



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

I Background Information:

A 510(k) Number

K254194

B Applicant

QIAGEN GmbH

C Proprietary and Established Names

QIAstat-Dx BCID GPF Plus AMR Panel

D Regulatory Information

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

B Measurand:

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

- *Bacillus cereus* group
- *Corynebacterium*
- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Listeria monocytogenes*
- *Micrococcus* spp.
- *Staphylococcus aureus*
- *Staphylococcus epidermidis*
- *Staphylococcus lugdunensis*
- *S. capitis/S. hominis*
- *Streptococcus agalactiae*
- *Streptococcus anginosus* group
- *Streptococcus pneumoniae*
- *Streptococcus pyogenes*
- *Cryptococcus neoformans/gattii*
- *Fusarium*
- *Candida auris*
- Pan Gram-Negative
- Pan Candida Group 1
- Pan Candida Group 2
- *aac(6')* *aph(2')*
- *cfr*
- *erm(A)*
- *erm(C)*
- *mecA*
- *mecC*
- *tet(K)*
- *tet(M)*
- *vanA*
- *vanB*

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-positive 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 GPF Plus AMR Panel is a qualitative multiplexed nucleic acid real-time PCR-based *in vitro* diagnostic test intended for use with the QIAstat-Dx Analyzer 2.0. The

QIAstat-Dx BCID GPF Plus AMR Panel is capable of simultaneous detection and identification of multiple gram-positive bacterial and fungal pathogens and selected genetic determinants associated with antimicrobial resistance. Additionally, the QIAstat-Dx BCID GPF Plus AMR Panel is capable of detecting a wide variety of gram-negative bacteria (Pan Gram Negative assay). The QIAstat-Dx BCID GPF Plus AMR Panel is intended for use in positive blood culture samples from patients with blood stream infections identified via Gram stain to contain gram-positive bacteria or fungi.

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

- *Bacillus cereus* group
- *Corynebacterium*
- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Listeria monocytogenes*
- *Micrococcus* spp.
- *Staphylococcus aureus*
- *Staphylococcus epidermidis*
- *Staphylococcus lugdunensis*
- *S. capitis/S. hominis*
- *Streptococcus agalactiae*
- *Streptococcus anginosus* group
- *Streptococcus pneumoniae*
- *Streptococcus pyogenes*

The following fungi are identified and differentiated using the QIAstat-Dx BCID GPF Plus AMR Panel:

- *Cryptococcus neoformans/gattii*
- *Fusarium*
- *Candida auris*

The QIAstat-Dx BCID GPF Plus AMR 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-Negative assay
- Candida Group 1: (detects but does not differentiate 6 species)
 - *Candida albicans*
 - *Candida tropicalis*
 - *Candida dubliniensis*
 - *Candida famata*
 - *Candida guilliermondii*
 - *Candida kefyr*
- Candida Group 2: (detects but does not differentiate 4 species)
 - *Candida glabrata*

- *Candida krusei*
- *Candida parapsilosis*
- *Candida lusitaniae*

The QIAstat-Dx BCID GPF Plus AMR Panel contains assays for the detection of the following genetic determinants associated with resistance to antimicrobial agents:

- *aac(6')* *aph(2')*
- *cfr*
- *erm(A)*
- *erm(C)*
- *mecA*
- *mecC*
- *tet(K)*
- *tet(M)*
- *vanA*
- *vanB*

The QIAstat-Dx BCID GPF Plus AMR Panel contains assays for the detection of genetic determinants associated with resistance to gentamicin/tobramycin/kanamycin (*aac(6')*-*aph(2')*), PhLOPSA multi-class resistance phenotype (*cfr*), erythromycin (*ermA* and *ermC*), methicillin (*mecA* and *mecC*), tetracycline (*tetK* and *tetM*) and vancomycin (*vanA* and *vanB*). 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 test is performed on blood culture samples identified as positive by a continuous monitoring blood culture system and gram-positive bacteria or fungi as determined by Gram stain. The QIAstat-Dx BCID GPF Plus AMR Panel is intended as an aid in diagnosis of bloodstream infections identifying specific pathogens and genetic determinants associated with resistance. Results should be used in conjunction with other clinical or laboratory information, *e.g.*, Gram stain results. Sub-culturing of positive blood cultures is necessary for identification of organisms not detected by QIAstat-Dx BCID GPF Plus AMR Panel and susceptibility testing. Results should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

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

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 GPF Plus AMR Panel is an automated test for the detection and identification of nucleic acids from gram-positive bacteria, fungi, and resistance markers in a positive blood culture sample. The test is performed directly on blood culture media using blood culture bottles identified as positive by a continuous monitoring blood culture system, and which contain gram-positive bacteria or fungi, as determined by Gram stain.

The QIAstat-Dx BCID GPF Plus AMR Panel test system consists of:

- The QIAstat-Dx BCID GPF Plus AMR Panel cartridge kit containing six (6) individually packed, single use cartridges, which are pre-packaged with wet and dry chemistry reagents necessary to perform sample preparation, nucleic acid amplification, and assay-specific PCR detection, and six (6) individually packed, single use transfer pipettes.
- The QIAstat-Dx Analyzer 2.0 consisting of one (1) Operational Module PRO and up to four (4) Analytical Modules with software version 1.6 or higher. The QIAstat-Dx Application Software is embedded in the QIAstat-Dx Analyzer 2.0. The Assay Definition File (ADF) is panel-specific software installed on the Operational Module PRO.

Calibrators and Controls: Negative and positive external controls are recommended but not provided with the QIAstat-Dx BCID GPF 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 located 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 GPF Plus AMR Panel is for use with the QIAstat-Dx Analyzer 2.0. Samples grown in BACT/ALERT and BACTEC bottles are diluted in saline prior to loading the cartridge into the instrument, while VersaTrek bottles do not require dilution. Following pre-dilution, the sample is loaded into the Lysis Chamber of the cartridge with a transfer pipette, and the cartridge is inserted into the Analytical Module of the analyzer. All reagents are pre-loaded and self-contained in the cartridge. The QIAstat-Dx Analyzer 2.0 runs the predefined assay protocols, and multiple steps are automatically performed by the analyzer.

Resuspension of Internal Control (IC) and Proteinase K: 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.

Cell Lysis: Lysis of the sample and IC occurs by a combination of chemical and mechanical processes using a rotor inside the lysis chamber in the presence of silica beads and a buffer that acts as a chemical agent in aiding the mechanical process. The fast movement of the rotor in the presence of the silica beads results in sample agitation, which creates turbulence and shear forces that lyses the cell wall. Following mechanical lysis, the primary lysate is transferred to the purification chamber through a frit of 80 µm pore size. The second lysis buffer (from Reservoir 2) is added to the primary lysate to complete chemical lysis.

Nucleic Acid Purification: Buffer containing a high chaotropic salt concentration (from Reservoir 4) is added to the lysate in the purification chamber and allowed to bind to the membrane, and the remaining unwanted cellular components of the lysate are washed away with washing buffer from Reservoirs 5 and 6. Once completed, the nucleic acids are released from the membrane using an elution buffer from Reservoir 8.

Rehydration of Master Mix: The eluate is delivered to the reservoir of the Dry Chemistry Container (DCC) to rehydrate the Master Mix and is mixed.

Aliquoting and PCR: Aliquots (15 µL) of mixed eluate/Master Mix are transferred to each of eight (8) Reaction Chambers containing the target-specific primers and probes. Within each Reaction Chamber, multiplex, real-time PCR is performed. Increase in fluorescence (indicative of detection of each target analyte) is detected directly within each Reaction Chamber.

Reporting of Results: Test results are generated in approximately 75 minutes. Detected targets are reported as “Positive/Detected”. Targets that are not detected are reported as “Negative/Not Detected”. 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 Positive (BCID-GP) Panel, ePlex Blood Culture Identification Fungal Pathogen (BCID-FP) Panel

B Predicate 510(k) Number(s):

K181663, K182690

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K251440</u>	<u>K181663</u>	<u>K182690</u>
Device Trade Name	QIAstat-Dx BCID GPF Plus AMR Panel	ePlex BCID-GP Panel	ePlex BCID-FP Panel
General Device Characteristic Similarities			

Intended Use/Indications For Use	The QIAstat-Dx BCID GPF Plus AMR Panel is a qualitative multiplexed nucleic acid real-time PCR-based <i>in vitro</i> diagnostic test intended for use with the QIAstat-Dx Analyzer 2.0. The QIAstat-Dx BCID GPF Plus AMR Panel is capable of simultaneous detection and identification of multiple gram-positive bacterial and fungal pathogens and selected genetic determinants associated with antimicrobial resistance. Additionally, the QIAstat-Dx BCID GPF Plus AMR Panel is capable of detecting a wide variety of gram-negative bacteria (Pan Gram Negative assay). The QIAstat-Dx BCID GPF Plus AMR Panel is intended for use in positive blood culture samples from patients with blood infections identified via Gram stain to contain gram-positive bacteria or fungi. The following gram-positive bacteria are identified and differentiated using the QIAstat-Dx BCID GPF Plus AMR Panel: [See list of organism targets below] The following fungi are identified and differentiated using the QIAstat-Dx BCID GPF Plus AMR Panel: [See list of organism targets below] The QIAstat-Dx BCID GPF Plus AMR 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-Negative assay • <i>Candida</i> Group 1 [See list of group targets below]	The GenMark ePlex Blood Culture Identification Gram-Positive (BCID-GP) 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-positive bacterial organisms and select determinants associated with antimicrobial resistance in positive blood culture. In addition, the ePlex BCID-GP Panel is capable of detecting a wide variety of gram-negative bacteria (Pan Gram-Negative assay) and several <i>Candida</i> species (Pan <i>Candida</i> assay). The ePlex BCID-GP Panel is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system and which contain gram-positive organism. The following bacterial organisms and genes associated with antibiotic resistance are identified using the ePlex BCID-GP Panel: [See list of organism targets below] The ePlex BCID-GP Panel contains assays for the detection of genetic determinants associated with resistance to methicillin (<i>mecA</i> and <i>mecC</i>) and vancomycin (<i>vanA</i> and <i>vanB</i>) to aid in the identification of potentially antimicrobial resistant organisms in positive blood culture samples. The antimicrobial resistance gene detected may or may not be associated with the agent responsible for disease. The ePlex BCID-GP Panel also contains targets designed to detect a broad range of organisms with a potentially misleading Gram stain result or	The GenMark ePlex Blood Culture Identification Fungal Pathogen (BCID-FP) Panel is a qualitative nucleic acid multiplex <i>in vitro</i> diagnostic test intended for use on GenMark's ePlex Instrument for simultaneous detection and identification of multiple potentially pathogenic fungal organisms in positive blood culture. The ePlex BCID-FP Panel is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system and which contain fungal organism. The following fungal organisms are identified using the ePlex BCID-FP Panel: [See list of organism targets below] The detection and identification of specific 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-FP Panel are intended to be interpreted in conjunction with Gram stain results and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Negative results in the setting of a suspected bloodstream infection may be due to infection with pathogens that are not detected by this test. Positive results do not rule out co-infection with other organisms; the organism(s) detected by the ePlex BCID-FP 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-FP Panel, susceptibility testing and
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	• <i>Candida</i> Group 2 [See list of group targets below] The QIAstat-Dx BCID GPF Plus AMR Panel contains assays for the detection of the following genetic determinants associated with resistance to antimicrobial agents: [See list of gene targets below] The QIAstat-Dx BCID GPF Plus AMR Panel contains assays for the detection of genetic determinants associated with resistance to gentamicin/tobramycin/kanamycin (<i>aac(6')</i>-<i>aph(2')</i>), PhLOPSA multi-class resistance phenotype (<i>cfr</i>), erythromycin (<i>ermA</i> and <i>ermC</i>), methicillin (<i>mecA</i> and <i>mecC</i>), tetracycline (<i>tetK</i> and <i>tetM</i>) and vancomycin (<i>vanA</i> and <i>vanB</i>). 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 test is performed on blood culture samples identified as positive by a continuous monitoring blood culture system and as gram-positive bacteria or fungi as determined by Gram stain. The QIAstat-Dx BCID GPF Plus AMR Panel is intended as an aid in diagnosis of bloodstream infections identifying specific pathogens and genetic determinants associated with resistance. Results should be used in conjunction with other clinical and laboratory information, e.g., Gram stain results. Sub-culturing of positive blood cultures is necessary for identification of organisms not detected by QIAstat-Dx BCID GPF Plus AMR Panel and susceptibility testing. Results	organisms that may be missed by Gram staining altogether, for example in the case of co-infections. These include a broad Pan Gram-Negative assay as well as a Pan <i>Candida</i> assay, which is designed to detect four of the most prevalent <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-GP Panel are intended to be interpreted in conjunction with Gram stain results and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Negative results in the setting of a suspected bloodstream infection may be due to infection with pathogens that are not detected by this test. Positive results do not rule out co-infection with other organisms; the organism(s) detected by the ePlex BCID-GP 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-GP 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 blood stream infection.	differentiation of mixed growth) and clinical presentation must be taken into consideration in the final diagnosis of bloodstream infection.
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	should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Negative results do not preclude the presence of pathogens that are not detected by this test. Positive QIAstat-Dx BCID GPF Plus AMR results do not rule out infection or co-infection with organisms not included in the QIAstat-Dx BCID GPF Plus AMR Panel.		
Measurand	Target DNA of gram-positive bacteria, fungi, and resistance markers	Target DNA of gram-positive bacteria and resistance markers	Target DNA of fungi
Specimen Type	Positive blood culture (PBC) bottles	Same	Same
Media Types	• 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	Same	Same plus: • BACTEC Myco • BACT/ALERT MP Mycobacteria
Test Design	Test cartridge	Same	Same
Test Technology	Multiplex, nucleic acid amplification test (NAAT)	Same	Same
Sample Processing and Extraction	Automated in instrument	Same	Same
Quality Controls	Internal processing control. External controls are recommended.	Internal control	Internal control
Results Output	Positive/Detected Negative/Not Detected	Same	Same
General Device Characteristic Differences			
Organisms Detected	Gram-positive: • <i>Bacillus cereus</i> group • <i>Corynebacterium</i>	• <i>Bacillus cereus</i> group • <i>Bacillus subtilis</i> group • <i>Corynebacterium</i>	• <i>Candida albicans</i> • <i>Candida auris</i>

	• <i>Enterococcus faecalis</i> • <i>Enterococcus faecium</i> • <i>Listeria monocytogenes</i> • <i>Micrococcus</i> spp. • <i>Staphylococcus aureus</i> • <i>Staphylococcus epidermidis</i> • <i>Staphylococcus lugdunensis</i> • <i>S. capitis/S. hominis</i> • <i>Streptococcus agalactiae</i> • <i>Streptococcus anginosus</i> group • <i>Streptococcus pneumoniae</i> • <i>Streptococcus pyogenes</i> Fungi: • <i>Cryptococcus neoformans/gattii</i> • <i>Fusarium</i> • <i>Candida auris</i> Pan Gram-negative Candida Group 1: • <i>Candida albicans</i> • <i>Candida tropicalis</i> • <i>Candida dubliniensis</i> • <i>Candida famata</i> • <i>Candida guilliermondii</i> • <i>Candida kefyr</i> Candida Group 2: • <i>Candida glabrata</i> • <i>Candida krusei</i> • <i>Candida parapsilosis</i> • <i>Candida.lusitaniae</i>	• <i>Cutibacterium acnes</i> (<i>Propionibacterium acnes</i>) • <i>Enterococcus</i> • <i>Enterococcus faecalis</i> • <i>Enterococcus faecium</i> • <i>Lactobacillus</i> • <i>Listeria</i> • <i>Listeria monocytogenes</i> • <i>Micrococcus</i> • <i>Staphylococcus</i> • <i>Staphylococcus aureus</i> • <i>Staphylococcus epidermidis</i> • <i>Staphylococcus lugdunensis</i> • <i>Streptococcus</i> • <i>Streptococcus agalactiae</i> (GBS) • <i>Streptococcus anginosus</i> group • <i>Streptococcus pneumoniae</i> • <i>Streptococcus pyogenes</i> (GAS) • Pan Gram-negative • Pan Candida	• <i>Candida dubliniensis</i> • <i>Candida famata</i> • <i>Candida glabrata</i> • <i>Candida guilliermondii</i> • <i>Candida kefyr</i> • <i>Candida krusei</i> • <i>Candida lusitaniae</i> • <i>Candida parapsilosis</i> • <i>Candida tropicalis</i> • <i>Cryptococcus gattii</i> • <i>Cryptococcus neoformans</i> • <i>Fusarium</i> • <i>Rhodotorula</i>.
Resistance Markers Detected	• <i>aac(6')</i> <i>aph(2')</i> • <i>cfr</i> • <i>erm(A)</i> • <i>erm(C)</i> • <i>mecA</i> • <i>mecC</i> • <i>tet(K)</i> • <i>tet(M)</i> • <i>vanA</i> • <i>vanB</i>	• <i>mecA</i> • <i>mecC</i> • <i>vanA</i> • <i>vanB</i>	N/A
Equipment Required	QIAstat-Dx Analyzer 2.0 with QIAstat-Dx Application Software and QIAstat-Dx BCID GPF Plus AMR Panel Assay Definition File	GenMark ePlex instrument with GenMark ePlex System Software and GenMark ePlex BCID-GP Panel Software	GenMark ePlex instrument with GenMark ePlex System Software and GenMark ePlex BCID-FP Panel Software

VI Standards/Guidance Documents Referenced:

Document #	Title
ISO 14971 Third Edition 2019-12	Medical Devices - Application of Risk Management to Medical Devices

IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes
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
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, Including Corrigendum 1. (2017-01)
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	Medial Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests (2014-02)
IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	Medical devices - Part 1: Application of usability engineering to medical devices

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 GPF 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 a range of organisms. 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). Positive samples were then prepared by combining equal volumes of each culture, with different cartridge reaction chambers detecting different targets within each pool. The negative sample was prepared by inoculating a blood culture bottle with whole blood and an off-panel organism and incubating until “positive ring”. **Table 1** shows the sample composition and testing strategy for precision/reproducibility studies. Studies were conducted in BD BACTEC Plus Aerobic bottles.

Table 1. Sample Composition and Test Strategy for Reproducibility Studies

Sample	Target(s)	Organism	Source ID
‘Positive’ or ‘High Positive’	<i>S. aureus</i> mecC	<i>S. aureus</i>	ATCC BAA 2313
	<i>E. faecalis</i> VanB Aac(6') aph(2')	<i>E. faecalis</i>	ATCC 51299
	<i>L. monocytogenes</i>	<i>L. monocytogenes</i>	NCTC 5105
	<i>S. anginosus</i> group	<i>S. anginosus</i>	CCUG 27298
	<i>C. neoformans/gattii</i>	<i>C. gattii</i>	ATCC MYA 4071
Mix 4 (Bottle positive) or 5 (Bottle positive + 24h)	<i>Candida</i> spp. Group 2	<i>C. glabrata</i>	ATCC 15126
	<i>Corynebacterium</i>	<i>Corynebacterium striatum</i>	ATCC 43735
	<i>S. aureus</i> tetK ermC mecA	<i>S. aureus</i>	ATCC 1556
	<i>B. cereus</i> group	<i>B. cereus</i>	ATCC 21769
Mix 6 (Bottle positive) or 7	<i>Fusarium</i>	<i>Fusarium proliferatum</i>	NCPF 7484
	Pan Gram Negative	<i>Acinetobacter baumannii</i>	NCTC 13302

(Bottle positive + 24h)	<i>S. epidermidis</i> Aac(6') aph(2') cfr mecA	<i>S. epidermidis</i>	PA212221
'Negative'	N/A	<i>Streptococcus peroris</i>	CCUG 39814

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 non-consecutive days, with two operators each performing three replicates per sample each day, resulting in 36 replicates of each sample per site (3 replicates × 1 run × 2 operators × 6 days × 3 sites = 108 replicates at each concentration). A single lot of the candidate device was used for all runs in this study.

A run was considered valid if no error code was detected by the software. Valid runs can be “Positive” (any target positive with passed Internal Control or “IC”) or “Negative” (all targets negative with passed IC). Any run that caused an error code was repeated to obtain a valid result. Results where there was a failed IC and at least one positive (“Positive with warning”) were considered invalid for analytical performance studies and were repeated to obtain a valid result. Acceptance criteria are ≥ 95% agreement of positive and high positive samples and 100% agreement of negative samples with expected results. For all positive samples, tested at all three (3) test sites, 100% detection was obtained for all expected targets (108/108 detected positive hits). Results are summarized in **Table 2** below.

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>B. cereus</i> group	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive +24 Hours	100% (37/37)	100% (37/37)	100% (36/36)	100% (110/110)	96.7%	100%
<i>Candida</i> spp. Group 2	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive +24 Hours	100% (37/37)	100% (37/37)	100% (36/36)	100% (110/110)	96.7%	100%
<i>Corynebacterium</i>	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive +24 Hours	100% (37/37)	100% (37/37)	100% (36/36)	100% (110/110)	96.7%	100%
<i>C. neoformans</i> / <i>gattii</i>	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive +24 Hours	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
<i>E. faecalis</i>	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive +24 Hours	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
<i>Fusarium</i>	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive +24 Hours	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%

Organism	Target Type	Agreement with Expected Results				95% C.I.	
		Site 1	Site 2	Site 3	Overall	Lower	Upper
<i>L. monocytogenes</i>	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive +24 Hours	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
Pan Gram Negative	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive +24 Hours	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
<i>S. aureus</i>	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive +24 Hours	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive +24 Hours	100% (37/37)	100% (37/37)	100% (36/36)	100% (110/110)	96.7%	100%
<i>S. epidermidis</i>	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive +24 Hours	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
<i>S. anginosus</i> group	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive +24 Hours	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
<i>S. peroris</i>	Off-panel Negative	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
Resistance Markers							
Aac(6') aph(2') (<i>E. faecalis</i>)	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive +24 Hours	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
Aac(6') aph(2') (<i>S. epidermidis</i>)	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive +24 Hours	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
cfr	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive +24 Hours	100% (37/37)	100% (37/37)	100% (36/36)	100% (110/110)	96.7%	100%
ermC	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive +24 Hours	100% (37/37)	97.3% (36/37)	100% (36/36)	99.1% (109/110)	95.0%	100%
mecA (<i>S. aureus</i>)	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive +24 Hours	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
mecA (<i>S. epidermidis</i>)	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%

Organism	Target Type	Agreement with Expected Results				95% C.I.	
		Site 1	Site 2	Site 3	Overall	Lower	Upper
	Ring Positive +24 Hours	100% (37/37)	100% (37/37)	100% (36/36)	100% (110/110)	96.7%	100%
mecC	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive +24 Hours	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
tetK	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive +24 Hours	100% (37/37)	100% (37/37)	100% (36/36)	100% (110/110)	96.7%	100%
VanB	Ring Positive	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%
	Ring Positive +24 Hours	100% (36/36)	100% (36/36)	100% (36/36)	100% (108/108)	96.6%	100%

Lot-to-Lot Variability

A lot-to-lot study was conducted at one site using one operator on three or four 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. For all positive samples, 100% detection was obtained for all expected targets (90/90 detected positive hits), and 100% negative calls were observed for the negative samples. Results are summarized in **Table 3** below.

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

Organism	Target Type	Agreement with Expected Results				95% C.I.	
		Lot 1	Lot 2	Lot 3	Overall	Lower	Upper
<i>B. cereus</i> group	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
	Ring Positive +24 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
<i>Candida</i> spp. Group 2	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
	Ring Positive +24 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
<i>Corynebacterium</i>	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
	Ring Positive +24 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
<i>C. neoformans</i> / <i>gattii</i>	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
	Ring Positive +24 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
<i>E. faecalis</i>	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
	Ring Positive +24 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
<i>Fusarium</i>	Ring Positive	100% (30/30)	100% (30/30)	100% (31/31)	100% (91/91)	96.0%	100%

Organism	Target Type	Agreement with Expected Results				95% C.I.	
		Lot 1	Lot 2	Lot 3	Overall	Lower	Upper
	Ring Positive +24 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
<i>L. monocytogenes</i>	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
	Ring Positive +24 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
Pan Gram Negative	Ring Positive	100% (30/30)	100% (30/30)	100% (31/31)	100% (91/91)	96.0%	100%
	Ring Positive +24 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
<i>S. aureus</i>	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
	Ring Positive +24 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
	Ring Positive +24 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
<i>S. epidermidis</i>	Ring Positive	100% (30/30)	100% (30/30)	100% (31/31)	100% (91/91)	96.0%	100%
	Ring Positive +24 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
<i>S. anginosus</i> group	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
	Ring Positive +24 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
<i>S. peroris</i>	Off-panel Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
Resistance Markers							
Aac(6') aph(2') (<i>E. faecalis</i>)	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
	Ring Positive +24 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
Aac(6') aph(2') (<i>S. epidermidis</i>)	Ring Positive	100% (30/30)	100% (30/30)	100% (31/31)	100% (91/91)	96.0%	100%
	Ring Positive +24 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
cfr	Ring Positive	100% (30/30)	100% (30/30)	100% (31/31)	100% (91/91)	96.0%	100%
	Ring Positive +24 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
ermC	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
	Ring Positive +24 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
mecA	Ring Positive	100% (30/30)	100% (30/30)	100% (31/31)	100% (91/91)	96.0%	100%
	Ring Positive +24 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%

Organism	Target Type	Agreement with Expected Results				95% C.I.	
		Lot 1	Lot 2	Lot 3	Overall	Lower	Upper
mecC	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
	Ring Positive +24 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
tetK	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
	Ring Positive +24 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
VanB	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%
	Ring Positive +24 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	96.0%	100%

2. Linearity:

This study is not applicable as the test device is a qualitative assay.

3. Analytical Specificity/Interference:

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

Cross-Reactivity

A total of 140 organisms, including those phylogenetically related to the on-panel organisms and organisms likely to be present in clinical blood culture specimens, were tested to verify the absence of cross-reactivity with the candidate device. Samples were prepared by spiking organisms at high concentration into blood culture bottles at a minimum concentration of $\geq 1.50 \times 10^8$ CFU/mL for bacteria and $\geq 1.50 \times 10^6$ CFU/mL for fungi and tested in triplicate. Where cross-reactivity was observed at the initial concentration (D0) tested, samples were diluted and retested until no cross-reactivity was detected. **Table 4** lists the organisms subjected to wet testing on the candidate device. **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 junii</i>	1.5E+08	<i>Neisseria lactamica</i>	1.5E+08
<i>Actinomyces odontolyticus</i>	1.5E+08	<i>Neisseria mucosa</i>	1.5E+08
<i>Aerococcus sanguinicola</i>	1.5E+08	<i>Ochrobactrum anthropic</i>	1.5E+08
<i>Aerococcus urinae</i>	1.5E+08	<i>Pediococcus acidilactici</i>	1.5E+08
<i>Aerococcus viridans</i>	1.5E+08	<i>Pediococcus pentosaceus</i>	1.5E+08
<i>Anaerococcus prevotii</i>	1.5E+08	<i>Penicillium/Talaromyces marneffe</i> (gDNA)	2.35E+07 copies/mL
<i>Arcanobacterium haemolyticum</i>	1.5E+08	<i>Peptostreptococcus anaerobius</i>	1.5E+08
<i>Bacillus amyloliquefaciens</i>	1.5E+08	<i>Prevotella oralis</i>	1.5E+08
<i>Bacillus atrophaeus</i>	1.5E+08	<i>Propionibacterium propionicum</i>	1.5E+08

Organism	Concentration Tested (CFU/mL)	Organism	Concentration Tested (CFU/mL)
<i>Bacillus badius</i>	1.5E+08	<i>Providencia rettgeri</i>	1.5E+08
<i>Bacillus licheniformis</i>	1.5E+08	<i>Pseudomonas putida</i>	1.5E+08
<i>Bacillus pumilus</i>	1.5E+08	<i>Raoultella ornithinolytica</i>	1.5E+08
<i>Bacillus subtilis</i>	1.5E+08	<i>Rhodococcus equi</i>	1.5E+08
<i>Bacteroides distasonis (Parabacteroides)</i>	1.5E+08	<i>Rhodococcus fascians</i>	1.5E+08
<i>Bacteroides eggerthii</i>	1.5E+08	<i>Rhodotorula glutinis</i>	1.5E+08
<i>Bacteroides ovatus</i>	1.5E+08	<i>Rhodotorula minuta</i>	1.5E+08
<i>Bacteroides ureolyticus (Campylobacter ureolyticus)</i>	1.5E+08	<i>Rhodotorula mucilaginosa</i>	1.5E+08
<i>Brochothrix thermosphacta</i>	1.5E+08	<i>Rothia dentocariosa</i>	1.5E+08
<i>Burkholderia cepacian</i>	1.5E+08	<i>Rothia mucilaginosa</i>	1.5E+08
<i>Candida lambica</i>	1.5E+08	<i>Saccharomyces cerevisiae</i>	1.5E+08
<i>Candida lipolytica</i>	1.5E+08	<i>Shigella boydii</i>	1.5E+08
<i>Candida metapsilosis</i>	1.5E+08	<i>Shigella sonnei</i>	1.5E+08
<i>Candida orthopsilosis</i>	1.5E+08	<i>Staphylococcus arlettae</i>	1.5E+08
<i>Candida pelliculosa/Wickerhamomyces</i>	1.5E+08	<i>Staphylococcus auricularis</i>	1.5E+08
<i>Candida/Wickerhamiella rugosa</i>	1.5E+08	<i>Staphylococcus carnosus</i>	1.5E+08
<i>Candida sake</i>	1.5E+08	<i>Staphylococcus chromogenes</i>	1.5E+08
<i>Candida utilis</i>	1.5E+08	<i>Staphylococcus cohnii</i>	1.5E+08
<i>Carnobacterium divergens</i>	1.5E+08	<i>Staphylococcus gallinarum</i>	1.5E+08
<i>Carnobacterium maltaromaticum</i>	1.5E+08	<i>Staphylococcus haemolyticus</i>	1.5E+08
<i>Cellulosimicrobium cellulans</i>	1.5E+08	<i>Staphylococcus hyicus</i>	1.5E+08
<i>Cellulomonas turbata</i>	1.5E+08	<i>Staphylococcus intermedius</i>	1.5E+08
<i>Clostridium clostridioforme</i>	1.5E+08	<i>Staphylococcus lentus</i>	1.5E+08
<i>Clostridium perfringens</i>	1.5E+08	<i>Staphylococcus muscae</i>	1.5E+08
<i>Propionibacterium/Cutibacterium acnes</i>	2.13E+08	<i>Staphylococcus pasteurii</i>	1.5E+08
<i>Priopionibacterium/Cutibacterium granulosum</i>	1.5E+08	<i>Staphylococcus pettenkoferi</i>	1.5E+08
<i>Enterobacter cowanii</i>	1.5E+08	<i>Staphylococcus pseudintermedius</i>	1.5E+08
<i>Enterococcus avium</i>	1.5E+08	<i>Staphylococcus saccharolyticus</i>	1.5E+08
<i>Enterococcus casseliflavus</i>	1.5E+08	<i>Staphylococcus saprophyticus</i>	1.5E+08
<i>Enterococcus cecorum</i>	1.5E+08	<i>Staphylococcus schleiferi</i>	1.5E+08
<i>Enterococcus dispar</i>	1.5E+08	<i>Staphylococcus sciuri</i>	1.5E+08
<i>Enterococcus durans</i>	1.5E+08	<i>Staphylococcus simulans</i>	1.5E+08
<i>Enterococcus gallinarum</i>	1.5E+08	<i>Staphylococcus vitulinus</i>	1.5E+08
<i>Enterococcus hirae</i>	1.5E+08	<i>Staphylococcus warneri</i>	1.5E+08
<i>Enterococcus italicus</i>	1.5E+08	<i>Staphylococcus warneri</i>	1.5E+08
<i>Enterococcus lactis</i>	1.5E+08	<i>Staphylococcus xylosus</i>	1.5E+08
<i>Enterococcus malodoratus</i>	1.5E+08	<i>Streptococcus canis</i>	1.5E+08
<i>Enterococcus pseudoavium</i>	1.5E+08	<i>Streptococcus criceti</i>	1.5E+08
<i>Enterococcus raffinosus</i>	1.5E+08	<i>Streptococcus dysgalactiae</i>	1.5E+08
<i>Enterococcus saccharolyticus</i>	1.5E+08	<i>Streptococcus equi</i>	1.5E+08
<i>Erysipelothrix rhusiopathiae</i>	1.5E+08	<i>Streptococcus equinus</i>	1.5E+08
<i>Gemella haemolysans</i>	1.5E+08	<i>Streptococcus gallolyticus</i>	1.5E+08
<i>Gemella morbillorum</i>	1.5E+08	<i>Streptococcus gordonii</i>	1.5E+08
<i>Geotrichum capitatum (Blastoschizomyces capitatus)</i>	1.5E+08	<i>Streptococcus infantarius</i>	1.5E+08
<i>Granulicatella adiacens</i>	1.5E+08	<i>Streptococcus infantis</i>	1.5E+08
<i>Granulicatella elegans</i>	1.5E+08	<i>Streptococcus mitis</i>	1.5E+08
<i>Kingella kingae</i>	1.5E+08	<i>Streptococcus oralis</i>	1.5E+08
<i>Kocuria kristinae</i>	1.5E+08	<i>Streptococcus parasanguinis</i>	1.5E+08
<i>Kocuria rhizophila</i>	1.5E+08	<i>Streptococcus peroris</i>	1.5E+08
<i>Kytococcus sedentarius</i>	1.5E+08	<i>Streptococcus pseudopneumoniae</i>	1.5E+08
<i>Lactobacillus zeae</i>	1.5E+08	<i>Streptococcus salivarius</i>	1.5E+08
<i>Lactococcus garvieae</i>	1.5E+08	<i>Streptococcus sanguinis</i>	1.5E+08
<i>Lactococcus lactis subsp.</i>	1.5E+08	<i>Streptococcus thoraltensis</i>	1.5E+08
<i>Lawsonella clevelandensis</i>	1.5E+08	<i>Trichosporon asahii</i>	8.00E+06

Organism	Concentration Tested (CFU/mL)	Organism	Concentration Tested (CFU/mL)
<i>Leuconostoc carnosum</i>	1.5E+08	<i>Trueperella bernardiae</i>	1.5E+08
<i>Leuconostoc citreum</i>	1.5E+08	<i>Vagococcus fluvialis</i>	1.5E+08
<i>Leuconostoc mesenteroides</i>	1.5E+08	<i>Vibrio parahaemolyticus</i>	1.5E+08
<i>Listeria ivanovii</i>	1.5E+08	<i>Weissella paramesenteroides</i>	1.5E+08
<i>Macroccoccus caseolyticus</i> (subsp. <i>Hominis</i>)	1.5E+08	<i>Corynebacterium simulans</i>	1.5E+08
<i>Mycobacterium tuberculosis</i> (gDNA)	1.5E+08 copies/mL	<i>Staphylococcus caprae</i>	1.5E+08

Table 5. List of Microorganisms Where Cross-Reactivity Observed

Organism	Target Detected	Concentration (CFU/mL)
<i>Bacteroides ureolyticus</i> (<i>Campylobacter ureolyticus</i>)	<i>Corynebacterium</i>	1.64E+06
<i>Propionibacterium/Cutibacterium acnes</i>	<i>Corynebacterium</i>	7.28 E+05
<i>Propionibacterium/Cutibacterium granulosum</i>	<i>Corynebacterium</i>	1.50E+05
<i>Mycobacterium tuberculosis</i>	<i>Corynebacterium</i>	5.20E+06
<i>Rhodococcus equi</i>	<i>Corynebacterium</i>	4.75E+07
<i>Rhodococcus fascians</i>	<i>Corynebacterium</i>	1.50E+07
<i>Rothia dentocariosa</i>	<i>Corynebacterium</i>	5.20E+06
<i>Rothia mucilaginosa</i>	<i>Corynebacterium</i>	1.64E+07
<i>Ochrobactrum anthropic</i>	<i>Corynebacterium</i>	1.64E+07
<i>Lawsonella clevelandensis</i>	<i>Corynebacterium</i>	1.64E+06
<i>Enterococcus lactis</i>	<i>Enterococcus faecium</i>	2.10E+03
<i>Staphylococcus caprae</i>	<i>Staphylococcus capitis/hominis</i>	1.50E+06

In silico Analysis

Primers and probes included in the QIAstat-Dx BCID GPF 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	<i>In silico</i> Prediction
<i>L. monocytogenes</i>	Cross-reaction with <i>L. innocua</i>
<i>Corynebacterium</i>	Cross-reaction with <i>M. luteus</i>
<i>S. anginosus</i> group	Cross-reaction with <i>S. periodonticum</i>
<i>S. capitis</i> / <i>S. hominis</i>	Cross-reaction with <i>S. caprae</i> , <i>S. debuckii</i> and <i>S. piscifermentans</i>
Pan Gram-Negative	Additional detection of <i>N. brasiliensis</i> by <i>N. meningitidis</i> . Additional detection of <i>S. acidaminiphila</i> , <i>S. riyadhensis</i> , and <i>S. tuberculopleuritidis</i> strains by <i>S. maltophilia</i> .

Competitive Inhibition (Microbial Interference)

A competitive inhibition study was conducted to evaluate the capability of the QIAstat-Dx BCID GPF 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-five samples from commercial suppliers or clinical isolates were used to create representative combinations of on-panel and off-panel organisms that are commonly found in polymicrobial positive blood cultures. Samples were prepared by inoculating culture bottles with isolates and whole blood and incubated in a blood culture instrument until “positive ring” plus 24 hours to ensure a high positive concentration. Mixtures were prepared by spiking one organism at high concentration into Negative Blood Culture Matrix (NBCM) (bottle positivity + 24 hours of incubation), and the second organism at a lower concentration (3x LoD). Studies were conducted in triplicate in BD BACTEC Plus Aerobic bottles. **Table 7** below lists the sample mixtures and concentrations used. Mixtures 4 (Tet(M) harbored by *E. faecium*), 9 (*S. capitis*), 12 (*S. aureus*), and 18 (*A. baumannii*) were only detected when the concentration was increased to 30x-300x LoD (~10⁶ CFU/mL).

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

Mixture	High Positive		Low Positive	
	Organism	Concentration (CFU/mL)	Organism	Concentration (CFU/mL)
01	<i>Candida albicans</i> (Candida Group 1)	1.83E+07	<i>Candida glabrata</i>	6.20E+05
	<i>Candida glabrata</i> (Candida Group 2)	6.21E+07	<i>Candida albicans</i>	2.04E+06
02	<i>Candida albicans</i> (Candida Group 1)	1.83E+07	<i>Enterococcus faecalis</i>	8.25E+05
	<i>Enterococcus faecalis</i>	4.64E+08	<i>Candida albicans</i>	2.04E+06
03	<i>Candida glabrata</i> (Candida Group 2)	6.21E+07	<i>Streptococcus pneumoniae</i>	2.10E+04
	<i>Streptococcus pneumoniae</i>	N/A	<i>Candida glabrata</i>	6.20E+05
04	<i>Enterococcus faecium</i>	8.96E+08	<i>Enterococcus faecalis</i>	1.50E+06
	<i>Enterococcus faecalis</i>	7.25E+08	<i>Enterococcus faecium</i>	4.08E+04
05	<i>Staphylococcus aureus</i>	2.09E+08	<i>Enterococcus faecalis</i>	1.50E+06
	<i>Enterococcus faecalis</i>	7.25E+08	<i>Staphylococcus aureus</i>	1.43E+04
06	<i>Streptococcus pneumoniae</i>	N/A	<i>Enterococcus faecalis</i>	1.50E+06
	<i>Enterococcus faecalis</i>	7.25E+08	<i>Streptococcus pneumoniae</i>	2.10E+04
07	<i>Streptococcus agalactiae</i>	4.16E+08	<i>Streptococcus anginosus</i>	1.45E+05
	<i>Streptococcus anginosus</i>	3.80E+07	<i>Streptococcus agalactiae</i>	9.00E+05
08	<i>Staphylococcus aureus</i>	2.09E+08	<i>Staphylococcus epidermidis</i>	1.03E+05
	<i>Staphylococcus epidermidis</i>	7.29E+08	<i>Staphylococcus aureus</i>	1.43E+04
09	<i>Staphylococcus epidermidis</i>	7.29E+08	<i>Staphylococcus capitis</i>	2.31E+05
	<i>Staphylococcus capitis</i>	2.86E+09	<i>Staphylococcus epidermidis</i>	1.03E+05
10	<i>Streptococcus pyogenes</i>	9.45E+07	<i>Micrococcus luteus</i>	8.65E+05
	<i>Micrococcus luteus</i>	2.13E+08	<i>Streptococcus pyogenes</i>	3.00E+05
11	<i>Staphylococcus lugdunensis</i>	1.96E+08	<i>Corynebacterium striatum</i>	2.14E+06
	<i>Corynebacterium striatum</i>	9.54E+08	<i>Staphylococcus lugdunensis</i>	4.50E+03
12	<i>Streptococcus agalactiae</i>	4.16E+08	<i>Staphylococcus aureus</i>	1.43E+04
	<i>Staphylococcus aureus</i>	2.09E+08	<i>Streptococcus agalactiae</i>	9.00E+05
13	<i>Streptococcus pneumoniae</i>	N/A	<i>Escherichia coli</i> (Pan GN)	1.21E+07
	<i>Escherichia coli</i> (Pan GN)	4.16E+08	<i>Streptococcus pneumoniae</i>	2.10E+04
14	<i>Staphylococcus aureus</i>	2.09E+08	<i>Acinetobacter baumannii</i> (Pan GN)	4.17E+04
	<i>Acinetobacter baumannii</i> (Pan GN)	2.72E+10	<i>Staphylococcus aureus</i>	1.43E+04
15	<i>Pseudomonas aeruginosa</i> (Pan GN)	1.41E+09	<i>Micrococcus luteus</i>	8.65E+05
16	<i>Cutibacterium acnes</i>	1.71E+08	<i>Bacillus cereus</i>	1.84E+06
17	<i>Klebsiella pneumoniae</i> (Pan GN)	1.40E+09	<i>Staphylococcus aureus</i>	1.43E+04
18	<i>Serratia marcescens</i> (Pan GN)	4.82E+08	<i>Enterococcus faecalis</i>	8.25E+05
19	<i>Proteus mirabilis</i> (Pan GN)	3.17E+09	<i>Staphylococcus aureus</i>	1.43E+04
20	<i>Bacteroides fragilis</i> (Pan GN)	2.27E+09	<i>Streptococcus anginosus</i>	1.45E+05
21	<i>Enterobacter cloacae</i> (Pan GN)	1.08E+09	<i>Candida albicans</i>	2.04E+06

Endogenous/Exogenous Interference

An interfering substances study was conducted to evaluate whether potentially interfering endogenous or exogenous substances that may be present in blood culture specimens impact the performance of the QIAstat-Dx BCID GPF Plus AMR Panel. Two positive sample mixes

were prepared by combining five and three representative, on-panel isolates covering the range of target organisms, with different reaction chambers detecting different targets. Stock isolates were inoculated with whole blood into blood culture bottles and incubated in a blood culture monitoring system until “positive ring”. Positive samples were then prepared by combining equal volumes of each culture (at 3x LoD). The list of representative organisms is shown in **Table 8**. Interfering substances were individually spiked into the positive mix to achieve the concentrations listed in **Table 9**. All targets were detected, and no interference was observed from any substance evaluated.

Table 8. List of Organisms in Test Mixtures

Mix	Organism	Concentration (CFU/mL)
1	<i>S. aureus</i>	1.43E+04
	<i>C. gattii</i>	3.00E+04
	<i>L. monocytogenes</i>	6.36E+04
	<i>E. faecalis</i>	6.36E+05
	<i>S. anginosus</i>	7.35E+04
2	<i>B. cereus</i>	3.86E+06
	<i>C. glabrata</i>	1.31E+06
	<i>A. baumannii</i>	8.78E+06

Table 9. List of Potentially Interfering Substances

Substance	Concentration in Sample (units/mL)	Solvent
Acetaminophen	0.156mg/mL	Water
Amoxicillin Clavulanate	0.075mg/mL	Water
Amphotericin B	0.002mg/mL	DMSO
Ara-C Triphosphate	2.64µg/mL	Water
Biotin (Vitamin B7)	0.00351mg/mL	Water
Sodium hypochlorite solution (Bleach)	5% (v/v)/55.5mg/mL	N/A
Caspofungin Diacetate	0.005mg/mL	DMSO
Ceftriaxone Disodium Hemiheptahydrate	0.966mg/mL	Water
Ciprofloxacin	0.01mg/mL	Water
Ethanol	5% (v/v)/39.5mg/mL	N/A
Fluconazole	0.075mg/mL	Ethanol
5-Fluorocytosine	0.09mg/mL	Water
Gentamicin sulfate	0.03mg/mL	Water
Heparin Sodium	3Units/mL	Water
Ibuprofen	0.219mg/mL	DMSO
Imipenem Monohydrate	0.5mg/mL	Water
Povidone (iodinated)	5mg/mL	Water
Salicylic Acid	0.0286mg/mL	Water
Sodium Polyanethol Sulfonate (SPS)	0.0025mg/mL	Water
Tetracycline Hydrochloride	0.015mg/mL	Water
Vancomycin (hydrochloride)	0.12mg/mL	Water
Bilirubin	0.25mg/mL	Chloroform
Cholesterol	0.5mg/mL	Ethanol
D-Glucose	5mg/mL	Water
γ-globulin	60mg/mL	NaCl
Hemoglobin	5mg/mL	Water
Magnesium Sulphate (MgSO4)	0.1mg/mL	Water
Human genomic DNA	10.55µg/mL	N/A

Human Serum Albumin	25mg/mL	Water
Triglycerides mixtures (Lipid standards)	15mg/mL	Chloroform
Fibrinogen	0.5mg/mL	NaCl

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 GPF 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 single spiked samples.

Twenty (20) sample mixtures were prepared by combining up to five organisms. Studies were conducted in BACTEC Plus Aerobic bottles. Stocks were inoculated into blood culture bottles and incubated until “positive ring”. Concentrations (in CFU/mL) in culture were determined, and organisms were combined to form sample mixtures. Mixtures were serially diluted, and if at least 19/20 replicates (95%) were positive for all intended targets and a minimum of two (2) dropouts (< 95%) were observed at the higher dilution (0.1x LoD), then the LoD was established. **Table 10** shows the results.

Table 10. Results for Combined LoD Studies

Target	Organism	LoD (CFU/mL)	Combined LoD (CFU/mL)
Aac(6')aph(2')	<i>E. faecalis</i>	5.00E+05	1.28E+05
	<i>S. epidermidis</i>	1.32E+05	
	<i>S. epidermidis</i>	3.41E+04	
	<i>S. epidermidis</i>	1.00E+04	
	<i>S. hominis</i>	3.87E+04	
	<i>E. faecalis</i>	5.03E+04	
<i>B. cereus</i>	<i>B. cereus</i>	6.11E+05	3.13E+05
	<i>B. thuringiensis</i>	1.54E+04	
<i>C. auris</i>	<i>C. auris</i>	1.74E+06	1.95E+06
	<i>C. auris</i>	2.17E+06	
<i>Candida</i> spp. Group 1	<i>C. tropicalis</i>	8.50E+04	2.10E+06
	<i>C. dublinensis</i>	3.88E+06	
	<i>C. famata</i>	6.25E+06	
	<i>C. guilliermondi</i>	4.75E+05	
	<i>C. kefyr</i>	1.25E+06	
	<i>C. albicans</i>	6.74E+05	
<i>Candida</i> spp. Group 2	<i>C. lusitanae</i>	4.83E+06	1.31E+06
	<i>C. glabrata</i>	2.07E+05	
	<i>C. krusei</i>	4.37E+04	
	<i>C. parapsilosis</i>	1.55E+05	
cfr	<i>S. aureus</i>	4.75E+03	6.84E+04
	<i>S. epidermidis</i>	1.32E+05	
<i>Corynebacterium</i>	<i>C. striatum</i>	7.12E+05	2.28E+06
	<i>C. jeikeium</i>	3.84E+06	
<i>Cryptococcus neoformans/gattii</i>	<i>C. neoformans</i>	1.00E+03	5.50E+03
	<i>C. gattii</i>	1.00E+04	
<i>E. faecalis</i>	<i>E. faecalis</i>	5.00E+05	2.75E+05
	<i>E. faecalis</i>	5.03E+04	
<i>E. faecium</i>	<i>E. faecium</i>	4.30E+04	1.36E+04
	<i>E. faecium</i>	1.36E+04	
Erm(A)	<i>S. epidermis</i>	3.41E+04	1.73E+04
	<i>S. aureus</i>	4.75E+02	

Target	Organism	LoD (CFU/mL)	Combined LoD (CFU/mL)
Erm(C)	<i>S. epidermidis</i>	1.00E+04	6.94E+03
	<i>S. hominis</i>	3.87E+03	
<i>Fusarium</i>	<i>F. oxysporum</i>	4.83E+03	7.72E+03
	<i>F. proliferatum</i>	1.06E+04	
<i>L. monocytogenes</i>	<i>L. monocytogenes</i>	6.50E+03	2.12E+04
	<i>L. monocytogenes</i>	3.58E+04	
MecA	<i>S. epidermidis</i>	1.00E+04	3.74E+04
	<i>S. aureus</i>	4.75E+03	
	<i>S. epidermidis</i>	3.41E+04	
	<i>S. aureus</i>	4.75E+03	
	<i>S. epidermidis</i>	1.32E+05	
	<i>S. hominis</i>	3.87E+04	
MecC	<i>S. aureus</i>	4.75E+03	2.61E+03
	<i>S. aureus</i>	4.75E+02	
<i>Micrococcus</i> spp.	<i>M. yunnanensis</i>	5.50E+05	2.89E+05
	<i>M. luteus</i>	2.89E+04	
Pan Gram Negative	<i>A. baumannii</i>	1.39E+06	2.72E+06
	<i>E. coli</i>	4.04E+06	
<i>S. agalactiae</i>	<i>S. agalactiae</i>	3.00E+05	2.25E+05
	<i>S. agalactiae</i>	1.50E+05	
<i>S. anginosus</i> group	<i>S. anginosus</i>	4.81E+04	2.45E+04
	<i>S. anginosus</i>	8.76E+02	
<i>S. capitis/hominis</i>	<i>S. capitis</i>	7.70E+04	4.04E+04
	<i>S. hominis</i>	3.87E+03	
<i>S. epidermidis</i>	<i>S. epidermidis</i>	1.00E+04	5.01E+04
	<i>S. epidermidis</i>	2.41E+04	
	<i>S. epidermidis</i>	3.41E+04	
	<i>S. epidermidis</i>	1.32E+05	
<i>S. lugdunensis</i>	<i>S. lugdunensis</i>	1.50E+03	5.08E+04
	<i>S. lugdunensis</i>	1.00E+05	
<i>S. pneumoniae</i>	<i>S. pneumoniae</i>	7.00E+02	3.85E+03
	<i>S. pneumoniae</i>	7.00E+03	
<i>S. pyogenes</i>	<i>S. pyogenes</i>	1.00E+05	5.50E+04
	<i>S. pyogenes</i>	1.00E+04	
<i>S. aureus</i>	<i>S. aureus</i>	4.75E+03	2.61E+03
	<i>S. aureus</i>	4.75E+03	
	<i>S. aureus</i>	4.75E+02	
	<i>S. aureus</i>	4.75E+02	
Tet(K)	<i>S. aureus</i>	4.75E+03	1.12E+04
	<i>S. epidermidis</i>	2.41E+04	
	<i>S. aureus</i>	4.75E+03	
Tet(M)	<i>S. aureus</i>	1.50E+04	1.71E+05
	<i>E. faecalis</i>	5.03E+05	
	<i>S. aureus</i>	4.75E+03	
VanA	<i>E. faecium</i>	4.30E+04	3.20E+04
	<i>E. faecalis</i>	5.03E+04	
VanB	<i>E. faecalis</i>	5.00E+05	3.18E+05
	<i>E. faecium</i>	1.36E+05	

Twenty-two single spiked samples detecting 29 targets (organism and resistance markers) were prepared in a second study to verify combined LoDs by inoculating into blood culture bottles and incubated until “positive ring”. Concentrations (in CFU/mL) in culture were determined, and samples were serially diluted. If at least 19/20 replicates (95%) were positive for all intended targets and a minimum of two dropouts (< 95%) were observed at the higher dilution (0.1x LoD), then the LoD was established. For 28 out of 29 targets, the

LoD was successfully confirmed. For the remaining *S. pneumoniae* target, the LoD was re-established as 2.21×10^2 CFU/mL (the combined LoD was determined as 7.00×10^3 CFU/mL). Results were compared to the Growth and Detection Study to ensure that LoDs were at or below the concentration in positive blood culture specimens.

Table 11. Results for Growth and Detection Study

Target	Organism	Established LoD (CFU/mL)	Bottle Positive Concentration (CFU/mL)
<i>B. cereus</i>	<i>B. cereus</i>	6.11E+05	2.78E+08
	<i>B. thuringiensis</i>	1.54E+04	
<i>C. auris</i>	<i>C. auris</i>	1.74E+06	8.08E+06
	<i>C. auris</i>	2.17E+06	
<i>Candida</i> spp. Group 1	<i>C. tropicalis</i>	8.50E+04	3.04E+06
	<i>C. dublinensis</i>	3.88E+06	9.90E+06
	<i>C. famata</i>	6.25E+06	N/A*
	<i>C. guilliermondi</i>	4.75E+05	3.80E+07
	<i>C. kefyr</i>	1.25E+06	1.29E+09
	<i>C. albicans</i>	6.74E+05	1.61E+06
<i>Candida</i> spp. Group 2	<i>C. lusitanae</i>	1.31E+06	2.90E+07
	<i>C. glabrata</i>	2.07E+05	1.55E+07
	<i>C. krusei</i>	4.37E+04	7.86E+06
	<i>C. parapsilosis</i>	1.55E+05	3.58E+06
<i>Corynebacterium</i>	<i>C. striatum</i>	7.12E+05	1.20E+08
	<i>C. jeikeium</i>	3.84E+06	
<i>C. neoformans/gattii</i>	<i>C. neoformans</i>	1.00E+03	1.78E+06
	<i>C. gattii</i>	1.00E+04	
<i>E. faecalis</i>	<i>E. faecalis</i>	5.00E+05	6.78E+08
	<i>E. faecalis</i>	5.03E+04	
<i>E. faecium</i>	<i>E. faecium</i>	1.36E+04	1.06E+09
	<i>E. faecium</i>	1.36E+04	
<i>Fusarium</i>	<i>F. oxysporum</i>	4.83E+03	8.10E+04
	<i>F. proliferatum</i>	1.06E+04	
<i>L. monocytogenes</i>	<i>L. monocytogenes</i>	6.50E+03	9.63E+07
	<i>L. monocytogenes</i>	3.58E+04	
<i>Micrococcus</i> spp.	<i>M. yunnanensis</i>	5.50E+05	2.17E+08
	<i>M. luteus</i>	2.89E+04	
Pan Gram Negative	<i>A. baumannii</i>	1.39E+06	2.17E+08
	<i>E. coli</i>	4.04E+06	
<i>S. agalactiae</i>	<i>S. agalactiae</i>	3.00E+05	3.02E+08
	<i>S. agalactiae</i>	1.50E+05	
<i>S. anginosus</i> group	<i>S. anginosus</i>	4.81E+04	4.38E+07
	<i>S. anginosus</i>	8.76E+02	
<i>S. capitis/hominis</i>	<i>S. capitis</i>	7.70E+04	3.60E+06
	<i>S. hominis</i>	3.87E+03	
<i>S. epidermidis</i>	<i>S. epidermidis</i>	1.00E+04	4.64E+07
	<i>S. epidermidis</i>	2.41E+04	
	<i>S. epidermidis</i>	3.41E+04	
	<i>S. epidermidis</i>	1.32E+05	
<i>S. lugdunensis</i>	<i>S. lugdunensis</i>	1.50E+03	1.28E+07
	<i>S. lugdunensis</i>	1.00E+05	
<i>S. pneumoniae</i>	<i>S. pneumoniae</i>	7.00E+02	9.59E+07
	<i>S. pneumoniae</i>	7.00E+03	
<i>S. pyogenes</i>	<i>S. pyogenes</i>	1.00E+05	7.37E+08
	<i>S. pyogenes</i>	1.00E+04	
<i>S. aureus</i>	<i>S. aureus</i>	4.75E+03	4.12E+06
	<i>S. aureus</i>	4.75E+03	
	<i>S. aureus</i>	4.75E+02	

	<i>S. aureus</i>	4.75E+02	
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* Concentration not available for *C. famata* (*Debaryomyces hansenii*) due to culture requirements.

Analytical Reactivity/Inclusivity

An analytical reactivity study was performed to evaluate the inclusivity of the QIAstat-Dx BCID GPF Plus AMR Panel through testing of clinically relevant subtypes, strains, genotypes, serotypes, species and AMR gene variants representing the genetic, temporal and geographic diversity for each on-panel reportable target. Strain mixtures containing up to five pathogens were prepared in negative blood culture matrix (NBCM) targeting ~3x LoD. All on-panel organisms (n = 209) were tested in triplicate and retested at higher concentrations if they were not initially detected. If 3/3 replicates were detected at a higher concentration, the strain was determined as “detected with reduced sensitivity”. If a strain was not detected at any concentration, it was reported as “not detected”. A list of tested organisms is shown in **Table 12**. Strains that did not achieve 100% detection and their corresponding test results are shown in **Table 13**. One false positive, *E. faecium* (ATCC BAA-2316) for the *Aac(6')aph(2'')* target was observed.

Table 12. List of Wet Tested Organisms for Inclusivity

Organism	Strain	Organism	Strain	Organism	Strain
<i>Acinetobacter baumannii</i>	NCTC 13302	<i>Bacillus cereus</i>	ATCC 2769	<i>Bacillus thuringiensis</i>	ATCC 35646
<i>Escherichia coli</i>	ATCC BAA 196	<i>Bacillus cereus</i>	CCUG 36593	<i>Bacillus cereus</i>	NCTC 10320
<i>Bacillus cereus</i>	NCTC 2599	<i>Bacillus mycoides</i>	NCTC 926	<i>Bacillus thuringiensis</i>	CCUG 7429T
<i>Bacteroides fragilis</i>	NCTC 8560	<i>Brenneria alni</i>	CCUG 48887T	<i>Proteus penneri</i>	CCUG 60543
<i>Candida albicans</i>	ATCC 10231	<i>Candida auris</i>	CBS 12372	<i>Candida auris</i>	CBS 14144
<i>Candida auris</i>	NCPF 8971	<i>Candida auris</i>	NCPF 8977	<i>Candida auris</i>	NCPF 8984
<i>Candida dublinensis</i>	NCPF 8516	<i>Candida famata</i>	CBS 767	<i>Candida glabrata</i>	ATCC 15126
<i>Candida glabrata</i>	ATCC 2001	<i>Candida guilliermondii</i>	NCPF 3896	<i>Candida krusei</i>	ATCC 32196
<i>Candida krusei</i>	NCPF 3930	<i>Candida lusitanae</i>	CCUG 69483	<i>Candida lusitanae</i>	NCPF 3968
<i>Candida parapsilosis</i>	ATCC 58895	<i>Candida parapsilosis</i>	NCPF 3207	<i>Candida tropicalis</i>	ATCC 750
<i>Cedecea davisae</i>	NCTC 13724	<i>Chania multitudinisentens</i>	LMG 28304	<i>Citrobacter koseri</i>	ATCC 27156
<i>Corynebacterium amycolatum</i>	CCUG 57527	<i>Corynebacterium afermentans</i> subsp. <i>Afermentans</i>	CCUG 32103	<i>Corynebacterium diphtheriae</i>	CCUG 33629
<i>Corynebacterium falseni</i>	ATCC BAA-596	<i>Corynebacterium imitans</i>	CCUG 36877	<i>Candida kefyr</i>	NCPF 8343
<i>Corynebacterium jeikeium</i>	ATCC BAA-949	<i>Corynebacterium jeikeium</i>	NCTC 11913	<i>Corynebacterium pseudotuberculosis</i>	ATCC 43924
<i>Corynebacterium ulcerans</i>	ATCC 51799	<i>Corynebacterium urealyticum</i>	ATCC 43044	<i>Cronobacter sakazakii</i>	ATCC 29004
<i>Cryptococcus gattii</i>	ATCC MYA-4071	<i>Cryptococcus gattii</i>	CCUG 43335	<i>Cryptococcus neoformans</i>	ATCC 208821
<i>Cryptococcus neoformans</i>	ATCC 90112	<i>Cryptococcus neoformans</i>	CCUG 23479	<i>Dickeya dadantii</i>	LMG 25991
<i>Edwardsiella tarda</i>	NCTC 10396	<i>Enterobacter asburiae</i>	ATCC 35955	<i>Enterococcus faecalis</i>	ATCC 51299
<i>Enterococcus faecalis</i>	ATCC 51575	<i>Enterococcus faecalis</i>	ATCC BAA-2365	<i>Enterococcus faecalis</i>	CCUG 19916
<i>Enterococcus faecalis</i>	NCTC 12203	<i>Enterococcus faecium</i>	ATCC 51559	<i>Enterococcus faecium</i>	ATCC BAA-2316

<i>Enterococcus faecium</i>	CCUG 68933	<i>Enterococcus faecium</i>	JMI 1031982	<i>Erwinia aphidicola</i>	ATCC 29919
<i>Enterococcus faecalis</i>	NCTC 13780	<i>Enterococcus faecium</i>	ATCC 51858	<i>Enterococcus faecium</i>	NCTC 12204
<i>Erwinia billingiae</i>	CCUG 50417	<i>Escherichia coli</i>	CCUG 67180	<i>Fusarium oxysporum</i>	CBS 267.50
<i>Fusarium proliferatum</i>	NCPF 7484	<i>Fusarium sacchari</i>	CBS 134.73	<i>Fusarium solani</i>	NCPF 7483
<i>Fusarium verticillioides</i>	CBS 115135	<i>Haemophilus influenzae</i>	CCUG 33775	<i>Hafnia alvei</i>	CCUG 59411
<i>Izhakiella capsodis</i>	LMG 28431	<i>Klebsiella pneumoniae</i>	CCUG 68728	<i>Kluyvera cryocrescens</i>	NCTC 10483
<i>Kosakonia quasiacchari</i>	NCTC 14272	<i>Leclercia adecarboxylata</i>	NCTC 13032	<i>Lelliota nimipressuralis</i>	CCUG 69901
<i>Listeria monocytogenes</i>	ATCC 19111	<i>Listeria monocytogenes</i>	ATCC 19115	<i>Listeria monocytogenes</i>	CCUG 67296
<i>Listeria monocytogenes</i>	NCTC 5105	<i>Listeria monocytogenes</i>	NCTC 5348	<i>Micrococcus luteus</i>	NCTC 196
<i>Micrococcus luteus</i>	NCTC 2665	<i>Micrococcus luteus</i>	NCTC 7011	<i>Micrococcus luteus</i>	NCTC 7743
<i>Micrococcus lylae</i>	CCUG 44721	<i>Micrococcus yunnanensis</i>	CCUG 59864	<i>Streptococcus pyogenes</i>	CCUG 74645
<i>Neisseria meningitidis</i>	CCUG 27650	<i>Obesumbacterium proteusstrain</i>	CCUG 26658	<i>Phytobacter diazotrophicus</i>	CCUG 74074
<i>Streptococcus agalactiae</i>	NCTC 8181	<i>Phytophthora/Pectobacterium/Dickeya chrysanthemi</i>	CCUG 47021	<i>Pluralibacter gergoviae</i>	CCUG 33719
<i>Pragia fontium</i>	CCUG 23265	<i>Proteus mirabilis</i>	ATCC BAA-2792	<i>Providencia stuartii</i>	CCUG 74678
<i>Pseudomonas aeruginosa</i>	ATCC BAA-2794	<i>Rahnella aquatilis</i>	CCUG 52909	<i>Raoultella terrigena</i>	NCTC 13038
<i>Salmonella enterica</i>	ATCC 6962	<i>Scandinaviu goeteborgensis</i>	NCTC 14286	<i>Serratia liquefaciens</i>	ATCC 27592
<i>Shigella sonnei</i>	CCUG 68726	<i>Shimwellia blattae</i>	NCTC 12127	<i>Staphylococcus aureus</i>	ATCC 700698
<i>Staphylococcus aureus</i>	ATCC BAA-977	<i>Staphylococcus aureus</i>	ATCC BAA-33591	<i>Staphylococcus aureus</i>	NCTC 13552
<i>Staphylococcus aureus</i>	ATCC BAA-1556	<i>Staphylococcus aureus</i>	ATCC BAA-1707	<i>Staphylococcus aureus</i>	ATCC BAA-2312
<i>Staphylococcus aureus</i>	CC398 / t011	<i>Staphylococcus aureus</i>	CCUG 74989	<i>Staphylococcus aureus</i>	NCTC 13140
<i>Staphylococcus aureus</i>	NCTC 14457	<i>Staphylococcus aureus</i>	NR-10187/HFH-29994	<i>Staphylococcus aureus</i>	NR-10189/HFH-30364
<i>Staphylococcus aureus</i>	NR-46069	<i>Staphylococcus aureus</i>	NR-46070/USA300-0114	<i>Staphylococcus aureus</i>	NR-46069
<i>Staphylococcus capitis</i>	ATCC 27840	<i>Staphylococcus capitis</i>	CCUG 35142T	<i>Staphylococcus capitis</i>	CCUG 42761
<i>Staphylococcus epidermidis</i>	JMI 1090853	<i>Staphylococcus epidermidis</i>	JMI 1151922	<i>Staphylococcus epidermidis</i>	JMI 1171320
<i>Staphylococcus epidermidis</i>	NCTC 13360	<i>Staphylococcus epidermidis</i>	NCTC 13924	<i>Staphylococcus epidermidis</i>	PA212221
<i>Staphylococcus epidermidis</i>	ATCC 35983	<i>Staphylococcus epidermidis</i>	ATCC 35984	<i>Staphylococcus lugdunensis</i>	CCUG 71098
<i>Staphylococcus hominis</i>	CCUG 35516	<i>Staphylococcus hominis</i> subsp. <i>hominis</i>	ATCC 25615	<i>Staphylococcus hominis</i> subsp. <i>novobiosepticus</i>	CCUG 42399T
<i>Staphylococcus aureus</i>	ATCC BAA-2313	<i>Staphylococcus lugdunensis</i>	ATCC 49576	<i>Staphylococcus lugdunensis</i>	CCUG 66510
<i>Staphylococcus lugdunensis</i>	CCUG 74993	<i>Staphylococcus lugdunensis</i>	NCTC 7990	<i>Stenotrophomonas maltophilia</i>	NCTC 10498

<i>Streptococcus agalactiae</i>	ATCC 12401	<i>Streptococcus agalactiae</i>	CCUG 62211	<i>Streptococcus agalactiae</i>	NCTC 9410
<i>Streptococcus agalactiae</i>	NCTC 9412	<i>Streptococcus anginosus</i>	ATCC 9895	<i>Streptococcus constellatus</i>	CCUG 67510
<i>Streptococcus constellatus</i>	NCTC 11325	<i>Streptococcus intermedius</i>	ATCC 27335	<i>Streptococcus pneumoniae</i>	ATCC 10357
<i>Streptococcus pneumoniae</i>	ATCC BAA-334	<i>Streptococcus pneumoniae</i>	CCUG 70149	<i>Streptococcus pneumoniae</i>	CCUG 71170
<i>Streptococcus pyogenes</i>	ATCC 12384	<i>Streptococcus pyogenes</i>	CCUG 58107	<i>Streptococcus pyogenes</i>	NCTC 12696
<i>Streptococcus pyogenes</i>	NCTC 5163	<i>Tatumella ptyseos</i>	NCTC 11468	<i>Xenorhabdus nematophila</i>	CCUG 14189T
<i>Yersinia enterocolitica</i> subsp. <i>enterocolitica</i>	NCTC 12982	<i>Yokenella regensburgei</i>	NCTC 12131	<i>Proteus vulgaris</i>	CCUG 55607
<i>Acinetobacter calcoaceticus</i>	CCUG 57816	<i>Haemophilus influenzae</i> type A	ATCC 9006	<i>Providencia alcalifaciens</i>	CCUG 6325T
<i>Acinetobacter haemolyticus</i>	CCUG 67703	<i>Haemophilus influenzae</i> Non-typeable	ATCC 51907	<i>Proteus rettgeri</i>	CCUG 23362
<i>Acinetobacter johnsonii</i>	CCUG 61200	<i>Haemophilus influenzae</i> type c	ATCC 49699	<i>Pseudomonas aeruginosa</i>	CCUG 23001
<i>Acinetobacter lwoffii</i>	CCUG 65000	<i>Haemophilus influenzae</i> type d	ATCC 9008	<i>Pseudomonas fluorescens</i>	CCUG 67000
<i>Acinetobacter nosocomialis</i>	CCUG 74064T	<i>Haemophilus influenzae</i> type e	ATCC 8142	<i>Pseudomonas putida</i>	CCUG 57833
<i>Acinetobacter pittii</i>	CCUG 72793	<i>Haemophilus influenzae</i> type f	ATCC 700223	<i>Salmonella bongori</i>	CCUG 63587
<i>Citrobacter amalonaticus</i>	CCUG 4860T	<i>Klebsiella aerogenes</i>	NRZ 101370	<i>Salmonella enterica</i> subsp. <i>enterica</i> serovar <i>Paratyphi</i>	ATCC 51962
<i>Citrobacter braakii</i>	CCUG 43795	<i>Klebsiella michiganensis</i>	CCUG 66352	<i>Salmonella enterica</i> subsp. <i>enterica</i> serovar <i>Typhi</i>	CECT 409
<i>Citrobacter farmeri</i>	CCUG 57349	<i>Klebsiella oxytoca</i>	NRZ 104905	<i>Serratia marcescens</i>	NRZ 79544
<i>Citrobacter freundii</i>	CCUG 418T	<i>Klebsiella variicola</i>	CCUG 73561	<i>Serratia odorifera</i>	CCUG 14508T
<i>Citrobacter werkmanii</i>	CCUG 30793T	<i>Klebsiella/Raoultella planticola</i>	CCUG 63333	<i>Serratia plymuthica</i>	CCUG 44368
<i>Citrobacter youngae</i>	CCUG 30791	<i>Neisseria meningitidis</i> Serotype A	ATCC 13077	<i>Serratia proteamaculans</i>	CCUG 51551
<i>Enterobacter cloacae</i>	AR Bank 841	<i>Neisseria meningitidis</i> Serotype B	ATCC 13092	<i>Shigella boydii</i>	CCUG 49022
<i>Enterobacter hormaechei</i>	CCUG 63317	<i>Neisseria meningitidis</i> Serotype C	ATCC 13102	<i>Shigella dysenteriae</i>	CECT 584
<i>Enterobacter ludwigii</i>	CCUG 64644	<i>Neisseria meningitidis</i> Serotype Y	ATCC 35561	<i>Shigella flexneri</i>	CCUG 56027
<i>Enterobacter roggenkampii</i>	CCUG 75192				

Table 13. Summary Results of Strains Tested at Higher Concentrations

Target	Organism	Detection Results	Concentration (CFU/mL)
Aac(6') aph(2')	<i>E. faecium</i>	Detected with reduced sensitivity	8.16E+06
	<i>S. aureus</i>	Detected with reduced sensitivity	1.87E+06
	<i>S. epidermidis</i>	Detected with reduced sensitivity	4.66E+06

<i>B. cereus</i>	<i>B. cereus</i>	Not detected	NA
	<i>B. mycoides</i>	Not detected	NA
<i>C. auris</i>	<i>C. auris</i>	Detected with reduced sensitivity	5.22E+07
<i>Candida</i> spp. Group 1			
	<i>C. famata (Debaryomyces hansenii)</i>	Detected with reduced sensitivity	6.25E+06
cfr	<i>S. epidermidis</i>	Detected with reduced sensitivity	3.81E+06
	<i>S. epidermidis</i>	Detected with reduced sensitivity	3.81E+06
<i>Corynebacterium</i>	<i>C. afermentans</i> subsp. <i>Afermentans</i>	Detected with reduced sensitivity	1.52E+08
Erm(A)	<i>S. aureus</i>	Detected with reduced sensitivity	1.87E+06
	<i>S. aureus</i>	Detected with reduced sensitivity	1.87E+05
Erm(C)	<i>S. aureus</i>	Detected with reduced sensitivity	3.93E+05
	<i>S. epidermidis</i>	Detected with reduced sensitivity	3.81E+06
	<i>S. epidermidis</i>	Detected with reduced sensitivity	3.81E+06
	<i>S. epidermidis</i>	Not detected	NA
<i>Fusarium</i>	<i>F. sacchari</i>	Detected with reduced sensitivity	1.44E+05
	<i>F. solani</i>	Detected with reduced sensitivity	2.32E+05
MecA	<i>S. aureus</i>	Detected with reduced sensitivity	1.87E+05
	<i>S. aureus</i>	Detected with reduced sensitivity	1.87E+06
	<i>S. aureus</i>	Detected with reduced sensitivity	1.87E+06
	<i>S. aureus</i>	Detected with reduced sensitivity	1.87E+06
	<i>S. aureus</i>	Detected with reduced sensitivity	1.87E+06
MecC	<i>S. aureus</i>	Detected with reduced sensitivity	1.87E+05
	<i>S. aureus</i>	Detected with reduced sensitivity	1.87E+05
<i>Micrococcus</i> spp.	<i>M. luteus</i>	Detected with reduced sensitivity	1.26E+07
	<i>M. lylae</i>	Not detected	NA
Pan Gram Negative	<i>Pseudomonas fluorescens</i>	Detected with reduced sensitivity	1.58E+08
	<i>P. putida</i>	Detected with reduced sensitivity	2.25E+08
	<i>S. dysenteriae</i>	Detected with reduced sensitivity	8.16E+07
<i>S. aureus</i>	<i>S. aureus</i>	Detected with reduced sensitivity	1.87E+05
	<i>S. aureus</i>	Detected with reduced sensitivity	1.87E+05
	<i>S. aureus</i>	Detected with reduced sensitivity	1.87E+05
	<i>S. aureus</i>	Detected with reduced sensitivity	1.87E+05
	<i>S. aureus</i>	Detected with reduced sensitivity	1.87E+05
<i>S. lugdunensis</i>	<i>S. lugdunensis</i>	Detected with reduced sensitivity	2.63E+06
<i>S. anginosus</i> group	<i>S. anginosus</i>	Detected with reduced sensitivity	8.52E+07
<i>S. pneumoniae</i>	<i>S. pneumoniae</i>	Detected with reduced sensitivity	2.78E+08
Tet(K)	<i>S. aureus</i>	Detected with reduced sensitivity	1.87E+06
	<i>S. aureus</i>	Detected with reduced sensitivity	1.87E+06
Tet(M)	<i>S. aureus</i>	Detected with reduced sensitivity	1.87E+05
	<i>S. aureus</i>	Detected with reduced sensitivity	1.87E+06
	<i>E. faecium</i>	Detected with reduced sensitivity	4.08E+06
	<i>E. faecium</i>	Detected with reduced sensitivity	5.00E+06

An *in silico* inclusivity assessment was also performed of all complete genomes available for every target organism/group in the Taxonomy Browser Tool of the NCBI database. Sequences were individually examined to predict detection by their corresponding assay primers and probes. A second assessment using a larger set of genomes was performed to predict reactivity using the BLAST homology analysis tool. Finally, a dedicated assessment of the AMR targets was performed using all available sequences in the Comprehensive Antibiotic Resistance Database (CARD). Results are shown in **Table 14**.

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

Target	Sequences Analyzed (% predicted to detect)	Detection Prediction
<i>L. monocytogenes</i>	595 (100.00%)	Inclusivity determined for <i>L. monocytogenes</i> (including serotypes 1/2a, 1/2b, 1/2c, 3a, 3b, 3c, 4a, 4b, 4c, 4d, 4e, 7)
<i>S. pyogenes</i>	407 (99.75%)	Only a single sequence (LS483520) not detected.
<i>B. cereus</i> group	646 (93.34%)	Inclusivity determined for <i>B. cereus</i> , <i>B. thuringiensis</i> , <i>B. albus</i> , <i>B. anthracis</i> , <i>B. bombysepticus</i> , <i>B. mobilis</i> , <i>B. nitratedreducens</i> , <i>B. pacificus</i> , <i>B. paramobilis</i> , <i>B. paranthracis</i> , <i>B. shihchuchen</i> , <i>B. tropicus</i> , <i>B. wiedmannii</i> . Partial inclusivity determined for <i>B. mycoides</i> , <i>B. weihenstephanensis</i> . Notes: • 5/216 and 4/134 not detected sequences for <i>B. cereus</i> and <i>B. thuringiensis</i>, respectively. • <i>B. mycoides</i> only 18.33% detected. • 1/27 not detected sequence of <i>B. paranthracis</i>. • 1/2 not detected sequences of <i>B. weihenstephanensis</i>.
<i>Corynebacterium</i>	702 (100.00%)	Inclusivity determined for all 131 <i>Corynebacterium</i> species described (<i>C. diphtheriae</i> , <i>C. ulcerans</i> , <i>C. pseudotuberculosis</i> , <i>C. urealyticum</i> , <i>C. argentoratense</i> , <i>C. flavum</i> , <i>C. accolens</i> , <i>C. afermentans</i> , <i>C. ammoniagenes</i> , <i>C. amycolatum</i> , <i>C. anserum</i> , <i>C. appendicis</i> , <i>C. aquatimens</i> , <i>C. aquilae</i> , <i>C. atrinae</i> , <i>C. atypicum</i> , <i>C. aurimucosum</i> , <i>C. auris</i> , <i>C. auriscanis</i> , <i>C. belfantii</i> , <i>C. bovis</i> , <i>C. breve</i> , <i>C. callunae</i> , <i>C. camporealensis</i> , <i>C. canis</i> , <i>C. capitovis</i> , <i>C. casei</i> , <i>C. caspium</i> , <i>C. choanae</i> , <i>C. ciconiae</i> , <i>C. comes</i> , <i>C. confusum</i> , <i>C. coyleae</i> , <i>C. crudilactis</i> , <i>C. cystitidis</i> , <i>C. dentalis</i> , <i>C. deserti</i> , <i>C. doosanense</i> , <i>C. durum</i> , <i>C. efficiens</i> , <i>C. endometrii</i> , <i>C. epidermidicantis</i> , <i>C. faecale</i> , <i>C. falsenii</i> , <i>C. felinum</i> , <i>C. flavescens</i> , <i>C. fourmieri</i> , <i>C. frankenforstense</i> , <i>C. freiburgense</i> , <i>C. frenyi</i> , <i>C. genitalium</i> , <i>C. gerontici</i> , <i>C. glaucum</i> , <i>C. glucuronolyticum</i> , <i>C. glutamicum</i> , <i>C. glyciniphilum</i> , <i>C. gottlingense</i> , <i>C. guangdongense</i> , <i>C. hadale</i> , <i>C. haemomassiliense</i> , <i>C. halotolerans</i> , <i>C. hansenii</i> , <i>C. heidelbergense</i> , <i>C. hesseae</i> , <i>C. hindlerae</i> , <i>C. humireducens</i> , <i>C. ihumii</i> , <i>C. imitans</i> , <i>C. incognita</i> , <i>C. jeddahense</i> , <i>C. jeikeium</i> , <i>C. kalinowskii</i> , <i>C. kefirresidentii</i> , <i>C. kroppenstedtii</i> , <i>C. kutscheri</i> , <i>C. lactis</i> , <i>C. liangguodongii</i> , <i>C. lizhenjunii</i> , <i>C. lujinxingii</i> , <i>C. macclintockiae</i> , <i>C. macginleyi</i> , <i>C. marinum</i> , <i>C. maris</i> , <i>C. marquesiae</i> , <i>C. massiliense</i> , <i>C. matruchotii</i> , <i>C. mayonis</i> , <i>C. minutissimum</i> , <i>C. mustelae</i> , <i>C. mycetoides</i> , <i>C. nuruki</i> , <i>C. occultum</i> , <i>C. pelargi</i> , <i>C. phocae</i> , <i>C. poyangense</i> , <i>C. propinquum</i> , <i>C. provencense</i> , <i>C. pseudodiphtheriticum</i> , <i>C. pseudogenitalium</i> , <i>C. pseudokroppenstedtii</i> , <i>C. pseudopelargi</i> , <i>C. pyruviciproducens</i> , <i>C. qintianiae</i> , <i>C. renale</i> , <i>C. resistens</i> , <i>C. rhinophilum</i> , <i>C. riegelii</i> , <i>C. rouxii</i> , <i>C. sanguinis</i> , <i>C. segmentosum</i> , <i>C. silvaticum</i> , <i>C. simulans</i> , <i>C. singulare</i> , <i>C. sphenisci</i> , <i>C. stationis</i> , <i>C. striatum</i> , <i>C. suedekumii</i> , <i>C. terpenotabidum</i> , <i>C. testudinoris</i> , <i>C. timonense</i> , <i>C. tuberculostearicum</i> , <i>C. uberis</i> , <i>C. ureicelerivorans</i> , <i>C. urogenitale</i> , <i>C. uterequi</i> , <i>C. variabile</i> , <i>C. vitaeruminis</i> , <i>C. wankanglinii</i> , <i>C. xerosis</i> , <i>C. yudongzhengii</i> , <i>C. zhongnanshanii</i>).
<i>S. epidermidis</i>	328 (98.00%)	Inclusivity determined for <i>S. epidermidis</i> .
<i>S. pneumoniae</i>	355 (100.00%)	Inclusivity determined for <i>S. pneumoniae</i> .
<i>S. lugdunensis</i>	42 (100.00%)	Inclusivity determined for <i>S. lugdunensis</i> .
<i>C. neoformans/gatti</i>	66 (100.00%)	Inclusivity determined for <i>C. neoformans/gatti</i> (including serotype A (<i>C. neoformans</i> var <i>neoformans</i>), serotype D (<i>C. neoformans</i> var <i>grubii</i>), serotypes B and C (<i>C. gattii</i> including all VGI, VGII, VGIII, VGIV molecular types))
<i>E. faecalis</i>	792 (99.87%)	Inclusivity determined for <i>E. faecalis</i> . Note: A single sequence (CP022312) was not detected.
<i>E. faecium</i>	951 (99.89%)	Inclusivity determined for <i>E. faecium</i> . Note: A single sequence (CP175041) was not detected.
<i>S. anginosus</i> group	56 (96.43%)	Inclusivity determined for the three major species in the group, including <i>S. anginosus</i> , <i>S. constellatus</i> and <i>S. intermedius</i> . Note: 2/32 sequences of <i>S. anginosus</i> (CP088916.1 and CP186002.1) were not detected.
<i>S. capitis/S. hominis</i>	71 (100.00%)	Inclusivity determined for <i>S. capitis</i> and <i>S. hominis</i> .
<i>S. aureus</i>	2971 (99.97%)	Inclusivity determined for <i>S. aureus</i> . Note: A single sequence (AP020315) was not detected.
<i>Fusarium</i> group	8726 (99.00%)	Inclusivity determined for <i>F. solani</i> species complex including at least <i>F. acutisporum</i> , <i>F. addoense</i> , <i>F. akasia</i> , <i>F. ambrosium</i> , <i>F. amplum</i> , <i>F. awan</i> , <i>F. bataticola</i> , <i>F. bomiense</i> , <i>F. borneense</i> , <i>F. bostrycoides</i> , <i>F. brasiliense</i> , <i>F. breve</i> , <i>F. breviconum</i> , <i>F. catenatum</i> , <i>F. crassipitatum</i> , <i>F. cf. crassum</i> , <i>F. crassum</i> , <i>F. croci</i> , <i>F. cucurbiticola</i> , <i>F. cuneirostrum</i> , <i>F. cyanescens</i> , <i>F. diminutum</i> , <i>F. drepaniforme</i> , <i>F. duplospermum</i> , <i>F. epipeda</i> , <i>F. euwallaceae</i> , <i>F. falciforme</i> , <i>F. ferrugineum</i> , <i>F. floridanum</i> , <i>F. gamtoosense</i> , <i>F. gannanense</i> , <i>F. haematococcum</i> , <i>F. helgardnirenbergiae</i> , <i>F. hengyangense</i> , <i>F. hypothememi</i> , <i>F. keratoplasticum</i> , <i>F. kuroshium</i> , <i>F. kurunegallense</i> , <i>F. lerouxii</i> , <i>F. lichenicola</i> , <i>F. liriodendri</i> , <i>F. macrosporium</i> , <i>F. martii</i> , <i>F. mekan</i> , <i>F. merckianum</i> , <i>F. metavorans</i> , <i>F. mori</i> , <i>F. neerlandicum</i> , <i>F. neocosmosporiellum</i> , <i>F. ngaiotongaense</i> , <i>F. noneumartii</i> , <i>F. obliquiseptatum</i> , <i>F. oblongum</i> , <i>F. oligoseptatum</i> , <i>F. papillatum</i> , <i>F. paraeumartii</i> , <i>F. paranaense</i> , <i>F. parceramosum</i> , <i>F. paulenelsonii</i> , <i>F. perseae</i> , <i>F. petroliphilum</i> , <i>F. phaseoli</i> , <i>F. piperis</i> , <i>F. populicola</i> , <i>F. protoensiforme</i> , <i>F. pseudensiforme</i> , <i>F. pseudopisi</i> , <i>F. pseudoradicicola</i> , <i>F. quercinum</i> , <i>F. rectiphorum</i> , <i>F. regulare</i> , <i>F. rekanum</i> , <i>F.</i>

Target	Sequences Analyzed (% predicted to detect)	Detection Prediction
		<i>riograndense</i>, <i>F. samuelsii</i>, <i>F. silvicola</i>, <i>F. solani</i>, <i>F. solani f. radicola</i>, <i>F. solani f. sp. eumartii</i>, <i>F. solani f. sp. passiflorae</i>, <i>F. solani-melongenae</i>, <i>F. spathulatum</i>, <i>F. stercicola</i>, <i>F. suttonianum</i>, <i>F. tenuicristatum</i>, <i>F. tonkinense</i>, <i>F. tuaranense</i>, <i>F. tucumaniae</i>, <i>F. tumidispermum</i>, <i>F. vanettenii</i>, <i>F. variasi</i>, <i>F. virguliforme</i>, <i>F. waltergamsii</i>, <i>F. warna</i>, <i>F. witzenhauseense</i>, <i>F. yamamotoi</i>, <i>Neocosmospora alboflava</i>, <i>N. anhuiensis</i>, <i>N. aquatica</i>, <i>N. australiana</i>, <i>N. australpacifica</i>, <i>N. caricae</i>, <i>N. citricola</i>, <i>N. dimorpha</i>, <i>N. easleyae</i>, <i>N. fangfangiae</i>, <i>N. fungicola</i>, <i>N. galbana</i>, <i>N. gerryae</i>, <i>N. guangdongensis</i>, <i>N. lechatii</i>, <i>N. lithocarpi</i>, <i>N. macnamarae</i>, <i>N. magnoliae</i>, <i>N. myrtaceicola</i>, <i>N. paphiopedili</i>, <i>N. paramacrospora</i>, <i>N. queenslandica</i>, <i>N. sorabjiae</i>, <i>N. striatispora</i>, <i>N. thailandica</i>, <i>N. wangariae</i>. Inclusivity determined for other <i>Fusarium</i> species including at least <i>F. arbusti</i>, <i>F. aurantii</i>, <i>F. babinda</i>, <i>F. camelliae</i>, <i>F. algeriense</i>, <i>F. beomiforme</i>, <i>F. burgessii</i>, <i>F. cartwrightiae</i>, <i>F. aseptatum</i>, <i>F. atrovinosum</i>, <i>F. aywerite</i>, <i>F. chlamydosporum</i>, <i>F. humicola</i>, <i>F. microconidium</i>, <i>F. nelsonii</i>, <i>F. peruvianum</i>, <i>F. spinosum</i>, <i>F. sporodochiale</i>, <i>F. tjaynera</i>, <i>F. cili</i>, <i>F. coffeibaccaae</i>, <i>F. anguioides</i>, <i>F. austroafricanum</i>, <i>F. bambusarum</i>, <i>F. concolor</i>, <i>F. verrucosum</i>, <i>F. echinatum</i>, <i>F. endophyticum</i>, <i>F. erosum</i>, <i>F. falsibabinda</i>, <i>F. acutatum</i>, <i>F. agapanthi</i>, <i>F. aglaonematis</i>, <i>F. ananatum</i>, <i>F. andiyazi</i>, <i>F. annulatum</i>, <i>F. anthophilum</i>, <i>F. aquaticum</i>, <i>F. awaxy</i>, <i>F. bactridioides</i>, <i>F. begoniae</i>, <i>F. bilaiae</i>, <i>F. brachiariae</i>, <i>F. brevicatenulatum</i>, <i>F. cf. brevicatenulatum</i>, <i>F. bulbicola</i>, <i>F. caapi</i>, <i>F. casha</i>, <i>F. chinhoiense</i>, <i>F. chuoi</i>, <i>F. circinatum</i>, <i>F. coicis</i>, <i>F. concentricum</i>, <i>F. concentricum x F. mangiferae</i>, <i>F. curculicola</i>, <i>F. cymbidii</i>, <i>F. dendrobii</i>, <i>F. denticulatum</i>, <i>F. dhileepanii</i>, <i>F. dlamini</i>, <i>F. ednaryanae</i>, <i>F. elaeagni</i>, <i>F. ficicrescens</i>, <i>F. fracticaudum</i>, <i>F. fractiflexum</i>, <i>F. fredkrugeri</i>, <i>F. fujikuroi</i>, <i>F. fujikuroi IMI 58289</i>, <i>Gibberella fujikuroi var. moniliformis</i>, <i>F. giganteum</i>, <i>F. globosum</i>, <i>F. guangdongense</i>, <i>F. guttiforme</i>, <i>F. hechiense</i>, <i>F. konzum</i>, <i>F. lacticis</i>, <i>F. humajangense</i>, <i>F. madaense</i>, <i>F. mangiferae</i>, <i>F. marasianum</i>, <i>F. mexicanum</i>, <i>F. mirum</i>, <i>F. mundagurra</i>, <i>F. napiforme</i>, <i>F. nygamai</i>, <i>F. ophioides</i>, <i>F. panlongense</i>, <i>F. parvisorum</i>, <i>F. phyllophilum</i>, <i>F. pilosicola</i>, <i>F. pininemorale</i>, <i>F. prieskaense</i>, <i>F. proliferatum</i>, <i>F. proliferatum ET1</i>, <i>F. pseudoanthophilum</i>, <i>F. pseudocircinatum</i>, <i>F. pseudonygamai</i>, <i>F. purpureum</i>, <i>F. ramigenum</i>, <i>F. sacchari</i>, <i>F. secorum</i>, <i>F. sororula</i>, <i>F. sterilihyphosum</i>, <i>F. subglutinans</i>, <i>F. succisae</i>, <i>F. sudanense</i>, <i>F. temperatum</i>, <i>F. thapsinum</i>, <i>F. tjaetaba</i>, <i>F. cf. tjaetaba</i>, <i>F. tupiense</i>, <i>F. udum</i>, <i>F. verticillioideis</i>, <i>F. verticillioideis 7600</i>, <i>F. volatile</i>, <i>F. xylarioides</i>, <i>F. xyrophilum</i>, <i>F. hanswilhelmii</i>, <i>F. idabrowniae</i>, <i>F. compactum</i>, <i>F. irdabamae</i>, <i>F. kazakhstanicum</i>, <i>F. kirstenboschense</i>, <i>F. cassiae</i>, <i>F. citri-sinensis</i>, <i>F. lateritium</i>, <i>F. magnoliae-champaca</i>, <i>F. ramsdenii</i>, <i>F. sarcochroum</i>, <i>F. stilboides</i>, <i>F. stramineum</i>, <i>F. velutinum</i>, <i>F. verruculosum</i>, <i>F. louisalawsoniae</i>, <i>F. malawiense</i>, <i>F. menglaense</i>, <i>F. microcylum</i>, <i>F. musae</i>, <i>F. nashariae</i>, <i>F. neoglobosum</i>, <i>F. newnesense</i>, <i>F. anoectochili</i>, <i>F. commune</i>, <i>F. gaditjirri</i>, <i>F. miscanthi</i>, <i>F. nisikadoi</i>, <i>F. paranisikadoi</i>, <i>F. oliniae</i>, <i>F. oxysporum species complex</i>, <i>F. callistephi</i>, <i>F. carminascens</i>, <i>F. contaminatum</i>, <i>F. cugenangense</i>, <i>F. curvatum</i>, <i>F. duoseptatum</i>, <i>F. elaeidis</i>, <i>F. fabacearum</i>, <i>F. foetens</i>, <i>F. glycines</i>, <i>F. gossypinum</i>, <i>F. grosmichelii</i>, <i>F. hexaseptatum</i>, <i>F. cf. hexaseptatum/cugenangense</i>, <i>F. hoodiae</i>, <i>F. inflexum</i>, <i>F. kalimantanense</i>, <i>F. languescens</i>, <i>F. libertatis</i>, <i>F. nirenbergiae</i>, <i>F. odoratissimum</i>, <i>F. odoratissimum NRRL 54006</i>, <i>F. oxysporum</i>, <i>F. oxysporum Fo47</i>, <i>F. oxysporum f. sp. asparagi</i>, <i>F. oxysporum</i>, <i>F. sp. cepae</i>, <i>F. oxysporum f. sp. ciceris</i>, <i>F. oxysporum f. sp. cubense</i>, <i>F. oxysporum f. sp. cumini</i>, <i>F. oxysporum f. sp. cyclaminis</i>, <i>F. oxysporum f. sp. dianthi</i>, <i>F. oxysporum f. sp. fragariae</i>, <i>F. oxysporum f. sp. koeae</i>, <i>F. oxysporum f. sp. lactuca</i>, <i>F. oxysporum f. sp. lycopersici 4287</i>, <i>F. oxysporum f. sp. medicaginis</i>, <i>F. oxysporum f. sp. melonis</i>, <i>F. oxysporum f. sp. niveum</i>, <i>F. oxysporum f. sp. opuntiarum</i>, <i>F. oxysporum f. sp. passiflorae</i>, <i>F. oxysporum f. sp. psidii</i>, <i>F. oxysporum f. sp. quitoense</i>, <i>F. oxysporum f. sp. radices-cucumerinum</i>, <i>F. oxysporum f. sp. rhois</i>, <i>F. oxysporum f. sp. tulipae</i>, <i>F. oxysporum f. sp. vasinfectum</i>, <i>F. oxysporum f. sp. zingiberi</i>, <i>F. cf. oxysporum</i>, <i>F. pharetrum</i>, <i>F. phialophorum</i>, <i>F. purpurascens</i>, <i>F. sangayamense</i>, <i>F. tardichlamydosporum</i>, <i>F. tardicrescens</i>, <i>F. triseptatum</i>, <i>F. vanleeuwenii</i>, <i>F. veterinarium</i>, <i>F. planum</i>, <i>F. queenslandicum</i>, <i>F. hostae</i>, <i>F. redolens</i>, <i>F. rhizicola</i>, <i>F. rosae-roxburghii</i>, <i>F. rufum</i>, <i>F. asiaticum</i>, <i>F. brachygibbosum</i>, <i>F. brachypes</i>, <i>F. cuspidatum</i>, <i>F. dimorphosporum</i>, <i>F. dolichosporum</i>, <i>F. hamatum</i>, <i>F. magnum</i>, <i>F. minutum</i>, <i>F. platysporum</i>, <i>F. poae</i>, <i>F. sagittatum</i>, <i>F. transvaalense</i>, <i>F. sanyaense</i>, <i>F. siculi</i>, <i>F. spartum</i>, <i>F. terricola</i>, <i>F. continuum</i>, <i>F. torreyae</i>, <i>F. zanthoxyli</i>, <i>F. valentineae</i>, <i>F. werrikimbe</i>, <i>F. wimaladesilvae</i>, <i>F. xishuangbannaense</i>, <i>F. youattiae</i>. Notes: • 1/2 sequences of <i>F. acutisporum</i> not detected. • 1/20 <i>F. chlamydosporum</i> sequences not detected. • 1/47 <i>F. coffeibaccaae</i> sequences not detected. • 1/83 <i>F. compactum</i> sequences detected. • 1/68 <i>F. lateritium</i> sequences not detected. • 1/2 <i>F. brachypes</i> sequences detected.
<i>Micrococcus</i> spp.	45 (84.44%)	Inclusivity determined for at least <i>M. luteus</i> and <i>M. yunnanensis</i> Notes: • All BLAST hit sequences corresponded to <i>M. luteus</i> • Some genomes were manually collected from NCBI for species not found in the initial

Target	Sequences Analyzed (% predicted to detect)	Detection Prediction
		BLAST analysis. The assay is not expected to detect <i>Micrococcus porci</i> (0/1), <i>Micrococcus antarcticus</i> (0/1), <i>Micrococcus terrae</i> (0/1), <i>Micrococcus lylae</i> (0/1), some unclassified <i>Micrococcus</i> sp. (1/4) and some <i>Micrococcus luteus</i> strains (2/33)
<i>S. agalactiae</i>	270 (99.63%)	Inclusivity determined for <i>S. agalactiae</i>. Note: A single sequence (CP187264) not detected.
PAN Gram-Negative	10109 (99.98%)	Inclusivity determined for <i>Bacteroides fragilis</i>. Inclusivity determined for all capsulated <i>N. meningitidis</i> strains (including serotypes A, B, C, D, E, H, I, K, L, NG, W, W135, X, Y, Z, 29E). Inclusivity determined for <i>S. maltophilia</i>. Inclusivity determined for all <i>H. influenzae</i> strains including all encapsulated serotypes (a, b, c, d, e, f) and unencapsulated strains (nontypable, NTHi) including var. <i>H. aegyptius</i>. Inclusivity determined for <i>Pseudomonas</i> species including at least <i>P. aeruginosa</i> group (<i>P. aeruginosa</i>, <i>P. azelaica</i>, <i>P. multiresistivora</i>, <i>P. nitritireducens</i>, <i>P. nitroreducens</i>, <i>P. paraaeruginosa</i>, <i>P. acephalica</i>, <i>P. allopuntida</i>, <i>P. azotoformans</i>, <i>P. baetica</i>, <i>P. brassicacearum</i>, <i>P. brenneri</i>, <i>P. ceruminis</i>, <i>P. chlororaphis</i>, <i>P. donghuensis</i>, <i>P. entomophila</i>, <i>P. extremaustralis</i>, <i>P. fluorescens</i>, <i>P. gessardii</i>, <i>P. grimontii</i>, <i>P. guzei</i>, <i>P. haemolytica</i>, <i>P. hunanensis</i>, <i>P. khavaziana</i>, <i>P. kielensis</i>, <i>P. kilonensis</i>, <i>P. libanensis</i>, <i>P. lini</i>, <i>P. linyingensis</i>, <i>P. lurida</i>, <i>P. lutea</i>, <i>P. luteola</i>, <i>P. marginalis</i>, <i>P. migulae</i>, <i>P. monteilii</i>, <i>P. mosselii</i>, <i>P. mucidolens</i>, <i>P. nicosulfuronedens</i>, <i>P. oryzihabitans</i>, <i>P. panipatensis</i>, <i>P. paralactis</i>, <i>P. plecoglossicida</i>, <i>P. poae</i>, <i>P. putida</i>, <i>P. quebecensis</i>, <i>P. rhizosphaerae</i>, <i>P. rhodesiae</i>, <i>P. shahriarae</i>, <i>P. sihuiensis</i>, <i>P. synxantha</i>, <i>P. taiwanensis</i>, <i>P. thivervalensis</i>, <i>P. tolaasii</i>, <i>P. trivialis</i>, <i>P. tropicalis</i>, <i>P. yamanorum</i>. Inclusivity determined for <i>Acinetobacter</i> species including at least <i>A. albensis</i>, <i>A. baumannii</i>, <i>A. baylyi</i>, <i>A. beijerinckii</i>, <i>A. bereziniae</i>, <i>A. bohemicus</i>, <i>A. brisouii</i>, <i>A. calcoaceticus</i>, <i>A. celticus</i>, <i>A. colistiniresistens</i>, <i>A. courvalinii</i>, <i>A. dispersus</i>, <i>A. geminorum</i>, <i>A. gyllenbergii</i>, <i>A. haemolyticus</i>, <i>A. halotolerans</i>, <i>A. ihumii</i>, <i>A. indicus</i>, <i>A. johnsonii</i>, <i>A. junii</i>, <i>A. kookii</i>, <i>A. lactuca</i>, <i>A. lwoffii</i>, <i>A. modestus</i>, <i>A. nosocomialis</i>, <i>A. oleivorans</i>, <i>A. parvus</i>, <i>A. pittii</i>, <i>A. plantarum</i>, <i>A. populi</i>, <i>A. proteolyticus</i>, <i>A. psychrotolerans</i>, <i>A. puyangensis</i>, <i>A. radioresistens</i>, <i>A. rhizosphaerae</i>, <i>A. schindleri</i>, <i>A. seifertii</i>, <i>A. septicus</i>, <i>A. soli</i>, <i>A. suaedae</i>, <i>A. tjernbergiae</i>, <i>A. townneri</i>, <i>A. ursingii</i>, <i>A. variabilis</i>, <i>A. venetianus</i>, <i>A. vivianii</i>. Inclusivity determined for <i>Enterobacteriales</i> genera including at least <i>Brenneria</i> (<i>B. rubrifaciens</i>); <i>Cedecea</i> (<i>C. lapagei</i>); <i>Chania</i> (<i>C. multitudinisens</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. condimentii</i>, <i>C. malonaticus</i>, <i>C. sakazakii</i>); <i>Dickeya</i> (<i>D. oryzae</i>, <i>D. zeae</i>); <i>Dryocola</i>; <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>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. intermedia</i>); <i>Kosakonia</i> (<i>K. pseudosacchari</i>, <i>K. radicincitans</i>); <i>Leclercia</i> (<i>L. adecarboxylata</i>, <i>L. pneumoniae</i>); <i>Lelliottia</i>; <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>Photobacterium</i> (<i>P. asymbiotica</i>, <i>P. luminescens</i>); <i>Phytobacter</i> (<i>P. diazotrophicus</i>, <i>P. ursingii</i>); <i>Pluralibacter</i> (<i>P. gergoviae</i>); <i>Pragia</i> (<i>P. fontium</i>); <i>Proteus</i> (<i>P. colymbae</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. rettgeri</i>, <i>P. stuartii</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. entomophila</i>, <i>S. marcescens</i>, <i>S. rhizosphaerae</i>, <i>S. rubidaea</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>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>). Notes: 2 sequences (CP078102 & CP133415) of <i>S. maltophilia</i> not detected. - Some genomes were manually collected from NCBI for species not found in the initial BLAST analysis.
<i>Candida</i> group 1	21 (95.24%)	Inclusivity determined for <i>Candida</i> species included in the <i>Candida</i> 1 group (<i>C. albicans</i>, <i>C. dubliniensis</i>, <i>C. famata</i>, <i>C. guilliermondii</i>, <i>C. kefyr</i>, <i>C. tropicalis</i>). Notes: - One <i>C. albicans</i> sequence corresponding to chromosome 7. No information regarding the remaining 7 chromosomes was available. <i>C. dubliniensis</i> analyzed under option B (BLAST) since there were no complete genomes available in NCBI.

Target	Sequences Analyzed (% predicted to detect)	Detection Prediction
		One <i>C. famata</i> genome (CP045114) not detected.
<i>Candida</i> group 2	36 (100.00%)	Inclusivity determined for <i>Candida</i> species in the <i>Candida</i> 2 group (<i>C. glabrata</i> , <i>C. krusei</i> , <i>C. lusitanae</i> , <i>C. parapsilosis</i>). Note: Some genomes of <i>C. krusei</i> contained two copies of the target gene within the same chromosome.
<i>C. auris</i>	70 (100.00%)	Inclusivity determined for <i>C. auris</i> .
<i>cfr</i>	42 (100.00%)	All sequences detected
<i>VanB</i>	33 (100.00%)	All sequences detected
<i>Tet(M)</i>	1003 (99.40%)	Six (6) out of 1003 accession numbers were predicted not to be detected (CP059743, CP059819, CP018072, LR135320, LR135327 & LR135256), because of a deletion in the AMR gene.
<i>VanA</i>	190 (100.00%)	All sequences detected
<i>MecA</i>	676 (100.00%)	All sequences detected
<i>Tet(K)</i>	122 (100.00%)	All sequences detected
<i>Erm(A)</i>	334 (94.61%)	Variant <i>Spyo_ermA_MLSb</i> (18 sequences) which has been found in some <i>S. pyogenes</i> is predicted not to be detected.
<i>Erm(C)</i>	82 (100.00%)	All sequences detected
<i>Aac(6') aph(2')</i>	460 (100.00%)	All sequences detected
<i>MecC</i>	3 (100.00%)	All sequences detected

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

Specimen Stability

A sample stability study was performed to demonstrate storage of Positive Blood Culture Matrix (PBCM) specimens at room temperature (15 to 25°C) or in a blood culture system (35 ± 1.5°C) for up to 24 hours after positivity but prior to testing does not impact performance of the QIAstat-Dx BCID GPF Plus AMR Panel. One or more representative isolates for each target organism or resistance marker were tested individually by inoculating negative whole human blood with pre-cultured isolates in blood culture media bottles. Studies were conducted in BACTEC Plus Aerobic bottles. Bottles were incubated in a blood culture instrument until “positive ring”, removed within two hours of positive detection, and split into three portions. One portion was tested to provide the t_0 timepoint, the second portion was stored at 15± 3°C (t_{1b}) for 27 hours, and the third portion was reloaded into the blood culture instrument at 35± 1.5°C (t_{1a}) for an additional 27 hours. Positive cultures were subsequently enumerated to obtain CFU/mL. For each timepoint, samples from the three portions were tested in triplicate, generating nine valid replicates per analyte. A 100% detection rate was achieved for all replicates and panel targets.

Table 15. List of Organisms and Results for Specimen Stability Study

Target	Bottle Positive + 27 h Concentration (CFU/mL)	Timepoint	Hit Rate	Percentage
<i>Streptococcus agalactiae</i> (GBS)	7.47E+08	t0	9 / 9	100.00%
		t1a	9 / 9	100.00%
		t1b	9 / 9	100.00%
<i>Streptococcus anginosus</i> (<i>Streptococcus anginosus</i> group)	7.50E+07	t0	9 / 9	100.00%
		t1a	9 / 9	100.00%
		t1b	9 / 9	100.00%
<i>Enterococcus faecalis</i> <i>Aac(6') aph(2')</i> <i>VanB</i>	2.86E+09	t0	9 / 9	100.00%
		t1a	9 / 9	100.00%
		t1b	9 / 9	100.00%
<i>Enterococcus faecium</i> <i>Tet(M)</i>	1.60E+09	t0	9 / 9	100.00%
		t1a	9 / 9	100.00%

VanA		t1b	9 / 9	100.00%
<i>Staphylococcus lugdunensis</i>	5.45E+08	t0	9 / 9	100.00%
		t1a	9 / 9	100.00%
		t1b	9 / 9	100.00%
<i>Listeria monocytogenes</i>	7.28E+08	t0	9 / 9	100.00%
		t1a	9 / 9	100.00%
		t1b	9 / 9	100.00%
<i>Candida albicans</i> (<i>Candida</i> spp. Group 1)	3.71E+07	t0	9 / 9	100.00%
		t1a	9 / 9	100.00%
		t1b	9 / 9	100.00%
<i>Candida glabrata</i> (<i>Candida</i> spp. Group 2)	1.44E+08	t0	9 / 9	100.00%
		t1a	9 / 9	100.00%
		t1b	9 / 9	100.00%
<i>Staphylococcus capitis/hominis</i>	3.45E+09	t0	10 / 10	100.00%
		t1a	9 / 9	100.00%
		t1b	9 / 9	100.00%
<i>Corynebacterium striatum</i> (<i>Corynebacterium</i>)	1.29E+09	t0	9 / 9	100.00%
		t1a	9 / 9	100.00%
		t1b	9 / 9	100.00%
<i>Staphylococcus aureus</i> Erm(C) Tet(K) MecA	1.03E+08	t0	9 / 9	100.00%
		t1a	9 / 9	100.00%
		t1b	9 / 9	100.00%
<i>Staphylococcus epidermidis</i> Aac(6') aph(2') MecA Erm(A)	1.57E+09	t0	10 / 10	100.00%
		t1a	9 / 9	100.00%
		t1b	9 / 9	100.00%
<i>Streptococcus pyogenes</i> (GAS)	2.28E+07	t0	9 / 9	100.00%
		t1a	9 / 9	100.00%
		t1b	9 / 9	100.00%
<i>Acinetobacter baumannii</i> (Pan Gram Neg)	4.16E+08	t0	9 / 9	100.00%
		t1a	9 / 9	100.00%
		t1b	9 / 9	100.00%
<i>Staphylococcus epidermidis</i> Aac(6') aph(2') MecA cfr	5.65E+08	t0	9 / 9	100.00%
		t1a	12 / 12	100.00%
		t1b	15 / 15	100.00%
<i>Staphylococcus epidermidis</i> Aac(6') aph(2') MecA cfr	1.50E+09	t0	3 / 3	100.00%
		t1a	6 / 6	100.00%
<i>Staphylococcus aureus</i> MecC	4.33E+08	t0	9 / 9	100.00%
		t1a	9 / 9	100.00%
		t1b	9 / 9	100.00%
<i>Bacillus cereus</i> group	4.23E+06	t0	9 / 9	100.00%
		t1a	9 / 9	100.00%
		t1b	9 / 9	100.00%
<i>Micrococcus luteus</i> (<i>Micrococcus</i> spp.)	2.01E+08	t0	9 / 9	100.00%
		t1a	14 / 14	100.00%
		t1b	19 / 20	95.00%
<i>Cryptococcus gattii</i> (<i>Cryptococcus neoformans/gattii</i>)	1.62E+07	t0	9 / 9	100.00%
		t1a	9 / 9	100.00%
		t1b	9 / 9	100.00%
<i>Streptococcus pneumoniae</i>	N/A**	t0	9 / 9	100.00%
		t1b	9 / 9	100.00%

<i>Streptococcus pneumoniae</i>	N/A**	t0	9 / 9	100.00%
		t1a	9 / 9	100.00%
<i>Fusarium proliferatum</i> (<i>Fusarium</i>)	4.83E+06	t0	9 / 9	100.00%
		t1a	9 / 9	100.00%
		t1b	9 / 9	100.00%
<i>Candida auris</i>	7.27E+07	t0	9 / 9	100.00%
		t1a	9 / 9	100.00%
		t1b	9 / 9	100.00%

* Culture/testing was repeated

** Enumeration not possible due reduced viability

Fresh Versus Frozen Study

A fresh versus frozen study was conducted to demonstrate that storage of Positive Blood Culture Matrix (PBCM) specimens at -90°C to -60°C for long periods and with ≤ two freeze-thaw cycles does not impact the performance of the QIAstat-Dx BCID GPF Plus AMR Panel compared to fresh samples. Organisms tested and concentrations are listed in **Table 16**. Twenty-two sample mixtures were prepared containing all panel targets, and aliquots of samples were tested in triplicate after each cycle alongside T0 samples (no freeze-thaw). Results for overall detection of the expected targets at each time point are shown in **Table 17**. A 100% positive hit rate was obtained for all expected targets except *C. albicans*. The dropouts observed for *C. albicans* were the result of poor viability of the strain in culture resulting in test concentrations below the established LoD for that organism.

Table 16. List of Organisms and Test Concentrations for Fresh Versus Frozen Study

Target	Organism	Concentration (CFU/mL)		
		Bottle 1	Bottle 2	Bottle 3
<i>Streptococcus agalactiae</i> (GBS)	<i>Streptococcus agalactiae</i>	2.21E+09	2.16E+09	1.97E+09
<i>Streptococcus anginosus</i> group	<i>Streptococcus anginosus</i>	1.36E+08	1.46E+07	1.22E+08
<i>Enterococcus faecalis</i> Aac(6') aph(2') VanB	<i>Enterococcus faecalis</i>	1.88E+08	1.82E+08	2.50E+08
<i>Enterococcus faecium</i> VanA	<i>Enterococcus faecium</i>	5.61E+08	5.56E+08	5.85E+08
<i>Staphylococcus lugdunensis</i>	<i>Staphylococcus lugdunensis</i>	1.84E+08	1.50E+08	1.29E+08
<i>Listeria monocytogenes</i>	<i>Listeria monocytogenes</i>	1.60E+08	2.06E+08	1.74E+08
<i>Candida</i> spp. Group 1	<i>Candida albicans</i>	3.96E+04	2.63E+04	4.88E+04
<i>Candida auris</i>	<i>Candida auris</i>	1.16E+07	1.31E+07	1.73E+07
<i>Staphylococcus capitis/hominis</i>	<i>Staphylococcus capitis</i>	5.17E+06	3.19E+06	4.56E+06
<i>Corynebacterium</i>	<i>Corynebacterium striatum</i>	4.29E+07	6.96E+07	2.14E+08
<i>Staphylococcus aureus</i> Erm(C) Tet(K) Meca	<i>Staphylococcus aureus</i>	2.20E+07	2.47E+07	1.97E+07
<i>Staphylococcus epidermidis</i> Erm(A)	<i>Staphylococcus epidermidis</i>	1.60E+08	1.34E+07	2.64E+07
<i>Streptococcus pyogenes</i> (GAS)	<i>Streptococcus pyogenes</i>	4.59E+08	3.99E+08	4.36E+08
Pan Gram Neg	<i>Acinetobacter baumannii</i>	4.02E+08	4.31E+08	5.46E+08
<i>Staphylococcus epidermidis</i> Aac(6') aph(2') Meca cfr	<i>Staphylococcus epidermidis</i>	6.56E+07	6.26E+07	6.59E+07
<i>Staphylococcus aureus</i> MecC	<i>Staphylococcus aureus</i>	2.33E+06	4.21E+06	4.37E+06
<i>Bacillus cereus</i> group	<i>Bacillus cereus</i>	2.30E+08	1.79E+08	1.53E+08

<i>Micrococcus</i> spp.	<i>Micrococcus luteus</i>	3.59E+07	1.19E+07	1.19E+08
<i>Cryptococcus neoformans/gattii</i>	<i>Cryptococcus gattii</i>	3.18E+06	2.08E+06	2.51E+06
<i>Streptococcus pneumoniae</i>	<i>Streptococcus pneumoniae</i>	6.00E+07	2.44E+08	1.13E+08
<i>Fusarium</i> spp.	<i>Fusarium proliferatum</i>	1.21E+05	1.21E+05	2.00E+05
<i>Candida auris</i>	<i>Candida auris</i>	7.76E+06	7.70E+06	6.51E+06
<i>Staphylococcus aureus</i> MecC	<i>Staphylococcus aureus</i>	5.08E+07	3.82E+06	2.56E+07
<i>Candida</i> spp. Group 2	<i>Candida glabrata</i>	3.70E+06	7.79E+06	3.35E+06

Table 17. Summary Results for Fresh Versus Frozen Study

Test Condition		Total Replicates	Positive Hits	Detection Hit Rate	Lower Confidence Interval	Upper Confidence Interval
# Freeze-Thaw Cycles	Mean Days from T0					
N/A	N/A	198	198	100 %	98.15%	100%
1	42	66	65	98.48 %	91.84%	99.96%
2	79	66	65	98.48 %	91.84%	99.96%
3	142	66	66	100 %	94.56%	100%
1	140	54	53	98.15 %	90.11%	99.95%
2	874	66	64	96.97%	89.48%	99.63%

In-Use Sample Stability

An in-use sample stability study of the QIAstat-Dx BCID GPF Plus AMR Panel was conducted to demonstrate stability of samples once samples are applied to cartridges and loaded into the instrument but prior to initiation of the test run. One positive sample mix was used, including eight target organisms spiked into NBCM (Negative Blood Culture Matrix) at ~3x LoD.

Table 18. List of Organisms and Test Concentrations for In-Use Stability Study

Target	Organism(s)	Concentration (T0) (CFU/mL)	Concentration (T7-13) (CFU/mL)
MecC	<i>E. faecalis</i>	NA	NA
VanB	<i>S. aureus</i>	NA	NA
<i>Cryptococcus neoformans/gattii</i>	<i>Cryptococcus gattii</i>	3.00E+04	3.16E+04
<i>Enterococcus faecalis</i>	<i>E. faecalis</i>	1.50E+06	6.70E+05
<i>Streptococcus anginosus</i> group	<i>S. intermedius</i> (T0) <i>S. anginosus</i> (T7-13)	2.63E+05	7.74E+04
<i>Staphylococcus aureus</i>	<i>S. aureus</i>	1.43E+04	1.50E+04
Aac(6') aph(2')	<i>E. faecalis</i>	NA	NA
<i>Listeria monocytogenes</i>	<i>L. monocytogenes</i>	1.07E+07	6.70E+04

Sample mixes were tested in replicates of eight in cartridge lots stored for 0, 7, 10 and 13 months under the following conditions.

- Opening and removing the cartridge from the aluminum pouch (primary packaging) and storing at 25°C ± 2°C for 30 minutes.

- Loading samples into the cartridge and keeping at 25°C ± 2°C for an additional 100 minutes.

Samples were run along samples held under control conditions where there were no delays in laboratory workflow. Results are shown in **Table 19** below.

Table 19. Summary Results for In-Use Stability Study

Targets	Detection Rate			
	T0	T7	T10	T13
MecC	8/8	8/8	8/8	8/8
VanB	8/8	8/8	8/8	8/8
<i>Cryptococcus neoformans/gattii</i>	8/8	8/8	8/8	8/8
<i>Enterococcus faecalis</i>	8/8	8/8	8/8	8/8
<i>Streptococcus anginosus</i> group	8/8	8/8	8/8	8/8
<i>Staphylococcus aureus</i>	8/8	8/8	8/8	8/8
Aac(6') aph(2')	8/8	8/8	8/8	8/8
<i>Listeria monocytogenes</i>	8/8	8/8	8/8	8/8

Expected Values (Controls)

Each QIAstat-Dx BCID GPF Plus AMR Panel cartridge includes an internal processing control that monitors performance of the test process, including extraction, amplification and detection of targets. External controls are not provided with the QIAstat-Dx BCID GPF Plus AMR Panel but are recommended in the package insert.

6. Assay Cut-Off:

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

7. Carryover:

Carryover of the QIAstat-Dx BCID GPF Plus AMR Panel on the QIAstat-Dx Analyzer 2.0 was evaluated for the potential of cross-contamination between consecutive runs using the checkerboard approach. Samples of blood culture media with alternating high-positive (at least 1.00E+09 CFU/mL) and negative samples were tested on two instruments during 22 runs over five 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:

Thirteen blood culture media bottles are compatible with the QIAstat-Dx BCID GPF Plus AMR Panel:

- 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

A matrix equivalency study was conducted to evaluate equivalence of the different blood culture bottle matrices from three different blood culture systems on the QIAstat-Dx BCID GPF Plus AMR Panel. A minimum of two lots per media bottle type were used, except for the BACTEC Standard Aerobic and BACTEC Standard Anaerobic bottles for which a single bottle lot was used. Two different sample preparation methods were utilized. For BACTEC and BACT/ALERT bottles, contrived positive blood cultures matrix (PBCM) samples were prepared by inoculating whole blood with representative target microorganisms into the blood culture media bottles. The bottles were then incubated on the corresponding blood culture instrument “bottle ring positive”. For VersaTREK bottles, the instrument was not available, so bottles were contrived by incubating with negative whole blood in a standard laboratory incubator at 37°C for five days and then spiking with representative target organisms at the concentration equivalent to levels present when a bottle is flagged as positive. **Table 21** lists the tested organisms.

Table 20. List of Tested Organisms for Bottle Equivalency Study

Organism	Target(s)	Strain ID
<i>S. agalactiae</i>	<i>S. agalactiae</i>	ATCC 12401
<i>S. anginosus</i>	<i>S. anginosus</i> Group	CCUG 27298
<i>E. faecalis</i>	<i>E. faecalis</i> , Aac(6') aph(2'), VanB	ATCC 51299
<i>E. faecium</i>	<i>E. faecium</i> , VanA, Aac(6') aph(2')	ATCC 51559
<i>S. lugdunensis</i>	<i>S. lugdunensis</i>	CCUG 66510
<i>L. monocytogenes</i>	<i>L. monocytogenes</i>	CCUG 74245
<i>C. albicans</i>	<i>Candida</i> Group 1	ATCC 10231
	<i>Candida</i> Group 1	NR-29437 / P75010
	<i>Candida</i> Group 1	NR-29446 / P94015
	<i>Candida</i> Group 1	NR-29443 / P78042
	<i>Candida</i> Group 1	NR-29442 / P76067
<i>C. auris</i>	<i>Candida</i> Group 2	NCPF 8971
	<i>Candida</i> Group 2	CBS 12372
	<i>Candida</i> Group 2	NCPF 8977
	<i>Candida</i> Group 2	NCPF 8984
	<i>Candida</i> Group 2	CBS 14144
<i>S. capitis</i>	<i>S. capitis</i> , <i>S. hominis</i>	CCUG 42761
<i>C. striatum</i>	<i>Corynebacterium</i>	ATCC 43735
<i>S. aureus</i>	<i>S. aureus</i> , Erm(C), MecA, Tet(K), Tet(M)	ATCC BAA 1556

Organism	Target(s)	Strain ID
<i>S. epidermidis</i>	<i>S. epidermidis</i> , Erm(A)	ATCC 35984
<i>S. pyogenes</i>	<i>S. pyogenes</i>	ATCC 12384
<i>A. baumannii</i>	Pan Gram Negative	NCTC 13302
<i>S. aureus</i>	<i>S. aureus</i> , cfr, Tet(M), Tet(K), MecA	t011-ST398/CC398
	<i>S. aureus</i> , mecC	ATCC BAA 2313
<i>B. cereus</i>	<i>B. cereus</i> Group	ATCC 21769
<i>M. luteus</i>	<i>Micrococcus</i> spp.	NCTC 7011
<i>C. gattii</i>	<i>Cryptococcus</i> spp.	ATCC MYA-4071
<i>S. pneumoniae</i>	<i>S. pneumoniae</i>	CCUG 70149
<i>F. proliferatum</i>	<i>Fusarium</i> spp.	NCPF 7484
<i>C. dubliniensis</i>	<i>Candida</i> Group 1	NCPF 8516
<i>C. famata</i>	<i>Candida</i> Group 1	CBS 767
<i>C. guilliermondii</i>	<i>Candida</i> Group 1	NCPF 3896
<i>C. kefyr</i>	<i>Candida</i> Group 1	NCPF 8343
<i>C. tropicalis</i>	<i>Candida</i> Group 1	ATCC 750
<i>C. glabrata</i>	<i>Candida</i> Group 2	ATCC 15126
<i>C. krusei</i>	<i>Candida</i> Group 2	ATCC 32196
<i>C. lusitaniae</i>	<i>Candida</i> Group 2	CCUG 69483
<i>C. parapsilosis</i>	<i>Candida</i> Group 2	ATCC 58895
<i>C. auris</i>	<i>Candida auris</i>	NCPF 8971
<i>S. aureus</i>	<i>S. aureus</i> , mecC	ATCC BAA 2313
<i>C. glabrata</i>	<i>Candida</i> Group 2	ATCC 15126

False positive results were observed during testing for *Micrococcus* spp. (4), *Enterococcus faecium* (1), *Enterococcus faecalis* (7), *Candida* Group 1 (1), *Corynebacterium* (1), *Candida* Group 2 (2), *Staphylococcus capitis/hominis* (1), Erm(C) (4), and MecA (4). Results are shown in **Table 21**. Twenty (20) false negative results were observed during testing and were shown in **Table 22**. Decreased sensitivity was observed for *C. auris* in BACTEC Lytic Anaerobic, BACT/Alert SN Standard Anaerobic, and VersaTREK Redox 2 EZ Draw Anaerobic bottle types and is noted as a limitation in the package labeling.

Table 21. Summary Results of Matrix Equivalency Study by Bottle Type

Bottle Type	Hits	N	% Agreement (95% CI)
BACTEC Plus Aerobic	199	200	99.5% (97.3-100%)
BACTEC Plus Anaerobic	150	150	100.0% (97.6-100%)
BACTEC Standard Aerobic	198	200	99.0% (96.4-99.9%)
BACTEC Standard Anaerobic	138	143	96.5% (92.0-98.9%)
BACTEC Peds Plus	198	200	99.0% (96.4-99.9%)
BACTEC Lytic Anaerobic	154	158	97.5% (93.7-99.3%)
BACT/ALERT SA Standard Aerobic	200	200	100.0% (98.2-100%)
BACT/ALERT SN Standard Anaerobic	187	189	98.9% (96.2-99.9%)
BACT/ALERT FA PLUS Aerobic	199	200	99.5% (97.2-100%)
BACT/ALERT FN PLUS Anaerobic	133	134	99.3% (96.0-100%)
BACT/ALERT PF PLUS Peds	201	201	100.0% (98.2-100%)

Versatrek Redox 1	184	184	100.0% (98.0-100%)
Versatrek Redox 2 EZ Draw Anaerobic	182	184	98.9% (96.1-99.9%)

Table 22. Summary of False Negative Results by Organism

Pathogen/Target	Bottle Type	Detection Rate
<i>C. albicans</i>	BACTEC Standard Anaerobic	28/30 (93.3%)
<i>C. albicans</i>	BACTEC Standard Aerobic	27/28 (96.4%)
<i>C. albicans</i>	BACTEC Peds Plus	26/28 (92.9%)
<i>C. albicans</i>	BACTEC Plus Aerobic	34/36 (94.4%)
	BACTEC Standard Aerobic	
	Total	147/154 (95.5%)
<i>C. dubliniensis</i>	BACT/ALERT FA PLUS Aerobic	36/38 (94.7%)
	VersaTREK Redox 2 EZ Draw Anaerobic	
<i>C. tropicalis</i>	BACTEC Standard Anaerobic	44/48 (91.7%)
	BACT/ALERT FN PLUS Anaerobic	
<i>S. aureus</i> MecA	BACTEC Lytic Anaerobic	52/54 (96.3%)
<i>C. auris</i>	VersaTREK Redox 2 EZ Draw Anaerobic	33/38 (87.0%)
	BACTEC Lytic Anaerobic	
	BACT/ALERT SN Standard Anaerobic	

C Clinical Studies:

1. Clinical Study:

Clinical performance of the QIAstat-Dx BCID GPF Plus AMR Panel was established in a multi-center prospective study. The study was conducted at 8 U.S. and 2 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 (clinical laboratories) and testing was performed by trained clinical laboratory personnel. Residual PBCM specimens from subjects meeting inclusion criteria were prospectively collected between November 2023 and May 2025 and either stored frozen or tested within the stability claims for fresh specimens. A total of 1,687 prospective and 421 retrospective PBCM specimens were collected. Of the 2,108 PBCM specimens, 1,024 prospective and 282 retrospective, archived PBCM specimens were enrolled for the clinical evaluation. Performance analysis of the QIAstat-Dx BCID GPF Plus AMR Panel consisted of 976 prospective and 281 retrospective PBCM specimens. Forty-six prospective specimens were excluded due to a change in the test procedure implemented after the study initiation, *i.e.*, 1:1 dilution in saline of BACT/ALERT and BACTEC bottles. One specimen was excluded due to incorrect testing and one specimen failed to generate a valid result on the QIAstat-Dx BCID GPF Plus AMR even after repeat testing. One retrospective specimen failed to generate a valid result after repeat testing. **Table 23** lists the site information about the collected specimens. **Tables 24 and 25** show the demographic information for prospectively collected samples. **Table 26** shows the demographic information for retrospectively collected samples

Table 23. List of Enrollment and Exclusions of Clinical Specimens by Site

	Prospective Fresh	Prospective Frozen	Retrospective	Total
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Site	Eligible	Evaluable	Eligible	Evaluable	Eligible	Evaluable	Eligible	Evaluable
1	122	118	1	1	56	56	179	175
2	121	121	0	0	14	14	135	135
3	91	82	9	9	0	0	100	91
4	105	94	0	0	6	6	111	100
5	85	78	0	0	33	32	118	110
6	38	37	10	10	0	0	48	47
7	113	113	39	39	0	0	152	152
8	111	95	0	0	0	0	111	95
9	91	91	0	0	173	173	264	264
10	87	87	1	1	0	0	88	88
Total	964	916	60	60	282	281	1306	1257

Table 24. Demographic Data for Evaluable Prospective Specimens

Specimen Type	Variable	Subgroup	N	%
Prospective Fresh	Age group	< 1 year	15	1.7
		1-17 years	16	1.8
		18-44 years	140	15.4
		45-64 years	262	28.9
		65-89 years	434	47.9
		90+ years	40	4.4
	Sex	Female	387	42.7
		Male	519	57.2
		Not Reported	1	0.1
Prospective Frozen	Age group	1-17 years	1	1.4
		18-44 years	8	11.6
		45-64 years	18	26.1
		65-89 years	39	56.5
		90+ years	3	4.3
	Sex	Female	40	58.0
		Male	29	42.0
Prospective Total	Age group	< 1 year	15	1.5
		1-17 years	17	1.7
		18-44 years	148	15.2
		45-64 years	280	28.7
		65-89 years	473	48.5
		90+ years	43	4.4
	Sex	Female	427	43.8
		Male	548	56.2
		Not Reported	1	0.0

Table 25. Summary of Blood Culture Bottle Types for Evaluable Prospective Specimens

Sample Type	Bottle Type	N	%
Prospective Fresh	BACTEC Lytic Anaerobic	191	21.1
	BACTEC PedPlus	18	2.0
	BACTEC Plus Aerobic	306	33.7
	BACTEC Plus Anaerobic	23	2.5
	BACT/Alert FA	121	13.3
	BACT/Alert FN	74	8.2
	BACT/Alert PF	53	5.8

Prospective Frozen	VersaTREK REDOX1 EZ Draw	104	11.5
	VersaTREK REDOX2 EZ Draw	17	1.9
	BACTEC Lytic Anaerobic	9	13.0
	BACTEC Plus Aerobic	10	14.5
	BACT/Alert FA	20	29.0
	BACT/Alert FN	13	18.8
	BACT/Alert PF	17	24.6
Prospective Total	BACTEC Lytic Anaerobic	200	20.5
	BACTEC PedPlus	18	1.8
	BACTEC Plus Aerobic	316	32.4
	BACTEC Plus Anaerobic	23	2.4
	BACT/Alert FA	141	14.4
	BACT/Alert FN	87	8.9
	BACT/Alert PF	70	7.2
	VersaTREK REDOX1 EZ Draw	104	10.7
	VersaTREK REDOX2 EZ Draw	17	1.7

Table 26. Demographic Data for Evaluable Retrospective Specimens

Specimen Type	Variable	Subgroup	N	%
Retrospective Archived	Age group	< 1 year	3	1.1
		1-17 years	7	2.5
		18-44 years	41	14.6
		45-64 years	77	27.4
		65-89 years	144	51.2
		90+ years	9	3.2
	Sex	Female	134	47.7
		Male	147	52.3
		Not Reported	3	1.1

Results of the QIAstat-Dx BCID GPF Plus AMR Panel were compared to standard laboratory procedures, including traditional and automated culture, MALDI-TOF MS, and microbiological and biochemical techniques for organism identification, and validated polymerase chain reaction (PCR) assays followed by bi-directional sequencing (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 27**.

Table 27. List of Comparator Method(s) by Panel Target

Target	Comparator Method(s)	Discordant Method(s)
<i>Bacillus cereus</i> group <i>Corynebacterium</i> <i>Enterococcus faecalis</i> <i>Enterococcus faecium</i> <i>Listeria monocytogenes</i> <i>Micrococcus</i> spp. <i>Staphylococcus aureus</i> <i>Staphylococcus epidermidis</i> <i>Staphylococcus lugdunensis</i>	Standard of Care and standard laboratory procedures for organism identification at each testing site	cobas eplex or MALDI-TOF MS

<i>Streptococcus agalactiae</i>		
<i>Streptococcus anginosus</i> group		
<i>Streptococcus pneumoniae</i>		
<i>Streptococcus pyogenes</i>		
<i>Staphylococcus capitis</i> / <i>hominis</i>		PCR-BDS
Pan Gram-Negative Assay		N/A
<i>Cryptococcus neoformans</i> / <i>gattii</i>		cobas eplex
<i>Fusarium</i>		
<i>Candida auris</i>		
Pan <i>Candida</i> Assay Group 1		
Pan <i>Candida</i> Assay Group 2		
Aac(6')-aph(2') cfr Erm(A) Erm(C) MecA MecC Tet(K) Tet(M) VanA VanB	PCR-BDS from the positive blood culture specimen	N/A

Positive percent agreement (PPA) was calculated by dividing the number of true positive (TP) results by the sum of TP and false negative (FN) results, while negative percent agreement (NPA) was calculated by dividing the number of true negative (TN) results by the sum of TN and false positive (FP) results. PPA and NPA were calculated for each target and reported as proportions and percentages with two-sided 95% confidence intervals (Wilson score method). Discordant results analysis was performed and reported as footnotes in the clinical performance tables. Positive results flagged with Internal Control (IC) warnings were included in the PPA. 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 28 to 31** according to target organism and resistance marker. Results of performance for retrospective, archived PBCM specimens are presented in **Tables 32 to 34**.

Table 28. Clinical Performance for Prospective Samples by Target Organism

Organism	Sample	TP/(TP+FN)	PPA (%)	95% CI	TN/(TN+FP)	NPA (%)	95% CI
<i>Bacillus cereus</i> group*	Prospective Fresh	5 / 6	83.3	43.6 - 97.0	901 / 901	100.0	99.6 - 100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7 - 100.0
	Total	5 / 6	83.3	43.6 - 97.0	970 / 970	100.0	99.6 - 100.0
<i>Corynebacterium</i> †	Prospective Fresh	12 / 14	85.7	60.1 - 96.0	880 / 893	98.5	97.5 - 99.1
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7 - 100.0
	Total	12 / 14	85.7	60.1 - 96.0	949 / 962	98.6	97.7 - 99.2
<i>Enterococcus faecalis</i> ‡	Prospective Fresh	48 / 48	100.0	92.6 - 100.0	859 / 859	100.0	99.6 - 100.0
	Prospective Frozen	6 / 7	85.7	48.7 - 97.4	62 / 62	100.0	94.2 - 100.0
	Total	54 / 55	98.2	90.4 - 99.7	921 / 921	100.0	99.6 - 100.0
<i>Enterococcus faecium</i> §	Prospective Fresh	29 / 29	100.0	88.3 - 100.0	871 / 878	99.2	98.4 - 99.6
	Prospective Frozen	1 / 1	100.0	20.7 - 100.0	64 / 68	94.1	85.8 - 97.7
	Total	30 / 30	100.0	88.6 - 100.0	935 / 946	98.8	97.9 - 99.3
<i>Listeria monocytogenes</i> ¶	Prospective Fresh	3 / 3	100.0	43.9 - 100.0	903 / 904	99.9	99.4 - 100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7 - 100.0
	Total	3 / 3	100.0	43.9 - 100.0	972 / 973	99.9	99.4 - 100.0
<i>Micrococcus</i> spp. **	Prospective Fresh	17 / 23	73.9	53.5 - 87.5	884 / 884	100.0	99.6 - 100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7 - 100.0
	Total	17 / 23	73.9	53.5 - 87.5	953 / 953	100.0	99.6 - 100.0
<i>Staphylococcus aureus</i> ††	Prospective Fresh	206 / 208	99.0	96.6 - 99.7	696 / 699	99.6	98.7 - 99.9
	Prospective Frozen	13 / 13	100.0	77.2 - 100.0	55 / 56	98.2	90.6 - 99.7
	Total	219 / 221	99.1	96.8 - 99.8	751 / 755	99.5	98.6 - 99.8

Organism	Sample	TP/(TP+FN)	PPA (%)	95% CI	TN/(TN+FP)	NPA (%)	95% CI
<i>Staphylococcus epidermidis</i> ^{††}	Prospective Fresh	228 / 232	98.3	95.7 - 99.3	662 / 675	98.1	96.7 - 98.9
	Prospective Frozen	26 / 28	92.9	77.4 - 98.0	41 / 41	100.0	91.4 - 100.0
	Total	254 / 260	97.7	95.1 - 98.9	703 / 716	98.2	96.9 - 98.9
<i>Staphylococcus lugdunensis</i> ^{§§}	Prospective Fresh	7 / 7	100.0	64.6 - 100.0	898 / 900	99.8	99.2 - 99.9
	Prospective Frozen	0 / 0	N/A	N/A	68 / 69	98.6	92.2 - 99.7
	Total	7 / 7	100.0	64.6 - 100.0	966 / 969	99.7	99.1 - 99.9
<i>S. capitis</i> / <i>S. hominis</i> ^{¶¶}	Prospective Fresh	110 / 113	97.3	92.5 - 99.1	770 / 794	97.0	95.5 - 98.0
	Prospective Frozen	3 / 3	100.0	43.9 - 100.0	60 / 66	90.9	81.6 - 95.8
	Total	113 / 116	97.4	92.7 - 99.1	830 / 860	96.5	95.1 - 97.5
<i>Streptococcus agalactiae</i> ^{***}	Prospective Fresh	26 / 28	92.9	77.4 - 98.0	879 / 879	100.0	99.6 - 100.0
	Prospective Frozen	1 / 1	100.0	20.7 - 100.0	68 / 68	100.0	94.7 - 100.0
	Total	27 / 29	93.1	78.0 - 98.1	947 / 947	100.0	99.6 - 100.0
<i>Streptococcus anginosus</i> group ^{†††}	Prospective Fresh	11 / 11	100.0	74.1 - 100.0	895 / 896	99.9	99.4 - 100.0
	Prospective Frozen	1 / 1	100.0	20.7 - 100.0	68 / 68	100.0	94.7 - 100.0
	Total	12 / 12	100.0	75.8 - 100.0	963 / 964	99.9	99.4 - 100.0
<i>Streptococcus pneumoniae</i> ^{‡‡‡}	Prospective Fresh	27 / 27	100.0	87.5 - 100.0	877 / 880	99.7	99.0 - 99.9
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7 - 100.0
	Total	27 / 27	100.0	87.5 - 100.0	946 / 949	99.7	99.1 - 99.9
<i>Streptococcus pyogenes</i>	Prospective Fresh	22 / 22	100.0	85.1 - 100.0	885 / 885	100.0	99.6 - 100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7 - 100.0
	Total	22 / 22	100.0	85.1 - 100.0	954 / 954	100.0	99.6 - 100.0
<i>Cryptococcus neoformans/gattii</i>	Prospective Fresh	2 / 2	100.0	34.2 - 100.0	905 / 905	100.0	99.6 - 100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7 - 100.0
	Total	2 / 2	100.0	34.2 - 100.0	974 / 974	100.0	99.6 - 100.0
<i>Fusarium</i>	Prospective Fresh	0 / 0	N/A	N/A	907 / 907	100.0	99.6 - 100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7 - 100.0
	Total	0 / 0	N/A	N/A	976 / 976	100.0	99.6 - 100.0
<i>Candida auris</i>	Prospective Fresh	1 / 1	100.0	20.7 - 100.0	906 / 906	100.0	99.6 - 100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7 - 100.0
	Total	1 / 1	100.0	20.7 - 100.0	975 / 975	100.0	99.6 - 100.0
Pan Gram-Negative ^{§§§}	Prospective Fresh	13 / 16	81.3	57.0 - 93.4	891 / 891	100.0	99.6 - 100.0
	Prospective Frozen	13 / 13	100.0	77.2 - 100.0	56 / 56	100.0	93.6 - 100.0
	Total	26 / 29	89.7	73.6 - 96.4	947 / 947	100.0	99.6 - 100.0
<i>Candida</i> group 1 ^{¶¶¶}	Prospective Fresh	16 / 16	100.0	80.6 - 100.0	889 / 891	99.8	99.2 - 99.9
	Prospective Frozen	1 / 1	100.0	20.7 - 100.0	68 / 68	100.0	94.7 - 100.0
	Total	17 / 17	100.0	81.6 - 100.0	957 / 959	99.8	99.2 - 99.9
<i>Candida</i> group 2 ^{****}	Prospective Fresh	18 / 19	94.7	75.4 - 99.1	888 / 888	100.0	99.6 - 100.0
	Prospective Frozen	1 / 1	100.0	20.7 - 100.0	68 / 68	100.0	94.7 - 100.0
	Total	19 / 20	95.0	76.4 - 99.1	956 / 956	100.0	99.6 - 100.0

* For the false negative *Bacillus cereus* group discordant sample, no organisms were detected using PCR/BDS.

† Of the thirteen (13) false positive *Corynebacterium* samples, no organisms were detected using PCR/BDS. Of the two (2) false negative samples, the organism was detected using PCR/BDS in one (1) sample.

‡ For the false negative *Enterococcus faecalis* discordant sample, no PCR/BDS result was available.

§ Of the eleven (11) *Enterococcus faecium* false positive samples, no organisms were detected using PCR/BDS in seven (7) samples and no PCR/BDS results were available for the remaining four (4) samples.

¶ For the false positive *Listeria monocytogenes* discordant sample, organism was detected using PCR/BDS.

** For the six (6) false negative *Micrococcus* spp samples, organism was detected using PCR/BDS in four (4) samples, no organisms were detected in the remaining two (2) samples.

†† Of the four (4) false positive *Staphylococcus aureus* results, no organism was detected in three (3) samples with PCR/BDS; the organism was detected in the remaining false positive sample using PCR/BDS. Of the two (2) false negative samples, the organism was detected in one (1) sample using PCR/BDS; no organisms were detected in the remaining false negative sample.

‡‡ Of the thirteen (13) false positive *Staphylococcus epidermidis* samples, the organism was detected in eight (8) samples using PCR/BDS; no organisms were detected in the five (5) remaining samples using PCR/BDS. Of the six (6) false negative prospective samples, the organism was detected in one (1) sample using PCR/BDS.

§§ Of the three (3) false positive *Staphylococcus lugdunensis* samples, the organism was detected in one (1) sample using PCR/BDS, no organisms were detected in the second false positive sample, and no PCR/BDS results were available for the third false positive sample.

¶¶ Of the thirty (30) false positive *S. capitis* / *S. hominis* samples, organisms were detected in twenty-six (26) samples using PCR/BDS, no organisms were detected in one (1) sample with PCR/BDS, and no PCR/BDS results were available for the three (3) remaining false positive samples. Of the three (3) false negative prospective samples, organisms were detected in all samples using PCR/BDS.

**** Of the two (2) false positive *Streptococcus agalactiae* samples, no organisms were detected using PCR/BDS.

††† For the false positive *Streptococcus anginosus* group sample, no organisms were detected using PCR/BDS.

‡‡‡ Of the three (3) false positive *Streptococcus pneumoniae* samples, no organisms were detected using PCR/BDS.

§§§ Of the three (3) false negative Pan Gram-Negative samples, no PCR/BDS results were available.

¶¶¶ Of the two (2) false positive *Candida* group 1 sample, no organisms were detected using PCR/BDS.

**** For the false negative *Candida* group 2 sample, no PCR/BDS results were available.

Table 29. Clinical Performance for Genus Level and Pan Targets Stratified by Species

Species	Prospective			Retrospective Archived			Contrived			Total		
	TP/ (TP+F N)	%	95% CI	TP/ (TP+F N)	%	95% CI	TP/ (TP+F N)	%	95% CI	TP/ (TP+F N)	%	95% CI
<i>Bacillus cereus</i> group	5 / 6	83.3	43.6- 97.0	10 / 12	83.3	55.2- 95.3	50 / 50	100.0	92.9- 100.0	65 / 68	95.6	87.8- 98.5
<i>B. cereus</i>	3 / 3	100.0	43.9- 100.0	8 / 10	80.0	49.0- 94.3	40 / 40	100.0	91.2- 100.0	51 / 53	96.2	87.2- 99.0
<i>B. cereus</i> group (not specified)	2 / 2	100.0	34.2- 100.0	1 / 1	100.0	20.7- 100.0	0/0	N/A	N/A	3 / 3	100.0	43.9- 100.0
<i>B. mycoides</i>	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>B. thuringiensis</i>	0/0	N/A	N/A	1 / 1	100.0	20.7- 100.0	10 / 10	100.0	72.2- 100.0	11 / 11	100.0	74.1- 100.0
<i>Corynebacterium</i>	12 / 14	85.7	60.1- 96.0	33 / 36	91.7	78.2- 97.1	0/0	N/A	N/A	45 / 50	90.0	78.6- 95.7
<i>Corynebacterium</i>	6 / 7	85.7	48.7- 97.4	1 / 3	33.3	6.1- 79.2	0/0	N/A	N/A	7 / 10	70.0	39.7- 89.2
<i>C. afermentans</i>	1 / 1	100.0	20.7- 100.0	5 / 5	100.0	56.6- 100.0	0/0	N/A	N/A	6 / 6	100.0	61.0- 100.0
<i>C. amycolatum</i>	0/0	N/A	N/A	2 / 2	100.0	34.2- 100.0	0/0	N/A	N/A	2 / 2	100.0	34.2- 100.0
<i>C. aurimucosum</i>	0/0	N/A	N/A	5 / 5	100.0	56.6- 100.0	0/0	N/A	N/A	5 / 5	100.0	56.6- 100.0
<i>C. bovis</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>C. coylea</i>	0/0	N/A	N/A	2 / 2	100.0	34.2- 100.0	0/0	N/A	N/A	2 / 2	100.0	34.2- 100.0
<i>C. glucuronolyticum</i>	0/0	N/A	N/A	1 / 1	100.0	20.7- 100.0	0/0	N/A	N/A	1 / 1	100.0	20.7- 100.0
<i>C. imitans</i>	0/0	N/A	N/A	3 / 3	100.0	43.9- 100.0	0/0	N/A	N/A	3 / 3	100.0	43.9- 100.0
<i>C. jeikeium</i>	0/0	N/A	N/A	1 / 1	100.0	20.7- 100.0	0/0	N/A	N/A	1 / 1	100.0	20.7- 100.0
<i>C. minutissimum</i>	0/0	N/A	N/A	2 / 2	100.0	34.2- 100.0	0/0	N/A	N/A	2 / 2	100.0	34.2- 100.0
<i>C. mucifaciens</i>	0/0	N/A	N/A	4 / 4	100.0	51.0- 100.0	0/0	N/A	N/A	4 / 4	100.0	51.0- 100.0
<i>C. pyruviceproduces</i>	0/0	N/A	N/A	1 / 1	100.0	20.7- 100.0	0/0	N/A	N/A	1 / 1	100.0	20.7- 100.0
<i>C. simulans</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>C. singulare</i>	0/0	N/A	N/A	2 / 3	66.7	20.8- 93.9	0/0	N/A	N/A	2 / 3	66.7	20.8- 93.9
<i>C. striatum</i>	3 / 4	75.0	30.1- 95.4	3 / 3	100.0	43.9- 100.0	0/0	N/A	N/A	6 / 7	85.7	48.7- 97.4
<i>C. tuberculostearicum</i>	0/0	N/A	N/A	1 / 1	100.0	20.7- 100.0	0/0	N/A	N/A	1 / 1	100.0	20.7- 100.0
<i>Micrococcus</i> spp.	17 / 23	73.9	53.5- 87.5	34 / 36	94.4	81.9- 98.5	0/0	N/A	N/A	51 / 59	86.4	75.5- 93.0
<i>M. flavus</i>	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>M. luteus</i>	12 / 15	80.0	54.8- 93.0	34 / 36	94.4	81.9- 98.5	0/0	N/A	N/A	46 / 51	90.2	79.0- 95.7
<i>Micrococcus</i> (not specified)	5 / 7	71.4	35.9- 91.8	0/0	N/A	N/A	0/0	N/A	N/A	5 / 7	71.4	35.9- 91.8
<i>Fusarium</i>	0 / 0	N/A	N/A	1 / 1	100.0	20.7- 100.0	49 / 50	98.0	89.5- 99.6	50 / 51	98.0	89.7- 99.7
<i>F. annulatum</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>F. petrophilum</i>	0/0	N/A	N/A	0/0	N/A	N/A	9 / 10	90.0	59.6- 98.2	9 / 10	90.0	59.6- 98.2

Species	Prospective			Retrospective Archived			Contrived			Total		
	TP/ (TP+F N)	%	95% CI	TP/ (TP+F N)	%	95% CI	TP/ (TP+F N)	%	95% CI	TP/ (TP+F N)	%	95% CI
<i>F. proliferatum</i>	0/0	N/A	N/A	1 / 1	100.0	20.7- 100.0	0/0	N/A	N/A	1 / 1	100.0	20.7- 100.0
<i>F. sacchari</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>F. solani</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>F. verticilloides</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
Pan Gram-Negative	26 / 29	89.7	73.6- 96.4	6 / 6	100.0	61.0- 100.0	0/0	N/A	N/A	32 / 35	91.4	77.6- 97.0
<i>Acinetobacter calcoaceticus-baumannii</i> complex	0/0	N/A	N/A	1 / 1	100.0	20.7- 100.0	0/0	N/A	N/A	1 / 1	100.0	20.7- 100.0
<i>Bacteroides fragilis</i>	0/0	N/A	N/A	4 / 4	100.0	51.0- 100.0	0/0	N/A	N/A	4 / 4	100.0	51.0- 100.0
<i>Enterobacter cloacae</i> complex	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>Enterobacteriales</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>Escherichia coli</i>	11 / 11	100.0	74.1- 100.0	1 / 1	100.0	20.7- 100.0	0/0	N/A	N/A	12 / 12	100.0	75.8- 100.0
<i>Klebsiella pneumonia</i>	6 / 6	100.0	61.0- 100.0	1 / 1	100.0	20.7- 100.0	0/0	N/A	N/A	7 / 7	100.0	64.6- 100.0
<i>Proteus mirabilis</i>	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>Pseudomonas aeruginosa</i>	2 / 3	66.7	20.8- 93.9	0/0	N/A	N/A	0/0	N/A	N/A	2 / 3	66.7	20.8- 93.9
<i>Pseudomonas putida</i> group	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>Salmonella</i> spp.	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>	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
Candida group 1	17 / 17	100.0	81.6- 100.0	2 / 2	100.0	34.2- 100.0	50 / 50	100.0	92.9- 100.0	69 / 69	100.0	94.7- 100.0
<i>Candida albicans</i>	10 / 10	100.0	72.2- 100.0	1 / 1	100.0	20.7- 100.0	10 / 10	100.0	72.2- 100.0	21 / 21	100.0	84.5- 100.0
<i>Candida dubliniensis</i>	2 / 2	100.0	34.2- 100.0	1 / 1	100.0	20.7- 100.0	10 / 10	100.0	72.2- 100.0	13 / 13	100.0	77.2- 100.0
<i>Candida guilliermondii</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>Candida kefyr</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>Candida tropicalis</i>	5 / 5	100.0	56.6- 100.0	0/0	N/A	N/A	10 / 10	100.0	72.2- 100.0	15 / 15	100.0	79.6- 100.0
Candida group 2	19 / 20	95.0	76.4- 99.1	9 / 9	100.0	70.1- 100.0	50 / 50	100.0	92.9- 100.0	78 / 79	98.7	93.2- 99.8
<i>C. lusitanae</i>	1 / 1	100.0	20.7- 100.0	1 / 1	100.0	20.7- 100.0	10 / 10	100.0	72.2- 100.0	12 / 12	100.0	75.8- 100.0
<i>C. parapsilosis</i>	6 / 7	85.7	48.7- 97.4	0/0	N/A	N/A	10 / 10	100.0	72.2- 100.0	16 / 17	94.1	73.0- 99.0
<i>N. glabrata</i> (<i>C. glabrata</i>)	13 / 13	100.0	77.2- 100.0	7 / 7	100.0	64.6- 100.0	20 / 20	100.0	83.9- 100.0	40 / 40	100.0	91.2- 100.0
<i>Pichia kudriavzevii</i> (<i>C. krusei</i>)	0/0	N/A	N/A	1 / 1	100.0	20.7- 100.0	10 / 10	100.0	72.2- 100.0	11 / 11	100.0	74.1- 100.0

Table 30. Clinical Performance for Prospective Samples by Target Resistance Marker

Target	Sample	TP/(TP+FN)	PPA (%)	95% CI	TN/(TN+FP)	NPA (%)	95% CI
<i>cfr</i>	Prospective Fresh	0 / 0	N/A	N/A	586 / 586	100.0%	99.3% - 100.0%
	Prospective Frozen	0 / 0	N/A	N/A	40 / 40	100.0%	91.2% - 100.0%
	Total	0 / 0	N/A	N/A	626 / 626	100.0%	99.4% - 100.0%
<i>erm(A)</i>	Prospective Fresh	39 / 43	90.7%	78.4% - 96.3%	647 / 652	99.2%	98.2% - 99.7%

	Prospective Frozen	5 / 5	100.0%	56.6% - 100.0%	41 / 42	97.6%	87.7% - 99.6%
	Total	44 / 48	91.7%	80.4% - 96.7%	688 / 694	99.1%	98.1% - 99.6%
<i>erm(C)</i>	Prospective Fresh	124 / 141	87.9%	81.5% - 92.3%	536 / 544	98.5%	97.1% - 99.3%
	Prospective Frozen	12 / 12	100.0%	75.8% - 100.0%	34 / 34	100.0%	89.8% - 100.0%
	Total	136 / 153	88.9%	82.9% - 92.9%	570 / 578	98.6%	97.3% - 99.3%
<i>mecA</i>	Prospective Fresh	262 / 286	91.6%	87.8% - 94.3%	235 / 249	94.4%	90.8% - 96.6%
	Prospective Frozen	22 / 23	95.7%	79.0% - 99.2%	16 / 16	100.0%	80.6% - 100.0%
	Total	284 / 309	91.9%	88.3% - 94.5%	251 / 265	94.7%	91.3% - 96.8%
<i>mecC</i>	Prospective Fresh	0 / 0	N/A	N/A	206 / 206	100.0%	98.2% - 100.0%
	Prospective Frozen	0 / 0	N/A	N/A	13 / 13	100.0%	77.2% - 100.0%
	Total	0 / 0	N/A	N/A	219 / 219	100.0%	98.3% - 100.0%
<i>vanA</i>	Prospective Fresh	12 / 12	100.0%	75.8% - 100.0%	267 / 271	98.5%	96.3% - 99.4%
	Prospective Frozen	1 / 1	100.0%	20.7% - 100.0%	18 / 18	100.0%	82.4% - 100.0%
	Total	13 / 13	100.0%	77.2% - 100.0%	285 / 289	98.6%	96.5% - 99.5%
<i>vanB</i>	Prospective Fresh	2 / 2	100.0%	34.2% - 100.0%	281 / 281	100.0%	98.7% - 100.0%
	Prospective Frozen	0 / 0	N/A	N/A	19 / 19	100.0%	83.2% - 100.0%
	Total	2 / 2	100.0%	34.2% - 100.0%	300 / 300	100.0%	98.7% - 100.0%
<i>tet(M)</i>	Prospective Fresh	83 / 91	91.2%	83.6% - 95.5%	589 / 599	98.3%	97.0% - 99.1%
	Prospective Frozen	9 / 9	100.0%	70.1% - 100.0%	36 / 38	94.7%	82.7% - 98.5%
	Total	92 / 100	92.0%	85.0% - 95.9%	625 / 637	98.1%	96.7% - 98.9%
<i>tet(K)</i>	Prospective Fresh	86 / 98	87.8%	79.8% - 92.9%	562 / 567	99.1%	98.0% - 99.6%
	Prospective Frozen	6 / 7	85.7%	48.7% - 97.4%	39 / 39	100.0%	91.0% - 100.0%
	Total	92 / 105	87.6%	80.0% - 92.6%	601 / 606	99.2%	98.1% - 99.6%
<i>aac(6') aph(2')</i>	Prospective Fresh	73 / 94	77.7%	68.2% - 84.9%	537 / 543	98.9%	97.6% - 99.5%
	Prospective Frozen	5 / 6	83.3%	43.6% - 97.0%	39 / 40	97.5%	87.1% - 99.6%
	Total	78 / 100	78.0%	68.9% - 85.0%	576 / 583	98.8%	97.5% - 99.4%

Table 31. Clinical Performance for Prospective Samples by Target Resistance Marker and Associated Organism(s)

Target	Organism	TP/ (TP+FN)	PPA (%)	95% CI	TN/ (TN+FP)	NPA (%)	95% CI
<i>cfr</i>	<i>E. faecium</i>	0 / 0	N/A	N/A	29 / 29	100.0%	88.3% - 100.0%
	<i>S. aureus</i>	0 / 0	N/A	N/A	215 / 215	100.0%	98.2% - 100.0%
	<i>S. capitis/S. hominis</i>	0 / 0	N/A	N/A	92 / 92	100.0%	96.0% - 100.0%
	<i>S. epidermidis</i>	0 / 0	N/A	N/A	210 / 210	100.0%	98.2% - 100.0%
	<i>S. pneumoniae</i>	0 / 0	N/A	N/A	27 / 27	100.0%	87.5% - 100.0%
	<i>E. faecium, S. capitis/ S. hominis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>S. aureus, S. capitis/ S. hominis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>S. aureus, S. epidermidis</i>	0 / 0	N/A	N/A	4 / 4	100.0%	51.0% - 100.0%
	<i>S. capitis/S. hominis, S. epidermidis</i>	0 / 0	N/A	N/A	47 / 47	100.0%	92.4% - 100.0%
<i>erm(A)</i>	<i>E. faecalis</i>	0 / 1	0.0%	0.0% - 79.3%	47 / 48	97.9%	89.1% - 99.6%
	<i>S. aureus</i>	27 / 27	100.0%	87.5% - 100.0%	181 / 185	97.8%	94.6% - 99.2%
	<i>S. capitis/S. hominis</i>	3 / 3	100.0%	43.9% - 100.0%	87 / 87	100.0%	95.8% - 100.0%
	<i>S. epidermidis</i>	12 / 13	92.3%	66.7% - 98.6%	197 / 197	100.0%	98.1% - 100.0%
	<i>S. lugdunensis</i>	1 / 1	100.0%	20.7% - 100.0%	4 / 4	100.0%	51.0% - 100.0%
	<i>E. faecium, E. faecalis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>E. faecium, S. capitis/S. hominis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>E. faecalis, S. anginosus group</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>E. faecalis, S. capitis/S. hominis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>E. faecalis, S. epidermidis</i>	0 / 0	N/A	N/A	2 / 2	100.0%	34.2% - 100.0%
	<i>S. aureus, S. capitis/S. hominis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>S. aureus, S. epidermidis</i>	0 / 0	N/A	N/A	4 / 4	100.0%	51.0% - 100.0%
	<i>S. aureus, S. lugdunensis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>S. aureus, S. pyogenes</i>	0 / 0	N/A	N/A	2 / 2	100.0%	34.2% - 100.0%
	<i>S. capitis/S. hominis, S.</i>	1 / 3	33.3%	6.1% - 79.2%	42 / 43	97.7%	87.9% - 99.6%

Target	Organism	TP/ (TP+FN)	PPA (%)	95% CI	TN/ (TN+FP)	NPA (%)	95% CI
	<i>epidermidis</i>						
	<i>S. capitis/S. hominis, S. lugdunensis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>S. capitis/S. hominis, S. epidermidis, S. lugdunensis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
erm(C)	<i>E. faecium</i>	0 / 0	N/A	N/A	28 / 28	100.0%	87.9% - 100.0%
	<i>E. faecalis</i>	1 / 2	50.0%	9.5% - 90.5%	47 / 48	97.9%	89.1% - 99.6%
	<i>S. aureus</i>	13 / 16	81.3%	57.0% - 93.4%	195 / 196	99.5%	97.2% - 99.9%
	<i>S. capitis/S. hominis</i>	25 / 28	89.3%	72.8% - 96.3%	61 / 62	98.4%	91.4% - 99.7%
	<i>S. epidermidis</i>	71 / 74	95.9%	88.7% - 98.6%	132 / 136	97.1%	92.7% - 98.9%
	<i>S. lugdunensis</i>	0 / 0	N/A	N/A	5 / 5	100.0%	56.6% - 100.0%
	<i>E. faecium, E. faecalis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>E. faecium, S. capitis/S. hominis</i>	0 / 1	0.0%	0.0% - 79.3%	0 / 0	N/A	N/A
	<i>E. faecium, S. capitis/S. hominis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>E. faecalis, S. epidermidis</i>	0 / 0	N/A	N/A	2 / 2	100.0%	34.2% - 100.0%
	<i>S. aureus, S. capitis/S. hominis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>S. aureus, S. epidermidis</i>	0 / 2	0.0%	0.0% - 65.8%	2 / 2	100.0%	34.2% - 100.0%
	<i>S. aureus, S. lugdunensis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>S. aureus, S. pyogenes</i>	0 / 0	N/A	N/A	2 / 2	100.0%	34.2% - 100.0%
	<i>S. capitis/S. hominis, S. epidermidis</i>	25 / 28	89.3%	72.8% - 96.3%	17 / 18	94.4%	74.2% - 99.0%
	<i>S. capitis/S. hominis, S. lugdunensis</i>	1 / 1	100.0%	20.7% - 100.0%	0 / 0	N/A	N/A
	<i>S. capitis/S. hominis, S. epidermidis, S. lugdunensis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
mecA	<i>S. aureus</i>	71 / 83	85.5%	76.4% - 91.5%	127 / 131	96.9%	92.4% - 98.8%
	<i>S. capitis/S. hominis</i>	35 / 41	85.4%	71.6% - 93.1%	50 / 51	98.0%	89.7% - 99.7%
	<i>S. epidermidis</i>	136 / 142	95.8%	91.1% - 98.0%	61 / 68	89.7%	80.2% - 94.9%
	<i>S. lugdunensis</i>	0 / 1	0.0%	0.0% - 79.3%	4 / 4	100.0%	51.0% - 100.0%
	<i>S. aureus, S. capitis/S. hominis</i>	1 / 1	100.0%	20.7% - 100.0%	0 / 0	N/A	N/A
	<i>S. aureus, S. epidermidis</i>	4 / 4	100.0%	51.0% - 100.0%	0 / 0	N/A	N/A
	<i>S. aureus, S. lugdunensis</i>	1 / 1	100.0%	20.7% - 100.0%	0 / 0	N/A	N/A
	<i>S. capitis/S. hominis, S. epidermidis</i>	36 / 36	100.0%	90.4% - 100.0%	8 / 9	88.9%	56.5% - 98.0%
	<i>S. capitis/S. hominis, S. lugdunensis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
mecC	<i>S. capitis/S. hominis, S. epidermidis, S. lugdunensis</i>	0 / 0	N/A	N/A	0 / 1	0.0%	0.0% - 79.3%
	<i>S. aureus</i>	0 / 0	N/A	N/A	219 / 219	100.0%	98.3% - 100.0%
vanA	<i>E. faecium</i>	12 / 12	100.0%	75.8% - 100.0%	13 / 17	76.5%	52.7% - 90.4%
	<i>E. faecalis</i>	0 / 0	N/A	N/A	53 / 53	100.0%	93.2% - 100.0%
	<i>S. aureus</i>	0 / 0	N/A	N/A	219 / 219	100.0%	98.3% - 100.0%
	<i>E. faecium, E. faecalis</i>	1 / 1	100.0%	20.7% - 100.0%	0 / 0	N/A	N/A
vanB	<i>E. faecium</i>	2 / 2	100.0%	34.2% - 100.0%	27 / 27	100.0%	87.5% - 100.0%
	<i>E. faecalis</i>	0 / 0	N/A	N/A	53 / 53	100.0%	93.2% - 100.0%
	<i>S. aureus</i>	0 / 0	N/A	N/A	219 / 219	100.0%	98.3% - 100.0%
	<i>E. faecium, E. faecalis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
tet(M)	<i>E. faecium</i>	14 / 15	93.3%	70.2% - 98.8%	10 / 13	76.9%	49.7% - 91.8%
	<i>E. faecalis</i>	30 / 30	100.0%	88.6% - 100.0%	14 / 19	73.7%	51.2% - 88.2%
	<i>S. agalactiae</i>	16 / 16	100.0%	80.6% - 100.0%	9 / 10	90.0%	59.6% - 98.2%
	<i>S. anginosus group</i>	3 / 4	75.0%	30.1% - 95.4%	6 / 7	85.7%	48.7% - 97.4%
	<i>S. aureus</i>	10 / 11	90.9%	62.3% - 98.4%	202 / 202	100.0%	98.1% - 100.0%
	<i>S. capitis/S. hominis</i>	0 / 1	0.0%	0.0% - 79.3%	90 / 90	100.0%	95.9% - 100.0%
	<i>S. epidermidis</i>	4 / 6	66.7%	30.0% - 90.3%	204 / 204	100.0%	98.2% - 100.0%
	<i>S. pneumoniae</i>	3 / 3	100.0%	43.9% - 100.0%	23 / 24	95.8%	79.8% - 99.3%
	<i>S. pyogenes</i>	7 / 8	87.5%	52.9% - 97.8%	12 / 12	100.0%	75.8% - 100.0%
	<i>E. faecium, E. faecalis</i>	0 / 0	N/A	N/A	0 / 1	0.0%	0.0% - 79.3%
	<i>E. faecium, S. capitis/S.</i>	1 / 1	100.0%	20.7% - 100.0%	0 / 0	N/A	N/A

Target	Organism	TP/ (TP+FN)	PPA (%)	95% CI	TN/ (TN+FP)	NPA (%)	95% CI
	<i>hominis</i>						
	<i>E. faecalis</i> , <i>S. anginosus</i> group	1 / 1	100.0%	20.7% - 100.0%	0 / 0	N/A	N/A
	<i>E. faecalis</i> , <i>S. capitis</i> / <i>S. hominis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>E. faecalis</i> , <i>S. epidermidis</i>	0 / 0	N/A	N/A	2 / 2	100.0%	34.2% - 100.0%
	<i>S. agalactiae</i> , <i>S. aureus</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>S. agalactiae</i> , <i>S. capitis</i> / <i>S. hominis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>S. aureus</i> , <i>S. capitis</i> / <i>S. hominis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>S. aureus</i> , <i>S. epidermidis</i>	0 / 0	N/A	N/A	4 / 4	100.0%	51.0% - 100.0%
	<i>S. aureus</i> , <i>S. pyogenes</i>	2 / 2	100.0%	34.2% - 100.0%	0 / 0	N/A	N/A
	<i>S. capitis</i> / <i>S. hominis</i> , <i>S. epidermidis</i>	1 / 2	50.0%	9.5% - 90.5%	45 / 45	100.0%	92.1% - 100.0%
<i>tet(K)</i>	<i>E. faecium</i>	0 / 1	0.0%	0.0% - 79.3%	27 / 27	100.0%	87.5% - 100.0%
	<i>E. faecalis</i>	0 / 0	N/A	N/A	50 / 50	100.0%	92.9% - 100.0%
	<i>S. agalactiae</i>	0 / 1	0.0%	0.0% - 79.3%	25 / 25	100.0%	86.7% - 100.0%
	<i>S. aureus</i>	14 / 17	82.4%	59.0% - 93.8%	197 / 197	100.0%	98.1% - 100.0%
	<i>S. capitis</i> / <i>S. hominis</i>	24 / 27	88.9%	71.9% - 96.1%	60 / 63	95.2%	86.9% - 98.4%
	<i>S. epidermidis</i>	33 / 35	94.3%	81.4% - 98.4%	173 / 175	98.9%	95.9% - 99.7%
	<i>S. lugdunensis</i>	0 / 0	N/A	N/A	5 / 5	100.0%	56.6% - 100.0%
	<i>S. pneumoniae</i>	0 / 0	N/A	N/A	27 / 27	100.0%	87.5% - 100.0%
	<i>E. faecium</i> , <i>E. faecalis</i>	0 / 1	0.0%	0.0% - 79.3%	0 / 0	N/A	N/A
	<i>E. faecium</i> , <i>S. capitis</i> / <i>S. hominis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>E. faecalis</i> , <i>S. capitis</i> / <i>S. hominis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>E. faecalis</i> , <i>S. epidermidis</i>	0 / 0	N/A	N/A	2 / 2	100.0%	34.2% - 100.0%
	<i>S. agalactiae</i> , <i>S. aureus</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>S. agalactiae</i> , <i>S. capitis</i> / <i>S. hominis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>S. aureus</i> , <i>S. capitis</i> / <i>S. hominis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>S. aureus</i> , <i>S. epidermidis</i>	1 / 1	100.0%	20.7% - 100.0%	3 / 3	100.0%	43.9% - 100.0%
	<i>S. aureus</i> , <i>S. lugdunensis</i>	1 / 1	100.0%	20.7% - 100.0%	0 / 0	N/A	N/A
	<i>S. capitis</i> / <i>S. hominis</i> , <i>S. epidermidis</i>	19 / 21	90.5%	71.1% - 97.3%	25 / 25	100.0%	86.7% - 100.0%
	<i>S. capitis</i> / <i>S. hominis</i> , <i>S. lugdunensis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>S. capitis</i> / <i>S. hominis</i> , <i>S. epidermidis</i> , <i>S. lugdunensis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
<i>aac(6') aph(2')</i>	<i>E. faecium</i>	8 / 18	44.4%	24.6% - 66.3%	10 / 10	100.0%	72.2% - 100.0%
	<i>E. faecalis</i>	5 / 7	71.4%	35.9% - 91.8%	42 / 43	97.7%	87.9% - 99.6%
	<i>S. agalactiae</i>	0 / 0	N/A	N/A	25 / 25	100.0%	86.7% - 100.0%
	<i>S. aureus</i>	5 / 6	83.3%	43.6% - 97.0%	207 / 208	99.5%	97.3% - 99.9%
	<i>S. capitis</i> / <i>S. hominis</i>	9 / 11	81.8%	52.3% - 94.9%	79 / 79	100.0%	95.4% - 100.0%
	<i>S. epidermidis</i>	42 / 44	95.5%	84.9% - 98.7%	166 / 166	100.0%	97.7% - 100.0%
	<i>S. lugdunensis</i>	0 / 0	N/A	N/A	5 / 5	100.0%	56.6% - 100.0%
	<i>E. faecium</i> , <i>E. faecalis</i>	0 / 0	N/A	N/A	0 / 1	0.0%	0.0% - 79.3%
	<i>E. faecium</i> , <i>S. capitis</i> / <i>S. hominis</i>	1 / 1	100.0%	20.7% - 100.0%	0 / 0	N/A	N/A
	<i>E. faecalis</i> , <i>S. capitis</i> / <i>S. hominis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>E. faecalis</i> , <i>S. epidermidis</i>	0 / 0	N/A	N/A	1 / 2	50.0%	9.5% - 90.5%
	<i>S. agalactiae</i> , <i>S. aureus</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>S. agalactiae</i> , <i>S. capitis</i> / <i>S. hominis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>S. aureus</i> , <i>S. capitis</i> / <i>S. hominis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>S. aureus</i> , <i>S. epidermidis</i>	1 / 1	100.0%	20.7% - 100.0%	3 / 3	100.0%	43.9% - 100.0%
	<i>S. aureus</i> , <i>S. lugdunensis</i>	0 / 0	N/A	N/A	0 / 1	0.0%	0.0% - 79.3%
	<i>S. capitis</i> / <i>S. hominis</i> , <i>S. epidermidis</i>	7 / 12	58.3%	32.0% - 80.7%	33 / 34	97.1%	85.1% - 99.5%

Target	Organism	TP/(TP+FN)	PPA (%)	95% CI	TN/(TN+FP)	NPA (%)	95% CI
	<i>S. capitis/S. hominis, S. lugdunensis</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>S. capitis/S. hominis, S. epidermidis, S. lugdunensis</i>	0 / 0	N/A	N/A	0 / 1	0.0%	0.0% - 79.3%

Table 32. Clinical Performance for Archived Samples by Target Organism

Organism	TP/(TP+FN)	PPA (%)	95% CI	TN/(TN+FP)	NPA (%)	95% CI
<i>Bacillus cereus</i> group*	10 / 12	83.3%	55.2% - 95.3%	269 / 269	100.0%	98.6% - 100.0%
<i>Corynebacterium</i> †	33 / 36	91.7%	78.2% - 97.1%	242 / 245	98.8%	96.5% - 99.6%
<i>Enterococcus faecalis</i>	0 / 0	N/A	N/A	281 / 281	100.0%	98.7% - 100.0%
<i>Enterococcus faecium</i>	0 / 0	N/A	N/A	281 / 281	100.0%	98.7% - 100.0%
<i>Listeria monocytogenes</i>	14 / 14	100.0%	78.5% - 100.0%	267 / 267	100.0%	98.6% - 100.0%
<i>Micrococcus</i> spp. ‡	34 / 36	94.4%	81.9% - 98.5%	245 / 245	100.0%	98.5% - 100.0%
<i>Staphylococcus aureus</i>	0 / 0	N/A	N/A	281 / 281	100.0%	98.7% - 100.0%
<i>Staphylococcus epidermidis</i> §	1 / 2	50.0%	9.5% - 90.5%	277 / 279	99.3%	97.4% - 99.8%
<i>Staphylococcus lugdunensis</i>	7 / 7	100.0%	64.6% - 100.0%	274 / 274	100.0%	98.6% - 100.0%
<i>S. capitis / S. hominis</i> ¶	22 / 22	100.0%	85.1% - 100.0%	257 / 259	99.2%	97.2% - 99.8%
<i>Streptococcus agalactiae</i>	35 / 35	100.0%	90.1% - 100.0%	246 / 246	100.0%	98.5% - 100.0%
<i>Streptococcus anginosus</i> group	29 / 29	100.0%	88.3% - 100.0%	252 / 252	100.0%	98.5% - 100.0%
<i>Streptococcus pneumoniae</i>	37 / 37	100.0%	90.6% - 100.0%	244 / 244	100.0%	98.5% - 100.0%
<i>Streptococcus pyogenes</i>	39 / 39	100.0%	91.0% - 100.0%	242 / 242	100.0%	98.4% - 100.0%
<i>Cryptococcus neoformans/gattii</i>	1 / 1	100.0%	20.7% - 100.0%	280 / 280	100.0%	98.6% - 100.0%
<i>Fusarium</i>	1 / 1	100.0%	20.7% - 100.0%	280 / 280	100.0%	98.6% - 100.0%
<i>Candida auris</i>	1 / 1	100.0%	20.7% - 100.0%	280 / 280	100.0%	98.6% - 100.0%
Pan Gram-Negative**	6 / 6	100.0%	61.0% - 100.0%	273 / 275	99.3%	97.4% - 99.8%
<i>Candida</i> group 1	2 / 2	100.0%	34.2% - 100.0%	279 / 279	100.0%	98.6% - 100.0%
<i>Candida</i> group 2	9 / 9	100.0%	70.1% - 100.0%	272 / 272	100.0%	98.6% - 100.0%

* Of the two (2) *Bacillus cereus* group false negative samples, the organism was detected using PCR/BDS in one (1) sample; no PCR/BDS result was available in the remaining false negative sample.

† Of the three (3) false positive *Corynebacterium* samples, no organisms were detected using PCR/BDS. Of the 3 false negative *Corynebacterium* samples, no organisms were detected using PCR/BDS.

‡ Of the two (2) *Micrococcus* spp false negative samples, organisms was detected using PCR/BDS.

§ Of the two (2) *Staphylococcus epidermidis* false positive samples, the organism was detected in one (1) sample; no organism was detected using PCR/BDS in the remaining sample. For the false negative *Staphylococcus epidermidis* sample, the organism was detected using PCR/BDS.

¶ Of the two (2) *S. capitis / S. hominis* false positive samples, the organisms were detected using PCR/BDS.

** Of the two (2) false positive Pan Gram-Negative samples, no PCR/BDS results were available

Table 33. Clinical Performance for Archived Samples by Target Resistance Marker

Target	TP/(TP+FN)	PPA (%)	95% CI	TN/(TN+FP)	NPA (%)	95% CI
<i>cfr</i>	0 / 0	N/A	N/A	61 / 61	100.0%	94.1% - 100.0%
<i>erm(A)</i>	0 / 0	N/A	N/A	168 / 168	100.0%	97.8% - 100.0%
<i>erm(C)</i>	2 / 3	66.7%	20.8% - 93.9%	136 / 136	100.0%	97.3% - 100.0%
<i>mecA</i>	6 / 6	100.0%	61.0% - 100.0%	25 / 25	100.0%	86.7% - 100.0%
<i>tet(M)</i>	34 / 34	100.0%	89.8% - 100.0%	126 / 127	99.2%	95.7% - 99.9%
<i>tet(K)</i>	4 / 4	100.0%	51.0% - 100.0%	98 / 98	100.0%	96.2% - 100.0%
<i>aac(6') aph(2')</i>	1 / 1	100.0%	20.7% - 100.0%	64 / 64	100.0%	94.3% - 100.0%

Table 34. Clinical Performance for Retrospective Samples by Target Resistance Marker and Associated Organism(s)

Target	Organism	TP/(TP+FN)	PPA (%)	95% CI	TN/(TN+FP)	NPA (%)	95% CI
<i>cfr</i>	<i>S. capitis/S. hominis</i>	0 / 0	N/A	N/A	21 / 21	100.0%	84.5% - 100.0%

Target	Organism	TP/ (TP+FN)	PPA (%)	95% CI	TN/ (TN+FP)	NPA (%)	95% CI
	<i>S. pneumoniae</i>	0 / 0	N/A	N/A	37 / 37	100.0%	90.6% - 100.0%
	<i>S. capitis/S. hominis, S. epidermidis</i>	0 / 0	N/A	N/A	3 / 3	100.0%	43.9% - 100.0%
<i>erm(A)</i>	<i>S. agalactiae</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>S. capitis/S. hominis</i>	0 / 0	N/A	N/A	19 / 19	100.0%	83.2% - 100.0%
	<i>S. lugdunensis</i>	0 / 0	N/A	N/A	7 / 7	100.0%	64.6% - 100.0%
	<i>S. capitis/S. hominis, S. epidermidis</i>	0 / 0	N/A	N/A	3 / 3	100.0%	43.9% - 100.0%
	<i>S. capitis/S. hominis, S. pyogenes</i>	0 / 0	N/A	N/A	2 / 2	100.0%	34.2% - 100.0%
<i>erm(C)</i>	<i>S. agalactiae</i>	0 / 0	N/A	N/A	1 / 1	100.0%	20.7% - 100.0%
	<i>S. capitis/S. hominis</i>	1 / 1	100.0%	20.7% - 100.0%	18 / 18	100.0%	82.4% - 100.0%
	<i>S. lugdunensis</i>	1 / 1	100.0%	20.7% - 100.0%	6 / 6	100.0%	61.0% - 100.0%
	<i>S. capitis/S. hominis, S. epidermidis</i>	0 / 1	0.0%	0.0% - 79.3%	2 / 2	100.0%	34.2% - 100.0%
	<i>S. capitis/S. hominis, S. pyogenes</i>	0 / 0	N/A	N/A	2 / 2	100.0%	34.2% - 100.0%
<i>mecA</i>	<i>S. capitis/S. hominis</i>	1 / 1	100.0%	20.7% - 100.0%	20 / 20	100.0%	83.9% - 100.0%
	<i>S. lugdunensis</i>	2 / 2	100.0%	34.2% - 100.0%	5 / 5	100.0%	56.6% - 100.0%
	<i>S. capitis/S. hominis, S. epidermidis</i>	3 / 3	100.0%	43.9% - 100.0%	0 / 0	N/A	N/A
<i>tet(M)</i>	<i>S. agalactiae</i>	19 / 19	100.0%	83.2% - 100.0%	14 / 15	93.3%	70.2% - 98.8%
	<i>S. anginosus group</i>	5 / 5	100.0%	56.6% - 100.0%	24 / 24	100.0%	86.2% - 100.0%
	<i>S. capitis/S. hominis</i>	0 / 0	N/A	N/A	19 / 19	100.0%	83.2% - 100.0%
	<i>S. pneumoniae</i>	2 / 2	100.0%	34.2% - 100.0%	35 / 35	100.0%	90.1% - 100.0%
	<i>S. pyogenes</i>	7 / 7	100.0%	64.6% - 100.0%	30 / 30	100.0%	88.6% - 100.0%
	<i>S. capitis/S. hominis, S. epidermidis</i>	1 / 1	100.0%	20.7% - 100.0%	2 / 2	100.0%	34.2% - 100.0%
	<i>S. capitis/S. hominis, S. pyogenes</i>	0 / 0	N/A	N/A	2 / 2	100.0%	34.2% - 100.0%
<i>tet(K)</i>	<i>S. agalactiae</i>	0 / 0	N/A	N/A	34 / 34	100.0%	89.8% - 100.0%
	<i>S. capitis/S. hominis</i>	2 / 2	100.0%	34.2% - 100.0%	19 / 19	100.0%	83.2% - 100.0%
	<i>S. lugdunensis</i>	1 / 1	100.0%	20.7% - 100.0%	6 / 6	100.0%	61.0% - 100.0%
	<i>S. pneumoniae</i>	0 / 0	N/A	N/A	37 / 37	100.0%	90.6% - 100.0%
	<i>S. capitis/S. hominis, S. epidermidis</i>	1 / 1	100.0%	20.7% - 100.0%	2 / 2	100.0%	34.2% - 100.0%
<i>aac(6') aph(2')</i>	<i>S. agalactiae</i>	1 / 1	100.0%	20.7% - 100.0%	33 / 33	100.0%	89.6% - 100.0%
	<i>S. capitis/S. hominis</i>	0 / 0	N/A	N/A	21 / 21	100.0%	84.5% - 100.0%
	<i>S. lugdunensis</i>	0 / 0	N/A	N/A	7 / 7	100.0%	64.6% - 100.0%
	<i>S. capitis/S. hominis, S. epidermidis</i>	0 / 0	N/A	N/A	3 / 3	100.0%	43.9% - 100.0%

2. Contrived Study:

Contrived samples were prepared and tested for targets for which low prevalence was expected. Results are summarized in **Table 35**.

Table 35. Clinical Performance for Contrived Samples

Target	TP/(TP+FN)	PPA (%)	95% CI
<i>Bacillus cereus group</i>	50 / 50	100.0%	92.9% - 100.0%
<i>Enterococcus faecalis</i>	59 / 59	100.0%	93.9% - 100.0%
<i>Enterococcus faecium</i>	40 / 40	100.0%	91.2% - 100.0%
<i>Listeria monocytogenes</i>	50 / 50	100.0%	92.9% - 100.0%
<i>Staphylococcus aureus</i>	69 / 69	100.0%	94.7% - 100.0%
<i>Staphylococcus epidermidis</i>	49 / 49	100.0%	92.7% - 100.0%
<i>Staphylococcus lugdunensis</i>	50 / 50	100.0%	92.9% - 100.0%

<i>Cryptococcus neoformans/gattii</i>	50 / 50	100.0%	92.9% - 100.0%
<i>Fusarium</i>	49 / 50	98.0%	89.5% - 99.6%
<i>Candida auris</i>	49 / 50	98.0%	89.5% - 99.6%
<i>Candida</i> group 1	50 / 50	100.0%	92.9% - 100.0%
<i>Candida</i> group 2	50 / 50	100.0%	92.9% - 100.0%
cfr	46 / 49	93.9%	83.5% - 97.9%
Erm(C)	56 / 59	94.9%	86.1% - 98.3%
MecA	68 / 69	98.6%	92.2% - 99.7%
MecC	49 / 49	100.0%	92.7% - 100.0%
VanA	60 / 60	100.0%	94.0% - 100.0%
VanB	50 / 50	100.0%	92.9% - 100.0%
Tet(M)	76 / 80	95.0%	87.8% - 98.0%
Tet(K)	19 / 20	95.0%	76.4% - 99.1%
Aac(6') aph(2')	116 / 129	89.9%	83.5% - 94.0%

3. Combined Performance:

The combined prospective, retrospective and contrived performance is shown in **Tables 36 and 37**. **Tables 38 to 45** show combined clinical performance of the QIAstat-Dx BCID GPF Plus AMR Panel compared to phenotypic antimicrobial susceptibility testing (AST) results for the AMR gene targets.

Table 36. Combined Clinical Performance by Target Organism

Target	Sample	TP/(TP+FN)	PPA (%)	95% CI	TN/(TN+FP)	NPA (%)	95% CI
<i>Bacillus cereus</i> group	Archived	10 / 12	83.3	55.2 - 95.3	269 / 269	100.0	98.6 - 100.0
	Contrived	50 / 50	100.0	92.9 - 100.0	0 / 0	N/A	N/A
	Prospective Fresh	5 / 6	83.3	43.6 - 97.0	901 / 901	100.0	99.6 - 100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7 - 100.0
	Total	65 / 68	95.6	87.8 - 98.5	1239 / 1239	100.0	99.7 - 100.0
<i>Corynebacterium</i>	Archived	33 / 36	91.7	78.2 - 97.1	242 / 245	98.8	96.5 - 99.6
	Prospective Fresh	12 / 14	85.7	60.1 - 96.0	880 / 893	98.5	97.5 - 99.1
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7 - 100.0
	Total	45 / 50	90.0	78.6 - 95.7	1191 / 1207	98.7	97.9 - 99.2
<i>Enterococcus faecalis</i>	Archived	0 / 0	N/A	N/A	281 / 281	100.0	98.7 - 100.0
	Contrived	59 / 59	100.0	93.9 - 100.0	0 / 0	N/A	N/A
	Prospective Fresh	48 / 48	100.0	92.6 - 100.0	859 / 859	100.0	99.6 - 100.0
	Prospective Frozen	6 / 7	85.7	48.7 - 97.4	62 / 62	100.0	94.2 - 100.0
	Total	113 / 114	99.1	95.2 - 99.8	1202 / 1202	100.0	99.7 - 100.0
<i>Enterococcus faecium</i>	Archived	0 / 0	N/A	N/A	281 / 281	100.0	98.7 - 100.0
	Contrived	40 / 40	100.0	91.2 - 100.0	0 / 0	N/A	N/A
	Prospective Fresh	29 / 29	100.0	88.3 - 100.0	871 / 878	99.2	98.4 - 99.6
	Prospective Frozen	1 / 1	100.0	20.7 - 100.0	64 / 68	94.1	85.8 - 97.7
	Total	70 / 70	100.0	94.8 - 100.0	1216 / 1227	99.1	98.4 - 99.5
<i>Listeria monocytogenes</i>	Archived	14 / 14	100.0	78.5 - 100.0	267 / 267	100.0	98.6 - 100.0
	Contrived	50 / 50	100.0	92.9 - 100.0	0 / 0	N/A	N/A
	Prospective Fresh	3 / 3	100.0	43.9 - 100.0	903 / 904	99.9	99.4 - 100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7 - 100.0
	Total	67 / 67	100.0	94.6 - 100.0	1239 / 1240	99.9	99.5 - 100.0
<i>Micrococcus</i> spp.	Archived	34 / 36	94.4	81.9 - 98.5	245 / 245	100.0	98.5 - 100.0
	Prospective Fresh	17 / 23	73.9	53.5 - 87.5	884 / 884	100.0	99.6 - 100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7 - 100.0
	Total	51 / 59	86.4	75.5 - 93.0	1198 / 1198	100.0	99.7 - 100.0
<i>Staphylococcus aureus</i>	Archived	0 / 0	N/A	N/A	281 / 281	100.0	98.7 - 100.0
	Contrived	69 / 69	100.0	94.7 - 100.0	0 / 0	N/A	N/A

Target	Sample	TP/(TP+FN)	PPA (%)	95% CI	TN/(TN+FP)	NPA (%)	95% CI
	Prospective Fresh	206 / 208	99.0	96.6 - 99.7	696 / 699	99.6	98.7 - 99.9
	Prospective Frozen	13 / 13	100.0	77.2 - 100.0	55 / 56	98.2	90.6 - 99.7
	Total	288 / 290	99.3	97.5 - 99.8	1032 / 1036	99.6	99.0 - 99.8
<i>Staphylococcus epidermidis</i>	Archived	1 / 2	50.0	9.5 - 90.5	277 / 279	99.3	97.4 - 99.8
	Contrived	49 / 49	100.0	92.7 - 100.0	0 / 0	N/A	N/A
	Prospective Fresh	228 / 232	98.3	95.7 - 99.3	662 / 675	98.1	96.7 - 98.9
	Prospective Frozen	26 / 28	92.9	77.4 - 98.0	41 / 41	100.0	91.4 - 100.0
	Total	304 / 311	97.7	95.4 - 98.9	980 / 995	98.5	97.5 - 99.1
<i>Staphylococcus lugdunensis</i>	Archived	7 / 7	100.0	64.6 - 100.0	274 / 274	100.0	98.6 - 100.0
	Contrived	50 / 50	100.0	92.9 - 100.0	0 / 0	N/A	N/A
	Prospective Fresh	7 / 7	100.0	64.6 - 100.0	898 / 900	99.8	99.2 - 99.9
	Prospective Frozen	0 / 0	N/A	N/A	68 / 69	98.6	92.2 - 99.7
	Total	64 / 64	100.0	94.3 - 100.0	1240 / 1243	99.8	99.3 - 99.9
<i>S. capitis / S. hominis</i>	Archived	22 / 22	100.0	85.1 - 100.0	257 / 259	99.2	97.2 - 99.8
	Prospective Fresh	110 / 113	97.3	92.5 - 99.1	770 / 794	97.0	95.5 - 98.0
	Prospective Frozen	3 / 3	100.0	43.9 - 100.0	60 / 66	90.9	81.6 - 95.8
	Total	135 / 138	97.8	93.8 - 99.3	1087 / 1119	97.1	96.0 - 98.0
<i>Streptococcus agalactiae</i>	Archived	35 / 35	100.0	90.1 - 100.0	246 / 246	100.0	98.5 - 100.0
	Prospective Fresh	26 / 28	92.9	77.4 - 98.0	879 / 879	100.0	99.6 - 100.0
	Prospective Frozen	1 / 1	100.0	20.7 - 100.0	68 / 68	100.0	94.7 - 100.0
	Total	62 / 64	96.9	89.3 - 99.1	1193 / 1193	100.0	99.7 - 100.0
<i>Streptococcus anginosus</i> group	Archived	29 / 29	100.0	88.3 - 100.0	252 / 252	100.0	98.5 - 100.0
	Prospective Fresh	11 / 11	100.0	74.1 - 100.0	895 / 896	99.9	99.4 - 100.0
	Prospective Frozen	1 / 1	100.0	20.7 - 100.0	68 / 68	100.0	94.7 - 100.0
	Total	41 / 41	100.0	91.4 - 100.0	1215 / 1216	99.9	99.5 - 100.0
<i>Streptococcus pneumoniae</i>	Archived	37 / 37	100.0	90.6 - 100.0	244 / 244	100.0	98.5 - 100.0
	Prospective Fresh	27 / 27	100.0	87.5 - 100.0	877 / 880	99.7	99.0 - 99.9
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7 - 100.0
	Total	64 / 64	100.0	94.3 - 100.0	1190 / 1193	99.7	99.3 - 99.9
<i>Streptococcus pyogenes</i>	Archived	39 / 39	100.0	91.0 - 100.0	242 / 242	100.0	98.4 - 100.0
	Prospective Fresh	22 / 22	100.0	85.1 - 100.0	885 / 885	100.0	99.6 - 100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7 - 100.0
	Total	61 / 61	100.0	94.1 - 100.0	1196 / 1196	100.0	99.7 - 100.0
<i>Cryptococcus neoformans/gattii</i>	Archived	1 / 1	100.0	20.7 - 100.0	280 / 280	100.0	98.6 - 100.0
	Contrived	50 / 50	100.0	92.9 - 100.0	0 / 0	N/A	N/A
	Prospective Fresh	2 / 2	100.0	34.2 - 100.0	905 / 905	100.0	99.6 - 100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7 - 100.0
	Total	53 / 53	100.0	93.2 - 100.0	1254 / 1254	100.0	99.7 - 100.0
<i>Fusarium</i>	Archived	1 / 1	100.0	20.7 - 100.0	280 / 280	100.0	98.6 - 100.0
	Contrived	49 / 50	98.0	89.5 - 99.6	0 / 0	N/A	N/A
	Prospective Fresh	0 / 0	N/A	N/A	907 / 907	100.0	99.6 - 100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7 - 100.0
	Total	50 / 51	98.0	89.7 - 99.7	1256 / 1256	100.0	99.7 - 100.0
<i>Candida auris</i>	Archived	1 / 1	100.0	20.7 - 100.0	280 / 280	100.0	98.6 - 100.0
	Contrived	49 / 50	98.0	89.5 - 99.6	0 / 0	N/A	N/A
	Prospective Fresh	1 / 1	100.0	20.7 - 100.0	906 / 906	100.0	99.6 - 100.0
	Prospective Frozen	0 / 0	N/A	N/A	69 / 69	100.0	94.7 - 100.0
	Total	51 / 52	98.1	89.9 - 99.7	1255 / 1255	100.0	99.7 - 100.0
Pan Gram-Negative	Archived	6 / 6	100.0	61.0 - 100.0	273 / 275	99.3	97.4 - 99.8
	Prospective Fresh	13 / 16	81.3	57.0 - 93.4	891 / 891	100.0	99.6 - 100.0
	Prospective Frozen	13 / 13	100.0	77.2 - 100.0	56 / 56	100.0	93.6 - 100.0
	Total	32 / 35	91.4	77.6 - 97.0	1220 / 1222	99.8	99.4 - 100.0
<i>Candida</i> group 1	Archived	2 / 2	100.0	34.2 - 100.0	279 / 279	100.0	98.6 - 100.0
	Contrived	50 / 50	100.0	92.9 - 100.0	0 / 0	N/A	N/A
	Prospective Fresh	16 / 16	100.0	80.6 - 100.0	889 / 891	99.8	99.2 - 99.9
	Prospective Frozen	1 / 1	100.0	20.7 - 100.0	68 / 68	100.0	94.7 - 100.0
	Total	69 / 69	100.0	94.7 - 100.0	1236 / 1238	99.8	99.4 - 100.0
<i>Candida</i> group 2	Archived	9 / 9	100.0	70.1 - 100.0	272 / 272	100.0	98.6 - 100.0

Target	Sample	TP/(TP+FN)	PPA (%)	95% CI	TN/(TN+FP)	NPA (%)	95% CI
	Contrived	50 / 50	100.0	92.9 - 100.0	0 / 0	N/A	N/A
	Prospective Fresh	18 / 19	94.7	75.4 - 99.1	888 / 888	100.0	99.6 - 100.0
	Prospective Frozen	1 / 1	100.0	20.7 - 100.0	68 / 68	100.0	94.7 - 100.0
	Total	78 / 79	98.7	93.2 - 99.8	1228 / 1228	100.0	99.7 - 100.0

Table 37. Combined Clinical Performance by Target Resistance Marker

Target	Sample	TP/(TP+FN)	PPA (%)	95% CI	TN/(TN+FP)	NPA (%)	95% CI
cfr	Archived Frozen	0 / 0	N/A	N/A	61 / 61	100.0%	94.1% - 100.0%
	Contrived	46 / 49	93.9%	83.5% - 97.9%	0 / 0	N/A	N/A
	Prospective Fresh	0 / 0	N/A	N/A	586 / 586	100.0%	99.3% - 100.0%
	Prospective Frozen	0 / 0	N/A	N/A	40 / 40	100.0%	91.2% - 100.0%
	Total	46 / 49	93.9%	83.5% - 97.9%	687 / 687	100.0%	99.4% - 100.0%
Erm(A)	Archived Frozen	0 / 0	N/A	N/A	168 / 168	100.0%	97.8% - 100.0%
	Prospective Fresh	39 / 43	90.7%	78.4% - 96.3%	647 / 652	99.2%	98.2% - 99.7%
	Prospective Frozen	5 / 5	100.0%	56.6% - 100.0%	41 / 42	97.6%	87.7% - 99.6%
	Total	44 / 48	91.7%	80.4% - 96.7%	856 / 862	99.3%	98.5% - 99.7%
Erm(C)	Archived Frozen	2 / 3	66.7%	20.8% - 93.9%	136 / 136	100.0%	97.3% - 100.0%
	Contrived	56 / 59	94.9%	86.1% - 98.3%	0 / 0	N/A	N/A
	Prospective Fresh	124 / 141	87.9%	81.5% - 92.3%	536 / 544	98.5%	97.1% - 99.3%
	Prospective Frozen	12 / 12	100.0%	75.8% - 100.0%	34 / 34	100.0%	89.8% - 100.0%
	Total	194 / 215	90.2%	85.5% - 93.5%	706 / 714	98.9%	97.8% - 99.4%
MecA	Archived Frozen	6 / 6	100.0%	61.0% - 100.0%	25 / 25	100.0%	86.7% - 100.0%
	Contrived	68 / 69	98.6%	92.2% - 99.7%	0 / 0	N/A	N/A
	Prospective Fresh	262 / 286	91.6%	87.8% - 94.3%	235 / 249	94.4%	90.8% - 96.6%
	Prospective Frozen	22 / 23	95.7%	79.0% - 99.2%	16 / 16	100.0%	80.6% - 100.0%
	Total	358 / 384	93.2%	90.3% - 95.3%	276 / 290	95.2%	92.1% - 97.1%
MecC	Contrived	49 / 49	100.0%	92.7% - 100.0%	0 / 0	N/A	N/A
	Prospective Fresh	0 / 0	N/A	N/A	206 / 206	100.0%	98.2% - 100.0%
	Prospective Frozen	0 / 0	N/A	N/A	13 / 13	100.0%	77.2% - 100.0%
	Total	49 / 49	100.0%	92.7% - 100.0%	219 / 219	100.0%	98.3% - 100.0%
VanA	Contrived	60 / 60	100.0%	94.0% - 100.0%	0 / 0	N/A	N/A
	Prospective Fresh	12 / 12	100.0%	75.8% - 100.0%	267 / 271	98.5%	96.3% - 99.4%
	Prospective Frozen	1 / 1	100.0%	20.7% - 100.0%	18 / 18	100.0%	82.4% - 100.0%
	Total	73 / 73	100.0%	95.0% - 100.0%	285 / 289	98.6%	96.5% - 99.5%
VanB	Contrived	50 / 50	100.0%	92.9% - 100.0%	0 / 0	N/A	N/A
	Prospective Fresh	2 / 2	100.0%	34.2% - 100.0%	281 / 281	100.0%	98.7% - 100.0%
	Prospective Frozen	0 / 0	N/A	N/A	19 / 19	100.0%	83.2% - 100.0%
	Total	52 / 52	100.0%	93.1% - 100.0%	300 / 300	100.0%	98.7% - 100.0%
Tet(M)	Archived Frozen	34 / 34	100.0%	89.8% - 100.0%	126 / 127	99.2%	95.7% - 99.9%
	Contrived	76 / 80	95.0%	87.8% - 98.0%	0 / 0	N/A	N/A
	Prospective Fresh	83 / 91	91.2%	83.6% - 95.5%	589 / 599	98.3%	97.0% - 99.1%
	Prospective Frozen	9 / 9	100.0%	70.1% - 100.0%	36 / 38	94.7%	82.7% - 98.5%
	Total	202 / 214	94.4%	90.5% - 96.8%	751 / 764	98.3%	97.1% - 99.0%
Tet(K)	Archived Frozen	4 / 4	100.0%	51.0% - 100.0%	98 / 98	100.0%	96.2% - 100.0%
	Contrived	19 / 20	95.0%	76.4% - 99.1%	0 / 0	N/A	N/A
	Prospective Fresh	86 / 98	87.8%	79.8% - 92.9%	562 / 567	99.1%	98.0% - 99.6%
	Prospective Frozen	6 / 7	85.7%	48.7% - 97.4%	39 / 39	100.0%	91.0% - 100.0%
	Total	115 / 129	89.1%	82.6% - 93.4%	699 / 704	99.3%	98.3% - 99.7%
Aac(6') aph(2')	Archived Frozen	1 / 1	100.0%	20.7% - 100.0%	64 / 64	100.0%	94.3% - 100.0%
	Contrived	116 / 129	89.9%	83.5% - 94.0%	0 / 0	N/A	N/A
	Prospective Fresh	73 / 94	77.7%	68.2% - 84.9%	537 / 543	98.9%	97.6% - 99.5%
	Prospective Frozen	5 / 6	83.3%	43.6% - 97.0%	39 / 40	97.5%	87.1% - 99.6%
	Total	195 / 230	84.8%	79.6% - 88.9%	640 / 647	98.9%	97.8% - 99.5%

Table 38. Combined Clinical Performance of *mecA* and *mecC* Compared to Phenotypic AST Results for Oxacillin

Organism	<i>mecA</i>		<i>mecC</i>		Combined	
	PPA (n/n) (95%CI)	NPA (n/n) (95%CI)	PPA (n/n) (95%CI)	NPA (n/n) (95%CI)	PPA (n/n) (95%CI)	NPA (n/n) (95%CI)
<i>S. capitis/ hominis</i>	80.0 (8/10) 49.0 - 94.3	72.7 (8/11) 43.4 - 90.3	N/A	N/A	80.0 (8/10) 49.0 - 94.3	72.7 (8/11) (43.4 - 90.3)
<i>S. aureus</i>	98.4 (63/64) (91.7 - 99.7)	94.5 (121/128) (89.1 - 97.3)	0.0 (0/64) (0.0 - 5.7)	100.0 (127/127) (97.1 - 100.0)	98.4 (63/64) (91.7 - 99.7)	94.5 (121/128) (89.1 - 97.3)
<i>S. epidermidis</i>	98.1 (53/54) (90.2 - 99.7)	85.0 (17/20) (64.0 - 94.8)	N/A	N/A	98.1 (53/54) (90.2 - 99.7)	85.0 (17/20) (64.0 - 94.8)
<i>S. lugdunensis</i>	100.0 (3/3) (43.9 - 100.0)	100.0 (4/4) (51.0 - 100.0)	N/A	N/A	100.0 (3/3) (43.9 - 100.0)	100.0 (4/4) (51.0 - 100.0)

Table 39. Combined Clinical Performance of *vanA* and *vanB* Compared to Phenotypic AST Results for Vancomycin

Organism	<i>vanA</i>		<i>vanB</i>		Combined	
	PPA (n/n) (95%CI)	NPA (n/n) (95%CI)	PPA (n/n) (95%CI)	NPA (n/n) (95%CI)	PPA (n/n) (95%CI)	NPA (n/n) (95%CI)
<i>E. faecalis</i>	83.3 (10/12) 55.2 - 95.3	98.0 (48/49) 89.3 - 99.6	93.8 (30/32) 79.9 - 98.3	100.0 (49/49) 92.7 - 100.0	95.2 (40/42) 84.2 - 98.7	98.0 (48/49) 89.3 - 99.6
<i>E. faecium</i>	95.7 (45/47) 85.8 - 98.8	100.0 (10/10) 72.2 - 100.0	59.5 (22/37) 43.5 - 73.7	100.0 (10/10) 72.2 - 100.0	100.0 (57/57) 93.7 - 100.0	100.0 (10/10) 72.2 - 100.0
<i>S. aureus</i>	0/0	100.0 (186/186) 98.0 - 100.0	0/0	100.0 (186/186) 98.0 - 100.0	0/0	100.0 (186/186) 98.0 - 100.0

Table 40. Combined Clinical Performance of *aac(6')-aph(2'')* Compared to Phenotypic AST Results for Gentamicin High-Level Resistance

Organism	<i>aac(6')-aph(2'')</i>	
	PPA (n/n) (95%CI)	NPA (n/n) (95%CI)
<i>E. faecalis</i>	100.0 (3/3) 43.9 - 100.0	94.3 (33/35) 81.4 - 98.4
<i>E. faecium</i>	83.3 (5/6) 43.6 - 97.0	87.5 (14/16) 64.0 - 96.5

Table 41. Combined Clinical Performance of *aac(6')-aph(2'')* Compared to Phenotypic AST Results for Gentamicin

Organism	<i>aac(6')-aph(2'')</i>	
	PPA (n/n) (95%CI)	NPA (n/n) (95%CI)
<i>S. capitis/hominis</i>	100.0% (2/2) 34.2% - 100.0%	87.5% (14/16) 64.0% - 96.5%
<i>S. aureus</i>	100.0% (3/3) 43.9% - 100.0%	97.9% (92/94) 92.6% - 99.4%
<i>S. epidermidis</i>	80.0% (8/10) 49.0% - 94.3%	78.3% (36/46) 64.4% - 87.7%
<i>S. lugdunensis</i>	0/0	75.0% (3/4) 30.1% - 95.4%

Table 42. Combined Clinical Performance of *cfr*, *ermA* and *ermC* Compared to Phenotypic AST Results for Clindamycin

Organism	<i>cfr</i>		<i>ermA</i>		<i>ermC</i>		Combined	
	PPA (95%CI)	NPA (95%CI)	PPA (95%CI)	NPA (95%CI)	PPA (95%CI)	NPA (95%CI)	PPA (95%CI)	NPA (95%CI)
<i>S. capitis /hominis</i>	0.0 (0/11) 0.0 - 25.9	100.0 (61/61) 94.1 - 100.0	0.0 (0/11) 0.0 - 25.9	98.4 (60/61) 91.3 - 99.7	72.7 (8/11) 43.4 - 90.3	88.5 (54/61) 78.2 - 94.3	72.7 (8/11) 43.4 - 90.3	86.9 (53/61) 76.2 - 93.2
<i>S. aureus</i>	0.0 (0/26) 0.0 - 12.9	100.0 (107/107) 96.5 - 100.0	73.1 (19/26) 53.9 - 86.3	100.0 (107/107) 96.5 - 100.0	19.2 (5/26) 8.5 - 37.9	99.1 (106/107) 94.9 - 99.8	92.3 (24/26) 75.9 - 97.9	99.1 (106/107) 94.9 - 99.8

Organism	<i>cfr</i>		<i>ermA</i>		<i>ermC</i>		Combined	
	PPA (95%CI)	NPA (95%CI)	PPA (95%CI)	NPA (95%CI)	PPA (95%CI)	NPA (95%CI)	PPA (95%CI)	NPA (95%CI)
<i>S. epidermidis</i>	52.3 (46/88) 42.0 - 62.4	100.0 (43/43) 91.8 - 100.0	17.5 (7/40) 8.7 - 31.9	95.3 (41/43) 84.5 - 98.7	57.5 (23/40) 42.2 - 71.5	83.7 (36/43) 70.0 - 91.9	84.3 (75/89) 75.3 - 90.4	79.1 (34/43) 64.8 - 88.6
<i>S. lugdunensis</i>	N/A	N/A	0/0	100.0 (6/6) 61.0 - 100.0	0/0	100.0 (6/6) 61.0 - 100.0	0/0	100.0 (6/6) 61.0 - 100.0
<i>S. pneumoniae</i>	0.0 (0/3) 0.0 - 56.1	100.0 (29/29) 88.3 - 100.0	N/A	N/A	N/A	N/A	0.0 (0/3) 0.0 - 56.1	100.0 (29/29) 88.3 - 100.0

Table 43. Combined Clinical Performance of *ermA* and *ermC* Compared to Phenotypic AST Results for Erythromycin

Organism	<i>ermA</i>		<i>ermC</i>		Combined	
	PPA (95%CI)	NPA (95%CI)	PPA (95%CI)	NPA (95%CI)	PPA (95%CI)	NPA (95%CI)
<i>S. capitis/hominis</i>	3.1 (1/32) 0.6 - 15.7	100.0 (40/40) 91.2 - 100.0	46.9 (15/32) 30.9 - 63.6	97.5 (39/40) 87.1 - 99.6	50.0 (16/32) 33.6 - 66.4	97.5 (39/40) 87.1 - 99.6
<i>S. aureus</i>	21.2 (18/85) 13.8 - 31.0	100.0 (69/69) 94.7 - 100.0	10.6 (9/85) 5.7 - 18.9	100.0 (69/69) 94.7 - 100.0	31.8 (27/85) 22.8 - 42.3	100.0 (69/69) 94.7 - 100.0
<i>S. epidermidis</i>	10.9 (7/64) 5.4 - 20.9	90.9 (20/22) 72.2 - 97.5	45.3 (29/64) 33.7 - 57.4	90.9 (20/22) 72.2 - 97.5	54.7 (35/64) 42.6 - 66.3	81.8 (18/22) 61.5 - 92.7
<i>S. lugdunensis</i>	50.0 (1/2) 9.5 - 90.5	100.0 (6/6) 61.0 - 100.0	0.0 (0/2) 0.0 - 65.8	100.0 (6/6) 61.0 - 100.0	50.0 (1/2) 9.5 - 90.5	100.0 (6/6) 61.0 - 100.0

Table 44. Combined Clinical Performance of *cfr* Compared to Phenotypic AST Results for Linezolid

Organism	<i>cfr</i>	
	PPA (95%CI)	NPA (95%CI)
<i>E. faecium</i>	0/0	100.0 (24/24) 86.2 - 100.0
<i>S. capitis/hominis</i>	0.0 (0/36) 0.0 - 9.6	100.0 (27/27) 87.5 - 100.0
<i>S. aureus</i>	0.0 (0/9) 0.0 - 29.9	100.0 (44/44) 92.0 - 100.0
<i>S. epidermidis</i>	82.1 (46/56) 70.2 - 90.0	100.0 (47/47) 92.4 - 100.0
<i>S. pneumoniae</i>	0/0	100.0 (19/19) 83.2 - 100.0

Table 45. Combined Clinical Performance of *tetK* and *tetM* Compared to Phenotypic AST Results for Doxycycline and Tetracycline

Organism	<i>tetK</i>		<i>tetM</i>		Combined	
	PPA (95%CI)	NPA (95%CI)	PPA (95%CI)	NPA (95%CI)	PPA (95%CI)	NPA (95%CI)
Doxycycline susceptibility testing						
<i>E. faecalis</i>	0.0 (0/3) 0.0 - 56.1	100.0 (1/1) 20.7 - 100.0	100.0 (3/3) 43.9 - 100.0	100.0 (1/1) 20.7 - 100.0	100.0 (3/3) 43.9 - 100.0	100.0 (1/1) 20.7 - 100.0
<i>E. faecium</i>	0.0 (0/2) 0.0 - 65.8	100.0 (1/1) 20.7 - 100.0	100.0 (2/2) 34.2 - 100.0	0.0 (0/1) 0.0 - 79.3	100.0 (2/2) 34.2 - 100.0	0.0 (0/1) 0.0 - 79.3
<i>S. capitis/hominis</i>	100.0 (3/3) 43.9 - 100.0	77.8 (7/9) 45.3 - 93.7	0.0 (0/3) 0.0 - 56.1	100.0 (9/9) 70.1 - 100.0	100.0 (3/3) 43.9 - 100.0	77.8 (7/9) 45.3 - 93.7
<i>S. aureus</i>	66.7 (2/3) 20.8 - 93.9	98.0 (48/49) 89.3 - 99.6	33.3 (1/3) 6.1 - 79.2	98.0 (48/49) 89.3 - 99.6	100.0 (3/3) 43.9 - 100.0	95.9 (47/49) 86.3 - 98.9
<i>S. epidermidis</i>	75.0 (3/4) 30.1 - 95.4	88.9 (32/36) 74.7 - 95.6	0.0 (0/4) 0.0 - 49.0	100.0 (36/36) 90.4 - 100.0	75.0 (3/4) 30.1 - 95.4	88.9 (32/36) 74.7 - 95.6
<i>S. lugdunensis</i>	0/0	100.0 (1/1) 20.7 - 100.0	N/A	N/A	0/0	100.0 (1/1) 20.7 - 100.0
<i>S. pneumoniae</i>	0.0 (0/1) 0.0 - 79.3	100.0 (4/4) 51.0 - 100.0	100.0 (1/1) 20.7 - 100.0	100.0 (4/4) 51.0 - 100.0	100.0 (1/1) 20.7 - 100.0	100.0 (4/4) 51.0 - 100.0
Tetracycline susceptibility testing						
<i>S. capitis/hominis</i>	100.0 (4/4) 51.0 - 100.0	66.7 (6/9) 35.4 - 87.9	0.0 (0/4) 0.0 - 49.0	100.0 (9/9) 70.1 - 100.0	100.0 (4/4) 51.0 - 100.0	66.7 (6/9) 35.4 - 87.9

Organism	<i>tetK</i>		<i>tetM</i>		Combined	
	PPA (95%CI)	NPA (95%CI)	PPA (95%CI)	NPA (95%CI)	PPA (95%CI)	NPA (95%CI)
<i>S. aureus</i>	63.6 (7/11) 35.4 - 84.8	98.1 (104/106) 93.4 - 99.5	36.4 (4/11) 15.2 - 64.6	100.0 (106/106) 96.5 - 100.0	100.0 (11/11) 74.1 - 100.0	98.1 (104/106) 93.4 - 99.5
<i>S. epidermidis</i>	85.7 (6/7) 48.7 - 97.4	75.0 (24/32) 57.9 - 86.7	0.0 (0/7) 0.0 - 35.4	93.8 (30/32) 79.9 - 98.3	85.7 (6/7) 48.7 - 97.4	68.8 (22/32) 51.4 - 82.0
<i>S. lugdunensis</i>	0.0 (0/1) 0.0 - 79.3	100.0 (4/4) 51.0 - 100.0	N/A	N/A	0.0 (0/1) 0.0 - 79.3	100.0 (4/4) 51.0 - 100.0
<i>S. agalactiae</i>	0.0 (0/3) 0.0 - 56.1	100.0 (4/4) 51.0 - 100.0	100.0 (3/3) 43.9 - 100.0	100.0 (4/4) 51.0 - 100.0	100.0 (3/3) 43.9 - 100.0	100.0 (4/4) 51.0 - 100.0
<i>S. anginosus</i> group	N/A	N/A	0/0	100.0 (2/2) 34.2 - 100.0	0/0	100.0 (2/2) 34.2 - 100.0
<i>S. pneumoniae</i>	0.0 (0/2) 0.0 - 65.8	100.0 (9/9) 70.1 - 100.0	100.0 (2/2) 34.2 - 100.0	100.0 (9/9) 70.1 - 100.0	100.0 (2/2) 34.2 - 100.0	100.0 (9/9) 70.1 - 100.0
<i>S. pyogenes</i>	N/A	N/A	100.0 (2/2) 34.2 - 100.0	100.0 (4/4) 51.0 - 100.0	100.0 (2/2) 34.2 - 100.0	100.0 (4/4) 51.0 - 100.0

D Expected Values/Reference Range:

The QIAstat-Dx BCID GPF Plus AMR Panel multi-site, prospective clinical study was conducted to evaluate clinical performance of the device using positive blood culture media (PBCM) specimens. The expected values of each target organism and resistance marker in the prospective samples by age are presented in **Table 46**.

Table 46. Expected Values by Age Group (Prospective Samples)

Target	Overall (n=976)	<1 year (n=15)	1-17 years (n=17)	18-44 years (n=148)	45-64 years (n=280)	65-89 years (n=473)	90+ years (n=43)
<i>Bacillus cereus</i> group	5 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.7%)	2 (0.4%)	1 (2.3%)
<i>Corynebacterium</i>	25 (2.6%)	0 (0.0%)	0 (0.0%)	3 (2.0%)	9 (3.2%)	11 (2.3%)	2 (4.7%)
<i>Enterococcus faecalis</i>	54 (5.5%)	1 (6.7%)	0 (0.0%)	4 (2.7%)	19 (6.8%)	29 (6.1%)	1 (2.3%)
<i>Enterococcus faecium</i>	41 (4.2%)	0 (0.0%)	0 (0.0%)	11 (7.4%)	10 (3.6%)	18 (3.8%)	2 (4.7%)
<i>Listeria monocytogenes</i>	4 (0.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)	0 (0.0%)	2 (0.4%)	1 (2.3%)
<i>Micrococcus</i> spp.	17 (1.7%)	1 (6.7%)	0 (0.0%)	4 (2.7%)	2 (0.7%)	9 (1.9%)	1 (2.3%)
<i>Staphylococcus aureus</i>	223 (22.8%)	4 (26.7%)	5 (29.4%)	39 (26.4%)	66 (23.6%)	100 (21.1%)	9 (20.9%)
<i>Staphylococcus epidermidis</i>	267 (27.4%)	4 (26.7%)	4 (23.5%)	41 (27.7%)	81 (28.9%)	124 (26.2%)	13 (30.2%)
<i>Staphylococcus lugdunensis</i>	10 (1.0%)	0 (0.0%)	0 (0.0%)	2 (1.4%)	2 (0.7%)	6 (1.3%)	0 (0.0%)
<i>S. capitis</i> / <i>S. hominis</i>	143 (14.7%)	1 (6.7%)	1 (5.9%)	20 (13.5%)	36 (12.9%)	79 (16.7%)	6 (14.0%)
<i>Streptococcus agalactiae</i>	27 (2.8%)	2 (13.3%)	0 (0.0%)	3 (2.0%)	8 (2.9%)	13 (2.7%)	1 (2.3%)
<i>Streptococcus anginosus</i> group	13 (1.3%)	0 (0.0%)	1 (5.9%)	1 (0.7%)	5 (1.8%)	6 (1.3%)	0 (0.0%)
<i>Streptococcus pneumoniae</i>	30 (3.1%)	0 (0.0%)	1 (5.9%)	3 (2.0%)	9 (3.2%)	11 (2.3%)	6 (14.0%)
<i>Streptococcus pyogenes</i>	22 (2.3%)	0 (0.0%)	0 (0.0%)	7 (4.7%)	7 (2.5%)	8 (1.7%)	0 (0.0%)
<i>Cryptococcus neoformans/gattii</i>	2 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.4%)	0 (0.0%)	1 (2.3%)
<i>Fusarium</i>	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
<i>Candida auris</i>	1 (0.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
Pan Gram-Negative	26 (2.7%)	0 (0.0%)	2 (11.8%)	5 (3.4%)	7 (2.5%)	11 (2.3%)	1 (2.3%)
<i>Candida</i> group 1	19 (1.9%)	1 (6.7%)	0 (0.0%)	3 (2.0%)	10 (3.6%)	5 (1.1%)	0 (0.0%)
<i>Candida</i> group 2	19 (1.9%)	0 (0.0%)	2 (11.8%)	1 (0.7%)	8 (2.9%)	8 (1.7%)	0 (0.0%)
cfr	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Erm(A)	50 (5.1%)	1 (6.7%)	1 (5.9%)	3 (2.0%)	10 (3.6%)	29 (6.1%)	6 (14.0%)
Erm(C)	145 (14.9%)	1 (6.7%)	1 (5.9%)	21 (14.2%)	45 (16.1%)	72 (15.2%)	5 (11.6%)
MecA	300 (30.7%)	4 (26.7%)	5 (29.4%)	38 (25.7%)	86 (30.7%)	157 (33.2%)	10 (23.3%)
MecC	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

VanA	17 (1.7%)	0 (0.0%)	0 (0.0%)	7 (4.7%)	3 (1.1%)	7 (1.5%)	0 (0.0%)
VanB	2 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.4%)	0 (0.0%)
Tet(M)	106 (10.9%)	1 (6.7%)	1 (5.9%)	20 (13.5%)	29 (10.4%)	53 (11.2%)	2 (4.7%)
Tet(K)	97 (9.9%)	0 (0.0%)	0 (0.0%)	14 (9.5%)	26 (9.3%)	50 (10.6%)	7 (16.3%)
Aac(6') aph(2')	87 (8.9%)	0 (0.0%)	0 (0.0%)	10 (6.8%)	18 (6.4%)	55 (11.6%)	4 (9.3%)

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.