



December 20, 2018

GenMark Diagnostics, Incorporated
Alan Maderazo
VP, Quality, Regulatory & Clinical Affairs
5964 La Place Court
Carlsbad, California 92008

Re: K181663

Trade/Device Name: ePlex Blood Culture Identification Panel - Gram Positive (BCID-GP) Panel
Regulation Number: 21 CFR 866.3365
Regulation Name: Multiplex nucleic acid assay for identification of microorganisms and resistance markers from positive blood cultures
Regulatory Class: Class II
Product Code: PAM, PEN, PEO
Dated: June 22, 2018
Received: June 25, 2018

Dear Alan Maderazo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Uwe Scherf -S

Uwe Scherf, M.Sc., Ph.D.

Director

Division of Microbiology Devices

Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K181663

Device Name
ePlex Blood Culture Identification Gram-Positive (BCID-GP) Panel

Indications for Use (Describe)

The GenMark ePlex Blood Culture Identification Gram-Positive (BCID-GP) Panel is a qualitative nucleic acid multiplex *in vitro* 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 *Candida* species (Pan *Candida* 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: *Bacillus cereus* group, *Bacillus subtilis* group, *Corynebacterium*, *Cutibacterium acnes* (*Propionibacterium acnes*), *Enterococcus*, *Enterococcus faecalis*, *Enterococcus faecium*, *Lactobacillus*, *Listeria*, *Listeria monocytogenes*, *Micrococcus*, *Staphylococcus*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus lugdunensis*, *Streptococcus*, *Streptococcus agalactiae* (GBS), *Streptococcus anginosus* group, *Streptococcus pneumoniae*, *Streptococcus pyogenes* (GAS), *mecA*, *mecC*, *vanA* and *vanB*.

The ePlex BCID-GP Panel contains assays for the detection of genetic determinants associated with resistance to methicillin (*mecA* and *mecC*) and vancomycin (*vanA* and *vanB*) 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 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 *Candida* assay, which is designed to detect four of the most prevalent *Candida* species: *Candida albicans*, *Candida glabrata*, *Candida krusei* and *Candida parapsilosis*.

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.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Summary of Safety and Effectiveness

Submitter Information

Submitter: GenMark Diagnostics, Incorporated
5964 La Place Court
Carlsbad, CA 92008

Manufacturer: GenMark Diagnostics, Incorporated
5964 La Place Court
Carlsbad, CA 92008

Establishment Registration Number: 3008632402

Contact: Alan Maderazo, Ph.D., RAC
Vice President, Quality, Regulatory and Clinical Affairs

Phone: 760-448-4308

Fax: 760-683-6961

E-mail: Al.Maderazo@genmarkdx.com

Alternate Contact: Beth Stofka
Sr. Regulatory Affairs Specialist

Phone: 760-579-4778

Fax: 760-683-6961

E-mail: Beth.Stofka@genmarkdx.com

Date Prepared: June 22, 2018

Name of Device and Classification

Product Name: ePlex[®] Blood Culture Identification Gram-Positive (BCID-GP) Panel

Device Classification: 866.3980, Multiplex nucleic acid assay for identification of microorganisms and resistance markers from positive blood cultures, Class II

Product Code(s): PAM, PEN, PEO

Predicate Device

Predicate: FilmArray Blood Culture Identification Panel; BioFire Diagnostics;
K130914

Device Description

The ePlex Blood Culture Identification Gram-Positive (BCID-GP) Panel is based on the principles of competitive nucleic acid hybridization using a sandwich assay format, wherein a single-stranded target binds concurrently to a sequence-specific solution-phase signal probe and a solid-phase electrode-bound capture probe. The test employs nucleic acid extraction, target amplification via polymerase chain reaction (PCR) or reverse transcription PCR (RT-PCR) and hybridization of target DNA. In the process, the double-stranded PCR amplicons are digested with exonuclease to generate single-stranded DNA suitable for hybridization.

Nucleic acid extraction from biological samples occurs within the cartridge via cell lysis, nucleic acid capture onto magnetic beads, and release for amplification. The nucleic acid extraction is processed through microfluidic liquid handling. Once the nucleic acid targets are captured and inhibitors are washed away, the magnetic particles are delivered to the electrowetting environment on the printed circuit board (PCB) and the targets are eluted from the particles and amplified.

During hybridization, the single-stranded target DNA binds to a complementary, single-stranded capture probe immobilized on the working gold electrode surface. Single-stranded signal probes (labeled with electrochemically active ferrocenes) bind to specific target sequence / region adjacent to the capture probe. Simultaneous hybridization of target to signal probes and capture probe is detected by alternating current voltammetry (ACV). Each working electrode on the array contains specific capture probes, and sequential analysis of each electrode allows detection of multiple analyte targets.

Intended Use/Indications for Use

The GenMark ePlex[®] Blood Culture Identification Gram-Positive (BCID-GP) Panel is a qualitative nucleic acid multiplex *in vitro* 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 *Candida* species (Pan *Candida* 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: *Bacillus cereus* group, *Bacillus subtilis* group, *Corynebacterium*, *Cutibacterium acnes* (*Propionibacterium acnes*), *Enterococcus*, *Enterococcus faecalis*, *Enterococcus faecium*, *Lactobacillus*, *Listeria*, *Listeria monocytogenes*, *Micrococcus*, *Staphylococcus*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus lugdunensis*, *Streptococcus*, *Streptococcus agalactiae* (GBS), *Streptococcus anginosus* group, *Streptococcus pneumoniae*, *Streptococcus pyogenes* (GAS), *mecA*, *mecC*, *vanA* and *vanB*.

The ePlex BCID-GP Panel contains assays for the detection of genetic determinants associated with resistance to methicillin (*mecA* and *mecC*) and vancomycin (*vanA* and *vanB*) 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 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 *Candida* assay, which is designed to detect four of the most prevalent *Candida* species: *Candida albicans*, *Candida glabrata*, *Candida krusei* and *Candida parapsilosis*.

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.

Summary of Technological Characteristics of the Device Compared to the Predicate Device

The GenMark ePlex Blood Culture Identification Gram-Positive (BCID-GP) Panel (“Subject Device”) and the legally marketed device, FilmArray Blood Culture Identification Gram-Positive Panel, K130914, (“Predicate Device”) are described below:

Characteristic	Subject Device	Predicate Device
Product Name	ePlex BCID-GP Panel	FilmArray BCID Panel
Manufacturer	GenMark Diagnostics, Inc.	BioFire Diagnostics, Inc.
Organisms Detected	• <i>Bacillus cereus</i> group • <i>Bacillus subtilis</i> group • <i>Corynebacterium</i> • <i>Cutibacterium acnes</i> (<i>P. 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>Enterococci</i> , <i>Listeria monocytogenes</i> , commonly encountered <i>Staphylococci</i> (including specific differentiation of <i>Staphylococcus aureus</i>), commonly encountered <i>Streptococci</i> (with specific differentiation of <i>Streptococcus agalactiae</i> , <i>Streptococcus pneumoniae</i> , and <i>Streptococcus pyogenes</i>), <i>Acinetobacter baumannii</i> , commonly encountered <i>Enterobacteriaceae</i> (including specific differentiation of the <i>Enterobacter cloacae</i> complex, <i>Escherichia coli</i> , <i>Klebsiella oxytoca</i> ,

Characteristic	Subject Device	Predicate Device
	• <i>Staphylococcus lugdunensis</i> • <i>Streptococcus</i> • <i>Streptococcus agalactiae</i> (GBS) • <i>Streptococcus anginosus</i> group • <i>Streptococcus pneumonia</i> • <i>Streptococcus pyogenes</i> (GAS) • Pan Gram-Negative • Pan <i>Candida</i>	<i>Klebsiella pneumoniae</i> , <i>Proteus</i> , and <i>Serratia marcescens</i>), <i>Haemophilus influenzae</i> , <i>Neisseria meningitidis</i> (encapsulated), <i>Pseudomonas aeruginosa</i> , <i>Candida albicans</i> , <i>Candida glabrata</i> , <i>Candida krusei</i> , <i>Candida parapsilosis</i> , and <i>Candida tropicalis</i> .
Resistance Genes Detected	Genetic determinants of resistance to methicillin (<i>mecA</i> and <i>mecC</i>) and vancomycin (<i>vanA</i> and <i>vanB</i>)	Genetic determinants of resistance to methicillin (<i>mecA</i>), vancomycin (<i>vanA</i> and <i>vanB</i>), and carbapenems (<i>bla_{KPC}</i>)
Indication for Use	The GenMark BCID-GP panel is indicated as an aid in the diagnosis of specific agents of bacteremia. The use of additional laboratory testing (e.g. sub-culturing of positive blood cultures for identification of organisms not detected by 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.	FilmArray BCID is indicated as an aid in the diagnosis of specific agents of bacteremia and fungemia and results should be used in conjunction with other clinical and laboratory findings.
Specimen Type	Gram-Positive Blood Culture	Gram-Positive & Gram-Negative Blood Culture
Chemistry	Reagents on cartridge include: sample lysis and nucleic acid extraction, PCR amplification and hybridization-based electrochemical detection reagents.	The FilmArray BCID pouch contains freeze-dried reagents to perform nucleic acid purification and nested, multiplex PCR with DNA melt analysis.
Hardware	GenMark ePlex Instrument & Single Use Cartridge	FilmArray Instrument and assay pouch
Software Interface Result Reporting	• GenMark ePlex System Software • GenMark ePlex BCID-GP Panel Software	The FilmArray Software automatically interprets the results of each DNA melt curve analysis and combines the data with the results of the internal pouch controls to provide a test result for each organism and antimicrobial resistance gene on the panel.

Analysis of the similarities and differences indicate that the devices are substantially equivalent in their intended uses/indications for use, and are generally the same regarding user process, ease

of use and general operator protocol. Comparison of technological similarities and differences between the proposed device and the predicate do not raise new or different questions of safety and effectiveness, and therefore render the proposed device as substantially equivalent to the predicate device.

Summary of Performance Data

EXPECTED VALUES

A prospective, multicenter clinical study was conducted to evaluate the clinical performance of the ePlex BCID-GP Panel in positive blood culture samples. A total of 711 samples were prospectively collected at 7 clinical sites in 2 phases from patients of all ages and genders. In the first phase from June 2014 through July 2016, 399 samples were prospectively collected and frozen; from January through February 2018, 312 samples were prospectively collected and tested fresh (never frozen). The expected values of individual analytes based on the ePlex BCID-GP Panel results in prospective samples are summarized by age group and by site in **Table 1** and **Table 2**, respectively.

Table 1: Expected Value by Age Group (Prospective Samples)

Target	All Ages (N=711)	Age <1 (N=27)	Age 1-17 (N=42)	Age 18-44 (N=121)	Age 45-64 (N=2500)	Age 65-84 (N=217)	Age 85+ (N=54)
<i>Bacillus cereus</i> group	5 (0.7)	0 (0.0)	0 (0.0)	3 (2.5)	2 (0.8)	0 (0.0)	0 (0.0)
<i>Bacillus subtilis</i> group	2 (0.3)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.9)
<i>Corynebacterium</i>	14 (2.0)	1 (3.7)	0 (0.0)	4 (3.3)	5 (2.0)	4 (1.8)	0 (0.0)
<i>Cutibacterium acnes</i> (<i>P. acnes</i>)	8 (1.1)	0 (0.0)	0 (0.0)	3 (2.5)	2 (0.8)	3 (1.4)	0 (0.0)
<i>Enterococcus</i>	62 (8.7)	0 (0.0)	6 (14.3)	8 (6.6)	20 (8.0)	24 (11.1)	4 (7.4)
<i>Enterococcus faecalis</i>	50 (7.0)	0 (0.0)	6 (14.3)	6 (5.0)	15 (6.0)	20 (9.2)	3 (5.6)
<i>Enterococcus faecium</i>	12 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	6 (2.4)	5 (2.3)	0 (0.0)
<i>Lactobacillus</i>	5 (0.7)	0 (0.0)	0 (0.0)	2 (1.7)	1 (0.4)	1 (0.5)	1 (1.9)
<i>Listeria</i>	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)
<i>Listeria monocytogenes</i>	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<i>Micrococcus</i>	19 (2.7)	0 (0.0)	3 (7.1)	2 (1.7)	8 (3.2)	5 (2.3)	1 (1.9)
<i>Staphylococcus</i>	452 (63.6)	23 (85.2)	23 (54.8)	78 (64.5)	154 (61.6)	139 (64.1)	35 (64.8)
<i>Staphylococcus aureus</i>	162 (22.8)	8 (29.6)	4 (9.5)	37 (30.6)	69 (27.6)	38 (17.5)	6 (11.1)
<i>Staphylococcus epidermidis</i>	182 (25.6)	10 (37.0)	11 (26.2)	26 (21.5)	54 (21.6)	62 (28.6)	19 (35.2)
<i>Staphylococcus lugdunensis</i>	5 (0.7)	1 (3.7)	0 (0.0)	0 (0.0)	3 (1.2)	0 (0.0)	1 (1.9)
<i>Streptococcus</i>	110 (15.5)	5 (18.5)	9 (21.4)	16 (13.2)	40 (16.0)	31 (14.3)	9 (16.7)
<i>Streptococcus agalactiae</i>	12 (1.7)	1 (3.7)	0 (0.0)	1 (0.8)	5 (2.0)	5 (2.3)	0 (0.0)
<i>Streptococcus anginosus</i> group	10 (1.4)	0 (0.0)	0 (0.0)	2 (1.7)	3 (1.2)	3 (1.4)	2 (3.7)
<i>Streptococcus pneumoniae</i>	28 (3.9)	2 (7.4)	2 (4.8)	3 (2.5)	12 (4.8)	8 (3.7)	1 (1.9)
<i>Streptococcus pyogenes</i>	8 (1.1)	0 (0.0)	0 (0.0)	1 (0.8)	5 (2.0)	2 (0.9)	0 (0.0)
Pan <i>Candida</i>	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pan Gram-Negative	25 (3.5)	0 (0.0)	4 (9.5)	4 (3.3)	10 (4.0)	6 (2.8)	1 (1.9)
<i>mecA</i> (<i>Staphylococcus</i>)	261 (36.7)	14 (51.9)	10 (23.8)	41 (33.9)	83 (33.2)	94 (43.3)	19 (35.2)
<i>mecA</i> (<i>S. aureus</i>)	86 (12.1)	4 (14.8)	1 (2.4)	17 (14.0)	35 (14.0)	26 (12.0)	3 (5.6)
<i>mecA</i> (<i>S. epidermidis</i>)	137 (19.3)	8 (29.6)	9 (21.4)	19 (15.7)	38 (15.2)	48 (22.1)	15 (27.8)
<i>mecA</i> (<i>S. lugdunensis</i>)	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
<i>mecA</i> (CoNS excluding <i>S. epidermidis</i> / <i>S. lugdunensis</i>)	40 (5.6)	2 (7.4)	0 (0.0)	6 (5.0)	10 (4.0)	20 (9.2)	2 (3.7)
<i>mecC</i> (<i>Staphylococcus</i>)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<i>vanA</i> (<i>Enterococcus</i>)	9 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	6 (2.4)	3 (1.4)	0 (0.0)
<i>vanA</i> (<i>E. faecalis</i>)	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
<i>vanA</i> (<i>E. faecium</i>)	8 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	5 (2.0)	3 (1.4)	0 (0.0)
<i>vanB</i> (<i>Enterococcus</i>)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 2: Expected Value by Collection Site (Prospective Samples)

Target	All Sites (N=711)	Site 1 (N=161)	Site 2 (N=58)	Site 3 (N=164)	Site 4 (N=145)	Site 5 (N=77)	Site 6 (N=33)	Site 7 (N=73)
<i>Bacillus cereus</i> group	5 (0.7)	3 (1.9)	1 (1.7)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<i>Bacillus subtilis</i> group	2 (0.3)	0 (0.0)	1 (1.7)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)
<i>Corynebacterium</i>	14 (2.0)	2 (1.2)	2 (3.4)	0 (0.0)	6 (4.1)	2 (2.6)	0 (0.0)	2 (2.7)
<i>Cutibacterium acnes</i> (<i>P. acnes</i>)	8 (1.1)	1 (0.6)	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)	0 (0.0)	4 (5.5)
<i>Enterococcus</i>	62 (8.7)	20 (12.4)	7 (12.1)	15 (9.1)	9 (6.2)	10 (13.0)	1 (3.0)	0 (0.0)
<i>Enterococcus faecalis</i>	50 (7.0)	14 (8.7)	6 (10.3)	13 (7.9)	8 (5.5)	8 (10.4)	1 (3.0)	0 (0.0)
<i>Enterococcus faecium</i>	12 (1.7)	6 (3.7)	1 (1.7)	1 (0.6)	2 (1.4)	2 (2.6)	0 (0.0)	0 (0.0)
<i>Lactobacillus</i>	5 (0.7)	1 (0.6)	1 (1.7)	2 (1.2)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)
<i>Listeria</i>	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
<i>Listeria monocytogenes</i>	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<i>Micrococcus</i>	19 (2.7)	2 (1.2)	2 (3.4)	5 (3.0)	6 (4.1)	0 (0.0)	0 (0.0)	4 (5.5)
<i>Staphylococcus</i>	452 (63.6)	106 (65.8)	27 (46.6)	109 (66.5)	98 (67.6)	52 (67.5)	24 (72.7)	36 (49.3)
<i>Staphylococcus aureus</i>	162 (22.8)	36 (22.4)	7 (12.1)	56 (34.1)	27 (18.6)	18 (23.4)	6 (18.2)	12 (16.4)
<i>Staphylococcus epidermidis</i>	182 (25.6)	41 (25.5)	14 (24.1)	34 (20.7)	44 (30.3)	23 (29.9)	13 (39.4)	13 (17.8)
<i>Staphylococcus lugdunensis</i>	5 (0.7)	0 (0.0)	0 (0.0)	2 (1.2)	2 (1.4)	0 (0.0)	0 (0.0)	1 (1.4)
<i>Streptococcus</i>	110 (15.5)	18 (11.2)	9 (15.5)	28 (17.1)	20 (13.8)	11 (14.3)	5 (15.2)	19 (26.0)
<i>Streptococcus agalactiae</i>	12 (1.7)	2 (1.2)	0 (0.0)	2 (1.2)	2 (1.4)	2 (2.6)	2 (6.1)	2 (2.7)
<i>Streptococcus anginosus</i> group	10 (1.4)	2 (1.2)	0 (0.0)	6 (3.7)	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)
<i>Streptococcus pneumoniae</i>	28 (3.9)	3 (1.9)	5 (8.6)	5 (3.0)	4 (2.8)	1 (1.3)	0 (0.0)	10 (13.7)
<i>Streptococcus pyogenes</i>	8 (1.1)	1 (0.6)	0 (0.0)	3 (1.8)	1 (0.7)	1 (1.3)	0 (0.0)	2 (2.7)
Pan <i>Candida</i>	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pan Gram-Negative	25 (3.5)	9 (5.6)	4 (6.9)	3 (1.8)	2 (1.4)	5 (6.5)	1 (3.0)	1 (1.4)
<i>mecA</i> (<i>Staphylococcus</i>)	261 (36.7)	69 (42.9)	17 (29.3)	68 (41.5)	55 (37.9)	25 (32.5)	13 (39.4)	14 (19.2)
<i>mecA</i> (<i>S. aureus</i>)	86 (12.1)	19 (11.8)	5 (8.6)	28 (17.1)	19 (13.1)	7 (9.1)	3 (9.1)	5 (6.8)
<i>mecA</i> (<i>S. epidermidis</i>)	137 (19.3)	36 (22.4)	10 (17.2)	31 (18.9)	29 (20.0)	17 (22.1)	8 (24.2)	6 (8.2)
<i>mecA</i> (<i>S. lugdunensis</i>)	1 (0.1)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<i>mecA</i> (CoNS excluding <i>S. epidermidis</i> / <i>S. lugdunensis</i>)	40 (5.6)	15 (9.3)	2 (3.4)	9 (5.5)	7 (4.8)	2 (2.6)	2 (6.1)	3 (4.1)
<i>mecC</i> (<i>Staphylococcus</i>)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<i>vanA</i> (<i>Enterococcus</i>)	9 (1.3)	6 (3.7)	0 (0.0)	1 (0.6)	1 (0.7)	1 (1.3)	0 (0.0)	0 (0.0)
<i>vanA</i> (<i>E. faecalis</i>)	1 (0.1)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<i>vanA</i> (<i>E. faecium</i>)	8 (1.1)	5 (3.1)	0 (0.0)	1 (0.6)	1 (0.7)	1 (1.3)	0 (0.0)	0 (0.0)
<i>vanB</i> (<i>Enterococcus</i>)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

PERFORMANCE CHARACTERISTICS

Clinical Performance

Samples with final, valid ePlex BCID-GP Panel test results and a valid comparator result were evaluable and included in summaries and analyses of demographics, expected values (positivity rate), and performance characteristics. Evaluable samples included 312 prospective fresh and 399 prospective frozen samples as well as 586 retrospective samples and 565 contrived samples.

Comparator Method

The performance of the ePlex BCID-GP Panel was compared to standard laboratory procedures, including traditional and automated culture, MALDI-TOF IVD, and microbiological and biochemical techniques for organism identification. Identification for samples with *Corynebacterium*, *Staphylococcus epidermidis*, *Staphylococcus hominis*, or *Candida parapsilosis* identified by standard laboratory procedures were confirmed using analytically validated PCR assays followed by bi-directional sequencing or 16S sequencing. For antibiotic resistance genes, the ePlex BCID-GP Panel was compared to analytically validated qPCR amplification assays followed by bi-directional sequencing in samples with an associated organism identified (i.e., *Staphylococcus*, *Enterococcus*).

The comparator method(s) results were used to determine the Detected / Not Detected status for each target organism on the ePlex BCID-GP Panel. The comparator methods for each target are summarized in **Table 3**.

Table 3: Comparator Method(s) by ePlex BCID-GP Panel Target

Target	Comparator Method
<i>Bacillus cereus</i> group	Standard laboratory procedures for organism identification.
<i>Bacillus subtilis</i> group	
<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 lugdunensis</i>	
<i>Streptococcus</i>	
<i>Streptococcus agalactiae</i>	
<i>Streptococcus anginosus</i> group	
<i>Streptococcus pneumoniae</i>	
<i>Streptococcus pyogenes</i>	
Pan Gram-Negative	
<i>Corynebacterium</i>	Standard laboratory procedures for organism ID. PCR/sequencing and 16S sequencing to confirm (or identify Coryneform) or exclude <i>Corynebacterium</i> species not included in this panel target*
<i>Staphylococcus epidermidis</i>	Standard laboratory procedures for organism ID. PCR/sequencing to confirm <i>S. epidermidis</i> , <i>S. hominis</i>
Pan <i>Candida</i>	Standard laboratory procedures for organism ID. PCR/sequencing to confirm <i>C. parapsilosis</i> or identify <i>C. metapsilosis</i> , <i>C. orthopsilosis</i>
<i>mecA</i>	qPCR/sequencing in samples with <i>Staphylococcus</i> identified
<i>mecC</i>	
<i>vanA</i>	qPCR/sequencing in samples with <i>Enterococcus</i> identified
<i>vanB</i>	

* The *Corynebacterium* assay is not designed to detect the following *Corynebacterium* species: *C. amycolatum*, *C. argenterotense*, *C. bovis*, *C. durum*, *C. glucuronolyticum*, *C. macginleyi*, *C. propinquum*, *C. riegliei*, and *C. sundsvallense*

Demographics of Clinical Samples

Clinical performance was evaluated in positive blood culture samples prospectively and retrospectively collected. Prospective samples were collected at 7 clinical sites in 2 phases. From June 2014 through July 2016, 400 samples were prospectively collected and frozen; from January through February 2018, 319 samples were prospectively collected and tested fresh (never frozen) for a total of 719 samples across the 2 phases. 8 of these samples were withdrawn;

5 due to the sample coming from a patient already enrolled; 1 was collected outside of the required timeframe; 1 was not viable upon subculture and 1 was from an autopsy. Samples with final, valid ePlex BCID-GP Panel results and a valid comparator result were considered evaluable. Of the 711 prospectively-collected samples eligible for testing, all 711 were evaluable. Demographic information for prospectively-collected samples is described in **Table 4**. Subjects enrolled in this study were from a diverse demographic distribution and represent the intended patient population.

To supplement the number of positives for low prevalence targets in the prospective collection, 586 samples were collected retrospectively, and all 586 were evaluable. Demographic information for retrospectively-collected samples is described in **Table 5**.

Table 4: Demographic Data for Clinical Samples by Collection Site (Prospective Collection)

	All Sites N = 711	Site 1 N = 161	Site 2 N = 58	Site 3 N = 164	Site 4 N = 145	Site 5 N = 77	Site 6 N = 33	Site 7 N = 73
Sex								
Male	377 (53.0)	93 (57.8)	28 (48.3)	91 (55.5)	66 (45.5)	42 (54.5)	17 (51.5)	40 (54.8)
Female	334 (47.0)	68 (42.2)	30 (51.7)	73 (44.5)	79 (54.5)	35 (45.5)	16 (48.5)	33 (45.2)
Age								
<1 yr	27 (3.8)	3 (1.9)	0 (0.0)	8 (4.9)	10 (6.9)	4 (5.2)	2 (6.1)	0 (0.0)
1-17 yrs	42 (5.9)	8 (5.0)	2 (3.4)	11 (6.7)	10 (6.9)	7 (9.1)	2 (6.1)	2 (2.7)
18-44 yrs	121 (17)	32 (19.9)	9 (15.5)	24 (14.6)	24 (16.6)	13 (16.9)	4 (12.1)	15 (20.5)
45-64 yrs	250 (35.2)	66 (41.0)	18 (31.0)	67 (40.9)	36 (24.8)	25 (32.5)	11 (33.3)	27 (37.0)
65-84 yrs	217 (30.5)	44 (27.3)	20 (34.5)	41 (25.0)	51 (35.2)	23 (29.9)	13 (39.4)	25 (34.2)
85+ yrs	54 (7.6)	8 (5.0)	9 (15.5)	13 (7.9)	14 (9.7)	5 (6.5)	1 (3.0)	4 (5.5)

Table 5: Demographic Data for Clinical Samples by Collection Site (Retrospective Collection)

	All Sites N = 586	Site 1 N = 80	Site 2 N = 98	Site 3 N = 51	Site 4 N = 43	Site 5 N = 3	Site 6 N = 61	Site 7 N = 85	Site 8 N = 25	Site 9 N = 46	Site 10 N = 94
Sex											
Male	317 (54.1)	39 (48.8)	59 (60.2)	24 (47.1)	20 (46.5)	1 (33.3)	36 (59.0)	45 (52.9)	17 (68.0)	28 (60.9)	48 (51.1)
Female	269 (45.9)	41 (51.3)	39 (39.8)	27 (52.9)	23 (53.5)	2 (66.7)	25 (41.0)	40 (47.1)	8 (32.0)	18 (39.1)	46 (48.9)
Age											
<1 yr	11 (1.9)	1 (1.3)	2 (2)	0 (0)	3 (7)	0 (0)	1 (1.6)	0 (0)	0 (0)	1 (2.2)	3 (3.2)
1-17 yrs	17 (2.9)	6 (7.5)	1 (1)	0 (0)	4 (9.3)	0 (0)	0 (0)	0 (0)	1 (4)	1 (2.2)	4 (4.3)
18-44 yrs	104 (17.7)	14 (17.5)	13 (13.3)	5 (9.8)	9 (20.9)	0 (0)	15 (24.6)	11 (12.9)	7 (28)	5 (10.9)	25 (26.6)
45-64 yrs	193 (32.9)	25 (31.3)	33 (33.7)	17 (33.3)	15 (34.9)	1 (33.3)	21 (34.4)	30 (35.3)	10 (40)	12 (26.1)	29 (30.9)
65-84 yrs	209 (35.7)	26 (32.5)	42 (42.9)	22 (43.1)	9 (20.9)	0 (0)	20 (32.8)	35 (41.2)	7 (28)	18 (39.1)	30 (31.9)
85+ yrs	50 (8.5)	8 (10)	7 (7.1)	7 (13.7)	3 (7)	2 (66.7)	4 (6.6)	7 (8.2)	0 (0)	9 (19.6)	3 (3.2)
Unknown	2 (0.3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2.4)	0 (0)	0 (0)	0 (0)

Clinical Performance

Sensitivity or 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 specificity or 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. A TP result being defined as a sample where the detected ePlex BCID-GP Panel result matched the detected comparator method result, while a TN result was one where a negative ePlex BCID-GP Panel result matched a negative comparator method result. The two-sided 95% confidence interval was also calculated.

A total of 711 prospectively-collected samples (312 tested fresh and 399 tested after previously frozen) and 586 retrospectively collected samples as well as 565 contrived samples were evaluated for the ePlex BCID-GP Panel targets. Contrived samples were prepared by spiking an isolate into a blood culture bottle and growing until flagged positive by a continuously monitoring blood culture system. Samples were removed from the system within 8 hours of positivity and stored frozen until the time of testing. PPA and NPA results are summarized by target in **Tables 6-30** and the strains used to contrive samples are summarized in **Table 31**.

Table 6: Clinical Performance for *Bacillus cereus* group

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Bacillus cereus</i> group	Prospective (Fresh)	2/2	100 (34.2-100)	310/310	100 (98.8-100)
	Prospective (Frozen)	3/3	100 (43.9-100)	396/396	100 (99.0-100)
	Prospective (All)	5/5	100 (56.6-100)	706/706	100 (99.5-100)
	Retrospective	6/7	85.7 (48.7-97.4)	579/579	100 (99.3-100)
	Prospective/Retrospective	11/12	91.7 (64.6-98.5)	1765/1765	100 (99.8-100)
	Contrived	46/46	100 (92.3-100)	519/519	100 (99.3-100)
	Overall	57/58	98.3 (90.9-99.7)	2284/2284	100 (99.8-100)

CI= Confidence Interval

Table 7: Clinical Performance for *Bacillus subtilis* group

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Bacillus subtilis</i> group	Prospective (Fresh)	2/2	100 (34.2-100)	309/309	100 (98.8-100)
	Prospective (Frozen)	0/0	---	399/399	100 (99.0-100)
	Prospective (All)	2/2	100 (34.2-100)	708/708	100 (99.5-100)
	Retrospective	0/0	---	586/586	100 (99.3-100)
	Prospective/Retrospective	2/2	100 (34.2-100)	1294/1294	100 (99.7-100)
	Contrived	50/50	100 (92.9-100)	515/515	100 (99.3-100)
	Overall	52/52	100 (93.1-100)	1809/1809	100 (99.8-100)

Table 8: Clinical Performance for *Corynebacterium*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Corynebacterium</i>	Prospective (Fresh)	5/7	71.4 (35.9-91.8)	304/305	99.7 (98.2-99.9)
	Prospective (Frozen)	8/12	66.7 (39.1-86.2)	387/387	100 (99.0-100)
	Prospective (All)	13/19	68.4 (46.0-84.6)	691/692	99.9 (99.2-100)
	Retrospective	27/32	84.4 (68.2-93.1)	553/554	99.8 (99.0-100)
	Prospective/Retrospective	40/51^A	78.4 (65.4-87.5)	1244/1246^B	99.8 (99.4-100)
	Contrived	20/20	100 (83.9-100)	545/545	100 (99.3-100)
	Overall	60/71	84.5 (74.3-91.1)	1789/1791	99.9 (99.6-100)

A. *Corynebacterium* was not detected in 4 of the false negative samples using PCR/sequencing, but 16S sequencing instead detected *Staphylococcus pettenkoferi*, *Macrococcus caseolyticus*, *Lactobacillus fermentum*, and *Cutibacterium acnes*, which were not identified by standard laboratory procedures.

B. *Corynebacterium* was detected in 2/2 false positive samples using PCR/sequencing.

Table 9: Clinical Performance for *Cutibacterium acnes*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Cutibacterium acnes</i>	Prospective (Fresh)	4/5	80.0 (37.6-96.4)	306/307	99.7 (98.2-99.9)
	Prospective (Frozen)	2/2	100 (34.2-100)	396/397	99.7 (98.6-100)
	Prospective (All)	6/7	85.7 (48.7-97.4)	702/704	99.7 (99.0-99.9)
	Retrospective	12/13	92.3 (66.7-98.6)	573/573	100 (99.3-100)
	Prospective/Retrospective	18/20	90.0 (69.9-97.2)	1275/1277 ^A	99.8 (99.4-100)
	Contrived	25/26	96.2 (81.1-99.3)	539/539	100 (99.3-100)
	Overall	43/46	93.5 (82.5-97.8)	1814/1816	99.9 (99.6-100)

A. *Cutibacterium acnes* was detected in 1/2 false positive samples using PCR/sequencing.

Table 10: Clinical Performance for *Enterococcus*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Enterococcus</i>	Prospective (Fresh)	25/25	100 (86.7-100)	287/287	100 (98.7-100)
	Prospective (Frozen)	36/36	100 (90.4-100)	362/363	99.7 (98.5-100)
	Prospective (All)	61/61	100 (94.1-100)	649/650	99.8 (99.1-100)
	Retrospective	139/147	94.6 (89.6-97.2)	439/439	100 (99.1-100)
	Prospective/Retrospective	200/208 ^A	96.2 (92.6-98.0)	1088/1089 ^B	99.9 (99.5-100)
	Contrived	126/126	100 (97.0-100)	439/439	100 (99.1-100)
	Overall	326/334	97.6 (95.3-98.8)	1527/1528	99.9 (99.6-100)

A. *Enterococcus* was not detected in 1 false negative sample, but PCR/sequencing instead detected *Lactococcus lactis*, which was not identified by standard laboratory procedures.

B. *Enterococcus* was detected in 1/1 false positive samples using PCR/sequencing.

Table 11: Clinical Performance for *Enterococcus faecalis*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Enterococcus faecalis</i>	Prospective (Fresh)	21/21	100 (84.5-100)	291/291	100 (98.7-100)
	Prospective (Frozen)	28/28	100 (87.9-100)	370/370	100 (99.0-100)
	Prospective (All)	49/49	100 (92.7-100)	661/661	100 (99.4-100)
	Retrospective	82/90	91.1 (83.4-95.4)	496/496	100 (99.2-100)
	Prospective/Retrospective	131/139 ^A	94.2 (89.1-97.1)	1157/1157	100 (99.7-100)
	Contrived	52/52	100 (93.1-100)	513/513	100 (99.3-100)
	Overall	183/191	95.8 (92.0-97.9)	1670/1670	100 (99.8-100)

A. *Enterococcus faecalis* was not detected in 4 false negative samples, but PCR/sequencing instead detected *Enterococcus faecium* (3) and *Lactococcus lactis* (1), which were not identified by standard laboratory procedures.

Table 12: Clinical Performance for *Enterococcus faecium*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Enterococcus faecium</i>	Prospective (Fresh)	3/3	100 (43.9-100)	309/309	100 (98.8-100)
	Prospective (Frozen)	8/9	88.9 (56.5-98.0)	388/389	99.7 (98.6-100)
	Prospective (All)	11/12	91.7 (64.6-98.5)	697/698	99.9 (99.2-100)
	Retrospective	52/53	98.1 (90.1-99.7)	526/533	98.7 (97.3-99.4)
	Prospective/Retrospective	63/65	96.9 (89.5-99.2)	1223/1231 ^A	99.4 (98.7-99.7)
	Contrived	60/60	100 (94.0-100)	505/505	100 (99.2-100)
	Overall	123/125	98.4 (94.4-99.6)	1728/1736	99.5 (99.1-99.8)

A. *Enterococcus faecium* was detected in 5/8 false positive samples using PCR/sequencing.

Table 13: Clinical Performance for *Lactobacillus*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Lactobacillus</i>	Prospective (Fresh)	2/2	100 (34.2-100)	309/310	99.7 (98.2-99.9)
	Prospective (Frozen)	2/2	100 (34.2-100)	397/397	100 (99.0-100)
	Prospective (All)	4/4	100 (51.0-100)	706/707	99.9 (99.2-100)
	Retrospective	9/9	100 (70.1-100)	576/577	99.8 (99.0-100)
	Prospective/Retrospective	13/13	100 (77.2-100)	1282/1284 ^A	99.8 (99.4-100)
	Contrived	32/33	97.0 (84.7-99.5)	532/532	100 (99.3-100)
	Overall	45/46	97.8 (88.7-99.6)	1814/1816	99.9 (99.6-100)

A. *Lactobacillus casei* was detected in 1/2 false positive samples using PCR/sequencing.

Table 14: Clinical Performance for *Listeria*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Listeria</i>	Prospective (Fresh)	0/0	---	312/312	100 (98.8-100)
	Prospective (Frozen)	0/0	---	398/399	99.7 (98.6-100)
	Prospective (All)	0/0	---	710/711	99.9 (99.2-100)
	Retrospective	2/2	100 (34.2-100)	584/584	100 (99.3-100)
	Prospective/Retrospective	2/2	100 (34.2-100)	1294/1295	99.9 (99.6-100)
	Contrived	74/75	98.7 (92.8-99.8)	490/490	100 (99.2-100)
	Overall	76/77	98.7 (93.0-99.8)	1784/1785	99.9 (99.7-100)

Table 15: Clinical Performance for *Listeria monocytogenes*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Listeria monocytogenes</i>	Prospective (Fresh)	0/0	---	312/312	100 (98.8-100)
	Prospective (Frozen)	0/0	---	399/399	100 (99.0-100)
	Prospective (All)	0/0	---	711/711	100 (99.5-100)
	Retrospective	2/2	100 (34.2-100)	584/584	100 (99.3-100)
	Prospective/Retrospective	2/2	100 (34.2-100)	1295/1295	100 (99.7-100)
	Contrived	46/46	100 (92.3-100)	519/519	100 (99.3-100)
	Overall	48/48	100 (92.6-100)	1814/1814	100 (99.8-100)

Table 16: Clinical Performance for *Micrococcus*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Micrococcus</i>	Prospective (Fresh)	9/10	90.0 (59.6-98.2)	302/302	100 (98.7-100)
	Prospective (Frozen)	10/11	90.9 (62.3-98.4)	388/388	100 (99.0-100)
	Prospective (All)	19/21	90.5 (71.1-97.3)	690/690	100 (99.4-100)
	Retrospective	20/23	87.0 (67.9-95.5)	562/563	99.8 (99.0-100)
	Prospective/Retrospective	39/44^A	88.6 (76.0-95.0)	1252/1253	99.9 (99.5-100)
	Contrived	27/27	100 (87.5-100)	538/538	100 (99.3-100)
	Overall	66/71	93.0 (84.6-97.0)	1790/1791	99.9 (99.7-100)

A. *Micrococcus* was not detected in 3 false negative samples, but PCR/sequencing instead detected *Brevibacterium ravensturnense*, *Nesterenkonia halotolerans*, and *Staphylococcus pettenkoferi*, which were not identified by standard laboratory procedures.

Table 17: Clinical Performance for *Staphylococcus*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Staphylococcus</i>	Prospective (Fresh)	178/182	97.8 (94.5-99.1)	127/130	97.7 (93.4-99.2)
	Prospective (Frozen)	269/274	98.2 (95.8-99.2)	123/125	98.4 (94.4-99.6)
	Prospective (All)	447/456	98.0 (96.3-99.0)	250/255	98.0 (95.5-99.2)
	Retrospective	185/191	96.9 (93.3-98.6)	390/395	98.7 (97.1-99.5)
	Prospective/Retrospective	632/647^A	97.7 (96.2-98.6)	640/650^B	98.5 (97.2-99.2)
	Contrived	105/105	100 (96.5-100)	460/460	100 (99.2-100)
	Overall	737/752	98.0 (96.7-98.8)	1100/1110	99.1 (98.3-99.5)

A. *Staphylococcus* was not detected in 3 false negative samples, but PCR/sequencing instead detected *Escherichia coli*, *Klebsiella pneumoniae*, and *Streptococcus salivarius*, which were not identified by standard laboratory procedures.

B. *Staphylococcus* was detected in 9/10 false positive samples using PCR/sequencing.

Table 18: Clinical Performance for *Staphylococcus aureus*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Staphylococcus aureus</i>	Prospective (Fresh)	62/65	95.4 (87.3-98.4)	244/245	99.6 (97.7-99.9)
	Prospective (Frozen)	98/101	97.0 (91.6-99.0)	222/223	99.6 (97.5-99.9)
	Prospective (All)	160/166	96.4 (92.3-98.3)	466/468	99.6 (98.5-99.9)
	Retrospective	122/125	97.6 (93.2-99.2)	454/458	99.1 (97.8-99.7)
	Prospective/Retrospective	282/291^A	96.9 (94.2-98.4)	920/926^B	99.4 (98.6-99.7)
	Contrived	59/59	100 (93.9-100)	506/506	100 (99.2-100)
	Overall	341/350	97.4 (95.2-98.6)	1426/1432	99.6 (99.1-99.8)

A. *Staphylococcus aureus* was not detected in 3 false negative samples, but PCR/sequencing instead detected *Klebsiella pneumoniae*, *Staphylococcus simulans*, and *Streptococcus agalactiae*, which were not identified by standard laboratory procedures.

B. *Staphylococcus aureus* was detected in 5/6 false positive samples using PCR/sequencing.

Table 19: Clinical Performance for *Staphylococcus epidermidis*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Staphylococcus epidermidis</i>	Prospective (Fresh)	59/63	93.7 (84.8-97.5)	223/229	97.4 (94.4-98.8)
	Prospective (Frozen)	56/58	96.6 (88.3-99.0)	258/265	97.4 (94.6-98.7)
	Prospective (All)	115/121	95.0 (89.6-97.7)	481/494	97.4 (95.6-98.5)
	Retrospective	33/38	86.8 (72.7-94.2)	539/545	98.9 (97.6-99.5)
	Prospective/Retrospective	148/159^A	93.1 (88.0-96.1)	1020/1039^B	98.2 (97.2-98.8)
	Contrived	1/1	100 (20.7-100)	564/564	100 (99.3-100)
	Overall	149/160	93.1 (88.1-96.1)	1584/1603	98.8 (98.2-99.2)

A. *Staphylococcus epidermidis* was not detected in 7 false negative samples, but PCR/sequencing instead detected *Staphylococcus aureus* (4), *Staphylococcus capitis* (1), *Staphylococcus pettenkoferi* (1), and *Escherichia coli* (1), which were not identified by standard laboratory procedures.

B. *Staphylococcus epidermidis* was detected in 3/19 false positive samples using PCR/sequencing.

Table 20: Clinical Performance for *Staphylococcus lugdunensis*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Staphylococcus lugdunensis</i>	Prospective (Fresh)	1/1	100 (20.7-100)	290/291	99.7 (98.1-99.9)
	Prospective (Frozen)	1/1	100 (20.7-100)	321/322	99.7 (98.3-99.9)
	Prospective (All)	2/2	100 (34.2-100)	611/613	99.7 (98.8-99.9)
	Retrospective	4/4	100 (51.0-100)	579/579	100 (99.3-100)
	Prospective/Retrospective	6/6	100 (61.0-100)	1190/1192^A	99.8 (99.4-100)
	Contrived	45/45	100 (92.1-100)	519/520	99.8 (98.9-100)
	Overall	51/51	100 (93.0-100)	1709/1712	99.8 (99.5-99.9)

A. *Staphylococcus lugdunensis* was detected in 2/2 false positive samples using PCR/sequencing.

Table 21: Clinical Performance for *Streptococcus*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Streptococcus</i>	Prospective (Fresh)	54/55	98.2 (90.4-99.7)	253/257	98.4 (96.1-99.4)
	Prospective (Frozen)	49/55	89.1 (78.2-94.9)	341/344	99.1 (97.5-99.7)
	Prospective (All)	103/110	93.6 (87.4-96.9)	594/601	98.8 (97.6-99.4)
	Retrospective	171/173	98.8 (95.9-99.7)	411/413	99.5 (98.3-99.9)
	Prospective/Retrospective	274/283	96.8 (94.1-98.3)	1005/1014^A	99.1 (98.3-99.5)
	Contrived	57/57	100 (93.7-100)	508/508	100 (99.2-100)
	Overall	331/340	97.4 (95.0-98.6)	1513/1522	99.4 (98.9-99.7)

A. *Streptococcus* was detected in 8/9 false positive samples using PCR/sequencing.

Table 22: Clinical Performance for *Streptococcus agalactiae*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Streptococcus agalactiae</i>	Prospective (Fresh)	5/6	83.3 (43.6-97.0)	298/300	99.3 (97.6-99.8)
	Prospective (Frozen)	5/5	100 (56.6-100)	374/374	100 (99.0-100)
	Prospective (All)	10/11	90.9 (62.3-98.4)	672/674	99.7 (98.9-99.9)
	Retrospective	36/37	97.3 (86.2-99.5)	548/548	100 (99.3-100)
	Prospective/Retrospective	46/48^A	95.8 (86.0-98.8)	1220/1222^B	99.8 (99.4-100)
	Contrived	8/8	100 (67.6-100)	557/557	100 (99.3-100)
	Overall	54/56	96.4 (87.9-99.0)	1777/1779	99.9 (99.6-100)

A. *Streptococcus agalactiae* was not detected in 1 false negative sample, but PCR/sequencing instead detected *Streptococcus mitis*, which was not identified by standard laboratory procedures.

B. *Streptococcus agalactiae* was detected in 1/2 false positive samples using PCR/sequencing.

Table 23: Clinical Performance for *Streptococcus anginosus* group

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Streptococcus anginosus</i> group	Prospective (Fresh)	3/3	100 (43.9-100)	303/303	100 (98.7-100)
	Prospective (Frozen)	1/2	50.0 (9.5-90.5)	375/377	99.5 (98.1-99.9)
	Prospective (All)	4/5	80.0 (37.6-96.4)	678/680	99.7 (98.9-99.9)
	Retrospective	38/40	95.0 (83.5-98.6)	544/545	99.8 (99.0-100)
	Prospective/Retrospective	42/45^A	93.3 (82.1-97.7)	1222/1225^B	99.8 (99.3-99.9)
	Contrived	23/23	100 (85.7-100)	542/542	100 (99.3-100)
	Overall	65/68	95.6 (87.8-98.5)	1764/1767	99.8 (99.5-99.9)

A. *Streptococcus anginosus* group was not detected in 3 false negative samples, but PCR/sequencing instead detected *Granulicatella adiacens*, *Streptococcus dysgalactiae*, and *Streptococcus lutetiensis*, which were not identified by standard laboratory procedures.

B. *Streptococcus intermedius* was detected in 1/3 false positive samples using PCR/sequencing.

Table 24: Clinical Performance for *Streptococcus pneumoniae*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Streptococcus pneumoniae</i>	Prospective (Fresh)	19/19	100 (83.2-100)	286/287	99.7 (98.1-99.9)
	Prospective (Frozen)	8/9	88.9 (56.5-98.0)	370/370	100 (99.0-100)
	Prospective (All)	27/28	96.4 (82.3-99.4)	656/657	99.8 (99.1-100)
	Retrospective	39/41	95.1 (83.9-98.7)	542/543	99.8 (99.0-100)
	Prospective/Retrospective	66/69^A	95.7 (88.0-98.5)	1198/1200^B	99.8 (99.4-100)
	Contrived	0/0	---	565/565	100 (99.3-100)
	Overall	66/69	95.7 (88.0-98.5)	1763/1765	99.9 (99.6-100)

A. *Streptococcus pneumoniae* was not detected in 3 false negative samples, but PCR/sequencing instead detected *Streptococcus mitis* (2) and *Streptococcus anginosus* (1), which were not detected by standard laboratory procedures.

B. *Streptococcus pneumoniae* was detected in 1/2 false positive samples using PCR/sequencing.

Table 25: Clinical Performance for *Streptococcus pyogenes*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Streptococcus pyogenes</i>	Prospective (Fresh)	4/4	100 (51.0-100)	302/302	100 (98.7-100)
	Prospective (Frozen)	4/4	100 (51.0-100)	375/375	100 (99.0-100)
	Prospective (All)	8/8	100 (67.6-100)	677/677	100 (99.4-100)
	Retrospective	19/20	95.0 (76.4-99.1)	564/564	100 (99.3-100)
	Prospective/Retrospective	27/28	96.4 (82.3-99.4)	1241/1241	100 (99.7-100)
	Contrived	26/26	100 (87.1-100)	539/539	100 (99.3-100)
	Overall	53/54	98.1 (90.2-99.7)	1780/1780	100 (99.8-100)

Table 26: Clinical Performance for *mecA*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>mecA</i> <i>Staphylococcus</i>	Prospective (Fresh)	86/89	96.6 (90.6-98.8)	85/93	91.4 (83.9-95.6)
	Prospective (Frozen)	164/171	95.9 (91.8-98.0)	101/103	98.1 (93.2-99.5)
	Prospective (All)	250/260	96.2 (93.1-97.9)	186/196	94.9 (90.9-97.2)
	Retrospective	151/153	98.7 (95.4-99.6)	37/38	97.4 (86.5-99.5)
	Prospective/Retrospective	401/413	97.1 (95.0-98.3)	223/234^A	95.3 (91.8-97.4)
	Contrived	11/11	100 (74.1-100)	94/94	100 (96.1-100)
	Overall	412/424	97.2 (95.1-98.4)	317/328	96.6 (94.1-98.1)
<i>mecA</i> <i>Staphylococcus aureus</i>	Prospective (Fresh)	27/28	96.4 (82.3-99.4)	34/37	91.9 (78.7-97.2)
	Prospective (Frozen)	56/58	96.6 (88.3-99.0)	43/43	100 (91.8-100)
	Prospective (All)	83/86	96.5 (90.2-98.8)	77/80	96.3 (89.5-98.7)
	Retrospective	107/108	99.1 (94.9-99.8)	16/17	94.1 (73.0-99.0)
	Prospective/Retrospective	190/194	97.9 (94.8-99.2)	93/97	95.9 (89.9-98.4)
	Contrived	10/10	100 (72.2-100)	49/49	100 (92.7-100)
	Overall	200/204	98.0 (95.1-99.2)	142/146	97.3 (93.2-98.9)
<i>mecA</i> <i>Staphylococcus epidermidis</i>	Prospective (Fresh)	36/36	100 (90.4-100)	24/27	88.9 (71.9-96.1)
	Prospective (Frozen)	41/43	95.3 (84.5-98.7)	15/15	100 (79.6-100)
	Prospective (All)	77/79	97.5 (91.2-99.3)	39/42	92.9 (81.0-97.5)
	Retrospective	30/30	100 (88.6-100)	43/289	87.5 (52.9-97.8)
	Prospective/Retrospective	107/109	98.2 (93.6-99.5)	46/50	92.0 (81.2-96.8)
	Contrived	1/1	100 (20.7-100)	0/0	---
	Overall	108/110	98.2 (93.6-99.5)	46/50	92.0 (81.2-96.8)
<i>mecA</i> <i>Staphylococcus lugdunensis</i>	Prospective (Fresh)	0/0	---	1/1	100 (20.7-100)
	Prospective (Frozen)	0/0	---	1/1	100 (20.7-100)
	Prospective (All)	0/0	---	2/2	100 (34.2-100)
	Retrospective	1/1	100 (20.7-100)	3/3	100 (43.9-100)
	Prospective/Retrospective	1/1	100 (20.7-100)	5/5	100 (56.6-100)
	Contrived	0/0	---	45/45	100 (92.1-100)
	Overall	1/1	100 (20.7-100)	50/50	100 (92.9-100)

A. *mecA* was detected in 4 of the 7 false positive samples that were tested with an FDA-cleared multiplex assay.

Table 27: Clinical Performance for *mecC*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>mecC</i> <i>Staphylococcus</i>	Prospective (Fresh)	0/0	---	182/182	100 (97.9-100)
	Prospective (Frozen)	0/0	---	274/274	100 (98.6-100)
	Prospective (All)	0/0	---	456/456	100 (99.2-100)
	Retrospective	0/0	---	191/191	100 (98.0-100)
	Prospective/Retrospective	0/0	---	647/647	100 (99.4-100)
	Contrived	49/49	100 (92.7-100)	56/56	100 (93.6-100)
	Overall	49/49	100 (92.7-100)	703/703	100 (99.5-100)
<i>mecC</i> <i>Staphylococcus aureus</i>	Prospective (Fresh)	0/0	---	65/65	100 (94.4-100)
	Prospective (Frozen)	0/0	---	101/101	100 (96.3-100)
	Prospective (All)	0/0	---	166/166	100 (97.7-100)
	Retrospective	0/0	---	125/125	100 (97.0-100)
	Prospective/Retrospective	0/0	---	291/291	100 (98.7-100)
	Contrived	49/49	100 (92.7-100)	10/10	100 (72.2-100)
	Overall	49/49	100 (92.7-100)	301/301	100 (98.7-100)
<i>mecC</i> <i>Staphylococcus epidermidis</i>	Prospective (Fresh)	0/0	---	63/63	100 (94.3-100)
	Prospective (Frozen)	0/0	---	58/58	100 (93.8-100)
	Prospective (All)	0/0	---	121/121	100 (96.9-100)
	Retrospective	0/0	---	38/38	100 (90.8-100)
	Prospective/Retrospective	0/0	---	159/159	100 (97.6-100)
	Contrived	0/0	---	1/1	100 (20.7-100)
	Overall	0/0	---	160/160	100 (97.7-100)
<i>mecC</i> <i>Staphylococcus lugdunensis</i>	Prospective (Fresh)	0/0	---	1/1	100 (20.7-100)
	Prospective (Frozen)	0/0	---	1/1	100 (20.7-100)
	Prospective (All)	0/0	---	2/2	100 (34.2-100)
	Retrospective	0/0	---	4/4	100 (51.0-100)
	Prospective/Retrospective	0/0	---	6/6	100 (61.0-100)
	Contrived	0/0	---	45/45	100 (92.1-100)
	Overall	0/0	---	51/51	100 (93.0-100)

Table 28: Clinical Performance for *vanA*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>vanA</i> <i>Enterococcus</i>	Prospective (Fresh)	0/0	---	24/25	96.0 (80.5-99.3)
	Prospective (Frozen)	8/8	100 (67.6-100)	28/28	100 (87.9-100)
	Prospective (All)	8/8	100 (67.6-100)	52/53	98.1 (90.1-99.7)
	Retrospective	53/57	93.0 (83.3-97.2)	89/90	98.9 (94.0-99.8)
	Prospective/Retrospective	61/65^A	93.8 (85.2-97.6)	141/143^B	98.6 (95.0-99.6)
	Contrived	60/60	100 (94.0-100)	66/66	100 (94.5-100)
	Overall	121/125	96.8 (92.1-98.7)	207/209	99.0 (96.6-99.7)
<i>vanA</i> <i>Enterococcus faecalis</i>	Prospective (Fresh)	0/0	---	21/21	100 (84.5-100)
	Prospective (Frozen)	1/1	100 (20.7-100)	27/27	100 (87.5-100)
	Prospective (All)	1/1	100 (20.7-100)	48/48	100 (92.6-100)
	Retrospective	11/14	78.6 (52.4-92.4)	76/76	100 (95.2-100)
	Prospective/Retrospective	12/15	80.0 (54.8-93.0)	124/124	100 (97.0-100)
	Contrived	10/10	100 (72.2-100)	42/42	100 (91.6-100)
	Overall	22/25	88.0 (70.0-95.8)	166/166	100 (97.7-100)
<i>vanA</i> <i>Enterococcus faecium</i>	Prospective (Fresh)	0/0	---	2/3	66.7 (20.8-93.9)
	Prospective (Frozen)	7/7	100 (64.6-100)	2/2	100 (34.2-100)
	Prospective (All)	7/7	100 (64.6-100)	4/5	80.0 (37.6-96.4)
	Retrospective	44/44	100 (92.0-100)	8/9	88.9 (56.5-98.0)
	Prospective/Retrospective	51/51	100 (93.0-100)	12/14	85.7 (60.1-96.0)
	Contrived	50/50	100 (92.9-100)	10/10	100 (72.2-100)
	Overall	101/101	100 (96.3-100)	22/24	91.7 (74.2-97.7)

A. *vanA* was not detected in 1 false negative sample using an FDA-cleared multiplex assay.B. *vanA* was detected in the 1 false positive sample that was tested using an FDA-cleared multiplex assay.

Table 29: Clinical Performance for *vanB*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>vanB</i> <i>Enterococcus</i>	Prospective (Fresh)	0/0	---	25/25	100 (86.7-100)
	Prospective (Frozen)	0/0	---	36/36	100 (90.4-100)
	Prospective (All)	0/0	---	61/61	100 (94.1-100)
	Retrospective	1/1	100 (20.7-100)	146/146	100 (97.4-100)
	Prospective/Retrospective	1/1	100 (20.7-100)	207/207	100 (98.2-100)
	Contrived	52/52	100 (93.1-100)	74/74	100 (95.1-100)
	Overall	53/53	100 (93.2-100)	281/281	100 (98.7-100)
<i>vanB</i> <i>Enterococcus faecalis</i>	Prospective (Fresh)	0/0	---	21/21	100 (84.5-100)
	Prospective (Frozen)	0/0	---	28/28	100 (87.9-100)
	Prospective (All)	0/0	---	49/49	100 (92.7-100)
	Retrospective	1/1	100 (20.7-100)	89/89	100 (95.9-100)
	Prospective/Retrospective	1/1	100 (20.7-100)	138/138	100 (97.3-100)
	Contrived	42/42	100 (91.6-100)	10/10	100 (72.2-100)
	Overall	43/43	100 (91.8-100)	148/148	100 (97.5-100)
<i>vanB</i> <i>Enterococcus faecium</i>	Prospective (Fresh)	0/0	---	3/3	100 (43.9-100)
	Prospective (Frozen)	0/0	---	9/9	100 (70.1-100)
	Prospective (All)	0/0	---	12/12	100 (75.8-100)
	Retrospective	0/0	---	53/53	100 (93.2-100)
	Prospective/Retrospective	0/0	---	65/65	100 (94.4-100)
	Contrived	10/10	100 (72.2-100)	50/50	100 (92.9-100)
	Overall	10/10	100 (72.2-100)	115/115	100 (96.8-100)

Pan Targets

In addition to the evaluable prospective and retrospective samples that contain gram-positive organisms, the clinical performance of the Pan *Candida* and Pan Gram-Negative targets was evaluated by testing an additional 480 non-intended use retrospective samples with gram-negative or fungal organisms; these are denoted as Retrospective (Non-Intended Use) samples. Results from those samples are summarized in **Table 30**.

Table 30: Clinical Performance for Pan Targets

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Pan <i>Candida</i>	Prospective (Fresh)	0/0	---	312/312	100 (98.8-100)
	Prospective (Frozen)	0/0	---	399/399	100 (99.0-100)
	Prospective (All)	0/0	---	711/711	100 (99.5-100)
	Retrospective	7/9	77.8 (45.3-93.7)	576/577	99.8 (99.0-100)
	Retrospective (Non-Intended Use)	90/96	93.8 (87.0-97.1)	383/384 ^A	99.7 (98.5-100)
	Contrived	0/0	---	565/565	100 (99.3-100)
Pan Gram-Negative	Prospective (Fresh)	10/11	90.9 (62.3-98.4)	299/301	99.3 (97.6-99.8)
	Prospective (Frozen)	12/12	100 (75.8-100)	386/387	99.7 (98.6-100)
	Prospective (All)	22/23	95.7 (79.0-99.2)	685/688 ^B	99.6 (98.7-99.9)
	Retrospective	36/43	83.7 (70.0-91.9)	540/543 ^C	99.4 (98.4-99.8)
	Retrospective (Non-Intended Use)	364/375	97.1 (94.8-98.4)	104/105	99.0 (94.8-99.8)
	Contrived	0/0	---	565/565	100 (99.3-100)

A. *Candida glabrata* was detected in 1/1 false positive samples using PCR/sequencing.

B. A gram-negative organism, *Klebsiella pneumoniae*, was detected in 1/3 false positive samples using PCR/sequencing.

C. A gram-negative organism, *Escherichia coli*, was detected in 1/3 false positive samples using PCR/sequencing.

Table 31: Contrived Sample Summary

Target	Organism	Strain	Independent Contrived Samples Tested
<i>Bacillus cereus</i> group	<i>Bacillus cereus</i>	ATCC 10876	11
		ATCC 21769	10
		ATCC 31430	9
		ATCC 53522	10
	<i>Bacillus thuringiensis</i>	ATCC 33679	1
		ATCC 10792	2
		ATCC 55173	3
	<i>Bacillus cereus</i> group total		46
<i>Bacillus subtilis</i> group	<i>Bacillus amyloliquefaciens</i>	ATCC 23350	3
		ATCC 23845	4
		ATCC 53495	3
	<i>Bacillus atrophaeus</i>	ATCC 51189	4
		ATCC 6455	3
		ATCC 6537	4
	<i>Bacillus licheniformis</i>	ATCC 21039	3
		ATCC 21667	3
		ATCC 53926	4
	<i>Bacillus subtilis</i>	ATCC 15040	5
		ATCC 15561	8
		ATCC 55614	6
	<i>Bacillus subtilis</i> group total		50
<i>Corynebacterium</i>	<i>Corynebacterium coyleae</i>	ATCC 700219	7
	<i>Corynebacterium falsenii</i>	ATCC BAA-596	9
	<i>Corynebacterium striatum</i>	ATCC BAA-1293	4
	<i>Corynebacterium</i> total		20

Target	Organism	Strain	Independent Contrived Samples Tested
Enterococcus	<i>Enterococcus faecalis, vanA</i>	JMI 876745	10
	<i>Enterococcus faecalis, vanB</i>	ATCC 51299	11
		ATCC 51575	11
		ATCC 700802	10
		ATCC BAA-2365	10
	<i>Enterococcus faecium, vanA</i>	ATCC 51559	4
		ATCC 700221	3
		ATCC BAA-2316	5
		ATCC BAA-2317	3
		ATCC BAA-2318	5
		ATCC BAA-2319	5
		ATCC BAA-2320	3
		LMC 002867	3
		LMC 003921	4
		LMC 032261	4
		LMC 055971	3
		LMC 103676	5
		LMC 104266	3
	<i>Enterococcus faecium, vanB</i>	ATCC 51858	10
	<i>Enterococcus flavescens</i>	ATCC 49996	3
	<i>Enterococcus gallinarum</i>	ATCC 49610	1
		ATCC 700425	3
	<i>Enterococcus hirae</i>	ATCC 10541	1
	<i>Enterococcus malodoratus</i>	ATCC 43197	3
	<i>Enterococcus raffinosus</i>	ATCC 49464	2
	<i>Enterococcus saccharolyticus</i>	ATCC 43076	1
	<i>Enterococcus total</i>		126
Lactobacillus	<i>Lactobacillus casei</i>	ATCC 25598	2
		ATCC 334	6
		ATCC 39392	4
	<i>Lactobacillus paracasei</i>	148-260 *	3
		ATCC 27092	2
		ATCC BAA-52	6
	<i>Lactobacillus rhamnosus</i>	ATCC 39595	3
		ATCC 53103	5
		ATCC 55915	2
	<i>Lactobacillus total</i>		33
Listeria	<i>Listeria innocua</i>	ATCC 33090	4
		NCTC 11288	5
	<i>Listeria ivanovii</i>	ATCC 19119	2
		ATCC 700402	4
		ATCC BAA-139	4
	<i>Listeria monocytogenes</i>	ATCC 13932	5
		ATCC 19111	3
		ATCC 19112	4
		ATCC 19114	5
		ATCC 19116	5
		ATCC 19117	5
		ATCC 19118	5
		ATCC 7644	5
		ATCC BAA-751	5
		NCTC 10890	4

Target	Organism	Strain	Independent Contrived Samples Tested
	<i>Listeria seeligeri</i>	ATCC 35967	5
	<i>Listeria welshimeri</i>	ATCC 35897	5
	<i>Listeria total</i>		75
<i>Micrococcus</i>	<i>Micrococcus luteus</i>	ATCC 10240	3
		ATCC 19212	3
		ATCC 400	3
		ATCC 4698	3
		ATCC 49732	3
		ATCC 53598	4
	<i>Micrococcus lylae</i>	ATCC 27566	4
	<i>Micrococcus yunnanensis</i>	ATCC 7468	4
	<i>Micrococcus total</i>		27
<i>Cutibacterium acnes</i>	<i>Cutibacterium acnes</i>	ATCC 11827	8
		ATCC 11828	6
		ATCC 33179	4
		ATCC 6919	8
	<i>Cutibacterium acnes total</i>		26
<i>Staphylococcus</i>	<i>Staphylococcus aureus, mecA</i>	ATCC 33591	3
		ATCC BAA-44	5
		NCTC 12493	2
	<i>Staphylococcus aureus, mecC</i>	ATCC BAA-2312	23
		ATCC BAA-2313	26
	<i>Staphylococcus epidermidis, mecA</i>	ATCC 35984	1
	<i>Staphylococcus lugdunensis</i>	ATCC 49576	9
		NRS 878	9
		NRS 879	9
		NRS 880	9
		NRS 881	9
	<i>Staphylococcus total</i>		105
<i>Streptococcus</i>	<i>Streptococcus agalactiae</i>	ATCC 12403	2
		ATCC 12973	2
		ATCC 13813	2
		ATCC 27956	2
	<i>Streptococcus anginosus</i>	ATCC 700231	5
		ATCC 9895	3
		NCTC 10713	5
	<i>Streptococcus constellatus</i>	ATCC 27513	4
		ATCC 27823	2
	<i>Streptococcus intermedius</i>	ATCC 27335	4
	<i>Streptococcus pyogenes</i>	ATCC 12344	5
		ATCC 12384	4
		ATCC 14289	4
		ATCC 19615	4
		ATCC 49399	5
		NCIMB 13285	4
	<i>Streptococcus total</i>		57

*Derived from clinical specimen

Genus and Group Assay Species Stratification

The ePlex BCID-GP Panel reports genus or group level results for *Bacillus cereus* group, *Bacillus subtilis* group, *Corynebacterium*, *Enterococcus*, *Lactobacillus*, *Listeria*, *Micrococcus*, *Staphylococcus*, *Streptococcus*, *Streptococcus anginosus* group, Pan Gram-Negative and Pan *Candida* targets. Sensitivity/PPA of these genus and group level targets for species as determined by comparator methods for all evaluable samples tested are summarized in **Table 32**.

Table 32: Species Detected in Genus and Group Assays by Comparator Methods

Target Species detected by Comparator Method	Sensitivity/PPA (Prospective)		Sensitivity/PPA (Retrospective)		Sensitivity/PPA (Contrived)		Sensitivity/PPA (Combined)	
	TP/ TP+FN	% (95% CI)	TP/ TP+FN	% (95% CI)	TP/ TP+FN	% (95% CI)	TP/ TP+FN	% (95% CI)
<i>Bacillus cereus</i> group	5/5	100 (56.6-100)	6/7	85.7 (48.7-97.4)	46/46	100 (92.3-100)	57/58	98.3 (90.9-99.7)
<i>Bacillus cereus</i>	3/3	100 (43.9-100)	6/7	85.7 (48.7-97.4)	40/40	100 (91.2-100)	49/50	98.0 (89.5-99.6)
<i>Bacillus thuringiensis</i>	2/2	100 (34.2-100)	-	-	6/6	100 (61.0-100)	8/8	100 (67.6-100)
<i>Bacillus subtilis</i> group	2/2	100 (34.2-100)	-	-	50/50	100 (92.9-100)	52/52	100 (93.1-100)
<i>Bacillus amyloliquefaciens</i>	1/1	100 (20.7-100)	-	-	10/10	100 (72.2-100)	11/11	100 (74.1-100)
<i>Bacillus atrophaeus</i>	-	-	-	-	11/11	100 (74.1-100)	11/11	100 (74.1-100)
<i>Bacillus licheniformis</i>	-	-	-	-	10/10	100 (72.2-100)	10/10	100 (72.2-100)
<i>Bacillus subtilis</i>	1/1	100 (20.7-100)	-	-	19/19	100 (83.2-100)	20/20	100 (83.9-100)
<i>Corynebacterium</i>	13/19	68.4 (46.0-84.6)	27/32	84.4 (68.2-93.1)	20/20	100 (83.9-100)	60/71	84.5 (74.3-91.1)
<i>Corynebacterium</i>	4/9	44.4 (18.9-73.3)	5/7	71.4 (35.9-91.8)	-	-	9/16	56.3 (33.2-76.9)
<i>Corynebacterium afermentans</i>	0/1	0.0 (0.0-79.3)	3/3	100 (43.9-100)	-	-	3/4	75.0 (30.1-95.4)
<i>Corynebacterium amycolatum</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Corynebacterium aurimucosum</i>	1/1	100 (20.7-100)	1/1	100 (20.7-100)	-	-	2/2	100 (34.2-100)
<i>Corynebacterium casei</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Corynebacterium coyleae</i>	1/1	100 (20.7-100)	2/2	100 (34.2-100)	7/7	100 (64.6-100)	10/10	100 (72.2-100)
<i>Corynebacterium falsenii</i>	-	-	-	-	9/9	100 (70.1-100)	9/9	100 (70.1-100)
<i>Corynebacterium imitans</i>	2/2	100 (34.2-100)	2/2	100 (34.2-100)	-	-	4/4	100 (51.0-100)
<i>Corynebacterium jeikeium</i>	-	-	4/5	80.0 (37.6-96.4)	-	-	4/5	80.0 (37.6-96.4)
<i>Corynebacterium kroppenstedtii</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Corynebacterium matruchotii</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Corynebacterium mucifaciens</i>	1/1	100 (20.7-100)	2/2	100 (34.2-100)	-	-	3/3	100 (43.9-100)
<i>Corynebacterium pseudotuberculosis</i>	-	-	0/1	0.0 (0.0-79.3)	-	-	0/1	0.0 (0.0-79.3)
<i>Corynebacterium striatum</i>	1/1	100 (20.7-100)	6/6	100 (61.0-100)	4/4	100 (51.0-100)	11/11	100 (74.1-100)
<i>Corynebacterium tuberculostrictum</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Corynebacterium urealyticum</i>	-	-	0/1	0.0 (0.0-79.3)	-	-	0/1	0.0 (0.0-79.3)

Target Species detected by Comparator Method	Sensitivity/PPA (Prospective)		Sensitivity/PPA (Retrospective)		Sensitivity/PPA (Contrived)		Sensitivity/PPA (Combined)	
	TP/ TP+FN	% (95% CI)	TP/ TP+FN	% (95% CI)	TP/ TP+FN	% (95% CI)	TP/ TP+FN	% (95% CI)
<i>Enterococcus</i>	61/61	100 (94.1-100)	139/147	94.6 (89.6-97.2)	126/126	100 (97.0-100)	326/334	97.6 (95.3-98.8)
<i>Enterococcus</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Enterococcus avium</i>	1/1	100 (20.7-100)	2/3	66.7 (20.8-93.9)	-	-	3/4	75.0 (30.1-95.4)
<i>Enterococcus casseliflavus</i>	-	-	0/1	0.0 (0.0-79.3)	-	-	0/1	0.0 (0.0-79.3)
<i>Enterococcus casseliflavus / gallinarum</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Enterococcus faecalis</i>	49/49	100 (92.7-100)	85/90	94.4 (87.6-97.6)	52/52	100 (93.1-100)	186/191	97.4 (94.0-98.9)
<i>Enterococcus faecium</i>	12/12	100 (75.8-100)	52/53	98.1 (90.1-99.7)	60/60	100 (94.0-100)	124/125	99.2 (95.6-99.9)
<i>Enterococcus flavescens</i>	-	-	-	-	3/3	100 (43.9-100)	3/3	100 (43.9-100)
<i>Enterococcus gallinarum</i>	-	-	2/2	100 (34.2-100)	4/4	100 (51.0-100)	6/6	100 (61.0-100)
<i>Enterococcus hirae</i>	-	-	-	-	1/1	100 (20.7-100)	1/1	100 (20.7-100)
<i>Enterococcus malodoratus</i>	-	-	-	-	3/3	100 (43.9-100)	3/3	100 (43.9-100)
<i>Enterococcus raffinosus</i>	-	-	-	-	2/2	100 (34.2-100)	2/2	100 (34.2-100)
<i>Enterococcus saccharolyticus</i>	-	-	-	-	1/1	100 (20.7-100)	1/1	100 (20.7-100)
<i>Lactobacillus</i>	4/4	100 (51.0-100)	9/9	100 (70.1-100)	32/33	97.0 (84.7-99.5)	45/46	97.8 (88.7-99.6)
<i>Lactobacillus casei</i>	-	-	1/1	100 (20.7-100)	12/12	100 (75.8-100)	13/13	100 (77.2-100)
<i>Lactobacillus paracasei</i>	1/1	100 (20.7-100)	-	-	11/11	100 (74.1-100)	12/12	100 (75.8-100)
<i>Lactobacillus rhamnosus</i>	2/2	100 (34.2-100)	8/8	100 (67.6-100)	9/10	90.0 (59.6-98.2)	19/20	95.0 (76.4-99.1)
<i>Lactobacillus zeae</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Listeria</i>	-	-	2/2	100 (34.2-100)	74/75	98.7 (92.8-99.8)	76/77	98.7 (93.0-99.8)
<i>Listeria innocua</i>	-	-	-	-	9/9	100 (70.1-100)	9/9	100 (70.1-100)
<i>Listeria ivanovii</i>	-	-	-	-	9/10	90.0 (59.6-98.2)	9/10	90.0 (59.6-98.2)
<i>Listeria monocytogenes</i>	-	-	2/2	100 (34.2-100)	46/46	100 (92.3-100)	48/48	100 (92.6-100)
<i>Listeria seeligeri</i>	-	-	-	-	5/5	100 (56.6-100)	5/5	100 (56.6-100)
<i>Listeria welshimeri</i>	-	-	-	-	5/5	100 (56.6-100)	5/5	100 (56.6-100)
<i>Micrococcus</i>	19/21	90.5 (71.1-97.3)	20/23	87.0 (67.9-95.5)	27/27	100 (87.5-100)	66/71	93.0 (84.6-97.0)
<i>Micrococcus</i>	8/9	88.9 (56.5-98.0)	10/13	76.9 (49.7-91.8)	-	-	18/22	81.8 (61.5-92.7)
<i>Micrococcus luteus</i>	9/9	100 (70.1-100)	8/8	100 (67.6-100)	19/19	100 (83.2-100)	36/36	100 (90.4-100)
<i>Micrococcus luteus/lylae</i>	2/3	66.7 (20.8-93.9)	2/2	100 (34.2-100)	-	-	4/5	80.0 (37.6-96.4)
<i>Micrococcus lylae</i>	-	-	-	-	4/4	100 (51.0-100)	4/4	100 (51.0-100)
<i>Micrococcus yunnanensis</i>	-	-	-	-	4/4	100 (51.0-100)	4/4	100 (51.0-100)

Target Species detected by Comparator Method	Sensitivity/PPA (Prospective)		Sensitivity/PPA (Retrospective)		Sensitivity/PPA (Contrived)		Sensitivity/PPA (Combined)	
	TP/ TP+FN	% (95% CI)	TP/ TP+FN	% (95% CI)	TP/ TP+FN	% (95% CI)	TP/ TP+FN	% (95% CI)
<i>Staphylococcus</i>	447/456	98.0 (96.3-99.0)	185/191	96.9 (93.3-98.6)	105/105	100 (96.5-100)	737/752	98.0 (96.7-98.8)
<i>Coagulase-negative staphylococci (CoNS)</i>	18/18	100 (82.4-100)	-	-	-	-	18/18	100 (82.4-100)
<i>CoNS (Not S. epidermidis, S. lugdunensis)</i>	2/2	100 (34.2-100)	-	-	-	-	2/2	100 (34.2-100)
<i>Staphylococcus</i>	74/78	94.9 (87.5-98.0)	1/3	33.3 (6.1-79.2)	-	-	75/81	92.6 (84.8-96.6)
<i>Staphylococcus aureus</i>	158/160	98.8 (95.6-99.7)	121/123	98.4 (94.3-99.6)	59/59	100 (93.9-100)	338/342	98.8 (97.0-99.5)
<i>Staphylococcus aureus</i> subsp. <i>aureus</i>	6/6	100 (61.0-100)	2/2	100 (34.2-100)	-	-	8/8	100 (67.6-100)
<i>Staphylococcus auricularis</i>	2/2	100 (34.2-100)	2/2	100 (34.2-100)	-	-	4/4	100 (51.0-100)
<i>Staphylococcus capitis</i>	14/14	100 (78.5-100)	7/7	100 (64.6-100)	-	-	21/21	100 (84.5-100)
<i>Staphylococcus carnosus</i> subsp. <i>carnosus</i>	-	-	0/1	0.0 (0.0-79.3)	-	-	0/1	0.0 (0.0-79.3)
<i>Staphylococcus cohnii</i>	1/2	50.0 (9.5-90.5)	-	-	-	-	1/2	50.0 (9.5-90.5)
<i>Staphylococcus epidermidis</i>	117/121	96.7 (91.8-98.7)	37/38	97.4 (86.5-99.5)	1/1	100 (20.7-100)	155/160	96.9 (92.9-98.7)
<i>Staphylococcus haemolyticus</i>	6/6	100 (61.0-100)	2/2	100 (34.2-100)	-	-	8/8	100 (67.6-100)
<i>Staphylococcus hominis</i>	24/24	100 (86.2-100)	13/13	100 (77.2-100)	-	-	37/37	100 (90.6-100)
<i>Staphylococcus hominis</i> subsp. <i>hominis</i>	22/22	100 (85.1-100)	5/5	100 (56.6-100)	-	-	27/27	100 (87.5-100)
<i>Staphylococcus hominis</i> subsp. <i>novobiosepticus</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Staphylococcus lugdunensis</i>	2/2	100 (34.2-100)	4/4	100 (51.0-100)	45/45	100 (92.1-100)	51/51	100 (93.0-100)
<i>Staphylococcus pettenkoferi</i>	2/2	100 (34.2-100)	-	-	-	-	2/2	100 (34.2-100)
<i>Staphylococcus saccharolyticus</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Staphylococcus saprophyticus</i>	1/1	100 (20.7-100)	1/1	100 (20.7-100)	-	-	2/2	100 (34.2-100)
<i>Staphylococcus schleiferi</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Staphylococcus simulans</i>	3/3	100 (43.9-100)	-	-	-	-	3/3	100 (43.9-100)
<i>Staphylococcus warneri</i>	4/4	100 (51.0-100)	-	-	-	-	4/4	100 (51.0-100)

Target Species detected by Comparator Method	Sensitivity/PPA (Prospective)		Sensitivity/PPA (Retrospective)		Sensitivity/PPA (Contrived)		Sensitivity/PPA (Combined)	
	TP/ TP+FN	% (95% CI)	TP/ TP+FN	% (95% CI)	TP/ TP+FN	% (95% CI)	TP/ TP+FN	% (95% CI)
<i>Streptococcus</i>	103/110	93.6 (87.4-96.9)	171/173	98.8 (95.9-99.7)	57/57	100 (93.7-100)	331/340	97.4 (95.0-98.6)
<i>Alpha Hemolytic</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Streptococcus</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Gamma Hemolytic</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Streptococcus</i>	5/7	71.4 (35.9-91.8)	-	-	-	-	5/7	71.4 (35.9-91.8)
<i>Streptococcus</i> (Group G)	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Streptococcus agalactiae</i>	10/11	90.9 (62.3-98.4)	37/37	100 (90.6-100)	8/8	100 (67.6-100)	55/56	98.2 (90.6-99.7)
<i>Streptococcus anginosus</i>	1/1	100 (20.7-100)	13/13	100 (77.2-100)	13/13	100 (77.2-100)	27/27	100 (87.5-100)
<i>Streptococcus anginosus</i> group	4/4	100 (51.0-100)	22/22	100 (85.1-100)	-	-	26/26	100 (87.1-100)
<i>Streptococcus bovis</i>	-	-	2/2	100 (34.2-100)	-	-	2/2	100 (34.2-100)
<i>Streptococcus bovis</i> group	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Streptococcus constellatus</i>	-	-	-	-	6/6	100 (61.0-100)	6/6	100 (61.0-100)
<i>Streptococcus constellatus</i> subsp. <i>constellatus</i>	-	-	2/2	100 (34.2-100)	-	-	2/2	100 (34.2-100)
<i>Streptococcus constellatus</i> subsp. <i>pharyngis</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Streptococcus dysgalactiae</i>	-	-	2/2	100 (34.2-100)	-	-	2/2	100 (34.2-100)
<i>Streptococcus dysgalactiae</i> (Group G)	4/4	100 (51.0-100)	1/1	100 (20.7-100)	-	-	5/5	100 (56.6-100)
<i>Streptococcus gallolyticus</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Streptococcus gordonii</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Streptococcus infantarius</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Streptococcus intermedius</i>	-	-	2/2	100 (34.2-100)	4/4	100 (51.0-100)	6/6	100 (61.0-100)
<i>Streptococcus mitis</i>	9/10	90.0 (59.6-98.2)	14/15	93.3 (70.2-98.8)	-	-	23/25	92.0 (75.0-97.8)
<i>Streptococcus mitis</i> group	10/10	100 (72.2-100)	-	-	-	-	10/10	100 (72.2-100)
<i>Streptococcus mutans</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Streptococcus oralis</i>	-	-	3/3	100 (43.9-100)	-	-	3/3	100 (43.9-100)
<i>Streptococcus parasanguinis</i>	2/2	100 (34.2-100)	4/4	100 (51.0-100)	-	-	6/6	100 (61.0-100)
<i>Streptococcus pneumoniae</i>	28/28	100 (87.9-100)	41/41	100 (91.4-100)	-	-	69/69	100 (94.7-100)
<i>Streptococcus pyogenes</i>	8/8	100 (67.6-100)	19/20	95.0 (76.4-99.1)	26/26	100 (87.1-100)	53/54	98.1 (90.2-99.7)
<i>Streptococcus salivarius</i>	4/4	100 (51.0-100)	5/5	100 (56.6-100)	-	-	9/9	100 (70.1-100)
<i>Streptococcus vestibularis</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Streptococcus viridans</i> group	14/17	82.4 (59.0-93.8)	2/2	100 (34.2-100)	-	-	16/19	84.2 (62.4-94.5)
<i>Streptococcus anginosus</i> group	4/5	80.0 (37.6-96.4)	38/40	95.0 (83.5-98.6)	23/23	100 (85.7-100)	65/68	95.6 (87.8-98.5)
<i>Streptococcus anginosus</i>	0/1	0.0 (0.0-79.3)	12/13	92.3 (66.7-98.6)	13/13	100 (77.2-100)	25/27	92.6 (76.6-97.9)
<i>Streptococcus anginosus</i> group	4/4	100 (51.0-100)	21/22	95.5 (78.2-99.2)	-	-	25/26	96.2 (81.1-99.3)
<i>Streptococcus constellatus</i>	-	-	-	-	6/6	100 (61.0-100)	6/6	100 (61.0-100)
<i>Streptococcus constellatus</i> spp <i>constellatus</i>	-	-	2/2	100 (34.2-100)	-	-	2/2	100 (34.2-100)
<i>Streptococcus constellatus</i> spp <i>pharynges</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Streptococcus intermedius</i>	-	-	2/2	100 (34.2-100)	4/4	100 (51.0-100)	6/6	100 (61.0-100)

Target Species detected by Comparator Method	Sensitivity/PPA (Prospective)		Sensitivity/PPA (Retrospective)		Sensitivity/PPA (Contrived)		Sensitivity/PPA (Combined)	
	TP/ TP+FN	% (95% CI)	TP/ TP+FN	% (95% CI)	TP/ TP+FN	% (95% CI)	TP/ TP+FN	% (95% CI)
<i>Pan Candida</i>	-	-	7/9	77.8 (45.3-93.7)	-	-	7/9	77.8 (45.3-93.7)
<i>Candida albicans</i>	-	-	4/4	100 (51.0-100)	-	-	4/4	100 (51.0-100)
<i>Candida glabrata</i>	-	-	1/2	50 (9.5-90.5)	-	-	1/2	50 (9.5-90.5)
<i>Candida krusei</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Candida parapsilosis</i>	-	-	1/2	50 (9.5-90.5)	-	-	1/2	50 (9.5-90.5)
Pan Gram-Negative	22/23	95.7 (79.0-99.2)	36/43	83.7 (70.0-91.9)	-	-	58/66	87.9 (77.9-93.7)
<i>Acinetobacter baumannii</i>	3/3	100 (43.9-100)	2/4	50.0 (15.0-85.0)	-	-	5/7	71.4 (35.9-91.8)
<i>Acinetobacter lwoffii</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Aeromonas caviae</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Bacteroides fragilis</i>	2/2	100 (34.2-100)	-	-	-	-	2/2	100 (34.2-100)
<i>Campylobacter gracilis</i>	0/1	0.0 (0.0-79.3)	-	-	-	-	0/1	0.0 (0.0-79.3)
<i>Citrobacter braakii</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Citrobacter freundii</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Citrobacter koseri</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Enterobacter aerogenes</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Enterobacter cloacae</i>	-	-	4/4	100 (51.0-100)	-	-	4/4	100 (51.0-100)
<i>Escherichia coli</i>	4/4	100 (51.0-100)	14/14	100 (78.5-100)	-	-	18/18	100 (82.4-100)
<i>Klebsiella oxytoca</i>	1/1	100 (20.7-100)	3/3	100 (43.9-100)	-	-	4/4	100 (51.0-100)
<i>Klebsiella pneumoniae</i>	4/4	100 (51.0-100)	4/5	80.0 (37.6-96.4)	-	-	8/9	88.9 (56.5-98.0)
<i>Moraxella (Branhamella) catarrhalis</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Moraxella catarrhalis</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Morganella morganii</i>	-	-	2/2	100 (34.2-100)	-	-	2/2	100 (34.2-100)
<i>Pediococcus pentosaceus</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Proteus mirabilis</i>	5/5	100 (56.6-100)	4/5	80.0 (37.6-96.4)	-	-	9/10	90.0 (59.6-98.2)
<i>Proteus vulgaris</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Providencia stuartii</i>	1/1	100 (20.7-100)	0/1	0.0 (0.0-79.3)	-	-	1/2	50.0 (9.5-90.5)
<i>Pseudomonas</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Pseudomonas aeruginosa</i>	1/1	100 (20.7-100)	1/2	50.0 (9.5-90.5)	-	-	2/3	66.7 (20.8-93.9)
<i>Serratia marcescens</i>	2/2	100 (34.2-100)	-	-	-	-	2/2	100 (34.2-100)
<i>Stenotrophomonas maltophilia</i>	1/1	100 (20.7-100)	1/1	100 (20.7-100)	-	-	2/2	100 (34.2-100)
<i>Veillonella species</i>	-	-	0/1	0.0 (0.0-79.3)	-	-	0/1	0.0 (0.0-79.3)
Non-fermenting gram-negative bacilli	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)

Resistance Gene Assay Species Stratification

Test results for resistance genes are only reported when an associated organism assay is positive in the same sample. See **Table 33** for organisms specifically associated with the four resistance markers on the ePlex BCID-GP Panel.

Table 33: Resistance Marker Organism Associations

Resistance Gene Result	Associated Targets
<i>mecA</i> and/or <i>mecC</i>	Any <i>Staphylococcus</i> assay (<i>Staphylococcus</i> , <i>S. aureus</i> , <i>S. epidermidis</i> , <i>S. lugdunensis</i>)
<i>vanA</i> and/or <i>vanB</i>	Any <i>Enterococcus</i> assay (<i>Enterococcus</i> , <i>E. faecalis</i> , <i>E. faecium</i>)

mecA/mecC

The PPA and NPA of the BCID-GP Panel *mecA* target stratified by the *Staphylococcus* species identified by comparator methods for prospective, retrospective and contrived samples are shown in **Table 34**.

Table 34: Clinical Performance of *mecA* Target by *Staphylococcus* Species Detected by Comparator Methods

Species detected by Comparator Method		Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Coagulase-negative Staphylococci</i> (CoNS)	Prospective	12/12	100 (75.8-100)	6/6	100 (61.0-100)
	Retrospective	-	-	-	-
	Contrived	-	-	-	-
	Combined	12/12	100 (75.8-100)	6/6	100 (61.0-100)
<i>CoNS</i> (not <i>S. epidermidis</i> / <i>S. lugdunensis</i>)	Prospective	1/1	100 (20.7-100)	0/1	0.0 (0.0-79.3)
	Retrospective	-	-	-	-
	Contrived	-	-	-	-
	Combined	1/1	100 (20.7-100)	0/1	0.0 (0.0-79.3)
<i>Staphylococcus</i>	Prospective	49/52	94.2 (84.4-98.0)	24/26	92.3 (75.9-97.9)
	Retrospective	1/2	50.0 (9.5-90.5)	1/1	100 (20.7-100)
	Contrived	-	-	-	-
	Combined	50/54	92.6 (82.4-97.1)	25/27	92.6 (76.6-97.9)
<i>Staphylococcus aureus</i>	Prospective	80/83	96.4 (89.9-98.8)	74/77	96.1 (89.2-98.7)
	Retrospective	105/106	99.1 (94.8-99.8)	16/17	94.1 (73.0-99.0)
	Contrived	10/10	100 (72.2-100)	49/49	100 (92.7-100)
	Combined	195/199	98.0 (94.9-99.2)	139/143	97.2 (93.0-98.9)

Species detected by Comparator Method		Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Staphylococcus aureus</i> subsp. <i>aureus</i>	Prospective	3/3	100 (43.9-100)	3/3	100 (43.9-100)
	Retrospective	2/2	100 (34.2-100)	0/0	-
	Contrived	-	-	-	-
	Combined	5/5	100 (56.6-100)	3/3	100 (43.9-100)
<i>Staphylococcus auricularis</i>	Prospective	1/1	100 (20.7-100)	1/1	100 (20.7-100)
	Retrospective	0/0	-	2/2	100 (34.2-100)
	Contrived	-	-	-	-
	Combined	1/1	100 (20.7-100)	3/3	100 (43.9-100)
<i>Staphylococcus capitis</i>	Prospective	4/5	80.0 (37.6-96.4)	5/5	100 (56.6-100)
	Retrospective	4/4	100 (51.0-100)	7/7	100 (64.6-100)
	Contrived	-	-	-	-
	Combined	8/9	88.9 (56.5-98.0)	12/12	100 (75.8-100)
<i>Staphylococcus carnosus</i> subsp. <i>carnosus</i>	Prospective	-	-	-	-
	Retrospective	0/0	-	1/1	100 (20.7-100)
	Contrived	-	-	-	-
	Combined	0/0	-	1/1	100 (20.7-100)
<i>Staphylococcus cohnii</i>	Prospective	0/1	0.0 (0.0-79.3)	1/1	100 (20.7-100)
	Retrospective	-	-	-	-
	Contrived	-	-	-	-
	Combined	0/1	0.0 (0.0-79.3)	1/1	100 (20.7-100)
<i>Staphylococcus epidermidis</i>	Prospective	77/79	97.5 (91.2-99.3)	39/42	92.9 (81.0-97.5)
	Retrospective	30/30	100 (88.6-100)	7/8	87.5 (52.9-97.8)
	Contrived	1/1	100 (20.7-100)	0/0	-
	Combined	108/110	98.2 (93.6-99.5)	46/50	92.0 (81.2-96.8)
<i>Staphylococcus haemolyticus</i>	Prospective	4/4	100 (51.0-100)	2/2	100 (34.2-100)
	Retrospective	2/2	100 (34.2-100)	0/0	-
	Contrived	-	-	-	-
	Combined	6/6	100 (61.0-100)	2/2	100 (34.2-100)
<i>Staphylococcus hominis</i>	Prospective	12/13	92.3 (66.7-98.6)	10/11	90.9 (62.3-98.4)
	Retrospective	12/12	100 (75.8-100)	1/1	100 (20.7-100)
	Contrived	-	-	-	-
	Combined	24/25	96.0 (80.5-99.3)	11/12	91.7 (64.6-98.5)
<i>Staphylococcus hominis</i> subsp. <i>hominis</i>	Prospective	10/11	90.9 (62.3-98.4)	11/11	100 (74.1-100)
	Retrospective	2/2	100 (34.2-100)	3/3	100 (43.9-100)
	Contrived	-	-	-	-
	Combined	12/13	92.3 (66.7-98.6)	14/14	100 (78.5-100)
<i>Staphylococcus hominis</i> subsp. <i>novobiosepticus</i>	Prospective	1/1	100 (20.7-100)	0/0	-
	Retrospective	-	-	-	-
	Contrived	-	-	-	-
	Combined	1/1	100 (20.7-100)	0/0	-

Species detected by Comparator Method		Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Staphylococcus lugdunensis</i>	Prospective	0/0	---	2/2	100 (34.2-100)
	Retrospective	1/1	100 (20.7-100)	3/3	100 (43.9-100)
	Contrived	0/0	---	45/45	100 (92.1-100)
	Combined	1/1	100 (20.7-100)	50/50	100 (92.9-100)
<i>Staphylococcus pettenkoferi</i>	Prospective	0/0	-	1/2	50.0 (9.5-90.5)
	Retrospective	-	-	-	-
	Contrived	-	-	-	-
	Combined	0/0	-	1/2	50.0 (9.5-90.5)
<i>Staphylococcus saccharolyticus</i>	Prospective	0/0	-	1/1	100 (20.7-100)
	Retrospective	-	-	-	-
	Contrived	-	-	-	-
	Combined	0/0	-	1/1	100 (20.7-100)
<i>Staphylococcus saprophyticus</i>	Prospective	1/1	100 (20.7-100)	0/0	-
	Retrospective	0/0	-	1/1	100 (20.7-100)
	Contrived	-	-	-	-
	Combined	1/1	100 (20.7-100)	1/1	100 (20.7-100)
<i>Staphylococcus schleiferi</i>	Prospective	-	-	-	-
	Retrospective	0/0	-	1/1	100 (20.7-100)
	Contrived	-	-	-	-
	Combined	0/0	-	1/1	100 (20.7-100)
<i>Staphylococcus simulans</i>	Prospective	1/1	100 (20.7-100)	2/2	100 (34.2-100)
	Retrospective	-	-	-	-
	Contrived	-	-	-	-
	Combined	1/1	100 (20.7-100)	2/2	100 (34.2-100)
<i>Staphylococcus warneri</i>	Prospective	0/0	-	4/4	100 (51.0-100)
	Retrospective	-	-	-	-
	Contrived	-	-	-	-
	Combined	0/0	-	4/4	100 (51.0-100)

A comparison of specific *Staphylococcus* species and *mecA* identified by comparator methods versus the ePlex BCID-GP Panel results are shown in **Table 35** and **Table 36** for prospective and retrospective samples.

Table 35: Distribution of *mecA* Results in *Staphylococcus aureus* Prospective/Retrospective Samples

	Comparator Method			
BCID-GP	Org+/ARG+	Org+/ARG-	Org-	Total
Org+/ARG+	190	2	2	194
Org+/ARG-	2	88	4	94
Org-	2	7	1000	1009
Total	194	97	1006	1297
% Agreement (95% CI) for Org+/ARG+: 190/194=97.9 (94.8-99.2) % Agreement (95% CI) for Org+/ARG-: 88/97=90.7 (83.3-95.0) % Agreement (95% CI) for Org-: 1000/1006=99.4 (98.7-99.7)				

Table 36: Distribution of *mecA* Results in *Staphylococcus* Species (Excluding Known *S. aureus*, *S. epidermidis*, *S. lugdunensis*) Prospective/Retrospective Samples

	Comparator Method			
BCID-GP	Org+/ARG+	Org+/ARG-	Org-	Total
Org+/ARG+	33	1	4	38
Org+/ARG-	3	45	8	56
Org-	10*	4	1091	1105
Total	46	50	1103	1199
% Agreement (95% CI) for Org+/ARG+: 33/46=71.7 (57.5-82.7) % Agreement (95% CI) for Org+/ARG-: 45/50=90.0 (78.6-95.7) % Agreement (95% CI) for Org-: 1091/1103=98.9 (98.1-99.4)				

*10 samples had a *Staphylococcus* species (not *S. aureus*, *S. epidermidis*, or *S. lugdunensis*) with *mecA* identified by comparator methods, whereas ePlex BCID-GP Panel detected *S. epidermidis* with *mecA*.

A table for *mecC* is not provided because *mecC* was only detected in a single species, *Staphylococcus aureus*. In the 49 contrived samples with *Staphylococcus aureus* containing *mecC*, the resulting PPA and NPA were both 100%.

vanA/vanB

The PPA and NPA of the BCID-GP Panel *vanA* target stratified by the *Enterococcus* species identified by comparator methods for 208 clinical prospective/retrospective samples and 126 contrived samples are shown in **Table 37**.

A table for *vanB* is not provided because *vanB* was only detected in 53 samples comprised of two species, *E. faecalis* (n=43) and *E. faecium* (n=10), resulting in PPA and NPA of 100%.

Table 37: Clinical Performance of *vanA* Target by *Enterococcus* Species Detected by Comparator Methods

Species detected by Comparator Method		Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Enterococcus</i>	Prospective	0/0	-	1/1	100 (20.7-100)
	Retrospective	-	-	-	-
	Contrived	-	-	-	-
	Combined	0/0	-	1/1	100 (20.7-100)
<i>Enterococcus avium</i>	Prospective	0/0	-	1/1	100 (20.7-100)
	Retrospective	0/1	0.0 (0.0-79.3)	2/2	100 (34.2-100)
	Contrived	-	-	-	-
	Combined	0/1	0.0 (0.0-79.3)	3/3	100 (43.9-100)
<i>Enterococcus casseliflavus</i>	Prospective	-	-	-	-
	Retrospective	0/0	---	1/1	100 (20.7-100)
	Contrived	-	-	-	-
	Combined	0/0	-	1/1	100 (20.7-100)
<i>Enterococcus casseliflavus</i> / <i>E. gallinarum</i>	Prospective	-	-	-	-
	Retrospective	0/0	---	1/1	100 (20.7-100)
	Contrived	-	-	-	-
	Combined	0/0	-	1/1	100 (20.7-100)
<i>Enterococcus faecalis</i>	Prospective	1/1	100 (20.7-100)	48/48	100 (92.6-100)
	Retrospective	11/14	78.6 (52.4-92.4)	76/76	100 (95.2-100)
	Contrived	10/10	100 (72.2-100)	42/42	100 (91.6-100)
	Combined	22/25	88.0 (70.0-95.8)	166/166	100 (97.7-100)
<i>Enterococcus faecium</i>	Prospective	7/7	100 (64.6-100)	4/5	80.0 (37.6-96.4)
	Retrospective	44/44	100 (92.0-100)	8/9	88.9 (56.5-98.0)
	Contrived	50/50	100 (92.9-100)	10/10	100 (72.2-100)
	Combined	101/101	100 (96.3-100)	22/24	91.7 (74.2-97.7)
<i>Enterococcus flavescens</i>	Prospective	-	-	-	-
	Retrospective	-	-	-	-
	Contrived	0/0	---	3/3	100 (43.9-100)
	Combined	0/0	-	3/3	100 (43.9-100)

Species detected by Comparator Method		Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>Enterococcus gallinarum</i>	Prospective	-	-	-	-
	Retrospective	0/0	-	2/2	100 (34.2-100)
	Contrived	0/0	---	4/4	100 (51.0-100)
	Combined	0/0	-	6/6	100 (61.0-100)
<i>Enterococcus hirae</i>	Prospective	-	-	-	-
	Retrospective	-	-	-	-
	Contrived	0/0	---	1/1	100 (20.7-100)
	Combined	0/0	-	1/1	100 (20.7-100)
<i>Enterococcus malodoratus</i>	Prospective	-	-	-	-
	Retrospective	-	-	-	-
	Contrived	0/0	---	3/3	100 (43.9-100)
	Combined	0/0	-	3/3	100 (43.9-100)
<i>Enterococcus raffinosus</i>	Prospective	-	-	-	-
	Retrospective	-	-	-	-
	Contrived	0/0	---	2/2	100 (34.2-100)
	Combined	0/0	-	2/2	100 (34.2-100)
<i>Enterococcus saccharolyticus</i>	Prospective	-	-	-	-
	Retrospective	-	-	-	-
	Contrived	0/0	---	1/1	100 (20.7-100)
	Combined	0/0	-	1/1	100 (20.7-100)

A comparison of *Enterococcus faecalis*/*Enterococcus faecium* and *vanA* identified by comparator methods versus the ePlex BCID-GP Panel results is shown in **Table 38** and **Table 39** for prospective and retrospective samples.

Table 38: Distribution of *vanA* Results in *Enterococcus faecalis* Prospective/Retrospective Samples

	Comparator Method			
BCID-GP	Org+/ARG+	Org+/ARG-	Org-	Total
Org+/ARG+	10	0	0	10
Org+/ARG-	1	120	1	122
Org-	4*	4	1157	1165
Total	15	124	1158	1297
% Agreement (95% CI) for Org+/ARG+: 10/15=66.7 (41.7-84.8) % Agreement (95% CI) for Org+/ARG-: 120/124=96.8 (92.0-98.7) % Agreement (95% CI) for Org-: 1157/1158=99.9 (99.5-100)				

*2 of the 4 samples had *E. faecium* with *vanA* detected by the ePlex BCID-GP Panel.

Table 39: Distribution of *vanA* Results in *Enterococcus faecium* Prospective/Retrospective Samples

	Comparator Method			
BCID-GP	Org+/ARG+	Org+/ARG-	Org-	Total
Org+/ARG+	51	2	3	56
Org+/ARG-	0	10	5	15
Org-	0	2	1224	1226
Total	51	14	1232	1297
% Agreement (95% CI) for Org+/ARG+: 51/51=100.0 (93.0-100) % Agreement (95% CI) for Org+/ARG-: 10/14=71.4 (45.4-88.3) % Agreement (95% CI) for Org-: 1224/1232=99.4 (98.7-99.7)				

Co-detections in Clinical Samples

The ePlex BCID-GP Panel identified a total of 103 bacterial co-detections in 1297 clinical samples (prospective/retrospective). In the 711 prospective samples of the clinical study, 38/711 (5.3%) had double detections and 1/711 (0.1%) had a triple detection. In the 586 retrospective samples, 56/586 (9.6%) had co-detections and 8/586 (1.4%) had triple detections. Neither the prospective nor the retrospective arms of the clinical studies contained a sample with more than 3 organisms detected.

In prospective samples, the most common co-detection combination identified by the ePlex BCID-GP Panel was *Enterococcus faecalis* with Pan Gram-Negative which was detected in 6 samples. Pan Gram-Negative was identified in 17 co-detections, *Staphylococcus* was identified in 26 co-detections, *Enterococcus* was identified in 13 co-detections, and *Streptococcus* was identified in 12 co-detections.

In retrospective samples, the most common co-detection combination identified by the ePlex BCID-GP Panel was *Enterococcus faecalis* with Pan Gram-Negative which was detected in 9 samples, 2 of which also had *vanA* detected. Pan Gram-Negative was identified in 33 co-detections, *Staphylococcus* was identified in 22 co-detections, *Enterococcus* was identified in 34 co-detections, and *Streptococcus* was identified in 24 co-detections. See **Tables 40-41** below for summaries of co-detections in prospective and retrospective samples in targets as determined by the ePlex BCID-GP Panel.

Table 40: Co-Detections Identified by the ePlex BCID-GP Panel in Prospective Clinical Samples by Target

Distinct Co-Detection Combinations Detected by the ePlex BCID-GP Panel in Prospective Clinical Samples				Number Samples (Number Discrepant)	Discrepant Organism(s) / Resistance Marker(s)*
Target 1	Target 2	Target 3	Resistance Marker		
<i>C. acnes</i>	<i>Staphylococcus</i>			1 (1)	<i>C. acnes</i> (1)
<i>Corynebacterium</i>	<i>S. epidermidis</i>		<i>mecA</i>	2 (0)	
<i>E. faecalis</i>	<i>E. faecium</i>			2 (1)	<i>E. faecium</i> (1)
<i>E. faecalis</i>	Pan GN			6 (0)	
<i>E. faecalis</i>	<i>S. epidermidis</i>		<i>mecA</i>	1 (0)	
<i>E. faecalis</i>	<i>Staphylococcus</i>			1 (0)	
<i>E. faecalis</i>	<i>Staphylococcus</i>		<i>mecA</i>	1 (0)	

Distinct Co-Detection Combinations Detected by the ePlex BCID-GP Panel in Prospective Clinical Samples				Number Samples (Number Discrepant)	Discrepant Organism(s) / Resistance Marker(s)*
Target 1	Target 2	Target 3	Resistance Marker		
<i>E. faecium</i>	Pan GN	<i>Staphylococcus</i>	<i>mecA</i> , <i>vanA</i>	1 (0)	
<i>E. faecium</i>	<i>S. epidermidis</i>		<i>mecA</i> , <i>vanA</i>	1 (0)	
<i>Lactobacillus</i>	<i>Streptococcus</i>			1 (1)	<i>Lactobacillus</i> (1)
<i>Listeria</i>	<i>Staphylococcus</i>			1 (1)	<i>Listeria</i> (1)
Pan GN	<i>S. anginosus</i> group			2 (0)	
Pan GN	<i>S. aureus</i>			1 (0)	
Pan GN	<i>S. epidermidis</i>		<i>mecA</i>	2 (2)	Pan GN (1), <i>S. epidermidis</i> (1)
Pan GN	<i>S. pneumoniae</i>			1 (1)	<i>S. pneumoniae</i> (1)
Pan GN	<i>Staphylococcus</i>			2 (0)	
Pan GN	<i>Staphylococcus</i>		<i>mecA</i>	1 (0)	
Pan GN	<i>Streptococcus</i>			1 (0)	
<i>S. agalactiae</i>	<i>S. aureus</i>			1 (0)	
<i>S. anginosus</i> group	<i>Staphylococcus</i>			2 (2)	<i>S. anginosus</i> gp (1), <i>Staphylococcus</i> (1)
<i>S. aureus</i>	<i>S. epidermidis</i>		<i>mecA</i>	2 (2)	<i>S. epidermidis</i> (2)
<i>S. epidermidis</i>	<i>S. lugdunensis</i>			1 (1)	<i>S. epidermidis</i> (1), <i>S. lugdunensis</i> (1)
<i>S. epidermidis</i>	<i>S. lugdunensis</i>		<i>mecA</i>	1 (1)	<i>S. lugdunensis</i> (1)
<i>S. epidermidis</i>	<i>Streptococcus</i>			2 (1)	<i>S. epidermidis</i> (1)
<i>Staphylococcus</i>	<i>Streptococcus</i>			1 (0)	
<i>Staphylococcus</i>	<i>Streptococcus</i>		<i>mecA</i>	1 (1)	<i>Streptococcus</i> (1)

* A discrepant result is one that was detected by the ePlex BCID-GP Panel but not by the comparator method(s). 7/16 discrepant organisms were detected using PCR/sequencing as shown below:

- In 1/1 false positive *E. faecium* samples, *E. faecium* was detected.
- In 1/1 false positive *Lactobacillus* samples, *Lactobacillus* was detected.
- In 2/5 false positive *S. epidermidis* samples, *S. epidermidis* was detected.
- In 2/2 false positive *S. lugdunensis* samples, *S. lugdunensis* was detected.
- In 1/1 false positive *Streptococcus* samples, *Streptococcus* was detected.

Table 41: Co-Detections Identified by the ePlex BCID-GP Panel in Retrospective Clinical Samples by Target

Distinct Co-Detection Combinations Detected by the ePlex BCID-GP Panel in Retrospective Clinical Samples				Number Samples (Number Discrepant)	Discrepant Organism(s) / Resistance Marker(s)*
Target 1	Target 2	Target 3	Resistance Marker		
<i>Corynebacterium</i>	<i>S. epidermidis</i>	<i>S. lugdunensis</i>	<i>mecA</i>	1 (1)	<i>Corynebacterium</i> (1)
<i>Corynebacterium</i>	<i>Staphylococcus</i>			1 (0)	
<i>Corynebacterium</i>	<i>Staphylococcus</i>		<i>mecA</i>	1 (0)	
<i>E. faecalis</i>	<i>E. faecium</i>			4 (3)	<i>E. faecium</i> (3)
<i>E. faecalis</i>	<i>E. faecium</i>		<i>vanA</i>	3 (1)	<i>E. faecium</i> (1)

Distinct Co-Detection Combinations Detected by the ePlex BCID-GP Panel in Retrospective Clinical Samples				Number Samples (Number Discrepant)	Discrepant Organism(s) / Resistance Marker(s)*
Target 1	Target 2	Target 3	Resistance Marker		
<i>E. faecalis</i>	Pan <i>Candida</i>			1 (0)	
<i>E. faecalis</i>	Pan GN			6 (0)	
<i>E. faecalis</i>	Pan GN		<i>vanA</i>	2 (0)	
<i>E. faecalis</i>	Pan GN	<i>S. aureus</i>		1 (0)	
<i>E. faecalis</i>	<i>S. aureus</i>		<i>mecA</i>	1 (0)	
<i>E. faecalis</i>	<i>Staphylococcus</i>		<i>vanA</i>	1 (1)	<i>Staphylococcus</i> (1)
<i>E. faecium</i>	<i>Lactobacillus</i>	Pan GN	<i>vanA</i>	1 (1)	<i>Lactobacillus</i> (1)
<i>E. faecium</i>	Pan <i>Candida</i>		<i>vanA</i>	1 (1)	<i>E. faecium</i> (1)
<i>E. faecium</i>	Pan <i>Candida</i>	<i>S. epidermidis</i>	<i>mecA, vanA</i>	1 (1)	<i>S. epidermidis</i> (1)
<i>E. faecium</i>	Pan GN			3 (0)	
<i>E. faecium</i>	Pan GN		<i>vanA</i>	5 (0)	
<i>E. faecium</i>	Pan GN	<i>Staphylococcus</i>	<i>mecA, vanA</i>	1 (0)	
<i>E. faecium</i>	<i>S. aureus</i>		<i>mecA, vanA</i>	1 (0)	
<i>E. faecium</i>	<i>Streptococcus</i>		<i>vanA</i>	1 (1)	<i>Streptococcus</i> (1)
<i>Enterococcus</i>	<i>S. anginosus</i> group			1 (0)	
<i>Lactobacillus</i>	<i>S. anginosus</i> group			1 (0)	
<i>Micrococcus</i>	<i>S. pyogenes</i>			1 (1)	<i>Micrococcus</i> (1)
Pan <i>Candida</i>	<i>S. epidermidis</i>		<i>mecA</i>	2 (0)	
Pan <i>Candida</i>	<i>S. pneumoniae</i>			1 (0)	
Pan GN	<i>S. agalactiae</i>			2 (1)	Pan GN (1)
Pan GN	<i>S. anginosus</i> group			4 (0)	
Pan GN	<i>S. anginosus</i> group	<i>S. aureus</i>		1 (1)	Pan GN (1)
Pan GN	<i>S. aureus</i>			1 (0)	
Pan GN	<i>S. aureus</i>	<i>S. epidermidis</i>	<i>mecA</i>	1 (1)	<i>S. epidermidis</i> (1)
Pan GN	<i>S. pneumoniae</i>			2 (0)	
Pan GN	<i>Streptococcus</i>			3 (0)	
<i>S. agalactiae</i>	<i>S. aureus</i>			2 (0)	
<i>S. agalactiae</i>	<i>S. aureus</i>		<i>mecA</i>	1 (0)	
<i>S. agalactiae</i>	<i>S. aureus</i>	<i>S. epidermidis</i>	<i>mecA</i>	1 (1)	<i>S. epidermidis</i> (1)
<i>S. aureus</i>	<i>S. epidermidis</i>		<i>mecA</i>	1 (0)	
<i>S. aureus</i>	<i>Streptococcus</i>		<i>mecA</i>	2 (1)	<i>Streptococcus</i> (1)
<i>S. epidermidis</i>	<i>Streptococcus</i>		<i>mecA</i>	1 (0)	

* A discrepant result is one that was detected by the ePlex BCID-GP Panel but not by the comparator method(s). 6/16 discrepant organisms were detected using PCR/sequencing as shown below:

- In 1/1 false positive *Corynebacterium* samples, *Corynebacterium* was detected.
- In 2/5 false positive *E. faecium* samples, *E. faecium* was detected.
- In 1/1 false positive *Staphylococcus* samples, *Staphylococcus* was detected.
- In 2/2 false positive *Streptococcus* samples, *Streptococcus* was detected.

Additional co-detection combinations identified by comparator method(s) are summarized in **Table 42** and **Table 43** for prospective and retrospective samples, respectively.

Table 42: Additional Co-Detections Identified by Comparator Method(s) in Prospective Clinical Samples by Organism

Distinct Co-Detection Combinations Detected by the Comparator Methods in Prospective Clinical Samples					Number Samples (Number Discrepant)	Discrepant Organism(s)/ Resistance Markers(s)*
Organism 1	Organism 2	Organism 3	Organism 4	Resistance Marker		
<i>A. baumannii</i>	<i>E. faecium</i>	<i>Staphylococcus</i>		<i>mecA, vanA</i>	1 (0)	
<i>A. baumannii</i>	<i>S. aureus</i>				1 (0)	
<i>A. baumannii</i>	<i>Staphylococcus</i>			<i>mecA</i>	1 (0)	
<i>Acinetobacter lwoffii</i>	<i>Staphylococcus hominis</i>			<i>mecA</i>	1 (0)	
<i>Aerococcus viridans</i> ^A	<i>K. oxytoca</i>	<i>S. epidermidis</i>	<i>Staphylococcus cohnii</i>	<i>mecA</i>	1 (1)	<i>S. cohnii</i> (1), <i>S. epidermidis</i> (1), <i>mecA</i> (1)
<i>Aerococcus viridans</i> ^A	<i>Staphylococcus hominis</i>				1 (0)	
<i>B. fragilis</i>	<i>Clostridium</i> species ^A				1 (0)	
<i>B. fragilis</i>	<i>S. anginosus</i> gp				1 (0)	
<i>C. acnes</i>	<i>S. epidermidis</i>				1 (1)	<i>S. epidermidis</i> (1)
<i>C. acnes</i>	<i>S. lugdunensis</i>				1 (1)	<i>C. acnes</i> (1)
<i>Citrobacter freundii</i>	<i>K. pneumoniae</i>	<i>Staphylococcus hominis</i>		<i>mecA</i>	1 (1)	<i>mecA</i> (1)
<i>Citrobacter koseri</i>	<i>E. faecalis</i>				1 (0)	
<i>Corynebacterium</i>	<i>S. epidermidis</i>	<i>Streptococcus</i>		<i>mecA</i>	1 (1)	<i>Streptococcus</i> (1)
<i>Corynebacterium</i>	<i>Streptococcus</i>				1 (1)	<i>Corynebacterium</i> (1)
<i>E. coli</i>	<i>E. faecalis</i>	<i>P. mirabilis</i>			1 (0)	
<i>E. coli</i>	<i>Lactococcus lactis</i> ^A				1 (0)	
<i>E. coli</i>	<i>P. mirabilis</i>	<i>Providencia stuartii</i>	<i>S. anginosus</i> gp		1 (0)	
<i>E. faecalis</i>	<i>E. faecium</i>				1 (1)	<i>E. faecium</i> (1)
<i>E. faecalis</i>	<i>K. pneumoniae</i>				2 (0)	
<i>E. faecalis</i>	<i>P. mirabilis</i>				1 (0)	
<i>E. faecalis</i>	<i>S. aureus</i>			<i>mecA</i>	1 (1)	<i>S. aureus</i> (1), <i>mecA</i> (1)
<i>E. faecalis</i>	<i>S. marcescens</i>				1 (0)	
<i>E. faecalis</i>	<i>Staphylococcus (CoNS)</i>			<i>mecA</i>	1 (0)	
<i>E. faecium</i>	<i>S. epidermidis</i>	<i>Staphylococcus haemolyticus</i>		<i>mecA, vanA</i>	1 (0)	
<i>K. pneumoniae</i>	<i>Staphylococcus haemolyticus</i>	non-fermenting GN bacilli			1 (0)	
<i>P. aeruginosa</i>	<i>P. mirabilis</i>	<i>Streptococcus - viridans</i> group			1 (0)	
<i>P. mirabilis</i>	<i>Staphylococcus</i>			<i>mecA</i>	1 (1)	<i>Staphylococcus</i> (1), <i>mecA</i> (1)
<i>Peptostreptococcus</i> species ^A	<i>Staphylococcus</i>				1 (0)	

Distinct Co-Detection Combinations Detected by the Comparator Methods in Prospective Clinical Samples					Number Samples (Number Discrepant)	Discrepant Organism(s)/ Resistance Markers(s)*
Organism 1	Organism 2	Organism 3	Organism 4	Resistance Marker		
<i>Rothia</i> (stomatococcus) <i>mucilagenosus</i> ^A	<i>S. epidermidis</i>				1 (0)	
<i>Rothia mucilagenosa</i> ^A	<i>Streptococcus - viridans</i> group				1 (0)	
<i>S. agalactiae</i>	<i>S. aureus</i>	<i>Staphylococcus</i>		<i>mecA</i>	1 (1)	<i>S. aureus</i> (1), <i>Staphylococcus</i> (1), <i>mecA</i> (1)
<i>S. anginosus</i>	<i>Streptococcus mitis</i>				1 (1)	<i>S. anginosus</i> (1)
<i>S. epidermidis</i>	<i>Staphylococcus capitis</i>			<i>mecA</i>	1 (0)	
<i>S. epidermidis</i>	<i>Staphylococcus hominis</i>				2 (0)	
<i>S. epidermidis</i>	<i>Staphylococcus hominis</i>			<i>mecA</i>	4 (1)	<i>S. epidermidis</i> (1)
<i>S. epidermidis</i>	<i>Staphylococcus hominis</i>	<i>Staphylococcus warneri</i>			1 (0)	
<i>S. epidermidis</i>	<i>Streptococcus - viridans</i> group				1 (1)	<i>S. epidermidis</i> (1)
<i>S. epidermidis</i>	<i>Streptococcus parasanguinis</i>				1 (0)	
<i>S. maltophilia</i>	<i>Streptococcus</i>				1 (1)	<i>Streptococcus</i> (1)
<i>S. marcescens</i>	<i>Streptococcus mitis</i> group	<i>Streptococcus salivarius</i>			1 (0)	
<i>Staphylococcus cohnii</i>	<i>Streptococcus - viridans</i> group				1 (1)	<i>S. viridans</i> group (1)
<i>Staphylococcus hominis</i>	<i>Staphylococcus pettenkoferi</i>				1 (0)	
<i>Staphylococcus hominis</i>	<i>Streptococcus mitis</i>			<i>mecA</i>	1 (1)	<i>mecA</i> (1)

* A discrepant result is one that was detected by the comparator method(s) but not by the ePlex BCID-GP Panel (excludes organisms not targeted by the ePlex BCID-GP Panel). 16 discrepant organisms were investigated using PCR/sequencing; 1 discrepant organism was not detected:

-In 1/1 false negative *S. anginosus* group sample, PCR/Sequencing instead detected *Streptococcus dysgalactiae*.

^A. Off-panel organisms not targeted by the ePlex BCID-GP Panel.

Table 43: Additional Co-Detections Identified by Comparator Method(s) in Retrospective Clinical Samples by Organism

Distinct Co-Detection Combinations Detected by the Comparator Methods in Retrospective Clinical Samples					Number Samples (Number Discrepant)	Discrepant Organism(s)/ Resistance Markers(s)*
Organism 1	Organism 2	Organism 3	Organism 4	Resistance Marker		
<i>A. baumannii</i>	<i>E. faecalis</i>			<i>vanA</i>	2 (2)	<i>A. baumannii</i> (2)
<i>A. baumannii</i>	<i>E. faecalis</i>	<i>S. aureus</i>		<i>mecA</i>	1 (1)	<i>mecA</i> (1)
<i>A. baumannii</i>	<i>E. faecium</i>			<i>vanA</i>	1 (0)	
<i>Aerococcus sanguinicola</i> ^A	<i>Corynebacterium</i>	<i>Staphylococcus saprophyticus</i>			1 (0)	

Distinct Co-Detection Combinations Detected by the Comparator Methods in Retrospective Clinical Samples					Number Samples (Number Discrepant)	Discrepant Organism(s)/ Resistance Markers(s)*
Organism 1	Organism 2	Organism 3	Organism 4	Resistance Marker		
<i>Aeromonas caviae</i>	<i>E. coli</i>	<i>Enterococcus casseliflavus</i>	<i>K. oxytoca</i>		1 (1)	<i>E. casseliflavus</i> (1)
<i>C. acnes</i>	<i>Enterococcus avium</i>			<i>vanA</i>	1 (1)	<i>E. avium</i> (1), <i>vanA</i> (1)
<i>C. albicans</i>	<i>E. faecalis</i>			<i>vanA</i>	1 (1)	<i>E. faecalis</i> (1)
<i>C. albicans</i>	<i>E. faecium</i>	<i>Staphylococcus hominis</i>		<i>mecA</i> , <i>vanA</i>	1 (0)	
<i>C. albicans</i>	<i>S. epidermidis</i>			<i>mecA</i>	1 (0)	
<i>C. glabrata</i>	<i>Lactobacillus rhamnosus</i>				1 (1)	<i>C. glabrata</i> (1)
<i>C. glabrata</i>	<i>S. pneumoniae</i>				1 (0)	
<i>C. krusei</i>	<i>S. epidermidis</i>			<i>mecA</i>	1 (0)	
<i>C. parapsilosis</i>	<i>E. faecalis</i>				1 (0)	
<i>C. parapsilosis</i>	<i>E. faecalis</i>			<i>vanA</i>	1 (1)	<i>C. parapsilosis</i> (1)
<i>Citrobacter braakii</i>	<i>Streptococcus oralis</i>				1 (0)	
<i>E. cloacae</i>	<i>E. faecalis</i>				1 (0)	
<i>E. cloacae</i>	<i>E. faecium</i>			<i>vanA</i>	1 (0)	
<i>E. cloacae</i>	<i>E. faecium</i>	<i>Staphylococcus hominis</i>		<i>mecA</i> , <i>vanA</i>	1 (0)	
<i>E. cloacae</i>	<i>S. anginosus gp</i>				1 (0)	
<i>E. coli</i>	<i>E. faecalis</i>				3 (0)	
<i>E. coli</i>	<i>E. faecalis</i>	<i>K. pneumoniae</i>			1 (0)	
<i>E. coli</i>	<i>E. faecalis</i>	<i>P. mirabilis</i>			1 (0)	
<i>E. coli</i>	<i>E. faecium</i>				2 (0)	
<i>E. coli</i>	<i>K. oxytoca</i>	<i>Streptococcus infantarius</i>			1 (0)	
<i>E. coli</i>	<i>S. agalactiae</i>				1 (0)	
<i>E. coli</i>	<i>S. anginosus gp</i>				1 (0)	
<i>E. coli</i>	<i>S. aureus</i>			<i>mecA</i>	1 (0)	
<i>E. coli</i>	<i>S. pneumoniae</i>				1 (0)	
<i>E. coli</i>	<i>Streptococcus bovis</i>				1 (0)	
<i>E. faecalis</i>	<i>K. pneumoniae</i>			<i>vanA</i>	1 (1)	<i>E. faecalis</i> (1), <i>K. pneumoniae</i> (1)
<i>E. faecalis</i>	<i>M. morgani</i>			<i>vanA</i>	1 (0)	
<i>E. faecalis</i>	<i>M. morgani</i>	<i>Proteus vulgaris</i>		<i>vanA</i>	1 (1)	<i>E. faecalis</i> (1), <i>vanA</i> (1)
<i>E. faecalis</i>	<i>P. aeruginosa</i>	<i>S. aureus</i>		<i>mecA</i>	1 (1)	<i>E. faecalis</i> (1), <i>P. aeruginosa</i> (1)
<i>E. faecalis</i>	<i>P. mirabilis</i>				2 (2)	<i>E. faecalis</i> (1), <i>P. mirabilis</i> (1)
<i>E. faecalis</i>	<i>P. mirabilis</i>			<i>vanA</i>	1 (1)	<i>E. faecalis</i> (1), <i>vanA</i> (1)
<i>E. faecalis</i>	<i>Providencia stuartii</i>				1 (1)	<i>P. stuartii</i> (1)
<i>E. faecalis</i>	<i>S. maltophilia</i>			<i>vanA</i>	1 (0)	
<i>E. faecium</i>	<i>K. pneumoniae</i>				1 (0)	

Distinct Co-Detection Combinations Detected by the Comparator Methods in Retrospective Clinical Samples					Number Samples (Number Discrepant)	Discrepant Organism(s)/ Resistance Markers(s)*
Organism 1	Organism 2	Organism 3	Organism 4	Resistance Marker		
<i>E. faecium</i>	<i>Moraxella (Branhamella) catarrhalis</i>	<i>Pediococcus pentosaceus</i>		<i>vanA</i>	1 (0)	
<i>E. faecium</i>	<i>P. aeruginosa</i>			<i>vanA</i>	1 (0)	
<i>E. faecium</i>	<i>P. mirabilis</i>			<i>vanA</i>	1 (0)	
<i>E. faecium</i>	<i>Pseudomonas</i>			<i>vanA</i>	1 (0)	
<i>E. faecium</i>	<i>S. epidermidis</i>	<i>Staphylococcus hominis</i>		<i>mecA</i>	1 (1)	<i>E. faecium</i> (1)
<i>Enterobacter aerogenes</i>	<i>S. anginosus gp</i>				1 (0)	
<i>Enterococcus avium</i>	<i>S. anginosus gp</i>				1 (0)	
<i>K. oxytoca</i>	<i>S. anginosus gp</i>				1 (0)	
<i>K. pneumoniae</i>	<i>S. aureus</i>				2 (1)	<i>S. aureus</i> (1)
<i>L. monocytogenes</i>	<i>Staphylococcus</i>			<i>mecA</i>	1 (1)	<i>Staphylococcus</i> (1), <i>mecA</i> (1)
<i>Lactobacillus casei</i>	<i>Veillonella species</i>				1 (1)	<i>Veillonella species</i> (1)
<i>Lactobacillus rhamnosus</i>	<i>Pediococcus acidilactici</i> ^A				1 (0)	
<i>Lactobacillus rhamnosus</i>	<i>S. anginosus gp</i>	<i>Staphylococcus</i>	<i>Streptococcus - viridans group</i>		1 (1)	<i>Staphylococcus</i> (1)
<i>Micrococcus</i>	<i>Pseudoclavibacter</i> ^A				1 (0)	
<i>Moraxella catarrhalis</i>	<i>S. pneumoniae</i>				1 (0)	
<i>S. agalactiae</i>	<i>S. aureus</i>				1 (1)	<i>S. aureus</i> (1)
<i>S. agalactiae</i>	<i>S. aureus</i>	<i>Streptococcus - viridans group</i>			1 (0)	
<i>S. aureus</i>	<i>S. epidermidis</i>				1 (1)	<i>S. aureus</i> (1)
<i>S. aureus</i>	<i>S. pyogenes</i>			<i>mecA</i>	1 (1)	<i>S. pyogenes</i> (1)
<i>S. aureus</i>	<i>Staphylococcus capitis</i>				1 (0)	
<i>S. aureus</i>	<i>Streptococcus mitis</i>			<i>mecA</i>	1 (0)	
<i>S. epidermidis</i>	<i>Staphylococcus hominis</i>				1 (0)	
<i>S. epidermidis</i>	<i>Staphylococcus hominis</i>			<i>mecA</i>	3 (0)	
<i>S. epidermidis</i>	<i>Staphylococcus hominis</i>	<i>Streptococcus parasanguinis</i>		<i>mecA</i>	1 (0)	
<i>Staphylococcus capitis</i>	<i>Staphylococcus hominis</i>			<i>mecA</i>	1 (0)	

* A discrepant result is one that was detected by the comparator method(s) but not by the ePlex BCID-GP Panel (excludes organisms not targeted by the ePlex BCID-GP Panel). 24 discrepant organisms were investigated using PCR/sequencing; 2 discrepant organisms were not detected:

-In 2/6 false negative *E. faecalis* samples, PCR/Sequencing instead detected *Enterococcus faecium*.

^A. Off-panel organisms not targeted by the ePlex BCID-GP Panel.

Clinical Study ePlex Instrument Performance

A total of 2354 samples (including prospective, retrospective, and contrived samples) were initially tested in the clinical evaluations. Of these, 24/2354 (1.0%) did not complete the run and the sample was retested. After repeat testing, all 2354 samples completed testing and 2246/2354 (95.4%, 95% CI: 94.5%-96.2%) generated valid results and 108/2354 (4.6%, 95% CI: 3.8%-5.5%) generated invalid results on the first completed attempt.

Upon repeat testing of the 108 samples with initially invalid results, 3/108 (2.8%) did not complete the run and the sample was retested. After repeat testing, all 108 samples completed testing and 106/108 (98.1%) generated valid results. Overall, after final testing, 2/2354 (0.1%, 95% CI: 0.0%-0.3%) had final, invalid results, resulting in a final validity rate of 2352/2354 (99.9%, 95% CI: 99.7%-100%).

ANALYTICAL PERFORMANCE CHARACTERISTICS

Limit of Detection (Analytical Sensitivity)

The limit of detection (LoD), or analytical sensitivity, was identified and verified for each assay on the BCID-GP Panel using at least two quantified reference strains in simulated blood culture sample matrix, which is defined as a whole blood with EDTA added to a blood culture bottle in the same ratio as the manufacturer recommends and incubated for 8 hours. At least 20 replicates per target were tested for each condition. The limit of detection was defined as the lowest concentration of each target that is detected in $\geq 95\%$ of tested replicates. The confirmed LoD for each ePlex BCID-GP Panel organism is shown in **Table 44**.

Table 44: LoD Results Summary

Target	Organism	Strain	LoD Concentration (CFU/mL)
<i>B. cereus</i> group	<i>Bacillus cereus</i>	ATCC 21769	1 x 10 ⁵
	<i>Bacillus thuringiensis</i>	ATCC 35646	1 x 10 ⁵
<i>B. subtilis</i> group	<i>Bacillus subtilis</i>	ATCC 55614	1 x 10 ⁶
	<i>Bacillus atrophaeus</i>	ATCC 51189	1 x 10 ⁶
<i>Corynebacterium</i>	<i>Corynebacterium striatum</i>	ATCC 43735	1 x 10 ⁶
	<i>Corynebacterium jeikeium</i>	ATCC 43217	1 x 10 ⁷
<i>Cutibacterium acnes</i> (<i>P. acnes</i>)	<i>Cutibacterium acnes</i> (<i>P. acnes</i>)	ATCC 33179	1 x 10 ⁷
	<i>Cutibacterium acnes</i> (<i>P. acnes</i>)	ATCC 6919	1 x 10 ⁸
<i>Enterococcus</i>	<i>Enterococcus faecium</i>	ATCC BAA-2316	1 x 10 ⁵
	<i>Enterococcus faecium</i>	ATCC BAA-2317	1 x 10 ⁶
	<i>Enterococcus raffinosus</i>	ATCC 49464	1 x 10 ⁶
<i>Enterococcus faecium</i>	<i>Enterococcus faecium</i>	ATCC BAA-2316	1 x 10 ⁵
	<i>Enterococcus faecium</i>	ATCC BAA-2317	1 x 10 ⁶
<i>Enterococcus faecalis</i>	<i>Enterococcus faecalis</i>	ATCC 51575	1 x 10 ⁶
	<i>Enterococcus faecalis</i>	ATCC 700802	1 x 10 ⁶
<i>Lactobacillus</i>	<i>Lactobacillus paracasei</i>	ATCC 25598	1 x 10 ⁵
	<i>Lactobacillus casei</i>	ATCC 334	1 x 10 ⁵
<i>Listeria</i>	<i>Listeria seeligeri</i>	ATCC 35967	1 x 10 ⁵
	<i>Listeria monocytogenes</i>	ATCC 10890	1 x 10 ⁵
	<i>Listeria monocytogenes</i>	ATCC 19111	1 x 10 ⁶
<i>Listeria monocytogenes</i>	<i>Listeria monocytogenes</i>	ATCC 10890	1 x 10 ⁵
	<i>Listeria monocytogenes</i>	ATCC 19111	1 x 10 ⁵
<i>Micrococcus</i>	<i>Micrococcus luteus</i>	ATCC 19212	1 x 10 ⁶
	<i>Micrococcus luteus</i>	ATCC 10240	1 x 10 ⁷
<i>Staphylococcus</i>	<i>Staphylococcus aureus</i>	ATCC BAA-2313	1 x 10 ⁴
	<i>Staphylococcus aureus</i>	ATCC BAA-2312	1 x 10 ⁵
	<i>Staphylococcus epidermidis</i>	ATCC 35983	1 x 10 ⁵
	<i>Staphylococcus epidermidis</i>	ATCC 35984	1 x 10 ⁵
	<i>Staphylococcus lugdunensis</i>	NRS 879	1 x 10 ⁵
	<i>Staphylococcus lugdunensis</i>	ATCC 49576	1 x 10 ⁶
	<i>Staphylococcus haemolyticus</i>	NRS 62	1 x 10 ⁷
<i>Staphylococcus aureus</i>	<i>Staphylococcus aureus</i>	ATCC BAA-2313	1 x 10 ⁵
	<i>Staphylococcus aureus</i>	ATCC BAA-2312	1 x 10 ⁵
<i>Staphylococcus epidermidis</i>	<i>Staphylococcus epidermidis</i>	ATCC 35983	1 x 10 ⁵
	<i>Staphylococcus epidermidis</i>	ATCC 35984	1 x 10 ⁵
<i>Staphylococcus lugdunensis</i>	<i>Staphylococcus lugdunensis</i>	NRS 879	1 x 10 ⁵
	<i>Staphylococcus lugdunensis</i>	ATCC 49576	1 x 10 ⁵
<i>Streptococcus</i>	<i>Streptococcus pneumoniae</i>	ATCC BAA-475	1 x 10 ⁵
	<i>Streptococcus pneumoniae</i>	ATCC 10357	1 x 10 ⁵
	<i>Streptococcus gordonii</i>	ATCC 10558	1 x 10 ⁶
	<i>Streptococcus agalactiae</i>	ATCC 12401	1 x 10 ⁶
	<i>Streptococcus agalactiae</i>	ATCC 13813	1 x 10 ⁷

Target	Organism	Strain	LoD Concentration (CFU/mL)
<i>Streptococcus agalactiae</i>	<i>Streptococcus agalactiae</i>	ATCC 12401	1 x 10 ⁵
	<i>Streptococcus agalactiae</i>	ATCC 13813	1 x 10 ⁶
<i>Streptococcus anginosus</i> group	<i>Streptococcus intermedius</i>	ATCC 27335	1 x 10 ⁴
	<i>Streptococcus anginosus</i>	ATCC 9895	1 x 10 ⁶
<i>Streptococcus pneumoniae</i>	<i>Streptococcus pneumoniae</i>	ATCC BAA-475	1 x 10 ⁵
	<i>Streptococcus pneumoniae</i>	ATCC 10357	1 x 10 ⁵
<i>Streptococcus pyogenes</i>	<i>Streptococcus pyogenes</i>	ATCC 12384	1 x 10 ⁵
	<i>Streptococcus pyogenes</i>	ATCC 49399	1 x 10 ⁵
Pan Gram-Negative	<i>Stenotrophomonas maltophilia</i>	ATCC 13636	1 x 10 ⁶
	<i>Enterobacter cloacae</i>	ATCC 13047	1 x 10 ⁶
	<i>Escherichia coli</i>	ATCC 4157	1 x 10 ⁶
	<i>Klebsiella pneumoniae</i>	ATCC BAA-1706	1 x 10 ⁶
	<i>Serratia marcescens</i>	ATCC 8100	1 x 10 ⁶
	<i>Proteus mirabilis</i>	ATCC 43071	1 x 10 ⁶
	<i>Acinetobacter baumannii</i>	NCTC13302	1 x 10 ⁷
	<i>Neisseria meningitidis</i>	ATCC 13113	1 x 10 ⁷
	<i>Pseudomonas aeruginosa</i>	ATCC 15442	1 x 10 ⁷
Pan <i>Candida</i>	<i>Candida albicans</i>	ATCC 24433	1 x 10 ⁶
	<i>Candida glabrata</i>	ATCC 66032	1 x 10 ⁶
<i>mecA</i>	<i>Staphylococcus epidermidis</i>	ATCC 35983	1 x 10 ⁵
	<i>Staphylococcus epidermidis</i>	ATCC 35984	1 x 10 ⁵
<i>mecC</i>	<i>Staphylococcus aureus</i>	ATCC BAA-2313	1 x 10 ⁴
	<i>Staphylococcus aureus</i>	ATCC BAA-2312	1 x 10 ⁴
<i>vanA</i>	<i>Enterococcus faecium</i>	ATCC BAA-2316	1 x 10 ⁴
	<i>Enterococcus faecium</i>	ATCC BAA-2317	1 x 10 ⁵
<i>vanB</i>	<i>Enterococcus faecalis</i>	ATCC 51575	1 x 10 ⁵
	<i>Enterococcus faecalis</i>	ATCC 700802	1 x 10 ⁵

Analytical Reactivity (Inclusivity)

A panel of 459 strains/isolates representing the genetic, temporal and geographic diversity of each target on the ePlex BCID-GP Panel was evaluated to demonstrate analytical reactivity. Each bacterial strain was tested in triplicate at 1 x 10⁸ CFU/mL or less and each fungal strain was tested at 1 x 10⁶ CFU/mL. In the cases where the initial testing concentration did not result in a “Detected” result, the concentration was increased to the point where detection was observed (see footnotes for concentrations of these strains). Organisms detected are shown in **Table 45**. Additional strains were detected as a part of the Limit of Detection (Analytical Sensitivity) study and can be found in **Table 44**.

Table 45: Analytical Reactivity (Inclusivity) Results

Organism	Strain
<i>Bacillus cereus</i>	
<i>Bacillus cereus</i>	ATCC 21769
	ATCC 10876
	ATCC 31430
	ATCC 53522
<i>Bacillus thuringiensis</i>	ATCC 35646
	ATCC 33679
	ATCC 55173
	ATCC 10792
<i>Bacillus subtilis</i>	
<i>Bacillus amyloliquefaciens</i>	ATCC 23845
	ATCC 23842
	ATCC 23350
	ATCC 53495
<i>Bacillus atrophaeus</i>	ATCC 51189
	ATCC 6455
	ATCC 49337
	ATCC 7972
	ATCC 6537
<i>Bacillus licheniformis</i>	ATCC 53926
	ATCC 55768
	ATCC 21039
	ATCC 21667
<i>Bacillus subtilis</i>	ATCC 55614
	ATCC 15561
	ATCC 21008
	ATCC 15040
<i>Corynebacterium</i>	
<i>Corynebacterium afermentans</i> subsp. <i>afermentans</i>	ATCC 51403 ^A
<i>Corynebacterium afermentans</i> subsp. <i>lipophilum</i>	ATCC 51404
<i>Corynebacterium confusum</i>	ATCC 38268 ^A
<i>Corynebacterium coyleae</i>	ATCC 700219
<i>Corynebacterium diphtheriae</i>	ATCC 13812
<i>Corynebacterium falsenii</i>	ATCC BAA-596 ^A
<i>Corynebacterium freneyi</i>	ATCC 64424 ^B
<i>Corynebacterium imitans</i>	ATCC 700354 ^B
<i>Corynebacterium jeikeium</i>	ATCC 43217
	ATCC 43216
	ATCC 43734
	ATCC BAA-949
<i>Corynebacterium minutissimum</i>	ATCC 23348
<i>Corynebacterium resistens</i>	CCUG 50093T
<i>Corynebacterium simulans</i>	ATCC BAA-15
<i>Corynebacterium striatum</i>	ATCC BAA-1293
	ATCC 43735
	ATCC 7094

Organism	Strain
<i>Staphylococcus lentus</i>	ATCC 700403
<i>Staphylococcus lugdunensis</i>	NRS-879
	ATCC 49576
	NRS-878
	NRS-880
<i>Staphylococcus muscae</i>	ATCC 49910
<i>Staphylococcus pasteurii</i>	ATCC 51129
<i>Staphylococcus pasteurii</i> (mecC+)	ATCC 51128
<i>Staphylococcus pettenkoferi</i>	DSM-19554
<i>Staphylococcus pseudintermedius</i>	ATCC 49444
<i>Staphylococcus saccharolyticus</i>	ATCC 14953
<i>Staphylococcus saprophyticus</i>	ATCC 15305
	ATCC 35552
<i>Staphylococcus schleiferi</i>	ATCC 49545
	ATCC 43808
<i>Staphylococcus sciuri</i>	ATCC 29060
	ATCC 29061
	ATCC 29059
	ATCC 49575
	ATCC 29062
<i>Staphylococcus simulans</i>	ATCC 27848
	ATCC 27850
	ATCC 31432
	ATCC 27851
<i>Staphylococcus species</i>	ATCC 155
<i>Staphylococcus species</i> (mecA+)	ATCC 27626
<i>Staphylococcus vitulinus</i>	ATCC 51699
	ATCC 51161
<i>Staphylococcus warneri</i>	ATCC 27836
<i>Staphylococcus xylosus</i>	ATCC 49148
	ATCC 29971
<i>Staphylococcus aureus</i>	
<i>Staphylococcus aureus</i>	ATCC 25923
	ATCC 29247
	ATCC 6538P
	ATCC 29213
	NR-45889
	NR-45890
	NR-46074
	NR-45881
<i>Staphylococcus aureus</i>	NR-46411
	NR-46414
	NR-46418
<i>Staphylococcus aureus</i>	NR-46417
<i>Staphylococcus aureus</i> (mecA+)	NR-13524
	NR-13527

Organism	Strain
<i>Corynebacterium timonense</i>	CCUG 64728 ^A
<i>Corynebacterium ulcerans</i>	ATCC 51799
<i>Corynebacterium urealyticum</i>	ATCC 43044
	ATCC 43042
	ATCC 43043
<i>Corynebacterium ureicelerivorans</i>	CCUG 59144
<i>Cutibacterium acnes</i>	
<i>Cutibacterium acnes</i>	ATCC 11827
	ATCC 11828
	ATCC 33179
	ATCC 6919
<i>Enterococcus</i>	
<i>Enterococcus avium</i>	ATCC 14025
<i>Enterococcus casseliflavus</i>	ATCC 700668
	ATCC 25788
	ATCC 700327
<i>Enterococcus cecorum</i>	ATCC 43198
<i>Enterococcus dispar</i>	ATCC 51266
<i>Enterococcus durans</i>	ATCC 11576
<i>Enterococcus faecalis</i>	ATCC 51575
	ATCC 700802
	ATCC 10100
	ATCC 12399
	ATCC 14506
	ATCC 33186
	ATCC 49532
	ATCC 49533
	ATCC 7080
	ATCC 49474
	ATCC 49332
	ATCC 29200
	ATCC BAA-2128
	ATCC 51188
	ATCC 49149
	NCTC-775
	ATCC 19433
	ATCC 49452
<i>Enterococcus faecalis (vanA+)</i>	JMI 876745
<i>Enterococcus faecalis (vanB+)</i>	ATCC BAA-2365
	ATCC 51299
<i>Enterococcus faecium</i>	ATCC 19434
	ATCC 23828
	ATCC 27273
	ATCC BAA-2127
	ATCC 6057
	ATCC 49624
<i>Enterococcus faecium</i>	ATCC 6569
	ATCC BAA-472
	ATCC 9756

Organism	Strain
	NR-13525
	NR-13526
	NRS-123
	NR-46805
	NRS-662
	ATCC BAA-1707
	ATCC 43300
	NRS-383
	NCTC-12493
	NRS-676
	NRS-678
	NRS-648
	NRS-651
	NRS-643
	NRS-484
	NRS-385
	NRS-384
	ATCC BAA-40
	ATCC 700698
	NRS-382
	NRS-659
	NRS-657
	NRS-655
	NRS-654
	NRS-647
	ATCC BAA-42
	ATCC BAA-41
	NRS-483
	NRS-675
	NRS-645
	NRS-687
	NRS-667
	NRS-677
	NRS-683
	NRS-688
	NRS-22
	NRS-387
	NRS-70
<i>Staphylococcus aureus (mecA+)</i>	ATCC 33591
<i>Staphylococcus aureus (mecC+)</i>	ATCC BAA-2312
	ATCC BAA-2313
<i>Staphylococcus epidermidis</i>	
<i>Staphylococcus epidermidis</i>	ATCC 12228
	ATCC 49134
	NCIMB-8853
	ATCC 700583
	ATCC 14990
<i>Staphylococcus epidermidis (mecA+)</i>	ATCC 35983
	ATCC 35984

Organism	Strain
	ATCC 49224
	ATCC BAA-2846
	ATCC 19953
	ATCC 27270
	ATCC 35667
<i>Enterococcus faecium</i> (vanA+)	ATCC BAA-2316
	ATCC BAA-2317
	ATCC 700221
	ATCC BAA-2319
	ATCC BAA-2320
	LMC 003921
	LMC 103676
	LMC 089524
	LMC 104266
	LMC 032261
	LMC 110371
	LMC 002867
	LMC 055971
	ATCC 51559
	ATCC BAA-2318
<i>Enterococcus faecium</i> (vanB+)	ATCC 51858
<i>Enterococcus gallinarum</i>	ATCC 49573
	ATCC 49609
	ATCC 49610
	ATCC 700425
	ATCC 49608
<i>Enterococcus hirae</i>	ATCC 49479
	ATCC 10541
<i>Enterococcus italicus</i>	CCUG 47860
<i>Enterococcus malodoratus</i>	ATCC 43197
<i>Enterococcus pseudoavium</i>	CCUG 33310T
<i>Enterococcus raffinosus</i>	ATCC 49464
<i>Enterococcus saccharolyticus</i>	ATCC 43076
<i>Enterococcus sanguinicola</i>	DSM-21767
<i>Enterococcus faecalis</i>	
<i>Enterococcus faecalis</i>	ATCC 51575
	ATCC 700802
	ATCC 10100
	ATCC 12399
<i>Enterococcus faecalis</i>	ATCC 14506
	ATCC 33186
	ATCC 49532
	ATCC 49533
	ATCC 7080
	ATCC 49474
	ATCC 49332
<i>Enterococcus faecalis</i>	ATCC 29200
	ATCC BAA-2128
	ATCC 51188

Organism	Strain
	ATCC 29887
	ATCC 49461
	ATCC 700565
	ATCC 51625
<i>Staphylococcus lugdunensis</i>	
<i>Staphylococcus lugdunensis</i>	NRS-879
	ATCC 49576
	NRS-878
	NRS-880
<i>Streptococcus</i>	
<i>Streptococcus agalactiae</i>	ATCC 12401
	ATCC 13813
	ATCC 12386
	ATCC 12973
	ATCC 27956
	NCTC-8017
	ATCC 12403
	ATCC 9895
<i>Streptococcus anginosus</i>	ATCC 33397
	NCTC-10713
	ATCC 33317
<i>Streptococcus bovis</i>	ATCC 35034
	ATCC 27513
<i>Streptococcus constellatus</i>	ATCC 27513
<i>Streptococcus criceti</i>	ATCC 19642 ^C
<i>Streptococcus dysgalactiae</i>	ATCC 35666
	ATCC 43078
	ATCC 12394
<i>Streptococcus equi</i>	ATCC 43079
	ATCC 9528
<i>Streptococcus equinus</i>	ATCC 15351
	ATCC 9812
<i>Streptococcus gallolyticus</i>	ATCC 49475
	ATCC 9809
	ATCC 43144
<i>Streptococcus gordonii</i>	ATCC 10558
	ATCC 35557
<i>Streptococcus infantarius</i>	ATCC BAA-102
	ATCC BAA-103
<i>Streptococcus infantis</i>	ATCC BAA-2089
	ATCC 700779
<i>Streptococcus intermedius</i>	ATCC 27335
<i>Streptococcus mitis</i>	ATCC 15914
	ATCC 6249
<i>Streptococcus mitis</i>	ATCC 49456
	NCIMB-13770
<i>Streptococcus oralis</i>	ATCC 35037
<i>Streptococcus oralis</i>	ATCC 55229
<i>Streptococcus parasanguinis</i>	ATCC 15909
<i>Streptococcus peroris</i>	ATCC 700780

Organism	Strain
	ATCC 49149
	NCTC-775
	ATCC 19433
	ATCC 49452
<i>Enterococcus faecalis</i> (vanA+)	JMI 876745
<i>Enterococcus faecalis</i> (vanB+)	ATCC BAA-2365
	ATCC 51299
<i>Enterococcus faecium</i>	
<i>Enterococcus faecium</i>	ATCC 19434
	ATCC 23828
	ATCC 27273
	ATCC BAA-2127
	ATCC 6057
	ATCC 49624
	ATCC 6569
	ATCC BAA-472
	ATCC 9756
	ATCC 49224
	ATCC BAA-2846
	ATCC 19953
	ATCC 27270
	ATCC 35667
<i>Enterococcus faecium</i> (vanA+)	ATCC BAA-2316
	ATCC BAA-2317
<i>Enterococcus faecium</i> (vanA+)	ATCC 700221
	ATCC BAA-2319
	ATCC BAA-2320
	LMC 003921
	LMC 103676
	LMC 089524
	LMC 104266
	LMC 032261
<i>Enterococcus faecium</i> (vanA+)	LMC 110371
	LMC 002867
<i>Enterococcus faecium</i> (vanA+)	LMC 055971
	ATCC 51559
<i>Enterococcus faecium</i> (vanA+)	ATCC BAA-2318
<i>Enterococcus faecium</i> (vanB+)	ATCC 51858
<i>Lactobacillus</i>	
<i>Lactobacillus casei</i>	ATCC 334
	ATCC 55825

Organism	Strain
<i>Streptococcus pneumoniae</i>	ATCC BAA-475
	ATCC 10357
	ATCC 49619
	ATCC 49136
	ATCC BAA-659
	ATCC 6315
	ATCC BAA-1667
	ATCC 700674
	ATCC 6321
	ATCC 700673
	ATCC 51916
	ATCC 8338
	ATCC 6301
	ATCC 8335
	NCIMB-13286
	ATCC BAA-1656
<i>Streptococcus pyogenes</i>	ATCC 12384
	ATCC 49399
	ATCC 12344
	ATCC 19615
	NCIMB-13285
	ATCC 14289
<i>Streptococcus salivarius</i>	ATCC 13419 ^c
	ATCC 7073
<i>Streptococcus salivarius</i>	ATCC 25975
	ATCC 31067 ^c
<i>Streptococcus sanguinis</i>	ATCC 10556
<i>Streptococcus thoraltensis</i>	ATCC 700865
<i>Streptococcus agalactiae</i>	
<i>Streptococcus agalactiae</i>	ATCC 12401
	ATCC 13813
	ATCC 12386
	ATCC 12973
	ATCC 27956
	NCTC-8017
	ATCC 12403
<i>Streptococcus anginosus</i> group	
<i>Streptococcus anginosus</i>	ATCC 9895
	ATCC 33397
	NCTC-10713
<i>Streptococcus constellatus</i>	ATCC 27513

Organism	Strain
	ATCC 39392
	ATCC 25598
<i>Lactobacillus paracasei</i>	ATCC BAA-52
	ATCC 27092
	ATCC 39595
<i>Lactobacillus rhamnosus</i>	ATCC 53103
	ATCC 55915
<i>Lactobacillus zeae</i>	ATCC 15820
<i>Listeria</i>	
<i>Listeria innocua</i>	NCTC-11288
	ATCC 33090
	ATCC 19119
<i>Listeria ivanovii</i>	ATCC BAA-139
	ATCC 700402
	ATCC 10890
	ATCC 19111
	ATCC 13932
<i>Listeria monocytogenes</i>	ATCC 19114
	ATCC 7644
	ATCC 19112
	ATCC BAA-751
	ATCC 19118
	ATCC 19115
<i>Listeria seeligeri</i>	ATCC 35967
<i>Listeria welshimeri</i>	ATCC 35897
<i>Listeria monocytogenes</i>	
	ATCC 10890
<i>Listeria monocytogenes</i>	ATCC 19111
	ATCC 13932
<i>Listeria monocytogenes</i>	ATCC 19114
	ATCC 7644
	ATCC 19112
<i>Listeria monocytogenes</i>	ATCC BAA-751
	ATCC 19118
	ATCC 19115
<i>Micrococcus</i>	
	ATCC 19212
	ATCC 10240
	ATCC 400
<i>Micrococcus luteus</i>	ATCC 53598
	ATCC 49732
	ATCC 4698
<i>Micrococcus lylae</i>	ATCC 27566
<i>Micrococcus yunnanensis</i>	ATCC 7468
<i>Staphylococcus</i>	
<i>Staphylococcus arlettae</i>	ATCC 43957
	ATCC 25923
<i>Staphylococcus aureus</i>	ATCC 29247

Organism	Strain
<i>Streptococcus intermedius</i>	ATCC 27335
<i>Streptococcus pneumoniae</i>	
	ATCC BAA-475
	ATCC 10357
<i>Streptococcus pneumoniae</i>	ATCC 49619
	ATCC 49136
	ATCC BAA-659
	ATCC 6315
	ATCC BAA-1667
	ATCC 700674
	ATCC 6321
	ATCC 700673
	ATCC 51916
	ATCC 8338
	ATCC 6301
	ATCC 8335
	NCIMB-13286
	ATCC BAA-1656
<i>Streptococcus pyogenes</i>	
	ATCC 12384
	ATCC 49399
<i>Streptococcus pyogenes</i>	ATCC 12344
	ATCC 19615
	NCIMB-13285
	ATCC 14289
<i>Pan Candida</i>	
	ATCC 24433
<i>Candida albicans</i>	ATCC MYA-4441
	ATCC 14053
<i>Candida albicans</i>	ATCC 90028
	ATCC 66032
<i>Candida glabrata</i>	ATCC 15126
	ATCC MYA-2950
	ATCC 2001
<i>Candida krusei</i>	ATCC 34135
	ATCC 32196
	ATCC 14243
	ATCC 90018 ^D
<i>Candida parapsilosis</i>	ATCC 58895
	ATCC 22019
<i>Pan Gram-Negative</i>	
<i>Acinetobacter baumannii</i>	NCTC-13302
	NCTC-13422
<i>Acinetobacter haemolyticus</i>	ATCC 19002
<i>Acinetobacter junii</i>	ATCC 17908
<i>Acinetobacter lwoffii</i>	ATCC 15309
<i>Acinetobacter ursingii</i>	ATCC BAA-617
<i>Bacteroides fragilis</i>	NCTC-9343

Organism	Strain
	ATCC 6538P
	ATCC 29213
	NR-45889
	NR-45890
	NR-46074
	NR-45881
	NR-46411
	NR-46414
	NR-46418
	NR-46417
<i>Staphylococcus aureus (mecA+)</i>	NR-13524
	NR-13527
	NR-13525
	NR-13526
	NRS-123
	NR-46805
	NRS-662
	ATCC BAA-1707
	ATCC 43300
	NRS-383
	NCTC-12493
	NRS-676
<i>Staphylococcus aureus (mecA+)</i>	NRS-678
	NRS-648
	NRS-651
	NRS-643
	NRS-484
	NRS-385
	NRS-384
	ATCC BAA-40
	ATCC 700698
	NRS-382
	NRS-659
	NRS-657
<i>Staphylococcus aureus (mecA+)</i>	NRS-655
	NRS-654
	NRS-647
	ATCC BAA-42
	ATCC BAA-41
	NRS-483
	NRS-675

Organism	Strain
<i>Burkholderia cepacia</i>	ATCC 25416
<i>Cedecea davisiae</i>	ATCC 43025
<i>Citrobacter freundii</i>	NCTC-9750
<i>Citrobacter koseri</i>	ATCC 27156
<i>Cronobacter muytjensii</i>	ATCC 51329
<i>Cronobacter sakazakii</i>	ATCC 12868
<i>Edwardsiella tarda</i>	ATCC 15947
<i>Enterobacter aerogenes</i>	ATCC 13048
<i>Enterobacter amnigenus</i>	ATCC 51816
<i>Enterobacter asburiae</i>	ATCC 35953
<i>Enterobacter cloacae</i>	ATCC 13047
	ATCC 23373
	ATCC 23355
	ATCC 35030
<i>Enterobacter hormaechei</i>	ATCC 700323
<i>Erwinia aphidicola</i>	ATCC 27991
<i>Escherichia coli</i>	ATCC 4157
	ATCC 14948
	ATCC 25922
	ATCC BAA-196
<i>Escherichia fergusonii</i>	ATCC 35469
<i>Escherichia hermannii</i>	ATCC 700368
<i>Escherichia vulneris</i>	ATCC 33821
<i>Fusobacterium necrophorum</i>	ATCC 25286
<i>Fusobacterium nucleatum</i>	ATCC 25586
<i>Haemophilus influenzae</i>	ATCC 10211
	ATCC 49144
	ATCC 43065
<i>Haemophilus influenzae</i>	NCTC-8468
<i>Haemophilus parainfluenzae</i>	ATCC 9796
<i>Hafnia alvei</i>	ATCC 51815
<i>Klebsiella oxytoca</i>	ATCC 700324
	ATCC 43165
	ATCC 43863
<i>Klebsiella ozaenae</i>	ATCC 11296
<i>Klebsiella pneumoniae</i>	ATCC BAA-1706
	NCTC-9633
	NCTC-13440
	ATCC 51503
<i>Kluyvera ascorbata</i>	ATCC 14236
<i>Kluyvera cryocrescens</i>	ATCC 14240

Organism	Strain
	NRS-645
	NRS-687
	NRS-667
	NRS-677
	NRS-683
	NRS-688
	NRS-22
	NRS-387
	NRS-70
	ATCC 33591
<i>Staphylococcus aureus (mecC+)</i>	ATCC BAA-2312
	ATCC BAA-2313
<i>Staphylococcus auricularis</i>	ATCC 33750
	ATCC 33753
<i>Staphylococcus capitis</i>	ATCC 27840
	NRS-866
	ATCC 35661
<i>Staphylococcus caprae</i>	ATCC 51548
<i>Staphylococcus carnosus</i>	ATCC 51365
<i>Staphylococcus chromogenes</i>	ATCC 43764
<i>Staphylococcus cohnii</i>	ATCC 29974
<i>Staphylococcus epidermidis</i>	ATCC 12228
	ATCC 49134
	NCIMB-8853
	ATCC 700583
	ATCC 14990
<i>Staphylococcus epidermidis (mecA+)</i>	ATCC 35983
	ATCC 35984
	ATCC 29887
	ATCC 49461
	ATCC 700565
	ATCC 51625
<i>Staphylococcus gallinarum</i>	ATCC 700401
	ATCC 35539
<i>Staphylococcus haemolyticus</i>	ATCC 29970
	ATCC 31874
<i>Staphylococcus haemolyticus (mecA+)</i>	NRS-62
	ATCC BAA-1693
	NRS-69
<i>Staphylococcus hominis</i>	NRS-871

Organism	Strain
<i>Legionella pneumophila</i>	ATCC 33823
<i>Moraxella catarrhalis</i>	ATCC 23246
<i>Moraxella nonliquefaciens</i>	ATCC 17953
<i>Moraxella osloensis</i>	ATCC 10973
<i>Morganella morganii</i>	ATCC 25829
<i>Neisseria lactamica</i>	ATCC 23970
<i>Neisseria meningitidis</i>	ATCC 13090
	ATCC 13113
	ATCC 13077
	ATCC 13102
<i>Neisseria mucosa</i>	ATCC 19695
<i>Neisseria sicca</i>	ATCC 29193
<i>Pantoea agglomerans</i>	ATCC 14537
<i>Pasteurella aerogenes</i>	ATCC 27883
<i>Proteus mirabilis</i>	ATCC 43071
	CDC#0155
	CDC#0159
<i>Proteus penneri</i>	ATCC 35197
<i>Proteus vulgaris</i>	ATCC 6380
<i>Providencia alcalifaciens</i>	ATCC 9886
<i>Providencia rettgeri</i>	ATCC 9919
<i>Providencia stuartii</i>	ATCC 33672
<i>Pseudomonas aeruginosa</i>	ATCC 15442
	NCIMB-12469
	ATCC 10145
<i>Pseudomonas fluorescens</i>	ATCC 13525
<i>Pseudomonas luteola</i>	ATCC 35970
<i>Pseudomonas putida</i>	ATCC 31483
<i>Raoultella terrigena</i>	ATCC 55553
<i>Salmonella bongori</i>	ATCC 43975
<i>Salmonella enterica</i> subsp. <i>enterica</i>	ATCC 51957
<i>Salmonella enterica</i> Choleraesuis	ATCC 12011
<i>Salmonella enterica</i> Paratyphi	FSL S5-0447
<i>Salmonella typhi</i>	ATCC 19430
<i>Serratia fonticola</i>	ATCC 29844
<i>Serratia liquefaciens</i>	ATCC 27592
<i>Serratia marcescens</i>	ATCC 8100
	ATCC 14756
	ATCC 13880
<i>Serratia odorifera</i>	ATCC 33077

Organism	Strain
	NRS-870
	ATCC 27844
<i>Staphylococcus hominis</i> (<i>mecA</i> +))	ATCC 700237
	ATCC 700236
<i>Staphylococcus hyicus</i>	ATCC 11249
<i>Staphylococcus intermedius</i>	ATCC 29663
	ATCC 49052

^A Detected at 2×10^8 CFU/mL

^B Detected at 2×10^9 CFU/mL

^C Detected at 4×10^8 CFU/mL

^D Detected at 1×10^7 CFU/mL

Organism	Strain
<i>Serratia rubidaea</i>	ATCC 27593
<i>Shigella boydii</i>	ATCC 9207
<i>Shigella dysenteriae</i>	ATCC 13313
<i>Shigella sonnei</i>	ATCC 29930
<i>Stenotrophomonas maltophilia</i>	ATCC 13636
<i>Tatumella ptyseos</i>	ATCC 33302
<i>Yersinia enterocolitica</i> subsp. <i>Enterocolitica</i>	ATCC 9610

Predicted (*in silico*) Reactivity for Genus and Group Assays

Note: the performance of the ePlex BCID-GP Panel has not been established for all of the organisms listed in the tables below. See the Analytical Reactivity (Inclusivity) and Limit of Detection (Analytical Sensitivity) sections for data on organisms for which performance characteristics have been established (indicated with an asterisk in Tables 46-57). Some species were not assessed *in silico* due to lack of sequence data, though they may appear in the analytical sensitivity or specificity studies.

In addition to species-specific assays, the ePlex BCID-GP Panel contains a number of broader genus or group-level assays; including *Bacillus cereus* group, *Bacillus subtilis* group, *Corynebacterium*, *Enterococcus*, *Lactobacillus*, *Listeria*, *Micrococcus*, *Staphylococcus*, *Streptococcus*, *Streptococcus anginosus* group, Pan *Candida* and Pan Gram-Negative assays. Tables 46-57 summarize the predicted (*in silico*) reactivity (inclusivity) for these assay targets.

Table 46: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Bacillus cereus* group

Detection Predicted for ≥95% of target sequences		
<i>Bacillus thuringiensis</i> *	<i>Bacillus toyonensis</i>	<i>Bacillus weihenstephanensis</i>
Detection Predicted for 85%-94% of target sequences		
<i>Bacillus cereus</i> *		
Detection Predicted for <85% of target sequences		
None Identified		
Detection Not Predicted		
<i>Bacillus mycoides</i> *	<i>Bacillus pseudomycoides</i>	

Table 47 Predicted (*in silico*) Reactivity (Inclusivity) Results for *Bacillus subtilis* group

Detection Predicted for ≥95% of target sequences		
<i>Bacillus subtilis</i> *	<i>Bacillus licheniformis</i> *	<i>Bacillus siamensis</i>
<i>Bacillus amyloliquefaciens</i> *	<i>Bacillus methylotrophicus</i> / <i>Bacillus velezensis</i>	<i>Bacillus tequilensis</i>
<i>Bacillus atrophaeus</i> *	<i>Bacillus paralicheniformis</i>	<i>Bacillus vallismortis</i>
Detection Predicted for 85%-94% of target sequences		
None Identified		
Detection Predicted for <85% of target sequences		
<i>Bacillus mojavensis</i> (77.8%)	<i>Bacillus sonorensis</i> (83.3%)	
Detection Not Predicted		
None Identified		

Table 48: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Corynebacterium*

Detection Predicted for ≥95% of target sequences		
<i>Corynebacterium afermentans</i>	<i>Corynebacterium glaucum</i>	<i>Corynebacterium renale</i>
<i>Corynebacterium afermentans</i> subsp. <i>afermentans</i> *	<i>Corynebacterium halotolerans</i>	<i>Corynebacterium simulans</i> *
<i>Corynebacterium afermentans</i> subsp. <i>lipophilum</i> *	<i>Corynebacterium hansenii</i>	<i>Corynebacterium singulare</i>
<i>Corynebacterium appendicis</i>	<i>Corynebacterium humireducens</i>	<i>Corynebacterium sputi</i>
<i>Corynebacterium auris</i>	<i>Corynebacterium imitans</i> *	<i>Corynebacterium striatum</i> *
<i>Corynebacterium auriscanis</i>	<i>Corynebacterium lipophiloflavum</i>	<i>Corynebacterium suicordis</i>
<i>Corynebacterium camporealensis</i>	<i>Corynebacterium lowii</i>	<i>Corynebacterium terpenotabidum</i>
<i>Corynebacterium casei</i>	<i>Corynebacterium marinum</i>	<i>Corynebacterium testudinoris</i>
<i>Corynebacterium ciconiae</i>	<i>Corynebacterium massiliense</i>	<i>Corynebacterium timonense</i> *
<i>Corynebacterium coyleae</i> *	<i>Corynebacterium minutissimum</i> *	<i>Corynebacterium tuscaniense</i>
<i>Corynebacterium doosanense</i>	<i>Corynebacterium mucifaciens</i>	<i>Corynebacterium ulceribovis</i>
<i>Corynebacterium falsenii</i> *	<i>Corynebacterium mycetoides</i>	<i>Corynebacterium urealyticum</i> *
<i>Corynebacterium felinum</i>	<i>Corynebacterium nuruki</i>	<i>Corynebacterium ureicelerivorans</i> *
<i>Corynebacterium freneyi</i> *	<i>Corynebacterium oculi</i>	<i>Corynebacterium xerosis</i>
<i>Corynebacterium genitalium</i>	<i>Corynebacterium pilosum</i>	
Detection Predicted for 85%-94% of target sequences		
None Identified		
Detection Predicted for <85% of target sequences		
<i>Corynebacterium aurimucosum</i> (50.0%)	<i>Corynebacterium jeikeium</i> (38.7%)* ^A	<i>Corynebacterium variabile</i> (75.0%)
<i>Corynebacterium diphtheriae</i> (76.4%)*	<i>Corynebacterium ulcerans</i> (47.4%)* ^A	<i>Corynebacterium vitaeruminis</i> (75.0%)
Detection Not Predicted		
<i>Corynebacterium accolens</i>	<i>Corynebacterium epidermidicantis</i>	<i>Corynebacterium propinquum</i>
<i>Corynebacterium ammoniagenes</i>	<i>Corynebacterium flavescens</i>	<i>Corynebacterium pseudodiphtheriticum</i>
<i>Corynebacterium amycolatum</i>	<i>Corynebacterium frankenforstense</i>	<i>Corynebacterium pseudogenitalium</i>
<i>Corynebacterium aquilae</i>	<i>Corynebacterium freiburgense</i>	<i>Corynebacterium pseudotuberculosis</i>
<i>Corynebacterium argentoratense</i>	<i>Corynebacterium glucuronolyticum</i>	<i>Corynebacterium pyruviciproducens</i>
<i>Corynebacterium atypicum</i>	<i>Corynebacterium glutamicum</i>	<i>Corynebacterium resistens</i>
<i>Corynebacterium bovis</i>	<i>Corynebacterium glyciniphilum</i>	<i>Corynebacterium riegelii</i>
<i>Corynebacterium callunae</i>	<i>Corynebacterium kroppenstedtii</i>	<i>Corynebacterium sphenisci</i>
<i>Corynebacterium capitovis</i>	<i>Corynebacterium kutscheri</i>	<i>Corynebacterium spheniscorum</i>
<i>Corynebacterium caspium</i>	<i>Corynebacterium lactis</i>	<i>Corynebacterium stationis</i>
<i>Corynebacterium confusum</i>	<i>Corynebacterium lubricantis</i>	<i>Corynebacterium sundsvallense</i>
<i>Corynebacterium crenatum</i>	<i>Corynebacterium maris</i>	<i>Corynebacterium thomssenii</i>
<i>Corynebacterium cystitidis</i>	<i>Corynebacterium mastitidis</i>	<i>Corynebacterium tuberculostearicum</i>

<i>Corynebacterium deserti</i>	<i>Corynebacterium matruchotii</i>	<i>Corynebacterium uropygiale</i>
<i>Corynebacterium durum</i>	<i>Corynebacterium mustelae</i>	<i>Corynebacterium uterequi</i>
<i>Corynebacterium efficiens</i>	<i>Corynebacterium phocae</i>	

- A. 38.7% of sequences in NCBI for *C. jeikeium* were predicted to be detected bioinformatically; 47.4% of sequences in NCBI for *C. ulcerans* were predicted to be detected bioinformatically. All strains tested for these species were detected as a part of the Analytical Reactivity (Inclusivity) or Limit of Detection (Analytical Sensitivity) studies.

Table 49: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Enterococcus*

Detection Predicted for ≥95% of target sequences		
<i>Enterococcus avium</i> *	<i>Enterococcus flavescens</i>	<i>Enterococcus raffinosus</i>
<i>Enterococcus dispar</i> *	<i>Enterococcus italicus</i> *	<i>Enterococcus saccharolyticus</i> *
<i>Enterococcus durans</i>	<i>Enterococcus lactis</i>	<i>Enterococcus thailandicus</i>
<i>Enterococcus faecalis</i> *	<i>Enterococcus malodoratus</i>	
<i>Enterococcus faecium</i> *	<i>Enterococcus pseudoavium</i>	
Detection Predicted for 85%-94% of target sequences		
<i>Enterococcus casseliflavus</i>	<i>Enterococcus gallinarum</i>	
<i>Enterococcus cecorum</i>	<i>Enterococcus hirae</i> *	
Detection Predicted for <85% of target sequences		
<i>Enterococcus mundtii</i> (9.1%)		
Detection Not Predicted		
<i>Enterococcus aquimarinus</i>	<i>Enterococcus hawaiiensis</i>	<i>Enterococcus rotai</i>
<i>Enterococcus asini</i>	<i>Enterococcus hermanniensis</i>	<i>Enterococcus silesiacus</i>
<i>Enterococcus caccae</i>	<i>Enterococcus pallens</i>	<i>Enterococcus sulfureus</i>
<i>Enterococcus camelliae</i>	<i>Enterococcus pernyi</i>	<i>Enterococcus termitis</i>
<i>Enterococcus canintestini</i>	<i>Enterococcus phoeniculicola</i>	<i>Enterococcus ureasiticus</i>
<i>Enterococcus canis</i>	<i>Enterococcus plantarum</i>	<i>Enterococcus ureilyticus</i>
<i>Enterococcus columbae</i>	<i>Enterococcus quebecensis</i>	<i>Enterococcus villorum</i>
<i>Enterococcus devriesei</i>	<i>Enterococcus ratti</i>	
<i>Enterococcus haemoperoxidus</i>	<i>Enterococcus rivorum</i>	

Table 50 Predicted (*in silico*) Reactivity (Inclusivity) Results for *Lactobacillus*

Detection Predicted for ≥95% of target sequences		
<i>Lactobacillus casei</i> *	<i>Lactobacillus rhamnosus</i> *	
<i>Lactobacillus paracasei</i> *	<i>Lactobacillus zeae</i> *	
Detection Predicted for 85%-94% of target sequences		
None Identified		
Detection Predicted for <85% of target sequences		
None Identified		
Detection Not Predicted		
<i>Lactobacillus acetotolerans</i>	<i>Lactobacillus ghanensis</i>	<i>Lactobacillus panis</i>
<i>Lactobacillus acidifarinae</i>	<i>Lactobacillus gigeriorum</i>	<i>Lactobacillus pantheris</i>
<i>Lactobacillus acidipiscis</i>	<i>Lactobacillus ginsenosidimutans</i>	<i>Lactobacillus parabrevis</i>
<i>Lactobacillus acidophilus</i>	<i>Lactobacillus gorillae</i>	<i>Lactobacillus parabuchneri</i>
<i>Lactobacillus agilis</i>	<i>Lactobacillus graminis</i>	<i>Lactobacillus paracollinoides</i>
<i>Lactobacillus algidus</i>	<i>Lactobacillus hammesii</i>	<i>Lactobacillus parafarraginis</i>
<i>Lactobacillus alimentarius</i>	<i>Lactobacillus hamsteri</i>	<i>Lactobacillus parakefiri</i>
<i>Lactobacillus amylolyticus</i>	<i>Lactobacillus harbinensis</i>	<i>Lactobacillus paralimentarius</i>
<i>Lactobacillus amylophilus</i>	<i>Lactobacillus hayakitensis</i>	<i>Lactobacillus paraplantarum</i>
<i>Lactobacillus amylotrophicus</i>	<i>Lactobacillus heilongjiangensis</i>	<i>Lactobacillus pasteurii</i>
<i>Lactobacillus amylovorus</i>	<i>Lactobacillus helsingborgensis</i>	<i>Lactobacillus paucivorans</i>
<i>Lactobacillus animalis</i>	<i>Lactobacillus helveticus</i>	<i>Lactobacillus pentosus</i>
<i>Lactobacillus antri</i>	<i>Lactobacillus herbarum</i>	<i>Lactobacillus perolens</i>
<i>Lactobacillus apinorum</i>	<i>Lactobacillus hilgardii</i>	<i>Lactobacillus plantarum</i>
<i>Lactobacillus apis</i>	<i>Lactobacillus hokkaidonensis</i>	<i>Lactobacillus pobuzihii</i>
<i>Lactobacillus apodemi</i>	<i>Lactobacillus hominis</i>	<i>Lactobacillus pontis</i>
<i>Lactobacillus aquaticus</i>	<i>Lactobacillus homohiochii</i>	<i>Lactobacillus psittaci</i>
<i>Lactobacillus aviarius</i>	<i>Lactobacillus hordei</i>	<i>Lactobacillus rapi</i>
<i>Lactobacillus backii</i>	<i>Lactobacillus iners</i>	<i>Lactobacillus rennini</i>
<i>Lactobacillus bif fermentans</i>	<i>Lactobacillus ingluviei</i>	<i>Lactobacillus reuteri</i>
<i>Lactobacillus bombi</i>	<i>Lactobacillus intestinalis</i>	<i>Lactobacillus rodentium</i>
<i>Lactobacillus bombicola</i>	<i>Lactobacillus jensenii</i>	<i>Lactobacillus rossiae</i>
<i>Lactobacillus brantae</i>	<i>Lactobacillus johnsonii</i>	<i>Lactobacillus ruminis</i>
<i>Lactobacillus brevis</i>	<i>Lactobacillus kalixensis</i>	<i>Lactobacillus saerimneri</i>
<i>Lactobacillus buchneri</i>	<i>Lactobacillus kefirano faciens</i>	<i>Lactobacillus sakei</i>
<i>Lactobacillus cacaonum</i>	<i>Lactobacillus kefiri</i>	<i>Lactobacillus salivarius</i>
<i>Lactobacillus camelliae</i>	<i>Lactobacillus kimbladii</i>	<i>Lactobacillus sanfranciscensis</i>
<i>Lactobacillus capillatus</i>	<i>Lactobacillus kimchicus</i>	<i>Lactobacillus saniviri</i>
<i>Lactobacillus ceti</i>	<i>Lactobacillus kimchiensis</i>	<i>Lactobacillus satsumensis</i>

<i>Lactobacillus coleohominis</i>	<i>Lactobacillus kisonensis</i>	<i>Lactobacillus secaliphilus</i>
<i>Lactobacillus collinoides</i>	<i>Lactobacillus kitasatonis</i>	<i>Lactobacillus selangorensis</i>
<i>Lactobacillus composti</i>	<i>Lactobacillus koreensis</i>	<i>Lactobacillus senioris</i>
<i>Lactobacillus concavus</i>	<i>Lactobacillus kullabergensis</i>	<i>Lactobacillus senmaizukei</i>
<i>Lactobacillus coryniformis</i>	<i>Lactobacillus kunkeei</i>	<i>Lactobacillus sharpeae</i>
<i>Lactobacillus crispatus</i>	<i>Lactobacillus letivazi</i>	<i>Lactobacillus shenzhenensis</i>
<i>Lactobacillus crustorum</i>	<i>Lactobacillus lindneri</i>	<i>Lactobacillus silagei</i>
<i>Lactobacillus curieae</i>	<i>Lactobacillus malefermentans</i>	<i>Lactobacillus siliginis</i>
<i>Lactobacillus curvatus</i>	<i>Lactobacillus mali</i>	<i>Lactobacillus similis</i>
<i>Lactobacillus delbrueckii</i>	<i>Lactobacillus manihotivorans</i>	<i>Lactobacillus spicheri</i>
<i>Lactobacillus dextrinicus</i>	<i>Lactobacillus mellifer</i>	<i>Lactobacillus sucicola</i>
<i>Lactobacillus diolivorans</i>	<i>Lactobacillus mellis</i>	<i>Lactobacillus suebicus</i>
<i>Lactobacillus equi</i>	<i>Lactobacillus melliventris</i>	<i>Lactobacillus sunkii</i>
<i>Lactobacillus equicursoris</i>	<i>Lactobacillus mindensis</i>	<i>Lactobacillus suntoryeus</i>
<i>Lactobacillus equigenerosi</i>	<i>Lactobacillus mucosae</i>	<i>Lactobacillus taiwanensis</i>
<i>Lactobacillus fabifermentans</i>	<i>Lactobacillus murinus</i>	<i>Lactobacillus thailandensis</i>
<i>Lactobacillus farciminis</i>	<i>Lactobacillus nagelii</i>	<i>Lactobacillus tucseti</i>
<i>Lactobacillus farraginis</i>	<i>Lactobacillus namurensis</i>	<i>Lactobacillus ultunensis</i>
<i>Lactobacillus fermentum</i>	<i>Lactobacillus nantensis</i>	<i>Lactobacillus uvarum</i>
<i>Lactobacillus floricola</i>	<i>Lactobacillus nasuensis</i>	<i>Lactobacillus vaccinofermentans</i>
<i>Lactobacillus florum</i>	<i>Lactobacillus nodensis</i>	<i>Lactobacillus vaginalis</i>
<i>Lactobacillus fructivorans</i>	<i>Lactobacillus odoratitofui</i>	<i>Lactobacillus versmoldensis</i>
<i>Lactobacillus frumenti</i>	<i>Lactobacillus oeni</i>	<i>Lactobacillus vini</i>
<i>Lactobacillus fuchuensis</i>	<i>Lactobacillus oligofermentans</i>	<i>Lactobacillus wasatchensis</i>
<i>Lactobacillus futsaii</i>	<i>Lactobacillus oris</i>	<i>Lactobacillus xiangfangensis</i>
<i>Lactobacillus gallinarum</i>	<i>Lactobacillus oryzae</i>	<i>Lactobacillus zymae</i>
<i>Lactobacillus gasseri</i>	<i>Lactobacillus otakiensis</i>	
<i>Lactobacillus gastricus</i>	<i>Lactobacillus ozensis</i>	

Table 51: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Listeria*

Detection Predicted for ≥95% of target sequences		
<i>Listeria monocytogenes</i> *	<i>Listeria marthii</i>	<i>Listeria welshimeri</i> *
<i>Listeria ivanovii</i> *	<i>Listeria seeligeri</i> *	
Detection Predicted for 85%-94% of target sequences		
<i>Listeria innocua</i> *		
Detection Predicted for <85% of target sequences		
None Identified		
Detection Not Predicted		
<i>Listeria grayi</i>		

Table 52: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Micrococcus*

Detection Predicted for ≥95% of target sequences		
<i>Micrococcus luteus</i> *	<i>Micrococcus aquilus</i>	<i>Micrococcus yunnanensis</i> *
<i>Micrococcus alkanovora</i>	<i>Micrococcus flavus</i>	
<i>Micrococcus alcoverae</i>	<i>Micrococcus thailandicus</i>	
Detection Predicted for 85%-94% of target sequences		
<i>Micrococcus endophyticus</i>	<i>Micrococcus indicus</i>	
Detection Predicted for <85% of target sequences		
<i>Micrococcus lylae</i> (50.0%)*		
Detection Not Predicted		
<i>Micrococcus antarcticus</i>	<i>Micrococcus lactis</i>	
<i>Micrococcus chenggongense</i>	<i>Micrococcus terreus</i>	

Table 53: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Staphylococcus*

Detection Predicted for ≥95% of target sequences		
<i>Staphylococcus aureus</i> *	<i>Staphylococcus haemolyticus</i> *	<i>Staphylococcus pseudintermedius</i> *
<i>Staphylococcus agnetis</i>	<i>Staphylococcus hominis</i> *	<i>Staphylococcus pseudolugdunensis</i>
<i>Staphylococcus argensis</i>	<i>Staphylococcus hominis</i> subsp. <i>novobioceticus</i>	<i>Staphylococcus pulvereri</i>
<i>Staphylococcus argenteus</i>	<i>Staphylococcus hyicus</i> *	<i>Staphylococcus rostri</i>
<i>Staphylococcus auricularis</i> *	<i>Staphylococcus jettensis</i>	<i>Staphylococcus saprophyticus</i> *
<i>Staphylococcus capitis</i> *	<i>Staphylococcus kloosii</i>	<i>Staphylococcus schleiferi</i> *
<i>Staphylococcus caprae</i> *	<i>Staphylococcus lentus</i> *	<i>Staphylococcus schweitzeri</i>
<i>Staphylococcus carnosus</i> *	<i>Staphylococcus lugdunensis</i> *	<i>Staphylococcus sciuri</i> *
<i>Staphylococcus chromogenes</i> *	<i>Staphylococcus lutrae</i>	<i>Staphylococcus simiae</i>
<i>Staphylococcus cohnii</i> *	<i>Staphylococcus massiliensis</i>	<i>Staphylococcus simulans</i> *
<i>Staphylococcus delphini</i>	<i>Staphylococcus microti</i>	<i>Staphylococcus stepanovicii</i>
<i>Staphylococcus devriesei</i>	<i>Staphylococcus muscae</i> *	<i>Staphylococcus succinus</i>
<i>Staphylococcus epidermidis</i> *	<i>Staphylococcus nepalensis</i>	<i>Staphylococcus vitulinus</i> *
<i>Staphylococcus equorum</i>	<i>Staphylococcus pasteurii</i> *	<i>Staphylococcus warneri</i> *
<i>Staphylococcus felis</i>	<i>Staphylococcus petrasii</i>	<i>Staphylococcus xylosum</i> *
<i>Staphylococcus fleurettii</i>	<i>Staphylococcus pettenkoferi</i> *	
<i>Staphylococcus gallinarum</i> *	<i>Staphylococcus piscifermentans</i>	
Detection Predicted for 85%-94% of target sequences		
<i>Staphylococcus arlettae</i>	<i>Staphylococcus intermedius</i> *	
<i>Staphylococcus condimenti</i>	<i>Staphylococcus saccharolyticus</i> *	
Detection Predicted for <85% of target sequences		
None Identified		
Detection Not Predicted		
<i>Staphylococcus caseolyticus</i> ^A		

^A Data for only one strain available in NCBI.**Table 54: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Streptococcus***

Detection Predicted for ≥95% of target sequences		
<i>Streptococcus agalactiae</i> *	<i>Streptococcus infantarius</i> *	<i>Streptococcus phocae</i>
<i>Streptococcus alactolyticus</i>	<i>Streptococcus infantis</i> *	<i>Streptococcus pneumoniae</i> *
<i>Streptococcus anginosus</i> *	<i>Streptococcus intermedius</i> *	<i>Streptococcus porcinus</i>
<i>Streptococcus australis</i>	<i>Streptococcus intestinalis</i>	<i>Streptococcus porcorum</i>
<i>Streptococcus caballi</i>	<i>Streptococcus lactarius</i>	<i>Streptococcus pseudopneumoniae</i>
<i>Streptococcus constellatus</i> *	<i>Streptococcus loxodonta salivarius</i>	<i>Streptococcus pseudoporcinus</i>
<i>Streptococcus criceti</i> *	<i>Streptococcus luteicae</i>	<i>Streptococcus pyogenes</i> *

<i>Streptococcus cristatus</i>	<i>Streptococcus lutetiensis</i>	<i>Streptococcus rifensis</i>
<i>Streptococcus danieliae</i>	<i>Streptococcus macedonicus</i>	<i>Streptococcus rubneri</i>
<i>Streptococcus dentasini</i>	<i>Streptococcus marimammalium</i>	<i>Streptococcus salivarius*</i>
<i>Streptococcus dentisani</i>	<i>Streptococcus massiliensis</i>	<i>Streptococcus saliviroxodontae</i>
<i>Streptococcus didelphis</i>	<i>Streptococcus mitis*</i>	<i>Streptococcus sanguinis*</i>
<i>Streptococcus difficilis</i>	<i>Streptococcus moroccensis</i>	<i>Streptococcus seminale</i>
<i>Streptococcus dysgalactiae</i> subsp. <i>dysgalactiae</i>	<i>Streptococcus oligofermentans</i>	<i>Streptococcus sinensis</i>
<i>Streptococcus dysgalactiae</i> subsp. <i>equisimilis</i>	<i>Streptococcus oralis*</i>	<i>Streptococcus suis</i>
<i>Streptococcus dysgalactiae*</i>	<i>Streptococcus oricebi</i>	<i>Streptococcus thermophilus</i>
<i>Streptococcus equi*</i>	<i>Streptococcus orisratti</i>	<i>Streptococcus thoraltensis*</i>
<i>Streptococcus equinus*</i>	<i>Streptococcus panodentis</i>	<i>Streptococcus tigurinus</i>
<i>Streptococcus fryi</i>	<i>Streptococcus parasanguinis*</i>	<i>Streptococcus troglodytae</i>
<i>Streptococcus gallolyticus*</i>	<i>Streptococcus parasuis</i>	<i>Streptococcus troglodytidis</i>
<i>Streptococcus gordonii*</i>	<i>Streptococcus parauberis</i>	<i>Streptococcus urinalis</i>
<i>Streptococcus himalayensis</i>	<i>Streptococcus pasteurii</i>	<i>Streptococcus ursoris</i>
<i>Streptococcus hongkongensis</i>	<i>Streptococcus pasteurianus</i>	<i>Streptococcus vestibularis</i>
<i>Streptococcus hyointestinalis</i>	<i>Streptococcus peroris*</i>	<i>Streptococcus waiu</i>
Detection Predicted for 85%-94% of target sequences		
<i>Streptococcus bovis*</i>	<i>Streptococcus uberis</i>	
Detection Predicted for <85% of target sequences		
<i>Streptococcus canis</i> (15.8%)	<i>Streptococcus henryi</i> (10.0%)	<i>Streptococcus ratti</i> (75.0%)
<i>Streptococcus halichoeri</i> (66.7%)	<i>Streptococcus iniae</i> (6.9%)	
Detection Not Predicted		
<i>Streptococcus acidominimus</i>	<i>Streptococcus entericus</i>	<i>Streptococcus orisasini</i>
<i>Streptococcus azizii</i>	<i>Streptococcus ferus</i>	<i>Streptococcus orisuis</i>
<i>Streptococcus cameli</i>	<i>Streptococcus gallinaceus</i>	<i>Streptococcus ovis</i>
<i>Streptococcus castoreus</i>	<i>Streptococcus hyovaginalis</i>	<i>Streptococcus pharyngis</i>
<i>Streptococcus cremoris</i>	<i>Streptococcus ictaluri</i>	<i>Streptococcus pluranimalium</i>
<i>Streptococcus criae</i>	<i>Streptococcus lactis</i>	<i>Streptococcus plurextorum</i>
<i>Streptococcus cuniculi</i>	<i>Streptococcus macacae</i>	<i>Streptococcus plutanimalium</i>
<i>Streptococcus dentapri</i>	<i>Streptococcus marmotae</i>	<i>Streptococcus porci</i>
<i>Streptococcus dentiloxodontae</i>	<i>Streptococcus merionis</i>	<i>Streptococcus rupicaprae</i>
<i>Streptococcus dentirousetti</i>	<i>Streptococcus milleri</i>	<i>Streptococcus sobrinus</i>
<i>Streptococcus devriesei</i>	<i>Streptococcus minor</i>	<i>Streptococcus tangierensis</i>
<i>Streptococcus downei</i>	<i>Streptococcus oriloxodontae</i>	

Table 55: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Streptococcus anginosus* group

Detection Predicted for ≥95% of target sequences		
<i>Streptococcus anginosus</i> *	<i>Streptococcus constellatus</i> *	<i>Streptococcus intermedius</i> *
Detection Predicted for 85%-94% of target sequences		
None Identified		
Detection Predicted for <85% of target sequences		
None Identified		
Detection Not Predicted		
None Identified		

Table 56: Predicted (*in silico*) Reactivity (Inclusivity) Results for Pan *Candida*

Detection Predicted for ≥95% of target sequences		
<i>Candida albicans</i> *	<i>Candida glabrata</i> *	<i>Candida krusei</i> *
<i>Candida parapsilosis</i> *		
Detection Predicted for 85%-94% of target sequences		
None Identified		
Detection Predicted for <85% of target sequences		
None Identified		
Detection Not Predicted		
<i>Candida lusitanae</i> *	<i>Candida orthopsilosis</i> *	
<i>Candida metapsilosis</i> *	<i>Candida tropicalis</i> *	

Table 57: Predicted (*in silico*) Reactivity (Inclusivity) Results for Pan Gram-Negative

The Pan Gram-Negative assay was designed to be broadly inclusive of the majority of gram-negative organisms.

Analytical Specificity (Cross-Reactivity and Exclusivity)

Cross-reactivity of on-panel and off-panel analytes was evaluated with the BCID-GP Panel.

Bacterial targets were tested in triplicate at a concentration of $\geq 1 \times 10^9$ CFU/mL while fungi were tested in triplicate at a concentration of $\geq 1 \times 10^7$ CFU/mL. If the target concentration could not be reached, the organism was diluted 2-fold from stock for use.

No cross reactivity was observed for any of the on-panel gram-positive organisms. Three organisms showed cross-reactivity, *Burkholderia cepacia* cross reacts with the *Corynebacterium* assay at levels $\geq 1 \times 10^7$ CFU/mL, an unspiciated *Rhodococcus* strain (ATCC 49988) cross reacts with the *Micrococcus* assay at levels $\geq 1 \times 10^7$ CFU/mL and *Bacillus badius* cross reacts with the *Bacillus subtilis* group assay at 7×10^7 CFU/mL. See **Table 44** and **Table 45** for summaries of the on-panel strains tested as a part of the Limit of Detection (Analytical Sensitivity) and Analytical Reactivity (Inclusivity) studies and **Table 58** for a summary of off-panel strains tested.

Off Panel Exclusivity

Table 58: Targets Assessed for Cross-Reactivity with the ePlex BCID-GP Panel (Exclusivity)

Organism	Strain ID	Organism	Strain ID
<i>Abiotrophia defectiva</i>	ATCC 49176	<i>Granulicatella elegans</i>	ATCC 700633 ^C
<i>Actinomyces odontolyticus</i>	ATCC 17929	<i>Kocuria kristinae</i>	ATCC BAA-752
<i>Aerococcus sanguinicola</i>	ATCC BAA-465	<i>Kocuria rhizophila</i>	ATCC 9341
<i>Aerococcus urinae</i>	ATCC 700306	<i>Kytococcus sedentarius</i>	ATCC 27575
<i>Aerococcus viridans</i>	ATCC 10400	<i>Lactococcus garvieae</i>	ATCC 43921 ^D
<i>Anaerococcus prevotii</i>	ATCC 9321	<i>Lactococcus lactis</i>	ATCC 49032
<i>Arcanobacterium bernardiae</i>	ATCC 51728	<i>Leuconostoc carnosum</i>	ATCC 49367
<i>Arcanobacterium haemolyticum</i>	ATCC BAA-1784 ^A	<i>Leuconostoc citreum</i>	ATCC 13146
<i>Arthrobacter psychrolactophilus</i>	ATCC 700733	<i>Leuconostoc mesenteroides</i>	ATCC 8293
<i>Aspergillus fumigatus</i>	ATCC 204305 ^B	<i>Macrococcus caseolyticus</i>	ATCC 29750
<i>Bacillus badius</i>	ATCC 14574	<i>Macrococcus caseolyticus</i>	ATCC 51834
<i>Bacillus pumilus</i>	ATCC 14884	<i>Mycobacterium avium complex</i>	ATCC 15769
<i>Brochothrix thermosphacta</i>	ATCC 11509	<i>Mycobacterium fortuitum</i>	ATCC 6841
<i>Candida lusitanae</i>	ATCC 34449	<i>Mycobacterium mucogenicum</i>	ATCC 49650
<i>Candida metapsilosis</i>	ATCC 96144	<i>Mycobacterium tuberculosis</i>	ATCC 25177
<i>Candida orthopsilosis</i>	ATCC 96139	<i>Mycoplasma pneumoniae</i>	ATCC 39505
<i>Candida tropicalis</i>	ATCC 1369	<i>Pediococcus acidilactici</i>	ATCC 8042
<i>Carnobacterium divergens</i>	ATCC 35677	<i>Pediococcus pentosaceus</i>	ATCC 33316
<i>Carnobacterium maltaromaticum</i>	ATCC 27865 ^C	<i>Penicillium marneffeii</i>	ATCC 200050

Organism	Strain ID
<i>Cellulomonas turbata</i>	ATCC 25835
<i>Cellulosimicrobium cellulans</i>	ATCC 27402
<i>Clostridium clostridioforme</i>	ATCC 25537
<i>Clostridium perfringens</i>	ATCC 13124
<i>Clostridium ramosum</i>	ATCC 25582
<i>Cryptococcus gattii</i>	ATCC 76108
<i>Cryptococcus grubii</i>	ATCC 208821
<i>Cryptococcus neoformans</i>	ATCC 14116
<i>Cutibacterium granulosum</i>	ATCC 11829
<i>Erysipelothrix rhusiopathiae</i>	ATCC 35457
<i>Gemella haemolysans</i>	ATCC 10379
<i>Gemella morbillorum</i>	ATCC 27824
<i>Geotrichum capitatum</i>	ATCC 10663
<i>Granulicatella adiacens</i>	ATCC 43205

Organism	Strain ID
<i>Peptostreptococcus anaerobius</i>	ATCC 27337
<i>Planococcus species</i>	ATCC 35671
<i>Propionibacterium propionicum</i>	ATCC 14157
<i>Rhodococcus equi</i>	ATCC 6939
<i>Rhodococcus species</i>	ATCC 49988
<i>Rhodotorula glutinis</i>	ATCC 32766
<i>Rhodotorula minuta</i>	ATCC 36236
<i>Rhodotorula mucilaginosa</i>	ATCC 9449
<i>Rothia dentocariosa</i>	ATCC 31918
<i>Rothia mucilaginosa</i>	ATCC 25296
<i>Saccharomyces cerevisiae</i>	ATCC 18824
<i>Trichosporon asahii</i>	ATCC 201110
<i>Vagococcus fluvialis</i>	ATCC 49515
<i>Weissella paramesenteroides</i>	ATCC 33313

^A Final testing concentration of 4.05×10^8 CFU/mL

^B Final testing concentration of 2.5×10^6 CFU/mL

^C Final testing concentration of 3.63×10^8 CFU/mL

^D Final testing concentration of 2.78×10^8 CFU/mL

Bottle Positivity

Several representative bacterial and fungal organisms were spiked into blood culture bottles along with the manufacturer's recommended volume of human whole blood and grown to positivity in a commercially-available continuously monitoring blood culture system. Bottles were removed from the incubator within two hours of being identified as positive as well as eight hours after bottle positivity. At least two independent positive blood culture replicates were quantified for each organism on culture plates. Organisms tested and approximate bottle positivity concentrations are summarized in **Table 59**. Concentrations shown below represent approximate levels that may be observed in a clinical setting. All estimated bottle positivity concentrations are equivalent or greater than the established Limit of Detection (LOD) for each of the assays of the ePlex BCID-GP Panel.

Table 59: Bottle Positivity Concentrations

Organism	Strain ID	Mean Bottle Positivity Concentration	Mean Bottle Positivity +8 hours Concentration
Gram-positive Organisms			
<i>Corynebacterium striatum</i>	ATCC BAA-1293	4.5 x 10 ⁶ CFU/mL	2.7 x 10 ⁹ CFU/mL
<i>Cutibacterium acnes (P. acnes)</i>	ATCC 6919	3.0 x 10 ⁸ CFU/mL	3.5 x 10 ⁸ CFU/mL
<i>Enterococcus faecium</i>	ATCC BAA-2317	4.9 x 10 ⁷ CFU/mL	3.6 x 10 ⁷ CFU/mL
<i>Lactobacillus casei</i>	ATCC 39392	4.8 x 10 ⁷ CFU/mL	3.1 x 10 ¹¹ CFU/mL
<i>Staphylococcus aureus</i>	NRS 483	2.8 x 10 ⁷ CFU/mL	2.1 x 10 ⁷ CFU/mL
<i>Streptococcus anginosus</i>	ATCC 33397	4.1 x 10 ⁷ CFU/mL	4.0 x 10 ⁸ CFU/mL
Gram-negative Organisms			
<i>Acinetobacter baumannii</i>	NCTC 13301	4.4 x 10 ⁸ CFU/mL	3.8 x 10 ⁸ CFU/mL
<i>Bacteroides fragilis</i>	ATCC 700786	4.7 x 10 ⁸ CFU/mL	6.7 x 10 ⁹ CFU/mL
<i>Enterobacter cloacae</i>	NCTC 13464	2.8 x 10 ⁸ CFU/mL	7.7 x 10 ⁸ CFU/mL
<i>Escherichia coli</i>	NCTC 13476	2.3 x 10 ⁸ CFU/mL	1.5 x 10 ⁹ CFU/mL
<i>Fusobacterium nucleatum</i>	ATCC 31647	6.5 x 10 ⁷ CFU/mL	4.9 x 10 ⁸ CFU/mL
<i>Haemophilus influenzae</i>	ATCC 19418	6.9 x 10 ⁸ CFU/mL	1.2 x 10 ⁹ CFU/mL
<i>Klebsiella oxytoca</i>	CDC #0147	9.3 x 10 ⁸ CFU/mL	1.5 x 10 ⁹ CFU/mL
<i>Neisseria meningitidis</i>	ATCC 13102	3.1 x 10 ⁷ CFU/mL	2.1 x 10 ⁸ CFU/mL
<i>Pseudomonas aeruginosa</i>	NCTC 13476	1.6 x 10 ⁸ CFU/mL	8.4 x 10 ⁸ CFU/mL
<i>Serratia marcescens</i>	ATCC 14041	1.2 x 10 ⁹ CFU/mL	2.2 x 10 ⁹ CFU/mL
Fungal Organism			
<i>Candida albicans</i>	ATCC 90082	1.6 x 10 ⁶ CFU/mL	1.4 x 10 ⁶ CFU/mL

Reproducibility

Four positive mixes including 9 on-panel organisms and 3 antibiotic resistance genes representing 15 targets at two concentrations and one negative mix including an off-panel organism were tested. Concentrations in the positive mixes reflected those observed at time of bottle positivity plus 8 hours (BP+8) and time of bottle positivity (BP) and one mix containing an off-panel organism grown to bottle positivity, which is expected to yield a negative result. Bottle concentrations used in this study are summarized in **Table 60**. Testing occurred at three sites with two operators testing the mixes over six days using three cartridge lots.

The percent agreement of each target with the expected result is summarized in **Tables 61-75**. The ePlex BCID-GP Panel demonstrates a high level of agreement with the expected results.

Table 60: Bottle Positivity Concentrations

Organism	Bottle Positivity Concentration	Bottle Positivity +8 Hours Concentration
<i>Corynebacterium striatum</i>	4 x 10 ⁶ CFU/mL	1 x 10 ⁸ CFU/mL
<i>Cutibacterium acnes</i> (<i>P. acnes</i>)	1 x 10 ⁸ CFU/mL	4.4 x 10 ⁷ CFU/mL
<i>Enterococcus faecium</i> (<i>vanA</i> +))	1 x 10 ⁷ CFU/mL	1 x 10 ⁸ CFU/mL
<i>Enterococcus faecalis</i> (<i>vanB</i> +))	1 x 10 ⁷ CFU/mL	1 x 10 ⁸ CFU/mL
<i>Lactobacillus casei</i>	1 x 10 ⁷ CFU/mL	1 x 10 ⁸ CFU/mL
<i>Staphylococcus aureus</i> (<i>mecA</i> +))	1 x 10 ⁷ CFU/mL	1 x 10 ⁸ CFU/mL
<i>Streptococcus anginosus</i>	1 x 10 ⁷ CFU/mL	1 x 10 ⁸ CFU/mL
<i>Candida albicans</i> (Pan <i>Candida</i> target)	1 x 10 ⁶ CFU/mL	1 x 10 ⁷ CFU/mL
<i>Klebsiella pneumoniae</i> (Pan Gram-Negative target)	1 x 10 ⁸ CFU/mL	1 x 10 ⁹ CFU/mL

Table 61: Percent Agreement for *Corynebacterium*

Concentration of <i>Corynebacterium striatum</i>	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours (1x10 ⁸ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Bottle Positive (4x10 ⁶ CFU/mL)	1	35/36	97.2	(85.8-99.5)
	2	35/36	97.2	(85.8-99.5)
	3	33/36	91.7	(78.2-97.1)
	All	103/108	95.4	(89.6-98.0)
Negative	1	108/108	100	(96.6-100)
	2	107/108	99.1	(94.9-99.8)
	3	107/107	100	(96.5-100)
	All	322/323	99.7	(98.3-99.9)

CI=Confidence Interval

Table 62: Percent Agreement for *Cutibacterium acnes* (*Propionibacterium acnes*)

Concentration of <i>Cutibacterium acnes</i>	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours (4.4x10 ⁷ CFU/mL)	1	32/36	88.9	(74.7-95.6)
	2	33/36	91.7	(78.2-97.1)
	3	36/36	100	(90.4-100)
	All	101/108	93.5 ^A	(87.2-96.8)
Bottle Positive (1.1x10 ⁸ CFU/mL)	1	36/36	100	(90.4-100)
	2	33/36	91.7	(78.2-97.1)
	3	35/36	97.2	(85.8-99.5)
	All	104/108	96.3 ^B	(90.9-98.6)
Negative	1	108/108	100	(96.6-100)
	2	108/108	100	(96.6-100)
	3	107/107	100	(96.5-100)
	All	323/323	100	(98.8-100)

A. <95% agreement is expected because the *C. acnes* organism concentration is more than 0.5 log below the limit of detection of this assay (1.0 x 10⁸ CFU/mL).

B. 95% agreement is expected because the *C. acnes* organism concentration is approximately equal to the limit of detection of this assay (1.0 x 10⁸ CFU/mL).

Table 63: Percent Agreement for *Enterococcus*

Concentration of <i>Enterococcus</i>	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours (1x10 ⁸ CFU/mL)	1	72/72	100	(94.9-100)
	2	72/72	100	(94.9-100)
	3	72/72	100	(94.9-100)
	All	216/216	100	(98.3-100)
Bottle Positive (1x10 ⁷ CFU/mL)	1	72/72	100	(94.9-100)
	2	72/72	100	(94.9-100)
	3	72/72	100	(94.9-100)
	All	216/216	100	(98.3-100)
Negative	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	35/35	100	(90.1-100)
	All	107/107	100	(96.5-100)

Table 64: Percent Agreement for *Enterococcus faecalis*

Concentration of <i>Enterococcus faecalis</i>	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours (1x10 ⁸ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Bottle Positive (1x10 ⁷ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Negative	1	108/108	100	(96.6-100)
	2	108/108	100	(96.6-100)
	3	107/107	100	(96.5-100)
	All	323/323	100	(98.8-100)

Table 65: Percent Agreement for *Enterococcus faecium*

Concentration of <i>Enterococcus faecium</i>	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours (1x10 ⁸ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Bottle Positive (1x10 ⁷ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Negative	1	108/108	100	(96.6-100)
	2	108/108	100	(96.6-100)
	3	107/107	100	(96.5-100)
	All	323/323	100	(98.8-100)

Table 66: Percent Agreement for *Lactobacillus*

Concentration of <i>Lactobacillus casei</i>	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours (1x10 ⁸ CFU/mL)	1	36/36	100	(90.1-100)
	2	36/36	100	(89.8-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.5-100)
Bottle Positive (1x10 ⁷ CFU/mL)	1	36/36	100	(89.8-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.1-100)
	All	108/108	100	(96.5-100)
Negative	1	108/108	100	(90.4-100)
	2	108/108	100	(89.8-100)
	3	107/107	100	(90.1-100)
	All	323/323	100	(96.5-100)

Table 67: Percent Agreement for *Staphylococcus*

Concentration of <i>Staphylococcus</i>	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours (1x10 ⁸ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Bottle Positive (1x10 ⁷ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.48-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Negative	1	108/108	100	(96.6-100)
	2	106/108	98.1	(93.5-99.5)
	3	107/107	100	(96.5-100)
	All	321/323	99.4	(97.8-99.8)

Table 68: Percent Agreement for *Staphylococcus aureus*

Concentration of <i>Staphylococcus aureus</i>	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours (1x10 ⁸ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Bottle Positive (1x10 ⁷ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Negative	1	108/108	100	(96.6-100)
	2	108/108	100	(96.6-100)
	3	107/107	100	(96.5-100)
	All	323/323	100	(98.8-100)

Table 69: Percent Agreement for *Streptococcus*

Concentration of <i>Streptococcus</i>	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours (1x10 ⁸ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Bottle Positive (1x10 ⁷ CFU/mL)	1	36/36	100	(90.4-100)
	2	35/36	97.2	(85.8-99.5)
	3	36/36	100	(90.4-100)
	All	107/108	99.1	(94.9-99.8)
Negative	1	108/108	100	(96.6-100)
	2	107/108	99.1	(94.9-99.8)
	3	107/107	100	(96.5-100)
	All	322/323	99.7	(98.3-99.9)

Table 70: Percent Agreement for *Streptococcus anginosus* group

Concentration of <i>Streptococcus anginosus</i>	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours (1x10 ⁸ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Bottle Positive (1x10 ⁷ CFU/mL)	1	36/36	100	(90.4-100)
	2	35/36	97.2	(85.8-99.5)
	3	36/36	100	(90.4-100)
	All	107/108	99.1	(94.9-99.8)
Negative	1	108/108	100	(96.6-100)
	2	108/108	100	(96.6-100)
	3	107/107	100	(96.5-100)
	All	323/323	100	(98.8-100)

Table 71: Percent Agreement for Pan *Candida*

Concentration of <i>Candida albicans</i>	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours (1x10 ⁷ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Bottle Positive (1x10 ⁶ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Negative	1	108/108	100	(96.6-100)
	2	108/108	100	(96.6-100)
	3	107/107	100	(96.5-100)
	All	323/323	100	(98.8-100)

Table 72: Percent Agreement for Pan Gram-Negative

Concentration of <i>Klebsiella pneumoniae</i>	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours (1x10 ⁹ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Bottle Positive (1x10 ⁸ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Negative	1	108/108	100	(96.6-100)
	2	107/108	99.1	(94.9-99.8)
	3	107/107	100	(96.5-100)
	All	322/323	99.7	(98.3-99.9)

Table 73: Percent Agreement for *mecA*

Concentration of <i>Staphylococcus aureus</i>	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours (1x10 ⁸ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Bottle Positive (1x10 ⁷ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Negative	1	108/108	100	(96.6-100)
	2	108/108	100	(96.6-100)
	3	107/107	100	(96.5-100)
	All	323/323	100	(98.8-100)

Table 74: Percent Agreement for *vanA*

Concentration of <i>Enterococcus faecium</i>	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours (1x10 ⁸ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Bottle Positive (1x10 ⁷ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Negative	1	108/108	100	(96.6-100)
	2	108/108	100	(96.6-100)
	3	107/107	100	(96.5-100)
	All	323/323	100	(98.8-100)

Table 75: Percent Agreement for *vanB*

Concentration of <i>Enterococcus faecalis</i>	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours (1x10 ⁸ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Bottle Positive (1x10 ⁷ CFU/mL)	1	36/36	100	(90.4-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	108/108	100	(96.6-100)
Negative	1	108/108	100	(96.6-100)
	2	108/108	100	(96.6-100)
	3	107/107	100	(96.5-100)
	All	323/323	100	(98.8-100)

Interfering Substances and Sample Matrix Equivalency (Bottle Evaluation)

Two organism mixes consisting of 9 on-panel organisms representing 14 targets and negative blood matrix were used to assess potentially interfering substances and bottle types for interference. The concentration of each organism tested is summarized in **Table 76**.

Table 76: Interfering Substance and Bottle Equivalency Concentrations

Organism	Concentration
<i>Cutibacterium acnes</i>	3 x 10 ⁸ CFU/mL
<i>Enterococcus faecalis</i> (vanB+)	4 x 10 ⁷ CFU/mL
<i>Enterococcus faecium</i> (vanA+)	4 x 10 ⁷ CFU/mL
<i>Lactobacillus casei</i>	4 x 10 ⁷ CFU/mL
<i>Staphylococcus aureus</i>	2 x 10 ⁷ CFU/mL
<i>Staphylococcus epidermidis</i>	2 x 10 ⁷ CFU/mL
<i>Streptococcus pneumoniae</i>	4 x 10 ⁷ CFU/mL
<i>Klebsiella pneumoniae</i> (Pan Gram-Negative target)	5 x 10 ⁸ CFU/mL
<i>Candida albicans</i> (Pan <i>Candida</i> target)	1 x 10 ⁶ CFU/mL

Interfering Substances

Eighteen substances were used to assess the ePlex BCID-GP Panel for potential interference. The organisms in **Table 76** were spiked into negative blood matrix and tested in triplicate with and without each potentially interfering substance. Negative blood matrix was tested to control for potential positive interference. Potentially interfering substances are summarized in **Table 77**. None of the eighteen substances commonly found in blood culture specimens or as medications commonly used to treat skin or bloodstream infections were found to inhibit the ePlex BCID-GP Panel at clinically relevant concentrations. The effect of interfering substances has only been evaluated for the organisms listed in **Table 76**. Interference due to substances other than those described in this section can lead to erroneous results.

Table 77: Potentially Interfering Substances: Substance List

Endogenous Substances	Testing Concentration
Bilirubin	60 µg/mL
Hemoglobin	0.6 g/L
Human Genomic DNA	6 x 10 ⁵ copies/mL
Triglycerides	1000 mg/dL
γ-globulin	0.425 g/dL
Exogenous Substances	Testing Concentration
Amoxicillin/Clavulanate	3.5 µg/mL
Amphotericin B	2 µg/mL
Caspofungin	5 µg/mL
Ceftriaxone	0.23 mg/mL
Ciprofloxacin	3 mg/L
Fluconazole	25 mg/L
Flucytosine	90 µg/mL
Gentamicin sulfate	3 µg/mL
Heparin	0.9 U/mL
Imipenem	83 µg/mL
Sodium Polyanethol Sulfonate	0.25% w/v
Tetracycline	5 mg/L
Vancomycin	30 mg/L

Sample Matrix Equivalency (Bottle Evaluation)

Thirteen bottle types were tested for interference with each of the organisms listed in **Table 76**. Five replicates of each organism were tested in each of two bottle lots. Negative blood matrix was run as a negative control. Eleven of the bottle types tested showed no interference for any of the targets tested. One lot of the BACTEC™ Plus Anaerobic bottles showed false positive results for Pan Gram-Negative. The BacT/ALERT® FN Plus bottle type showed lower sensitivity for some targets (Pan Gram-Negative and *E. faecium* with *vanA*). A summary of the bottle types assessed and the study outcomes is found in **Table 78**.

Table 78: Sample Matrix Equivalency (Bottle Evaluation) Bottle Types

Manufacturer	Bottle Brand	Bottle Type	Study Outcome
BD	BACTEC™	Plus Aerobic	No interference observed
BD	BACTEC™	Plus Anaerobic	False positive results for Pan Gram-Negative target were observed in one lot.
BD	BACTEC™	Standard Aerobic	No interference observed
BD	BACTEC™	Standard Anaerobic	No interference observed
BD	BACTEC™	Peds Plus™	No interference observed
BD	BACTEC™	Lytic Anaerobic	No interference observed
bioMérieux	BACT/ALERT®	SA Standard Aerobic	No interference observed
bioMérieux	BACT/ALERT®	SN Standard Anaerobic	No interference observed
bioMérieux	BACT/ALERT®	FA Plus	No interference observed
bioMérieux	BACT/ALERT®	FN Plus	False negative results were observed for Pan Gram-Negative and <i>E.faecium/vanA</i> targets
bioMérieux	BACT/ALERT®	PF Plus	No interference observed
Thermo Scientific™	VersaTREK™	REDOX™ 1 EZ Draw Aerobic	No interference observed
Thermo Scientific™	VersaTREK™	REDOX™ 2 EZ Draw Anaerobic	No interference observed

Carryover and Cross-Contamination

Carryover and cross-contamination were evaluated for the ePlex BCID-GP Panel within and between runs by alternating high positive and negative samples across multiple runs over 5 rounds of testing. A high-titer mix of *mecA* positive *Staphylococcus aureus*, *vanA* positive *Enterococcus faecium* and *Klebsiella pneumoniae* (a Pan Gram-Negative target organism) was prepared at 1×10^9 CFU/mL each as well as *Candida albicans* (a Pan *Candida* target organism) at 1×10^7 CFU/mL to simulate clinically relevant high positive samples for positive testing. Negative blood culture matrix was used to represent negative samples. Over 120 runs, all valid positive runs resulted in detection of *Staphylococcus aureus*, *mecA*, *Enterococcus faecium*, *vanA*, Pan Gram-Negative and Pan *Candida* and no false positives were detected in the negative runs.

Competitive Inhibition Study

Competitive inhibition was evaluated for the ePlex BCID-GP Panel by pairing eight clinically relevant organisms (including a Pan Gram-Negative assay target, a Pan *Candida* assay target, and an off-panel gram-positive organism) in four simulated dual infection sample mixes. Each dual infection mix was tested in combination with each of the three other mixes, such that all organisms were tested at low titer (concentrations expected at bottle positivity) while in the presence of other organisms at higher titer (concentrations expected at 8 hours beyond bottle positivity, or one log higher than that expected at bottle positivity). No competitive inhibition was observed in any replicates of the twelve testing conditions. A summary of the organisms assessed and testing concentrations is found in **Table 79**.

Table 79: Competitive Inhibition Organisms and Concentrations Tested

Organism	High Concentration	Low Concentration
<i>Enterococcus faecium</i>	1 x 10 ⁸ CFU/mL	4 x 10 ⁷ CFU/mL
<i>Staphylococcus aureus</i>	1 x 10 ⁸ CFU/mL	2 x 10 ⁷ CFU/mL
<i>Staphylococcus epidermidis</i>	1 x 10 ⁸ CFU/mL	2 x 10 ⁷ CFU/mL
<i>Streptococcus agalactiae</i>	4 x 10 ⁸ CFU/mL	4 x 10 ⁷ CFU/mL
<i>Streptococcus pneumoniae</i>	4 x 10 ⁸ CFU/mL	4 x 10 ⁷ CFU/mL
<i>Candida albicans</i>	1 x 10 ⁷ CFU/mL	1 x 10 ⁶ CFU/mL
<i>Escherichia coli</i>	1 x 10 ⁹ CFU/mL	2 x 10 ⁸ CFU/mL
<i>Cutibacterium granulosum</i> ^A	1 x 10 ⁹ CFU/mL	3 x 10 ⁸ CFU/mL

^A Off-panel organism