0% - 65.8%	86.2% - 99.5%	0.0% - 65.8%	90.6% - 100.0%	0.0% - 65.8%	86.2% - 99.5%
<i>Escherichia coli</i>	34.3% (12/35)	94.0% (221/235)	0.0% (0/35)	100.0% (235/235)	34.3% (12/35)	94.0% (221/235)
	20.8% - 50.8%	90.2% - 96.4%	0.0% - 9.9%	98.4% - 100.0%	20.8% - 50.8%	90.2% - 96.4%
<i>Klebsiella</i> spp.	88.9% (8/9)	96.9% (126/130)	0.0% (0/9)	100.0% (130/130)	88.9% (8/9)	96.9% (126/130)
	56.5% - 98.0%	92.4% - 98.8%	0.0% - 29.9%	97.1% - 100.0%	56.5% - 98.0%	92.4% - 98.8%
<i>Proteus</i> spp.	0.0% (0/5)	97.5% (39/40)	0.0% (0/5)	100.0% (40/40)	0.0% (0/5)	97.5% (39/40)
	0.0% - 43.4%	87.1% - 99.6%	0.0% - 43.4%	91.2% - 100.0%	0.0% - 43.4%	87.1% - 99.6%
<i>Pseudomonas aeruginosa</i>	0.0% (0/7)	100.0% (18/18)	0.0% (0/7)	100.0% (18/18)	0.0% (0/7)	100.0% (18/18)
	0.0% - 35.4%	82.4% - 100.0%	0.0% - 35.4%	82.4% - 100.0%	0.0% - 35.4%	82.4% - 100.0%
<i>Salmonella</i> spp.	0/0	100.0% (20/20)	0/0	100.0% (20/20)	0/0	100.0% (20/20)
		83.9% - 100.0%		83.9% - 100.0%		83.9% - 100.0%
<i>Serratia</i> spp.	0/0	100.0% (30/30)	0/0	100.0% (30/30)	0/0	100.0% (30/30)
		88.6% - 100.0%		88.6% - 100.0%		88.6% - 100.0%
Tobramycin susceptibility testing						
<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/1)	100.0% (3/3)	100.0% (1/1)	100.0% (3/3)	100.0% (1/1)	100.0% (3/3)
	0.0% - 79.3%	43.9% - 100.0%	20.7% - 100.0%	43.9% - 100.0%	20.7% - 100.0%	43.9% - 100.0%
<i>Enterobacter</i> spp.	0/0	95.2% (20/21)	0/0	100.0% (21/21)	0/0	95.2% (20/21)
		77.3% - 99.2%		84.5% - 100.0%		77.3% - 99.2%
<i>Escherichia coli</i>	54.5% (18/33)	98.5% (128/130)	0.0% (0/33)	100.0% (130/130)	54.5% (18/33)	98.5% (128/130)
	38.0% - 70.2%	94.6% - 99.6%	0.0% - 10.4%	97.1% - 100.0%	38.0% - 70.2%	94.6% - 99.6%
<i>Klebsiella</i> spp.	88.9% (8/9)	100.0% (75/75)	0.0% (0/9)	100.0% (75/75)	88.9% (8/9)	100.0% (75/75)
	56.5% - 98.0%	95.1% - 100.0%	0.0% - 29.9%	95.1% - 100.0%	56.5% - 98.0%	95.1% - 100.0%
<i>Proteus</i> spp.	0.0% (0/2)	100.0% (21/21)	0.0% (0/2)	100.0% (21/21)	0.0% (0/2)	100.0% (21/21)
	0.0% - 65.8%	84.5% - 100.0%	0.0% - 65.8%	84.5% - 100.0%	0.0% - 65.8%	84.5% - 100.0%
<i>Pseudomonas aeruginosa</i>	0.0% (0/3)	100.0% (26/26)	0.0% (0/3)	100.0% (26/26)	0.0% (0/3)	100.0% (26/26)
	0.0% - 56.1%	87.1% - 100.0%	0.0% - 56.1%	87.1% - 100.0%	0.0% - 56.1%	87.1% - 100.0%
<i>Serratia</i> spp.	0.0% (0/3)	100.0% (14/14)	0.0% (0/3)	100.0% (14/14)	0.0% (0/3)	100.0% (14/14)
	0.0% - 56.1%	78.5% - 100.0%	0.0% - 56.1%	78.5% - 100.0%	0.0% - 56.1%	78.5% - 100.0%

Table 36: Performance of *armA* Compared to Phenotypic AST Results for Amikacin and Tobramycin in Contrived Samples

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

The performance of SHV and TEM resistance markers compared to phenotypic AST results for penicillin-class antibiotics by relevant organisms is presented in **Table 37**. 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 37: 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)	0/0	0.0% (0/16)	0/0	6.3% (1/16)	0/0
	1.1% - 28.3%		0.0% - 19.4%		1.1% - 28.3%	
<i>Escherichia coli</i>	6.5% (11/168)	99.0% (95/96)	70.6% (120/170)	97.9% (94/96)	74.7% (127/170)	96.9% (93/96)
	3.7% - 11.3%	94.3% - 99.8%	63.3% - 76.9%	92.7% - 99.4%	67.7% - 80.6%	91.2% - 98.9%
<i>Haemophilus influenzae</i>	N/A	N/A	27.3% (3/11)	100.0% (6/6)	27.3% (3/11)	100.0% (6/6)
			9.7% - 56.6%	61.0% - 100.0%	9.7% - 56.6%	61.0% - 100.0%
<i>Klebsiella</i> spp.	73.3% (55/75)	66.7% (2/3)	17.3% (13/75)	100.0% (3/3)	73.3% (55/75)	66.7% (2/3)
	62.4% - 82.0%	20.8% - 93.9%	10.4% - 27.4%	43.9% - 100.0%	62.4% - 82.0%	20.8% - 93.9%
<i>Proteus</i> spp.	0.0% (0/10)	100.0% (32/32)	30.0% (3/10)	100.0% (32/32)	30.0% (3/10)	100.0% (32/32)
	0.0% - 27.8%	89.3% - 100.0%	10.8% - 60.3%	89.3% - 100.0%	10.8% - 60.3%	89.3% - 100.0%
<i>Salmonella</i> spp.	0.0% (0/1)	100.0% (27/27)	100.0% (1/1)	100.0% (27/27)	100.0% (1/1)	100.0% (27/27)
	0.0% - 79.3%	87.5% - 100.0%	20.7% - 100.0%	87.5% - 100.0%	20.7% - 100.0%	87.5% - 100.0%
<i>Serratia</i> spp.	14.3% (1/7)	100.0% (1/1)	0.0% (0/7)	100.0% (1/1)	14.3% (1/7)	100.0% (1/1)
	2.6% - 51.3%	20.7% - 100.0%	0.0% - 35.4%	20.7% - 100.0%	2.6% - 51.3%	20.7% - 100.0%
Penicillin susceptibility testing						
<i>Bacteroides fragilis</i>	N/A	N/A	0.0% (0/1)	0/0	0.0% (0/1)	0/0
			0.0% - 79.3%		0.0% - 79.3%	
<i>Neisseria meningitidis</i>	N/A	N/A	0.0% (0/1)	100.0% (2/2)	0.0% (0/1)	100.0% (2/2)

			0.0% - 79.3%	34.2% - 100.0%	0.0% - 79.3%	34.2% - 100.0%
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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 38-40**. The combined results for clinical specimens and contrived samples are provided in **Table 38** while the breakdown is shown in **Table 39a** and **Table 39b** for clinical specimens and **Table 40** for contrived specimens.

Table 38: 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)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)
		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%		
<i>Enterobacter</i> spp.	0.0% (0/5)	100.0% (4/4)	0.0% (0/5)	100.0% (4/4)	0.0% (0/5)	100.0% (4/4)	0.0% (0/5)	100.0% (4/4)	0.0% (0/5)	100.0% (4/4)	0.0% (0/5)	100.0% (4/4)	0.0% (0/5)	100.0% (4/4)
	0.0% - 43.4%	51.0% - 100.0%	0.0% - 43.4%	51.0% - 100.0%	0.0% - 43.4%	51.0% - 100.0%	0.0% - 43.4%	51.0% - 100.0%	0.0% - 43.4%	51.0% - 100.0%	0.0% - 43.4%	51.0% - 100.0%	0.0% - 43.4%	51.0% - 100.0%
<i>Escherichia coli</i>	71.4% (5/7)	37.5% (9/24)	28.6% (2/7)	95.8% (23/24)	0.0% (0/7)	100.0% (24/24)	71.4% (5/7)	100.0% (24/24)	0.0% (0/7)	100.0% (24/24)	0.0% (0/7)	100.0% (24/24)	100.0% (7/7)	33.3% (8/24)
	35.9% - 91.8%	21.2% - 57.3%	8.2% - 64.1%	79.8% - 99.3%	0.0% - 35.4%	86.2% - 100.0%	35.9% - 91.8%	86.2% - 100.0%	0.0% - 35.4%	86.2% - 100.0%	0.0% - 35.4%	86.2% - 100.0%	64.6% - 100.0%	18.0% - 53.3%
<i>Klebsiella</i> spp.	66.7% (2/3)	100.0% (10/10)	100.0% (3/3)	40.0% (4/10)	0.0% (0/3)	100.0% (10/10)	100.0% (3/3)	100.0% (10/10)	0.0% (0/3)	100.0% (10/10)	0.0% (0/3)	100.0% (10/10)	100.0% (3/3)	40.0% (4/10)
	20.8% - 93.9%	72.2% - 100.0%	43.9% - 100.0%	16.8% - 68.7%	0.0% - 56.1%	72.2% - 100.0%	43.9% - 100.0%	72.2% - 100.0%	0.0% - 56.1%	72.2% - 100.0%	0.0% - 56.1%	72.2% - 100.0%	43.9% - 100.0%	16.8% - 68.7%
<i>Proteus</i> spp.	0.0% (0/1)	83.3% (5/6)	0.0% (0/1)	100.0% (6/6)	0.0% (0/1)	100.0% (6/6)	0.0% (0/1)	100.0% (6/6)	0.0% (0/1)	100.0% (6/6)	N/A	N/A	0.0% (0/1)	83.3% (5/6)
	0.0% - 79.3%	43.6% - 97.0%	0.0% - 79.3%	61.0% - 100.0%	0.0% - 79.3%	61.0% - 100.0%	0.0% - 79.3%	61.0% - 100.0%	0.0% - 79.3%	61.0% - 100.0%			0.0% - 79.3%	43.6% - 97.0%
<i>Salmonella</i> spp.	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	N/A	N/A	0/0	100.0% (1/1)
		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%						
Ceftazidime susceptibility testing														
<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/3)	100.0% (7/7)	0.0% (0/3)	100.0% (7/7)	33.3% (1/3)	100.0% (7/7)	0.0% (0/3)	100.0% (7/7)	0.0% (0/3)	100.0% (7/7)	0.0% (0/3)	100.0% (7/7)	33.3% (1/3)	100.0% (7/7)
	0.0% - 56.1%	64.6% - 100.0%	0.0% - 56.1%	64.6% - 100.0%	6.1% - 79.2%	64.6% - 100.0%	0.0% - 56.1%	64.6% - 100.0%	0.0% - 56.1%	64.6% - 100.0%	0.0% - 56.1%	64.6% - 100.0%	6.1% - 79.2%	64.6% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/9)	100.0% (13/13)	0.0% (0/9)	92.3% (12/13)	0.0% (0/9)	100.0% (13/13)	0.0% (0/9)	100.0% (13/13)	0.0% (0/9)	100.0% (13/13)	0.0% (0/9)	100.0% (13/13)	0.0% (0/9)	92.3% (12/13)
	0.0% - 29.9%	77.2% - 100.0%	0.0% - 29.9%	66.7% - 98.6%	0.0% - 29.9%	77.2% - 100.0%	0.0% - 29.9%	77.2% - 100.0%	0.0% - 29.9%	77.2% - 100.0%	0.0% - 29.9%	77.2% - 100.0%	0.0% - 29.9%	66.7% - 98.6%
<i>Escherichia coli</i>	52.2% (12/23)	54.8% (57/104)	17.4% (4/23)	97.1% (101/104)	24.2% (8/33)	100.0% (104/104)	60.9% (14/23)	98.1% (102/104)	0.0% (0/23)	100.0% (104/104)	0.0% (0/23)	100.0% (104/104)	84.8% (28/33)	51.0% (53/104)
	33.0% - 70.8%	45.2% - 64.0%	7.0% - 37.1%	91.9% - 99.0%	12.8% - 41.0%	96.4% - 100.0%	40.8% - 77.8%	93.3% - 99.5%	0.0% - 14.3%	96.4% - 100.0%	0.0% - 14.3%	96.4% - 100.0%	69.1% - 93.3%	41.5% - 60.4%
<i>Klebsiella</i> spp.	71.4% (5/7)	94.8% (55/58)	100.0% (7/7)	34.5% (20/58)	56.3% (9/16)	100.0% (58/58)	100.0% (7/7)	96.6% (56/58)	58.8% (10/17)	100.0% (58/58)	58.8% (10/17)	100.0% (58/58)	100.0% (36/36)	32.8% (19/58)

	35.9% - 91.8%	85.9% - 98.2%	64.6% - 100.0%	23.6% - 47.3%	33.2% - 76.9%	93.8% - 100.0%	64.6% - 100.0%	88.3% - 99.0%	36.0% - 78.4%	93.8% - 100.0%	36.0% - 78.4%	93.8% - 100.0%	90.4% - 100.0%	22.1% - 45.6%
<i>Proteus</i> spp.	0.0% (0/2)	90.3% (28/31)	0.0% (0/2)	100.0% (31/31)	0.0% (0/2)	100.0% (31/31)	0.0% (0/2)	100.0% (31/31)	0.0% (0/2)	100.0% (31/31)	N/A	N/A	0.0% (0/2)	90.3% (28/31)
	0.0% - 65.8%	75.1% - 96.7%	0.0% - 65.8%	89.0% - 100.0%	0.0% - 65.8%	89.0% - 100.0%	0.0% - 65.8%	89.0% - 100.0%	0.0% - 65.8%	89.0% - 100.0%			0.0% - 65.8%	75.1% - 96.7%
<i>Pseudomonas aeruginosa</i>	0.0% (0/4)	100.0% (22/22)	0.0% (0/4)	100.0% (22/22)	83.3% (20/24)	100.0% (22/22)	0.0% (0/4)	100.0% (22/22)	90.5% (38/42)	100.0% (22/22)	83.3% (20/24)	100.0% (22/22)	95.1% (78/82)	100.0% (22/22)
	0.0% - 49.0%	85.1% - 100.0%	0.0% - 49.0%	85.1% - 100.0%	64.1% - 93.3%	85.1% - 100.0%	0.0% - 49.0%	85.1% - 100.0%	77.9% - 96.2%	85.1% - 100.0%	64.1% - 93.3%	85.1% - 100.0%	88.1% - 98.1%	85.1% - 100.0%
<i>Salmonella</i> spp.	0.0% (0/1)	94.7% (18/19)	0.0% (0/1)	100.0% (19/19)	0.0% (0/1)	100.0% (19/19)	0.0% (0/1)	100.0% (19/19)	0.0% (0/1)	100.0% (19/19)	N/A	N/A	0.0% (0/1)	94.7% (18/19)
	0.0% - 79.3%	75.4% - 99.1%	0.0% - 79.3%	83.2% - 100.0%	0.0% - 79.3%	83.2% - 100.0%	0.0% - 79.3%	83.2% - 100.0%	0.0% - 79.3%	83.2% - 100.0%			0.0% - 79.3%	75.4% - 99.1%
<i>Serratia</i> spp.	0.0% (0/1)	100.0% (11/11)	0.0% (0/1)	90.9% (10/11)	N/A	N/A	0.0% (0/1)	100.0% (11/11)	N/A	N/A	0.0% (0/1)	100.0% (11/11)	0.0% (0/1)	90.9% (10/11)
	0.0% - 79.3%	74.1% - 100.0%	0.0% - 79.3%	62.3% - 98.4%			0.0% - 79.3%	74.1% - 100.0%			0.0% - 79.3%	62.3% - 98.4%		
Ceftriaxone susceptibility testing														
<i>A. calcoaceticus-baumannii</i> complex	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)
		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%				
<i>Enterobacter</i> spp.	0.0% (0/3)	100.0% (2/2)	0.0% (0/3)	50.0% (1/2)	0.0% (0/3)	100.0% (2/2)	0.0% (0/3)	100.0% (2/2)	0.0% (0/3)	100.0% (2/2)	0.0% (0/3)	100.0% (2/2)	0.0% (0/3)	50.0% (1/2)
	0.0% - 56.1%	34.2% - 100.0%	0.0% - 56.1%	9.5% - 90.5%	0.0% - 56.1%	34.2% - 100.0%	0.0% - 56.1%	34.2% - 100.0%	0.0% - 56.1%	34.2% - 100.0%	0.0% - 56.1%	34.2% - 100.0%	0.0% - 56.1%	9.5% - 90.5%
<i>Escherichia coli</i>	20.0% (6/30)	50.9% (85/167)	3.3% (1/30)	97.0% (160/165)	20.0% (8/40)	100.0% (165/165)	93.3% (28/30)	98.8% (163/165)	0.0% (0/30)	100.0% (165/165)	0.0% (0/30)	100.0% (165/165)	95.0% (38/40)	48.5% (81/167)
	9.5% - 37.3%	43.4% - 58.4%	0.6% - 16.7%	93.1% - 98.7%	10.5% - 34.8%	97.7% - 100.0%	78.7% - 98.2%	95.7% - 99.7%	0.0% - 11.4%	97.7% - 100.0%	0.0% - 11.4%	97.7% - 100.0%	83.5% - 98.6%	41.0% - 56.0%
<i>Haemophilus influenzae</i>	0/0	100.0% (2/2)	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%												34.2% - 100.0%
<i>Klebsiella</i> spp.	76.9% (10/13)	96.4% (80/83)	100.0% (13/13)	32.5% (27/83)	40.9% (9/22)	100.0% (83/83)	100.0% (13/13)	98.8% (82/83)	43.5% (10/23)	100.0% (83/83)	43.5% (10/23)	100.0% (83/83)	100.0% (42/42)	31.3% (26/83)
	49.7% - 91.8%	89.9% - 98.8%	77.2% - 100.0%	23.4% - 43.2%	23.3% - 61.3%	95.6% - 100.0%	77.2% - 100.0%	93.5% - 99.8%	25.6% - 63.2%	95.6% - 100.0%	25.6% - 63.2%	95.6% - 100.0%	91.6% - 100.0%	22.4% - 41.9%
<i>Neisseria meningitidis</i>	0/0	100.0% (6/6)	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%												61.0% - 100.0%
<i>Proteus</i> spp.	0/0	95.7% (22/23)	0/0	100.0% (23/23)	0/0	100.0% (23/23)	0/0	100.0% (23/23)	0/0	100.0% (23/23)	N/A	N/A	0/0	95.7% (22/23)
		79.0% - 99.2%		85.7% - 100.0%		85.7% - 100.0%		85.7% - 100.0%		79.0% - 99.2%				
<i>Salmonella</i> spp.	0/0	93.8% (15/16)	0/0	100.0% (16/16)	0/0	100.0% (16/16)	0/0	100.0% (16/16)	0/0	100.0% (16/16)	N/A	N/A	0/0	93.8% (15/16)
		71.7% - 98.9%		80.6% - 100.0%		80.6% - 100.0%		80.6% - 100.0%		71.7% - 98.9%				
<i>Serratia</i> spp.	0.0% (0/1)	100.0% (9/9)	0.0% (0/1)	88.9% (8/9)	N/A	N/A	0.0% (0/1)	100.0% (9/9)	N/A	N/A	0.0% (0/1)	100.0% (9/9)	0.0% (0/1)	88.9% (8/9)
	0.0% - 79.3%	70.1% - 100.0%	0.0% - 79.3%	56.5% - 98.0%			0.0% - 79.3%	70.1% - 100.0%			0.0% - 79.3%	56.5% - 98.0%		

Table 39a: Performance of TEM, SHV, and PER Compared to Phenotypic AST Results for Cefotaxime, Ceftazidime and Ceftriaxone in Clinical Specimens

Pathogen	TEM	SHV	PER	Combined
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							(TEM, SHV, PER, CTX-M, VEB, GES)	
	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
Cefotaxime susceptibility testing								
<i>A. calcoaceticus-baumannii</i> complex	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)
		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%		
<i>Enterobacter</i> spp.	0.0% (0/5)	100.0% (4/4)	0.0% (0/5)	100.0% (4/4)	0.0% (0/5)	100.0% (4/4)	0.0% (0/5)	100.0% (4/4)
	0.0% - 43.4%	51.0% - 100.0%	0.0% - 43.4%	51.0% - 100.0%	0.0% - 43.4%	51.0% - 100.0%	0.0% - 43.4%	51.0% - 100.0%
<i>Escherichia coli</i>	71.4% (5/7)	37.5% (9/24)	28.6% (2/7)	95.8% (23/24)	0.0% (0/7)	100.0% (24/24)	100.0% (7/7)	33.3% (8/24)
	35.9% - 91.8%	21.2% - 57.3%	8.2% - 64.1%	79.8% - 99.3%	0.0% - 35.4%	86.2% - 100.0%	64.6% - 100.0%	18.0% - 53.3%
<i>Klebsiella</i> spp.	66.7% (2/3)	100.0% (10/10)	100.0% (3/3)	40.0% (4/10)	0.0% (0/3)	100.0% (10/10)	100.0% (3/3)	40.0% (4/10)
	20.8% - 93.9%	72.2% - 100.0%	43.9% - 100.0%	16.8% - 68.7%	0.0% - 56.1%	72.2% - 100.0%	43.9% - 100.0%	16.8% - 68.7%
<i>Proteus</i> spp.	0.0% (0/1)	83.3% (5/6)	0.0% (0/1)	100.0% (6/6)	0.0% (0/1)	100.0% (6/6)	0.0% (0/1)	83.3% (5/6)
	0.0% - 79.3%	43.6% - 97.0%	0.0% - 79.3%	61.0% - 100.0%	0.0% - 79.3%	61.0% - 100.0%	0.0% - 79.3%	43.6% - 97.0%
<i>Salmonella</i> spp.	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)
		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%		
Ceftazidime susceptibility testing								
<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/3)	100.0% (7/7)	0.0% (0/3)	100.0% (7/7)	33.3% (1/3)	100.0% (7/7)	33.3% (1/3)	100.0% (7/7)
	0.0% - 56.1%	64.6% - 100.0%	0.0% - 56.1%	64.6% - 100.0%	6.1% - 79.2%	64.6% - 100.0%	6.1% - 79.2%	64.6% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/9)	100.0% (13/13)	0.0% (0/9)	92.3% (12/13)	0.0% (0/9)	100.0% (13/13)	0.0% (0/9)	92.3% (12/13)
	0.0% - 29.9%	77.2% - 100.0%	0.0% - 29.9%	66.7% - 98.6%	0.0% - 29.9%	77.2% - 100.0%	0.0% - 29.9%	66.7% - 98.6%
<i>Escherichia coli</i>	52.2% (12/23)	54.8% (57/104)	17.4% (4/23)	97.1% (101/104)	0.0% (0/23)	100.0% (104/104)	87.0% (20/23)	51.0% (53/104)
	33.0% - 70.8%	45.2% - 64.0%	7.0% - 37.1%	91.9% - 99.0%	0.0% - 14.3%	96.4% - 100.0%	67.9% - 95.5%	41.5% - 60.4%
<i>Klebsiella</i> spp.	71.4% (5/7)	94.8% (55/58)	100.0% (7/7)	34.5% (20/58)	0.0% (0/7)	100.0% (58/58)	100.0% (7/7)	32.8% (19/58)
	35.9% - 91.8%	85.9% - 98.2%	64.6% - 100.0%	23.6% - 47.3%	0.0% - 35.4%	93.8% - 100.0%	64.6% - 100.0%	22.1% - 45.6%
<i>Proteus</i> spp.	0.0% (0/2)	90.3% (28/31)	0.0% (0/2)	100.0% (31/31)	0.0% (0/2)	100.0% (31/31)	0.0% (0/2)	90.3% (28/31)
	0.0% - 65.8%	75.1% - 96.7%	0.0% - 65.8%	89.0% - 100.0%	0.0% - 65.8%	89.0% - 100.0%	0.0% - 65.8%	75.1% - 96.7%
<i>Pseudomonas aeruginosa</i>	0.0% (0/4)	100.0% (22/22)	0.0% (0/4)	100.0% (22/22)	0.0% (0/4)	100.0% (22/22)	0.0% (0/4)	100.0% (22/22)
	0.0% - 49.0%	85.1% - 100.0%	0.0% - 49.0%	85.1% - 100.0%	0.0% - 49.0%	85.1% - 100.0%	0.0% - 49.0%	85.1% - 100.0%
<i>Salmonella</i> spp.	0.0% (0/1)	94.7% (18/19)	0.0% (0/1)	100.0% (19/19)	0.0% (0/1)	100.0% (19/19)	0.0% (0/1)	94.7% (18/19)
	0.0% - 79.3%	75.4% - 99.1%	0.0% - 79.3%	83.2% - 100.0%	0.0% - 79.3%	83.2% - 100.0%	0.0% - 79.3%	75.4% - 99.1%
<i>Serratia</i> spp.	0.0% (0/1)	100.0% (11/11)	0.0% (0/1)	90.9% (10/11)	N/A	N/A	0.0% (0/1)	90.9% (10/11)
	0.0% - 79.3%	74.1% - 100.0%	0.0% - 79.3%	62.3% - 98.4%			0.0% - 79.3%	62.3% - 98.4%
Ceftriaxone susceptibility testing								

<i>A. calcoaceticus-baumannii</i> complex	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)
		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/3)	100.0% (2/2)	0.0% (0/3)	50.0% (1/2)	0.0% (0/3)	100.0% (2/2)	0.0% (0/3)	50.0% (1/2)
	0.0% - 56.1%	34.2% - 100.0%	0.0% - 56.1%	9.5% - 90.5%	0.0% - 56.1%	34.2% - 100.0%	0.0% - 56.1%	9.5% - 90.5%
<i>Escherichia coli</i>	20.0% (6/30)	50.9% (85/167)	3.3% (1/30)	97.0% (160/165)	0.0% (0/30)	100.0% (165/165)	100.0% (30/30)	48.5% (81/167)
	9.5% - 37.3%	43.4% - 58.4%	0.6% - 16.7%	93.1% - 98.7%	0.0% - 11.4%	97.7% - 100.0%	88.6% - 100.0%	41.0% - 56.0%
<i>Haemophilus influenzae</i>	0/0	100.0% (2/2)	N/A	N/A	N/A	N/A	0/0	100.0% (2/2)
		34.2% - 100.0%						34.2% - 100.0%
<i>Klebsiella</i> spp.	76.9% (10/13)	96.4% (80/83)	100.0% (13/13)	32.5% (27/83)	0.0% (0/13)	100.0% (83/83)	100.0% (13/13)	31.3% (26/83)
	49.7% - 91.8%	89.9% - 98.8%	77.2% - 100.0%	23.4% - 43.2%	0.0% - 22.8%	95.6% - 100.0%	77.2% - 100.0%	22.4% - 41.9%
<i>Neisseria meningitidis</i>	0/0	100.0% (6/6)	N/A	N/A	N/A	N/A	0/0	100.0% (6/6)
		61.0% - 100.0%						61.0% - 100.0%
<i>Proteus</i> spp.	0/0	95.7% (22/23)	0/0	100.0% (23/23)	0/0	100.0% (23/23)	0/0	95.7% (22/23)
		79.0% - 99.2%		85.7% - 100.0%		85.7% - 100.0%		79.0% - 99.2%
<i>Salmonella</i> spp.	0/0	93.8% (15/16)	0/0	100.0% (16/16)	0/0	100.0% (16/16)	0/0	93.8% (15/16)
		71.7% - 98.9%		80.6% - 100.0%		80.6% - 100.0%		71.7% - 98.9%
<i>Serratia</i> spp.	0.0% (0/1)	100.0% (9/9)	0.0% (0/1)	88.9% (8/9)	N/A	N/A	0.0% (0/1)	88.9% (8/9)
	0.0% - 79.3%	70.1% - 100.0%	0.0% - 79.3%	56.5% - 98.0%			0.0% - 79.3%	56.5% - 98.0%

Table 39b: Performance of CTX-M, VEB and GES Compared to Phenotypic AST Results for Cefotaxime, Ceftazidime and Ceftriaxone in Clinical Specimens

Pathogen	CTX-M		VEB		GES		Combined (TEM, SHV, PER, CTX-M, VEB, GES)	
	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
Cefotaxime susceptibility testing								
<i>A. calcoaceticus-baumannii</i> complex	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)
		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/5)	100.0% (4/4)	0.0% (0/5)	100.0% (4/4)	0.0% (0/5)	100.0% (4/4)	0.0% (0/5)	100.0% (4/4)
	0.0% - 43.4%	51.0% - 100.0%	0.0% - 43.4%	51.0% - 100.0%	0.0% - 43.4%	51.0% - 100.0%	0.0% - 43.4%	51.0% - 100.0%
<i>Escherichia coli</i>	71.4% (5/7)	100.0% (24/24)	0.0% (0/7)	100.0% (24/24)	0.0% (0/7)	100.0% (24/24)	100.0% (7/7)	33.3% (8/24)
	35.9% - 91.8%	86.2% - 100.0%	0.0% - 35.4%	86.2% - 100.0%	0.0% - 35.4%	86.2% - 100.0%	64.6% - 100.0%	18.0% - 53.3%
<i>Klebsiella</i> spp.	100.0% (3/3)	100.0% (10/10)	0.0% (0/3)	100.0% (10/10)	0.0% (0/3)	100.0% (10/10)	100.0% (3/3)	40.0% (4/10)
	43.9% - 100.0%	72.2% - 100.0%	0.0% - 56.1%	72.2% - 100.0%	0.0% - 56.1%	72.2% - 100.0%	43.9% - 100.0%	16.8% - 68.7%
<i>Proteus</i> spp.	0.0% (0/1)	100.0% (6/6)	0.0% (0/1)	100.0% (6/6)	N/A	N/A	0.0% (0/1)	83.3% (5/6)

	0.0% - 79.3%	61.0% - 100.0%	0.0% - 79.3%	61.0% - 100.0%			0.0% - 79.3%	43.6% - 97.0%
Salmonella spp.	0/0	100.0% (1/1)	0/0	100.0% (1/1)	N/A	N/A	0/0	100.0% (1/1)
		20.7% - 100.0%		20.7% - 100.0%				
Ceftazidime susceptibility testing								
A. calcoaceticus-baumannii complex	0.0% (0/3)	100.0% (7/7)	0.0% (0/3)	100.0% (7/7)	0.0% (0/3)	100.0% (7/7)	33.3% (1/3)	100.0% (7/7)
	0.0% - 56.1%	64.6% - 100.0%	0.0% - 56.1%	64.6% - 100.0%	0.0% - 56.1%	64.6% - 100.0%	6.1% - 79.2%	64.6% - 100.0%
Enterobacter spp.	0.0% (0/9)	100.0% (13/13)	0.0% (0/9)	100.0% (13/13)	0.0% (0/9)	100.0% (13/13)	0.0% (0/9)	92.3% (12/13)
	0.0% - 29.9%	77.2% - 100.0%	0.0% - 29.9%	77.2% - 100.0%	0.0% - 29.9%	77.2% - 100.0%	0.0% - 29.9%	66.7% - 98.6%
Escherichia coli	60.9% (14/23)	98.1% (102/104)	0.0% (0/23)	100.0% (104/104)	0.0% (0/23)	100.0% (104/104)	87.0% (20/23)	51.0% (53/104)
	40.8% - 77.8%	93.3% - 99.5%	0.0% - 14.3%	96.4% - 100.0%	0.0% - 14.3%	96.4% - 100.0%	67.9% - 95.5%	41.5% - 60.4%
Klebsiella spp.	100.0% (7/7)	96.6% (56/58)	0.0% (0/7)	100.0% (58/58)	0.0% (0/7)	100.0% (58/58)	100.0% (7/7)	32.8% (19/58)
	64.6% - 100.0%	88.3% - 99.0%	0.0% - 35.4%	93.8% - 100.0%	0.0% - 35.4%	93.8% - 100.0%	64.6% - 100.0%	22.1% - 45.6%
Proteus spp.	0.0% (0/2)	100.0% (31/31)	0.0% (0/2)	100.0% (31/31)	N/A	N/A	0.0% (0/2)	90.3% (28/31)
	0.0% - 65.8%	89.0% - 100.0%	0.0% - 65.8%	89.0% - 100.0%			0.0% - 65.8%	75.1% - 96.7%
Pseudomonas aeruginosa	0.0% (0/4)	100.0% (22/22)	0.0% (0/4)	100.0% (22/22)	0.0% (0/4)	100.0% (22/22)	0.0% (0/4)	100.0% (22/22)
	0.0% - 49.0%	85.1% - 100.0%	0.0% - 49.0%	85.1% - 100.0%	0.0% - 49.0%	85.1% - 100.0%	0.0% - 49.0%	85.1% - 100.0%
Salmonella spp.	0.0% (0/1)	100.0% (19/19)	0.0% (0/1)	100.0% (19/19)	N/A	N/A	0.0% (0/1)	94.7% (18/19)
	0.0% - 79.3%	83.2% - 100.0%	0.0% - 79.3%	83.2% - 100.0%			0.0% - 79.3%	75.4% - 99.1%
Serratia spp.	0.0% (0/1)	100.0% (11/11)	N/A	N/A	0.0% (0/1)	100.0% (11/11)	0.0% (0/1)	90.9% (10/11)
	0.0% - 79.3%	74.1% - 100.0%			0.0% - 79.3%	74.1% - 100.0%	0.0% - 79.3%	62.3% - 98.4%
Ceftriaxone susceptibility testing								
A. calcoaceticus-baumannii complex	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)
		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%		
Enterobacter spp.	0.0% (0/3)	100.0% (2/2)	0.0% (0/3)	100.0% (2/2)	0.0% (0/3)	100.0% (2/2)	0.0% (0/3)	50.0% (1/2)
	0.0% - 56.1%	34.2% - 100.0%	0.0% - 56.1%	34.2% - 100.0%	0.0% - 56.1%	34.2% - 100.0%	0.0% - 56.1%	9.5% - 90.5%
Escherichia coli	93.3% (28/30)	98.8% (163/165)	0.0% (0/30)	100.0% (165/165)	0.0% (0/30)	100.0% (165/165)	100.0% (30/30)	48.5% (81/167)
	78.7% - 98.2%	95.7% - 99.7%	0.0% - 11.4%	97.7% - 100.0%	0.0% - 11.4%	97.7% - 100.0%	88.6% - 100.0%	41.0% - 56.0%
Haemophilus influenzae	N/A	N/A	N/A	N/A	N/A	N/A	0/0	100.0% (2/2)
								34.2% - 100.0%
Klebsiella spp.	100.0% (13/13)	98.8% (82/83)	0.0% (0/13)	100.0% (83/83)	0.0% (0/13)	100.0% (83/83)	100.0% (13/13)	31.3% (26/83)
	77.2% - 100.0%	93.5% - 99.8%	0.0% - 22.8%	95.6% - 100.0%	0.0% - 22.8%	95.6% - 100.0%	77.2% - 100.0%	22.4% - 41.9%
Neisseria meningitidis	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	100.0% (23/23)	0/0	100.0% (23/23)	N/A	N/A	0/0	95.7% (22/23)
		85.7% - 100.0%		85.7% - 100.0%				79.0% - 99.2%
<i>Salmonella</i> spp.	0/0	100.0% (16/16)	0/0	100.0% (16/16)	N/A	N/A	0/0	93.8% (15/16)
		80.6% - 100.0%		80.6% - 100.0%				71.7% - 98.9%
<i>Serratia</i> spp.	0.0% (0/1)	100.0% (9/9)	N/A	N/A	0.0% (0/1)	100.0% (9/9)	0.0% (0/1)	88.9% (8/9)
	0.0% - 79.3%	70.1% - 100.0%			0.0% - 79.3%	70.1% - 100.0%	0.0% - 79.3%	56.5% - 98.0%

Table 40: 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)	0/0	N/A	N/A	N/A	N/A	80.0% (8/10)	0/0
	49.0% - 94.3%						49.0% - 94.3%	
<i>Klebsiella</i> spp.	100.0% (9/9)	0/0	100.0% (10/10)	0/0	100.0% (10/10)	0/0	100.0% (29/29)	0/0
	70.1% - 100.0%		72.2% - 100.0%		72.2% - 100.0%		88.3% - 100.0%	
<i>Pseudomonas aeruginosa</i>	100.0% (20/20)	0/0	100.0% (38/38)	0/0	100.0% (20/20)	0/0	100.0% (78/78)	0/0
	83.9% - 100.0%		90.8% - 100.0%		83.9% - 100.0%		95.3% - 100.0%	
Ceftriaxone susceptibility testing								
<i>Escherichia coli</i>	80.0% (8/10)	0/0	N/A	N/A	N/A	N/A	80.0% (8/10)	0/0
	49.0% - 94.3%						49.0% - 94.3%	
<i>Klebsiella</i> spp.	100.0% (9/9)	0/0	100.0% (10/10)	0/0	100.0% (10/10)	0/0	100.0% (29/29)	0/0
	70.1% - 100.0%		72.2% - 100.0%		72.2% - 100.0%		88.3% - 100.0%	

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 **Tables 41-43**. The combined results for clinical specimens and contrived samples are provided in **Table 41** while the breakdown is shown in **Table 42** for clinical specimens and **Table 43** and for contrived specimens.

Table 41: 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
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									(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)	100.0% (5/5)	0.0% (0/3)	100.0% (5/5)	0.0% (0/3)	80.0% (4/5)	0.0% (0/3)	100.0% (5/5)	0.0% (0/3)	80.0% (4/5)
	0.0% - 56.1%	56.6% - 100.0%	0.0% - 56.1%	56.6% - 100.0%	0.0% - 56.1%	37.6% - 96.4%	0.0% - 56.1%	56.6% - 100.0%	0.0% - 56.1%	37.6% - 96.4%
<i>Escherichia coli</i>	0.0% (0/9)	100.0% (53/53)	0.0% (0/9)	98.1% (52/53)	88.9% (8/9)	98.1% (52/53)	0.0% (0/9)	100.0% (53/53)	94.7% (18/19)	96.2% (51/53)
	0.0% - 29.9%	93.2% - 100.0%	0.0% - 29.9%	90.1% - 99.7%	56.5% - 98.0%	90.1% - 99.7%	0.0% - 29.9%	93.2% - 100.0%	75.4% - 99.1%	87.2% - 99.0%
<i>Klebsiella</i> spp.	76.9% (10/13)	100.0% (36/36)	0.0% (0/3)	100.0% (36/36)	100.0% (3/3)	97.2% (35/36)	0.0% (0/3)	100.0% (36/36)	100.0% (13/13)	97.2% (35/36)
	49.7% - 91.8%	90.4% - 100.0%	0.0% - 56.1%	90.4% - 100.0%	43.9% - 100.0%	85.8% - 99.5%	0.0% - 56.1%	90.4% - 100.0%	77.2% - 100.0%	85.8% - 99.5%
<i>Proteus</i> spp.	0/0	100.0% (12/12)	0/0	91.7% (11/12)	0/0	100.0% (12/12)	0/0	100.0% (12/12)	0/0	91.7% (11/12)
		75.8% - 100.0%		64.6% - 98.5%		75.8% - 100.0%		75.8% - 100.0%		64.6% - 98.5%
<i>Pseudomonas aeruginosa</i>	88.4% (38/43)	100.0% (12/12)	0.0% (0/5)	91.7% (11/12)	0.0% (0/5)	100.0% (12/12)	0.0% (0/5)	100.0% (12/12)	90.6% (48/53)	91.7% (11/12)
	75.5% - 94.9%	75.8% - 100.0%	0.0% - 43.4%	64.6% - 98.5%	0.0% - 43.4%	75.8% - 100.0%	0.0% - 43.4%	75.8% - 100.0%	79.7% - 95.9%	64.6% - 98.5%
<i>Serratia</i> spp.	N/A	N/A	0/0	100.0% (6/6)	0/0	100.0% (6/6)	0/0	100.0% (6/6)	0/0	23.1% (6/26)
				61.0% - 100.0%		61.0% - 100.0%		61.0% - 100.0%		11.0% - 42.1%

Table 42: 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)	100.0% (5/5)	0.0% (0/3)	100.0% (5/5)	0.0% (0/3)	80.0% (4/5)	0.0% (0/3)	100.0% (5/5)	0.0% (0/3)	80.0% (4/5)
	0.0% - 56.1%	56.6% - 100.0%	0.0% - 56.1%	56.6% - 100.0%	0.0% - 56.1%	37.6% - 96.4%	0.0% - 56.1%	56.6% - 100.0%	0.0% - 56.1%	37.6% - 96.4%
<i>Escherichia coli</i>	0.0% (0/9)	100.0% (53/53)	0.0% (0/9)	98.1% (52/53)	88.9% (8/9)	98.1% (52/53)	0.0% (0/9)	100.0% (53/53)	94.7% (18/19)	96.2% (51/53)
	0.0% - 29.9%	93.2% - 100.0%	0.0% - 29.9%	90.1% - 99.7%	56.5% - 98.0%	90.1% - 99.7%	0.0% - 29.9%	93.2% - 100.0%	75.4% - 99.1%	87.2% - 99.0%

<i>Klebsiella</i> spp.	0.0% (0/3)	100.0% (36/36)	0.0% (0/3)	100.0% (36/36)	100.0% (3/3)	97.2% (35/36)	0.0% (0/3)	100.0% (36/36)	100.0% (3/3)	97.2% (35/36)
	0.0% - 56.1%	90.4% - 100.0%	0.0% - 56.1%	90.4% - 100.0%	43.9% - 100.0%	85.8% - 99.5%	0.0% - 56.1%	90.4% - 100.0%	43.9% - 100.0%	85.8% - 99.5%
<i>Proteus</i> spp.	0/0	100.0% (12/12)	0/0	91.7% (11/12)	0/0	100.0% (12/12)	0/0	100.0% (12/12)	0/0	91.7% (11/12)
		75.8% - 100.0%		64.6% - 98.5%		75.8% - 100.0%		75.8% - 100.0%		64.6% - 98.5%
<i>Pseudomonas aeruginosa</i>	0.0% (0/5)	100.0% (12/12)	0.0% (0/5)	91.7% (11/12)	0.0% (0/5)	100.0% (12/12)	0.0% (0/5)	100.0% (12/12)	0.0% (0/5)	91.7% (11/12)
	0.0% - 43.4%	75.8% - 100.0%	0.0% - 43.4%	64.6% - 98.5%	0.0% - 43.4%	75.8% - 100.0%	0.0% - 43.4%	75.8% - 100.0%	0.0% - 43.4%	64.6% - 98.5%
<i>Serratia</i> spp.	N/A	N/A	0/0	100.0% (6/6)	0/0	100.0% (6/6)	0/0	100.0% (6/6)	0/0	100.0% (6/6)
				61.0% - 100.0%		61.0% - 100.0%		61.0% - 100.0%		61.0% - 100.0%

Table 43: 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)	0/0
	72.2% - 100.0%	
<i>Pseudomonas aeruginosa</i>	100.0% (38/38)	0/0
	90.8% - 100.0%	
<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 44a, 44b, 45a, 45b, 46a, and 46b**. The combined results for clinical specimens and contrived samples are provided in **Table 44a** and **Table 44b** while the breakdown is shown in **Table 45a** and **Table 45b** for clinical specimens and **Table 46a** and **Table 46b** for contrived specimens.

Table 44a: Performance of KPC, NDM, IMP, SPM, and GES Compared to Phenotypic AST Results for Carbapenem in Clinical Specimens and Contrived Samples Combined

Pathogen	KPC	NDM	IMP	SPM	GES	Combined
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											(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
Ertapenem susceptibility testing												
Enterobacter spp.	71.4% (10/14)	100.0% (13/13)	0.0% (0/4)	100.0% (13/13)	0.0% (0/4)	100.0% (13/13)	N/A	N/A	0.0% (0/4)	100.0% (13/13)	71.4% (10/14)	100.0% (13/13)
	45.4% - 88.3%	77.2% - 100.0%	0.0% - 49.0%	77.2% - 100.0%	0.0% - 49.0%	77.2% - 100.0%			0.0% - 49.0%	77.2% - 100.0%	45.4% - 88.3%	77.2% - 100.0%
Escherichia coli	0.0% (0/6)	100.0% (106/106)	16.7% (1/6)	100.0% (106/106)	0.0% (0/6)	100.0% (105/105)	N/A	N/A	0.0% (0/6)	100.0% (106/106)	33.3% (2/6)	91.4% (106/116)
	0.0% - 39.0%	96.5% - 100.0%	3.0% - 56.4%	96.5% - 100.0%	0.0% - 39.0%	96.5% - 100.0%			0.0% - 39.0%	96.5% - 100.0%	9.7% - 70.0%	84.9% - 95.3%
Klebsiella spp.	90.9% (10/11)	100.0% (64/64)	100.0% (1/1)	100.0% (64/64)	0.0% (0/1)	100.0% (64/64)	N/A	N/A	0.0% (0/1)	100.0% (64/64)	100.0% (31/31)	100.0% (64/64)
	62.3% - 98.4%	94.3% - 100.0%	20.7% - 100.0%	94.3% - 100.0%	0.0% - 79.3%	94.3% - 100.0%			0.0% - 79.3%	94.3% - 100.0%	89.0% - 100.0%	94.3% - 100.0%
Proteus spp.	0.0% (0/1)	100.0% (18/18)	100.0% (1/1)	100.0% (18/18)	0.0% (0/1)	100.0% (18/18)	N/A	N/A	N/A	N/A	100.0% (1/1)	100.0% (18/18)
	0.0% - 79.3%	82.4% - 100.0%	20.7% - 100.0%	82.4% - 100.0%	0.0% - 79.3%	82.4% - 100.0%					20.7% - 100.0%	82.4% - 100.0%
Salmonella spp.	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	N/A	N/A	N/A	N/A	0/0	100.0% (1/1)
		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%						
Serratia spp.	0/0	100.0% (7/7)	0/0	100.0% (7/7)	0/0	100.0% (7/7)	N/A	N/A	0/0	100.0% (7/7)	100.0% (10/10)	41.2% (7/17)
		64.6% - 100.0%		64.6% - 100.0%		64.6% - 100.0%				72.2% - 100.0%	21.6% - 64.0%	
Imipenem susceptibility testing												
A. calcoaceticus-baumannii complex	0/0	100.0% (1/1)	100.0% (10/10)	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	100.0% (130/130)	100.0% (1/1)
		20.7% - 100.0%	72.2% - 100.0%	20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%		97.1% - 100.0%	20.7% - 100.0%	
Enterobacter spp.	100.0% (10/10)	100.0% (12/12)	0/0	100.0% (12/12)	0/0	100.0% (12/12)	N/A	N/A	0/0	100.0% (12/12)	100.0% (10/10)	100.0% (12/12)
	72.2% - 100.0%	75.8% - 100.0%		75.8% - 100.0%		75.8% - 100.0%				72.2% - 100.0%	75.8% - 100.0%	
Escherichia coli	90.9% (10/11)	100.0% (53/53)	72.7% (8/11)	100.0% (53/53)	0.0% (0/1)	100.0% (52/52)	N/A	N/A	0.0% (0/1)	100.0% (53/53)	93.5% (29/31)	100.0% (53/53)
	62.3% - 98.4%	93.2% - 100.0%	43.4% - 90.3%	93.2% - 100.0%	0.0% - 79.3%	93.1% - 100.0%			0.0% - 79.3%	93.2% - 100.0%	79.3% - 98.2%	93.2% - 100.0%
Klebsiella spp.	100.0% (20/20)	100.0% (28/28)	100.0% (10/10)	100.0% (28/28)	0/0	100.0% (28/28)	N/A	N/A	100.0% (10/10)	100.0% (28/28)	100.0% (50/50)	100.0% (28/28)
	83.9% - 100.0%	87.9% - 100.0%	72.2% - 100.0%	87.9% - 100.0%		87.9% - 100.0%			72.2% - 100.0%	87.9% - 100.0%	92.9% - 100.0%	87.9% - 100.0%
Proteus spp.	0.0% (0/7)	0/0	14.3% (1/7)	0/0	0.0% (0/7)	0/0	N/A	N/A	N/A	N/A	14.3% (1/7)	0/0
	0.0% - 35.4%		2.6% - 51.3%		0.0% - 35.4%						2.6% - 51.3%	
Pseudomonas aeruginosa	0/0	100.0% (5/5)	100.0% (44/44)	100.0% (5/5)	100.0% (11/11)	100.0% (5/5)	80.0% (16/20)	100.0% (5/5)	0/0	20.0% (5/25)	93.8% (60/64)	20.0% (5/25)
		56.6% - 100.0%	92.0% - 100.0%	56.6% - 100.0%	74.1% - 100.0%	56.6% - 100.0%	58.4% - 91.9%	56.6% - 100.0%		8.9% - 39.1%	85.0% - 97.5%	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%
<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
Meropenem susceptibility testing												
<i>A. calcoaceticus-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%	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%	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%	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%	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	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%	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%	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%
<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%

Table 44b: Performance of 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	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
Ertapenem susceptibility testing												
<i>Enterobacter</i> spp.	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%

Escherichia coli	16.7% (1/6)	91.4% (106/116)	N/A	N/A	0.0% (0/6)	100.0% (106/106)	N/A	N/A	0.0% (0/6)	100.0% (106/106)	33.3% (2/6)	91.4% (106/116)
	3.0% - 56.4%	84.9% - 95.3%			0.0% - 39.0%	96.5% - 100.0%			0.0% - 39.0%	96.5% - 100.0%	9.7% - 70.0%	84.9% - 95.3%
Klebsiella spp.	0.0% (0/1)	100.0% (64/64)	0.0% (0/1)	100.0% (64/64)	95.2% (20/21)	100.0% (64/64)	0.0% (0/1)	100.0% (64/64)	0.0% (0/1)	100.0% (64/64)	100.0% (31/31)	100.0% (64/64)
	0.0% - 79.3%	94.3% - 100.0%	0.0% - 79.3%	94.3% - 100.0%	77.3% - 99.2%	94.3% - 100.0%	0.0% - 79.3%	94.3% - 100.0%	0.0% - 79.3%	94.3% - 100.0%	89.0% - 100.0%	94.3% - 100.0%
Proteus spp.	0.0% (0/1)	100.0% (18/18)	0.0% (0/1)	100.0% (18/18)	0.0% (0/1)	100.0% (18/18)	0.0% (0/1)	100.0% (18/18)	0.0% (0/1)	100.0% (18/18)	100.0% (1/1)	100.0% (18/18)
	0.0% - 79.3%	82.4% - 100.0%	0.0% - 79.3%	82.4% - 100.0%	0.0% - 79.3%	82.4% - 100.0%	0.0% - 79.3%	82.4% - 100.0%	0.0% - 79.3%	82.4% - 100.0%	20.7% - 100.0%	82.4% - 100.0%
Salmonella spp.	0/0	100.0% (1/1)	N/A	N/A	0/0	100.0% (1/1)	N/A	N/A	N/A	N/A	0/0	100.0% (1/1)
		20.7% - 100.0%				20.7% - 100.0%						20.7% - 100.0%
Serratia spp.	100.0% (10/10)	41.2% (7/17)	N/A	N/A	0/0	100.0% (7/7)	N/A	N/A	N/A	N/A	100.0% (10/10)	41.2% (7/17)
	72.2% - 100.0%	21.6% - 64.0%				64.6% - 100.0%					72.2% - 100.0%	21.6% - 64.0%
Imipenem susceptibility testing												
A. calcoaceticus-baumannii complex	0/0	100.0% (1/1)	100.0% (60/60)	100.0% (1/1)	N/A	N/A	100.0% (40/40)	100.0% (1/1)	100.0% (50/50)	100.0% (1/1)	100.0% (130/130)	100.0% (1/1)
		20.7% - 100.0%	94.0% - 100.0%	20.7% - 100.0%			91.2% - 100.0%	20.7% - 100.0%	92.9% - 100.0%	20.7% - 100.0%	97.1% - 100.0%	20.7% - 100.0%
Enterobacter spp.	0/0	100.0% (12/12)	N/A	N/A	0/0	100.0% (12/12)	N/A	N/A	0/0	100.0% (12/12)	100.0% (10/10)	100.0% (12/12)
		75.8% - 100.0%				75.8% - 100.0%				75.8% - 100.0%	72.2% - 100.0%	75.8% - 100.0%
Escherichia coli	100.0% (11/11)	100.0% (53/53)	N/A	N/A	0.0% (0/1)	100.0% (53/53)	N/A	N/A	0.0% (0/1)	100.0% (53/53)	93.5% (29/31)	100.0% (53/53)
	74.1% - 100.0%	93.2% - 100.0%			0.0% - 79.3%	93.2% - 100.0%			0.0% - 79.3%	93.2% - 100.0%	79.3% - 98.2%	93.2% - 100.0%
Klebsiella spp.	0/0	100.0% (28/28)	0/0	100.0% (28/28)	100.0% (20/20)	100.0% (28/28)	0/0	100.0% (28/28)	0/0	100.0% (28/28)	100.0% (50/50)	100.0% (28/28)
		87.9% - 100.0%		87.9% - 100.0%	83.9% - 100.0%	87.9% - 100.0%		87.9% - 100.0%		92.9% - 100.0%	87.9% - 100.0%	
Proteus spp.	0.0% (0/7)	0/0	0.0% (0/7)	0/0	0.0% (0/7)	0/0	0.0% (0/7)	0/0	0.0% (0/7)	0/0	14.3% (1/7)	0/0
	0.0% - 35.4%		0.0% - 35.4%		0.0% - 35.4%		0.0% - 35.4%		0.0% - 35.4%		2.6% - 51.3%	
Pseudomonas aeruginosa	0/0	33.3% (5/15)	0/0	100.0% (5/5)	0/0	100.0% (5/5)	0/0	100.0% (5/5)	0/0	100.0% (5/5)	93.8% (60/64)	20.0% (5/25)
		15.2% - 58.3%		56.6% - 100.0%		56.6% - 100.0%		56.6% - 100.0%		56.6% - 100.0%	85.0% - 97.5%	8.9% - 39.1%
Salmonella spp.	0/0	100.0% (1/1)	N/A	N/A	0/0	100.0% (1/1)	N/A	N/A	N/A	N/A	0/0	100.0% (1/1)
		20.7% - 100.0%				20.7% - 100.0%						
Serratia spp.	100.0% (20/20)	0/0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100.0% (20/20)	0/0
	83.9% - 100.0%										83.9% - 100.0%	
Meropenem susceptibility testing												
A. calcoaceticus-baumannii complex	0.0% (0/1)	100.0% (11/11)	100.0% (61/61)	100.0% (11/11)	N/A	N/A	97.6% (40/41)	100.0% (11/11)	98.0% (50/51)	100.0% (11/11)	100.0% (131/131)	100.0% (11/11)
	0.0% - 79.3%	74.1% - 100.0%	94.1% - 100.0%	74.1% - 100.0%			87.4% - 99.6%	74.1% - 100.0%	89.7% - 99.7%	74.1% - 100.0%	97.2% - 100.0%	74.1% - 100.0%
Enterobacter spp.	0.0% (0/1)	100.0% (31/31)	N/A	N/A	0.0% (0/1)	100.0% (31/31)	N/A	N/A	0.0% (0/1)	100.0% (31/31)	90.9% (10/11)	100.0% (31/31)

	0.0% - 79.3%	89.0% - 100.0%			0.0% - 79.3%	89.0% - 100.0%			0.0% - 79.3%	89.0% - 100.0%	62.3% - 98.4%	89.0% - 100.0%
<i>Escherichia coli</i>	64.7% (11/17)	100.0% (233/233)	N/A	N/A	0.0% (0/7)	99.6% (232/233)	N/A	N/A	0.0% (0/7)	100.0% (233/233)	81.1% (30/37)	99.6% (232/233)
	41.3% - 82.7%	98.4% - 100.0%			0.0% - 35.4%	97.6% - 99.9%			0.0% - 35.4%	98.4% - 100.0%	65.8% - 90.5%	97.6% - 99.9%
<i>Klebsiella</i> spp.	0.0% (0/1)	100.0% (103/103)	0.0% (0/1)	100.0% (103/103)	95.2% (20/21)	100.0% (103/103)	0.0% (0/1)	100.0% (103/103)	0.0% (0/1)	100.0% (103/103)	100.0% (51/51)	100.0% (103/103)
	0.0% - 79.3%	96.4% - 100.0%	0.0% - 79.3%	96.4% - 100.0%	77.3% - 99.2%	96.4% - 100.0%	0.0% - 79.3%	96.4% - 100.0%	0.0% - 79.3%	96.4% - 100.0%	93.0% - 100.0%	96.4% - 100.0%
<i>Proteus</i> spp.	0.0% (0/1)	100.0% (33/33)	0.0% (0/1)	100.0% (33/33)	0.0% (0/1)	100.0% (33/33)	0.0% (0/1)	100.0% (33/33)	0.0% (0/1)	100.0% (33/33)	100.0% (1/1)	100.0% (33/33)
	0.0% - 79.3%	89.6% - 100.0%	0.0% - 79.3%	89.6% - 100.0%	0.0% - 79.3%	89.6% - 100.0%	0.0% - 79.3%	89.6% - 100.0%	0.0% - 79.3%	89.6% - 100.0%	20.7% - 100.0%	89.6% - 100.0%
<i>Pseudomonas aeruginosa</i>	88.9% (24/27)	100.0% (31/31)	0.0% (0/3)	100.0% (31/31)	0.0% (0/3)	100.0% (31/31)	0.0% (0/3)	100.0% (31/31)	0.0% (0/3)	100.0% (31/31)	92.3% (84/91)	75.6% (31/41)
	71.9% - 96.1%	89.0% - 100.0%	0.0% - 56.1%	89.0% - 100.0%	0.0% - 56.1%	89.0% - 100.0%	0.0% - 56.1%	89.0% - 100.0%	0.0% - 56.1%	89.0% - 100.0%	85.0% - 96.2%	60.7% - 86.2%
<i>Salmonella</i> spp.	0.0% (0/2)	100.0% (20/20)	N/A	N/A	0.0% (0/2)	100.0% (20/20)	N/A	N/A	N/A	N/A	0.0% (0/2)	100.0% (20/20)
	0.0% - 65.8%	83.9% - 100.0%			0.0% - 65.8%	83.9% - 100.0%					0.0% - 65.8%	83.9% - 100.0%
<i>Serratia</i> spp.	100.0% (20/20)	100.0% (22/22)	N/A	N/A	0/0	100.0% (22/22)	N/A	N/A	N/A	N/A	100.0% (20/20)	100.0% (22/22)
	83.9% - 100.0%	85.1% - 100.0%				85.1% - 100.0%					83.9% - 100.0%	85.1% - 100.0%

Table 45a: Performance of KPC, NDM, IMP, SPM, and GES Compared to Phenotypic AST Results for Carbapenem in Clinical Specimens

Pathogen	KPC		NDM		IMP		SPM		GES		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
Ertapenem susceptibility testing												
<i>Enterobacter</i> spp.	0.0% (0/4)	100.0% (13/13)	0.0% (0/4)	100.0% (13/13)	0.0% (0/4)	100.0% (13/13)	N/A	N/A	0.0% (0/4)	100.0% (13/13)	0.0% (0/4)	100.0% (13/13)
	0.0% - 49.0%	77.2% - 100.0%	0.0% - 49.0%	77.2% - 100.0%	0.0% - 49.0%	77.2% - 100.0%			0.0% - 49.0%	77.2% - 100.0%	0.0% - 49.0%	77.2% - 100.0%
<i>Escherichia coli</i>	0.0% (0/6)	100.0% (106/106)	16.7% (1/6)	100.0% (106/106)	0.0% (0/6)	100.0% (105/105)	N/A	N/A	0.0% (0/6)	100.0% (106/106)	33.3% (2/6)	100.0% (106/106)
	0.0% - 39.0%	96.5% - 100.0%	3.0% - 56.4%	96.5% - 100.0%	0.0% - 39.0%	96.5% - 100.0%			0.0% - 39.0%	96.5% - 100.0%	9.7% - 70.0%	96.5% - 100.0%
<i>Klebsiella</i> spp.	0.0% (0/1)	100.0% (64/64)	100.0% (1/1)	100.0% (64/64)	0.0% (0/1)	100.0% (64/64)	N/A	N/A	0.0% (0/1)	100.0% (64/64)	100.0% (1/1)	100.0% (64/64)
	0.0% - 79.3%	94.3% - 100.0%	20.7% - 100.0%	94.3% - 100.0%	0.0% - 79.3%	94.3% - 100.0%			0.0% - 79.3%	94.3% - 100.0%	20.7% - 100.0%	94.3% - 100.0%
<i>Proteus</i> spp.	0.0% (0/1)	100.0% (18/18)	100.0% (1/1)	100.0% (18/18)	0.0% (0/1)	100.0% (18/18)	N/A	N/A	N/A	N/A	100.0% (1/1)	100.0% (18/18)
	0.0% - 79.3%	82.4% - 100.0%	20.7% - 100.0%	82.4% - 100.0%	0.0% - 79.3%	82.4% - 100.0%					20.7% - 100.0%	82.4% - 100.0%
<i>Salmonella</i> spp.	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	N/A	N/A	N/A	N/A	0/0	100.0% (1/1)
		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%						20.7% - 100.0%
<i>Serratia</i> spp.	0/0	100.0% (7/7)	0/0	100.0% (7/7)	0/0	100.0% (7/7)	N/A	N/A	0/0	100.0% (7/7)	0/0	100.0% (7/7)
		64.6% - 100.0%		64.6% - 100.0%		64.6% - 100.0%						64.6% - 100.0%

Imipenem susceptibility testing												
<i>A. calcoaceticus-baumannii</i> complex	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)
		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%				
<i>Enterobacter</i> spp.	0/0	100.0% (12/12)	0/0	100.0% (12/12)	0/0	100.0% (12/12)	N/A	N/A	0/0	100.0% (12/12)	0/0	100.0% (12/12)
		75.8% - 100.0%		75.8% - 100.0%		75.8% - 100.0%						
<i>Escherichia coli</i>	0.0% (0/1)	100.0% (53/53)	0.0% (0/1)	100.0% (53/53)	0.0% (0/1)	100.0% (52/52)	N/A	N/A	0.0% (0/1)	100.0% (53/53)	100.0% (1/1)	100.0% (53/53)
	0.0% - 79.3%	93.2% - 100.0%	0.0% - 79.3%	93.2% - 100.0%	0.0% - 79.3%	93.1% - 100.0%			0.0% - 79.3%	93.2% - 100.0%	20.7% - 100.0%	93.2% - 100.0%
<i>Klebsiella</i> spp.	0/0	100.0% (28/28)	0/0	100.0% (28/28)	0/0	100.0% (28/28)	N/A	N/A	0/0	100.0% (28/28)	0/0	100.0% (28/28)
		87.9% - 100.0%		87.9% - 100.0%		87.9% - 100.0%						
<i>Proteus</i> spp.	0.0% (0/7)	0/0	14.3% (1/7)	0/0	0.0% (0/7)	0/0	N/A	N/A	N/A	N/A	14.3% (1/7)	0/0
	0.0% - 35.4%		2.6% - 51.3%		0.0% - 35.4%						2.6% - 51.3%	
<i>Pseudomonas aeruginosa</i>	0/0	100.0% (5/5)	0/0	100.0% (5/5)	0/0	100.0% (5/5)	0/0	100.0% (5/5)	0/0	100.0% (5/5)	0/0	100.0% (5/5)
		56.6% - 100.0%		56.6% - 100.0%		56.6% - 100.0%		56.6% - 100.0%				
<i>Salmonella</i> spp.	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)	N/A	N/A	N/A	N/A	0/0	100.0% (1/1)
		20.7% - 100.0%		20.7% - 100.0%		20.7% - 100.0%						
Meropenem susceptibility testing												
<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/1)	100.0% (11/11)	0.0% (0/1)	100.0% (11/11)	0.0% (0/1)	100.0% (11/11)	0.0% (0/1)	100.0% (11/11)	0.0% (0/1)	100.0% (11/11)	100.0% (1/1)	100.0% (11/11)
	0.0% - 79.3%	74.1% - 100.0%	0.0% - 79.3%	74.1% - 100.0%	0.0% - 79.3%	74.1% - 100.0%	0.0% - 79.3%	74.1% - 100.0%	0.0% - 79.3%	74.1% - 100.0%	20.7% - 100.0%	74.1% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/1)	100.0% (31/31)	0.0% (0/1)	100.0% (31/31)	0.0% (0/1)	100.0% (29/29)	N/A	N/A	0.0% (0/1)	100.0% (31/31)	0.0% (0/1)	100.0% (31/31)
	0.0% - 79.3%	89.0% - 100.0%	0.0% - 79.3%	89.0% - 100.0%	0.0% - 79.3%	88.3% - 100.0%			0.0% - 79.3%	89.0% - 100.0%	0.0% - 79.3%	89.0% - 100.0%
<i>Escherichia coli</i>	0.0% (0/7)	100.0% (233/233)	14.3% (1/7)	100.0% (233/233)	0.0% (0/7)	100.0% (217/217)	N/A	N/A	0.0% (0/7)	100.0% (233/233)	28.6% (2/7)	99.6% (232/233)
	0.0% - 35.4%	98.4% - 100.0%	2.6% - 51.3%	98.4% - 100.0%	0.0% - 35.4%	98.3% - 100.0%			0.0% - 35.4%	98.4% - 100.0%	8.2% - 64.1%	97.6% - 99.9%
<i>Klebsiella</i> spp.	0.0% (0/1)	100.0% (103/103)	100.0% (1/1)	100.0% (103/103)	0.0% (0/1)	100.0% (98/98)	N/A	N/A	0.0% (0/1)	100.0% (103/103)	100.0% (1/1)	100.0% (103/103)
	0.0% - 79.3%	96.4% - 100.0%	20.7% - 100.0%	96.4% - 100.0%	0.0% - 79.3%	96.2% - 100.0%			0.0% - 79.3%	96.4% - 100.0%	20.7% - 100.0%	96.4% - 100.0%
<i>Proteus</i> spp.	0.0% (0/1)	100.0% (33/33)	100.0% (1/1)	100.0% (33/33)	0.0% (0/1)	100.0% (33/33)	N/A	N/A	N/A	N/A	100.0% (1/1)	100.0% (33/33)
	0.0% - 79.3%	89.6% - 100.0%	20.7% - 100.0%	89.6% - 100.0%	0.0% - 79.3%	89.6% - 100.0%					20.7% - 100.0%	89.6% - 100.0%
<i>Pseudomonas aeruginosa</i>	0.0% (0/3)	100.0% (31/31)	0.0% (0/3)	100.0% (31/31)	0.0% (0/3)	100.0% (31/31)	0.0% (0/3)	100.0% (30/30)	0.0% (0/3)	100.0% (31/31)	0.0% (0/3)	100.0% (31/31)
	0.0% - 56.1%	89.0% - 100.0%	0.0% - 56.1%	89.0% - 100.0%	0.0% - 56.1%	89.0% - 100.0%	0.0% - 56.1%	88.6% - 100.0%	0.0% - 56.1%	89.0% - 100.0%	0.0% - 56.1%	89.0% - 100.0%
<i>Salmonella</i> spp.	0.0% (0/2)	100.0% (20/20)	0.0% (0/2)	100.0% (20/20)	0.0% (0/2)	100.0% (15/15)	N/A	N/A	N/A	N/A	0.0% (0/2)	100.0% (20/20)
	0.0% - 65.8%	83.9% - 100.0%	0.0% - 65.8%	83.9% - 100.0%	0.0% - 65.8%	79.6% - 100.0%					0.0% - 65.8%	83.9% - 100.0%
<i>Serratia</i> spp.	0/0	100.0% (22/22)	0/0	100.0% (22/22)	0/0	100.0% (22/22)	N/A	N/A	0/0	100.0% (22/22)	0/0	100.0% (22/22)
		85.1% - 100.0%		85.1% - 100.0%		85.1% - 100.0%						

Table 45b: Performance of VIM, OXA-23, OXA-48-like, OXA-24/40 and OXA-58 Compared to Phenotypic AST Results for Carbapenem in Clinical Specimens

Pathogen	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
Ertapenem susceptibility testing												
Enterobacter spp.	0.0% (0/4)	100.0% (13/13)	N/A	N/A	0.0% (0/4)	100.0% (13/13)	N/A	N/A	0.0% (0/4)	100.0% (13/13)	0.0% (0/4)	100.0% (13/13)
	0.0% - 49.0%	77.2% - 100.0%			0.0% - 49.0%	77.2% - 100.0%			0.0% - 49.0%	77.2% - 100.0%		
Escherichia coli	16.7% (1/6)	100.0% (106/106)	N/A	N/A	0.0% (0/6)	100.0% (106/106)	N/A	N/A	0.0% (0/6)	100.0% (106/106)	33.3% (2/6)	100.0% (106/106)
	3.0% - 56.4%	96.5% - 100.0%			0.0% - 39.0%	96.5% - 100.0%			0.0% - 39.0%	96.5% - 100.0%	9.7% - 70.0%	96.5% - 100.0%
Klebsiella spp.	0.0% (0/1)	100.0% (64/64)	0.0% (0/1)	100.0% (64/64)	0.0% (0/1)	100.0% (64/64)	0.0% (0/1)	100.0% (64/64)	0.0% (0/1)	100.0% (64/64)	100.0% (1/1)	100.0% (64/64)
	0.0% - 79.3%	94.3% - 100.0%	0.0% - 79.3%	94.3% - 100.0%	0.0% - 79.3%	94.3% - 100.0%	0.0% - 79.3%	94.3% - 100.0%	0.0% - 79.3%	94.3% - 100.0%	20.7% - 100.0%	94.3% - 100.0%
Proteus spp.	0.0% (0/1)	100.0% (18/18)	0.0% (0/1)	100.0% (18/18)	0.0% (0/1)	100.0% (18/18)	0.0% (0/1)	100.0% (18/18)	0.0% (0/1)	100.0% (18/18)	100.0% (1/1)	100.0% (18/18)
	0.0% - 79.3%	82.4% - 100.0%	0.0% - 79.3%	82.4% - 100.0%	0.0% - 79.3%	82.4% - 100.0%	0.0% - 79.3%	82.4% - 100.0%	0.0% - 79.3%	82.4% - 100.0%	20.7% - 100.0%	82.4% - 100.0%
Salmonella spp.	0/0	100.0% (1/1)	N/A	N/A	0/0	100.0% (1/1)	N/A	N/A	N/A	N/A	0/0	100.0% (1/1)
		20.7% - 100.0%				20.7% - 100.0%						20.7% - 100.0%
Serratia spp.	0/0	100.0% (7/7)	N/A	N/A	0/0	100.0% (7/7)	N/A	N/A	N/A	N/A	0/0	100.0% (7/7)
		64.6% - 100.0%				64.6% - 100.0%						64.6% - 100.0%
Imipenem susceptibility testing												
A. calcoaceticus-baumannii complex	0/0	100.0% (1/1)	0/0	100.0% (1/1)	N/A	N/A	0/0	100.0% (1/1)	0/0	100.0% (1/1)	0/0	100.0% (1/1)
		20.7% - 100.0%		20.7% - 100.0%				20.7% - 100.0%				
Enterobacter spp.	0/0	100.0% (12/12)	N/A	N/A	0/0	100.0% (12/12)	N/A	N/A	0/0	100.0% (12/12)	0/0	100.0% (12/12)
		75.8% - 100.0%				75.8% - 100.0%				75.8% - 100.0%		
Escherichia coli	100.0% (1/1)	100.0% (53/53)	N/A	N/A	0.0% (0/1)	100.0% (53/53)	N/A	N/A	0.0% (0/1)	100.0% (53/53)	100.0% (1/1)	100.0% (53/53)
	20.7% - 100.0%	93.2% - 100.0%			0.0% - 79.3%	93.2% - 100.0%			0.0% - 79.3%	93.2% - 100.0%	20.7% - 100.0%	93.2% - 100.0%
Klebsiella spp.	0/0	100.0% (28/28)	0/0	100.0% (28/28)	0/0	100.0% (28/28)	0/0	100.0% (28/28)	0/0	100.0% (28/28)	0/0	100.0% (28/28)
		87.9% - 100.0%		87.9% - 100.0%		87.9% - 100.0%						
Proteus spp.	0.0% (0/7)	0/0	0.0% (0/7)	0/0	0.0% (0/7)	0/0	0.0% (0/7)	0/0	0.0% (0/7)	0/0	14.3% (1/7)	0/0
	0.0% - 35.4%		0.0% - 35.4%		0.0% - 35.4%		0.0% - 35.4%		0.0% - 35.4%		2.6% - 51.3%	
Pseudomonas aeruginosa	0/0	100.0% (5/5)	0/0	100.0% (5/5)	0/0	100.0% (5/5)	0/0	100.0% (5/5)	0/0	100.0% (5/5)	0/0	100.0% (5/5)
		56.6% - 100.0%		56.6% - 100.0%		56.6% - 100.0%		56.6% - 100.0%				
Salmonella spp.	0/0	100.0% (1/1)	N/A	N/A	0/0	100.0% (1/1)	N/A	N/A	N/A	N/A	0/0	100.0% (1/1)
		20.7% - 100.0%				20.7% - 100.0%						
Meropenem susceptibility testing												

<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/1)	100.0% (11/11)	100.0% (1/1)	100.0% (11/11)	N/A	N/A	0.0% (0/1)	100.0% (11/11)	0.0% (0/1)	100.0% (11/11)	100.0% (1/1)	100.0% (11/11)
	0.0% - 79.3%	74.1% - 100.0%	20.7% - 100.0%	74.1% - 100.0%			0.0% - 79.3%	74.1% - 100.0%	0.0% - 79.3%	74.1% - 100.0%	20.7% - 100.0%	74.1% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/1)	100.0% (31/31)	N/A	N/A	0.0% (0/1)	100.0% (31/31)	N/A	N/A	0.0% (0/1)	100.0% (31/31)	0.0% (0/1)	100.0% (31/31)
	0.0% - 79.3%	89.0% - 100.0%			0.0% - 79.3%	89.0% - 100.0%			0.0% - 79.3%	89.0% - 100.0%	0.0% - 79.3%	89.0% - 100.0%
<i>Escherichia coli</i>	14.3% (1/7)	100.0% (233/233)	N/A	N/A	0.0% (0/7)	99.6% (232/233)	N/A	N/A	0.0% (0/7)	100.0% (233/233)	28.6% (2/7)	99.6% (232/233)
	2.6% - 51.3%	98.4% - 100.0%			0.0% - 35.4%	97.6% - 99.9%			0.0% - 35.4%	98.4% - 100.0%	8.2% - 64.1%	97.6% - 99.9%
<i>Klebsiella</i> spp.	0.0% (0/1)	100.0% (103/103)	0.0% (0/1)	100.0% (103/103)	0.0% (0/1)	100.0% (103/103)	0.0% (0/1)	100.0% (103/103)	0.0% (0/1)	100.0% (103/103)	100.0% (1/1)	100.0% (103/103)
	0.0% - 79.3%	96.4% - 100.0%	0.0% - 79.3%	96.4% - 100.0%	0.0% - 79.3%	96.4% - 100.0%	0.0% - 79.3%	96.4% - 100.0%	0.0% - 79.3%	96.4% - 100.0%	20.7% - 100.0%	96.4% - 100.0%
<i>Proteus</i> spp.	0.0% (0/1)	100.0% (33/33)	0.0% (0/1)	100.0% (33/33)	0.0% (0/1)	100.0% (33/33)	0.0% (0/1)	100.0% (33/33)	0.0% (0/1)	100.0% (33/33)	100.0% (1/1)	100.0% (33/33)
	0.0% - 79.3%	89.6% - 100.0%	0.0% - 79.3%	89.6% - 100.0%	0.0% - 79.3%	89.6% - 100.0%	0.0% - 79.3%	89.6% - 100.0%	0.0% - 79.3%	89.6% - 100.0%	20.7% - 100.0%	89.6% - 100.0%
<i>Pseudomonas aeruginosa</i>	0.0% (0/3)	100.0% (31/31)	0.0% (0/3)	100.0% (31/31)	0.0% (0/3)	100.0% (31/31)	0.0% (0/3)	100.0% (31/31)	0.0% (0/3)	100.0% (31/31)	0.0% (0/3)	100.0% (31/31)
	0.0% - 56.1%	89.0% - 100.0%	0.0% - 56.1%	89.0% - 100.0%	0.0% - 56.1%	89.0% - 100.0%	0.0% - 56.1%	89.0% - 100.0%	0.0% - 56.1%	89.0% - 100.0%	0.0% - 56.1%	89.0% - 100.0%
<i>Salmonella</i> spp.	0.0% (0/2)	100.0% (20/20)	N/A	N/A	0.0% (0/2)	100.0% (20/20)	N/A	N/A	N/A	N/A	0.0% (0/2)	100.0% (20/20)
	0.0% - 65.8%	83.9% - 100.0%			0.0% - 65.8%	83.9% - 100.0%					0.0% - 65.8%	83.9% - 100.0%
<i>Serratia</i> spp.	0/0	100.0% (22/22)	N/A	N/A	0/0	100.0% (22/22)	N/A	N/A	N/A	N/A	0/0	100.0% (22/22)
		85.1% - 100.0%				85.1% - 100.0%						85.1% - 100.0%

Table 46a: Performance of KPC, NDM, IMP, GES, and VIM Compared to Phenotypic AST Results for Carbapenem in Contrived Samples

Pathogen	KPC		NDM		IMP		GES		VIM		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	
Ertapenem susceptibility testing													
Enterobacter spp.	100.0% (10/10)	0/0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100.0% (10/10)	0/0	
	72.2% - 100.0%										72.2% - 100.0%		
Escherichia coli	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0/0	0.0% (0/10)	0/0	0.0% (0/10)	
										0.0% - 27.8%		0.0% - 27.8%	
Klebsiella spp.	100.0% (10/10)	0/0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100.0% (30/30)	0/0	
	72.2% - 100.0%										88.6% - 100.0%		
Serratia spp.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100.0% (10/10)	0.0% (0/10)	100.0% (10/10)	0.0% (0/10)	
									72.2% - 100.0%	0.0% - 27.8%	72.2% - 100.0%	0.0% - 27.8%	
Imipenem 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	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	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	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	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%	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	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	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	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	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	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	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	95.5% (84/88) 88.9% - 98.2%	0.0% (0/10) 0.0% - 27.8%
<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	100.0% (20/20) 83.9% - 100.0%	0/0

Table 46b: Performance of SPM, OXA-23, OXA-48-like, OXA-24/40 and OXA-58 , Compared to Phenotypic AST Results for Carbapenem in Contrived Samples

Pathogen	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	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
Ertapenem susceptibility testing												
<i>Enterobacter</i> spp.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100.0% (10/10)	0/0
											72.2% - 100.0%	
<i>Escherichia coli</i>	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</i> spp.	N/A	N/A	N/A	N/A	100.0% (20/20)	0/0	N/A	N/A	N/A	N/A	100.0% (30/30)	0/0
					83.9% - 100.0%						88.6% - 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% (10/10)	0.0% (0/10)
											72.2% - 100.0%	0.0% - 27.8%
Imipenem susceptibility testing												
<i>A. calcoaceticus-baumannii</i> complex	N/A	N/A	100.0% (60/60)	0/0	N/A	N/A	100.0% (40/40)	0/0	100.0% (50/50)	0/0	100.0% (130/130)	0/0
			94.0% - 100.0%				91.2% - 100.0%		92.9% - 100.0%		97.1% - 100.0%	
<i>Enterobacter</i> spp.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100.0% (10/10)	0/0
											72.2% - 100.0%	
<i>Escherichia coli</i>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	93.3% (28/30)	0/0
											78.7% - 98.2%	
<i>Klebsiella</i> spp.	N/A	N/A	N/A	N/A	100.0% (20/20)	0/0	N/A	N/A	N/A	N/A	100.0% (50/50)	0/0
					83.9% - 100.0%						92.9% - 100.0%	
<i>Pseudomonas aeruginosa</i>	80.0% (16/20)	0/0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	93.8% (60/64)	0.0% (0/20)
	58.4% - 91.9%										85.0% - 97.5%	0.0% - 16.1%
<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)	0/0
											83.9% - 100.0%	
Meropenem susceptibility testing												
<i>A. calcoaceticus-baumannii</i> complex	N/A	N/A	100.0% (60/60)	0/0	N/A	N/A	100.0% (40/40)	0/0	100.0% (50/50)	0/0	100.0% (130/130)	0/0
			94.0% - 100.0%				91.2% - 100.0%		92.9% - 100.0%		97.1% - 100.0%	
<i>Enterobacter</i> spp.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100.0% (10/10)	0/0
											72.2% - 100.0%	
<i>Escherichia coli</i>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	93.3% (28/30)	0/0
											78.7% - 98.2%	

<i>Klebsiella</i> spp.	N/A	N/A	N/A	N/A	100.0% (20/20)	0/0	N/A	N/A	N/A	N/A	100.0% (50/50)	0/0
					83.9% - 100.0%						92.9% - 100.0%	
<i>Pseudomonas aeruginosa</i>	80.0% (16/20)	0/0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	95.5% (84/88)	0.0% (0/10)
	58.4% - 91.9%										88.9% - 98.2%	0.0% - 27.8%
<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)	0/0
											83.9% - 100.0%	

The performance of plasmid *ampC* resistance markers compared to phenotypic AST results for beta-lactam-class antibiotics by relevant organisms is presented from **Table 47-55**. The combined results for clinical specimens and contrived samples are provided in **Table 47, 50, and 53** while the breakdown is shown in **Table 48, 51, and 54** for clinical specimens and **Table 49, 52, and 55** for contrived specimens.

Table 47: 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)	0/0
	22.4% - 57.5%	
<i>Escherichia coli</i>	4.2% (7/168)	100.0% (96/96)
	2.0% - 8.3%	96.2% - 100.0%
<i>Klebsiella</i> spp.	1.3% (1/75)	100.0% (3/3)
	0.2% - 7.2%	43.9% - 100.0%
<i>Proteus</i> spp.	10.0% (1/10)	93.8% (30/32)
	1.8% - 40.4%	79.9% - 98.3%
<i>Serratia</i> spp.	58.8% (10/17)	100.0% (1/1)
	36.0% - 78.4%	20.7% - 100.0%

Table 48: 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
	0.0% - 19.4%	
<i>Escherichia coli</i>	4.2% (7/168)	100.0% (96/96)
	2.0% - 8.3%	96.2% - 100.0%
<i>Klebsiella</i> spp.	1.3% (1/75)	100.0% (3/3)
	0.2% - 7.2%	43.9% - 100.0%
<i>Proteus</i> spp.	10.0% (1/10)	93.8% (30/32)
	1.8% - 40.4%	79.9% - 98.3%

<i>Serratia</i> spp.	0.0% (0/7)	100.0% (1/1)
	0.0% - 35.4%	20.7% - 100.0%

Table 49: Performance of plasmid *ampC* Compared to Phenotypic AST Results for Ampicillin in Contrived Samples

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

Table 50: 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)	0/0
	25.6% - 63.2%	
<i>Escherichia coli</i>	6.2% (5/81)	100.0% (95/95)
	2.7% - 13.6%	96.1% - 100.0%
<i>Klebsiella</i> spp.	0.0% (0/34)	98.3% (58/59)
	0.0% - 10.2%	91.0% - 99.7%
<i>Proteus</i> spp.	11.8% (2/17)	100.0% (7/7)
	3.3% - 34.3%	64.6% - 100.0%
<i>Serratia</i> spp.	38.5% (10/26)	0/0
	22.4% - 57.5%	

Table 51: 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
	0.0% - 22.8%	
<i>Escherichia coli</i>	6.2% (5/81)	100.0% (95/95)
	2.7% - 13.6%	96.1% - 100.0%
<i>Klebsiella</i> spp.	0.0% (0/34)	98.3% (58/59)
	0.0% - 10.2%	91.0% - 99.7%
<i>Proteus</i> spp.	11.8% (2/17)	100.0% (7/7)
	3.3% - 34.3%	64.6% - 100.0%
<i>Serratia</i> spp.	0.0% (0/16)	0/0
	0.0% - 19.4%	

Table 52: 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)	0/0
	72.2% - 100.0%	
<i>Serratia</i> spp.	100.0% (10/10)	0/0
	72.2% - 100.0%	

Table 53: 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	ampC	
	PPA	NPA
Cefotaxime susceptibility testing		
A. calcoaceticus-baumannii complex	0/0	100.0% (1/1)
		20.7% - 100.0%
Enterobacter spp.	66.7% (10/15)	100.0% (4/4)
	41.7% - 84.8%	51.0% - 100.0%
Escherichia coli	0.0% (0/7)	95.8% (23/24)
	0.0% - 35.4%	79.8% - 99.3%
Klebsiella spp.	0.0% (0/3)	100.0% (10/10)
	0.0% - 56.1%	72.2% - 100.0%
Proteus spp.	0.0% (0/1)	100.0% (6/6)
	0.0% - 79.3%	61.0% - 100.0%
Serratia spp.	100.0% (10/10)	0/0
	72.2% - 100.0%	
Ceftazidime susceptibility testing		
A. calcoaceticus-baumannii complex	0.0% (0/3)	100.0% (7/7)
	0.0% - 56.1%	64.6% - 100.0%
Enterobacter spp.	0.0% (0/9)	100.0% (13/13)
	0.0% - 29.9%	77.2% - 100.0%
Escherichia coli	13.0% (3/23)	100.0% (104/104)
	4.5% - 32.1%	96.4% - 100.0%
Klebsiella spp.	0.0% (0/7)	100.0% (58/58)
	0.0% - 35.4%	93.8% - 100.0%
Proteus spp.	50.0% (1/2)	96.8% (30/31)
	9.5% - 90.5%	83.8% - 99.4%
Pseudomonas aeruginosa	0.0% (0/4)	95.5% (21/22)
	0.0% - 49.0%	78.2% - 99.2%
Serratia spp.	0.0% (0/1)	100.0% (11/11)
	0.0% - 79.3%	74.1% - 100.0%
Ceftriaxone susceptibility testing		
A. calcoaceticus-baumannii complex	0/0	100.0% (1/1)

		20.7% - 100.0%
<i>Enterobacter</i> spp.	76.9% (10/13)	100.0% (2/2)
	49.7% - 91.8%	34.2% - 100.0%
<i>Escherichia coli</i>	6.7% (2/30)	98.2% (162/165)
	1.8% - 21.3%	94.8% - 99.4%
<i>Klebsiella</i> spp.	43.5% (10/23)	98.8% (82/83)
	25.6% - 63.2%	93.5% - 99.8%
<i>Proteus</i> spp.	0/0	95.7% (22/23)
		79.0% - 99.2%
<i>Serratia</i> spp.	90.9% (10/11)	100.0% (9/9)
	62.3% - 98.4%	70.1% - 100.0%
Cefoxitin susceptibility testing		
<i>Enterobacter</i> spp.	41.7% (10/24)	0/0
	24.5% - 61.2%	
<i>Escherichia coli</i>	16.7% (2/12)	99.1% (109/110)
	4.7% - 44.8%	95.0% - 99.8%
<i>Klebsiella</i> spp.	0.0% (0/12)	100.0% (49/49)
	0.0% - 24.2%	92.7% - 100.0%
<i>Proteus</i> spp.	0.0% (0/1)	92.9% (13/14)
	0.0% - 79.3%	68.5% - 98.7%
<i>Serratia</i> spp.	37.0% (10/27)	0/0
	21.5% - 55.8%	

Table 54: 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)	100.0% (4/4)
	0.0% - 43.4%	51.0% - 100.0%
<i>Escherichia coli</i>	0.0% (0/7)	95.8% (23/24)
	0.0% - 35.4%	79.8% - 99.3%
<i>Klebsiella</i> spp.	0.0% (0/3)	100.0% (10/10)
	0.0% - 56.1%	72.2% - 100.0%
<i>Proteus</i> spp.	0.0% (0/1)	100.0% (6/6)
	0.0% - 79.3%	61.0% - 100.0%
Ceftazidime susceptibility testing		
<i>A. calcoaceticus-baumannii</i> complex	0.0% (0/3)	100.0% (7/7)
	0.0% - 56.1%	64.6% - 100.0%
<i>Enterobacter</i> spp.	0.0% (0/9)	100.0% (13/13)
	0.0% - 29.9%	77.2% - 100.0%
<i>Escherichia coli</i>	13.0% (3/23)	100.0% (104/104)

	4.5% - 32.1%	96.4% - 100.0%
<i>Klebsiella</i> spp.	0.0% (0/7)	100.0% (58/58)
	0.0% - 35.4%	93.8% - 100.0%
<i>Proteus</i> spp.	50.0% (1/2)	96.8% (30/31)
	9.5% - 90.5%	83.8% - 99.4%
<i>Pseudomonas aeruginosa</i>	0.0% (0/4)	95.5% (21/22)
	0.0% - 49.0%	78.2% - 99.2%
<i>Serratia</i> spp.	0.0% (0/1)	100.0% (11/11)
	0.0% - 79.3%	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)	100.0% (2/2)
	0.0% - 56.1%	34.2% - 100.0%
<i>Escherichia coli</i>	6.7% (2/30)	98.2% (162/165)
	1.8% - 21.3%	94.8% - 99.4%
<i>Klebsiella</i> spp.	0.0% (0/13)	98.8% (82/83)
	0.0% - 22.8%	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)	100.0% (9/9)
	0.0% - 79.3%	70.1% - 100.0%
Cefoxitin susceptibility testing		
<i>Enterobacter</i> spp.	0.0% (0/14)	0/0
	0.0% - 21.5%	
<i>Escherichia coli</i>	16.7% (2/12)	99.1% (109/110)
	4.7% - 44.8%	95.0% - 99.8%
<i>Klebsiella</i> spp.	0.0% (0/12)	100.0% (49/49)
	0.0% - 24.2%	92.7% - 100.0%
<i>Proteus</i> spp.	0.0% (0/1)	92.9% (13/14)
	0.0% - 79.3%	68.5% - 98.7%
<i>Serratia</i> spp.	0.0% (0/17)	0/0
	0.0% - 18.4%	

Table 55: 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)	0/0
	72.2% - 100.0%	
<i>Serratia</i> spp.	100.0% (10/10)	0/0
	72.2% - 100.0%	
Ceftriaxone susceptibility testing		

<i>Enterobacter</i> spp.	100.0% (10/10)	0/0
	72.2% - 100.0%	
<i>Klebsiella</i> spp.	100.0% (10/10)	0/0
	72.2% - 100.0%	
<i>Serratia</i> spp.	100.0% (10/10)	0/0
	72.2% - 100.0%	
Cefoxitin susceptibility testing		
<i>Enterobacter</i> spp.	100.0% (10/10)	0/0
	72.2% - 100.0%	
<i>Serratia</i> spp.	100.0% (10/10)	0/0
	72.2% - 100.0%	

D Clinical Cut-Off:

Not Applicable

E Expected Values/Reference Range:

The number and percentage of positive results as determined by the QIAstat-Dx BCID GN Plus AMR Panel on the prospective samples, stratified by age group are presented in **Table 56**.

Table 56: Summary of prevalence of target pathogens, as identified by QIAstat-Dx BCID GN Plus AMR Panel, stratified by age

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</i> spp.	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</i> spp.	145 (21.9%)	0 (0.0%)	1 (5.6%)	18 (22.8%)	43 (25.0%)	79 (21.9%)	4 (16.0%)
<i>Proteus</i> spp.	39 (5.9%)	0 (0.0%)	0 (0.0%)	1 (1.3%)	10 (5.8%)	25 (6.9%)	3 (12.0%)
<i>Salmonella</i> spp.	12 (1.8%)	0 (0.0%)	6 (33.3%)	4 (5.1%)	2 (1.2%)	0 (0.0%)	0 (0.0%)
<i>Serratia</i> spp.	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%)
<i>ampC</i> (CMY/LAT/DHA/FOX)	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%)
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%)

F Other Supportive Instrument Performance Characteristics Data:

Not Applicable

VIII Proposed Labeling:

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

IX Conclusion:

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