GenMark Diagnostics, Incorporated April 27, 2022
Alan Maderazo
VP, Quality, Regulatory & Clinical Affairs
5964 La Place Court
Carlsbad, California 92008

Re: K213236
    Trade/Device Name: ePlex Blood Culture Identification Gram Negative (BCID-GN) Panel
    Regulation Number: 21 CFR 866.3365
    Regulation Name: Multiplex Nucleic Acid Assay For Identification Of Microorganisms And Resistance
                      Markers From Positive Blood Cultures
    Regulatory Class: Class II
    Product Code: PEN, PAM, PEO
    Dated: September 29, 2021
    Received: September 30, 2021

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Noel Gerald, Ph.D.
Chief
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
    and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

510(k) Number *(if known)*
K213236

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

Indications for Use *(Describe)*
The GenMark ePlex® Blood Culture Identification Gram-Negative (BCID-GN) 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-negative bacterial organisms and select determinants associated with antimicrobial resistance in positive blood culture. In addition, the ePlex BCID-GN Panel is capable of detecting several gram-positive bacteria (Pan Gram-Positive assay) and several Candida species (Pan Candida assay). The ePlex BCID-GN Panel is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system and which contain gram-negative organism.

The following bacterial organisms and genes associated with antibiotic resistance are identified using the ePlex BCID-GN Panel: Acinetobacter baumannii, Bacteroides fragilis, Citrobacter, Cronobacter sakazakii, Enterobacter cloacae complex, Enterobacter (non-cloacae complex), Escherichia coli, Fusobacterium necrophorum, Fusobacterium nucleatum, Haemophilus influenzae, Klebsiella oxytoca, Klebsiella pneumoniae group, Morganella morganii, Neisseria meningitidis, Proteus, Proteus mirabilis, Pseudomonas aeruginosa, Salmonella, Serratia, Serratia marcescens, Stenotrophomonas maltophilia, CTX-M (blaCTX-M), IMP (blaIMP) , KPC (blaKPC) , NDM (blaNDM), OXA (blaOXA) (OXA-23 and OXA-48 groups only), and VIM (blaVIM).

The ePlex BCID-GN Panel contains assays for the detection of genetic determinants associated with resistance to antimicrobial agents including CTX-M(blaCTX-M), which is associated with resistance to extended spectrum beta-lactamase (ESBL)-mediated resistance to penicillins, cephalosporins, and monobactams, as well as OXA (blaOXA) (OXA-23 and OXA-48 groups only), KPC (blaKPC), and metallo-beta-lactamases IMP (blaIMP), VIM (blaVIM), and NDM (blaNDM), which is associated with carbapenemase-mediated resistance. The antimicrobial resistance gene detected may or may not be associated with the agent responsible for disease. Negative results for these select antimicrobial resistance assays do not indicate susceptibility, as there are multiple mechanisms of resistance in gram-negative bacteria.

The ePlex BCID-GN Panel also contains targets designed to detect a broad range of organisms with a potentially misleading Gram stain result or organisms that may be missed by Gram staining altogether, for example in the case of co-infections. These include a broad Pan Gram-Positive assay (which is designed to detect Bacillus cereus group, Bacillus subtilis group, Enterococcus, Staphylococcus, and Streptococcus), as well as a Pan Candida assay, which is designed to detect four 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-GN Panel are intended to be interpreted in conjunction with Gram stain results and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Negative results in the setting of a suspected bloodstream infection may be due to infection with pathogens that are not detected by this test. Positive results do not rule out co-infection with other organisms; the organism(s) detected by the ePlex BCID-GN Panel may not be the definite cause of disease. Additional laboratory testing (e.g. sub-culturing of positive blood cultures for identification of organisms not detected by ePlex BCID-GN Panel and for susceptibility testing, differentiation of mixed growth, and association of antimicrobial resistance marker genes to a specific organism) and clinical presentation must be taken into consideration in the final diagnosis of bloodstream infection.

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.

5.0   510(k) Summary

The 510(k) Summary was updated to align with the most current revision of the package insert, which incorporates changes in the ***Limit of Detection (LoD)*** section based on the results from studies conducted to support implementation of a design change (i.e., addition of oligonucleotides to improve robustness and inclusivity of the *E.coli*, *Citrobacter*, *Enterococcus*, and *P. aeruginosa* assays). The addition of oligonucleotides to specific PCR reactions introduces performance risks to the resident assays contained in those affected PCR reactions. As a result, the following studies were conducted to mitigate the identified risks to product performance.

1. **Evaluation of overall BCID-GN Panel Performance**: this study utilized a multianalyte test mix (containing a representative analyte from each of the eight multiplex PCR pools) to systematically assess overall performance of the BCID-GN Panel. This design was utilized to ensure that the proposed change does not introduce any unexpected issues that result in a systematic assay failure.

2. **LoD Verification Study**: this study verified that the LoDs of the targets affected by the change are not adversely impacted. These results demonstrate that the analytical sensitivity of the test remains equivalent.

3. **Clinical Sample Evaluation**: this study utilized characterized clinical samples to verify that the proposed change does not adversely impact clinical performance.

All studies met the predetermined acceptance criteria demonstrating no adverse impact to the BCID-GN Panel performance, which supports implementation of the proposed change.

The changes to the 510(k) Summary include identification of the following strains (in **Table 56** of the 510(k) Summary) that were tested as part of the LoD verification study:

- *H. influenzae* (ATCC33930)
- *N. meningitidis* (NCTC10026)
- *E. coli* (JHU01-D80401147)
- *P. aeruginosa* (SDx071)

All other information in the 510(k) Summary are unchanged.

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: April 4, 2022

Name of Device and Classification

Product Name: ePlex® Blood Culture Identification Gram-Negative (BCID-GN) 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):   PEN, PAM, PEO

Predicate Device

Predicate: The ePlex Blood Culture Identification Gram-Negative (BCID-GN) Panel;
GenMark Diagnostics, Inc.; K182619

Device Description

The ePlex Blood Culture Identification Gram-Negative (BCID-GN) 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-Negative (BCID-GN) 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-negative bacterial organisms and select determinants associated with antimicrobial resistance in positive blood culture. In addition, the ePlex BCID-GN Panel is capable of detecting several gram-positive bacteria (Pan Gram-Positive assay) and several *Candida* species (Pan *Candida* assay). The ePlex BCID-GN Panel is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system and which contain gram-negative organism.

The following bacterial organisms and genes associated with antibiotic resistance are identified using the ePlex BCID-GN Panel: *Acinetobacter baumannii, Bacteroides fragilis, Citrobacter, Cronobacter sakazakii, Enterobacter cloacae* complex*, Enterobacter* (non-*cloacae* complex)*, Escherichia coli, Fusobacterium necrophorum, Fusobacterium nucleatum, Haemophilus influenzae, Klebsiella oxytoca, Klebsiella pneumoniae* group*, Morganella morganii, Neisseria meningitidis, Proteus, Proteus mirabilis, Pseudomonas aeruginosa, Salmonella, Serratia, Serratia marcescens, Stenotrophomonas maltophilia,* CTX-M (bla_{CTX-M}), IMP (bla_{IMP}) , KPC (bla_{KPC}) , NDM (bla_{NDM}), OXA (bla_{OXA}) (OXA-23 and OXA-48 groups only), and VIM (bla_{VIM}).

The ePlex BCID-GN Panel contains assays for the detection of genetic determinants associated with resistance to antimicrobial agents including CTX-M(bla_{CTX-M}), which is associated with resistance to extended spectrum beta-lactamase (ESBL)-mediated resistance to penicillins, cephalosporins and monobactams, as well as OXA (bla_{OXA}) (OXA-23 and OXA-48 groups only), KPC (bla_{KPC}), and metallo-beta-lactamases IMP (bla_{IMP}), VIM (bla_{VIM}), and NDM (bla_{NDM}), which is associated with carbapenemase-mediated resistance. The antimicrobial resistance gene detected may or may not be associated with the agent responsible for disease. Negative results for these select antimicrobial resistance assays do not indicate susceptibility, as there are multiple mechanisms of resistance in gram-negative bacteria.

The ePlex BCID-GN Panel also contains targets designed to detect a broad range of organisms with a potentially misleading Gram stain result or organisms that may be missed by Gram staining altogether, for example in the case of co-infections. These include a broad Pan Gram-Positive assay (which is designed to detect *Bacillus cereus* group, *Bacillus subtilis* group, *Enterococcus, Staphylococcus,* and *Streptococcus*), as well as a Pan *Candida* assay, which is designed to detect four *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-GN Panel are intended to be interpreted in conjunction with Gram stain results and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Negative results in the setting of a suspected bloodstream infection may be due to infection with pathogens that are not detected by this test. Positive results do not rule out co-infection with other organisms; the organism(s) detected by the ePlex BCID-GN Panel may not be the definite cause of disease. Additional laboratory testing (e.g. sub-culturing of positive blood cultures for identification of organisms not detected by ePlex BCID-GN Panel and for susceptibility testing, differentiation of mixed growth, and association of antimicrobial resistance marker genes to a specific organism) and clinical presentation must be taken into consideration in the final diagnosis of bloodstream infection.

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

The updated GenMark ePlex Blood Culture Identification Gram-Negative (BCID-GN) Panel (identified as the "SubjectDevice") and the legally marketed device, the original GenMark ePlex BCID-GN Panel (K182619) (identified as the "Predicate Device") are described below:

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Characteristic	Predicate Device (K182619)	Subject Device (Updated)
Product Name	ePlex BCID-GN Panel	Same
Manufacturer	GenMark Diagnostics, Inc.	Same
Organisms Detected	*Acinetobacter baumannii* *Bacteroides fragilis* *Citrobacter* *Cronobacter sakazakii* *Enterobacter cloacae* complex *Enterobacter (*non-*cloacae* complex) *Escherichia coli* *Fusobacterium necrophorum* *Fusobacterium nucleatum* *Haemophilus influenzae* *Klebsiella oxytoca* *Klebsiella pneumoniae* *Morganella morganii* *Neisseria meningitidis* *Proteus* *Proteus mirabilis* *Pseudomonas aeruginosa* *Salmonella* *Serratia* *Serratia marcescens* *Stenotrophomonas Saltophiliapyogenes (GAS)*	Same Additional strains were tested as part of the Limit of Detection (LoD) study which include the following: *H. influenzae* (ATCC33930) *N. meningitidis* (NCTC10026) *E. coli* (JHU01-D80401147) *P. aeruginosa* (SDx071)
Resistance Genes Detected	CTX-M, IMP, KPC, NDM, OXA, andVIM	Same
Indication for Use	The ePlex BCID-GN 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 the ePlex BCID-GN Panel and for susceptibility testing, differentiation of mixed growth, and association of antimicrobial resistance marker genes toa specific organism) and clinical presentation must be taken into consideration in the final diagnosis of blood stream infection.	Same
Specimen Type	Blood culture samples identified as positive by a continuous monitoringblood culture system that demonstrates the presence of organisms as confirmed by Gram stain.	Same

Characteristic	Predicate Device (K182619)	Subject Device (Updated)
Chemistry	Reagents on cartridge include: sample lysis and nucleic acid extraction, PCR amplification and hybridization-based electrochemical detection reagents.	Same
Hardware	GenMark ePlex Instrument & SingleUse Cartridge	Same
SoftwareInterface Result Reporting	• GenMark ePlex System Software • GenMark ePlex BCID-GN Panel Software	Same

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-GN Panel in positive blood culture samples. A total of 349 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, 182 samples were prospectively collected and frozen; from June through July 2018, 167 samples were prospectively collected and tested fresh (never frozen). The expected values of individual analytes based on the ePlex BCID-GN Panel results in prospective samples are summarized by age group and by site in **Tables 1** and **2** below.

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

Target	All Ages (N=349) n (%)	Age <1 (N=7) n (%)	Age 1-17 (N=10) n (%)	Age 18-44 (N=50) n (%)	Age 45-64 (N=124) n (%)	Age 65-84 (N=125) n (%)	Age 85+ (N=33) n (%)
Acinetobacter baumannii	4 (1.1)	0 (0.0)	0 (0.0)	1 (2.0)	2 (1.6)	1 (0.8)	0 (0.0)
Bacteroides fragilis	11 (3.2)	0 (0.0)	0 (0.0)	2 (4.0)	4 (3.2)	2 (1.6)	3 (9.1)
Citrobacter	8 (2.3)	0 (0.0)	0 (0.0)	2 (4.0)	1 (0.8)	2 (1.6)	3 (9.1)
Cronobacter sakazakii	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Enterobacter (non-*cloacae* complex)	9 (2.6)	0 (0.0)	1 (10.0)	2 (4.0)	5 (4.0)	1 (0.8)	0 (0.0)
Enterobacter cloacae complex	23 (6.6)	3 (42.9)	1 (10.0)	6 (12.0)	5 (4.0)	8 (6.4)	0 (0.0)
Escherichia coli	132 (37.8)	2 (28.6)	2 (20.0)	16 (32.0)	41 (33.1)	55 (44.0)	16 (48.5)
Fusobacterium necrophorum	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Fusobacterium nucleatum	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Haemophilus influenzae	7 (2.0)	0 (0.0)	0 (0.0)	3 (6.0)	1 (0.8)	1 (0.8)	2 (6.1)
Klebsiella oxytoca	12 (3.4)	0 (0.0)	0 (0.0)	3 (6.0)	8 (6.5)	1 (0.8)	0 (0.0)
Klebsiella pneumoniae group	59 (16.9)	1 (14.3)	1 (10.0)	10 (20.0)	26 (21.0)	17 (13.6)	4 (12.1)
Morganella morganii	3 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	1 (0.8)	0 (0.0)
Neisseria meningitidis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Proteus	22 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	6 (4.8)	13 (10.4)	3 (9.1)
Proteus mirabilis	22 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	6 (4.8)	13 (10.4)	3 (9.1)
Pseudomonas aeruginosa	28 (8.0)	0 (0.0)	2 (20.0)	3 (6.0)	12 (9.7)	10 (8.0)	1 (3.0)
Salmonella	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
Serratia	10 (2.9)	0 (0.0)	1 (10.0)	0 (0.0)	5 (4.0)	4 (3.2)	0 (0.0)
Serratia marcescens	9 (2.6)	0 (0.0)	1 (10.0)	0 (0.0)	4 (3.2)	4 (3.2)	0 (0.0)
Stenotrophomonas maltophilia	3 (0.9)	0 (0.0)	0 (0.0)	3 (6.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pan *Candida*	2 (0.6)	1 (14.3)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
Pan Gram-Positive	24 (6.9)	1 (14.3)	2 (20.0)	5 (10.0)	7 (5.6)	7 (5.6)	2 (6.1)
CTX-M	24 (6.9)	0 (0.0)	0 (0.0)	2 (4.0)	7 (5.6)	12 (9.6)	3 (9.1)
IMP	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
KPC	3 (0.9)	0 (0.0)	0 (0.0)	1 (2.0)	1 (0.8)	1 (0.8)	0 (0.0)
NDM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OXA	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
VIM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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

Target	All Sites (N=349) n (%)	Site 1 (N=88) n (%)	Site 2 (N=23) n (%)	Site 3 (N=98) n (%)	Site 4 (N=58) n (%)	Site 5 (N=46) n (%)	Site 6 (N=28) n (%)	Site 7 (N=8) n (%)
Acinetobacter baumannii	4 (1.1)	3 (3.4)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bacteroides fragilis	11 (3.2)	2 (2.3)	3 (13.0)	3 (3.1)	2 (3.4)	1 (2.2)	0 (0.0)	0 (0.0)
Citrobacter	8 (2.3)	2 (2.3)	0 (0.0)	3 (3.1)	1 (1.7)	1 (2.2)	1 (3.6)	0 (0.0)
Cronobacter sakazakii	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Enterobacter (non-*cloacae* complex)	9 (2.6)	2 (2.3)	0 (0.0)	4 (4.1)	0 (0.0)	1 (2.2)	2 (7.1)	0 (0.0)
Enterobacter cloacae complex	23 (6.6)	3 (3.4)	1 (4.3)	10 (10.2)	1 (1.7)	6 (13.0)	2 (7.1)	0 (0.0)
Escherichia coli	132 (37.8)	30 (34.1)	8 (34.8)	37 (37.8)	25 (43.1)	17 (37.0)	12 (42.9)	3 (37.5)
Fusobacterium necrophorum	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Fusobacterium nucleatum	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Haemophilus influenzae	7 (2.0)	1 (1.1)	0 (0.0)	2 (2.0)	2 (3.4)	1 (2.2)	1 (3.6)	0 (0.0)
Klebsiella oxytoca	12 (3.4)	5 (5.7)	0 (0.0)	3 (3.1)	1 (1.7)	2 (4.3)	1 (3.6)	0 (0.0)
Klebsiella pneumoniae group	59 (16.9)	17 (19.3)	3 (13.0)	20 (20.4)	5 (8.6)	7 (15.2)	4 (14.3)	3 (37.5)
Morganella morganii	3 (0.9)	0 (0.0)	1 (4.3)	2 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neisseria meningitidis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Proteus	22 (6.3)	9 (10.2)	0 (0.0)	5 (5.1)	5 (8.6)	2 (4.3)	1 (3.6)	0 (0.0)
Proteus mirabilis	22 (6.3)	9 (10.2)	0 (0.0)	5 (5.1)	5 (8.6)	2 (4.3)	1 (3.6)	0 (0.0)
Pseudomonas aeruginosa	28 (8.0)	5 (5.7)	2 (8.7)	10 (10.2)	8 (13.8)	2 (4.3)	1 (3.6)	0 (0.0)
Salmonella	2 (0.6)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	0 (0.0)
Serratia	10 (2.9)	1 (1.1)	2 (8.7)	1 (1.0)	3 (5.2)	3 (6.5)	0 (0.0)	0 (0.0)
Serratia marcescens	9 (2.6)	1 (1.1)	2 (8.7)	1 (1.0)	3 (5.2)	2 (4.3)	0 (0.0)	0 (0.0)
Stenotrophomonas maltophilia	3 (0.9)	1 (1.1)	0 (0.0)	0 (0.0)	1 (1.7)	0 (0.0)	1 (3.6)	0 (0.0)
Pan *Candida*	2 (0.6)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	1 (3.6)	0 (0.0)
Pan Gram-Positive	24 (6.9)	15 (17.0)	1 (4.3)	5 (5.1)	1 (1.7)	0 (0.0)	2 (7.1)	0 (0.0)
CTX-M	24 (6.9)	9 (10.2)	1 (4.3)	3 (3.1)	4 (6.9)	5 (10.9)	2 (7.1)	0 (0.0)
IMP	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
KPC	3 (0.9)	1 (1.1)	0 (0.0)	1 (1.0)	1 (1.7)	0 (0.0)	0 (0.0)	0 (0.0)
NDM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
OXA	1 (0.3)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
VIM	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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PERFORMANCE CHARACTERISTICS

Clinical Performance

Samples with final, valid ePlex BCID-GN 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 167 prospective fresh and 182 prospective frozen samples as well as 577 retrospective samples and 777 contrived samples.

Comparator Method

The performance of the ePlex BCID-GN Panel was compared to standard laboratory procedures for identification of blood culture isolates, including traditional and automated identification methods, MALDI-TOF IVD, and microbiological and biochemical techniques. Identification for samples with *Acinetobacter baumannii* or *Candida parapsilosis* identified by standard laboratory procedures was confirmed using analytically validated PCR assays followed by bi-directional sequencing. For antibiotic resistance genes, the ePlex BCID-GN Panel was compared to analytically validated qPCR amplification assays followed by bi-directional sequencing in samples with an associated organism identified by culture (See **Table 3** for organism associations).

Table 3: Resistance Marker Organism Associations

Organism	Resistance Gene					
	CTX-M	**IMP**	**KPC**	**NDM**	**OXA**	**VIM**
Acinetobacter baumannii	X	X	X	X	X	X
Bacteroides fragilis						
Citrobacter	X	X	X	X	X	X
Cronobacter sakazakii			X			
Enterobacter cloacae complex	X	X	X	X	X	X
Enterobacter (non-cloacae complex)	X	X	X	X	X	X
Escherichia coli	X	X	X	X	X	X
Fusobacterium necrophorum						
Fusobacterium nucleatum						
Haemophilus influenzae						
Klebsiella oxytoca	X	X	X	X	X	X
Klebsiella pneumoniae	X	X	X	X	X	X
Morganella morganii	X	X	X	X	X	X
Neisseria meningitidis						
Proteus	X	X	X	X	X	X
Proteus mirabilis	X	X	X	X	X	X
Pseudomonas aeruginosa	X	X	X	X	X	X
Salmonella	X	X	X	X	X	X
Serratia	X	X	X	X	X	X
Serratia marcescens	X	X	X	X	X	X
Stenotrophomonas maltophilia	X					

The comparator method(s) results were used to determine the Detected / Not Detected status for each target organism on the ePlex BCID-GN Panel. The comparator methods for each target are summarized in **Table 4**.

Table 4: Comparator Method(s) by ePlex BCID-GN Panel Target

Target	Comparator Method
Acinetobacter baumannii	Standard laboratory procedures for organism ID. PCR/sequencing to confirm *Acinetobacter baumannii* or different *Acinetobacter* species not included in this panel.
Bacteroides fragilis	Standard laboratory procedures for organism identification.
Citrobacter	
Cronobacter sakazakii	
Enterobacter cloacae complex	
Enterobacter non-*cloacae* complex	
Escherichia coli	
Fusobacterium necrophorum	
Fusobacterium nucleatum	
Haemophilus influenzae	
Klebsiella oxytoca	
Klebsiella pneumoniae	
Morganella morganii	
Neisseria meningitidis	
Proteus	
Proteus mirabilis	
Pseudomonas aeruginosa	
Salmonella	
Serratia	
Serratia marcescens	
Stenotrophomonas maltophilia	
Pan Gram-Negative	
Pan *Candida*	Standard laboratory procedures for organism ID. PCR/sequencing to confirm *C. parapsilosis* or identify *C. metapsilosis, C. orthopsilosis.*
CTX-M, IMP, KPC, NDM, OXA, VIM	qPCR/sequencing in samples with associated organism detected by comparator method. See **Table 3** for organism associations.

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, 183 samples were prospectively collected and frozen; from June through July 2018, 171 samples were prospectively collected and tested fresh (never frozen) for a total of 354 samples across the 2 phases. One of these samples was withdrawn due to organism identification from unacceptable methods. Of the 353 prospectively-collected samples eligible for testing, 349 were evaluable. Samples with final, valid ePlex BCID-GN Panel results and a valid comparator result were evaluable. Four samples were not evaluable because they did not have final, valid ePlex BCID-GN Panel results and were excluded from performance evaluations. Demographic information for prospectively-collected samples is described in **Table 5.** 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, 578 samples were collected retrospectively, 577 were evaluable. One sample was not evaluable because it did not have a final, valid ePlex BCID-GN Panel result and was excluded from performance evaluations. Demographic information for retrospectively-collected samples is described in **Table 6**.

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

	All Sites N = 349 n (%)	Site 1 N = 88 n (%)	Site 2 N = 23 n (%)	Site 3 N = 98 n (%)	Site 4 N = 58 n (%)	Site 5 N = 46 n (%)	Site 6 N = 28 n (%)	Site 7 N = 8 n (%)
Sex								
Male	168 (48.1)	37 (42.0)	12 (52.2)	52 (53.1)	28 (48.3)	21 (45.7)	13 (46.4)	5 (62.5)
Female	181 (51.9)	51 (58.0)	11 (47.8)	46 (46.9)	30 (51.7)	25 (54.3)	15 (53.6)	3 (37.5)
Age								
<1 yr	7 (2.0)	2 (2.3)	0 (0.0)	4 (4.1)	0 (0.0)	1 (2.2)	0 (0.0)	0 (0.0)
1-17 yrs	10 (2.9)	4 (4.5)	1 (4.3)	3 (3.1)	1 (1.7)	1 (2.2)	0 (0.0)	0 (0.0)
18-44 yrs	50 (14.3)	10 (11.4)	3 (13.0)	20 (20.4)	3 (5.2)	8 (17.4)	6 (21.4)	0 (0.0)
45-64 yrs	124 (35.5)	35 (39.8)	9 (39.1)	28 (28.6)	21 (36.2)	14 (30.4)	13 (46.4)	4 (50.0)
65-84 yrs	125 (35.8)	29 (33.0)	8 (34.8)	35 (35.7)	25 (43.1)	17 (37.0)	7 (25.0)	4 (50.0)
85+ yrs	33 (9.5)	8 (9.1)	2 (8.7)	8 (8.2)	8 (13.8)	5 (10.9)	2 (7.1)	0 (0.0)

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Table 6: Demographic Data for Clinical Samples by Collection Site (Retrospective Collection)

	All Sites N = 577 n (%)	Site 1 N = 78 n (%)	Site 2 N = 73 n (%)	Site 3 N = 31 n (%)	Site 4 N = 93 n (%)	Site 5 N = 1 n (%)	Site 6 N = 80 n (%)	Site 7 N = 67 n (%)	Site 8 N = 48 n (%)	Site 9 N = 29 n (%)	Site 10 N = 77 n (%)
Sex											
Male	307 (53.2)	36 (46.2)	41 (56.2)	15 (48.4)	49 (52.7)	0 (0.0)	47 (58.8)	38 (56.7)	29 (60.4)	19 (65.5)	33 (42.9)
Female	270 (46.8)	42 (53.8)	32 (43.8)	16 (51.6)	44 (47.3)	1 (100)	33 (41.3)	29 (43.3)	19 (39.6)	10 (34.5)	44 (57.1)
Age											
<1 yr	9 (1.6)	1 (1.3)	0 (0.0)	0 (0.0)	3 (3.2)	0 (0.0)	2 (2.5)	0 (0.0)	1 (2.1)	0 (0.0)	2 (2.6)
1-17 yrs	20 (3.5)	1 (1.3)	0 (0.0)	1 (3.2)	8 (8.6)	0 (0.0)	6 (7.5)	0 (0.0)	0 (0.0)	1 (3.4)	3 (3.9)
18-44 yrs	78 (13.5)	13 (16.7)	7 (9.6)	2 (6.5)	10 (10.8)	1 (100)	15 (18.8)	8 (11.9)	8 (16.7)	6(20.7)	8 (10.4)
45-64 yrs	193 (33.4)	27 (34.6)	18 (24.7)	13 (41.9)	27 (29.0)	0 (0.0)	32 (40.0)	27 (40.3)	16 (33.3)	9 (31.0)	24 (31.2)
65-84 yrs	226 (39.2)	29 (37.2)	40 (54.8)	11 (35.5)	40 (43.0)	0 (0.0)	20 (25.0)	24 (35.8)	21 (43.8)	11 (37.9)	30 (39.0)
85+ yrs	49 (8.5)	7 (9.0)	8 (11.0)	4 (12.9)	5 (5.4)	0 (0.0)	5 (6.3)	6 (9.0)	2 (4.2)	2 (6.9)	10 (13.0)
Unknown	2 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.0)	0 (0.0)	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-GN Panel result matched the detected comparator method result, while a TN result was one where a negative ePlex BCID-GN Panel result matched a negative comparator method result. The two-sided 95% confidence interval was also calculated.

A total of 349 prospectively-collected samples (167 tested fresh and 182 tested after previously frozen) and 577 retrospectively collected samples from blood culture bottles flagged positive in a continuously monitoring blood culture system and removed from the system within 8 hours of positivity were evaluated for the ePlex BCID-GN Panel targets. Specimens evaluated were determined to contain gram-negative or gram-variable organisms based on Gram stain. A total of 777 contrived samples were prepared by spiking an isolate into a blood culture bottle with human whole blood and growing until flagged positive by a continuously monitoring blood culture system. Contrived 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 7-34** below, and the strains used to contrive samples are summarized in **Table 35**.

Table7: Clinical Performance for *Acinetobacter baumannii*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Acinetobacter baumannii	Prospective (Fresh)	0/0	---	167/167	100 (97.8-100)
	Prospective (Frozen)	4/4	100 (51.0-100)	178/178	100 (97.9-100)
	Prospective (All)	**4/4**	**100 (51.0-100)**	**345/345**	**100 (98.9-100)**
	Retrospective	15/15	100 (79.6-100)	560/561	99.8 (99.0-100)
	Prospective / Retrospective	**19/19**	**100 (83.2-100)**	**905/906[A]**	**99.9 (99.4-100)**
	Contrived	55/55	100 (93.5-100)	722/722	100 (99.5-100)
	Overall	**74/74**	**100 (95.1-100)**	**1627/1628**	**99.9 (99.7-100)**

CI= Confidence Interval

A.   *Acinetobacter baumanii* was detected in the 1/1 false positive sample using PCR/sequencing.

Table 8: Clinical Performance for *Bacteroides fragilis*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Bacteroides fragilis	Prospective (Fresh)	6/6	100 (61.0-100)	161/161	100 (97.7-100)
	Prospective (Frozen)	5/5	100 (56.6-100)	177/177	100 (97.9-100)
	Prospective (All)	**11/11**	**100 (74.1-100)**	**338/338**	**100 (98.9-100)**
	Retrospective	14/17	82.4 (59.0-93.8)	558/560	99.6 (98.7-99.9)
	Prospective / Retrospective	**25/28[A]**	**89.3 (72.8-96.3)**	**896/898[B]**	**99.8 (99.2-99.9)**
	Contrived	40/40	100 (91.2-100)	737/737	100 (99.5-100)
	Overall	**65/68**	**95.6 (87.8-98.5)**	**1633/1635**	**99.9 (99.6-100)**

A.   *B. fragilis* was not detected in 2 false negative samples, but PCR/sequencing instead detected *B. caccae* and *B. thetaiotaomicron*, which were not identified by standard laboratory procedures.

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

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Table 9: Clinical Performance for *Citrobacter*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Citrobacter	Prospective (Fresh)	3/3	100 (43.9-100)	163/164	99.4 (96.6-99.9)
	Prospective (Frozen)	2/2	100 (34.2-100)	178/180	98.9 (96.0-99.7)
	Prospective (All)	**5/5**	**100 (56.6-100)**	**341/344**	**99.1 (97.5-99.7)**
	Retrospective	20/21	95.2 (77.3-99.2)	555/556	99.8 (99.0-100)
	Prospective / Retrospective	**25/26**	**96.2 (81.1-99.3)**	**896/900[A]**	**99.6 (98.9-99.8)**
	Contrived	43/43	100 (91.8-100)	734/734	100 (99.5-100)
	Overall	**68/69**	**98.6 (92.2-99.7)**	**1630/1634**	**99.8 (99.4-99.9)**

A. *Citrobacter braakii* (2) and *Citrobacter freundii* (2) were detected in 4/4 false positive samples using PCR/sequencing.

Table 10: Clinical Performance for *Cronobacter sakazakii*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Cronobacter sakazakii	Prospective (Fresh)	0/0	---	167/167	100 (97.8-100)
	Prospective (Frozen)	0/0	---	182/182	100 (97.9-100)
	Prospective (All)	**0/0**	**---**	**349/349**	**100 (98.9-100)**
	Retrospective	1/1	100 (20.7-100)	576/576	100 (99.3-100)
	Prospective / Retrospective	**1/1**	**100 (20.7-100)**	**925/925**	**100 (99.6-100)**
	Contrived	45/45	100 (92.1-100)	732/732	100 (99.5-100)
	Overall	**46/46**	**100 (92.3-100)**	**1657/1657**	**100 (99.8-100)**

Table 11: Clinical Performance for *Enterobacter cloacae* complex

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Enterobacter cloacae complex	Prospective (Fresh)	12/12	100 (75.8-100)	153/155	98.7 (95.4-99.6)
	Prospective (Frozen)	7/7	100 (64.6-100)	173/175	98.9 (95.9-99.7)
	Prospective (All)	**19/19**	**100 (83.2-100)**	**326/330**	**98.8 (96.9-99.5)**
	Retrospective	47/50	94.0 (83.8-97.9)	526/527	99.8 (98.9-100)
	Prospective / Retrospective	**66/69[A]**	**95.7 (88.0-98.5)**	**852/857[B]**	**99.4 (98.6-99.8)**
	Contrived	35/37[C]	94.6 (82.3-98.5)	739/740	99.9 (99.2-100)
	Overall	**101/106**	**95.3 (89.4-98.0)**	**1591/1597**	**99.6 (99.2-99.8)**

A. A species of the *Enterobacter cloacae* complex was not detected in 1 false negative sample, but PCR/sequencing and MALDI-TOF instead detected *E. coli*. Standard laboratory procedures identified *E. cloacae* only.
B. *E. cloacae* was detected in 2/5 false positive samples using PCR/sequencing.
C. *E. cloacae* complex was not detected in 2 samples containing *Enterobacter asburiae.*

Table 12: Clinical Performance for *Enterobacter* (non-*cloacae* complex)

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Enterobacter -non-*cloacae* complex	Prospective (Fresh)	3/3	100 (43.9-100)	163/164	99.4 (96.6-99.9)
	Prospective (Frozen)	5/7	71.4 (35.9-91.8)	175/175	100 (97.9-100)
	Prospective (All)	**8/10**	**80.0 (49.0-94.3)**	**338/339**	**99.7 (98.3-99.9)**
	Retrospective	12/12	100 (75.8-100)	565/565	100 (99.3-100)
	Prospective / Retrospective	**20/22[A]**	**90.9 (72.2-97.5)**	**903/904[B]**	**99.9 (99.4-100)**
	Contrived	36/36	100 (90.4-100)	741/741	100 (99.5-100)
	Overall	**56/58**	**96.6 (88.3-99.0)**	**1644/1645**	**99.9 (99.7-100)**

A. A species of the *Enterobacter* non-*cloacae* complex was not detected in 2 false negative samples. Standard laboratory procedures identified *E. aerogenes* and PCR/sequencing detected *E. cloacae*.,.
B. A species of the *Enterobacter* non-*cloacae* complex was not detected in the false positive sample using PCR/sequencing.

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Table 13: Clinical Performance for *Escherichia coli*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Escherichia coli	Prospective (Fresh)	59/60	98.3 (91.1-99.7)	106/107	99.1 (94.9-99.8)
	Prospective (Frozen)	72/73	98.6 (92.6-99.8)	109/109	100 (96.6-100)
	Prospective (All)	**131/133**	**98.5 (94.7-99.6)**	**215/216**	**99.5 (97.4-99.9)**
	Retrospective	132/140	94.3 (89.1-97.1)	435/437	99.5 (98.3-99.9)
	Prospective / Retrospective	**263/273**	**96.3 (93.4-98.0)**	**650/653**[A]	**99.5 (98.7-99.8)**
	Contrived	52/52	100 (93.1-100)	725/725	100 (99.5-100)
	Overall	**315/325**	**96.9 (94.4-98.3)**	**1375/1378**	**99.8 (99.4-99.9)**

A. *E. coli* was detected in 3/3 false positive samples using PCR/sequencing.

Table 14: Clinical Performance for *Fusobacterium necrophorum*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Fusobacterium necrophorum	Prospective (Fresh)	0/0	---	167/167	100 (97.8-100)
	Prospective (Frozen)	0/0	---	182/182	100 (97.9-100)
	Prospective (All)	**0/0**	**---**	**349/349**	**100 (98.9-100)**
	Retrospective	1/1	100 (20.7-100)	576/576	100 (99.3-100)
	Prospective / Retrospective	**1/1**	**100 (20.7-100)**	**925/925**	**100 (99.6-100)**
	Contrived	47/48	97.9 (89.1-99.6)	729/729	100 (99.5-100)
	Overall	**48/49**	**98.0 (89.3-99.6)**	**1654/1654**	**100 (99.8-100)**

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Table 15: Clinical Performance for *Fusobacterium nucleatum*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Fusobacterium nucleatum	Prospective (Fresh)	0/0	---	167/167	100 (97.8-100)
	Prospective (Frozen)	0/0	---	182/182	100 (97.9-100)
	Prospective (All)	**0/0**	**---**	**349/349**	**100 (98.9-100)**
	Retrospective	5/5	100 (56.6-100)	571/572	99.8 (99.0-100)
	Prospective / Retrospective	**5/5**	**100 (56.6-100)**	**920/921[A]**	**99.9 (99.4-100)**
	Contrived	47/47	100 (92.4-100)	730/730	100 (99.5-100)
	Overall	**52/52**	**100 (93.1-100)**	**1650/1651**	**99.9 (99.7-100)**

A. *F. nucleatum* was detected in the 1/1 false positive sample using PCR/sequencing.

Table 16: Clinical Performance for *Haemophilus influenzae*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Haemophilus influenzae	Prospective (Fresh)	3/3	100 (43.9-100)	164/164	100 (97.7-100)
	Prospective (Frozen)	4/4	100 (51.0-100)	178/178	100 (97.9-100)
	Prospective (All)	**7/7**	**100 (64.6-100)**	**342/342**	**100 (98.9-100)**
	Retrospective	7/7	100 (64.6-100)	570/570	100 (99.3-100)
	Prospective / Retrospective	**14/14**	**100 (78.5-100)**	**912/912**	**100 (99.6-100)**
	Contrived	41/41	100 (91.4-100)	736/736	100 (99.5-100)
	Overall	**55/55**	**100 (93.5-100)**	**1648/1648**	**100 (99.8-100)**

Table 17: Clinical Performance for *Klebsiella oxytoca*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Klebsiella oxytoca	Prospective (Fresh)	4/6	66.7 (30.0-90.3)	160/161	99.4 (96.6-99.9)
	Prospective (Frozen)	7/7	100 (64.6-100)	175/175	100 (97.9-100)
	Prospective (All)	**11/13**	**84.6 (57.8-95.7)**	**335/336**	**99.7 (98.3-99.9)**
	Retrospective	29/34	85.3 (69.9-93.6)	541/543	99.6 (98.7-99.9)
	Prospective / Retrospective	**40/47[A]**	**85.1 (72.3-92.6)**	**876/879[B]**	**99.7 (99.0-99.9)**
	Contrived	20/20	100 (83.9-100)	757/757	100 (99.5-100)
	Overall	**60/67**	**89.6 (80.0-94.8)**	**1633/1636**	**99.8 (99.5-99.9)**

A. *K.* oxytoca was not detected in 2 false negative samples using PCR/sequencing, but 16S sequencing instead detected *Raoultella ornithinolytica* and *Raoultella planticola*, which were not identified by standard laboratory procedures.
B. *Klebsiella oxytoca* was detected in 3/3 false positive samples using PCR/sequencing.

Table 18: Clinical Performance for *Klebsiella pneumoniae* group

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Klebsiella pneumoniae group	Prospective (Fresh)	29/30	96.7 (83.3-99.4)	136/137	99.3 (96.0-99.9)
	Prospective (Frozen)	29/31	93.5 (79.3-98.2)	151/151	100 (97.5-100)
	Prospective (All)	**58/61**	**95.1 (86.5-98.3)**	**287/288**	**99.7 (98.1-99.9)**
	Retrospective	106/108	98.1 (93.5-99.5)	466/469	99.4 (98.1-99.8)
	Prospective / Retrospective	**164/169[A]**	**97.0 (93.3-98.7)**	**753/757[B]**	**99.5 (98.6-99.8)**
	Contrived	72/72	100 (94.9-100)	705/705	100 (99.5-100)
	Overall	**236/241**	**97.9 (95.2-99.1)**	**1458/1462**	**99.7 (99.3-99.9)**

A. *K. pneumoniae* was not detected in 1 false negative sample, but PCR/sequencing and MALDI-TOF instead detected *K. oxytoca*, which was not identified by standard laboratory procedures.
B. *K. pneumoniae* was detected in 4/4 false positive samples using PCR/sequencing.

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Table 19: Clinical Performance for *Morganella morganii*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Morganella morganii	Prospective (Fresh)	3/3	100 (43.9-100)	164/164	100 (97.7-100)
	Prospective (Frozen)	0/0	---	182/182	100 (97.9-100)
	Prospective (All)	**3/3**	**100 (43.9-100)**	**346/346**	**100 (98.9-100)**
	Retrospective	10/10	100 (72.2-100)	566/567	99.8 (99.0-100)
	Prospective / Retrospective	**13/13**	**100 (77.2-100)**	**912/913[A]**	**99.9 (99.4-100)**
	Contrived	49/49	100 (92.7-100)	728/728	100 (99.5-100)
	Overall	**62/62**	**100 (94.2-100)**	**1640/1641**	**99.9 (99.7-100)**

A. *M. morganii* was detected in 1/1 false positive clinical samples using PCR/sequencing.

Table 20: Clinical Performance for *Neisseria meningitidis*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Neisseria meningitidis	Prospective (Fresh)	0/0	---	167/167	100 (97.8-100)
	Prospective (Frozen)	0/0	---	182/182	100 (97.9-100)
	Prospective (All)	**0/0**	**---**	**349/349**	**100 (98.9-100)**
	Retrospective	0/0	---	576/577	99.8 (99.0-100)
	Prospective / Retrospective	**0/0**	**---**	**925/926[A]**	**99.9 (99.4-100)**
	Contrived	44/44	100 (92.0-100)	733/733	100 (99.5-100)
	Overall	**44/44**	**100 (92.0-100)**	**1658/1659**	**99.9 (99.7-100)**

A. *N. meningitidis* was not detected in the false positive sample using PCR/sequencing.

Table 21: Clinical Performance for *Proteus*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Proteus	Prospective (Fresh)	7/8	87.5 (52.9-97.8)	159/159	100 (97.6-100)
	Prospective (Frozen)	15/15	100 (79.6-100)	167/167	100 (97.8-100)
	Prospective (All)	**22/23**	**95.7 (79.0-99.2)**	**326/326**	**100 (98.8-100)**
	Retrospective	54/55	98.2 (90.4-99.7)	522/522	100 (99.3-100)
	Prospective / Retrospective	**76/78**	**97.4 (91.1-99.3)**	**848/848**	**100 (99.5-100)**
	Contrived	9/9	100 (70.1-100)	768/768	100 (99.5-100)
	Overall	**85/87**	**97.7 (92.0-99.4)**	**1616/1616**	**100 (99.8-100)**

Table 22: Clinical Performance for *Proteus mirabilis*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Proteus mirabilis	Prospective (Fresh)	7/8	87.5 (52.9-97.8)	159/159	100 (97.6-100)
	Prospective (Frozen)	15/15	100 (79.6-100)	167/167	100 (97.8-100)
	Prospective (All)	**22/23**	**95.7 (79.0-99.2)**	**326/326**	**100 (98.8-100)**
	Retrospective	50/51	98.0 (89.7-99.7)	526/526	100 (99.3-100)
	Prospective / Retrospective	**72/74**	**97.3 (90.7-99.3)**	**852/852**	**100 (99.6-100)**
	Contrived	9/9	100 (70.1-100)	768/768	100 (99.5-100)
	Overall	**81/83**	**97.6 (91.6-99.3)**	**1620/1620**	**100 (99.8-100)**

Table 23: Clinical Performance for *Pseudomonas aeruginosa*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Pseudomonas aeruginosa	Prospective (Fresh)	10/10	100 (72.2-100)	157/157	100 (97.6-100)
	Prospective (Frozen)	17/18	94.4 (74.2-99.0)	163/164	99.4 (96.6-99.9)
	Prospective (All)	**27/28**	**96.4 (82.3-99.4)**	**320/321**	**99.7 (98.3-99.9)**
	Retrospective	56/60	93.3 (84.1-97.4)	514/517	99.4 (98.3-99.8)
	Prospective / Retrospective	**83/88**	**94.3 (87.4-97.5)**	**834/838[A]**	**99.5 (98.8-99.8)**
	Contrived	32/32	100 (89.3-100)	745/745	100 (99.5-100)
	Overall	**115/120**	**95.8 (90.6-98.2)**	**1579/1583**	**99.7 (99.4-99.9)**

A. *P. aeruginosa* was detected in 2/4 false positive samples using PCR/sequencing.

Table 24: Clinical Performance for *Salmonella*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Salmonella	Prospective (Fresh)	2/2	100 (34.2-100)	165/165	100 (97.7-100)
	Prospective (Frozen)	0/0	---	182/182	100 (97.9-100)
	Prospective (All)	**2/2**	**100 (34.2-100)**	**347/347**	**100 (98.9-100)**
	Retrospective	18/19	94.7 (75.4-99.1)	558/558	100 (99.3-100)
	Prospective / Retrospective	**20/21[A]**	**95.2 (77.3-99.2)**	**905/905**	**100 (99.6-100)**
	Contrived	34/35	97.1 (85.5-99.5)	742/742	100 (99.5-100)
	Overall	**54/56**	**96.4 (87.9-99.0)**	**1647/1647**	**100 (99.8-100)**

A. *Salmonella* was not detected in 1 false negative sample, but PCR/sequencing instead detected *E. coli*, which was not identified by standard laboratory procedures.

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Table 25: Clinical Performance for *Serratia*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Serratia	Prospective (Fresh)	6/6	100 (61.0-100)	161/161	100 (97.7-100)
	Prospective (Frozen)	4/4	100 (51.0-100)	178/178	100 (97.9-100)
	Prospective (All)	**10/10**	**100 (72.2-100)**	**339/339**	**100 (98.9-100)**
	Retrospective	34/34	100 (89.8-100)	542/543	99.8 (99.0-100)
	Prospective / Retrospective	**44/44**	**100 (92.0-100)**	**881/882[A]**	**99.9 (99.4-100)**
	Contrived	36/36	100 (90.4-100)	741/741	100 (99.5-100)
	Overall	**80/80**	**100 (95.4-100)**	**1622/1623**	**99.9 (99.7-100)**

A. *S. marcescens* was detected in the 1/1 false positive sample using PCR/sequencing.

Table 26: Clinical Performance for *Serratia marcescens*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Serratia marcescens	Prospective (Fresh)	5/5	100 (56.6-100)	162/162	100 (97.7-100)
	Prospective (Frozen)	4/4	100 (51.0-100)	178/178	100 (97.9-100)
	Prospective (All)	**9/9**	**100 (70.1-100)**	**340/340**	**100 (98.9-100)**
	Retrospective	34/34	100 (89.8-100)	542/543	99.8 (99.0-100)
	Prospective / Retrospective	**43/43**	**100 (91.8-100)**	**882/883[A]**	**99.9 (99.4-100)**
	Contrived	19/19	100 (83.2-100)	758/758	100 (99.5-100)
	Overall	**62/62**	**100 (94.2-100)**	**1640/1641**	**99.9 (99.7-100)**

A. *S. marcescens* was detected in the 1/1 false positive sample using PCR/sequencing.

Table 27: Clinical Performance for *Stenotrophomonas maltophilia*

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Stenotrophomonas maltophilia	Prospective (Fresh)	2/3	66.7 (20.8-93.9)	164/164	100 (97.7-100)
	Prospective (Frozen)	1/1	100 (20.7-100)	181/181	100 (97.9-100)
	Prospective (All)	**3/4**	**75.0 (30.1-95.4)**	**345/345**	**100 (98.9-100)**
	Retrospective	8/10	80.0 (49.0-94.3)	566/567	99.8 (99.0-100)
	Prospective / Retrospective	**11/14**	**78.6 (52.4-92.4)**	**911/912^A**	**99.9 (99.4-100)**
	Contrived	36/36	100 (90.4-100)	741/741	100 (99.5-100)
	Overall	**47/50**	**94.0 (83.8-97.9)**	**1652/1653**	**99.9 (99.7-100)**

A. *S. maltophilia* was detected in the 1/1 false positive sample using PCR/sequencing.

Table 28: Clinical Performance for CTX-M

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
CTX-M	Prospective (Fresh)	10/13	76.9 (49.7-91.8)	127/127	100 (97.1-100)
	Prospective (Frozen)	12/16	75.0 (50.5-89.8)	144/144	100 (97.4-100)
	Prospective (All)	**22/29**	**75.9 (57.9-87.8)**	**271/271**	**100 (98.6-100)**
	Retrospective	52/56	92.9 (83.0-97.2)	483/483	100 (99.2-100)
	Prospective / Retrospective	**74/85^A**	**87.1 (78.3-92.6)**	**754/754**	**100 (99.5-100)**
	Contrived	75/75	100 (95.1-100)	437/437	100 (99.1-100)
	Overall	**149/160**	**93.1 (88.1-96.1)**	**1191/1191**	**100 (99.7-100)**

A. In 3/11 false negative samples, CTX-M signal was above the threshold for detection; however, an associated organism was not detected by the BCID-GN Panel and the CTX-M target was reported as 'N/A'. Further testing of the 8/11 remaining false negative samples indicated that 7 of the 8 samples may have been contaminated during the original comparator extraction process and misidentified as having CTX-M present. Specifically, results for 7 of the 8 samples were negative for CTX-M from the following additional testing: 1) qPCR testing of 2 repeat extractions from the original sample, 2) qPCR testing of an extraction from the isolate, and 3) testing of the original sample with an FDA-cleared multiplex assay. For these 7 samples, the originally extracted sample was re-tested with qPCR and CTX-M was again detected, suggesting contamination during the original extraction process. The remaining 8th sample was positive for CTX-M from the repeat extractions, negative for CTX-M from the isolate, and negative for CTX-M when tested with an FDA-cleared multiplex assay. These inconsistent detection results suggest the 8th sample may be a true low-copy CTX-M positive sample.

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Table 29: Clinical Performance for IMP

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
IMP	Prospective (Fresh)	0/0	---	138/138	100 (97.3-100)
	Prospective (Frozen)	0/0	---	159/159	100 (97.6-100)
	Prospective (All)	**0/0**	**---**	**297/297**	**100 (98.7-100)**
	Retrospective	0/0	---	532/532	100 (99.3-100)
	Prospective / Retrospective	**0/0**	**---**	**829/829**	**100 (99.5-100)**
	Contrived	40/40	100 (91.2-100)	436/436	100 (99.1-100)
	Overall	**40/40**	**100 (91.2-100)**	**1265/1265**	**100 (99.7-100)**

Table 30: Clinical Performance for KPC

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
KPC	Prospective (Fresh)	2/2	100 (34.2-100)	136/136	100 (97.3-100)
	Prospective (Frozen)	1/1	100 (20.7-100)	158/158	100 (97.6-100)
	Prospective (All)	**3/3**	**100 (43.9-100)**	**294/294**	**100 (98.7-100)**
	Retrospective	4/5	80.0 (37.6-96.4)	527/528	99.8 (98.9-100)
	Prospective / Retrospective	**7/8**	**87.5 (52.9-97.8)**	**821/822**	**99.9 (99.3-100)**
	Contrived	44/44	100 (92.0-100)	477/477	100 (99.2-100)
	Overall	**51/52**	**98.1 (89.9-99.7)**	**1298/1299**	**99.9 (99.6-100)**

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Table 31: Clinical Performance for NDM

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
NDM	Prospective (Fresh)	0/0	---	138/138	100 (97.3-100)
	Prospective (Frozen)	0/0	---	159/159	100 (97.6-100)
	Prospective (All)	**0/0**	**---**	**297/297**	**100 (98.7-100)**
	Retrospective	0/0	---	532/532	100 (99.3-100)
	Prospective / Retrospective	**0/0**	**---**	**829/829**	**100 (99.5-100)**
	Contrived	54/54	100 (93.4-100)	422/422	100 (99.1-100)
	Overall	**54/54**	**100 (93.4-100)**	**1251/1251**	**100 (99.7-100)**

Table 32: Clinical Performance for OXA

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
OXA	Prospective (Fresh)	0/1	0.0 (0.0-79.3)	137/137	100 (97.3-100)
	Prospective (Frozen)	1/1	100 (20.7-100)	158/158	100 (97.6-100)
	Prospective (All)	**1/2**	**50.0 (9.5-90.5)**	**295/295**	**100 (98.7-100)**
	Retrospective	9/11	81.8 (52.3-94.9)	519/521	99.6 (98.6-99.9)
	Prospective / Retrospective	**10/13[A]**	**76.9 (49.7-91.8)**	**814/816**	**99.8 (99.1-99.9)**
	Contrived	37/37	100 (90.6-100)	439/439	100 (99.1-100)
	Overall	**47/50**	**94.0 (83.8-97.9)**	**1253/1255**	**99.8 (99.4-100)**

A. In 1/3 false negative samples, OXA signal was above the threshold for detection; however, an associated organism was not detected by the BCID-GN Panel and the OXA target was reported as 'N/A'. One additional false negative sample was tested with an FDA-cleared multiplex assay and OXA was not detected. The isolate from the remaining false negative sample tested negative for OXA-23 and OXA-48 by qPCR.

Table 33: Clinical Performance for VIM

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
VIM	Prospective (Fresh)	0/0	---	138/138	100 (97.3-100)
	Prospective (Frozen)	0/0	---	159/159	100 (97.6-100)
	Prospective (All)	**0/0**	**---**	**297/297**	**100 (98.7-100)**
	Retrospective	0/0	---	532/532	100 (99.3-100)
	Prospective / Retrospective	**0/0**	**---**	**829/829**	**100 (99.5-100)**
	Contrived	42/42	100 (91.6-100)	434/434	100 (99.1-100)
	Overall	**42/42**	**100 (91.6-100)**	**1263/1263**	**100 (99.7-100)**

Pan Targets

In addition to the evaluable prospective and retrospective samples that contain gram-negative organisms, the clinical performance of the Pan *Candida* and Pan Gram-Positive targets was evaluated by testing an additional 741 non-intended use retrospective samples with gram-positive or fungal organisms; these are denoted as Retrospective (Non-Intended Use) samples. Results for the Pan targets are summarized in **Table 34** and results stratified by species are summarized in **Table 36**. A summary of the strains used to prepare contrived samples and the number of strains for each target is shown in **Table 35**.

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Table 34: Clinical Performance for Pan Targets

Target	Sample Type	Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Pan *Candida*	Prospective (Fresh)	1/1	100 (20.7-100)	165/166	99.4 (96.7-99.9)
	Prospective (Frozen)	0/0	---	182/182	100 (97.9-100)
	Prospective (All)	**1/1**	**100 (20.7-100)**	**347/348[A]**	**99.7 (98.4-99.9)**
	Retrospective	4/7[B]	57.1 (25.0-84.2)	569/570[C]	99.8 (99.0-100)
	Retrospective (Non-Intended Use)	99/102[D]	97.1 (91.7-99.0)	638/639[E]	99.8 (99.1-100)
	Contrived	0/0	---	777/777	100 (99.5-100)
Pan Gram-Positive	Prospective (Fresh)	7/8	87.5 (52.9-97.8)	155/159	97.5 (93.7-99.0)
	Prospective (Frozen)	10/15	66.7 (41.7-84.8)	164/167	98.2 (94.9-99.4)
	Prospective (All)	**17/23[F]**	**73.9 (53.5-87.5)**	**319/326[G]**	**97.9 (95.6-99.0)**
	Retrospective	44/55[H]	80.0 (67.6-88.4)	512/522[I]	98.1 (96.5-99.0)
	Retrospective (Non-Intended Use)	567/571	99.3 (98.2-99.7)	165/170[J]	97.1 (93.3-98.7)
	Contrived	0/0	---	776/777	99.9 (99.3-100)

A. *Candida glabrata* was detected in the 1/1 false positive sample using PCR/sequencing.
B. 3 of 3 (100%) false negative results occurred in samples in mixed infections with bacterial organisms where the BCID-GN Panel results were correct for the other infections in these samples.
C. *Candida albicans* was detected in the 1/1 false positive sample using PCR/sequencing.
D. 2 of 3 (67%) false negative results occurred in samples in mixed infections with bacterial organisms where the BCID-GN Panel results were correct for the other infections in these samples.
E. *Candida glabrata* was detected in the 1/1 false positive sample using PCR/sequencing.
F. *Bacillus* (the gram-positive organism identified by standard laboratory procedures) was not detected in 2 false negative samples using PCR/sequencing, but 16S sequencing instead detected *Paenibacillus lautus* and *Paenibacillus urinalis*, which were not identified by standard laboratory procedures. 3 of the remaining 4 (75%) false negative results occurred in samples in mixed infections with bacterial organisms where the BCID-GN Panel correctly detected the gram-negative organisms present.
G. *Enterococcus* (1), *Staphylococcus* (3), or *Streptococcus* (2) were detected in 6/7 false positive samples using PCR/sequencing (testing was not performed for the remaining 1/7 false positive samples).
H. 11 of 11 (100%) false negative results occurred in samples in mixed infections with bacterial organisms where the BCID-GN Panel correctly detected the gram-negative organisms present.
I. *Enterococcus* (2), *Staphylococcus* (1), or *Streptococcus* (5) were detected in 8/10 false positive samples using PCR/sequencing (testing was not performed for the remaining 2/10 false positive samples).
J. *Bacillus* (1) or *Streptococcus* (1) were detected in 2/5 false positive samples using PCR/sequencing (testing was not performed for the remaining 3/5 false positive samples).

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Table 35: Contrived Sample Summary

Target	Organism	Strain	Independent Contrived Samples Tested
Acinetobacter baumannii	*Acinetobacter baumannii*	ATCC19606	2
		ATCCBAA-2093	4
		ATCCBAA-747	5
		NCIMB12457	2
		NCTC13302	3
		NCTC13303	4
		NCTC13423	17
	Acinetobacter baumannii, NDM	CDC#0033	5
	Acinetobacter baumannii, OXA-23	ATCCBAA-1605	5
		NCTC13304	5
		NCTC13305	3
	***Acinetobacter baumannii* Total**		**55**
Bacteroides fragilis	*Bacteroides fragilis*	ATCC23745	8
		ATCC25285	8
		ATCC43860	8
		ATCC700786	8
		NCTC9343	8
	***Bacteroides fragilis* Total**		**40**
Citrobacter	*Citrobacter braakii*	ATCC43162	4
		ATCC51113	4
	Citrobacter freundii	ATCC43864	4
		ATCC8090	4
		NCTC8581	4
		NCTC9750	5
	Citrobacter freundii, CTX-M	JMI2047	6
	Citrobacter freundii, KPC	CDC#0116	4
	Citrobacter koseri	ATCC27156	4
	Citrobacter youngae	ATCC29935	4
	***Citrobacter* Total**		**43**
Cronobacter sakazakii	*Cronobacter sakazakii*	ATCC12868	2

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Target	Organism	Strain	Independent Contrived Samples Tested
		ATCC29004	2
		ATCC29544	4
		ATCCBAA-894	3
		FSLF6-0023	4
		FSLF6-0028	4
		FSLF6-0029	4
		FSLF6-0034	3
		FSLF6-0035	3
		FSLF6-0043	4
		FSLF6-0049	3
		FSLF6-0050	4
		FSLF6-0051	5
	Cronobacter sakazakii **Total**		**45**
Enterobacter cloacae complex	*Enterobacter asburiae*	ATCC35953	2
		ATCC35955	1
		ATCC35956	4
		ATCC35957	1
	Enterobacter cloacae, CTX-M	CDC#0038	4
		NCTC13464	3
	Enterobacter cloacae, CTX-M, KPC	CDC#0163	2
	Enterobacter cloacae, CTX-M, NDM	CDC#0038	1
		JMI53571	12
	Enterobacter cloacae, VIM	CDC#0154	6
	Enterobacter hormaechei, KPC	ATCCBAA-2082	1
	Enterobacter cloacae **complex Total**		**37**
*Enterobacter (*non-*cloacae* complex)	*Enterobacter aerogenes*	ATCC13048	3
		ATCC29010	3
		ATCC51697	3
	Enterobacter aerogenes, IMP	CDC#0161	5
	Enterobacter aerogenes, OXA-48	CDC#0074	12
	Enterobacter amnigenus	ATCC33072	3

Target	Organism	Strain	Independent Contrived Samples Tested
		ATCC33731	3
		ATCC51816	4
	*Enterobacter (*non-*cloacae* complex) Total		**36**
Escherichia coli	*Escherichia coli*, CTX-M	CDC#0086	3
		NCTC13452	3
		NCTC13461	6
		NCTC13463	2
	Escherichia coli, CTX-M, NDM	CDC#0137	6
		CDC#0151	2
	Escherichia coli, IMP	NCTC13476	7
	Escherichia coli, KPC	ATCCBAA-2340	2
		CDC#0114	4
	Escherichia coli, NDM	CDC#0118	6
		CDC#0150	5
		CDC#0151	4
	Escherichia coli, VIM	JMI32465	2
	Escherichia coli Total		**52**
Fusobacterium necrophorum	*Fusobacterium necrophorum* subsp. *funduliforme*	ATCC51357	24
	Fusobacterium necrophorum subsp. *necrophorum*	ATCC27852	24
	Fusobacterium necrophorum Total		**48**
Fusobacterium nucleatum	*Fusobacterium nucleatum*	ATCC23726	8
		ATCC25586	20
		ATCC31647	19
	Fusobacterium nucleatum Total		**47**
Haemophilus influenzae	*Haemophilus influenzae*	ATCC10211	9
		ATCC43065	6
		ATCC49144	9
		NCTC12699	9
		NCTC8468	8
	Haemophilus influenzae Total		**41**

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Target	Organism	Strain	Independent Contrived Samples Tested
Klebsiella oxytoca	*Klebsiella oxytoca*	ATCC43086	4
		ATCC43165	4
		ATCC43863	2
		ATCC49131	4
		ATCC51817	3
		ATCC700324	3
	***Klebsiella oxytoca* Total**		**20**
Klebsiella pneumoniae group	*Klebsiella pneumoniae*, CTX-M	NCTC13465	5
	Klebsiella pneumoniae, CTX-M, NDM	ATCCBAA-2146	3
	Klebsiella pneumoniae, CTX-M, OXA	CDC#0140	12
	Klebsiella pneumoniae, IMP	CDC#0034	8
		CDC#0080	6
	Klebsiella pneumoniae, KPC	CDC#0112	1
		CDC#0113	1
		CDC#0115	4
		CDC#0117	4
		CDC#0120	4
		CDC#0125	4
		CDC#0129	4
	Klebsiella pneumoniae, VIM	LMC_DR00015	6
		NCTC13439	5
		NCTC13440	5
	***Klebsiella pneumoniae* group Total**		**72**
Morganella morganii	*Morganella morganii*	148-200	8
		148-204	8
		148-205	8
		148-206	9
		148-209	7
	Morganella morganii, CTX-M1, NDM	CDC#0057	5
	Morganella morganii, KPC	CDC#0133	4
	***Morganella morganii* Total**		**49**

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Target	Organism	Strain	Independent Contrived Samples Tested
Neisseria meningitidis	*Neisseria meningitidis*	ATCC13077	9
		ATCC13090	8
		ATCC13102	8
		ATCC13113	3
		ATCC35561	10
		NCTC10026	6
	***Neisseria meningitidis* Total**		**44**
Proteus mirabilis	*Proteus mirabilis*, KPC	CDC#0155	4
	Proteus mirabilis, NDM	CDC#0159	5
	***Proteus mirabilis* Total**		**9**
Pseudomonas aeruginosa	*Pseudomonas aeruginosa*, IMP	CDC#0092	5
		CDC#0103	8
	Pseudomonas aeruginosa, KPC	CDC#0090	1
	Pseudomonas aeruginosa, VIM	CDC#0054	5
		CDC#0100	4
		CDC#0108	4
		NCTC13437	5
	***Pseudomonas aeruginosa* Total**		**32**
Salmonella	*Salmonella* 4,5,12:I:-	FSLS5-0580	2
	Salmonella Heidelberg	ATCC8326	2
	Salmonella Infantis	ATCCBAA-1675	2
	Salmonella Javiana	ATCC10721	1
	Salmonella Montevideo	ATCC8387	8
	Salmonella Muenchen	ATCC8388	1
	Salmonella Newport	ATCC6962	6
	Salmonella Typhimurium	ATCC13311	7
	Salmonella enterica subspecies *enterica Enteritidis* (Group D1)	ATCCBAA-708	6
	***Salmonella* Total**		**35**
Serratia	*Serratia ficaria*	ATCC33105	4
	Serratia grimesii	ATCC14460	3

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Target	Organism	Strain	Independent Contrived Samples Tested
	Serratia plymuthica	ATCC53858	3
	Serratia rubidaea	ATCC27593	4
		ATCC29025	3
	***Serratia* Total**		**17**
Serratia marcescens	*Serratia marcescens*	ATCC13880	2
		ATCC14041	3
		ATCC14756	3
		ATCC43861	4
		ATCC43862	3
		ATCC8100	3
	Serratia marcescens, IMP	LMC-DR23105	1
	***Serratia marcescens* Total**		**19**
Stenotrophomonas maltophilia	*Stenotrophomonas maltophilia*	148-201	7
		148-222	6
		148-223	7
		148-224	8
		148-225	8
	***Stenotrophomonas maltophilia* Total**		**36**

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Genus and Group Assay Species Stratification

The ePlex BCID-GN Panel reports genus or group level results for *Citrobacter*, *Enterobacter cloacae* complex, *Enterobacter* non-*cloacae* complex, *Proteus*, *Salmonella*, *Serratia*, Pan *Candida* and Pan Gram-Positive 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 36** and for the Pan targets for non-intended use samples in **Table 37**.

Table 36: Species Detected in Genus and Group Assays by Comparator Methods

Target Species Detected by Comparator Method	Prospective Samples		Retrospective Samples		Contrived Samples		Combined Samples	
	Sensitivity/PPA		Sensitivity/PPA		Sensitivity/PPA		Sensitivity/PPA	
	TP/TP+FN	% (95% CI)	TP/TP+FN	% (95% CI)	TP/TP+FN	% (95% CI)	TP/TP+FN	% (95% CI)
Citrobacter	**5/5**	**100 (56.6-100)**	**20/21**	**95.2 (77.3-99.2)**	**43/43**	**100 (91.8-100)**	**68/69**	**98.6 (92.2-99.7)**
Citrobacter braakii			2/3	66.7 (20.8-93.9)	8/8	100 (67.6-100)	10/11	90.9 (62.3-98.4)
Citrobacter freundii	4/4	100 (51.0-100)	13/13	100 (77.2-100)	27/27	100 (87.5-100)	44/44	100 (92.0-100)
Citrobacter koseri	1/1	100 (20.7-100)	4/4	100 (51.0-100)	4/4	100 (51.0-100)	9/9	100 (70.1-100)
Citrobacter youngae			1/1	100 (20.7-100)	4/4	100 (51.0-100)	5/5	100 (56.6-100)
Enterobacter (non-cloacae complex)	**8/10**	**80.0 (49.0-94.3)**	**12/12**	**100 (75.8-100)**	**36/36**	**100 (90.4-100)**	**56/58**	**96.6 (88.3-99.0)**
Enterobacter aerogenes	7/9	77.8 (45.3-93.7)	12/12	100 (75.8-100)	26/26	100 (87.1-100)	45/47	95.7 (85.8-98.8)
Enterobacter amnigenus					10/10	100 (72.2-100)	10/10	100 (72.2-100)
Enterobacter gergoviae	1/1	100 (20.7-100)					1/1	100 (20.7-100)
Enterobacter cloacae complex	**19/19**	**100 (83.2-100)**	**47/50**	**94.0 (83.8-97.9)**	**35/37**	**94.6 (82.3-98.5)**	**101/106**	**95.3 (89.4-98.0)**
Enterobacter asburiae					6/8	75.0 (40.9-92.9)	6/8	75.0 (40.9-92.9)
Enterobacter cloacae	19/19	100 (83.2-100)	46/49	93.9 (83.5-97.9)	28/28	100 (87.9-100)	93/96	96.9 (91.2-98.9)
Enterobacter hormaechei			1/1	100 (20.7-100)	1/1	100 (20.7-100)	2/2	100 (34.2-100)
Proteus	**22/23**	**95.7 (79.0-99.2)**	**54/55**	**98.2 (90.4-99.7)**	**9/9**	**100 (70.1-100)**	**85/87**	**97.7 (92.0-99.4)**
Proteus mirabilis	22/23	95.7 (79.0-99.2)	50/51	98.0 (89.7-99.7)	9/9	100 (70.1-100)	81/83	97.6 (91.6-99.3)
Proteus vulgaris			5/5	100 (56.6-100)			5/5	100 (56.6-100)
Salmonella	**2/2**	**100 (34.2-100)**	**18/19**	**94.7 (75.4-99.1)**	**34/35**	**97.1 (85.5-99.5)**	**54/56**	**96.4 (87.9-99.0)**
Salmonella	2/2	100 (34.2-100)	15/15	100 (79.6-100)			17/17	100 (81.6-100)
Salmonella 4,5,12:i:-					2/2	100 (34.2-100)	2/2	100 (34.2-100)
Salmonella Heidelberg					2/2	100 (34.2-100)	2/2	100 (34.2-100)
Salmonella Infantis					2/2	100 (34.2-100)	2/2	100 (34.2-100)
Salmonella Javiana					1/1	100 (20.7-100)	1/1	100 (20.7-100)
Salmonella Montevideo					7/8	87.5 (52.9-97.8)	7/8	87.5 (52.9-97.8)
Salmonella Muenchen					1/1	100 (20.7-100)	1/1	100 (20.7-100)
Salmonella Newport					6/6	100 (61.0-100)	6/6	100 (61.0-100)
Salmonella Typhimurium					7/7	100 (64.6-100)	7/7	100 (64.6-100)
Salmonella choleraesuis subsp. *Arizonae*			0/1	0.0 (0.0-79.3)			0/1	0.0 (0.0-79.3)
Salmonella enterica subsp. *enterica* Enteritidis (Group D1)					6/6	100 (61.0-100)	6/6	100 (61.0-100)

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Target Species Detected by Comparator Method	Prospective Samples		Retrospective Samples		Contrived Samples		Combined Samples	
	Sensitivity/PPA		Sensitivity/PPA		Sensitivity/PPA		Sensitivity/PPA	
	TP/TP+FN	% (95% CI)	TP/TP+FN	% (95% CI)	TP/TP+FN	% (95% CI)	TP/TP+FN	% (95% CI)
Salmonella enterica subsp. *enterica* serovar *Typhimurium*			1/1	100 (20.7-100)			1/1	100 (20.7-100)
Salmonella Typhi			2/2	100 (34.2-100)			2/2	100 (34.2-100)
Serratia	**10/10**	**100 (72.2-100)**	**34/34**	**100 (89.8-100)**	**36/36**	**100 (90.4-100)**	**80/80**	**100 (95.4-100)**
Serratia ficaria					4/4	100 (51.0-100)	4/4	100 (51.0-100)
Serratia grimesii					3/3	100 (43.9-100)	3/3	100 (43.9-100)
Serratia liquefaciens	1/1	100 (20.7-100)					1/1	100 (20.7-100)
Serratia marcescens	9/9	100 (70.1-100)	34/34	100 (89.8-100)	19/19	100 (83.2-100)	62/62	100 (94.2-100)
Serratia plymuthica					3/3	100 (43.9-100)	3/3	100 (43.9-100)
Serratia rubidaea					7/7	100 (64.6-100)	7/7	100 (64.6-100)
Pan Candida	**1/1**	**100 (20.7-100)**	**4/7**	**57.1 (25.0-84.2)**	**N/A**	**N/A**	**5/8**	**62.5 (30.6-86.3)**
Candida albicans	1/1	100 (20.7-100)	2/4	50.0 (15.0-85.0)			3/5	60.0 (23.1-88.2)
Candida glabrata			1/2	50.0 (9.5-90.5)			1/2	50.0 (9.5-90.5)
Candida krusei			1/1	100 (20.7-100)			1/1	100 (20.7-100)
Candida parapsilosis								
Pan Gram-Positive	**17/23**	**73.9 (53.5-87.5)**	**44/55**	**80.0 (67.6-88.4)**	**N/A**	**N/A**	**61/78**	**78.2 (67.8-85.9)**
Bacillus (unspeciated)	1/4	25.0 (4.6-69.9)					1/4	25.0 (4.6-69.9)
Enterococcus (unspeciated)			0/1	0.0 (0.0-79.3)			0/1	0.0 (0.0-79.3)
Enterococcus casseliflavus			0/1	0.0 (0.0-79.3)			0/1	0.0 (0.0-79.3)
Enterococcus faecalis	5/7	71.4 (35.9-91.8)	18/20	90.0 (69.9-97.2)			23/27	85.2 (67.5-94.1)
Enterococcus faecium	1/1	100 (20.7-100)	8/9	88.9 (56.5-98.0)			9/10	90.0 (59.6-98.2)
Staphylococcus (unspeciated)	3/3	100 (43.9-100)	4/6	66.7 (30.0-90.3)			7/9	77.8 (45.3-93.7)
Staphylococcus aureus	2/2	100 (34.2-100)	5/6	83.3 (43.6-97.0)			7/8	87.5 (52.9-97.8)
Staphylococcus cohnii	1/1	100 (20.7-100)					1/1	100 (20.7-100)
Staphylococcus epidermidis	1/1	100 (20.7-100)	2/3	66.7 (20.8-93.9)			3/4	75.0 (30.1-95.4)
Staphylococcus haemolyticus	2/2	100 (34.2-100)					2/2	100 (34.2-100)
Staphylococcus hominis	1/1	100 (20.7-100)	3/3	100 (43.9-100)			4/4	100 (51.0-100)
Streptococcus	0/1	0.0 (0.0-79.3)					0/1	0.0 (0.0-79.3)
Streptococcus - viridans group	1/1	100 (20.7-100)	0/1	0.0 (0.0-79.3)			1/2	50.0 (9.5-90.5)

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Target Species Detected by Comparator Method	Prospective Samples		Retrospective Samples		Contrived Samples		Combined Samples	
	Sensitivity/PPA		Sensitivity/PPA		Sensitivity/PPA		Sensitivity/PPA	
	TP/TP+FN	% (95% CI)	TP/TP+FN	% (95% CI)	TP/TP+FN	% (95% CI)	TP/TP+FN	% (95% CI)
Streptococcus anginosus group	1/1	100 (20.7-100)	4/5	80.0 (37.6-96.4)			5/6	83.3 (43.6-97.0)
Streptococcus infantarius			1/1	100 (20.7-100)			1/1	100 (20.7-100)
Streptococcus mitis group			1/1	100 (20.7-100)			1/1	100 (20.7-100)
Streptococcus oralis			1/1	100 (20.7-100)			1/1	100 (20.7-100)
Streptococcus pneumoniae			1/1	100 (20.7-100)			1/1	100 (20.7-100)
Streptococcus salivarius			1/1	100 (20.7-100)			1/1	100 (20.7-100)

Table 37. Species Detected in Pan Assays by Comparator Methods for Samples in Retrospective (Non-Intended Use) Samples with Gram-Positive or Fungal Organisms

Target Species Detected by Comparator Method	Retrospective (Non-Intended Use) Samples	
	Sensitivity/PPA	
	TP/TP+FN	% (95% CI)
Pan Candida	99/102	97.1 (91.7-99.0)
Candida albicans	47/48	97.9 (89.1-99.6)
Candida glabrata	37/38	97.4 (86.5-99.5)
Candida krusei	3/3	100 (43.9-100)
Candida parapsilosis	15/16	93.8 (71.7-98.9)
Pan Gram-Positive	567/571	99.3 (98.2-99.7)
Bacillus (unspeciated)	4/4	100 (51.0-100)
Bacillus cereus	4/5	80.0 (37.6-96.4)
Bacillus cereus group - not anthracis	1/1	100 (20.7-100)
Enterococcus	1/1	100 (20.7-100)
Enterococcus faecalis	34/34	100 (89.8-100)
Enterococcus faecium	14/14	100 (78.5-100)
Coagulase-negative *Staphylococci* (CoNS)	14/14	100 (78.5-100)
Staphylococcus (unspeciated)	86/86	100 (95.7-100)
Staphylococcus aureus	173/174	99.4 (96.8-99.9)
Staphylococcus auricularis	3/3	100 (43.9-100)
Staphylococcus capitis	7/7	100 (64.6-100)
Staphylococcus cohnii	1/1	100 (20.7-100)

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Target Species Detected by Comparator Method	Retrospective (Non-Intended Use) Samples	
	Sensitivity/PPA	
	TP/TP+FN	% (95% CI)
Staphylococcus epidermidis	86/87	98.9 (93.8-99.8)
Staphylococcus haemolyticus	6/6	100 (61.0-100)
Staphylococcus hominis	19/19	100 (83.2-100)
Staphylococcus hominis ssp *hominis*	21/21	100 (84.5-100)
Staphylococcus intermedius	1/1	100 (20.7-100)
Staphylococcus lugdunensis	1/1	100 (20.7-100)
Staphylococcus saccharolyticus	1/1	100 (20.7-100)
Staphylococcus saprophyticus	1/1	100 (20.7-100)
Staphylococcus sciuri	1/1	100 (20.7-100)
Staphylococcus simulans	2/2	100 (34.2-100)
Staphylococcus warneri	4/4	100 (51.0-100)
Alpha Hemolytic *Streptococcus*	1/1	100 (20.7-100)
Beta Hemolytic *Streptococci*, Group G	1/1	100 (20.7-100)
Gamma Hemolytic *Streptococcus*	1/1	100 (20.7-100)
Streptococcus (unspeciated)	9/9	100 (70.1-100)
Streptococcus - viridans group	17/17	100 (81.6-100)
Streptococcus agalactiae	21/21	100 (84.5-100)
Streptococcus anginosus	2/2	100 (34.2-100)
Streptococcus bovis	2/2	100 (34.2-100)
Streptococcus constellatus ssp *constellatus*	1/1	100 (20.7-100)
Streptococcus dysgalactiae (Group G)	4/4	100 (51.0-100)
Streptococcus gordonii	1/1	100 (20.7-100)
Streptococcus intermedius	1/1	100 (20.7-100)
Streptococcus mitis	11/12	91.7 (64.6-98.5)
Streptococcus mitis group	2/2	100 (34.2-100)
Streptococcus pneumoniae	22/22	100 (85.1-100)
Streptococcus pyogenes	9/9	100 (70.1-100)
Streptococcus salivarius	2/2	100 (34.2-100)

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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 3** for organisms specifically associated with the six resistance markers on the ePlex BCID-GN Panel).

CTX-M

The PPA and NPA of the BCID-GN Panel CTX-M target stratified by the organism identified by comparator methods for prospective, retrospective and contrived samples are shown in **Table 38**.

Table 38: Clinical Performance of CTX-M Target in Samples with Associated Organisms Detected by Comparator Methods

Species Detected by Comparator Method		Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Acinetobacter baumannii	Prospective	0/0	---	4/4	100 (51.0-100)
	Retrospective	0/0	---	15/15	100 (79.6-100)
	Contrived	0/0	---	55/55	100 (93.5-100)
	Combined	**0/0**	**---**	**74/74**	**100 (95.1-100)**
Citrobacter	Prospective	0/0	---	5/5	100 (56.6-100)
	Retrospective	1/1	100 (20.7-100)	20/20	100 (83.9-100)
	Contrived	6/6	100 (61.0-100)	37/37	100 (90.6-100)
	Combined	**7/7**	**100 (64.6-100)**	**62/62**	**100 (94.2-100)**
Enterobacter (non-*cloacae* complex)	Prospective	0/0	---	10/10	100 (72.2-100)
	Retrospective	0/0	---	12/12	100 (75.8-100)
	Contrived	0/0	---	36/36	100 (90.4-100)
	Combined	**0/0**	**---**	**58/58**	**100 (93.8-100)**
Enterobacter cloacae complex	Prospective	0/0	---	19/19	100 (83.2-100)
	Retrospective	0/0	---	50/50	100 (92.9-100)
	Contrived	22/22	100 (85.1-100)	15/15	100 (79.6-100)
	Combined	**22/22**	**100 (85.1-100)**	**84/84**	**100 (95.6-100)**
Escherichia coli	Prospective	16/18	88.9 (67.2-96.9)	115/115	100 (96.8-100)
	Retrospective	35/37	94.6 (82.3-98.5)	103/103	100 (96.4-100)
	Contrived	22/22	100 (85.1-100)	30/30	100 (88.6-100)
	Combined	**73/77**	**94.8 (87.4-98.0)**	**248/248**	**100 (98.5-100)**
Klebsiella oxytoca	Prospective	0/1	0.0 (0.0-79.3)	12/12	100 (75.8-100)
	Retrospective	0/0	---	34/34	100 (89.8-100)
	Contrived	0/0	---	20/20	100 (83.9-100)
	Combined	**0/1**	**0.0 (0.0-79.3)**	**66/66**	**100 (94.5-100)**
Klebsiella pneumoniae group	Prospective	5/5	100 (56.6-100)	56/56	100 (93.6-100)
	Retrospective	14/15	93.3 (70.2-98.8)	93/93	100 (96.0-100)
	Contrived	20/20	100 (83.9-100)	52/52	100 (93.1-100)
	Combined	**39/40**	**97.5 (87.1-99.6)**	**201/201**	**100 (98.1-100)**
Morganella morganii	Prospective	0/0	---	3/3	100 (43.9-100)
	Retrospective	0/0	---	10/10	100 (72.2-100)
	Contrived	5/5	100 (56.6-100)	44/44	100 (92.0-100)
	Combined	**5/5**	**100 (56.6-100)**	**57/57**	**100 (93.7-100)**
Proteus	Prospective	2/5	40.0 (11.8-76.9)	18/18	100 (82.4-100)
	Retrospective	2/3	66.7 (20.8-93.9)	52/52	100 (93.1-100)
	Contrived	0/0	---	9/9	100 (70.1-100)
	Combined	**4/8**	**50.0 (21.5-78.5)**	**79/79**	**100 (95.4-100)**

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Species Detected by Comparator Method		Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Proteus mirabilis	Prospective	2/5	40.0 (11.8-76.9)	18/18	100 (82.4-100)
	Retrospective	2/3	66.7 (20.8-93.9)	48/48	100 (92.6-100)
	Contrived	0/0	---	9/9	100 (70.1-100)
	Combined	**4/8**	**50.0 (21.5-78.5)**	**75/75**	**100 (95.1-100)**
Pseudomonas aeruginosa	Prospective	0/1	0.0 (0.0-79.3)	27/27	100 (87.5-100)
	Retrospective	0/0	---	60/60	100 (94.0-100)
	Contrived	0/0	---	32/32	100 (89.3-100)
	Combined	**0/1**	**0.0 (0.0-79.3)**	**119/119**	**100 (96.9-100)**
Salmonella	Prospective	0/0	---	2/2	100 (34.2-100)
	Retrospective	1/1	100 (20.7-100)	18/18	100 (82.4-100)
	Contrived	0/0	---	35/35	100 (90.1-100)
	Combined	**1/1**	**100 (20.7-100)**	**55/55**	**100 (93.5-100)**
Serratia	Prospective	0/0	---	10/10	100 (72.2-100)
	Retrospective	0/0	---	34/34	100 (89.8-100)
	Contrived	0/0	---	36/36	100 (90.4-100)
	Combined	**0/0**	**---**	**80/80**	**100 (95.4-100)**
Serratia marcescens	Prospective	0/0	---	9/9	100 (70.1-100)
	Retrospective	0/0	---	34/34	100 (89.8-100)
	Contrived	0/0	---	19/19	100 (83.2-100)
	Combined	**0/0**	**---**	**62/62**	**100 (94.2-100)**
Stenotrophomonas maltophilia	Prospective	0/0	---	4/4	100 (51.0-100)
	Retrospective	0/0	---	10/10	100 (72.2-100)
	Contrived	0/0	---	36/36	100 (90.4-100)
	Combined	**0/0**	**---**	**50/50**	**100 (92.9-100)**

A comparison of CTX-M identified by comparator methods versus the ePlex BCID-GN Panel results are shown in **Table 39** for prospective and retrospective samples.

Table 39: Distribution of CTX-M in Clinical Samples

BCID-GN	Comparator Method			
	Org+/ARG+	Org+/ARG-	Org-	Total
Org+/ARG+	74	0	2	76
Org+/ARG-	8[A]	741	2	751
Org-	3[B]	13	83	99
Total	**85**	**754**	**87**	**926**

% Agreement (95% CI) for Org+/ARG+: 74/85=87.1% (78.3-92.6)
% Agreement (95% CI) for Org+/ARG-: 741/754=98.3% (97.1-99.0)
% Agreement (95% CI) for Org-: 83/87=95.4% (88.8-98.2)

A. Further testing of these 8 false negative samples indicated that 7 of the 8 samples may have been contaminated during the original extraction process and misidentified as having CTX-M present. Specifically, results for 7 of the 8 samples were negative for CTX-M from the following additional testing: 1) qPCR testing of 2 repeat extractions from the original sample, 2) qPCR testing of an extraction from the isolate, and 3) testing of the original sample with an FDA-cleared multiplex assay. For these 7 samples, the originally extracted sample was re-tested with qPCR and CTX-M was again detected, suggesting contamination during the original extraction process. The remaining 8th sample was positive for CTX-M from the repeat extractions, negative for CTX-M from the isolate, and negative for CTX-M when tested with an FDA-cleared multiplex assay. These inconsistent detection results suggest the 8th sample may be a true low-copy CTX-M positive sample.

B. For these 3 samples, CTX-M signal was above the threshold for detection; however, an associated organism was not detected by the ePlex BCID-GN Panel and the CTX-M target was reported as 'N/A'.

IMP

The PPA and NPA of the BCID-GN Panel IMP target stratified by the contrived organism are shown below in **Table 40**. No prospective or retrospective samples were found to contain IMP.

Table 40: Clinical Performance of IMP Target in Contrived Samples

Species Detected by Comparator Method	Sensitivity/PPA		Specificity/NPA	
	TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Acinetobacter baumannii	0/0	---	74/74	100 (95.1-100)
Citrobacter	0/0	---	69/69	100 (94.7-100)
Enterobacter (non-*cloacae* complex)	5/5	100 (56.6-100)	53/53	100 (93.2-100)
Enterobacter cloacae complex	0/0	---	106/106	100 (96.5-100)
Escherichia coli	7/7	100 (64.6-100)	318/318	100 (98.8-100)
Klebsiella oxytoca	0/0	---	67/67	100 (94.6-100)
Klebsiella pneumoniae group	14/14	100 (78.5-100)	227/227	100 (98.3-100)
Morganella morganii	0/0	---	62/62	100 (94.2-100)
Proteus	0/0	---	87/87	100 (95.8-100)
Proteus mirabilis	0/0	---	83/83	100 (95.6-100)
Pseudomonas aeruginosa	13/13	100 (77.2-100)	107/107	100 (96.5-100)
Salmonella	0/0	---	56/56	100 (93.6-100)
Serratia	1/1	100 (20.7-100)	79/79	100 (95.4-100)
Serratia marcescens	1/1	100 (20.7-100)	61/61	100 (94.1-100)

A comparison of IMP identified by comparator methods versus the ePlex BCID-GN Panel results are shown in **Table 41** for prospective and retrospective samples.

Table 41: Distribution of IMP in Clinical Samples

BCID-GN	Comparator Method			
	Org+/ARG+	Org+/ARG-	Org-	Total
Org+/ARG+	0	0	0	0
Org+/ARG-	0	812	4	816
Org-	0	17	93	110
Total	**0**	**829**	**97**	**926**

% Agreement (95% CI) for Org+/ARG+: 0/0= N/A
% Agreement (95% CI) for Org+/ARG-: 812/829=97.9% (96.7-98.7)
% Agreement (95% CI) for Org-: 93/97=95.9% (89.9-98.4)

KPC

The PPA and NPA of the BCID-GN Panel KPC target stratified by the organism identified by comparator methods for prospective, retrospective and contrived samples are shown in **Table 42**.

Table 42: Clinical Performance of KPC Target in Samples with Associated Organisms Detected by Comparator Methods

Species Detected by Comparator Method		Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Acinetobacter baumannii	Prospective	0/0	---	4/4	100 (51.0-100)
	Retrospective	0/0	---	15/15	100 (79.6-100)
	Contrived	0/0	---	55/55	100 (93.5-100)
	Combined	**0/0**	**---**	**74/74**	**100 (95.1-100)**
Citrobacter	Prospective	0/0	---	5/5	100 (56.6-100)
	Retrospective	0/0	---	21/21	100 (84.5-100)
	Contrived	4/4	100 (51.0-100)	39/39	100 (91.0-100)
	Combined	**4/4**	**100 (51.0-100)**	**65/65**	**100 (94.4-100)**
Cronobacter sakazakii	Prospective	---	---	---	---
	Retrospective	0/0	---	1/1	100 (20.7-100)
	Contrived	0/0	---	45/45	100 (92.1-100)
	Combined	**0/0**	**---**	**46/46**	**100 (92.3-100)**
Enterobacter (non-*cloacae* complex)	Prospective	0/0	---	10/10	100 (72.2-100)
	Retrospective	0/0	---	12/12	100 (75.8-100)
	Contrived	0/0	---	36/36	100 (90.4-100)
	Combined	**0/0**	**---**	**58/58**	**100 (93.8-100)**
Enterobacter cloacae complex	Prospective	0/0	---	19/19	100 (83.2-100)
	Retrospective	0/1	0.0 (0.0-79.3)	49/49	100 (92.7-100)
	Contrived	3/3	100 (43.9-100)	34/34	100 (89.8-100)
	Combined	**3/4**	**75.0 (30.1-95.4)**	**102/102**	**100 (96.4-100)**
Escherichia coli	Prospective	1/1	100 (20.7-100)	132/132	100 (97.2-100)
	Retrospective	0/0	---	140/140	100 (97.3-100)
	Contrived	6/6	100 (61.0-100)	46/46	100 (92.3-100)
	Combined	**7/7**	**100 (64.6-100)**	**318/318**	**100 (98.8-100)**
Klebsiella oxytoca	Prospective	0/0	---	13/13	100 (77.2-100)
	Retrospective	0/0	---	34/34	100 (89.8-100)
	Contrived	0/0	---	20/20	100 (83.9-100)
	Combined	**0/0**	**---**	**67/67**	**100 (94.6-100)**
Klebsiella pneumoniae group	Prospective	2/2	100 (34.2-100)	59/59	100 (93.9-100)
	Retrospective	4/4	100 (51.0-100)	103/104	99.0 (94.8-99.8)
	Contrived	22/22	100 (85.1-100)	50/50	100 (92.9-100)
	Combined	**28/28**	**100 (87.9-100)**	**212/213**	**99.5 (97.4-99.9)**
Morganella morganii	Prospective	0/0	---	3/3	100 (43.9-100)
	Retrospective	0/0	---	10/10	100 (72.2-100)
	Contrived	4/4	100 (51.0-100)	45/45	100 (92.1-100)
	Combined	**4/4**	**100 (51.0-100)**	**58/58**	**100 (93.8-100)**
Proteus	Prospective	0/0	---	23/23	100 (85.7-100)
	Retrospective	0/0	---	55/55	100 (93.5-100)
	Contrived	4/4	100 (51.0-100)	5/5	100 (56.6-100)
	Combined	**4/4**	**100 (51.0-100)**	**83/83**	**100 (95.6-100)**
Proteus mirabilis	Prospective	0/0	---	23/23	100 (85.7-100)
	Retrospective	0/0	---	51/51	100 (93.0-100)
	Contrived	4/4	100 (51.0-100)	5/5	100 (56.6-100)
	Combined	**4/4**	**100 (51.0-100)**	**79/79**	**100 (95.4-100)**
Pseudomonas aeruginosa	Prospective	0/0	---	28/28	100 (87.9-100)
	Retrospective	0/0	---	60/60	100 (94.0-100)
	Contrived	1/1	100 (20.7-100)	31/31	100 (89.0-100)
	Combined	**1/1**	**100 (20.7-100)**	**119/119**	**100 (96.9-100)**

Species Detected by Comparator Method		Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Salmonella	Prospective	0/0	---	2/2	100 (34.2-100)
	Retrospective	0/0	---	19/19	100 (83.2-100)
	Contrived	0/0	---	35/35	100 (90.1-100)
	Combined	**0/0**	**---**	**56/56**	**100 (93.6-100)**
Serratia	Prospective	0/0	---	10/10	100 (72.2-100)
	Retrospective	0/0	---	34/34	100 (89.8-100)
	Contrived	0/0	---	36/36	100 (90.4-100)
	Combined	**0/0**	**---**	**80/80**	**100 (95.4-100)**
Serratia marcescens	Prospective	0/0	---	9/9	100 (70.1-100)
	Retrospective	0/0	---	34/34	100 (89.8-100)
	Contrived	0/0	---	19/19	100 (83.2-100)
	Combined	**0/0**	**---**	**62/62**	**100 (94.2-100)**

A comparison of KPC identified by comparator methods versus the ePlex BCID-GN Panel results are shown in **Table 43** for prospective and retrospective samples.

Table 43: Distribution of KPC in Clinical Samples

BCID-GN	Comparator Method			
	Org+/ARG+	Org+/ARG-	Org-	Total
Org+/ARG+	7	1	0	8
Org+/ARG-	1	804	4	809
Org-	0	17	92	109
Total	**8**	**822**	**96**	**926**

% Agreement (95% CI) for Org+/ARG+: 7/8=87.5% (52.9-97.8)
% Agreement (95% CI) for Org+/ARG-: 804/822=97.8% (96.6-98.6)
% Agreement (95% CI) for Org-: 92/96=95.8% (89.8-98.4)

NDM

The PPA and NPA of the BCID-GN Panel NDM target stratified by the contrived organism are shown below in **Table 44**. No prospective or retrospective samples were found to contain NDM.

Table 44: Clinical Performance of NDM Target in Contrived Samples by Organism

Species Detected by Comparator Method	Sensitivity/PPA		Specificity/NPA	
	TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Acinetobacter baumannii	5/5	100 (56.6-100)	69/69	100 (94.7-100)
Citrobacter	0/0	---	69/69	100 (94.7-100)
Enterobacter (non-*cloacae* complex)	0/0	---	58/58	100 (93.8-100)
Enterobacter cloacae complex	13/13	100 (77.2-100)	93/93	100 (96.0-100)
Escherichia coli	23/23	100 (85.7-100)	302/302	100 (98.7-100)
Klebsiella oxytoca	0/0	---	67/67	100 (94.6-100)
Klebsiella pneumoniae group	3/3	100 (43.9-100)	238/238	100 (98.4-100)
Morganella morganii	5/5	100 (56.6-100)	57/57	100 (93.7-100)
Proteus	5/5	100 (56.6-100)	82/82	100 (95.5-100)
Proteus mirabilis	5/5	100 (56.6-100)	78/78	100 (95.3-100)
Pseudomonas aeruginosa	0/0	---	120/120	100 (96.9-100)
Salmonella	0/0	---	56/56	100 (93.6-100)
Serratia	0/0	---	80/80	100 (95.4-100)
Serratia marcescens	0/0	---	62/62	100 (94.2-100)

A comparison of NDM identified by comparator methods versus the ePlex BCID-GN Panel results are shown in **Table 45** for prospective and retrospective samples.

Table 45: Distribution of NDM in Clinical Samples

BCID-GN	Comparator Method			
	Org+/ARG+	Org+/ARG-	Org-	Total
Org+/ARG+	0	0	0	0
Org+/ARG-	0	812	4	816
Org-	0	17	93	110
Total	**0**	**829**	**97**	**926**

% Agreement (95% CI) for Org+/ARG+: 0/0= N/A
% Agreement (95% CI) for Org+/ARG-: 812/829=97.9% (96.7-98.7)
% Agreement (95% CI) for Org-: 93/97=95.9% (89.9-98.4)

OXA

The PPA and NPA of the BCID-GN Panel OXA target stratified by target identified by comparator methods for prospective, retrospective, and contrived samples are shown in **Table 46**.

Table 46: Clinical Performance of OXA Target in Samples with Associated Organisms Detected by Comparator Methods

Species Detected by Comparator Method		Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Acinetobacter baumannii	Prospective	1/1	100 (20.7-100)	3/3	100 (43.9-100)
	Retrospective	7/7	100 (64.6-100)	8/8	100 (67.6-100)
	Contrived	13/13	100 (77.2-100)	42/42	100 (91.6-100)
	Combined	21/21	100 (84.5-100)	53/53	100 (93.2-100)
Citrobacter	Prospective	0/0	---	5/5	100 (56.6-100)
	Retrospective	0/0	---	21/21	100 (84.5-100)
	Contrived	0/0	---	43/43	100 (91.8-100)
	Combined	0/0	---	69/69	100 (94.7-100)
Enterobacter (non-*cloacae* complex)	Prospective	0/0	---	10/10	100 (72.2-100)
	Retrospective	0/0	---	12/12	100 (75.8-100)
	Contrived	12/12	100 (75.8-100)	24/24	100 (86.2-100)
	Combined	12/12	100 (75.8-100)	46/46	100 (92.3-100)
Enterobacter cloacae complex	Prospective	0/0	---	19/19	100 (83.2-100)
	Retrospective	0/0	---	50/50	100 (92.9-100)
	Contrived	0/0	---	37/37	100 (90.6-100)
	Combined	0/0	---	106/106	100 (96.5-100)
Escherichia coli	Prospective	0/1	0.0 (0.0-79.3)	132/132	100 (97.2-100)
	Retrospective	1/2	50.0 (9.5-90.5)	138/138	100 (97.3-100)
	Contrived	0/0	---	52/52	100 (93.1-100)
	Combined	1/3	33.3 (6.1-79.2)	322/322	100 (98.8-100)
Klebsiella oxytoca	Prospective	0/0	---	13/13	100 (77.2-100)
	Retrospective	0/0	---	34/34	100 (89.8-100)
	Contrived	0/0	---	20/20	100 (83.9-100)
	Combined	0/0	---	67/67	100 (94.6-100)
Klebsiella pneumoniae group	Prospective	0/0	---	61/61	100 (94.1-100)
	Retrospective	0/1	0.0 (0.0-79.3)	107/107	100 (96.5-100)
	Contrived	12/12	100 (75.8-100)	60/60	100 (94.0-100)
	Combined	12/13	92.3 (66.7-98.6)	228/228	100 (98.3-100)
Morganella morganii	Prospective	0/0	---	3/3	100 (43.9-100)
	Retrospective	0/0	---	10/10	100 (72.2-100)
	Contrived	0/0	---	49/49	100 (92.7-100)
	Combined	0/0	---	62/62	100 (94.2-100)
Proteus	Prospective	0/0	---	23/23	100 (85.7-100)
	Retrospective	1/1	100 (20.7-100)	53/54	98.1 (90.2-99.7)
	Contrived	0/0	---	9/9	100 (70.1-100)
	Combined	1/1	100 (20.7-100)	85/86	98.8 (93.7-99.8)
Proteus mirabilis	Prospective	0/0	---	23/23	100 (85.7-100)
	Retrospective	0/0	---	50/51	98.0 (89.7-99.7)
	Contrived	0/0	---	9/9	100 (70.1-100)
	Combined	0/0	---	82/83	98.8 (93.5-99.8)
Pseudomonas aeruginosa	Prospective	0/0	---	28/28	100 (87.9-100)
	Retrospective	0/0	---	59/60	98.3 (91.1-99.7)
	Contrived	0/0	---	32/32	100 (89.3-100)
	Combined	0/0	---	119/120	99.2 (95.4-99.9)
Salmonella	Prospective	0/0	---	2/2	100 (34.2-100)
	Retrospective	0/0	---	19/19	100 (83.2-100)
	Contrived	0/0	---	35/35	100 (90.1-100)

Confidential

Species Detected by Comparator Method		Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
	Combined	0/0	---	56/56	100 (93.6-100)
Serratia	Prospective	0/0	---	10/10	100 (72.2-100)
	Retrospective	0/0	---	34/34	100 (89.8-100)
	Contrived	0/0	---	36/36	100 (90.4-100)
	Combined	0/0	---	80/80	100 (95.4-100)
Serratia marcescens	Prospective	0/0	---	9/9	100 (70.1-100)
	Retrospective	0/0	---	34/34	100 (89.8-100)
	Contrived	0/0	---	19/19	100 (83.2-100)
	Combined	0/0	---	62/62	100 (94.2-100)

A comparison of OXA identified by comparator methods versus the ePlex BCID-GN Panel results are shown in **Table 47** for prospective and retrospective samples.

Table 47: Distribution of OXA in Clinical Samples

BCID-GN	Comparator Method			
	Org+/ARG+	Org+/ARG-	Org-	Total
Org+/ARG+	10	2	0	12
Org+/ARG-	2[A]	798	4	804
Org-	1[B]	16	93	110
Total	13	816	97	926

% Agreement (95% CI) for Org+/ARG+: 10/13=76.9% (49.7-91.8)
% Agreement (95% CI) for Org+/ARG-: 798/816=97.8% (96.5-98.6)
% Agreement (95% CI) for Org-: 93/97=95.9% (89.9-98.4)
A. One false negative sample was tested with an FDA-cleared multiplex assay and OXA was not detected. The isolate from the remaining false negative sample tested negative for OXA-23 and OXA-48 by qPCR.
B. For this sample, OXA signal was above the threshold for detection; however, an associated organism was not detected by the ePlex BCID-GN Panel and the OXA target was reported as 'N/A'.

VIM

The PPA and NPA of the BCID-GN Panel VIM target stratified by the contrived organism are shown below in **Table 48**. No prospective or retrospective samples were found to contain VIM.

Table 48: Clinical Performance of VIM Target in Contrived Samples by Organism

Species Detected by Comparator Method	Sensitivity/PPA		Specificity/NPA	
	TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Acinetobacter baumannii	0/0	---	74/74	100 (95.1-100)
Citrobacter	0/0	---	69/69	100 (94.7-100)
Enterobacter (non-*cloacae* complex)	0/0	---	58/58	100 (93.8-100)
Enterobacter cloacae complex	6/6	100 (61.0-100)	100/100	100 (96.3-100)
Escherichia coli	2/2	100 (34.2-100)	323/323	100 (98.8-100)
Klebsiella oxytoca	0/0	---	67/67	100 (94.6-100)
Klebsiella pneumoniae group	16/16	100 (80.6-100)	225/225	100 (98.3-100)
Morganella morganii	0/0	---	62/62	100 (94.2-100)
Proteus	0/0	---	87/87	100 (95.8-100)
Proteus mirabilis	0/0	---	83/83	100 (95.6-100)
Pseudomonas aeruginosa	18/18	100 (82.4-100)	102/102	100 (96.4-100)
Salmonella	0/0	---	56/56	100 (93.6-100)
Serratia	0/0	---	80/80	100 (95.4-100)
Serratia marcescens	0/0	---	62/62	100 (94.2-100)

A comparison of VIM identified by comparator methods versus the ePlex BCID-GN Panel results are shown in **Table 49** for prospective and retrospective samples.

Table 49: Distribution of VIM in Clinical Samples

BCID-GN	Comparator Method			
	Org+/ARG+	Org+/ARG-	Org-	Total
Org+/ARG+	0	0	0	0
Org+/ARG-	0	812	4	816
Org-	0	17	93	110
Total	0	829	97	926

% Agreement (95% CI) for Org+/ARG+: 0/0= N/A
% Agreement (95% CI) for Org+/ARG-: 812/829=97.9% (96.7-98.7)
% Agreement (95% CI) for Org-: 93/97=95.9% (89.9-98.4)

Resistance Markers and Antimicrobial Resistance Susceptibility

A supplemental comparison of the CTX-M BCID-GN Panel target versus phenotypic antimicrobial susceptibility testing (AST) for extended spectrum beta-lactamase (ESBL) activity, Ceftazidime, Ceftriaxone, and Aztreonam, and a combination of the 4 results (ESBL/Combo) is provided in Table 57 for clinical isolates with available AST results. In total, 162 isolates had ESBL confirmatory testing and 770 isolates had ESBL confirmatory testing and/or AST results for 1 or more of Ceftazidime, Ceftriaxone, or Aztreonam. A true positive (TP) result was defined where CTX-M was detected by the BCID-GN Panel and the isolate was positive for the ESBL confirmatory test or resistant (R) or intermediate (I) to the specific antimicrobial. A false negative (FN) result was defined similarly when CTX-M was not detected by the BCID-GN Panel. PPA was calculated as 100 x (TP/(TP+FN)). A true negative (TN) result was defined where CTX-M was not detected by the BCID-GN Panel and the isolate was negative for the ESBL confirmatory test or susceptible (S) to the specific antimicrobial. A false positive (FP) result was defined similarly when CTX-M was detected by the BCID-GN Panel. NPA was calculated as 100 x (TN/(TN+FP)). For the ESBL/Combo analysis, the phenotypic AST result was positive or negative based on the ESBL confirmatory test, if available. If the ESBL confirmatory test was not available, then the phenotypic AST result was positive if any of the 3 antimicrobials were resistant or intermediate, otherwise, the result was negative if any of the 3 antimicrobials were susceptible. Note: ESBL resistance can be due to mechanisms other than acquisition of the CTX-M resistance gene.

Table 50: Clinical Performance of the BCID-GN Panel target CTX-M to Phenotypic Antimicrobial Susceptibility Testing for ESBL, Ceftazidime, Ceftriaxone, and Aztreonam

Associated Organism	ESBL confirmatory		Ceftazidime		Ceftriaxone		Aztreonam		ESBL/Combo	
	PPA TP/TP+FN (%)	NPA TN/TN+FP (%)	PPA TP/TP+FN (%)	NPA TN/TN+FP (%)	PPA TP/TP+FN (%)	NPA TN/TN+FP (%)	PPA TP/TP+FN (%)	NPA TN/TN+FP (%)	PPA TP/TP+FN (%)	NPA TN/TN+FP (%)
A. baumannii	---	---	0/10 (0.0%)	3/3 (100%)	0/11 (0.0%)	1/1 (100%)	0/3 (0.0%)	0/0	0/15 (0.0%)	2/2 (100%)
Citrobacter	---	---	0/2 (0.0%)	14/15 (93.3%)	0/3 (0.0%)	21/22 (95.5%)	0/1 (0.0%)	16/17 (94.1%)	0/3 (0.0%)	21/22 (95.5%)
Enterobacter	---	---	0/2 (0.0%)	12/12 (100%)	0/2 (0.0%)	18/18 (100%)	0/1 (0.0%)	9/9 (100%)	0/3 (0.0%)	17/17 (100%)
E. cloacae complex	---	---	0/10 (0.0%)	30/30 (100%)	0/17 (0.0%)	39/39 (100%)	0/5 (0.0%)	25/25 (100%)	0/18 (0.0%)	39/39 (100%)
E. coli	28/30 (93.3%)	82/82 (100%)	29/38 (76.3%)	159/167 (95.2%)	47/59 (79.7%)	180/181 (99.4%)	23/27 (85.2%)	118/120 (98.3%)	47/53 (88.7%)	196/197 (99.5%)
K. oxytoca	0/0	10/10 (100%)	0/1 (0.0%)	29/29 (100%)	0/2 (0.0%)	40/40 (100%)	0/2 (0.0%)	20/20 (100%)	0/2 (0.0%)	41/41 (100%)
K. pneumoniae group	7/11 (63.6%)	25/25 (100%)	13/23 (56.5%)	83/83 (100%)	17/27 (63.0%)	115/115 (100%)	10/12 (83.3%)	72/72 (100%)	17/26 (65.4%)	119/119 (100%)

Associated Organism	ESBL confirmatory		Ceftazidime		Ceftriaxone		Aztreonam		ESBL/Combo	
	PPA TP/TP+FN (%)	NPA TN/TN+FP (%)	PPA TP/TP+FN (%)	NPA TN/TN+FP (%)	PPA TP/TP+FN (%)	NPA TN/TN+FP (%)	PPA TP/TP+FN (%)	NPA TN/TN+FP (%)	PPA TP/TP+FN (%)	NPA TN/TN+FP (%)
M. morganii			0/1 (0.0%)	6/6 (100%)	0/2 (0.0%)	9/9 (100%)	0/0	4/4 (100%)	0/2 (0.0%)	9/9 (100%)
Proteus	3/3 (100%)	0/0	1/2 (50.0%)	46/48 (95.8%)	4/7 (57.1%)	59/59 (100%)	2/3 (66.7%)	35/36 (97.2%)	4/8 (50.0%)	59/59 (100%)
P. mirabilis	3/3 (100%)	0/0	1/2 (50.0%)	43/45 (95.6%)	4/5 (80.0%)	56/56 (100%)	2/3 (66.7%)	32/33 (97.0%)	4/6 (66.7%)	56/56 (100%)
P. aeruginosa			0/7 (0.0%)	46/46 (100%)	0/20 (0.0%)	0/0	0/9 (0.0%)	25/25 (100%)	0/32 (0.0%)	41/41 (100%)
Salmonella	1/1 (100%)	0/0	0/0	6/6 (100%)	1/2 (50.0%)	12/12 (100%)	1/1 (100%)	8/8 (100%)	1/2 (50.0%)	15/15 (100%)
Serratia			0/1 (0.0%)	25/25 (100%)	0/4 (0.0%)	32/32 (100%)	0/1 (0.0%)	20/20 (100%)	0/4 (0.0%)	34/34 (100%)
S. marcescens			0/1 (0.0%)	24/24 (100%)	0/4 (0.0%)	31/31 (100%)	0/1 (0.0%)	19/19 (100%)	0/4 (0.0%)	33/33 (100%)
S. maltophilia			0/2 (0.0%)	2/2 (100%)	0/3 (0.0%)	0/0	0/5 (0.0%)	0/0	0/5 (0.0%)	2/2 (100%)
Any Organism CI	42/48 (87.5%) (75.3-94.1)	117/117 (100%) (96.8-100)	44/102 (43.1%) (33.9-52.8)	528/541 (97.6%) (95.9-98.6)	73/168 (43.5%) (36.2-51.0)	613/615 (99.7%) (98.8-99.9)	38/74 (51.4%) (40.2-62.4)	403/408 (98.8%) (97.2-99.5)	73/183 (39.9%) (33.1-47.1)	684/686 (99.7%) (98.9-99.9)

CI= confidence interval

A supplemental comparison of the 5 BCID-GN Panel carbapenemase resistance gene (OXA, KPC, IMP, NDM, VIM) targets versus phenotypic antimicrobial susceptibility testing (AST) for Ertapenem, Imipenem, and Meropenem is provided in **Table 51** for clinical isolates with available AST results. In total, 731 isolates had AST results for 1 or more of Ertapenem, Imipenem, or Meropenem. A true positive (TP) result was defined where OXA, KPC, IMP, NDM and/or VIM was detected by the BCID-GN Panel and the isolate was resistant (R) or intermediate (I) to Ertapenem, Imipenem, or Meropenem. A false negative (FN) result was defined similarly when OXA, KPC, IMP, NDM and/or VIM was not detected by the BCID-GN Panel. PPA was calculated as 100 x (TP/(TP+FN)). A true negative (TN) result was defined where OXA, KPC, IMP, NDM and/or VIM was not detected by the BCID-GN Panel and the isolate was susceptible (S) to Ertapenem, Imipenem, or Meropenem. A false positive (FP) result was defined similarly when OXA, KPC, IMP, NDM and/or VIM was detected by the BCID-GN Panel. NPA was calculated as 100 x (TN/(TN+FP)). Note: Carbapenemase resistance can be due to mechanisms other than acquisition of the OXA, KPC, IMP, NDM and/or VIM resistance genes.

Table 51: Clinical Performance of the BCID-GN Panel Resistance Gene Targets Compared to Phenotypic Antimicrobial Susceptibility Testing for Ertapenem, Imipenem, and Meropenem

Associated Organism	OXA		KPC		IMP		NDM		VIM		Any Resistance Marker	
	PPA TP/TP+FN (%)	NPA TN/TN+FP (%)	PPA TP/TP+FN (%)	NPA TN/TN+FP (%)	PPA TP/TP+FN (%)	NPA TN/TN+FP (%)	PPA TP/TP+FN (%)	NPA TN/TN+FP (%)	PPA TP/TP+FN (%)	NPA TN/TN+FP (%)	PPA TP/TP+FN (%)	NPA TN/TN+FP (%)
A. baumannii	8/9 (88.9%)	9/9 (100%)	0/9 (0.0%)	9/9 (100%)	0/9 (0.0%)	9/9 (100%)	0/9 (0.0%)	9/9 (100%)	0/9 (0.0%)	9/9 (100%)	8/9 (88.9%)	9/9 (100%)
Citrobacter	0/1 (0.0%)	22/22 (100%)	0/1 (0.0%)	22/22 (100%)	0/1 (0.0%)	22/22 (100%)	0/1 (0.0%)	22/22 (100%)	0/1 (0.0%)	22/22 (100%)	0/1 (0.0%)	22/22 (100%)
C. sakazakii	---	---	0/0	1/1 (100%)	---	---	---	---	---	---	---	---
Enterobacter	0/0	15/15 (100%)	0/0	15/15 (100%)	0/0	15/15 (100%)	0/0	15/15 (100%)	0/0	15/15 (100%)	0/0	15/15 (100%)
E. cloacae complex	0/1 (0.0%)	51/51 (100%)	0/1 (0.0%)	51/51 (100%)	0/1 (0.0%)	51/51 (100%)	0/1 (0.0%)	51/51 (100%)	0/1 (0.0%)	51/51 (100%)	0/1 (0.0%)	51/51 (100%)
E. coli	0/2 (0.0%)	247/248 (99.6%)	1/2 (50.0%)	248/248 (100%)	0/2 (0.0%)	248/248 (100%)	0/2 (0.0%)	248/248 (100%)	0/2 (0.0%)	248/248 (100%)	1/2 (50.0%)	247/248 (99.6%)
K. oxytoca	0/0	40/40 (100%)	0/0	40/40 (100%)	0/0	40/40 (100%)	0/0	40/40 (100%)	0/0	40/40 (100%)	0/0	40/40 (100%)
K. pneumoniae group	0/8 (0.0%)	136/136 (100%)	5/8 (62.5%)	135/136 (99.3%)	0/8 (0.0%)	136/136 (100%)	0/8 (0.0%)	136/136 (100%)	0/8 (0.0%)	136/136 (100%)	5/8 (62.5%)	135/136 (99.3%)
M. morganii	0/0	10/10 (100%)	0/0	10/10 (100%)	0/0	10/10 (100%)	0/0	10/10 (100%)	0/0	10/10 (100%)	0/0	10/10 (100%)
Proteus	0/0	61/62 (98.4%)	0/0	62/62 (100%)	0/0	62/62 (100%)	0/0	62/62 (100%)	0/0	62/62 (100%)	0/0	61/62 (98.4%)
P. mirabilis	0/0	57/57 (100%)	0/0	57/57 (100%)	0/0	57/57 (100%)	0/0	57/57 (100%)	0/0	57/57 (100%)	0/0	57/57 (100%)
P. aeruginosa	0/5 (0.0%)	65/66 (98.5%)	0/5 (0.0%)	66/66 (100%)	0/5 (0.0%)	66/66 (100%)	0/5 (0.0%)	66/66 (100%)	0/5 (0.0%)	66/66 (100%)	0/5 (0.0%)	65/66 (98.5%)
Salmonella	0/0	8/8 (100%)	0/0	8/8 (100%)	0/0	8/8 (100%)	0/0	8/8 (100%)	0/0	8/8 (100%)	0/0	8/8 (100%)
Serratia	0/0	38/38 (100%)	0/0	38/38 (100%)	0/0	38/38 (100%)	0/0	38/38 (100%)	0/0	38/38 (100%)	0/0	38/38 (100%)
S. marcescens	0/0	37/37 (100%)	0/0	37/37 (100%)	0/0	37/37 (100%)	0/0	37/37 (100%)	0/0	37/37 (100%)	0/0	37/37 (100%)
Any Organism	8/26 (30.8%)	796/799 (99.6%)	6/26 (23.1%)	799/800 (99.9%)	0/26 (0.0%)	799/799 (100%)	0/26 (0.0%)	799/799 (100%)	0/26 (0.0%)	799/799 (100%)	14/26 (53.8%)	796/800 (99.5%)
CI	(16.5-50.0)	(98.9-99.9)	(11.0-42.1)	(99.3-100)	(0.0-12.9)	(99.5-100)	(0.0-12.9)	(99.5-100)	(0.0-12.9)	(99.5-100)	(35.5-71.2)	(98.7-99.8)

CI= confidence interval

Co-detections in Clinical Samples

The ePlex BCID-GN Panel identified a total of 103 bacterial co-detections in prospective and retrospective samples. Of the 349 prospective samples, 320 (91.7%) had single detections, 22 (6.2%) had double detections, and 7 (2.0%) had triple detections. Of the 577 retrospective samples, 503 (87.2%) had single detections, 62 (10.7%) had double detections, and 12 (2.1%) had triple detections. **Tables 52-55** below summarize co-detections detected in prospective and retrospective samples.

Table 52: Co-Detections Identified by the ePlex BCID-GN Panel (Prospective Samples)

Distinct Co-Detection Combinations Detected by the ePlex BCID-GN Panel in Prospective Clinical Samples				Number of Samples (Number Discrepant)	Discrepant Organism(s) / Resistance Marker(s)[A,B]
Target 1	**Target 2**	**Target 3**	**Resistance Marker**		
A. baumannii	Pan Gram-Positive			2 (0)	
Citrobacter	*E. cloacae* complex	*K. oxytoca*		2 (2)	*Citrobacter* (2), *E. cloacae* complex (2)
Citrobacter	*K. oxytoca*	*K. pneumoniae* group		1 (1)	*Citrobacter* (1)
Citrobacter	*P. mirabilis*	Pan Gram-Positive		1 (1)	Pan Gram-Positive (1)
E. cloacae complex	*E. coli*	*K. pneumoniae* group		1 (0)	
E. cloacae complex	Pan *Candida*	Pan Gram-Positive		1 (0)	
E. cloacae complex	Pan Gram-Positive			2 (0)	
E. coli	*K. oxytoca*			2 (1)	*K. oxytoca* (1)
E. coli	*K. pneumoniae* group		CTX-M	1 (1)	*E. coli* (1)
E. coli	Pan Gram-Positive			2 (1)	Pan Gram-Positive (1)
Enterobacter	*K. pneumoniae* group			1 (1)	*Enterobacter* (1)
K. oxytoca	Pan Gram-Positive			1 (0)	
K. oxytoca	*S. marcescens*			1 (0)	
K. pneumoniae group	*P. mirabilis*			1 (0)	
K. pneumoniae group	Pan Gram-Positive			2 (0)	
K. pneumoniae group	Pan Gram-Positive		CTX-M, KPC	1 (1)	Pan Gram-Positive (1)
M. morganii	*P. mirabilis*			1 (0)	

Distinct Co-Detection Combinations Detected by the ePlex BCID-GN Panel in Prospective Clinical Samples				Number of Samples (Number Discrepant)	Discrepant Organism(s) / Resistance Marker(s)[A,B]
Target 1	Target 2	Target 3	Resistance Marker		
P. aeruginosa	*P. mirabilis*	Pan Gram-Positive		1 (0)	
P. aeruginosa	Pan Gram-Positive			1 (0)	
P. mirabilis	Pan Gram-Positive			3 (2)	Pan Gram-Positive (2)
P. mirabilis	Pan Gram-Positive		CTX-M	1 (0)	

A. A discrepant organism or resistance marker is defined as one that was detected by the BCID-GN Panel but not by the comparator method(s).

B. 12/13 false positive organisms were investigated using PCR/sequencing; the discrepant organism was detected in 11/13 and not detected in 1.
   One false positive Pan Gram-Positive sample was not tested.
   i. In 3/3 false positive *Citrobacter* samples, *Citrobacter* was detected.
   ii. In 2/2 false positive *E. cloacae* complex samples, *E. cloacae* complex was detected.
   iii. An *Enterobacter* species was not detected in the 1 false positive *Enterobacter* (non-*cloacae* complex) sample.
   iv. In 1/1 false positive *E. coli* sample, *E. coli* was detected.
   v. In 1/1 false positive *K. oxytoca* sample, *K. oxytoca* was detected.
   vi. In 4/4 false positive Pan Gram-Positive samples, a Pan Gram-Positive organism was detected.

Table 53: Co-Detections Identified by the ePlex BCID-GN Panel (Retrospective Samples)

Distinct Co-Detection Combinations Detected by the ePlex BCID-GN Panel in Retrospective Clinical Samples				Number Samples (Number Discrepant)	Discrepant Organism(s) / Resistance Marker(s)[A,B]
Target 1	Target 2	Target 3	Resistance Marker		
A. baumannii	*K. pneumoniae* group	Pan Gram-Positive	CTX-M, OXA	1 (1)	*A. baumannii* (1), *K. pneumoniae* group (1), Pan Gram-Positive (1)
A. baumannii	Pan Gram-Positive			2 (0)	
A. baumannii	Pan Gram-Positive		OXA	4 (1)	Pan Gram-Positive (1)
B. fragilis	*E. cloacae* complex	Pan Gram-Positive		1 (1)	*B. fragilis* (1)
B. fragilis	*E. coli*			2 (1)	*B. fragilis* (1)
B. fragilis	Pan Gram-Positive			1 (0)	
Citrobacter	*E. cloacae* complex			1 (1)	*E. cloacae* complex (1)
Citrobacter	*E. coli*			1 (0)	
Citrobacter	*K. oxytoca*			1 (1)	*Citrobacter* (1)
Citrobacter	*K. oxytoca*	*K. pneumoniae* group		1 (1)	*K. oxytoca* (1)
Citrobacter	*K. pneumoniae* group			1 (0)	

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Distinct Co-Detection Combinations Detected by the ePlex BCID-GN Panel in Retrospective Clinical Samples				Number Samples (Number Discrepant)	Discrepant Organism(s) / Resistance Marker(s)[A,B]
Target 1	**Target 2**	**Target 3**	**Resistance Marker**		
Citrobacter	*K. pneumoniae* group	Pan Gram-Positive	CTX-M	1 (0)	
Citrobacter	*M. morganii*	Pan Gram-Positive		1 (1)	*M. morganii* (1)
Citrobacter	Pan Gram-Positive			3 (2)	Pan Gram-Positive (2)
E. cloacae complex	*K. pneumoniae* group			1 (0)	
E. cloacae complex	*P. aeruginosa*	Pan Gram-Positive		1 (1)	*P. aeruginosa* (1)
E. cloacae complex	Pan *Candida*			1 (1)	Pan *Candida* (1)
E. cloacae complex	Pan Gram-Positive			2 (1)	Pan Gram-Positive (1)
E. coli	*K. oxytoca*			1 (0)	
E. coli	*K. oxytoca*	Pan Gram-Positive		1 (0)	
E. coli	*K. pneumoniae* group			2 (0)	
E. coli	*M. morganii*			1 (0)	
E. coli	*P. mirabilis*			3 (0)	
E. coli	*P. mirabilis*	Pan Gram-Positive		1 (0)	
E. coli	Pan Gram-Positive			8 (2)	Pan Gram-Positive (2)
E. coli	Pan Gram-Positive		CTX-M	1 (0)	
Enterobacter	Pan *Candida*			1 (0)	
Enterobacter	Pan Gram-Positive			1 (0)	
H. influenzae	*N. meningitidis*	*P. aeruginosa*		1 (1)	*N. meningitidis* (1), *P. aeruginosa* (1)
K. oxytoca	*K. pneumoniae* group			2 (1)	*K. pneumoniae* group (1)
K. oxytoca	Pan Gram-Positive			3 (2)	Pan Gram-Positive (2)
K. oxytoca	*S. marcescens*			1 (1)	*S. marcescens* (1)
K. pneumoniae group	Pan Gram-Positive			4 (1)	Pan Gram-Positive (1)
K. pneumoniae group	Pan Gram-Positive	*S. marcescens*		1 (1)	*K. pneumoniae* group (1)

Distinct Co-Detection Combinations Detected by the ePlex BCID-GN Panel in Retrospective Clinical Samples				Number Samples (Number Discrepant)	Discrepant Organism(s) / Resistance Marker(s)[A,B]
Target 1	**Target 2**	**Target 3**	**Resistance Marker**		
K. pneumoniae group	*S. maltophilia*			1 (0)	
M. morganii	*P. aeruginosa*	Pan Gram-Positive		1 (1)	*P. aeruginosa* (1)
M. morganii	*P. mirabilis*			1 (0)	
M. morganii	Pan Gram-Positive	*Proteus*		1 (0)	
P. aeruginosa	Pan Gram-Positive			1 (0)	
P. mirabilis	Pan Gram-Positive			5 (0)	
Pan *Candida*	Pan Gram-Positive			2 (0)	
Pan Gram-Positive	*S. maltophilia*			1 (0)	
Pan Gram-Positive	*S. marcescens*			3 (0)	

A.　A discrepant organism or resistance marker is defined as one that was detected by the BCID-GN Panel but not by the comparator method(s).
B.　24/26 false positive organisms were investigated using PCR/sequencing; the discrepant organism was detected in 21/24, not detected in 2, and was indeterminate for one organism.
　　i.　In 1/1 false positive *A.baumannii* sample, *A. baumannii* was detected.
　　ii.　In 2/2 false positive *B. fragilis* samples, *B. fragilis* was detected.
　　iii.　In 1/1 false positive *Citrobacter* sample, *Citrobacter* was detected.
　　iv.　In the one false positive *E. cloacae* complex sample, PCR/sequencing was indeterminate.
　　v.　In 1/1 false positive K. oxytoca sample, K. oxytoca was detected.
　　vi.　In 3/3 false positive *K. pneumoniae* group samples, *K. pneumoniae* group was detected.
　　vii.　In 1/1 false positive sample, *M. morganii* was detected.
　　viii.　*N. meningitidis* was not detected in the 1 *N. meningitidis* false positive sample.
　　ix.　In 2/3 false positive *P. aeruginosa* samples, *P. aeruginosa* was detected. *P. aeruginosa* was not detected in the remaining sample.
　　x.　In 1/1 false positive pan *Candida* sample, Pan *Candida* was detected.
　　xi.　In 8/8 false positive Pan Gram-Positive samples, a Pan Gram-Positive organism was detected.
　　xii.　In 1/1 false positive *S. marcescens* sample, *S. marcescens* was detected.

Table 54: Additional Co-Detections Identified by the Comparator Method(s) (Prospective Samples)

Distinct Co-Detection Combinations Detected by the Comparator Method(s) in Prospective Clinical Samples					Number Samples (Number Discrepant)	Discrepant Organism(s) / Resistance Marker(s)[A]
Target 1	**Target 2**	**Target 3**	**Target 4**	**Resistance Marker**		
A. baumannii	*E. faecium*	*Staphylococcus*			1 (0)	
A. baumannii	*Staphylococcus*				1 (0)	
*Achromobacter xylosoxidans**	*E. cloacae*				1 (0)	

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Distinct Co-Detection Combinations Detected by the Comparator Method(s) in Prospective Clinical Samples					Number Samples (Number Discrepant)	Discrepant Organism(s) / Resistance Marker(s)[A]
Target 1	**Target 2**	**Target 3**	**Target 4**	**Resistance Marker**		
Acinetobacter lwoffii*	*Staphylococcus hominis*				1 (0)	
Acinetobacter pittii*	*S. aureus*				1 (0)	
Aerococcus viridans*	*K. oxytoca*	*S. epidermidis*	*Staphylococcus cohnii*		1 (0)	
Aerococcus viridans*	*Staphylococcus hominis*				1 (0)	
B. fragilis	*Clostridium species**				1 (0)	
Bacillus	*E. cloacae*				1 (0)	
C. acnes*	*E. coli*				1 (0)	
C. albicans	*E. cloacae*	*E. faecalis*			1 (0)	
C. freundii	*P. mirabilis*	*Providencia stuartii**			1 (0)	
Candida lusitaniae*	*S. liquefaciens*				1 (0)	
Citrobacter amalonaticus*	*E. coli*				1 (0)	
E. aerogenes	*K. oxytoca*	*Leclercia adecarboxylata**			2 (2)	*E. aerogenes* (2)
E. aerogenes	*P. aeruginosa*				1 (1)	*P. aeruginosa* (1)
E. cloacae	*E. coli*	*K. pneumoniae*			1 (0)	
E. cloacae	*S. aureus*				1 (0)	
E. coli	*E. faecalis*				1 (0)	
E. coli	*K. pneumoniae*				1 (1)	*E. coli* (1)
E. coli	*P. mirabilis*	*Providencia stuartii**	*S. anginosus* group	CTX-M	1 (1)	*E. coli* (1)
E. faecalis	*K. pneumoniae*				3 (1)	*E. faecalis* (1)
E. faecalis	*M. morganii*	*P. mirabilis*			1 (1)	*E. faecalis* (1)
E. faecalis	*Providencia stuartii**				1 (0)	
Enterobacteriaceae*	*K. pneumoniae*				1 (0)	

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Distinct Co-Detection Combinations Detected by the Comparator Method(s) in Prospective Clinical Samples					Number Samples (Number Discrepant)	Discrepant Organism(s) / Resistance Marker(s)[A]
Target 1	**Target 2**	**Target 3**	**Target 4**	**Resistance Marker**		
K. pneumoniae	*Staphylococcus haemolyticus*	non-fermenting Gram-Negative bacilli*			1 (1)	*K. pneumoniae* (1)
*Lactococcus lactis**	*P. mirabilis*				1 (0)	
*Micrococcus luteus**	*Sphingomonas paucimobilis**				1 (0)	
P. aeruginosa	*P. mirabilis*	*Streptococcus - viridans* group			1 (0)	
P. aeruginosa	*S. maltophilia*				1 (1)	*S. maltophilia* (1)
P. aeruginosa	*Staphylococcus haemolyticus*				1 (0)	
P. mirabilis	*Staphylococcus*				1 (0)	
S. maltophilia	*Streptococcus*				1 (1)	*Streptococcus* (1)

* Indicates an off-panel organism not detected by the BCID-GN Panel.

A. A discrepant organism or resistance marker is defined as one that was detected by the comparator method(s) but not by the BCID-GN Panel (excludes organisms not detected by the BCID-GN panel).

Table 55: Additional Co-Detections Identified by the Comparator Method(s) (Retrospective Samples)

Distinct Co-Detection Combinations Detected by the Comparator Method(s) in Retrospective Clinical Samples					Number Samples (Number Discrepant)	Discrepant Organism(s) / Resistance Marker(s)[A]
Target 1	**Target 2**	**Target 3**	**Target 4**	**Resistance Marker**		
A. baumannii	*E. faecalis*			OXA	2 (0)	
A. baumannii	*E. faecalis*	*S. aureus*			1 (0)	
A. baumannii	*E. faecium*			OXA	1 (0)	
A. baumannii	*Staphylococcus*				1 (0)	
*Acinetobacter radioresistens**	*P. vulgaris*			OXA	1 (0)	
*Aeromonas caviae**	*E. coli*	*Enterococcus casseliflavus*	*K. oxytoca*		1 (1)	*E. casseliflavus* (1)
*Aeromonas veronii**	*E. cloacae*				1 (1)	*E. cloacae* (1)
B. fragilis	*S. anginosus* group				1 (0)	

Distinct Co-Detection Combinations Detected by the Comparator Method(s) in Retrospective Clinical Samples					Number Samples (Number Discrepant)	Discrepant Organism(s) / Resistance Marker(s)[A]
Target 1	**Target 2**	**Target 3**	**Target 4**	**Resistance Marker**		
C. albicans	*E. faecalis*				1 (0)	
C. albicans	*E. faecium*	*Staphylococcus hominis*			1 (1)	*C. albicans* (1)
C. albicans	*P. aeruginosa*				1 (1)	*C. albicans* (1)
C. albicans	*S. epidermidis*				1 (0)	
C. braakii	*E. cloacae*	*K. oxytoca*			1 (1)	*C. braakii* (1), *K. oxytoca* (1)
C. braakii	*E. coli*				1 (0)	
C. braakii	*Streptococcus oralis*				1 (0)	
C. freundii	*Enterococcus*				1 (1)	*Enterococcus* (1)
C. freundii	*K. pneumoniae*				2 (0)	
C. freundii	*K. pneumoniae*	*Staphylococcus hominis*		CTX-M	1 (0)	
C. glabrata	*E. aerogenes*	*Staphylococcus*			1 (1)	*Staphylococcus* (1)
C. glabrata	*P. mirabilis*				1 (1)	*C. glabrata* (1)
C. koseri	*E. faecalis*				1 (0)	
C. krusei	*S. epidermidis*				1 (1)	*S. epidermidis* (1)
C. youngae	*K. oxytoca*				1 (1)	*K. oxytoca* (1)
*Clostridium perfringens**	*E. coli*				1 (0)	
E. aerogenes	*S. anginosus* group				1 (0)	
E. cloacae	*E. coli*				1 (1)	*E. coli* (1)
E. cloacae	*E. faecalis*				1 (1)	*E. faecalis* (1)
E. cloacae	*E. faecium*				1 (0)	
E. cloacae	*E. faecium*	*Staphylococcus hominis*			1 (0)	
E. cloacae	*K. pneumoniae*				1 (0)	
E. cloacae	*M. morganii*				1 (1)	*E. cloacae* (1)
E. cloacae	*S. anginosus* group				1 (0)	
E. cloacae	*S. maltophilia*				1 (1)	*S. maltophilia* (1)
E. coli	*E. faecalis*				2 (0)	

Distinct Co-Detection Combinations Detected by the Comparator Method(s) in Retrospective Clinical Samples					Number Samples (Number Discrepant)	Discrepant Organism(s) / Resistance Marker(s)[A]
Target 1	**Target 2**	**Target 3**	**Target 4**	**Resistance Marker**		
E. coli	*E. faecalis*			CTX-M	1 (0)	
E. coli	*E. faecalis*	*K. pneumoniae*			1 (1)	*E. coli* (1)
E. coli	*E. faecalis*	*P. mirabilis*			1 (0)	
E. coli	*E. faecium*				1 (0)	
E. coli	*E. faecium*			CTX-M	1 (1)	*E. faecium* (1)
E. coli	*K. oxytoca*	*Streptococcus infantarius*			1 (0)	
E. coli	*P. aeruginosa*				1 (1)	*P. aeruginosa* (1)
E. coli	*P. mirabilis*				1 (1)	*E. coli* (1)
E. coli	*P. mirabilis*	*P. vulgaris*	*Streptococcus - viridans* group		1 (1)	*S. viridans* group (1)
E. coli	*Propionibacteria**				1 (0)	
E. coli	*S. anginosus gp*				1 (1)	*S. anginosus* group (1)
E. coli	*S. aureus*				1 (0)	
E. coli	*S. pneumoniae*				1 (0)	
E. coli	*Staphylococcus*				1 (0)	
E. faecalis	*K. pneumoniae*				1 (1)	*K. pneumoniae* (1)
E. faecalis	*M. morganii*				1 (0)	
E. faecalis	*M. morganii*	*P. vulgaris*			1 (0)	
E. faecalis	*P. aeruginosa*	*S. aureus*			1 (1)	*P. aeruginosa* (1)
E. faecalis	*P. mirabilis*				3 (0)	
E. faecalis	*S. maltophilia*				1 (1)	*E. faecalis* (1)
E. faecalis	*S. marcescens*				1 (0)	
E. faecium	*K. pneumoniae*				1 (0)	
E. faecium	*P. aeruginosa*				1 (0)	
E. faecium	*P. mirabilis*				1 (0)	
K. oxytoca	*S. anginosus* group				1 (0)	
K. pneumoniae	*P. aeruginosa*				1 (1)	*P. aeruginosa* (1)
K. pneumoniae	*S. aureus*				2 (1)	*S. aureus* (1)

Distinct Co-Detection Combinations Detected by the Comparator Method(s) in Retrospective Clinical Samples					Number Samples (Number Discrepant)	Discrepant Organism(s) / Resistance Marker(s)[A]
Target 1	**Target 2**	**Target 3**	**Target 4**	**Resistance Marker**		
K. pneumoniae	*Staphylococcus*				1 (1)	*Staphylococcus* (1)
P. aeruginosa	*S. maltophilia*				1 (1)	S. maltophilia (1)
P. mirabilis	*Peptostreptococcus anaerobius**				1 (0)	
P. mirabilis	*Providencia stuartii**				2 (1)	*P. mirabilis* (1)
P. mirabilis	*Staphylococcus*				1 (0)	
*Pseudomonas putida**	*S. epidermidis*	*S. maltophilia*			1 (0)	
S. aureus	*S. marcescens*				1 (0)	
S. marcescens	*Staphylococcus*				1 (0)	
S. marcescens	*Streptococcus mitis* group	*Streptococcus salivarius*			1 (0)	

* Indicates an off-panel organism not detected by the BCID-GN Panel.

A. A discrepant organism or resistance marker is defined as one that was detected by the comparator method(s) but not by the BCID-GN Panel (excludes organisms not detected by the BCID-GN panel).

Clinical Study ePlex Instrument Performance

A total of 2460 samples (including prospective, retrospective, and contrived samples) were initially tested in the clinical evaluations. Of these, 23/2460 (0.9%) did not complete the run and the sample was retested. After repeat testing, all 2460 samples completed testing and 2334/2460 (94.9%, 95% CI: 93.9%-95.7%) generated valid results and 126/2460 (5.1%, 95% CI: 4.3%-6.1%) generated invalid results on the first completed attempt.

Upon repeat testing of the 126 samples with initially invalid results, 1/126 (0.8%) did not complete the run and the sample was retested. After repeat testing, all 126 samples completed testing and 114/126 (90.5%) generated valid results. Overall, after final testing, 12/2460 (0.5%, 95% CI: 0.3%-0.9%) had final, invalid results, resulting in a final validity rate of 2448/2460 (99.5%, 95% CI: 99.1%-99.7%).

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ANALYTICAL PERFORMANCE CHARACTERISTICS
Limit of Detection (LoD)

The limit of detection (LoD), or analytical sensitivity, was identified and verified for each target on the BCID-GN Panel using 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 ≥95% of tested replicates. The confirmed LoD for each ePlex BCID-GN Panel organism is shown in **Table 56**.

Table 56: LoD Results Summary

Target	Organism	Strain	LoD Concentration (CFU/mL)
Acinetobacter baumannii	*Acinetobacter baumannii*	NCTC 13421	1×10^6
	Acinetobacter baumannii	NCTC 13304	1×10^6
Bacteroides fragilis	*Bacteroides fragilis*	ATCC 25285	1×10^5
	Bacteroides fragilis	ATCC 43860	1×10^4
Citrobacter	*Citrobacter freundii*	NCTC 9750	1×10^6
	Citrobacter koseri	ATCC 27156	1×10^6
Cronobacter sakazakii	*Cronobacter sakazakii*	ATCC 29544	1×10^5
	Cronobacter sakazakii	ATCC 29004	1×10^6
Enterobacter (non-*cloacae* complex)	*Enterobacter aerogenes*	CDC#0074	1×10^6
	Enterobacter aerogenes	CDC#0161	1×10^5
	Enterobacter amnigenus	ATCC 33072	1×10^6
Enterobacter cloacae Complex	*Enterobacter cloacae*	CDC#0154	1×10^6
	Enterobacter asburiae	ATCC 35957	1×10^6
	Enterobacter hormaechei	ATCC BAA-2082	1×10^6
Escherichia coli	*Escherichia coli*	CDC#0118	1×10^7
	Escherichia coli	NCTC 13441	1×10^6
	Escherichia coli	JHU01-D80401147	1×10^7

Target	Organism	Strain	LoD Concentration (CFU/mL)
Fusobacterium necrophorum	*Fusobacterium necrophorum*	ATCC 51357	1×10^8
	Fusobacterium necrophorum	ATCC 27852	1×10^7
Fusobacterium nucleatum	*Fusobacterium nucleatum*	ATCC 25586	1×10^7
	Fusobacterium nucleatum	ATCC 23726	1×10^5
Haemophilus influenzae	*Haemophilus influenzae*	ATCC 19418	1×10^5
	Haemophilus influenzae	ATCC 9006	1×10^7
	Haemophilus influenzae	ATCC 33930	1×10^4
Klebsiella oxytoca	*Klebsiella oxytoca*	ATCC 43165	1×10^7
	Klebsiella oxytoca	ATCC 8724	1×10^7
Klebsiella pneumoniae group	*Klebsiella pneumoniae*	CDC#0160	1×10^6
	Klebsiella pneumoniae	CDC#0107	1×10^6
Morganella morganii	*Morganella morganii*	ATCC 25829	1×10^7
	Morganella morganii	CDC#0133	1×10^7
Neisseria meningitidis	*Neisseria meningitidis*	ATCC 13090	1×10^5
	Neisseria meningitidis	ATCC 13102	1×10^4
	Neisseria meningitidis	NCTC 10026	1×10^4
Proteus	*Proteus vulgaris*	ATCC 6896	1×10^7
	Proteus vulgaris	ATCC 6380	1×10^7
Proteus mirabilis	*Proteus mirabilis*	CDC#0159	1×10^6
	Proteus mirabilis	ATCC 43071	1×10^6
Pseudomonas aeruginosa	*Pseudomonas aeruginosa*	CDC#0103	1×10^6
	Pseudomonas aeruginosa	NCTC 13437	1×10^6
	Pseudomonas aeruginosa	SDx071	1×10^5
Salmonella	*Salmonella bongori*	ATCC 43975	1×10^5
	Salmonella enterica	ATCC 6962	1×10^5
Serratia	*Serratia liquefaciens*	ATCC 27592	1×10^6
	Serratia plymuthica	ATCC 53858	1×10^7
Serratia marcescens	*Serratia marcescens*	ATCC 14041	1×10^7
	Serratia marcescens	ATCC 14756	1×10^5
Stenotrophomonas maltophilia	*Stenotrophomonas maltophilia*	ATCC 13637	1×10^6
	Stenotrophomonas maltophilia	ATCC 17666	1×10^7

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Target	Organism	Strain	LoD Concentration (CFU/mL)
Pan Candida	*Candia albicans*	ATCC 10231	1×10^6
	Candia glabrata	ATCC 15126	1×10^5
Pan Gram-Positive	*Enterococcus faecalis*	ATCC 51575	1×10^5
	Enterococcus faecium	ATCC 31282	1×10^7
	Bacillus subtilis	ATCC 21008	1×10^6
	Staphylococcus aureus	ATCC BAA-2313	1×10^5
	Streptococcus agalactiae	ATCC 13813	1×10^6
	Streptococcus anginosus	ATCC 33397	1×10^6
CTX-M	*Escherichia coli* (CTX-M-15)	NCTC 13441	1×10^4
	Klebsiella pneumoniae (CTX-M-2)	CDC#0107	1×10^5
IMP	*Enterobacter aerogenes* (IMP-4)	CDC#0161	1×10^6
	Pseudomonas aeruginosa (IMP-1)	CDC#0103	1×10^5
KPC	*Enterobacter hormaechei* (KPC variant not known)	ATCC BAA-2082	1×10^6
	Morganella morganii (KPC-2)	CDC#0133	1×10^6
NDM	*Escherichia coli* (NDM-1)	CDC#0118	1×10^5
	Proteus mirabilis (NDM-1)	CDC#0159	1×10^5
OXA	*Acinetobacter baumannii* (OXA-23)	NCTC 13421	1×10^5
	Acinetobacter baumannii (OXA-27)	NCTC 13304	1×10^5
	Enterobacter aerogenes (OXA-48)	CDC#0074	1×10^6
	Klebsiella pneumoniae (OXA-48)	CDC#0160	1×10^6
VIM	*Enterobacter cloacae* (VIM-1)	CDC#0154	1×10^6
	Pseudomonas aeruginosa (VIM-10)	NCTC 13437	1×10^5

Analytical Reactivity (Inclusivity)

A panel of 336 strains/isolates representing the genetic, temporal and geographic diversity of each target on the ePlex BCID-GN Panel was evaluated to demonstrate analytical reactivity. Bacteria were tested at 1×10^9 CFU/mL or less and fungal strains were tested at 1×10^6 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 concentration of these strains). Organisms detected are shown in **Table 57**. Additional strains were detected as part of the **Limit of Detection (Analytical Sensitivity)** Study and can be found in **Table 56**. *Citrobacter* strains that were tested but not detected include the following: *C. amalonaticus*, *C. farmer*, *C. gillenii*, *C. murliniae*, and *C. sedlakii*. *Serratia odorifera* and *Staphylococcus simulans* were not detected at concentrations of 1×10^8 CFU/mL and only one of three replicates were detected at concentrations of 1×10^9 CFU/mL.

Table 57: Analytical Reactivity (Inclusivity)

Organism	Strain
Acinetobacter baumannii	
Acinetobacter baumannii	CDC#0052
	NCTC 13302
	NCTC 13303
	NCTC 13305
	NCTC 13420
	NCTC 13422
	NCTC 13423
Acinetobacter baumannii (NDM-1)	CDC#0033
Acinetobacter baumannii (OXA-23)	ATCC BAA-1605
	CDC#0045
	CDC#0056
	NCTC 13301
	NCTC 13424
Acinetobacter spp. (IMP only)	JMI4084[A]
Bacteroides fragilis	
Bacteroides fragilis	ATCC 23745
	ATCC 700786
	NCTC 9343
Citrobacter	
Citrobacter braakii	ATCC 43162
	ATCC 51113
Citrobacter freundii	ATCC 6879
	ATCC 8090
Citrobacter freundii (CTX)	JMI2047
Citrobacter freundii (KPC-2)	CDC#0116
Citrobacter koseri	ATCC 25409
	ATCC 27028
	ATCC 29225
	ATCC 29936
Citrobacter species (CTX-15, NDM-1)	CDC #0157
Citrobacter werkmanii	ATCC 51114
Citrobacter youngae	ATCC 29935

Organism	Strain
Cronobacter sakazakii	
Cronobacter sakazakii	ATCC 12868
	ATCC BAA-894
	FSL F6-0023
***Enterobacter* (non-cloacae complex)**	
Enterobacter aerogenes	ATCC 13048
	ATCC 29010
	ATCC 51697
Enterobacter amnigenus	ATCC 33731
	ATCC 51816[B]
Enterobacter gergoviae	ATCC 33028
	ATCC 33426
***Enterobacter cloacae* complex**	
Enterobacter asburiae	ATCC 35954
	ATCC 35955
	ATCC 35956
Enterobacter cloacae (CTX-15)	CDC#0038
Enterobacter cloacae (CTX-9)	NCTC 13464
Enterobacter cloacae (CTX-15, KPC-2)	CDC#0163
Enterobacter cloacae (CTX, NDM)	JMI53571
Enterobacter cloacae subsp. *cloacae*	ATCC 23355
	ATCC 35030
Enterobacter cloacae subsp. *dissolvens*	ATCC 23373
Enterobacter hormaechei	ATCC 700323
Enterobacter hormaechei subsp. *hormaechei*	ATCC 49162
Enterobacter hormaechei subsp. *oharae*	ATCC 49163
Enterobacter hormaechei subsp. *steigerwaltii*	CIP108489T
Enterobacter ludwigii	DSM-16688
Escherichia coli	
Escherichia coli	ATCC 14948
	ATCC 25922
	ATCC 33605
	ATCC 33876
	ATCC 35150
	ATCC 4157

Organism	Strain
	ATCC 43888
	ATCC 51446
	ATCC 51755
	ATCC 53498
	ATCC 700728
	NCIMB 8545
	NCTC 8620
	ATCC 9637
	ATCC BAA-196
	ATCC BAA-197
	ATCC BAA-198
	ATCC BAA-199
	ATCC BAA-200
	ATCC BAA-201
	ATCC BAA-202
	ATCC BAA-203
	ATCC BAA-204
	LMC_243094647
	LMC_243098776
	LMC_243098947
	LMC_243108047
	LMC_243109799
	LMC_243112411
	LMC_244006281
	LMC_244006433
	LMC_244008038
	LMC_244012579
	NCTC 13351
	NCTC 10279
	ATCC 10536
	ATCC 10538
	ATCC 10799
	ATCC 11229
	ATCC 13762
	ATCC 14169
Escherichia coli (CTX-14)	CDC#0086
	ATCC BAA-2326
	NCTC 13353
Escherichia coli (CTX-15)	NCTC 13400
	NCTC 13450
	NCTC 13451
Escherichia coli (CTX-3)	NCTC 13452
Escherichia coli (CTX-1)	NCTC 13461
Escherichia coli (CTX-2)	NCTC 13462
Escherichia coli (CTX-8)	NCTC 13463
Escherichia coli (CTX-15, NDM-6)	CDC#0137
Escherichia coli (CTX-15, NDM-7)	CDC#0162
Escherichia coli (IMP)	NCTC 13476
Escherichia coli (KPC)	ATCC BAA-2340
Escherichia coli (NDM-5)	CDC#0150
Escherichia coli (OXA)	LMC_DR00012
Escherichia coli (VIM)	JMI32465
Fusobacterium necrophorum	
Fusobacterium necrophorum subsp. *necrophorum*	ATCC 25286
	NCTC 10575
	NCTC 10577
Fusobacterium nucleatum	
Fusobacterium nucleatum subsp. *nucleatum*	ATCC 31647
Fusobacterium nucleatum subsp. *fusiforme*	ATCC 51190

Organism	Strain
Fusobacterium nucleatum subsp. *vincentii*	ATCC 49256
Haemophilus influenzae	
	ATCC 33930
	ATCC 43065
Haemophilus influenzae	ATCC 43163
	NCTC 11931
	NCTC 12699
	NCTC 8143
Haemophilus influenzae Type b	ATCC 10211
Haemophilus influenzae Type c	ATCC 9007
Haemophilus influenzae Type d	ATCC 9332
Haemophilus influenzae Type e	NCTC 8472
Haemophilus influenzae Type f	ATCC 9833
Klebsiella oxytoca	
	ATCC 43086
	ATCC 43863
Klebsiella oxytoca	ATCC 49131
	ATCC 700324
	ATCC 51817
Klebsiella oxytoca (KPC-3)	CDC#0147
Klebsiella pneumoniae group	
Klebsiella pneumoniae (CTX-15)	CDC#0109
Klebsiella pneumoniae (CTX-25)	NCTC 13465
Klebsiella pneumoniae (CTX, KPC)	IMH-C2261309
Klebsiella pneumoniae (CTX, NDM-1)	NCTC 13443
Klebsiella pneumoniae (CTX-15; NDM-1; OXA-232)	CDC#0153
Klebsiella pneumoniae (CTX-15, OXA-232)	CDC#0075
	CDC#0066
	CDC#0039
Klebsiella pneumoniae (CTX-15, OXA-181)	CDC#0140
	CDC#0141
	CDC#0142
Klebsiella pneumoniae (IMP-4)	CDC#0034
	CDC#0080
	CDC#0125
Klebsiella pneumoniae (KPC-3)	CDC#0112
	CDC#0113
	ATCC BAA-1705
	IMH-C2260742
Klebsiella pneumoniae (KPC)	IMH-C3151729
	IMH-C4151728
	IMH-C4171868
Klebsiella pneumoniae (OXA-48)	NCTC 13442
Klebsiella pneumoniae (CTX-15; VIM-27)	CDC#0040
	CDC#0135
Klebsiella pneumoniae (VIM-1)	NCTC 13439
	NCTC 13440
Klebsiella pneumoniae subsp. *Ozaenae*	ATCC 11296
	ATCC 13883
Klebsiella pneumoniae subsp. *pneumoniae*	ATCC 27736
	ATCC 51503
	ATCC 51504
Klebsiella quasipneumoniae	ATCC 700603
Klebsiella pneumoniae subsp. *rhinoscleromatis*	ATCC 9436
Klebsiella variicola	ATCC BAA-830
Morganella morganii	
Morganella morganii	ATCC 25830
	GM148-209

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Organism	Strain
Morganella morganii (CTX-15; NDM-1)	CDC#0057[C]
Neisseria meningitidis	
Neisseria meningitidis Serotype A	ATCC 13077
Neisseria meningitidis Serotype B	NCTC 10026
Neisseria meningitidis Serotype W135	NCTC 11203
Neisseria meningitidis Serotype Y	ATCC 35561
Proteus	
Proteus hauseri	ATCC 13315
Proteus mirabilis	ATCC 33583
	ATCC BAA-663
Proteus mirabilis (IMP)	JMI955389
Proteus mirabilis (KPC-6)	CDC#0155
Proteus penneri	ATCC 35197
Proteus vulgaris	ATCC 33420
	ATCC 49132
	ATCC 8427
	NCTC 4636
Pseudomonas aeruginosa	
Pseudomonas aeruginosa (IMP-14)	CDC#0092
Pseudomonas aeruginosa (IMP-1)	CDC#0241
Pseudomonas aeruginosa (IMP)	CDC#0439
Pseudomonas aeruginosa (KPC-5)	CDC#0090
Pseudomonas aeruginosa (VIM-2)	CDC#0100
Pseudomonas aeruginosa (VIM-4)	CDC#0054
Salmonella	
Salmonella enterica serovar 4,[5],12:i	FSL S5-0580
Salmonella enterica serovar Agona	ATCC 51957
Salmonella enterica serovar Bareilly	ATCC 9115
Salmonella enterica serovar Braenderup	ATCC 700136
Salmonella enterica serovar Enteritidis	ATCC BAA-708
Salmonella enterica serovar Hadar	ATCC 51956
Salmonella enterica serovar Heidelberg	ATCC 8326
Salmonella enterica serovar Infantis	ATCC BAA-1675
Salmonella enterica serovar Javiana	ATCC 10721
Salmonella enterica serovar Montevideo	ATCC 8387
Salmonella enterica serovar Muenchen	ATCC 8388
Salmonella enterica serovar Oranienburg	ATCC 9239
Salmonella enterica serovar Paratyphi B	FSL S5-0447
Salmonella enterica serovar Saintpaul	ATCC 9712
Salmonella enterica serovar Thompson	ATCC 8391
Salmonella enterica serovar Typhi	ATCC 19430
Salmonella enterica subsp. *arizonae*	ATCC 13314
Salmonella enterica subsp. *diarizonae*	ATCC 12325
Salmonella enterica subsp. *enterica* serovar Typhimurium	ATCC 14028
Salmonella enterica subsp. *houtenae*	ATCC 29834
Salmonella enterica subsp. *indica*	ATCC BAA-1578
Salmonella enterica subsp. *salamae*	ATCC 6959
Salmonella enterica subsp. *enterica* serovar Mississippi	FSL A4-0633
Salmonella enterica subsp. *enterica* serovar Schwarzengrund	FSL S5-0458
Serratia	
Serratia ficaria	ATCC 33105
Serratia fonticola	ATCC 29844
Serratia grimesii	ATCC 14460
Serratia marcescens	ATCC 13880
	ATCC 43861
	ATCC 43862
Serratia marcescens (CTX)	JMI10244

Organism	Strain
Serratia rubidaea	ATCC 27593
	ATCC 29025
Stenotrophomonas maltophilia	
Stenotrophomonas maltophilia	ATCC 13636
	GM148-207
	GM148-208
Pan-Gram Positive	
Bacillus amyloliquefaciens	ATCC 23845
Bacillus atrophaeus	ATCC 49337
Bacillus cereus	ATCC 10876
Bacillus licheniformis	ATCC 21039
Bacillus thuringiensis	ATCC 35646
Enterococcus avium	ATCC 14025
Enterococcus casseliflavus	ATCC 700327
Enterococcus faecalis	JMI876745
Enterococcus gallinarum	ATCC 49573
Enterococcus hirae	ATCC 49479
Enterococcus raffinosus	ATCC 49464
Enterococcus saccharolyticus	ATCC 43076[D]
Staphylococcus capitis	NRS866
Staphylococcus chromogenes	ATCC 43764
Staphylococcus cohnii	ATCC 29974
Staphylococcus epidermidis	ATCC 35984
Staphylococcus gallinarum	ATCC 700401
Staphylococcus haemolyticus	ATCC 29970
Staphylococcus hominis	ATCC 27844
Staphylococcus hyicus	ATCC 11249
Staphylococcus lentus	ATCC 700403
Staphylococcus lugdunensis	ATCC 49576
Staphylococcus pasteuri	ATCC 51128
Staphylococcus vitulinus	ATCC 51699
Streptococcus constellatus	ATCC 27513
Streptococcus dysgalactiae	ATCC 35666
Streptococcus equi	ATCC 9528
Streptococcus gallolyticus	ATCC 9809
Streptococcus gordonii	ATCC 35557
Streptococcus infantis	ATCC 700779
Streptococcus intermedius	ATCC 27335
Streptococcus mitis	ATCC 49456
Streptococcus oralis	ATCC 35037
Streptococcus parasanguinis	ATCC 15909
Streptococcus pneumoniae	ATCC 8335
Streptococcus pyogenes	ATCC 12344
Streptococcus salivarius	ATCC 7073
Streptococcus thoraltensis	ATCC 700865[E]
Pan Candida	
Candida albicans	ATCC 24433
	ATCC 90028
Candida glabrata	ATCC 2001
	ATCC 66032
Candida krusei	ATCC 14243
	ATCC 32196
	ATCC 34135[F]
Candida parapsilosis	ATCC 22019
	ATCC 58895
	ATCC 90018[G]

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A. Non-target species used to evaluate resistance marker.
B. 5/6 replicates detected at 2.0 x 10^8 CFU/mL.
C. 5/6 replicates detected at 4.5 x 10^8 CFU/mL.
D. Strain may have reduced sensitivity and was not 100% detected at concentrations <1 x 10^8 CFU/mL.
E. Strain may have reduced sensitivity and was not 100% detected at concentrations <4 x 10^8 CFU/mL.
F. In initial testing, 1/6 replicates was detected at 1x 10^6 CFU/mL; during additional testing, 3/3 replicates detected at bottle positivity.
G. In initial testing, 2/6 replicates were detected at 1 x 10^6 CFU/mL; during additional testing, 6/6 replicates detected at bottle positivity.

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

In addition to species-specific assays, the ePlex BCID-GN Panel contains a number of broader genus or group-level assays including: *Citrobacter*, *Enterobacter cloacae* complex, *Enterobacter* (non-*cloacae* complex), *Klebsiella pneumoniae* group, *Proteus, Serratia*, Pan *Candida*, and Pan Gram-Positive assays. **Tables 58-65** highlight the-predicted (*in silico*) reactivity (inclusivity) for these assay targets.

Note: the performance of the ePlex BCID-GN Panel has not been established for all of the organisms listed in the tables below. See the Analytical Reactivity section for data on organisms for which performance characteristics have been established (indicated with an asterisk in **Tables 58-65**). Some species were not assessed *in silico* due to lack of sequence data, though they may appear in the analytical sensitivity or specificity studies.

Table 58: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Citrobacter*

Detection Predicted for ≥95% of target sequences		
*Citrobacter koseri**	*Citrobacter intermedius*	
Detection Predicted for 85%-94% of target sequences		
*Citrobacter freundii**	*Citrobacter braakii**	
Detection Predicted for <85.0% of target sequences		
*Citrobacter werkmanii** (66.7%)	*Citrobacter youngae** (50.0%)	
Detection Not Predicted		
Citrobacter europaeus	*Citrobacter gillenii*	*Citrobacter amalonaticus*[A]
Citrobacter farmeri	*Citrobacter sedlakii*	*Citrobacter murliniae*

A.   Detection predicted *in silico*, however ATCCBAA-2563 was not detected in wet testing.

Table 59: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Enterobacter cloacae* complex

Detection Predicted for ≥95% of target sequences		
Enterobacter cloacae*	*Enterobacter asburiae**	*Enterobacter hormaechei**
Enterobacter xiangfangensis		
Detection Predicted for 85%-94% of target sequences		
None Identified		
Detection Predicted for <85.0% of target sequences		
Enterobacter ludwigii* (68.4%)	*Enterobacter nimipressuralis* (25.0%)	
Detection Not Predicted		
Enterobacter kobei	*Enterobacter cancerogenus*	

Table 60: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Enterobacter (*non-*cloacae* complex)

Detection Predicted for ≥95% of target sequences		
Enterobacter aerogenes*	*Enterobacter gergoviae**	
Detection Predicted for 85%-94% of target sequences		
None Identified		
Detection Predicted for <85.0% of target sequences		
Enterobacter amnigenus* (62.5%)		
Detection Not Predicted		
None Identified		

Table 61: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Klebsiella pneumoniae* Group

Detection Predicted for ≥95% of target sequences		
*Klebsiella pneumoniae**	*Klebsiella quasipneumoniae**	*Klebsiella variicola**
Detection Predicted for 85%-94% of target sequences		
None Identified		
Detection Predicted for <85.0% of target sequences		
None Identified		
Detection Not Predicted		
None Identified		

Table 62: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Proteus*

Detection Predicted for ≥95% of target sequences		
*Proteus mirabilis**	*Proteus penneri**	*Proteus vulgaris**
*Proteus hauseri**	*Proteus cibarius*	
Detection Predicted for 85%-94% of target sequences		
None Identified		
Detection Predicted for <85.0% of target sequences		
None Identified		
Detection Not Predicted		
Proteus myxofaciens		

Table 63: Predicted (*in silico*) Reactivity (Inclusivity) Results for S*erratia*

Detection Predicted for ≥95% of target sequences		
*Serratia marcescens**	*Serratia grimesii**	*Serratia rubidaea**
*Serratia ficaria**	*Serratia liquefaciens**	*Serratia proteamaculans*
*Serratia fonticola**	*Serratia plymuthica**	
Detection Predicted for 85%-94% of target sequences		
None Identified		
Detection Predicted for <85.0% of target sequences		
Serratia quinivorans (33.3%)		
Detection Not Predicted		
Serratia nematodiphila	*Serratia odorifera*[A]*	*Serratia ureilytica*

B. Not predicted *in silico,* however ATCC 33077 was intermittently detected in wet testing. See **Analytical Reactivity (Inclusivity) Study**.

Table 64: Predicted (*in silico*) Reactivity (Inclusivity) Results for Pan *Candida*

Detection Predicted for ≥95% of target sequences		
*Candida albicans**	*Candida glabrata**	*Candida krusei**
*Candida parapsilosis**		
Detection Predicted for 85%-94% of target sequences		
None Identified		
Detection Predicted for <85% of target sequences		
None Identified		
Detection Not Predicted		
Detection was not predicted by bioinformatic analysis for other *Candida* species for which sequence data was available.		

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Table 65: Predicted (*in silico*) Reactivity (Inclusivity) Results for Pan Gram-Positive

Detection Predicted for ≥95% of target sequences		
Bacillus		
Bacillus amyloliquefaciens*	Bacillus paralicheniformis	Bacillus toyonensis
Bacillus atrophaeus*	Bacillus siamensis	Bacillus vallismortis
Bacillus bombysepticus	Bacillus subtilis*	Bacillus velezensis
Bacillus licheniformis*	Bacillus tequilensis	Bacillus weihenstephanensis
Bacillus methylotrophicus	Bacillus thuringiensis*	
Enterococcus		
Enterococcus avium*	Enterococcus faecium*	Enterococcus raffinosus*
Enterococcus dispar	Enterococcus flavescens	Enterococcus saccharolyticus*
Enterococcus durans	Enterococcus malodoratus	Enterococcus thailandicus
Enterococcus faecalis*	Enterococcus pseudoavium	
Staphylococcus		
Staphylococcus aureus*	Staphylococcus haemolyticus*	Staphylococcus pseudintermedius
Staphylococcus agnetis	Staphylococcus hominis*	Staphylococcus pseudolugdunensis
Staphylococcus argensis	Staphylococcus hominis subsp. novobiosepticus	Staphylococcus pulvereri
Staphylococcus argenteus	Staphylococcus hyicus*	Staphylococcus rostri
Staphylococcus auricularis	Staphylococcus jettensis	Staphylococcus saprophyticus
Staphylococcus capitis*	Staphylococcus kloosii	Staphylococcus schleiferi
Staphylococcus caprae	Staphylococcus lentus*	Staphylococcus schweitzeri
Staphylococcus carnosus	Staphylococcus lugdunensis*	Staphylococcus sciuri
Staphylococcus chromogenes*	Staphylococcus lutrae	Staphylococcus simiae
Staphylococcus cohnii*	Staphylococcus massiliensis	Staphylococcus simulans
Staphylococcus delphini	Staphylococcus microti	Staphylococcus stepanovicii
Staphylococcus devriesei	Staphylococcus muscae	Staphylococcus succinus
Staphylococcus epidermidis*	Staphylococcus nepalensis	Staphylococcus vitulinus*
Staphylococcus equorum	Staphylococcus pasteuri*	Staphylococcus warneri
Staphylococcus felis	Staphylococcus petrasii	Staphylococcus xylosus
Staphylococcus fleurettii	Staphylococcus pettenkoferi	
Staphylococcus gallinarum*	Staphylococcus piscifermentans	
Streptococcus		
Streptococcus agalactiae	Streptococcus infantarius	Streptococcus phocae
Streptococcus alactolyticus	Streptococcus infantis*	Streptococcus pneumoniae*
Streptococcus anginosus	Streptococcus intermedius*	Streptococcus porcinus

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Streptococcus australis	Streptococcus intestinalis	Streptococcus porcorum
Streptococcus caballi	Streptococcus lactarius	Streptococcus pseudopneumoniae
Streptococcus constellatus	Streptococcus loxodontisalivarius	Streptococcus pseudoporcinus
Streptococcus criceti	Streptococcus luteciae	Strepotococcus pyogenes
Streptococcus cristatus	Streptococcus lutetiensis	Streptococcus rifensis
Streptococcus danieliae	Streptococcus macedonicus	Streptococcus rubneri
Streptococcus dentasini	Streptococcus marimammalium	Streptococcus salivarius*
Streptococcus dentisani	Streptococcus massiliensis	Streptococcus saliviloxodontae
Streptococcus didelphis	Streptococcus mitis*	Streptococcus sanguinis
Streptococcus difficilis	Streptococcus moroccensis	Streptococcus seminale
Streptococcus dysgalactiae subsp. dysgalactiae	Streptococcus oligofermentans	Streptococcus sinensis
Streptococcus dysgalactiae subsp. equisimilis	Streptococcus oralis*	Streptococcus suis
Streptococcus dysgalactiae*	Streptococcus oricebi	Streptococcus thermophilus
Streptococcus equi*	Streptococcus orisratti	Streptococcus thoraltensis*
Streptococcus equinus	Streptococcus panodentis	Streptococcus tigurinus
Streptococcus fryi	Streptococcus parasanguinis*	Streptococcus troglodytae
Streptococcus gallolyticus*	Streptococcus parasuis	Streptococcus troglodytidis
Streptococcus gordonii*	Streptococcus parauberis	Streptococcus urinalis
Streptococcus himalayensis	Streptococcus pasteuri	Streptococcus ursoris
Streptococcus hongkongensis	Streptococcus pasteurianus	Streptococcus vestibularis
Streptococcus hyointestinalis	Streptococcus peroris	Streptococcus waiu
Detection Predicted for 85%-94% of target sequences		
Bacillus cereus*	Enterococcus hirae*	Staphylococcus saccharolyticus
Enterococcus casseliflavus*	Staphylococcus arlettae	Streptococcus bovis
Enterococcus cecorum	Staphylococcus condimenti	Streptococcus uberis
Enterococcus gallinarum	Staphylococcus intermedius	
Detection Predicted for <85.0% of target sequences		
Bacillus mojavensis (77.8%)	Bacillus sonorensis (83.3%)	Streptococcus halichoeri (66.7%)
Streptococcus ratti (75.0%)		
Detection Not Predicted		
Bacillus pseudomycoides	Enterococcus sulfureus	Streptococcus hyovaginalis
Enterococcus aquimarinus	Enterococcus termitis	Streptococcus ictaluri
Enterococcus asini	Enterococcus ureasiticus	Streptococcus iniae
Enterococcus caccae	Enterococcus ureilyticus	Streptococcus lactis
Enterococcus camelliae	Enterococcus villorum	Streptococcus macacae

Enterococcus canintestini	*Staphylococcus caseolyticus*	*Streptococcus marmotae*
Enterococcus canis	*Streptococcus acidominimus*	*Streptococcus merionis*
Enterococcus columbae	*Streptococcus azizii*	*Streptococcus milleri*
Enterococcus devriesei	*Streptococcus cameli*	*Streptococcus minor*
Enterococcus haemoperoxidus	*Streptococcus canis*	*Streptococcus oriloxodontae*
Enterococcus hawaiiensis	*Streptococcus castoreus*	*Streptococcus orisasini*
Enterococcus hermanniensis	*Streptococcus cremoris*	*Streptococcus orisuis*
Enterococcus italicus	*Streptococcus criae*	*Streptococcus ovis*
Enterococcus mundtii	*Streptococcus cuniculi*	*Streptococcus pharyngis*
Enterococcus pallens	*Streptococcus dentapri*	*Streptococcus pluranimalium*
Enterococcus pernyi	*Streptococcus dentiloxodontae*	*Streptococcus plurextorum*
Enterococcus phoeniculicola	*Streptococcus dentirousetti*	*Streptococcus plutanimalium*
Enterococcus plantarum	*Streptococcus devriesei*	*Streptococcus porci*
Enterococcus quebecensis	*Streptococcus downei*	*Streptococcus rupicaprae*
Enterococcus ratti	*Streptococcus entericus*	*Streptococcus sobrinus*
Enterococcus rivorum	*Streptococcus ferus*	*Streptococcus tangierensis*
Enterococcus rotai	*Streptococcus gallinaceus*	
Enterococcus silesiacus	*Streptococcus henryi*	

Predicted (*in silico*) Reactivity for Resistance Markers

The ePlex BCID-GN Panel contains six resistance markers that were each assessed for predicted *in silico* reactivity. **Tables 66-76** highlight the-predicted (*in silico*) reactivity for CTX-M, IMP, KPC, NDM, OXA, and VIM. Strains that were tested as part of the **Analytical Reactivity (Inclusivity) Study** are marked with an asterisk in **Tables 66-76**. **It is noted that the performance of the ePlex BCID-GN Panel has not been established for all organisms listed in Tables 66-76**. **Table 77** includes all variants that are not predicted to be detected by the BCID-GN Panel by *in silico* analysis.

The CTX-M assay on the ePlex BCID-GN Panel is designed to detect the following CTX-M groups: CTX-M-1, CTX-M-2, CTX-M-8, CTX-M-9, and CTX-M-25.

Table 66: Predicted (*in silico*) Reactivity (Inclusivity) Results for CTX-M-1

Target	Associated Organism	Variant Detected	Target	Associated Organism	Variant Detected
Acinetobacter baumannii	*Acinetobacter baumannii*	CTX-M-15			CTX-M-33
					CTX-M-34
Ctirobacter		CTX-M-3			CTX-M-36
	Citrobacter freundii	CTX-M-15*			CTX-M-38
		CTX-M-30			CTX-M-42
		CTX-M-55			CTX-M-55
	Citrobacter koseri	CTX-M-3			CTX-M-58
		CTX-M-15			CTX-M-61
Enterobacter (non-*cloacae* Complex)	*Enterobacter aerogenes*	CTX-M-3			CTX-M-65
		CTX-M-15			CTX-M-69
	Enterobacter gergoviae	CTX-M-15			CTX-M-79
Enterobacter cloacae Complex	*Enterobacter asburiae*	CTX-M-15			CTX-M-82
	Enterobacter cloacae	CTX-M-3			CTX-M-101
		CTX-M-15*			CTX-M-103
		CTX-M-22			CTX-M-117
		CTX-M-37			CTX-M-123
		CTX-M-89			CTX-M-127
		CTX-M-177			CTX-M-132
	Enterobacter hormaechei	CTX-M-15			CTX-M-138
Escherichia coli	*Escherichia coli*	CTX-M-1*			CTX-M-139
		CTX-M-3*			CTX-M-142
		CTX-M-10			CTX-M-144
		CTX-M-12			CTX-M-150
		CTX-M-14*			CTX-M-158
		CTX-M-15*			CTX-M-163
		CTX-M-22			CTX-M-166
		CTX-M-23			CTX-M-169
		CTX-M-28			CTX-M-170
		CTX-M-29			CTX-M-171
		CTX-M-32			CTX-M-172

Target	Associated Organism	Variant Detected
		CTX-M-174
		CTX-M-175
		CTX-M-179
		CTX-M-180
		CTX-M-181
		CTX-M-182
		CTX-M-184
		CTX-M-186
Klebsiella oxytoca	*Klebsiella oxytoca*	CTX-M-3
		CTX-M-15
		CTX-M-28
		CTX-M-162
Klebsiella pneumoniae group	*Klebsiella pneumoniae*	CTX-M-1
		CTX-M-3
		CTX-M-10
		CTX-M-11
		CTX-M-12
		CTX-M-15*
		CTX-M-22
		CTX-M-28
		CTX-M-32
		CTX-M-52
		CTX-M-54
		CTX-M-55
		CTX-M-57
		CTX-M-60
		CTX-M-62
		CTX-M-71
		CTX-M-72
		CTX-M-96
		CTX-M-155
		CTX-M-156
		CTX-M-157
		CTX-M-173

Target	Associated Organism	Variant Detected
		CTX-M-176
		CTX-M-183
		CTX-M-197
		CTX-M-204
Morganella morganii	*Morganella morganii*	CTX-M-3
		CTX-M-15*
		CTX-M-55
Proteus mirabilis	*Proteus mirabilis*	CTX-M-1
		CTX-M-3
		CTX-M-15
		CTX-M-32
		CTX-M-66
		CTX-M-116
		CTX-M-136
		CTX-M-164
		CTX-M-167
Pseudomonas aeruginosa	*Pseudomonas aeruginosa*	CTX-M-15
		CTX-M-28
		CTX-M-32
Salmonella	*Salmonella enterica*	CTX-M-15
		CTX-M-53
		CTX-M-55
		CTX-M-57
		CTX-M-61
		CTX-M-88
	Salmonella sp.	CTX-M-3
	Salmonella typhimurium	CTX-M-37
		CTX-M-61
Serratia	*Serratia liquefaciens*	CTX-M-22
Serratia marcescens/ Serratia	*Serratia marcescens*	CTX-M-3
		CTX-M-15
		CTX-M-55
Stenotrophomonas maltophilia	*Stenotrophomonas maltophilia*	CTX-M-15

Table 67: Predicted (in silico) Reactivity (Inclusivity) Results for CTX-M-2

Target	Associated Organism	Variant Detected
Acinetobacter baumannii	*Acinetobacter baumannii*	CTX-M-2
		CTX-M-5
		CTX-M-43
		CTX-M-115
Enterobacter cloacae complex	*Enterobacter cloacae*	CTX-M-5
Escherichia coli	*Escherichia coli*	CTX-M-2*
		CTX-M-44
		CTX-M-56
		CTX-M-92
		CTX-M-97
		CTX-M-124
Klebsiella pneumoniae Group	*Klebsiella pneumoniae*	CTX-M-2
		CTX-M-35
		CTX-M-59
		CTX-M-141
		CTX-M-165

Target	Associated Organism	Variant Detected
		CTX-M-200
Morganella morganii	*Morganella morganii*	CTX-M-2
Proteus mirabilis/Proteus	*Proteus mirabilis*	CTX-M-2
		CTX-M-20
		CTX-M-171
Pseudomonas aeruginosa	*Pseudomonas aeruginosa*	CTX-1-2
		CTX-M-2
Salmonella	*Salmonella enterica*	CTX-M-2
		CTX-M-4
		CTX-M-5
		CTX-M-6
		CTX-M-7
	Salmonella typhimurium	CTX-M-2
		CTX-M-4
		CTX-M-5
		CTX-M-7

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Table 68: Predicted (*in silico*) Reactivity (Inclusivity) Results for CTX-M-8

Target	Associated Organism	Variant Detected
Citrobacter	*Citrobacter amalonaticus*	CTX-M-8
Enterobacter cloacae Complex	*Enterobacter cloacae*	CTX-M-8
Escherichia coli	*Escherichia coli*	CTX-M-8*

Target	Associated Organism	Variant Detected
Klebsiella pneumoniae Group	*Klebsiella pneumoniae*	CTX-M-8
		CTX-M-63
Morganella morganii	*Morganella morganii*	CTX-M-63
Salmonella	*Salmonella enterica*	CTX-M-8

Table 69: Predicted (*in silico*) Reactivity (Inclusivity) Results for CTX-M-9

Target	Associated Organism	Variant Detected
Citrobacter	*Citrobacter freundii*	CTX-M-14
		CTX-M-65
Enterobacter non-*cloacae* Complex	*Enterobacter aerogenes*	CTX-M-9
Enterobacter cloacae Complex	*Enterobacter cloacae*	CTX-M-9*
		CTX-M-13
		CTX-M-14
		CTX-M-64
		CTX-M-125
Escherichia coli	*Escherichia coli*	CTX-M-1/CTX-M-65
		CTX-M-9
		CTX-M-13
		CTX-M-14
		CTX-M-14/CTX-M-15
		CTX-M-15
		CTX-M-16
		CTX-M-19
		CTX-M-21
		CTX-M-24
		CTX-M-27
		CTX-M-38
		CTX-M-47
		CTX-M-51
		CTX-M-64
		CTX-M-65
		CTX-M-67
		CTX-M-73
		CTX-M-82
		CTX-M-87
		CTX-M-93
		CTX-M-97
		CTX-M-98
		CTX-M-102
		CTX-M-104
		CTX-M-105
		CTX-M-106
		CTX-M-121
		CTX-M-122
		CTX-M-126
		CTX-M-129
		CTX-M-130
		CTX-M-132
		CTX-M-134
		CTX-M-137
		CTX-M-148
		CTX-M-161

Target	Associated Organism	Variant Detected
		CTX-M-168
		CTX-M-173
		CTX-M-174
		CTX-M-176
		CTX-M-177
		CTX-M-191
		CTX-M-195
		CTX-M-196
		CTX-M-198
		CTX-M-199
Klebsiella pneumoniae Group	*Klebsiella pneumoniae*	CTX-M-9
		CTX-M-13
		CTX-M-14
		CTX-M-17
		CTX-M-18
		CTX-M-19
		CTX-M-24
		CTX-M-38
		CTX-M-46
		CTX-M-48
		CTX-M-49
		CTX-M-50
		CTX-M-65
		CTX-M-81
		CTX-M-99
		CTX-M-104
		CTX-M-147
		CTX-M-159
		CTX-M-201
Proteus mirabilis/*Proteus*	*Proteus mirabilis*	CTX-M-13
		CTX-M-14
		CTX-M-24
		CTX-M-65
		CTX-M-90
Salmonella	*Salmonella enterica*	CTX-M-9
		CTX-M-14
		CTX-M-25
		CTX-M-27
		CTX-M-65
		CTX-M-83
		CTX-M-84
		CTX-M-85
		CTX-M-86
		CTX-M-143
Serratia	*Serratia liquefaciens*	CTX-M-14

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Table 70: Predicted (*in silico*) Reactivity (Inclusivity) Results for CTX-M-25

Target	Associated Organism	Variant Detected
Escherichia coli	*Escherichia coli*	CTX-M-25
		CTX-M-39
		CTX-M-94
		CTX-M-100
Klebsiella pneumoniae Group	*Klebsiella pneumoniae*[A]*	CTX-M-26

Target	Associated Organism	Variant Detected
Proteus mirabilis/Proteus	*Proteus mirabilis*	CTX-M-41
		CTX-M-89
		CTX-M-91
		CTX-M-160
Salmonella	*Salmonella enterica*	CTX-M-25

A. CTX-M-25 detected in **Analytical Reactivity (Inclusivity) study**.

Table 71: Predicted (*in silico*) Reactivity (Inclusivity) Results for IMP

Target	Associated Organism	Variant Detected
Acinetobacter baumannii	*Acinetobacter baumannii*	IMP-1
		IMP-2
		IMP-4
		IMP-5
		IMP-8
		IMP-10
		IMP-11
		IMP-14
		IMP-19
		IMP-55
		IMP-61
Citrobacter	*Citrobacter freundii*	IMP-1
		IMP-4
		IMP-8
		IMP-23
		IMP-38
Enterobacter non-*cloacae* Complex	*Enterobacter aerogenes*	IMP-4
Enterobacter cloacae Complex	*Enterobacter cloacae*	IMP-1
		IMP-4
		IMP-8
		IMP-11
		IMP-26
		IMP-34
		IMP-60
Enterobacter cloacae Complex	*Enterobacter hormaechei*	IMP-13
		IMP-14
Escherichia coli	*Escherichia coli*	IMP-1
		IMP-4
		IMP-6
		IMP-8
		IMP-14
		IMP-30
		IMP-52
		IMP-59
		IMP-66
Klebsiella oxytoca	*Klebsiella oxytoca*	IMP-1
		IMP-4
		IMP-8
		IMP-28
		IMP-34
Klebsiella pneumoniae Group	*Klebsiella pneumoniae*	IMP-1
		IMP-4*
		IMP-6
		IMP-8
		IMP-10
		IMP-13

Target	Associated Organism	Variant Detected
		IMP-19
		IMP-26
		IMP-32
		IMP-38
Proteus mirabilis/Proteus	*Proteus mirabilis*	IMP-1
		IMP-27
		IMP-64
Pseudomonas aeruginosa	*Pseudomonas aeruginosa*	IMP-1*
		IMP-2
		IMP-4
		IMP-6
		IMP-7
		IMP-9
		IMP-10
		IMP-11
		IMP-13
		IMP-14*
		IMP-15
		IMP-16
		IMP-17
		IMP-18
		IMP-19
		IMP-20
		IMP-21
		IMP-22
		IMP-25
		IMP-26
		IMP-29
		IMP-30
		IMP-33
		IMP-34
		IMP-37
		IMP-40
		IMP-41
		IMP-43
		IMP-44
		IMP-45
		IMP-48
		IMP-49
		IMP-51
		IMP-53
		IMP-54
		IMP-56
		IMP-62
		IMP-63
Salmonella	*Salmonella enterica*	IMP-4
	Serratia marcescens	IMP-1

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Target	Associated Organism	Variant Detected
Serratia marcescens/*Serratia*		IMP-2
		IMP-6
		IMP-8

Target	Associated Organism	Variant Detected
		IMP-24
Stenotrophomonas maltophilia	*Stenotrophomonas maltophilia*	IMP-25

Table 72: Predicted (*in silico*) Reactivity (Inclusivity) Results for KPC

Target	Associated Organism	Variant Detected
Acinetobacter baumannii	*Acinetobacter baumannii*	KPC-2
		KPC-3
		KPC-10
Citrobacter	*Citrobacter freundii*	KPC-2*
		KPC-3
		KPC-18
Enterobacter non-*cloacae* Complex	*Enterobacter aerogenes*	KPC-2
		KPC-3
Enterobacter cloacae Complex	*Enterobacter cloacae*	KPC-2*
		KPC-3
		KPC-4
		KPC-13
		KPC-18
Escherichia coli	*Escherichia coli*	KPC-2
		KPC-3
		KPC-4
		KPC-5
		KPC-9
		KPC-18
		KPC-21
		KPC-28
Klebsiella oxytoca	*Klebsiella oxytoca*	KPC-2
		KPC-3*
Klebsiella pneumoniae Group	*Klebsiella pneumoniae*	KPC-1
		KPC-2
		KPC-3*
		KPC-4

Target	Associated Organism	Variant Detected
		KPC-5
		KPC-6
		KPC-7
		KPC-8
		KPC-11
		KPC-12
		KPC-14
		KPC-15
		KPC-16
		KPC-17
		KPC-19
		KPC-22
		KPC-24
		KPC-25
		KPC-26
		KPC-27
		KPC-30
Proteus mirabilis/*Proteus*	*Proteus mirabilis*	KPC-2
		KPC-6*
Pseudomonas aeruginosa	*Pseudomonas aeruginosa*	KPC-2
		KPC-5*
Salmonella	*Salmonella enterica*	KPC-2
Serratia marcescens/*Serratia*	*Serratia marcescens*	KPC-2
		KPC-3

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Table 73: Predicted (*in silico*) Reactivity (Inclusivity) Results for VIM

Target	Associated Organism	Variant Detected		Target	Associated Organism	Variant Detected
Acinetobacter baumannii	*Acinetobacter baumannii*	VIM-1				VIM-39
		VIM-2				VIM-42
		VIM-6				VIM-51
		VIM-11				VIM-52
Citrobacter	*Citrobacter freundii*	VIM-1		*Morganella morganii*	*Morganella morganii*	VIM-4
		VIM-2		*Proteus mirabilis/Proteus*	*Proteus mirabilis*	VIM-1
		VIM-4		*Pseudomonas aeruginosa*	*Pseudomonas aeruginosa*	VIM-1
		VIM-23				VIM-2*
Enterobacter non-*cloacae* Complex	*Enterobacter aerogenes*	VIM-1				VIM-3
						VIM-4*
Enterobacter cloacae Complex	*Enterobacter cloacae*	VIM-1				VIM-5
		VIM-2				VIM-6
		VIM-4				VIM-8
		VIM-23				VIM-9
		VIM-31				VIM-10
		VIM-40				VIM-11
	Enterobacter hormaechei	VIM-1				VIM-14
		VIM-4				VIM-15
		VIM-23				VIM-16
	Enterobacter xiangfangensis	VIM-1				VIM-17
						VIM-18
Escherichia coli	*Escherichia coli*[A]	VIM-1				VIM-20
		VIM-2				VIM-28
		VIM-19				VIM-30
		VIM-29				VIM-36
Klebsiella oxytoca	*Klebsiella oxytoca*	VIM-1				VIM-37
		VIM-2				VIM-41
		VIM-4				VIM-43
		VIM-32				VIM-44
		VIM-35				VIM-45
Klebsiella pneumoniae Group	*Klebsiella pneumoniae*	VIM-1*				VIM-46
		VIM-2				VIM-48
		VIM-4				VIM-50
		VIM-12		*Salmonella*	*Salmonella enterica*	VIM-1
		VIM-19		*Serratia marcescens/Serratia*	*Serratia marcescens*	VIM-2
		VIM-24				VIM-4
		VIM-26				VIM-54
		VIM-27*		*Stenotrophomonas maltophilia*	*Stenotrophomonas maltophilia*	VIM-2
		VIM-33				
		VIM-34				

A.   Unspecified VIM variant detected in **Analytical Reactivity (Inclusivity) study**.

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Table 74: Predicted (*in silico*) Reactivity (Inclusivity) Results for OXA-23

Target	Associated Organism	Variant Detected
Acinetobacter baumannii	*Acinetobacter baumannii*	OXA-23*
		OXA-49
		OXA-23/OXA-104
		OXA-23/OXA-64
		OXA-23/OXA-66
		OXA-23/OXA-69
		OXA-27
		OXA-65/OXA-239
		OXA-68
		OXA-146
		OXA-165
		OXA-166
		OXA-167
		OXA-168
		OXA-169
		OXA-170
		OXA-171
		OXA-183

Target	Associated Organism	Variant Detected
		OXA-225
		OXA-366
		OXA-398
		OXA-422
		OXA-423
		OXA-435
		OXA-440
		OXA-469
		OXA-481
		OXA-482
		OXA-483
		OXA-565
Escherichia coli	*Escherichia coli*	OXA-23
Klebsiella pneumoniae Group	*Klebsiella pneumoniae*	OXA-73
Proteus mirabilis	*Proteus mirabilis*	OXA-23

Table 75: Predicted (*in silico*) Reactivity (Inclusivity) Results for OXA-48

Target	Associated Organism	Variant Detected
Acinetobacter baumannii	*Acinetobacter baumannii*	OXA-48
Citrobacter	*Citrobacter freundii*	OXA-48
		OXA-181
Enterobacter non-cloacae Complex	*Enterobacter aerogenes*	OXA-244
Enterobacter cloacae Complex	*Enterobacter cloacae*	OXA-48
		OXA-163
		OXA-181
	Enterobacter hormaechei	OXA-370
	Enterobacter ludwigii	OXA-48
Escherichia coli	*Escherichia coli*[A]	OXA-48
		OXA-163
		OXA-181
		OXA-204
		OXA-232
		OXA-244
		OXA-438
		OXA-439
		OXA-566
		OXA-1/OXA-48

Target	Associated Organism	Variant Detected
Klebsiella pneumoniae Group	*Klebsiella pneumoniae*	OXA-48*
		OXA-10
		OXA-162
		OXA-181*
		OXA-204
		OXA-232*
		OXA-244
		OXA-245
		OXA-247
		OXA-484
		OXA-505
		OXA-517
		OXA-519
	Klebsiella variicola	OXA-181
Morganella morganii	*Morganella morganii*	OXA-181
Proteus mirabilis/*Proteus*	*Proteus mirabilis*	OXA-48
		OXA-244
Serratia marcescens/*Serratia*	*Serratia marcescens*	OXA-48
		OXA-405

A. Unspecified OXA variant detected in the Analytical Reactivity (Inclusivity) study.

Table 76: Predicted (*in silico*) Reactivity (Inclusivity) Results for NDM

Target	Associated Organism	Variant Detected	Target	Associated Organism	Variant Detected
Acinetobacter baumannii	*Acinetobacter baumannii*	NDM-1*			NDM-15
		NDM-2			NDM-16
Citrobacter	*Citrobacter braakii*	NDM-4			NDM-17
Citrobacter	*Citrobacter freundii*	NDM-1[A]			NDM-18
		NDM-4			NDM-19
		NDM-6	*Klebsiella oxytoca*	*Klebsiella oxytoca*	NDM-1
		NDM-7			NDM-4
Enterobacter non-*cloacae* Complex	*Enterobacter aerogenes*	NDM-1	*Klebsiella pneumoniae* Group	*Klebsiella pneumoniae*	NDM-1*
		NDM-4			NDM-4
		NDM-5			NDM-5
		NDM-7			NDM-6
Enterobacter cloacae Complex	*Enterobacter cloacae*[B]	NDM-1			NDM-7
		NDM-4			NDM-10
		NDM-7			NDM-16
	Enterobacter hormaechei	NDM-1	Morganella morganii	Morganella morganii	NDM-1[C]
	Enterobacter ludwigii	NDM-1	*Proteus mirabilis*/*Proteus*	*Proteus mirabilis*	NDM-1
Escherichia coli	*Escherichia coli*	NDM-1	*Pseudomonas aeruginosa*	*Pseudomonas aeruginosa*	NDM-1
		NDM-3			NDM-5
		NDM-4	*Salmonella*	*Salmonella enterica*	NDM-1
		NDM-5*			NDM-5
		NDM-6*	*Serratia marcescens*/Serratia	*Serratia marcescens*	NDM-1
		NDM-7*	*Stenotrophomonas maltophilia*	*Stenotrophomonas maltophilia*	NDM-1
		NDM-8			
		NDM-11			
		NDM-12			
		NDM-13			

A. Detected in a *Citrobacter* species in the **Analytical Reactivity (Inclusivity) study**.
B. Unspecified NDM variant detected in the **Analytical Reactivity (Inclusivity) study**.
C. NDM-1 was detected in Morganella morganii in the **Analytical Reactivity (Inclusivity) study** but no sequences were available for *in silico* analysis.

Table 77: Predicted (*in silico*) Reactivity (Inclusivity) Results for Variants Not Detected

Resistance Marker	Variant Not Detected	Associated Organism	No. of Sequences
CTX-M-1	CTX-M-80	*Klebsiella pneumoniae*	3
	CTX-M-15		
	Not Specified		
IMP	IMP-31	*Pseudomonas aeruginosa*	2
	IMP-35		2
	IMP-7		1
NDM	NDM-1	*Escherichia coli*	6
		Klebsiella variicola	3
		Salmonella enterica	1
	NDM-3	*Acinetobacter baumannii*	1
	NDM-4	*Escherichia coli*	1
	NDM-9	*Cronobacter sakazakii*	1
		Escherichia coli	1
		Klebsiella pneumoniae	2
	Not specified	*Escherichia coli*	2
		Klebsiella pneumoniae	1
		Klebsiella sp	1
		Pseudomonas aeruginosa	1
VIM	VIM-1	*Pseudomonas aeruginosa*	3
		Providencia vermicola	1
	VIM-2	*Klebsiella pneumoniae*	1
	VIM-5	*Enterobacter cloacae*	2
		Klebsiella pneumoniae	3
	VIM-7	*Pseudomonas aeruginosa*	4
	VIM-13		3
	VIM-25	*Acinetobacter baumannii*	1
		Proteus mirabilis	2

Resistance Marker	Variant Not Detected	Associated Organism	No. of Sequences
	VIM-38	*Pseudomonas aeruginosa*	2
	VIM-47		2
	VIM-49		2
	Not specified		1
OXA-48	OXA-232	*Escherichia coli*	1

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Analytical Specificity (Cross-Reactivity and Exclusivity)

Cross-reactivity of on-panel and off-panel analytes was evaluated with the BCID-GN Panel. Bacterial targets were tested in triplicate at a concentration of ~1×10^9 CFU/mL while fungi were tested in triplicate at a concentration of ~1×10^7 CFU/mL. If the target concentration could not be reached, the organism was diluted 2-fold from stock for use (indicated with an asterisk in **Tables 78-81**).

No cross reactivity was observed for any of the on-panel organisms. The following off-panel organisms showed cross reactivity: *Acinetobacter anitratus* (at a concentration of >1×10^4 CFU/mL) cross-reacts with the *Acinetobacter baumannii* assay, *Enterobacter cowanii* (at a concentration of >1×10^8 CFU/mL) cross-reacts with the *Enterobacter cloacae* complex assay, *Escherichia hermanii* cross-reacts with the *Enterobacter* (non-*cloacae* complex) assay (at a concentration of >1×10^6 CFU/mL) and with the *Serratia* assay (at a concentration of >1×10^7 CFU/mL), *Fusobacterium periodonticum* (at a concentration of 5×10^8 CFU/mL) and *Fusobacterium simiae* (at a concentration of 2.9×10^8 CFU/mL) cross-react with the *Fusobacterium nucleatum* assay, and *Shigella* (at a concentration of 1×10^9 CFU/mL) cross-reacts with the *Escherichia coli* assay (off-panel organisms showing cross-reactivity are **bolded** in the tables below). See **Table 56** for a summary of the on-panel strains tested and **Tables 78-81** for a summary of off-panel strains tested.

Additional *in silico* analysis was performed to identify any off-panel gram-negative and gram-positive organisms that may cross-react with the BCID-GN Panel (**Tables 82-83**).

Note: the performance of the ePlex BCID-GN Panel has not been established for organisms evaluated by *in silico* analysis alone.

Off-Panel Exclusivity

Table 78: Off-Panel Gram-Negative Organisms Assessed for Cross-reactivity with the ePlex BCID-GN Panel (Exclusivity)

Gram Negative Organism	Strain ID	Gram Negative Organism	Strain ID
Acinetobacter haemolyticus	ATCC 19002	*Kluyvera cochleae*	ATCC 51609
Acinetobacter lwoffii	ATCC 15309	*Legionella pneumoniae*	ATCC 33823
Acinetobacter junii	ATCC 17908	*Leclercia adecarboxylata*	ATCC 700325
***Acinetobacter anitratus*[A]**	ATCC 49139	*Methylobacterium mesophilicum**	ATCC 29983
Aeromonas hydrophila	JMI 938982	*Neisseria gonorrhoeae*	ATCC 19424
Aeromonas salmonicida	ATCC 33658	*Neisseria mucosa*	ATCC 19695
Aeromonas sobria	ATCC 35993	*Neisseria sicca*	ATCC 29193
Bacteroides distasonis (Parabacteroides)	ATCC 8503	*Neisseria flavecens*	ATCC 13115
Bacteroides merdae	ATCC 43184	*Neisseria lactamica*	ATCC 23970
Bacteroides thetaiotaomicron	ATCC 29741	*Neisseria perflava*	ATCC 14799
*Bacteroides vulgatus**	ATCC 8482	*Ochrobactrum anthropi*	ATCC BAA-749
Bacteroides caccae	ATCC 700189	*Pantoea agglomerans*	ATCC 14537
Bacteroides eggerthii	ATCC 27754	*Pantoea ananatis*	NRRL B-41502
*Bacteroides ovatus**	ATCC BAA-1296	*Pasteurella aerogenes*	ATCC 27883
*Bacteroides ureolyticus**	ATCC 33387	*Pasteurella multicida subsp multicide*	ATCC 12945
Bordetella pertussis	ATCC 9797	*Prevotella intermedia*	ATCC 15032
Burkholderia cepacia	ATCC 25416	*Prevotella corporis**	ATCC 33547
Citrobacter amalonaticus	ATCC BAA-2563	*Prevotella oralis**	ATCC 33269
Citrobacter gillenii	ATCC 51640	*Prevotella nigrescens**	ATCC 33563
Citrobacter sedlakii	ATCC 51493	*Providencia rettgeri*	ATCC 9250
Citrobacter farmer	ATCC 51112	*Providencia stuartii*	ATCC 33672
Citrobacter murliniae	ATCC 51642	*Providencia alcalifaciens*	ATCC 9886
Edwardsiella tarda	ATCC 15947	*Pseudomonas fluorescens*	ATCC 13525
Enterobacter kobei	ATCC BAA-260	*Pseudomonas putida*	ATCC 49128
Enterobacter cancerogenus	ATCC 35315	*Pseudomonas alcaligenes*	ATCC 14909
***Enterobacter cowanii*[B]**	DSM-18146	*Ralstonia insidiosa*	ATCC 49129
Escherichia albertii	DSM-17582	*Ralstonia pickettii*	ATCC 27511
Escherichia fergusonii	ATCC 35469	*Raoultella planticola (Klebsiella planticola)*	ATCC 31900
***Escherichia hermanii*[C]**	ATCC 33650	*Raoultella ornithinolytica*	CDC# 0134
*Ewingella americana**	ATCC 33853	*Raoultella terrigena (Klebsiella terrigena)*	ATCC 55553
Eikenella corrodens	ATCC BAA-1152	***Shigella boydii*[E]**	ATCC 9207
*Fusobacterium naviforme**	ATCC 25832	***Shigella sonnei*[E]**	ATCC 25931
Fusobacterium gonidiaformans	ATCC 25563	***Shigella flexneri*[E]**	ATCC 9199
*Fusobacterium necrogenes**	ATCC 25556	*Vibrio furnissii*	NCTC11218
***Fusobacterium periodonticum**[D]**	ATCC 33693	*Vibrio alginolyticus*	ATCC 17749
***Fusobacterium simiae**[D]**	ATCC 33568	*Vibrio parahaemolyticus*	ATCC 17802
Fusobacterium varium	ATCC 27725	*Yersinia enterocolitica* subsp *enterocolitica*	ATCC 9610
*Fusobacterium russii**	ATCC 25533	*Yersinia ruckeri*	ATCC 29473
Fusobacterium ulcerans	ATCC 49186	*Yersinia kristensenii*	ATCC 33639
Haemophilus haemolyticus	ATCC 33390		
Haemophilus parahaemolyticus	ATCC 10014		
Hafnia alvei	ATCC 51815		
*Kingella kingae**	ATCC 23331		

A. Cross-reactivity seen with *Acinetobacter baumanii* at a concentration > 1×10^4 CFU/mL.

B. Cross-reactivity seen with *Enterobacter cloacae* complex at a concentration > 1×10^8 CFU/mL.

C. Cross-reactivity seen with *Enterobacter* (non-*cloacae* complex) at a concentration > 1×10^6 CFU/mL and *Serratia* at a concentration of > 1×10^7 CFU/mL.

D. Cross-reactivity seen with the *Fusobacterium nucleatum* assay.

E. Cross-reactivity seen with the *Escherichia coli* assay.

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Table 79: Off-Panel Gram-Positive Organisms Assessed for Cross-reactivity with the ePlex BCID-GN Panel (Exclusivity)

Gram Positive Organisms	Strain ID
Actinomyces odontolyticus	ATCC 17929
Clostridium perfringens	ATCC 13124
Corynebacterium jeikeium	ATCC BAA-949
Corynebacterium renale	ATCC 19412
Corynebacterium ulcerans	ATCC 51799
Corynebacterium xerosis*	ATCC 373
Corynebacterium durum	ATCC 33449
Corynebacterium diphtheriae*	ATCC 13812
Corynebacterium pseudodiphtheriticum	ATCC 10700
Corynebacterium striatum*	ATCC 43735
Corynebacterium urealyticum	ATCC 43044
Lactobacillus casei	ATCC 39392
Lactobacillus paracasei*	ATCC 25598
Lactobacillus acidophilus*	ATCC 314
Lactobacillus crispatus	ATCC 33197
Lactobacillus rhamnosus	ATCC 39595
Lactococcus lactis	ATCC 49032
Listeria innocua	ATCC 33090
Listeria monocytogenes	ATCC 7644
Micrococcus luteus	ATCC 10240
Peptostreptococcus anaerobius	ATCC 27337
Propionibacterium acnes	ATCC 11827
Rothia mucilaginosa	ATCC 25296

Table 80: Off-Panel Fungal Organisms Assessed for Cross-reactivity with the ePlex BCID-GN Panel (Exclusivity)

Fungal Pathogens	Strain ID	Concentration Tested
*Aspergillus fumigatus**	ATCC 204305	2.50×10^6 CFU/mL
Candida orthopsilosis	ATCC 96139	1×10^7 CFU/mL
Candida metapsilosis	ATCC 96144	1×10^7 CFU/mL
Candida tropicalis	ATCC 1369	1×10^7 CFU/mL
Cryptococcus grubii	ATCC 208821	1×10^7 CFU/mL
Cryptococcus gattii	ATCC 76108	1×10^7 CFU/mL
Cryptococcus neoformans	ATCC 14116	1×10^7 CFU/mL
Geotrichum capitatum	ATCC 10663	1×10^7 CFU/mL
Histoplasma capsulatum	*In silico*	N/A
Penicillium marneffei	ATCC 200050	1×10^7 CFU/mL
Rhodotorula glutinis	ATCC 32765	1×10^7 CFU/mL
Rhodotorula mucilaginosa	ATCC 9449	1×10^7 CFU/mL
Rhodotorula minuta	ATCC 36236	1×10^7 CFU/mL
*Saccharomyces cervisiae**	ATCC 18824	5.55×10^6 CFU/mL
Trichosporon dermatis	ATCC MYA-4294	1×10^7 CFU/mL
Trichosporon mucoides	ATCC 90046	1×10^7 CFU/mL

Table 81: Off-Panel Resistance Genes Assessed for Cross-reactivity with the ePlex BCID-GN Panel (Exclusivity)

Antimicrobial Resistance Genes	Strain ID	Concentration Tested
FOX (Carried by *Klebsiella oxytoca*)*[A]	JMI 954306	8×10^8 CFU/mL
MOX (Carried by *Aeromonas hydrophila*)	JMI 938982	1×10^9 CFU/mL
SME (Carried by *Serratia marcescens*)[A]	CDC #0091	1×10^9 CFU/mL
SHV (Carried by *Klebsiella pneumoniae*)[A]	CDC #0087	1×10^9 CFU/mL
TEM (Carried by *Escherichia coli*)[A]	NCTC 13351	1×10^9 CFU/mL

A. The on-panel organism associated with the resistance gene was detected by the BCID-GN panel as expected

Table 82: Off-Panel Gram-Negative Organisms Assessed for Cross-Reactivity with the ePlex BCID-GN Panel based on *In Silico* Analysis

Cross-reactive Organism	ePlex BCID-GN Target	No. of Sequences	Predicted Cross-Reactive Sequences* n (%)
Fusobacterium hwasookii	*F. nucleatum*	10	5 (50%)
Haemophilus aegyptius	*H. influenzae*	3	3 (100%)
Klebsiella michiganensis	*Klebsiella oxytoca*	40	40 (100%)
Pseudomonas denitrificans	*Pseudomonas aeruginosa*	17	16 (94.1%)

Table 83: Off-Panel Gram-Positive Organisms Assessed for Cross-Reactivity with the Pan Gram-Positive Assay based on *In Silico* Analysis

Organism	Number of Sequences	Predicted Cross-Reactive Sequences n (%)
Brevibacterium halotolerans	3	3 (100%)
Domibacillus indicus	1	1 (100%)
Domibacillus robiginosus	1	1 (100%)
Salinibacillus aidingensis	2	1 (50%)
Terribacillus aidingensis	1	1 (100%
Terribacillus halophilus	2	1 (50%)
Terribacillus saccharophilus	1	1 (100%)
Planomicrobium okeanokoites	1	1 (100%)
Lactococcus chungangensis	4	4 (100%)
Lactococcus laudensis	1	1 (100%)
Lactococcus piscium	18	18 (100%)
Lactococcus plantarum	6	5 (83.8%)
Lactococcus raffinolactis	49	46 (93.9%)
Okadaella gastrococcus	4	4 (100%)

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 and three blood replicates were quantified for each organism on culture plates. Organisms tested and approximate bottle positivity concentrations are summarized in **Table 84**. 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. The following bottle types were used for the Bottle Positivity Study: BD BACTEC Plus Aerobic/F blood culture bottle (*E. faecium*, *S. aureus*, *S.anginosus*, *A. baumannii, E. cloacae*, *E. coli, H. influenzae*, *K. oxytoca, N. meningitidis*, *P. auerginosa*, and *S. marcescens*), BD BACTEC Lytic/10 Anaerobic/F (*B. fragilis* and *F. nucleatum*), and BD BACTEC Myco F/Lytic blood culture bottle (*C. albicans*).

Table 84: Bottle Positivity Concentrations

Organism	Strain ID	Mean Bottle Positivity Concentration	Mean Bottle Positivity +8 hours Concentration
Gram-positive Organisms			
Enterococcus faecium	ATCC BAA-2317	4.9×10^7 CFU/mL	3.6×10^7 CFU/mL
Staphylococcus aureus	NRS 483	2.8×10^7 CFU/mL	2.1×10^7 CFU/mL
Streptococcus anginosus	ATCC 33397	4.1×10^7 CFU/mL	4.0×10^8 CFU/mL
Gram-negative Organisms			
Acinetobacter baumannii	NCTC 13301	4.4×10^8 CFU/mL	3.8×10^8 CFU/mL
Bacteroides fragilis	ATCC 700786	4.7×10^8 CFU/mL	6.7×10^9 CFU/mL
Enterobacter cloacae	NCTC 13464	2.8×10^8 CFU/mL	7.7×10^8 CFU/mL
Escherichia coli	NCTC 13476	2.3×10^8 CFU/mL	1.5×10^9 CFU/mL
Fusobacterium nucleatum	ATCC 31647	6.5×10^7 CFU/mL	4.9×10^8 CFU/mL
Haemophilus influenzae	ATCC 19418	6.9×10^8 CFU/mL	1.2×10^9 CFU/mL
Klebsiella oxytoca	CDC #0147	9.3×10^8 CFU/mL	1.5×10^9 CFU/mL
Neisseria meningitidis	ATCC 13102	3.2×10^7 CFU/mL	2.1×10^8 CFU/mL
Pseudomonas aeruginosa	NCTC 13476	1.6×10^8 CFU/mL	8.4×10^8 CFU/mL
Serratia marcescens	ATCC 14041	1.2×10^9 CFU/mL	2.2×10^9 CFU/mL
Fungal Organisms			
Candida albicans	ATCC 90082	1.6×10^6 CFU/mL	1.4×10^6 CFU/mL

Reproducibility

Three positive mixes including 11 on-panel organisms and 5 antibiotic resistance genes representing 17 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 and time of bottle positivity, and the negative mix contained *Cutibacterium granulosum* grown in BD BACTEC Lytic/10 Anaerobic/F blood culture bottles to bottle positivity and bottle positivity plus eight hours, which is expected to yield a negative result. Bottle concentrations used in this study are summarized in **Table 85**. Each of the three positive mixes at two concentrations and the one negative mix were tested a minimum of 108 times. Testing occurred at three sites, with two operators testing the mixes over six days using three cartridge lots. For the negative mix, agreement with the expected negative result was 100% for all targets in the ePlex BCID-GN Panel.

Table 85: Bottle Positivity Concentrations

Organism	Bottle Positivity Concentration	Bottle Positivity +8 Hours Concentration
Acinetobacter baumannii (OXA)	1×10^8 CFU/mL	1×10^9 CFU/mL
Enterobacter cloacae (CTX-M, KPC)	1×10^8 CFU/mL	1×10^9 CFU/mL
Escherichia coli (IMP)	1×10^8 CFU/mL	1×10^9 CFU/mL
Fusobacterium nucleatum	1×10^7 CFU/mL	1×10^8 CFU/mL
Haemophilus influenzae	1×10^8 CFU/mL	1×10^9 CFU/mL
Klebsiella oxytoca	1×10^8 CFU/mL	1×10^9 CFU/mL
Neisseria meningitidis	3×10^7 CFU/mL	3×10^8 CFU/mL
Pseudomonas aeruginosa (VIM)	1×10^8 CFU/mL	1×10^9 CFU/mL
Serratia marcescens	1×10^8 CFU/mL	1×10^9 CFU/mL
Candida albicans (Pan *Candida* target)	1×10^6 CFU/mL	1×10^7 CFU/mL
Staphylococcus aureus (Pan Gram-Positive target)	1×10^7 CFU/mL	1×10^8 CFU/mL

The percent agreement of each target with the expected result is summarized in **Tables 86-102.** The ePlex BCID-GN assay demonstrates a high level of agreement (≥98%) with the expected results.

Table 86: Percent Agreement for *Acinetobacter baumannii*

Concentration of *Acinetobacter baumannii*	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	179/179	100	(97.9-100)
	2	178/179	99.4	(96.9-99.9)
	3	180/180	100	(97.9-100)
	All	**537/538**	**99.8**	**(99.0-100)**

CI=Confidence Interval

Table 87: Percent Agreement for *Enterobacter cloacae* complex

Concentration of *Enterobacter cloacae*	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	35/35	100	(90.1-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	**107/107**	**100**	**(96.5-100)**
Negative	1	180/180	100	(97.9-100)
	2	179/179	100	(97.9-100)
	3	180/180	100	(97.9-100)
	All	**539/539**	**100**	**(99.3-100)**

Table 88: Percent Agreement for *Escherichia coli*

Concentration of *Escherichia coli*	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	35/35	100	(90.1-100)
	3	36/36	100	(90.4-100)
	All	**107/107***	**100**	**(96.5-100)**
Negative	1	179/179	100	(97.9-100)
	2	180/180	100	(97.9-100)
	3	180/180	100	(97.9-100)
	All	**539/539**	**100**	**(99.3-100)**

* Two samples had a false positive *Bacteroides fragilis* result.

Table 89: Percent Agreement for *Fusobacterium nucleatum*

Concentration of *Fusobacterium nucleatum*	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	35/35	100	(90.1-100)
	3	36/36	100	(90.4-100)
	All	**107/107**	**100**	**(96.5-100)**
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	179/179	100	(97.9-100)
	2	180/180	100	(97.9-100)
	3	180/180	100	(97.9-100)
	All	**539/539**	**100**	**(99.3-100)**

* One sample had a false positive *Fusobacterium necrophorum* result.

Table 90: Percent Agreement for *Haemophilus influenzae*

Concentration of *Haemophilus influenzae*	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	179/179	100	(97.9-100)
	2	179/179	100	(97.9-100)
	3	180/180	100	(97.9-100)
	All	**538/538**	**100**	**(99.3-100)**

Table 91: Percent Agreement for *Klebsiella oxytoca*

Concentration of *Klebsiella oxytoca*	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	179/179	100	(97.9-100)
	2	179/179	100	(97.9-100)
	3	180/180	100	(97.9-100)
	All	**538/538**	**100**	**(99.3-100)**

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Table 92: Percent Agreement for *Neisseria meningitidis*

Concentration of *Neisseria meningitidis*	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours ($3x10^8$ CFU/mL)	1	35/35	100	(90.1-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	**107/107**	**100**	**(96.5-100)**
Bottle Positive ($3x10^7$ 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	180/180	100	(97.9-100)
	2	179/179	100	(97.9-100)
	3	180/180	100	(97.9-100)
	All	**539/539**	**100**	**(99.3-100)**

Table 93: Percent Agreement for *Pseudomonas aeruginosa*

Concentration of *Pseudomonas aeruginosa*	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	35/35	100	(90.1-100)
	3	36/36	100	(90.4-100)
	All	**107/107**	**100**	**(96.5-100)**
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	179/179	100	(97.9-100)
	2	180/180	100	(97.9-100)
	3	180/180	100	(97.9-100)
	All	**539/539**	**100**	**(99.3-100)**

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Table 94: Percent Agreement for *Serratia*

Concentration of *Serratia marcescens*	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours (1x10^9 CFU/mL)	1	35/35	100	(90.1-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	**107/107**	**100**	**(96.5-100)**
Bottle Positive (1x10^8 CFU/mL)	1	36/36	100	(90.4-100)
	2	33/33	100	(89.6-100)
	3	33/33	100	(89.6-100)
	All	**102/102**	**100**	**(96.4-100)**
Negative	1	180/180	100	(97.9-100)
	2	179/179	100	(97.9-100)
	3	180/180	100	(97.9-100)
	All	**539/539**	**100**	**(99.3-100)**

Table 95: Percent Agreement for *Serratia marcescens*

Concentration of *Serratia marcescens*	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours (1x10^9 CFU/mL)	1	35/35	100	(90.1-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	**107/107**	**100**	**(96.5-100)**
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	180/180	100	(97.9-100)
	2	179/179	100	(97.9-100)
	3	180/180	100	(97.9-100)
	All	**539/539**	**100**	**(99.3-100)**

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Table 96: Percent Agreement for Pan *Candida*

Concentration of *Candida albicans*	Site	Agreement with Expected Results		
		Agreed / N	%	95% CI
Bottle Positive + 8 Hours (1x10^7 CFU/mL)	1	35/35	100	(90.1-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	**107/107**	**100**	**(96.5-100)**
Bottle Positive (1x10^6 CFU/mL)	1	35/36	97.2	(85.8-99.5)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	**107/108**	**99.1**	**(94.9-99.8)**
Negative	1	180/180	100	(97.9-100)
	2	179/179	100	(97.9-100)
	3	180/180	100	(97.9-100)
	All	**539/539**	**100**	**(99.3-100)**

Table 97: Percent Agreement for Pan Gram-Positive

Concentration of *Staphylococcus aureus*	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	34/36	94.4	(81.9-98.5)
	2	35/35	100	(90.1-100)
	3	36/36	100	(90.4-100)
	All	**105/107**	**98.1**	**(93.4-99.5)**
Negative	1	179/179	100	(97.9-100)
	2	179/180	99.4	(96.9-99.9)
	3	180/180	100	(97.9-100)
	All	**538/539**	**99.8**	**(99.0-100)**

Table 98: Percent Agreement for CTX-M

Concentration of *Enterobacter cloacae* (CTX-M+, KPC+)	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	35/35	100	(90.1-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	**107/107**	**100**	**(96.5-100)**
Negative	1	144/144	100	(97.4-100)
	2	143/143	100	(97.4-100)
	3	144/144	100	(97.4-100)
	All	**431/431**	**100**	**(99.1-100)**

Table 99: Percent Agreement for IMP

Concentration of *Escherichia coli* (IMP+)	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	35/36	97.2	(85.8-99.5)
	3	36/36	100	(90.4-100)
	All	**107/108**	**99.1**	**(94.9-99.8)**
Bottle Positive (1x10^8 CFU/mL)	1	36/36	100	(90.4-100)
	2	35/35	100	(90.1-100)
	3	35/36	97.2	(85.8-99.5)
	All	**106/107**	**99.1**	**(94.9-99.8)**
Negative	1	143/143	100	(97.4-100)
	2	144/144	100	(97.4-100)
	3	144/144	100	(97.4-100)
	All	**431/431**	**100**	**(99.1-100)**

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Table 100: Percent Agreement for KPC

Concentration of *Enterobacter cloacae* (CTX-M+, KPC+)	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	**107/107**	**100**	**(96.5-100)**
Bottle Positive (1x10^8 CFU/mL)	1	35/35	100	(90.16-100)
	2	36/36	100	(90.4-100)
	3	36/36	100	(90.4-100)
	All	**107/107**	**100**	**(96.4-100)**
Negative	1	144/144	100	(97.4-100)
	2	143/143	100	(97.4-100)
	3	144/144	100	(97.4-100)
	All	**431/431**	**100**	**(99.1-100)**

Table 101: Percent Agreement for OXA

Concentration of *Acinetobacter baumannii* (OXA-23+)	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	143/143	100	(97.4-100)
	2	143/143	100	(97.4-100)
	3	144/144	100	(97.4-100)
	All	**430/430**	**100**	**(99.1-100)**

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Table 102: Percent Agreement for VIM

Concentration of *Pseudomonas aeruginosa* (VIM+)	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	35/35	100	(90.1-100)
	3	36/36	100	(90.4-100)
	All	**107/107**	**100**	**(96.5-100)**
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	143/1437	100	(97.4-100)
	2	144/144	100	(97.4-100)
	3	144/144	100	(97.4-100)
	All	**431/431**	**100**	**(99.1-100)**

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Interfering Substances and Sample Matrix Equivalency (Bottle Evaluation)

Three organism mixes consisting of 12 on-panel organisms representing 16 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 103.**

Table 103: Organism Concentrations for Interfering Substance and Bottle Equivalency Evaluations

Organism	Concentration
Acinetobacter baumanii	4 x 10^8 CFU/mL
Bacteroides fragilis	4 x 10^8 CFU/mL
Enterobacter aerogenes	2 x 10^8 CFU/mL
Enterobacter cloacae (CTX-M)	2 x 10^8 CFU/mL
Escherichia coli (OXA)	2 x 10^8 CFU/mL
Haemophilus influenzae	6 x 10^8 CFU/mL
Klebsiella oxytoca	9 x 10^8 CFU/mL
Neisseria meningitidis	3 x 10^7 CFU/mL
Pseudomonas aeruginosa (IMP)	1 x 10^8 CFU/mL
Serratia marcescens	1 x 10^9 CFU/mL
Staphylococcus aureus (Pan Gram-Positive target)	2 x 10^7 CFU/mL
Candida albicans (Pan Candida target)	1 x 10^6 CFU/mL

Interfering Substances

Eighteen substances were used to assess the ePlex BCID-GN Panel for potential interference. The organisms in **Table 103** 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 104**. 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-GN Panel at clinically relevant concentrations. The effect of interfering substances has only been evaluated for the substances listed in **Table 104**. Interference due to substances other than those described in this section can lead to erroneous results.

Table 104: Potentially Interfering Substances: Substance List

Endogenous Substances	Testing Concentration
Bilirubin	60 µg/mL
Hemoglobin	0.6 g/L
Human Genomic DNA	6×10^5 copies/mL
Triglycerides	1000 mg/dL
γ-globulin	1.7 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 **Table103**.

Five replicates of each organism were tested in each of two bottle lots. Negative blood matrix was run as a negative control. Twelve bottle types tested showed no interference for any of the targets tested. One of three lots of the BACTEC™ Lytic Anaerobic bottles tested showed reduced sensitivity for some targets. A summary of the bottle types assessed and the study outcomes is found in **Table 105**.

Table 105: 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	No interference observed
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*	False negative results were observed for Pan Candida, *Enterobacter cloacae*, *Escherichia coli*, CTX-M and OXA in one of three lots.*
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	No interference observed
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

* 2/15 replicates were false negative for Pan *Candida*; 1/15 replicates was false negative for *Enterobacter cloacae*; 1/15 replicates was false negative for *Escherichia coli* (OXA-48); 2/15 replicates were false negative for CTX-M

Carryover and Cross-Contamination

Carryover and cross-contamination were evaluated for the ePlex BCID-GN 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 OXA positive *Escherichia coli*, CTX-M and KPC positive *Enterobacter cloacae*, *Salmonella enterica*, and *Enterococcus faecalis* (a Pan Gram-Positive target organism) was prepared at 1 x 10^9 CFU/mL each as well as *Candida krusei* (a Pan *Candida* target organism) at 1x10^7 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 *Escherichia coli*, *Enterobacter cloacae* complex, *Salmonella*, OXA, CTX-M, KPC, Pan Gram-Positive, and Pan *Candida* and no false positives were detected in the negative runs.

Competitive Inhibition Study

Competitive inhibition was evaluated for the ePlex BCID-GN Panel by pairing eight clinically relevant organisms (including a Pan Gram-Positive 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 106**.

Table 106: Competitive Inhibition Organisms and Concentrations Tested

Organism	High Concentration	Low Concentration
Klebsiella pneumoniae	1×10^9 CFU/mL	9×10^8 CFU/mL
Escherichia coli (CTX-M+)	1×10^9 CFU/mL	2×10^8 CFU/mL
Enterobacter cloacae (VIM+)	7×10^8 CFU/mL	2×10^8 CFU/mL
Klebsiella oxytoca (KPC+)	1×10^9 CFU/mL	9×10^8 CFU/mL
Pseudomonas aeruginosa (IMP+)	8×10^8 CFU/mL	1×10^8 CFU/mL
Serratia marcescens	2×10^9 CFU/mL	1×10^9 CFU/mL
Staphylococcus aureus	1×10^8 CFU/mL	2×10^7 CFU/mL
Corynebacterium striatum[A]	2×10^9 CFU/mL	4×10^6 CFU/mL

[A]Off-panel organism