

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

A. 510(k) Number:

K181663

B. Purpose for Submission:

To obtain clearance for the ePlex Blood Culture Identification Gram-Positive (BCID-GP) Panel

C. Measurand:

Bacillus cereus group, *Bacillus subtilis* group, *Corynebacterium*, *Cutibacterium acnes* (*P. acnes*), *Enterococcus*, *Enterococcus faecalis*, *Enterococcus faecium*, *Lactobacillus*, *Listeria*, *Listeria monocytogenes*, *Micrococcus*, *Staphylococcus*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus lugdunensis*, *Streptococcus*, *Streptococcus agalactiae* (GBS), *Streptococcus anginosus* group, *Streptococcus pneumoniae*, *Streptococcus pyogenes* (GAS), *mecA*, *mecC*, *vanA* and *vanB*.

D. Type of Test:

A multiplexed nucleic acid-based test intended for use with the GenMark's ePlex instrument for the qualitative *in vitro* detection and identification of multiple bacterial and yeast nucleic acids and select genetic determinants of antimicrobial resistance. The BCID-GP assay is performed directly on positive blood culture samples that demonstrate the presence of organisms as determined by Gram stain.

E. Applicant:

GenMark Diagnostics, Incorporated

F. Proprietary and Established Names:

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

G. Regulatory Information:

1. Regulation section:

21 CFR 866.3365 - Multiplex Nucleic Acid Assay for Identification of Microorganisms and Resistance Markers from Positive Blood Cultures

2. Classification:

Class II

3. Product codes:

PAM, PEN, PEO

4. Panel:

83 (Microbiology)

H. Intended Use:

1. Intended use(s):

The GenMark ePlex Blood Culture Identification Gram-Positive (BCID-GP) Panel is a qualitative nucleic acid multiplex *in vitro* diagnostic test intended for use on GenMark's ePlex Instrument for simultaneous qualitative detection and identification of multiple potentially pathogenic gram-positive bacterial organisms and select determinants associated with antimicrobial resistance in positive blood culture. In addition, the ePlex BCID-GP Panel is capable of detecting a wide variety of gram-negative bacteria (Pan Gram-Negative assay) and several *Candida* species (Pan *Candida* assay). The ePlex BCID-GP Panel is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system and which contain gram-positive organism.

The following bacterial organisms and genes associated with antibiotic resistance are identified using the ePlex BCID-GP Panel: *Bacillus cereus* group, *Bacillus subtilis* group, *Corynebacterium*, *Cutibacterium acnes* (*Propionibacterium acnes*), *Enterococcus*, *Enterococcus faecalis*, *Enterococcus faecium*, *Lactobacillus*, *Listeria*, *Listeria monocytogenes*, *Micrococcus*, *Staphylococcus*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus lugdunensis*, *Streptococcus*, *Streptococcus agalactiae* (GBS), *Streptococcus anginosus* group, *Streptococcus pneumoniae*, *Streptococcus pyogenes* (GAS), *mecA*, *mecC*, *vanA* and *vanB*.

The ePlex BCID-GP Panel contains assays for the detection of genetic determinants associated with resistance to methicillin (*mecA* and *mecC*) and vancomycin (*vanA* and *vanB*) to aid in the identification of potentially antimicrobial resistant organisms in positive blood culture samples. The antimicrobial resistance gene detected may or may not be associated with the agent responsible for disease.

The ePlex BCID-GP Panel also contains targets designed to detect a broad range of organisms with a potentially misleading Gram stain result or organisms that may be missed by Gram staining altogether, for example in the case of co-infections. These include a broad Pan Gram-Negative assay as well as a Pan *Candida* assay, which is designed to detect four of the most prevalent *Candida* species: *Candida albicans*, *Candida glabrata*, *Candida krusei* and *Candida parapsilosis*.

The detection and identification of specific bacterial and fungal nucleic acids from individuals exhibiting signs and/or symptoms of bloodstream infection aids in the diagnosis of bloodstream infection when used in conjunction with other clinical information. The results from the ePlex BCID-GP Panel are intended to be interpreted in conjunction with Gram stain results and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

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

2. Indication(s) for use:

Same as Intended Use

3. Special conditions for use statement(s):

- For prescription use only
- For in vitro diagnostic use only

Limitations:

- For prescription use only.
- This test is a qualitative test and does not provide a quantitative value.
- This product should not be used with blood culture media that contains charcoal.
- False results were observed for some targets using the BacT Alert FN Plus bottle type (see the Sample Matrix Equivalency (Bottle Evaluation) section of the package insert for additional details) and with a specific lot of BD BACTEC™ Plus Anaerobic bottles.
- Bacterial and fungal nucleic acids may be present in blood culture, independent of bacterial or fungal viability. Detection of an assay target does not guarantee that the corresponding bacteria or fungi are infectious or are the causative agents for clinical symptoms.
- There is a risk of false negative results due to the presence of sequence variants in the bacterial or fungal targets of the test.
- For some strains within the *Corynebacterium*, *Streptococcus* and Pan *Candida* results, 100% detection was not observed at concentrations expected at bottle positivity. See the Analytical Reactivity (Inclusivity) section for additional details.
- A result of “No Targets Detected” on the ePlex BCID-GP Panel does not preclude the possibility of bacterial or fungal infection. A specimen with a result of No Targets Detected may contain an organism not targeted by the ePlex BCID-GP Panel.
- Antimicrobial resistance can occur via multiple mechanisms. A “Not Detected” result for

the BCID-GP antimicrobial resistance gene assays does not indicate antimicrobial susceptibility. Subculturing and standard susceptibility testing of isolates is required to determine antimicrobial susceptibility.

- In mixed cultures, the ePlex BCID-GP Panel may not identify all organisms in the specimen, depending upon the concentration of each target present.
- The results of the ePlex BCID-GP Panel should not be used as the sole basis for diagnosis, treatment or other patient management decisions.
- *Bacillus badius* was shown to cross-react with the *Bacillus subtilis* group assay.
- *Burkholderia cepacia* was shown to cross-react with the *Corynebacterium* assay at levels $\geq 1 \times 10^7$ CFU/mL.
- An unspciated *Rhodococcus* strain (ATCC 49988) was shown to cross-react with the *Micrococcus* assay at levels $\geq 1 \times 10^7$ CFU/mL.
- The genus level and group assays included as a part of the BCID-GP Panel are designed to detect a broad range of species but will not necessarily detect all species within a genus or group. For species detected by these assays please refer to the analytical and *in silico* inclusivity sections of this package insert.
- For genus level assays it is possible that an unspciated target may be masked in the case of a co-infection. For example, in the event that an unspciated *Staphylococcus* species is present in the same sample as a *Staphylococcus epidermidis*, there is no ability to determine that the unspciated *Staphylococcus* species is present.

4. Special instrument requirements:

For use with the GenMark ePlex instrument

I. **Device Description:**

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

Nucleic acid extraction from biological specimens 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.

A summary of the ePlex BCID-GP Panel nucleic acid targets is presented in Table 1 below.

Table 1: Targets Detected by the ePlex BCID-GP Panel

Bacterial Targets	
<i>Bacillus cereus</i> group	<i>Micrococcus</i>
<i>Bacillus subtilis</i> group	<i>Staphylococcus</i>
<i>Corynebacterium</i>	<i>Staphylococcus aureus</i>
<i>Cutibacterium acnes</i> (<i>Propionibacterium acnes</i>)	<i>Staphylococcus epidermidis</i>
<i>Enterococcus</i>	<i>Staphylococcus lugdunensis</i>
<i>Enterococcus faecalis</i>	<i>Streptococcus</i>
<i>Enterococcus faecium</i>	<i>Streptococcus agalactiae</i>
<i>Lactobacillus</i>	<i>Streptococcus anginosus</i> group
<i>Listeria</i>	<i>Streptococcus pneumoniae</i>
<i>Listeria monocytogenes</i>	<i>Streptococcus pyogenes</i>
Antimicrobial Resistance Markers	
<i>mecA</i> (methicillin resistance)	<i>vanA</i> (vancomycin resistance)
<i>mecC</i> (methicillin resistance)	<i>vanB</i> (vancomycin resistance)
Pan Targets	
Pan Gram-Negative	Pan <i>Candida</i>

Materials provided in each kit:

Product	Item	Components (quantity)	Storage
ePlex Blood Culture Identification Gram-Positive (BCID-GP)	EA003012	ePlex BCID-GP Panel Cartridge (12)	2–8 °C

Materials required but not provided:

- GenMark ePlex Instrument and Software
- Pipettes capable of delivering 50µL
- Printer (optional) - See ePlex Operator Manual for compatibility guidelines
- Pipette tips, aerosol resistant, RNase/DNase-free
- Disposable, powder free gloves
- 10% bleach for appropriate surfaces
- 70% ethanol or isopropyl alcohol (or equivalent) for appropriate surfaces
- 1.5mL RNase/DNase-free microcentrifuge tube or equivalent (optional)

Interpretation of Results

Results interpretation of the ePlex BCID-GP Panel is performed by the ePlex instrument, and the interpretation of results on the ePlex BCID-GP Panel Detection Report for each targeted analyte is summarized in Table 2 below.

Table 2: Interpretation of Results on the ePlex BCID-GP Panel Detection Report

Target Result	Explanation	Action
Detected	The test was completed successfully and the target has generated signal above its defined threshold and the Internal Control was reported as PASS.	All results are displayed on the ePlex BCID-GP Panel Detection Report. Test is valid, report results.
Not Detected	The test was completed successfully and the target did not generate signal above its defined threshold and the Internal Control was reported as PASS.	All results are displayed on the ePlex BCID-GP Panel Detection Report. Test is valid, report results.
Invalid	The test has not successfully completed and results for this test are not valid. This may be due to an instrument or software error.	No results are displayed on the ePlex BCID-GP Panel Detection Report. Test is not valid, repeat test.

Genus and Group Assay Result Interpretation

The ePlex BCID-GP Panel *Enterococcus* result is based on three assays: the species-specific *Enterococcus faecalis* and *Enterococcus faecium* assays and a broad *Enterococcus* assay. The broad *Enterococcus* assay will detect *Enterococcus faecalis* and *Enterococcus faecium*, however, its primary purpose is to detect non-*faecalis/faecium* *Enterococcus* species. If all three assays are negative, the *Enterococcus* result will be Not Detected. If any of the three assays is positive, the *Enterococcus* result will be 'Detected'. If only the *Enterococcus* assay is positive, an unspciated *Enterococcus* species has been detected. Interpretations of results for *Enterococcus* are described in Table 3 below.

Table 3: *Enterococcus* Target Results from ePlex BCID-GP Panel Detection Report

<i>Enterococcus</i> Result	<i>Enterococcus</i> Assay	<i>Enterococcus faecalis</i> Assay	<i>Enterococcus faecium</i> Assay	Description
Not Detected	Negative	Negative	Negative	No <i>Enterococcus</i> species Detected
Detected	Positive	Positive	Negative	<i>Enterococcus faecalis</i> Detected
Detected	Positive	Negative	Positive	<i>Enterococcus faecium</i> Detected
Detected	Positive	Positive	Positive	<i>Enterococcus faecalis</i> Detected <i>Enterococcus faecium</i> Detected
Detected	Positive	Negative	Negative	Unspciated <i>Enterococcus</i> Detected

The ePlex BCID-GP Panel *Listeria* result is based on two assays: the species-specific *Listeria monocytogenes* assay and a broad *Listeria* assay. The broad *Listeria* assay will detect multiple *Listeria* species including *Listeria monocytogenes*; however, its primary purpose is

to detect non-monocytogenes *Listeria* species. If either assay is positive, the *Listeria* result will be 'Detected'. If only the *Listeria* assay is positive, an unspciated *Listeria* species has been detected. Interpretations of *Listeria* results are described in Table 4 below.

Table 4: *Listeria* Target Results from ePlex BCID-GP Panel Detection Report

<i>Listeria</i> Result	<i>Listeria</i> Assay	<i>Listeria monocytogenes</i> Assay	Description
Not Detected	Negative	Negative	No <i>Listeria</i> species Detected
Detected	Positive	Positive	<i>Listeria monocytogenes</i> Detected
Detected	Positive	Negative	Unspciated <i>Listeria</i> Detected

The ePlex BCID-GP Panel *Staphylococcus* result is based on four assays: the species-specific *Staphylococcus aureus*, *Staphylococcus epidermidis* and *Staphylococcus lugdunensis* assays and a broad *Staphylococcus* assay. The broad *Staphylococcus* assay will detect each of the species targeted by the species-specific assays, but its primary purpose is to detect other *Staphylococcus* species. If all four assays are negative, the *Staphylococcus* result will be 'Not Detected'. If any of the four assays is positive, the *Staphylococcus* result will be 'Detected'. If only the *Staphylococcus* assay is positive, an unspciated *Staphylococcus* has been detected. Interpretations of *Staphylococcus* results are described in Table 5 below.

Table 5: *Staphylococcus* Target Results from ePlex BCID-GP Panel Detection Report

<i>Staphylococcus</i> Result	<i>Staphylococcus</i> Assay	<i>Staphylococcus aureus</i> Assay	<i>Staphylococcus epidermidis</i> Assay	<i>Staphylococcus lugdunensis</i> Assay	Description
Not Detected	Negative	Negative	Negative	Negative	No <i>Staphylococcus</i> species Detected
Detected	Positive	Positive	Negative	Negative	<i>Staphylococcus aureus</i> Detected
Detected	Positive	Negative	Positive	Negative	<i>Staphylococcus epidermidis</i> Detected
Detected	Positive	Negative	Negative	Positive	<i>Staphylococcus lugdunensis</i> Detected
Detected	Positive	Positive	Positive	Negative	<i>Staphylococcus aureus</i> Detected <i>Staphylococcus epidermidis</i> Detected
Detected	Positive	Positive	Negative	Positive	<i>Staphylococcus aureus</i> Detected <i>Staphylococcus lugdunensis</i> Detected
Detected	Positive	Negative	Positive	Positive	<i>Staphylococcus epidermidis</i> Detected <i>Staphylococcus lugdunensis</i> Detected
Detected	Positive	Positive	Positive	Positive	<i>Staphylococcus aureus</i> Detected <i>Staphylococcus epidermidis</i> Detected <i>Staphylococcus lugdunensis</i> Detected
Detected	Positive	Negative	Negative	Negative	Unspeciated <i>Staphylococcus</i> Detected

The ePlex BCID-GP Panel *Streptococcus* result is based on five assays: the species-specific *Streptococcus agalactiae*, *Streptococcus anginosus* group, *Streptococcus pneumoniae* and *Streptococcus pyogenes* assays and a broad *Streptococcus* assay. The broad *Streptococcus* assay will detect each of the species targeted by the species-specific assays, but its primary purpose is to detect other *Streptococcus* species. If all five assays are negative, the *Streptococcus* result will be 'Not Detected'. If any of the five assays is positive, the *Streptococcus* result will be 'Detected'. If only the *Streptococcus* assay is positive, an unspeciased *Streptococcus* species has been detected. Interpretations of *Streptococcus* results are described in Table 6 below.

Table 6: *Streptococcus* Target Results from ePlex BCID-GP Panel Detection Report

<i>Streptococcus</i> Result	<i>Streptococcus</i> Assay	<i>Streptococcus</i> <i>agalactiae</i> Assay	<i>Streptococcus</i> <i>anginosus</i> group Assay	<i>Streptococcus</i> <i>pneumoniae</i> Assay	<i>Streptococcus</i> <i>pyogenes</i> Assay	Description
Negative	Negative	Negative	Negative	Negative	Negative	No <i>Streptococcus</i> species Detected
Detected	Detected	Detected	Negative	Negative	Negative	<i>Streptococcus</i> <i>agalactiae</i> Detected
Detected	Detected	Negative	Detected	Negative	Negative	<i>Streptococcus</i> <i>anginosus</i> group Detected
Detected	Detected	Negative	Negative	Detected	Negative	<i>Streptococcus</i> <i>pneumoniae</i> Detected
Detected	Detected	Negative	Negative	Negative	Detected	<i>Streptococcus</i> <i>pyogenes</i> Detected
Detected	Detected	Detected	Detected	Negative	Negative	<i>Streptococcus</i> <i>agalactiae</i> Detected <i>Streptococcus</i> <i>anginosus</i> group Detected
Detected	Detected	Detected	Negative	Positive	Negative	<i>Streptococcus</i> <i>agalactiae</i> Detected <i>Streptococcus</i> <i>pneumoniae</i> Detected
Detected	Detected	Detected	Negative	Negative	Positive	<i>Streptococcus</i> <i>agalactiae</i>

<i>Streptococcus</i> Result	<i>Streptococcus</i> Assay	<i>Streptococcus</i> <i>agalactiae</i> Assay	<i>Streptococcus</i> <i>anginosus</i> group Assay	<i>Streptococcus</i> <i>pneumoniae</i> Assay	<i>Streptococcus</i> <i>pyogenes</i> Assay	Description
						Detected <i>Streptococcus</i> <i>pyogenes</i> Detected
Detected	Detected	Negative	Detected	Detected	Negative	<i>Streptococcus</i> <i>anginosus</i> group Detected <i>Streptococcus</i> <i>pneumoniae</i> Detected
Detected	Detected	Negative	Detected	Negative	Detected	<i>Streptococcus</i> <i>anginosus</i> group Detected <i>Streptococcus</i> <i>pyogenes</i> Detected
Detected	Detected	Negative	Negative	Detected	Detected	<i>Streptococcus</i> <i>pneumoniae</i> Detected <i>Streptococcus</i> <i>pyogenes</i> Detected
Detected	Detected	Detected	Detected	Detected	Negative	<i>Streptococcus</i> <i>agalactiae</i> Detected <i>Streptococcus</i> <i>anginosus</i> group Detected <i>Streptococcus</i> <i>pneumoniae</i> Detected

<i>Streptococcus</i> Result	<i>Streptococcus</i> Assay	<i>Streptococcus</i> <i>agalactiae</i> Assay	<i>Streptococcus</i> <i>anginosus</i> group Assay	<i>Streptococcus</i> <i>pneumoniae</i> Assay	<i>Streptococcus</i> <i>pyogenes</i> Assay	Description
Detected	Detected	Detected	Detected	Negative	Detected	<i>Streptococcus</i> <i>agalactiae</i> Detected <i>Streptococcus</i> <i>anginosus</i> group Detected <i>Streptococcus</i> <i>pyogenes</i> Detected
Detected	Detected	Detected	Negative	Detected	Detected	<i>Streptococcus</i> <i>agalactiae</i> Detected <i>Streptococcus</i> <i>pneumoniae</i> Detected <i>Streptococcus</i> <i>pyogenes</i> Detected
Detected	Detected	Negative	Detected	Detected	Detected	<i>Streptococcus</i> <i>anginosus</i> group Detected <i>Streptococcus</i> <i>pneumoniae</i> Detected <i>Streptococcus</i> <i>pyogenes</i> Detected
Detected	Detected	Detected	Detected	Detected	Detected	<i>Streptococcus</i> <i>agalactiae</i> Detected <i>Streptococcus</i> <i>anginosus</i> Detected <i>Streptococcus</i> <i>pneumoniae</i> Detected <i>Streptococcus</i> <i>pyogenes</i> Detected

<i>Streptococcus</i> Result	<i>Streptococcus</i> Assay	<i>Streptococcus agalactiae</i> Assay	<i>Streptococcus anginosus</i> group Assay	<i>Streptococcus pneumoniae</i> Assay	<i>Streptococcus pyogenes</i> Assay	Description
Detected	Detected	Negative	Negative	Negative	Negative	Unspecified <i>Streptococcus</i> Detected

Test results for resistance genes are only reported when an associated organism assay is positive in the same sample. See Table 7 for organisms specifically associated with the four resistance markers on the ePlex BCID-GP Panel.

Table 7: Resistance Marker Organism Associations

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

The ePlex BCID-GP Panel Pan Gram-Negative result is based on a broad assay that covers most gram-negative organisms which include but are not limited to *Acinetobacter*, *Bacteroides*, *Enterobacteriaceae*, *Neisseria*, *Pseudomonas*, *Serratia* and *Stenotrophomonas maltophilia*, as shown in Table 8.

Table 8: Pan Gram-Negative Target Results from ePlex BCID-GP Panel Detection Report

Pan Gram-Negative Result	Description
Not Detected	No gram-negative organism detected.
Detected	One or more gram-negative organisms detected: genera include but are not limited to <i>Acinetobacter</i> , <i>Bacteroides</i> , <i>Enterobacteriaceae</i> , <i>Neisseria</i> , <i>Pseudomonas</i> , <i>Serratia</i> , <i>Stenotrophomonas maltophilia</i> . Additional testing for identification is recommended.

The ePlex BCID-GP Panel Pan *Candida* result indicates the presence of one or more of the following *Candida* species targets: *Candida albicans*, *Candida glabrata*, *Candida krusei*, or *Candida parapsilosis* as shown in Table 9.

Table 9: Pan *Candida* Target Results from ePlex BCID-GP Panel Detection Report

Pan <i>Candida</i> Result	Description
Not Detected	No specified <i>Candida</i> species detected.
Detected	One or more of the following <i>Candida</i> organisms has been detected: <i>Candida albicans</i> , <i>Candida glabrata</i> , <i>Candida krusei</i> and/or <i>Candida parapsilosis</i> . Additional testing for identification is recommended.

ePlex BCID-GP Panel Test Reports

Several different reports are available on the ePlex System. Results are provided in a printable format and may be viewed electronically or exported for additional analysis. Reports can be customized with account specific information such as the address, logo and institutional specific footers on each report.

Detection Report

The ePlex BCID-GP Panel Detection Report includes the results for each individual sample run on the ePlex System. The Summary section indicates the overall test result and lists all detected targets in that sample. The Results section includes a list of all targets on the panel with an individual result for each target. Results are reported as Detected, Not Detected, or Invalid (displayed as a red x); results for the Internal Control are reported as PASS, FAIL, INVALID, or N/A.

External Control Report

The ePlex BCID-GP Panel External Control Report is generated for an external control that has been pre-defined in the ePlex BCID-GP Panel Software. For more information on defining external controls on the ePlex System, refer to the ePlex Operator Manual.

The Summary section indicates the overall result (PASS or FAIL status) and lists all detected targets for that external control. The Results section includes a list of all panel targets with the result, expected result and PASS/FAIL status for each. Results are reported as Detected, Not Detected, or Invalid (displayed as a red x). A target is reported as PASS if the actual result matches the expected result (as defined for that control); a target is reported as FAIL if the actual result does not match the expected result. If the actual result for each target matches the expected result (all targets reported as PASS), the overall result for the external control is reported as PASS in the Summary section. If the actual result for any target does not match the expected result, the overall result for the external control is reported as FAIL in the Summary section.

Summary Report

The Summary Report allows the operator to use searchable criteria to create customized reports, using specified targets, dates, range of dates, sample, external control, test bay, or operator.

J. Substantial Equivalence Information:

1. Predicate device name(s):

BioFire Diagnostics; FilmArray Blood Culture Identification (BCID) Panel

2. Predicate 510(k) number(s):

k130914

3. Comparison with predicate:

Similarities		
Item	Device: ePlex BCID-GP Panel (k181663)	Predicate: FilmArray BCID Panel (k130914)
Indication for Use	The GenMark ePlex Blood Culture Identification Gram-Positive (BCID-GP) Panel is a qualitative nucleic acid multiplex <i>in vitro</i> diagnostic test intended for use on GenMark's ePlex Instrument for simultaneous qualitative detection and identification of multiple potentially pathogenic gram-positive bacterial organisms and select determinants associated with antimicrobial resistance in positive blood culture. In addition, the ePlex BCID-GP Panel is capable of detecting a wide variety of gram-negative bacteria (Pan Gram-Negative assay) and several <i>Candida</i> species (Pan <i>Candida</i> assay). The ePlex BCID-GP Panel is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system and which contain gram-positive organism. The following bacterial organisms and genes associated with antibiotic resistance are identified using the ePlex BCID-GP Panel: <i>Bacillus cereus</i> group, <i>Bacillus subtilis</i> group, <i>Corynebacterium</i>, <i>Cutibacterium acnes</i> (<i>Propionibacterium acnes</i>), <i>Enterococcus</i>, <i>Enterococcus faecalis</i>, <i>Enterococcus faecium</i>, <i>Lactobacillus</i>, <i>Listeria</i>, <i>Listeria monocytogenes</i>, <i>Micrococcus</i>, <i>Staphylococcus</i>, <i>Staphylococcus aureus</i>, <i>Staphylococcus epidermidis</i>, <i>Staphylococcus lugdunensis</i>, <i>Streptococcus</i>, <i>Streptococcus agalactiae</i> (GBS), <i>Streptococcus anginosus</i> group, <i>Streptococcus pneumoniae</i>, <i>Streptococcus pyogenes</i> (GAS), <i>mecA</i>, <i>mecC</i>, <i>vanA</i> and <i>vanB</i>. The ePlex BCID-GP Panel contains assays	The FilmArray Blood Culture Identification (BCID) Panel is a qualitative multiplexed nucleic acid-based <i>in vitro</i> diagnostic test intended for use with the FilmArray Instrument. The FilmArray BCID Panel is capable of simultaneous detection and identification of multiple bacterial and yeast nucleic acids and select genetic determinants of antimicrobial resistance. The BCID assay is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system that demonstrates the presence of organisms as determined by Gram stain. The following gram-positive bacteria, gram-negative bacteria, and yeast are identified using the FilmArray BCID Panel: <i>Enterococci</i>, <i>Listeria monocytogenes</i>, commonly encountered <i>Staphylococci</i> (including specific differentiation of <i>Staphylococcus aureus</i>), commonly encountered <i>Streptococci</i> (with specific differentiation of <i>Streptococcus agalactiae</i>, <i>Streptococcus pneumoniae</i>, and <i>Streptococcus pyogenes</i>), <i>Acinetobacter baumannii</i>, commonly encountered <i>Enterobacteriaceae</i> (including specific differentiation of the <i>Enterobacter cloacae</i> complex, <i>Escherichia coli</i>, <i>Klebsiella oxytoca</i>, <i>Klebsiella pneumoniae</i>, <i>Proteus</i>, and <i>Serratia marcescens</i>), <i>Haemophilus influenzae</i>, <i>Neisseria meningitidis</i> (encapsulated), <i>Pseudomonas aeruginosa</i>, <i>Candida albicans</i>, <i>Candida glabrata</i>, <i>Candida krusei</i>, <i>Candida parapsilosis</i>, and <i>Candida tropicalis</i>. The FilmArray BCID Panel also contains assays for the detection of genetic determinants of resistance to methicillin (<i>mecA</i>), vancomycin (<i>vanA</i> and <i>vanB</i>), and carbapenems (<i>bla_{KPC}</i>) to aid in the identification of potentially antimicrobial resistant organisms in positive

Similarities		
Item	Device: ePlex BCID-GP Panel (k181663)	Predicate: FilmArray BCID Panel (k130914)
	for the detection of genetic determinants associated with resistance to methicillin (<i>mecA</i> and <i>mecC</i>) and vancomycin (<i>vanA</i> and <i>vanB</i>) to aid in the identification of potentially antimicrobial resistant organisms in positive blood culture samples. The antimicrobial resistance gene detected may or may not be associated with the agent responsible for disease. The ePlex BCID-GP Panel also contains targets designed to detect a broad range of organisms with a potentially misleading Gram stain result or organisms that may be missed by Gram staining altogether, for example in the case of co-infections. These include a broad Pan Gram-Negative assay as well as a Pan <i>Candida</i> assay, which is designed to detect four of the most prevalent <i>Candida</i> species: <i>Candida albicans</i>, <i>Candida glabrata</i>, <i>Candida krusei</i> and <i>Candida parapsilosis</i>. The detection and identification of specific bacterial and fungal nucleic acids from individuals exhibiting signs and/or symptoms of bloodstream infection aids in the diagnosis of bloodstream infection when used in conjunction with other clinical information. The results from the ePlex BCID-GP Panel are intended to be interpreted in conjunction with Gram stain results and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Negative results in the setting of a suspected bloodstream infection may be due to infection with pathogens that are not detected by this test. Positive results do not rule out co-infection with other organisms; the organism(s) detected by the ePlex BCID-GP Panel may not be the definite cause of disease. Additional laboratory testing (e.g. sub-culturing of positive blood cultures for identification of organisms not	blood culture samples. The antimicrobial resistance gene detected may or may not be associated with the agent responsible for disease. Negative results for these select antimicrobial resistance gene assays do not indicate susceptibility, as multiple mechanisms of resistance to methicillin, vancomycin, and carbapenems exist. FilmArray BCID is indicated as an aid in the diagnosis of specific agents of bacteremia and fungemia and results should be used in conjunction with other clinical and laboratory findings. Positive FilmArray results do not rule out co-infection with organisms not included in the FilmArray BCID Panel. FilmArray BCID is not intended to monitor treatment for bacteremia or fungemia. Subculturing of positive blood cultures is necessary to recover organisms for susceptibility testing and epidemiological typing, to identify organisms in the blood culture that are not detected by the FilmArray BCID Panel, and for species determination of some Staphylococci, Enterococci, Streptococci, and Enterobacteriaceae that are not specifically identified by the FilmArray BCID Panel assays.

Similarities		
Item	Device: ePlex BCID-GP Panel (k181663)	Predicate: FilmArray BCID Panel (k130914)
	detected by ePlex BCID-GP Panel and for susceptibility testing, differentiation of mixed growth and association of antimicrobial resistance marker genes to a specific organism) and clinical presentation must be taken into consideration in the final diagnosis of blood stream infection.	
Analyte	DNA	DNA
Sample Processing	Automated by instrument	Automated by instrument
Controls	Each cartridge includes internal controls that monitor performance of each step of the testing process, including extraction, amplification and detection of targets.	Two controls are included in each reagent pouch to control for sample processing and both stages of PCR and melt analysis.

Differences		
Item	Device: ePlex BCID-GP Panel (k181663)	Predicate: FilmArray BCID Panel (k130914)
Specimen Type	Gram-Positive Blood Culture	Gram-Positive & Gram-Negative Blood Culture
Test Principles	Reagents on cartridge include: sample lysis and nucleic acid extraction, PCR amplification and hybridization-based electrochemical detection reagents.	The FilmArray BCID pouch contains freeze-dried reagents to perform nucleic acid purification and nested, multiplex PCR with DNA melt analysis.
Instrumentation and Hardware	GenMark ePlex Instrument & Single Use Cartridge	FilmArray Instrument and assay pouch
Software Interface Result Reporting	- GenMark ePlex System Software - GenMark ePlex BCID-GP Panel Software	The FilmArray Software automatically interprets the results of each DNA melt curve analysis and combines the data with the results of the internal pouch controls to provide a test result for each organism and antimicrobial resistance gene on the panel.

K. Standard/Guidance Document Referenced

- Class II Special Controls Guideline: Multiplex Nucleic Acid Assay for Identification of Microorganisms and Resistance Markers from Positive Blood Cultures (May 2015)
- CLSI MM17-A, Vol. 28, No. 9, Verification and Validation of Multiplex Nucleic Acid Assays
- CLSI EP17-A2 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition (June 2012)

- CLSI EP07-A2: Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition (November 2005)
- CLSP EP25-A Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline (May 2013)

L. Test Principle:

The ePlex Blood Culture Identification Gram-Positive (BCID-GP) Panel is based on the principle 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.

M. Performance Characteristics:

1. Analytical performance:

a. *Analytical Sensitivity:*

The limit of detection (LoD) of the ePlex Blood Culture Identification Gram-Positive Panel was assessed with by testing pooled analytes at a range of concentrations (CFU/mL). Each pool was comprised of an organism mix combined together in negative blood matrix. LoD was determined using qualified stocks of organisms with documented CFU/mL that were pooled together and serially diluted to create organism mixes at the test concentrations. Each assay's LoD was determined by testing at least two strains or species. The Pan Gram-Negative assay was evaluated with 6 species due to its broad specificity. Testing was initially done using 3 test concentrations per multi-organism mix. Testing was performed with a minimum of two ePlex consumable lots using multiple instruments and

covered a minimum of two testing days. A minimum of 20 replicates per organism mix were tested at each concentration.

A summary of the determined LoD with the overall detection rate is shown in Table 10 below. The target LoD was conservatively established based on the observed testing outcomes. The species tested for each genus level call or antibiotic resistance marker is noted in parentheses, where appropriate.

Table 10: BCID-GP Panel LoD Results Summary

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

BCID-GP Panel	Organism Strain ID	Strain	LoD Concentration (CFU/mL)
<i>S. aureus</i>	<i>Staphylococcus aureus</i>	ATCC BAA-2313	1 x 10 ⁵
	<i>Staphylococcus aureus</i>	ATCC BAA-2312	1 x 10 ⁵
<i>S. epidermidis</i>	<i>Staphylococcus epidermidis</i>	ATCC 35983	1 x 10 ⁵
	<i>Staphylococcus epidermidis</i>	ATCC 35984	1 x 10 ⁵
<i>S. lugdunensis</i>	<i>Staphylococcus lugdunensis</i>	NRS 879	1 x 10 ⁵
	<i>Staphylococcus lugdunensis</i>	ATCC 49576	1 x 10 ⁵
Streptococcus	<i>Streptococcus pneumoniae</i>	ATCC BAA-475	1 x 10 ⁵
	<i>Streptococcus pneumoniae</i>	ATCC 10357	1 x 10 ⁵
	<i>Streptococcus gordonii</i>	ATCC 10558	1 x 10 ⁶
	<i>Streptococcus agalactiae</i>	ATCC 12401	1 x 10 ⁶
	<i>Streptococcus agalactiae</i>	ATCC 13813	1 x 10 ⁷
<i>S. agalactiae</i>	<i>Streptococcus agalactiae</i>	ATCC 12401	1 x 10 ⁵
	<i>Streptococcus agalactiae</i>	ATCC 13813	1 x 10 ⁶
<i>S. anginosus</i>	<i>Streptococcus intermedius</i>	ATCC 27335	1 x 10 ⁴
	<i>Streptococcus anginosus</i>	ATCC 9895	1 x 10 ⁶
<i>S. pneumoniae</i>	<i>Streptococcus pneumoniae</i>	ATCC BAA-475	1 x 10 ⁵
	<i>Streptococcus pneumoniae</i>	ATCC 10357	1 x 10 ⁵
<i>S. pyogenes</i>	<i>Streptococcus pyogenes</i>	ATCC 12384	1 x 10 ⁵
	<i>Streptococcus pyogenes</i>	ATCC 49399	1 x 10 ⁵
Pan Gram-Negative	<i>Stenotrophomonas maltophilia</i>	ATCC 13636	1 x 10 ⁶
	<i>Enterobacter cloacae</i>	ATCC 13047	1 x 10 ⁶
	<i>Escherichia coli</i>	ATCC 4157	1 x 10 ⁶
	<i>Klebsiella pneumoniae</i>	ATCC BAA-1706	1 x 10 ⁶
	<i>Serratia marcescens</i>	ATCC 8100	1 x 10 ⁶
	<i>Proteus mirabilis</i>	ATCC 43071	1 x 10 ⁶
	<i>Acinetobacter baumannii</i>	NCTC13302	1 x 10 ⁷
	<i>Neisseria meningitidis</i>	ATCC 13113	1 x 10 ⁷
	<i>Pseudomonas aeruginosa</i>	ATCC 15442	1 x 10 ⁷
Pan Candida	<i>Candida albicans</i>	ATCC 24433	1 x 10 ⁶
	<i>Candida glabrata</i>	ATCC 66032	1 x 10 ⁶
<i>mecA</i>	<i>Staphylococcus epidermidis</i>	ATCC 35983	1 x 10 ⁵
	<i>Staphylococcus epidermidis</i>	ATCC 35984	1 x 10 ⁵
<i>mecC</i>	<i>Staphylococcus aureus</i>	ATCC BAA-2313	1 x 10 ⁴
	<i>Staphylococcus aureus</i>	ATCC BAA-2312	1 x 10 ⁴
<i>vanA</i>	<i>Enterococcus faecium</i>	ATCC BAA-2316	1 x 10 ⁴
	<i>Enterococcus faecium</i>	ATCC BAA-2317	1 x 10 ⁵
<i>vanB</i>	<i>Enterococcus faecalis</i>	ATCC 51575	1 x 10 ⁵
	<i>Enterococcus faecalis</i>	ATCC 700802	1 x 10 ⁵

b. Reproducibility:

A multisite reproducibility study of the ePlex BCID-GP Panel was conducted at three testing sites (two external sites and one internal site) across major potential sources of variability, such as site-to-site, lot-to-lot, day-to-day, and operator-to-operator. One ePlex instrument per study site with four towers was employed in this reproducibility study. Two operators performed testing at each site on six days (five nonconsecutive days) with three unique lots of ePlex BCID-GP Panel cartridges. A reproducibility study panel consisting of four panel members; including 9 on-panel organisms and three antibiotic resistance genes representing 15 targets at two concentrations and one negative mix including an off-panel organism were tested in triplicate. Concentrations in the positive mixes reflected those observed at time of bottle positivity plus 8 hours (BP+8) and time of bottle positivity (BP) and one mix containing an off-panel organism grown to bottle positivity, which is expected to yield a negative result.

Summary results for the ePlex BCID-GP Panel reproducibility study are provided in Table 11 below.

Table 11: Summary of Reproducibility Results

BCID-GP Test Result	Organism Test Concentration	Site	Agreement with Expected Results		
			Agreed/N	%	95 % CI
<i>Corynebacterium striatum</i>	Bottle Positive + 8 Hours	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	1	35/36	97.2	(85.8-99.5)
		2	35/36	97.2	(85.8-99.5)
		3	33/36	91.7	(78.2-97.1)
		All	103/108	95.4	(89.6-98.0)
	Negative	1	108/108	100	(96.6-100)
		2	107/108	99.1	(94.9-99.8)
		3	107/107	100	(96.5-100)
		All	322/323	99.7	(98.3-99.9)
<i>Cutibacterium acnes</i> (<i>Propionibacterium acnes</i>)	Bottle Positive + 8 Hours	1	32/36	88.9	(74.7-95.6)
		2	33/36	91.7	(78.2-97.1)
		3	36/36	100	(90.4-100)
		All	101/108	93.5	(87.2-96.8)
	Bottle Positive	1	36/36	100	(90.4-100)
		2	33/36	91.7	(78.2-97.1)
		3	35/36	97.2	(85.8-99.5)
		All	104/108	96.3	(90.9-98.6)
	Negative	1	108/108	100	(96.6-100)
		2	108/108	100	(96.6-100)
		3	107/107	100	(96.5-100)
		All	323/323	100	(98.8-100)

<i>Enterococcus</i>	Bottle Positive + 8 Hours	1	72/72	100	(94.9-100)
		2	72/72	100	(94.9-100)
		3	72/72	100	(94.9-100)
		All	216/216	100	(98.3-100)
	Bottle Positive	1	72/72	100	(94.9-100)
		2	72/72	100	(94.9-100)
		3	72/72	100	(94.9-100)
		All	216/216	100	(98.3-100)
	Negative	1	36/36	100	(90.4-100)
		2	36/36	100	(90.4-100)
		3	35/35	100	(90.1-100)
		All	107/107	100	(96.5-100)
<i>Enterococcus faecalis</i>	Bottle Positive + 8 Hours	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	1	36/36	100	(90.4-100)
		2	36/36	100	(90.4-100)
		3	36/36	100	(90.4-100)
		All	108/108	100	(96.6-100)
	Negative	1	108/108	100	(96.6-100)
		2	108/108	100	(96.6-100)
		3	107/107	100	(96.5-100)
		All	323/323	100	(98.8-100)
<i>Enterococcus faecium</i>	Bottle Positive + 8 Hours	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	1	36/36	100	(90.4-100)
		2	36/36	100	(90.4-100)
		3	107-107	100	(96.5-100)
		All	108/108	100	(96.6-100)
	Negative	1	108/108	100	(96.6-100)
		2	108/108	100	(96.6-100)
		3	107/107	100	(96.5-100)
		All	323/323	100	(98.8-100)
<i>Lactobacillus</i>	Bottle Positive + 8 Hours	1	36/36	100	(90.1-100)
		2	36/36	100	(89.8-100)
		3	36/36	100	(90.4-100)
		All	108/108	100	(96.5-100)
	Bottle Positive	1	36/36	100	(89.8-100)
		2	36/36	100	(90.4-100)
		3	36/36	100	(90.1-100)
		All	108/108	100	(96.5-100)
	Negative	1	108/108	100	(90.4-100)

		2	108/108	100	(89.8-100)
		3	107/107	100	(90.1-100)
		All	323/323	100	(96.5-100)
<i>Staphylococcus</i>	Bottle Positive + 8 Hours	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	1	36/36	100	(90.4-100)
		2	35/36	97.2	(85.8-99.5)
		3	36/36	100	(90.4-100)
		All	107/108	99.1	(94.9-99.8)
	Negative	1	108/108	100	(96.6-100)
		2	107/108	99.1	(94.9-99.8)
		3	107/107	100	(96.5-100)
		All	322/323	99.7	(98.3-99.9)
<i>Staphylococcus aureus</i>	Bottle Positive + 8 Hours	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	1	36/36	100	(90.4-100)
		2	36/36	100	(90.4-100)
		3	36/36	100	(90.4-100)
		All	108/108	100	(96.6-100)
	Negative	1	108/108	100	(96.6-100)
		2	108/108	100	(96.6-100)
		3	107/107	100	(96.5-100)
		All	323/323	100	(98.8-100)
<i>Streptococcus</i>	Bottle Positive + 8 Hours	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	1	36/36	100	(90.4-100)
		2	35/36	97.2	(85.8-99.5)
		3	36/36	100	(90.4-100)
		All	107/108	99.1	(94.9-99.8)
	Negative	1	108/108	100	(96.6-100)
		2	107/108	99.1	(94.9-99.8)
		3	107/107	100	(96.5-100)
		All	322/323	99.7	(98.3-99.9)
<i>Streptococcus anginosus</i> group	Bottle Positive + 8 Hours	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	1	36/36	100	(90.4-100)
		2	35/36	97.2	(85.8-99.5)

	Negative	3	36/36	100	(90.4-100)
		All	107/108	99.1	(94.9-99.8)
		1	108/108	100	(96.6-100)
		2	108/108	100	(96.6-100)
		3	107/107	100	(96.5-100)
		All	323/323	100	(98.8-100)
Pan Candida	Bottle Positive + 8 Hours	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	1	36/36	100	(90.4-100)
		2	36/36	100	(90.4-100)
		3	36/36	100	(90.4-100)
		All	108/108	100	(96.6-100)
	Negative	1	108/108	100	(96.6-100)
		2	108/108	100	(96.6-100)
		3	107/107	100	(96.5-100)
		All	323/323	100	(98.8-100)
Pan Gram-Negative	Bottle Positive + 8 Hours	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	1	36/36	100	(90.4-100)
		2	36/36	100	(90.4-100)
		3	36/36	100	(90.4-100)
		All	108/108	100	(96.6-100)
	Negative	1	108/108	100	(96.6-100)
		2	107/108	99.1	(94.9-99.8)
		3	107/107	100	(96.5-100)
		All	322/323	99.7	(98.3-99.9)
mecA	Bottle Positive + 8 Hours	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	1	36/36	100	(90.4-100)
		2	36/36	100	(90.4-100)
		3	36/36	100	(90.4-100)
		All	108/108	100	(96.6-100)
	Negative	1	108/108	100	(96.6-100)
		2	108/108	100	(96.6-100)
		3	107/107	100	(96.5-100)
		All	323/323	100	(98.8-100)
vanA	Bottle Positive + 8 Hours	1	36/36	100	(90.4-100)
		2	36/36	100	(90.4-100)
		3	36/36	100	(90.4-100)

	Bottle Positive	All	108/108	100	(96.6-100)
		1	36/36	100	(90.4-100)
		2	36/36	100	(90.4-100)
		3	36/36	100	(90.4-100)
	Negative	All	108/108	100	(96.6-100)
		1	108/108	100	(96.6-100)
		2	108/108	100	(96.6-100)
		3	107/107	100	(96.5-100)
vanB	Bottle Positive + 8 Hours	All	323/323	100	(98.8-100)
		1	36/36	100	(90.4-100)
		2	36/36	100	(90.4-100)
		3	36/36	100	(90.4-100)
	Bottle Positive	All	108/108	100	(96.6-100)
		1	36/36	100	(90.4-100)
		2	36/36	100	(90.4-100)
		3	36/36	100	(90.4-100)
	Negative	All	108/108	100	(96.6-100)
		1	108/108	100	(96.6-100)
		2	108/108	100	(96.6-100)
		3	107/107	100	(96.5-100)
		All	323/323	100	(98.8-100)

c. *Linearity/assay reportable range:*

Not applicable

d. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Assay Controls

Internal Controls:

Each ePlex BCID- GP Panel cartridge includes internal controls that monitor performance of each step of the testing process, including extraction, amplification and detection of targets.

Each amplification reaction on the cartridge has an internal control and in each reaction either the internal control or a target must generate signal above the defined threshold for a valid test result. Internal control results are interpreted by the ePlex Software and displayed on the ePlex BCID-GP Panel Reports as Internal Control with a result of PASS, FAIL, N/A or INVALID. Table 12 includes details on the interpretation of Internal Control results.

Table 12: Internal Control Results

Internal Control Result	Explanation	Action
PASS	Signal above threshold has been detected from each amplification reaction. The test was completed and internal controls were successful, indicating valid results were generated.	All results are displayed on the ePlex BCID-GP Panel Detection Report. Test is valid, report results.
FAIL	Signal above threshold has not been detected from at least one amplification reaction. The test was completed but internal controls were not detected, indicating that results may not be valid.	No results are displayed on the ePlex BCID-GP Panel Detection Report. Test is not valid, repeat the test using a new cartridge.
N/A	The internal control in every amplification reaction does not generate signal above the threshold, but a target in every amplification reaction does generate signal above the threshold. The test was completed and internal controls were not successful, however detection of signal above the threshold for a target in every amplification reaction indicates valid results were generated.	All results are displayed on the ePlex BCID-GP Panel Detection Report. Test is valid, report results.
INVALID	An error has occurred during processing that prevents analysis of signal data. The test has not successfully completed and results for this test are not valid. This may be due to an instrument or software error.	No results are displayed on the ePlex BCID-GP Panel Detection Report. Test is not valid, repeat the test using a new cartridge.

Recommended External Controls: External controls are not provided with the ePlex BCID Gram-Positive Panel, but are recommended in the package insert. Positive and negative external controls should be tested with each new lot of reagents or monthly, whichever occurs first. Blood culture medium can be used as the negative control. Previously characterized positive samples or blood culture medium spiked with well characterized organisms can be used as the external positive control. External controls should be run in accordance with laboratory protocols and accrediting organizations, as applicable.

Specimen Stability

A specimen stability study was performed to confirm the stability of specimens stored under four different temperature conditions over multiple time points which vary based on storage temperature. Organism mixes whose members were at a concentration approximating bottle positivity were stored at $\leq -70^{\circ}\text{C}$, $\leq -20^{\circ}\text{C}$, $2^{\circ} - 8^{\circ}\text{C}$, and ambient temperature over various time points described in Table 13 below.

Table 13: Storage Conditions and Testing Time Points

Storage Condition	Time Points							
Ambient	T0	1 day	3 days	5 days	7 days	14 days	30 days	--
Refrigerated (2-8°C)	--	1 day	3 days	5 days	7 days	14 days	30 days	--
Frozen ($\leq -20^{\circ}\text{C}$)	1 week	2 weeks	1 mo.	3 mo.*	6 mo.	12 mo.	18 mo.	24 mo.
Frozen ($\leq -70^{\circ}\text{C}$)	1 week	2 weeks	1 mo.	3 mo.*	6 mo.	12 mo.	18 mo.	24 mo.
Bottle Incubator	Bottle positivity	12 hours post positivity	--	--	--	--	--	--

*Mix 1 was tested up to 3 months; Mix 2 was tested up to 1 month.

These organism mixes represent each of the eight multiplex amplification pools on the BCID-GP Panel and include common gram-positive bacteria, drug resistance genes, bottle contaminants (*Lactobacillus*, *Corynebacterium*, *Cutibacterium*), gram-negative (*Klebsiella pneumoniae*) and fungal (*Candida albicans*) targets. Twenty replicates were tested at the beginning of the study when organism mixes were freshly made (time point T0). Ten replicates were tested for each additional temperature and time point.

Ambient Storage Condition

All Mix 1 and Mix 2 analytes showed positivity rates of $>95\%$ when stored under ambient temperature for up to 1 month. The positivity rates and mean signals (nA) are summarized for Mix 1 and Mix 2 in Table 14 and Table 15, respectively.

Table 14: Mix 1 Ambient Storage Sample Stability

Time Point	n	Metric	Mix 1 Analytes Ambient Storage					
			<i>C. acnes</i>	<i>E. faecalis</i> *	<i>L. casei</i>	<i>Staphylococcus</i>	<i>S. epidermidis</i>	<i>vanB</i>
Day 0	20	% Detected	100	100	100	100	100	100
		Mean Signal (nA)	276.0	897.2	423.8	484.0	496.6	486.7
Day 1	10	% Detected	100	100	100	100	100	100
		Mean Signal (nA)	309.3	794.3	396.6	492.4	361.4	447.7
Day 3	10	% Detected	100	100	100	100	100	100
		Mean Signal (nA)	448.4	915.0	515.9	635.7	447.0	507.8
Day 5	10	% Detected	100	100	100	100	100	100
		Mean Signal (nA)	438.1	901.5	489.7	673.0	491.7	526.0
Week 1	10	% Detected	100	100	100	100	100	100
		Mean Signal (nA)	449.8	979.8	533.1	657.4	540.6	526.5
Week 2	10	% Detected	100	100	100	100	100	100
		Mean Signal (nA)	295.2	996.1	479.4	624.2	520.0	452.3
Month 1	20	% Detected	95	95	95	95	95	95
		Mean Signal (nA)	374.1	980.7	492.1	642.2	582.8	486.2

* The *Enterococcus* genus call is not sensitive to *Enterococcus faecalis* and is therefore forced by the software logic in the presence of *Enterococcus faecalis* signal as detected. Due to this, signal and detection rate for *Enterococcus* are not analyzed in this table.

Table 15: Mix 2 Ambient Storage Sample Stability

Time point	n	Metric	Mix 2 Analytes Ambient Storage								
			<i>Enterococcus</i>	<i>E. faecium</i>	<i>Staph</i>	<i>S. aureus</i>	<i>Streptococcus</i>	<i>S. pneumoniae</i>	<i>C. albicans</i>	<i>K. pneumo</i>	<i>vanA</i>
Day 0	20	% Detected	100	100	100	100	100	100	100	100	100
		Mean Signal (nA)	230.1	548.0	511.3	458.9	766.0	669.0	281.1	135.8	741.8
Day 1	10	% Detected	100	100	100	100	100	100	100	100	100
		Mean Signal (nA)	294.1	580.8	606.5	641.1	829.5	705.4	308.1	143.2	900.0
Day 3	10	% Detected	100	100	100	100	100	100	100	100	100
		Mean Signal (nA)	292.9	592.0	654.8	751.2	876.3	756.4	335.4	141.2	854.5
Day 5	10	% Detected	100	100	100	100	100	100	100	100	100
		Mean Signal (nA)	303.3	586.0	603.3	716.2	865.2	753.4	334.1	170.9	931.7
Week 1	10	% Detected	100	100	100	100	100	100	100	100	100
		Mean Signal (nA)	322.9	608.5	722.3	537.1	813.2	739.5	358.7	177.5	950.1
Week 2	20	% Detected	100	100	100	100	100	100	100	95	100
		Mean Signal (nA)	323.7	632.0	733.0	465.2	800.5	714.4	338.5	214.7	971.5
Month 1	20	% Detected	95	95	100	100	95	100	95	100	95
		Mean Signal (nA)	262.4	478.0	672.9	284.0	720.3	593.0	278.2	198.8	865.7

All Mix 1 and Mix 2 analytes showed positivity rates of $\geq 95\%$ when stored under refrigerated conditions (2°C-8°C) for up to 1 month. The positivity rates and mean signals (nA) are summarized for Mix 1 and Mix 2 in Table 16 and Table 17, respectively.

Table 16: Mix 1, 2-8°C Storage Sample Stability

Time Point	n	Metric	Mix 1 Analytes 2°C-8°C Storage					
			<i>C. acnes</i>	<i>E. faecalis</i> *	<i>L. casei</i>	<i>Staphylococcus</i>	<i>S. epidermidis</i>	<i>vanB</i>
Day 1	20	% Detected	95	100	100	100	100	100
		Mean Signal (nA)	377.9	909.5	489.8	578.7	515.3	473.4
Day 3	10	% Detected	100	100	100	100	100	100
		Mean Signal (nA)	341.1	830.7	446.7	496.2	451.5	466.7
Day 5	10	% Detected	100	100	100	100	100	100
		Mean Signal (nA)	427.8	900.4	500.2	566.2	461.2	493.6
Week 1	10	% Detected	100	100	100	100	100	100
		Mean Signal (nA)	298.5	778.6	418.9	488.7	414.7	503.3
Week 2	10	% Detected	100	100	100	100	100	100
		Mean Signal (nA)	316.8	1015.2	522.5	586.0	443.4	475.0
Month 1	10	% Detected	100	100	100	100	100	100
		Mean Signal (nA)	414.8	1134.2	563.7	685.1	721.7	514.7

* *The Enterococcus* genus call is not sensitive to *Enterococcus faecalis* and is therefore forced by the software logic in the presence of *Enterococcus faecalis* signal as detected. Due to this, signal and detection rate for *Enterococcus* are not analyzed in this table.

Table 17: Mix 2, 2°C-8°C Storage Sample Stability

Time Point	n	Metric	Mix 2 Analytes 2°C-8°C Storage								
			<i>Enterococcus</i>	<i>E. faecium</i>	<i>Staphylococcus</i>	<i>S. aureus</i>	<i>Streptococcus</i>	<i>S. pneumoniae</i>	<i>C. albicans</i>	<i>K. pneumoniae</i>	<i>vanA</i>
Day 1	10	% Detected	100	100	100	100	100	100	100	100	100
		Mean Signal (nA)	310.7	553.0	582.6	620.7	809.1	710.4	316.9	138.2	890.5
Day 3	10	% Detected	100	100	100	100	100	100	100	100	100
		Mean Signal (nA)	321.1	582.7	574.7	621.7	876.7	732.9	329.5	180.9	870.2
Day 5	10	% Detected	100	100	100	100	100	100	100	100	100
		Mean Signal (nA)	302.9	589.1	597.5	623.6	869.2	753.2	334.3	119.0	863.6
Week 1	10	% Detected	100	100	100	100	100	100	100	100	100
		Mean Signal (nA)	270.8	564.9	582.7	334.0	706.2	655.5	307.4	176.5	889.6
Week 2	10	% Detected	100	100	100	100	100	100	100	100	100
		Mean Signal (nA)	282.7	593.2	611.2	400.0	698.3	596.1	301.5	153.5	951.0
Month 1	10	% Detected	100	100	100	100	100	100	100	100	100
		Mean Signal (nA)	270.6	526.0	604.2	312.8	681.3	596.5	311.1	164.2	891.3

Frozen ($\leq -20^{\circ}\text{C}$) Storage Condition

All Mix 1 and Mix 2 analytes showed positivity rates of 100% when stored under frozen conditions ($\leq -20^{\circ}\text{C}$) for up to 1 month. The positivity rates and mean signals (nA) are summarized in Table 18 and Table 19, respectively. Mix 1 was also tested at the subsequent 3 month time point and continued to show 100% positivity for all analytes.

Table 18: Mix 1, $\leq -20^{\circ}\text{C}$ Storage Sample Stability

Time Point	n	Metric	Mix 1 Analytes $\leq -20^{\circ}\text{C}$ Storage					
			<i>C. acnes</i>	<i>E. faecalis</i> *	<i>L. casei</i>	<i>Staphylococcus</i>	<i>S. epidermidis</i>	<i>vanB</i>
Week 1	10	% Detected	100	100	100	100	100	100
		Mean Signal (nA)	447.0	986.2	537.1	651.5	504.6	545.1
Week 2	10	% Detected	100	100	100	100	100	100
		Mean Signal (nA)	299.7	943.0	458.3	553.9	445.6	467.9
Month 1	10	% Detected	100	100	100	100	100	100
		Mean Signal (nA)	373.2	934.2	490.5	581.8	661.4	474.3
Month 3	10	% Detected	100	100	100	100	100	100
		Mean Signal (nA)	214.7	853.6	440.2	637.3	584.0	505.4

* The *Enterococcus* genus call is not sensitive to *Enterococcus faecalis* and is therefore forced by the software logic in the presence of *Enterococcus faecalis* signal as detected. Due to this, signal and detection rate for *Enterococcus* are not analyzed in this table.

Table 19: Mix 2, $\leq -20^{\circ}\text{C}$ Storage Sample Stability

Time Point	n	Metric	Mix 2 Analytes $\leq -20^{\circ}\text{C}$ Storage								
			<i>Enterococcus</i>	<i>E. faecium</i>	<i>Staphylococcus</i>	<i>S. aureus</i>	<i>Streptococcus</i>	<i>S. pneumoniae</i>	<i>C. albicans</i>	<i>K. pneumoniae</i>	<i>vanA</i>
Week 1	20	% Detected	100	100	100	100	100	100	100	95	100
		Mean Signal (nA)	282.8	559.4	608.2	504.0	763.9	663.5	316.8	174.9	873.6
Week 2	10	% Detected	100	100	100	100	100	100	100	100	100
		Mean Signal (nA)	282.7	589.6	558.8	445.4	807.2	671.3	305.0	197.8	951.3
Month 1	10	% Detected	100	100	100	100	100	100	100	100	100
		Mean Signal (nA)	281.0	482.2	614.4	317.8	813.4	630.4	261.3	155.3	847.4

Frozen ($\leq -70^{\circ}\text{C}$) Storage Condition

Mix 1 analytes showed positivity rates of $\geq 95\%$ when stored under frozen conditions ($\leq -70^{\circ}\text{C}$) for up to 3 months with the exception of *C. acnes* and *L. casei*, which observed a positivity rate of 90% on the first week of storage at $\leq -70^{\circ}\text{C}$. Per the study acceptance criteria, subsequent time points were evaluated. At all other tested time points up to 3 months, *C. acnes* and *L. casei* showed $\geq 95\%$ positive detection indicating that the lower detection rates at the week 1

time point were not due to specimen stability issues. The observed positivity rates and mean signals (nA) for Mix 1 analytes are summarized in Table 20 below.

Table 20: Mix 1, $\leq -70^{\circ}\text{C}$ Storage Sample Stability

Time Point	n	Metric	Mix 1 Analytes $\leq -70^{\circ}\text{C}$ Storage					
			<i>C. acnes</i>	<i>E. faecalis</i> *	<i>L. casei</i>	<i>Staphylococcus</i>	<i>S. epidermidis</i>	<i>vanB</i>
Week 1	20	% Detected	90	100	90	100	100	95
		Mean Signal (nA)	328.8	796.8	448.6	465.6	367.4	473.9
Week 2	10	% Detected	100	100	100	100	100	100
		Mean Signal (nA)	275.3	795.4	385.8	505.3	420.9	414.6
Month 1	10	% Detected	100	100	100	100	100	100
		Mean Signal (nA)	308.3	872.4	428.5	490.3	590.9	469.8
Month 3	20	% Detected	95	100	100	100	100	100
		Mean Signal (nA)	206.3	795.0	405.4	514.7	481.8	500.2

* The *Enterococcus* genus call is not sensitive to *Enterococcus faecalis* and is therefore forced by the software logic in the presence of *Enterococcus faecalis* signal as detected. Due to this, signal and detection rate for *Enterococcus* are not analyzed in this table.

All Mix 2 analytes showed positivity rates of 100% when stored under frozen conditions ($\leq -70^{\circ}\text{C}$) for up to 1 month. The positivity rates and mean signals (nA) for Mix 2 analytes are summarized in Table 21.

Table 21: Mix 2, $\leq -70^{\circ}\text{C}$ Storage Sample Stability

Time Point	n	Metric	Mix 2 Analytes $\leq -70^{\circ}\text{C}$ Storage								
			<i>Enterococcus</i>	<i>E. faecium</i>	<i>Staphylococcus</i>	<i>S. aureus</i>	<i>Streptococcus</i>	<i>S. pneumoniae</i>	<i>C. albicans</i>	<i>K. pneumoniae</i>	<i>vanA</i>
Week 1	10	% Detected	100	100	100	100	100	100	100	100	100
		Mean Signal (nA)	295.6	587.2	591.5	466.9	733.6	677.2	318.6	143.0	893.8
Week 2	10	% Detected	100	100	100	100	100	100	100	100	100
		Mean Signal (nA)	278.8	507.3	555.2	431.2	793.7	643.4	297.5	167.0	885.2
Month 1	10	% Detected	100	100	100	100	100	100	100	100	100
		Mean Signal (nA)	267.2	498.5	609.1	349.2	775.5	617.6	306.6	182.3	862.9

Bottle Ring and 12 Hours Post Bottle Ring

The positivity rates and mean signals were calculated for the two organisms (*Staphylococcus lugdunensis* and *Streptococcus pyogenes*) grown to bottle positivity and incubated 12 hours post positivity. The positivity rates for *Staphylococcus lugdunensis* and *Streptococcus pyogenes* at bottle ring and 12 hours post bottle ring was 100% for both organisms. Results are summarized in Table 22.

Table 22: Bottle Ring and 12 hours Post Bottle Ring

Blood culture	Metric	Bottle ring		Bottle ring + 12 hrs	
		<i>Staphylococcus</i>	<i>S. lugdunensis</i>	<i>Staphylococcus</i>	<i>S. lugdunensis</i>
<i>Staphylococcus lugdunensis</i>	% Detected	100%	100%	100%	100%
	Mean Signal (nA)	617.7	833.8	537.8	800.1
Blood culture	Metric	<i>Streptococcus</i>	<i>S. pyogenes</i>	<i>Streptococcus</i>	<i>S. pyogenes</i>
<i>Streptococcus pyogenes</i>	% Detected	100%	100%	100%	100%
	Mean Signal (nA)	591.8	936.9	666.1	1045.9

Results demonstrated that specimens can be stored up to 1 month under the following temperature conditions without adversely impacting the performance of the BCID-GP Panel:

- Ambient temperature
- Refrigerated (2°C-8°C)
- Frozen ($\leq -20^{\circ}\text{C}$ and $\leq -70^{\circ}\text{C}$)

Specimens can also be tested when incubated up to 12 hours after bottle ring in a continuously monitoring blood culture device.

The specimen stability claims are summarized in the table below.

Storage Condition	Specimen Stability
Ambient	1 month
Refrigerated (2°C-8°C)	1 month
Frozen ($\leq -20^{\circ}\text{C}$)	1 month
Frozen ($\leq -70^{\circ}\text{C}$)	1 month
Post Bottle Ring	12 hours

Freeze-Thaw Study

A study was performed to assess the tolerance of the ePlex BCID-GP to correctly identify specimens containing bacterial and fungal organisms that have gone through one or two freeze/thaw cycles prior to testing. One hundred and ten positive clinical samples that were tested fresh during the BCID-GP Panel Clinical Performance Study were selected to best represent a variety of organisms in clinical samples. The samples were frozen at $\leq$

70°C and then thawed once or twice prior to re-testing with the BCID-GP Panel.

The positive agreement with the fresh condition at each freeze-thaw cycle was calculated and was above 95% for each condition. Table 23 below summarizes the concordance at each freeze-thaw cycle with a 95% confidence level.

Table 23: Concordance of Results with Fresh Condition

	1x Freeze Thaw	2x Freeze Thaw
Concordant Samples	98	101
Discordant Samples	4	1
Total Samples Tested	102	102
Concordance	96.08%	99.02%
CI Low	90.35%	94.65%
CI High	98.46%	99.83%

Results demonstrate that the BCID-GP Panel can detect the same organisms in samples that were tested fresh and in samples that have been frozen and thawed up to 2 times.

In-Cartridge Sample Stability Study

An analytical study was carried out to demonstrate performance under the following conditions:

- 1) Condition 1 (Open Pouch): the cartridge is stable for 2 hours after the pouch has been opened and the unloaded cartridge is exposed to the environment.
- 2) Condition 2 (In-Consumable Sample Stability): the cartridge can be stored at room temperature for at least 2 hours after the sample has been loaded prior to running the cartridge in an ePlex bay.

A test mix of five organisms was used in the study. The selected organisms represent each of the eight multiplex primer pools on the BCID-GP Panel and produce nine target results. Each organism was tested at a concentration approximating bottle positivity. A description of the test mix used for this study is summarized in the Table below.

Table 24: Representative Organisms Contained in Test Mix

Organism in Test Mix	Concentration in Mix (CFU/mL)	Primer Pool	ePlex BCID-GP Panel Expected Result
<i>Streptococcus pneumoniae</i>	4 x 10 ⁷	5	<i>Streptococcus pneumoniae</i>
			<i>Streptococcus</i> *
<i>Enterococcus faecium</i> / <i>vanA</i>	4 x 10 ⁷	1, 3, 4	<i>Enterococcus faecium</i>
			<i>Enterococcus</i> *
			<i>vanA</i>
<i>Candida albicans</i>	1 x 10 ⁶	2	Pan <i>Candida</i>
<i>Klebsiella pneumoniae</i>	5 x 10 ⁸	7	Pan Gram-Negative
<i>Staphylococcus aureus</i>	2 x 10 ⁷	6, 8	<i>Staphylococcus aureus</i>
			<i>Staphylococcus</i> *

* Software logic defines that when a *Staphylococcus*, *Streptococcus* or *Enterococcus* species is detected, the corresponding genus call is detected.

The open pouch stability study compared 20 replicates of cartridges that were kept in closed pouches until the cartridges were loaded with sample vs. 20 replicates of cartridges where the pouches were opened and the cartridges were exposed to ambient room temperature conditions for up to 2 hours before being loaded with sample.

To demonstrate that the consumable can be held at room temperature for at least 2 hours after the sample has been loaded (prior to running the consumable on an ePlex bay), 20 consumables were loaded with the organism mix, within 20 minutes of opening the pouch. The consumables were kept for 2 hours at room temperature and then run in the ePlex instrument.

A control condition was run wherein 20 replicates of the organism mix were loaded within 20 minutes of pouch opening and the consumables were run on the ePlex instrument within 20 minutes of sample loading. The data from the test conditions were compared to the control condition and all cartridges were run on the ePlex instrument following packing insert instructions.

The results of the study which assessed the interim storage conditions are summarized in Table 25. All representative targets were detected in all replicates (20/20) in the control and the two test conditions (Open Pouch Stability Condition and In-Consumable Sample Stability Condition).

Table 25: Detection Rates for All Conditions Tested

Detection Rate			
Target	Control Condition	Open Pouch Stability Condition	In-Consumable Sample Stability Condition
<i>Enterococcus</i>	100%	100%	100%
<i>Enterococcus faecium</i>	100%	100%	100%
<i>Staphylococcus</i>	100%	100%	100%
<i>Staphylococcus aureus</i>	100%	100%	100%
<i>Streptococcus</i>	100%	100%	100%
<i>Streptococcus pneumoniae</i>	100%	100%	100%
Pan <i>Candida</i>	100%	100%	100%
Pan Gram-Negative	100%	100%	100%
<i>vanA</i>	100%	100%	100%

The mean signal, standard deviation (SD), and mean minus 2SD were calculated for each target and test condition (Table 26). Mean minus 2SD values were all well above the assigned cutoff for each target/condition.

Table 26: Signals Remain Above Assay Cut-Offs in All Test Conditions

Target	Test Condition	Mean Signal (nA)	Std Dev (nA)	Mean minus 2SD (nA)	Target Cutoff (nA)
<i>Enterococcus</i>	Control	313.80	70.76	172.29	20
	In-Consumable Sample Stability Test	297.93	85.45	127.02	
	Open Pouch Stability Test	329.48	43.90	241.68	
<i>Enterococcus faecium</i>	Control	561.66	89.84	381.98	20*
	In-Consumable Sample Stability Test	539.41	113.24	312.92	
	Open Pouch Stability Test	574.44	74.49	425.46	
<i>Staphylococcus</i>	Control	704.29	109.10	486.09	20
	In-Consumable Sample Stability Test	694.93	119.17	456.59	
	Open Pouch Stability Test	679.21	129.69	419.83	
<i>Staphylococcus aureus</i>	Control	673.25	225.07	223.10	15
	In-Consumable Sample Stability Test	681.33	201.87	277.59	
	Open Pouch Stability Test	739.48	269.42	200.63	
<i>Streptococcus</i>	Control	682.97	187.04	308.88	30
	In-Consumable Sample Stability Test	652.05	202.44	247.17	

Target	Test Condition	Mean Signal (nA)	Std Dev (nA)	Mean minus 2SD (nA)	Target Cutoff (nA)
	Open Pouch Stability Test	785.78	132.81	520.15	
<i>Streptococcus pneumoniae</i>	Control	715.97	118.33	479.30	20
	In-Consumable Sample Stability Test	682.68	132.63	417.41	
	Open Pouch Stability Test	757.41	90.83	575.76	
<i>Pan Candida</i>	Control	350.90	68.35	214.20	40
	In-Consumable Sample Stability Test	338.80	76.92	184.96	
	Open Pouch Stability Test	347.09	68.26	210.56	
<i>Pan Gram-Negative</i>	Control	261.41	88.85	83.70	40
	In-Consumable Sample Stability Test	248.32	50.92	146.49	
	Open Pouch Stability Test	296.43	66.03	164.37	
<i>VanA</i>	Control	935.81	102.70	730.40	20
	In-Consumable Sample Stability Test	916.30	217.64	481.02	
	Open Pouch Stability Test	955.10	102.58	749.93	

**Enterococcus faecium* cutoff is 20nA when signal for *Enterococcus* is ≥ 20 nA. An *Enterococcus faecium* signal that is ≥ 400 nA is independent of the *Enterococcus* signal.

e. Growth and Detection Study

A study was performed to establish the range of expected organism concentrations present in incubated blood cultures at bottle positivity (i.e., bottle “ring”) and eight hours after bottle positivity/bottle “ring.” A total of 22 representative organisms (from organism glycerol stocks) were tested in this study. A minimum of eight organism-appropriate blood culture bottles were procured and decontaminated with 10% bleach and 70% isopropyl alcohol. The volume of negative human whole blood, determined by the manufacturer’s instructions, was inoculated into each bottle and grown to bottle positivity and bottle positivity + 8 hours. At the time of positivity (and/or eight hours after positivity), the blood culture was removed from the instrument for determination of organism concentration (CFU/mL using a plate count procedure) and ePlex BCID panel testing.

The following table summarizes the concentration of organism (CFU/mL) determined for a representative panel of 22 isolates. The concentration of *Corynebacterium striatum* at bottle positivity was observed to be the lowest of all the bacterial species tested so a second round of growth was tested to confirm the reproducibility of the counts. In addition, the *Corynebacterium* genus is large (at least 88 species) so additional species were cultured and

counted in order to ensure a representative average. Table 28 lists the concentration for multiple species of *Corynebacterium* at bottle positivity to obtain an average concentration.

Table 27: Average Bottle Positive Concentration by Genus

Analyte	Average Positive Concentration (CFU/mL)	Average Positive +8hrs Concentration (CFU/mL)
<i>Serratia</i>	1.2x10 ⁹	2.2 x10 ⁹
<i>Escherichia</i>	2.3 x10 ⁸	1.5 x10 ⁹
<i>Enterobacter</i>	2.8 x10 ⁸	7.7 x10 ⁸
<i>Neisseria</i>	3.2 x10 ⁷	2.1 x10 ⁸
<i>Haemophilus</i>	6.9 x10 ⁸	1.15 x10 ⁹
<i>Pseudomonas</i>	1.6 x10 ⁸	8.4 x10 ⁸
<i>Fusobacterium</i> *	6.5 x10 ⁷	4.9 x10 ⁸
<i>Acinetobacter</i>	4.4 x10 ⁸	3.8 x10 ⁸
<i>Klebsiella</i>	9.3 x10 ⁸	1.5 x10 ⁹
<i>Bacteroides</i> *	4.7x10 ⁸	6.7x10 ⁹
<i>Staphylococcus</i>	2.8 x10 ⁷	2.1 x10 ⁷
<i>Lactobacillus</i> *	4.8 x10 ⁷	3.1 x10 ¹¹
<i>Streptococcus</i>	4.1 x10 ⁷	4.0 x10 ⁸
<i>Enterococcus</i>	4.9 x10 ⁷	3.6 x10 ⁷
<i>Corynebacterium</i>	4.5 x10 ⁶	2.7 x10 ⁹
<i>Propionibacterium</i> * (<i>Cutibacterium</i>)	3.0 x10 ⁸	3.5 x10 ⁸
<i>Candida</i>	1.6 x10 ⁶	1.4 x10 ⁶
<i>Cryptococcus</i>	1.3 x10 ⁷	6.5 x10 ⁷
<i>Malassezia</i>	1.0 x10 ⁷	6.3 x10 ⁶
<i>Fusarium</i>	9.6 x10 ⁸	8.8 x10 ⁸
<i>Rhodotorula</i>	1.6 x10 ⁶	4.2 x10 ⁶
<i>Trichosporon</i>	2.1x10 ⁶	2.9 x10 ⁶

*Denotes a genus cultured under anaerobic conditions

Table 28: Average Bottle Positive Concentration for *Corynebacterium*

Analyte	Strain ID	Average Positive Concentration (CFU/mL)
<i>C. striatum</i> (1)	ATCC BAA-1293	4.5 x10 ⁶
<i>C. striatum</i> (2)	ATCC BAA-1293	8.1 x 10 ⁶
<i>C. minutissimum</i>	ATCC23348	1.1 x 10 ⁷
<i>C. timonense</i>	CCUG64728	2.3 x 10 ⁷
<i>C. falsenii</i>	ATCC BAA-596	6.4 x 10 ⁷
<i>C. coyleae</i>	ATCC700219	1.0 x 10 ⁷
Average =		2.0 x 10⁷

f. *Analytical Reactivity (Inclusivity):*

The analytical reactivity of the ePlex BCID-GP Panel was evaluated with a collection of 489 bacterial and fungal organisms that represent the diversity of the ePlex BCID-GP Panel analytes, including antimicrobial resistance genes. Isolates were selected to represent relevant species or serotypes and selection with specific inclusion of more commonly encountered species and known human pathogens. When possible, *in silico* analysis of sequence data was used to make predictions of assay reactivity for less common species that were not tested but that may be detected by the ePlex BCID-GP Panel.

Each isolate was initially tested in blood culture matrix at a concentration consistent with the levels of organism enumerated from blood cultures at the time of positivity (see Growth and Detection section above) and were tested in triplicate. If an isolate was not detected initially, the sample was retested at higher concentrations. If detected at the higher concentration(s), the species/isolate is indicated as detected with reduced sensitivity and the concentration of organism that was detected is indicated. If not detected at the highest concentration the isolate is listed as not detected by the ePlex BCID-GP Panel. Results are provided below:

Table 29: Analytical Reactivity (Inclusivity) Results for the BCID-GP Panel

Organism	Strain	Organism	Strain
<i>Bacillus cereus</i>		<i>Staphylococcus lentus</i>	ATCC 700403
<i>Bacillus cereus</i>	ATCC 21769	<i>Staphylococcus lugdunensis</i>	NRS-879
	ATCC 10876		ATCC 49576
	ATCC 31430		NRS-878
	ATCC 53522		NRS-880
<i>Bacillus thuringiensis</i>	ATCC 35646	<i>Staphylococcus muscae</i>	ATCC 49910
	ATCC 33679	<i>Staphylococcus pasteurii</i>	ATCC 51129
	ATCC 55173	<i>Staphylococcus pasteurii (mecC+)</i>	ATCC 51128
	ATCC 10792	<i>Staphylococcus pettenkoferi</i>	DSM-19554
<i>Bacillus subtilis</i>		<i>Staphylococcus pseudintermedius</i>	ATCC 49444
<i>Bacillus amyloliquefaciens</i>	ATCC 23845	<i>Staphylococcus saccharolyticus</i>	ATCC 14953
	ATCC 23842	<i>Staphylococcus saprophyticus</i>	ATCC 15305
	ATCC 23350		ATCC 35552
	ATCC 53495	<i>Staphylococcus schleiferi</i>	ATCC 49545
<i>Bacillus atrophaeus</i>	ATCC 51189		ATCC 43808
	ATCC 6455	<i>Staphylococcus sciuri</i>	ATCC 29060
	ATCC 49337		ATCC 29061
	ATCC 7972		ATCC 29059
	ATCC 6537		ATCC 49575
<i>Bacillus licheniformis</i>	ATCC 53926	<i>Staphylococcus simulans</i>	ATCC 29062
	ATCC 55768		ATCC 27848
	ATCC 21039		ATCC 27850
	ATCC 21667		ATCC 31432

Organism	Strain	Organism	Strain
<i>Bacillus subtilis</i>	ATCC 55614		ATCC 27851
	ATCC 15561	<i>Staphylococcus species</i>	ATCC 155
	ATCC 21008	<i>Staphylococcus species (mecA+)</i>	ATCC 27626
<i>Bacillus subtilis</i>	ATCC 15040	<i>Staphylococcus vitulinus</i>	ATCC 51699
<i>Corynebacterium</i>			ATCC 51161
<i>Corynebacterium afermentans</i> subsp. <i>afermentans</i>	ATCC 51403 ^A	<i>Staphylococcus warneri</i>	ATCC 27836
<i>Corynebacterium afermentans</i> subsp. <i>lipophilum</i>	ATCC 51404	<i>Staphylococcus xylosus</i>	ATCC 49148
<i>Corynebacterium confusum</i>	ATCC 38268 ^A		ATCC 29971
<i>Corynebacterium coyleae</i>	ATCC 700219	<i>Staphylococcus aureus</i>	
<i>Corynebacterium diphtheriae</i>	ATCC 13812	<i>Staphylococcus aureus</i>	ATCC 25923
<i>Corynebacterium falsenii</i>	ATCC BAA-596 ^A		ATCC 29247
<i>Corynebacterium freneyi</i>	ATCC 64424 ^B		ATCC 6538P
<i>Corynebacterium imitans</i>	ATCC 700354 ^B		ATCC 29213
<i>Corynebacterium jeikeium</i>	ATCC 43217		NR-45889
	ATCC 43216		NR-45890
	ATCC 43734		NR-46074
	ATCC BAA-949		NR-45881
<i>Corynebacterium minutissimum</i>	ATCC 23348		NR-46411
<i>Corynebacterium resistens</i>	CCUG 50093T		NR-46414
<i>Corynebacterium simulans</i>	ATCC BAA-15		<i>Staphylococcus aureus</i>
<i>Corynebacterium striatum</i>	ATCC BAA-1293	NR-46417	
	ATCC 43735	<i>Staphylococcus aureus (mecA+)</i>	NR-13524
	ATCC 7094		NR-13527
<i>Corynebacterium timonense</i>	CCUG 64728 ^A		NR-13525
<i>Corynebacterium ulcerans</i>	ATCC 51799		NR-13526
<i>Corynebacterium urealyticum</i>	ATCC 43044		NRS-123
	ATCC 43042		NR-46805
	ATCC 43043		NRS-662
<i>Corynebacterium ureicelerivorans</i>	CCUG 59144		ATCC BAA-1707
<i>Cutibacterium acnes</i>			ATCC 43300
<i>Cutibacterium acnes</i>	ATCC 11827		NRS-383
	ATCC 11828		NCTC-12493
	ATCC 33179		NRS-676
	ATCC 6919		NRS-678
<i>Enterococcus</i>			NRS-648
<i>Enterococcus avium</i>	ATCC 14025	NRS-651	
<i>Enterococcus casseliflavus</i>	ATCC 700668	NRS-643	
	ATCC 25788	NRS-484	
	ATCC 700327	NRS-385	
<i>Enterococcus cecorum</i>	ATCC 43198	NRS-384	
<i>Enterococcus dispar</i>	ATCC 51266	ATCC BAA-40	

Organism	Strain	Organism	Strain
<i>Enterococcus durans</i>	ATCC 11576		ATCC 700698
<i>Enterococcus faecalis</i>	ATCC 51575		NRS-382
	ATCC 700802		NRS-659
	ATCC 10100		NRS-657
	ATCC 12399		NRS-655
	ATCC 14506		NRS-654
	ATCC 33186		NRS-647
	ATCC 49532		ATCC BAA-42
	ATCC 49533		ATCC BAA-41
	ATCC 7080		NRS-483
	ATCC 49474		NRS-675
	ATCC 49332		NRS-645
	ATCC 29200		NRS-687
<i>Enterococcus faecalis</i>	ATCC BAA-2128	<i>Staphylococcus aureus (mecA+)</i>	NRS-667
	ATCC 51188		NRS-677
	ATCC 49149		NRS-683
	NCTC-775		NRS-688
	ATCC 19433		NRS-22
	ATCC 49452		NRS-387
<i>Enterococcus faecalis (vanA+)</i>	JMI 876745		NRS-70
<i>Enterococcus faecalis (vanB+)</i>	ATCC BAA-2365		ATCC 33591
	ATCC 51299	<i>Staphylococcus aureus (mecC+)</i>	ATCC BAA-2312
<i>Enterococcus faecium</i>	ATCC 19434		ATCC BAA-2313
	ATCC 23828	<i>Staphylococcus epidermidis</i>	
	ATCC 27273	<i>Staphylococcus epidermidis</i>	ATCC 12228
	ATCC BAA-2127		ATCC 49134
	ATCC 6057		NCIMB-8853
	ATCC 49624		ATCC 700583
	ATCC 6569		ATCC 14990
<i>Enterococcus faecium</i>	ATCC BAA-472	<i>Staphylococcus epidermidis (mecA+)</i>	ATCC 35983
	ATCC 9756		ATCC 35984
	ATCC 49224		ATCC 29887
	ATCC BAA-2846		ATCC 49461
	ATCC 19953		ATCC 700565
	ATCC 27270		ATCC 51625
	ATCC 35667	<i>Staphylococcus lugdunensis</i>	
<i>Enterococcus faecium (vanA+)</i>	ATCC BAA-2316	<i>Staphylococcus lugdunensis</i>	NRS-879
	ATCC BAA-2317		ATCC 49576

Organism	Strain	Organism	Strain
	ATCC 700221		NRS-878
	ATCC BAA-2319		NRS-880
	ATCC BAA-2320	<i>Streptococcus</i>	
	LMC 003921	<i>Streptococcus agalactiae</i>	ATCC 12401
	LMC 103676		ATCC 13813
	LMC 089524		ATCC 12386
	LMC 104266		ATCC 12973
	LMC 032261		ATCC 27956
	LMC 110371		NCTC-8017
	LMC 002867		ATCC 12403
	LMC 055971	<i>Streptococcus anginosus</i>	ATCC 9895
	ATCC 51559		ATCC 33397
	ATCC BAA-2318		NCTC-10713
<i>Enterococcus faecium</i> (vanB+)	ATCC 51858	<i>Streptococcus bovis</i>	ATCC 33317
	ATCC 49573		ATCC 35034
<i>Enterococcus gallinarum</i>	ATCC 49609	<i>Streptococcus constellatus</i>	ATCC 27513
	ATCC 49610	<i>Streptococcus criceti</i>	ATCC 19642 ^c
	ATCC 700425	<i>Streptococcus dysgalactiae</i>	ATCC 35666
	ATCC 49608		ATCC 43078
	ATCC 49479		ATCC 12394
<i>Enterococcus hirae</i>	ATCC 10541	<i>Streptococcus equi</i>	ATCC 43079
<i>Enterococcus italicus</i>	CCUG 47860		ATCC 9528
<i>Enterococcus malodoratus</i>	ATCC 43197	<i>Streptococcus equinus</i>	ATCC 15351
<i>Enterococcus pseudoavium</i>	CCUG 33310T		ATCC 9812
<i>Enterococcus raffinosus</i>	ATCC 49464	<i>Streptococcus gallolyticus</i>	ATCC 49475
<i>Enterococcus saccharolyticus</i>	ATCC 43076		ATCC 9809
<i>Enterococcus sanguinicola</i>	DSM-21767		ATCC 43144
<i>Enterococcus faecalis</i>		<i>Streptococcus gordonii</i>	ATCC 10558
<i>Enterococcus faecalis</i>	ATCC 51575	<i>Streptococcus infantarius</i>	ATCC 35557
	ATCC 700802		ATCC BAA-102
	ATCC 10100		ATCC BAA-103
	ATCC 12399	<i>Streptococcus infantis</i>	ATCC BAA-2089
<i>Enterococcus faecalis</i>	ATCC 14506		ATCC 700779
	ATCC 33186	<i>Streptococcus intermedius</i>	ATCC 27335
	ATCC 49532	<i>Streptococcus mitis</i>	ATCC 15914
	ATCC 49533		ATCC 6249
	ATCC 7080	<i>Streptococcus mitis</i>	ATCC 49456
	ATCC 49474		NCIMB-13770
	ATCC 49332	<i>Streptococcus oralis</i>	ATCC 35037

Organism	Strain	Organism	Strain
<i>Enterococcus faecalis</i>	ATCC 29200	<i>Streptococcus oralis</i>	ATCC 55229
	ATCC BAA-2128	<i>Streptococcus parasanguinis</i>	ATCC 15909
	ATCC 51188	<i>Streptococcus peroris</i>	ATCC 700780
	ATCC 49149	<i>Streptococcus pneumoniae</i>	ATCC BAA-475
	NCTC-775		ATCC 10357
	ATCC 19433		ATCC 49619
	ATCC 49452		ATCC 49136
<i>Enterococcus faecalis</i> (vanA+)	JMI 876745		ATCC BAA-659
<i>Enterococcus faecalis</i> (vanB+)	ATCC BAA-2365		ATCC 6315
	ATCC 51299		ATCC BAA-1667
<i>Enterococcus faecium</i>			ATCC 700674
<i>Enterococcus faecium</i>	ATCC 19434		ATCC 6321
	ATCC 23828		ATCC 700673
	ATCC 27273		ATCC 51916
	ATCC BAA-2127		ATCC 8338
	ATCC 6057		ATCC 6301
	ATCC 49624		ATCC 8335
	ATCC 6569		NCIMB-13286
	ATCC BAA-472		ATCC BAA-1656
	ATCC 9756	<i>Streptococcus pyogenes</i>	ATCC 12384
	ATCC 49224		ATCC 49399
	ATCC BAA-2846		ATCC 12344
	ATCC 19953		ATCC 19615
	ATCC 27270		NCIMB-13285
	ATCC 35667		ATCC 14289
	<i>Enterococcus faecium</i> (vanA+)	ATCC BAA-2316	<i>Streptococcus salivarius</i>
ATCC BAA-2317		ATCC 7073	
<i>Enterococcus faecium</i> (vanA+)	ATCC 700221	<i>Streptococcus salivarius</i>	ATCC 25975
	ATCC BAA-2319		ATCC 31067 ^c
	ATCC BAA-	<i>Streptococcus sanguinis</i>	ATCC 10556

Organism	Strain	Organism	Strain
	2320		
	LMC 003921	<i>Streptococcus thoraltensis</i>	ATCC 700865
	LMC 103676	<i>Streptococcus agalactiae</i>	
	LMC 089524	<i>Streptococcus agalactiae</i>	ATCC 12401
	LMC 104266		ATCC 13813
	LMC 032261		ATCC 12386
	LMC 110371		ATCC 12973
	LMC 002867		ATCC 27956
	LMC 055971		NCTC-8017
			ATCC 12403
<i>Enterococcus faecium</i> (vanA+)	ATCC 51559		<i>Streptococcus anginosus</i> group
	ATCC BAA-2318		
<i>Enterococcus faecium</i> (vanB+)	ATCC 51858	<i>Streptococcus anginosus</i>	ATCC 9895
<i>Lactobacillus</i>			ATCC 33397
<i>Lactobacillus casei</i>	ATCC 334		NCTC-10713
	ATCC 55825	<i>Streptococcus constellatus</i>	ATCC 27513
	ATCC 39392	<i>Streptococcus intermedius</i>	ATCC 27335
<i>Lactobacillus paracasei</i>	ATCC 25598	<i>Streptococcus pneum oniae</i>	
	ATCC BAA-52	<i>Streptococcus pneumoniae</i>	ATCC BAA-475
	ATCC 27092		ATCC 10357
<i>Lactobacillus rhamnosus</i>	ATCC 39595		ATCC 49619
	ATCC 53103		ATCC 49136
	ATCC 55915		ATCC BAA-659
<i>Lactobacillus zeae</i>	ATCC 15820		ATCC 6315
<i>Listeria</i>			ATCC BAA-1667
<i>Listeria innocua</i>	NCTC-11288		ATCC 700674
	ATCC 33090		ATCC 6321
<i>Listeria ivanovii</i>	ATCC 19119		ATCC 700673
	ATCC BAA-139		ATCC 51916
	ATCC 700402		ATCC 8338
<i>Listeria monocytogenes</i>	ATCC 10890		ATCC 6301
	ATCC 19111		ATCC 8335
	ATCC 13932		NCIMB-13286
	ATCC 19114		ATCC BAA-1656
	ATCC 7644	<i>Streptococcus pyogenes</i>	
	ATCC 19112	<i>Streptococcus pyogenes</i>	ATCC 12384
	ATCC BAA-751		ATCC 49399
	ATCC 19118		ATCC 12344

Organism	Strain	Organism	Strain
	ATCC 19115		ATCC 19615
<i>Listeria seeligeri</i>	ATCC 35967		NCIMB-13285
<i>Listeria welshimeri</i>	ATCC 35897		ATCC 14289
<i>Listeria monocytogenes</i>		<i>Pan Candida</i>	
<i>Listeria monocytogenes</i>	ATCC 10890	<i>Candida albicans</i>	ATCC 24433
	ATCC 19111		ATCC MYA-4441
	ATCC 13932		ATCC 14053
<i>Listeria monocytogenes</i>	ATCC 19114	<i>Candida albicans</i>	ATCC 90028
<i>Listeria monocytogenes</i>	ATCC 7644	<i>Candida glabrata</i>	ATCC 66032
	ATCC 19112		ATCC 15126
	ATCC BAA-751		ATCC MYA-2950
	ATCC 19118		ATCC 2001
	ATCC 19115	<i>Candida krusei</i>	ATCC 34135
<i>Micrococcus</i>			ATCC 32196
<i>Micrococcus luteus</i>	ATCC 19212		ATCC 14243
	ATCC 10240	<i>Candida parapsilosis</i>	ATCC 90018 ^D
	ATCC 400		ATCC 58895
	ATCC 53598		ATCC 22019
	ATCC 49732	<i>Pan Gram-Negative</i>	
ATCC 4698	<i>Acinetobacter baumannii</i>	NCTC-13302	
<i>Micrococcus lylae</i>		ATCC 27566	NCTC-13422
<i>Micrococcus yunnanensis</i>	ATCC 7468	<i>Acinetobacter haemolyticus</i>	ATCC 19002
<i>Staphylococcus</i>		<i>Acinetobacter junii</i>	ATCC 17908
<i>Staphylococcus arlettae</i>	ATCC 43957	<i>Acinetobacter lwoffii</i>	ATCC 15309
<i>Staphylococcus aureus</i>	ATCC 25923	<i>Acinetobacter ursingii</i>	ATCC BAA-617
	ATCC 29247	<i>Bacteroides fragilis</i>	NCTC-9343
	ATCC 6538P	<i>Burkholderia cepacia</i>	ATCC 25416
	ATCC 29213	<i>Cedecea davisiae</i>	ATCC 43025
	NR-45889	<i>Citrobacter freundii</i>	NCTC-9750
	NR-45890	<i>Citrobacter koseri</i>	ATCC 27156
	NR-46074	<i>Cronobacter muytjensii</i>	ATCC 51329
	NR-45881	<i>Cronobacter sakazakii</i>	ATCC 12868
	NR-46411	<i>Edwardsiella tarda</i>	ATCC 15947
	NR-46414	<i>Enterobacter aerogenes</i>	ATCC 13048
	NR-46418	<i>Enterobacter amnigenus</i>	ATCC 51816
	NR-46417	<i>Enterobacter asburiae</i>	ATCC 35953
<i>Staphylococcus aureus (mecA+)</i>	NR-13524	<i>Enterobacter cloacae</i>	ATCC 13047

Organism	Strain	Organism	Strain
	NR-13527		ATCC 23373
	NR-13525		ATCC 23355
	NR-13526		ATCC 35030
	NRS-123	<i>Enterobacter hormaechei</i>	ATCC 700323
	NR-46805	<i>Erwinia aphidicola</i>	ATCC 27991
	NRS-662	<i>Escherichia coli</i>	ATCC 4157
	ATCC BAA-1707		ATCC 14948
	ATCC 43300		ATCC 25922
<i>Staphylococcus aureus (mecA+)</i>	NRS-383	<i>Escherichia coli</i>	ATCC BAA-196
	NCTC-12493	<i>Escherichia fergusonii</i>	ATCC 35469
	NRS-676	<i>Escherichia hermannii</i>	ATCC 700368
<i>Staphylococcus aureus (mecA+)</i>	NRS-678	<i>Escherichia vulneris</i>	ATCC 33821
	NRS-648	<i>Fusobacterium necrophorum</i>	ATCC 25286
	NRS-651	<i>Fusobacterium nucleatum</i>	ATCC 25586
	NRS-643	<i>Haemophilus influenzae</i>	ATCC 10211
	NRS-484		ATCC 49144
	NRS-385		ATCC 43065
	NRS-384	<i>Haemophilus influenzae</i>	NCTC-8468
	ATCC BAA-40	<i>Haemophilus parainfluenzae</i>	ATCC 9796
	ATCC 700698	<i>Hafnia alvei</i>	ATCC 51815
	NRS-382	<i>Klebsiella oxytoca</i>	ATCC 700324
	NRS-659		ATCC 43165
	NRS-657		ATCC 43863
<i>Staphylococcus aureus (mecA+)</i>	NRS-655	<i>Klebsiella ozaenae</i>	ATCC 11296
	NRS-654	<i>Klebsiella pneumoniae</i>	ATCC BAA-1706
	NRS-647		NCTC-9633
	ATCC BAA-42		NCTC-13440
	ATCC BAA-41		ATCC 51503
	NRS-483	<i>Kluyvera ascorbata</i>	ATCC 14236
	NRS-675	<i>Kluyvera cryocrescens</i>	ATCC 14240
	NRS-645	<i>Legionella pneumophila</i>	ATCC 33823
	NRS-687	<i>Moraxella catarrhalis</i>	ATCC 23246
	NRS-667	<i>Moraxella nonliquefaciens</i>	ATCC 17953

Organism	Strain	Organism	Strain
	NRS-677	<i>Moraxella osloensis</i>	ATCC 10973
	NRS-683	<i>Morganella morganii</i>	ATCC 25829
	NRS-688	<i>Neisseria lactamica</i>	ATCC 23970
	NRS-22	<i>Neisseria meningitidis</i>	ATCC 13090
	NRS-387		ATCC 13113
	NRS-70		ATCC 13077
	ATCC 33591		ATCC 13102
<i>Staphylococcus aureus (mecC+)</i>	ATCC BAA-2312	<i>Neisseria mucosa</i>	ATCC 19695
	ATCC BAA-2313	<i>Neisseria sicca</i>	ATCC 29193
<i>Staphylococcus auricularis</i>	ATCC 33750	<i>Pantoea agglomerans</i>	ATCC 14537
	ATCC 33753	<i>Pasteurella aerogenes</i>	ATCC 27883
<i>Staphylococcus capitis</i>	ATCC 27840	<i>Proteus mirabilis</i>	ATCC 43071
	NRS-866		CDC#0155
	ATCC 35661		CDC#0159
<i>Staphylococcus caprae</i>	ATCC 51548	<i>Proteus penneri</i>	ATCC 35197
<i>Staphylococcus carnosus</i>	ATCC 51365	<i>Proteus vulgaris</i>	ATCC 6380
<i>Staphylococcus chromogenes</i>	ATCC 43764	<i>Providencia alcalifaciens</i>	ATCC 9886
<i>Staphylococcus cohnii</i>	ATCC 29974	<i>Providencia rettgeri</i>	ATCC 9919
<i>Staphylococcus epidermidis</i>	ATCC 12228	<i>Providencia stuartii</i>	ATCC 33672
	ATCC 49134	<i>Pseudomonas aeruginosa</i>	ATCC 15442
	NCIMB-8853		NCIMB-12469
	ATCC 700583		ATCC 10145
	ATCC 14990	<i>Pseudomonas fluorescens</i>	ATCC 13525
<i>Staphylococcus epidermidis (mecA+)</i>	ATCC 35983	<i>Pseudomonas luteola</i>	ATCC 35970
	ATCC 35984	<i>Pseudomonas putida</i>	ATCC 31483
	ATCC 29887	<i>Raoultella terrigena</i>	ATCC 55553
	ATCC 49461	<i>Salmonella bongori</i>	ATCC 43975
	ATCC 700565	<i>Salmonella enterica</i> subsp. <i>enterica</i>	ATCC 51957
	ATCC 51625	<i>Salmonella enterica</i> <i>Choleraesuis</i>	ATCC 12011
<i>Staphylococcus gallinarum</i>	ATCC 700401	<i>Salmonella enterica</i> <i>Paratyphi</i>	FSL S5-0447
	ATCC 35539	<i>Salmonella typhi</i>	ATCC 19430
<i>Staphylococcus haemolyticus</i>	ATCC 29970	<i>Serratia fonticola</i>	ATCC 29844
	ATCC 31874	<i>Serratia liquefaciens</i>	ATCC 27592
<i>Staphylococcus haemolyticus</i>	NRS-62	<i>Serratia marcescens</i>	ATCC 8100

Organism	Strain	Organism	Strain
(mecA+)	ATCC BAA-1693		ATCC 14756
	NRS-69		ATCC 13880
<i>Staphylococcus hominis</i>	NRS-871	<i>Serratia odorifera</i>	ATCC 33077
	NRS-870	<i>Serratia rubidaea</i>	ATCC 27593
	ATCC 27844	<i>Shigella boydii</i>	ATCC 9207
<i>Staphylococcus hominis</i> (mecA+)	ATCC 700237	<i>Shigella dysenteriae</i>	ATCC 13313
	ATCC 700236	<i>Shigella sonnei</i>	ATCC 29930
<i>Staphylococcus hyicus</i>	ATCC 11249	<i>Stenotrophomonas maltophilia</i>	ATCC 13636
<i>Staphylococcus intermedius</i>	ATCC 29663	<i>Tatumella ptyseos</i>	ATCC 33302
	ATCC 49052	<i>Yersinia enterocolitica</i> subsp. <i>Enterocolitica</i>	ATCC 9610

^A Detected at 2×10^8 CFU/mL ^C Detected at 4×10^8 CFU/mL

^B Detected at 2×10^9 CFU/mL ^D Detected at 1×10^7 CFU/mL

Ten additional samples did not achieve 100% detection after re-testing. These samples were then tested at 10-fold, or when necessary 100-fold, higher concentration to achieve 100% detection. These samples and their test results are listed in Table 30 below. These strains are expected to have lower sensitivity on the BCID-GP Panel.

Table 30: Samples Tested at Higher Concentrations

Organism	Initial Detection Result (3 replicates)	Retest Result (3 replicates)
<i>Corynebacterium falsenii</i> ATCCBAA-596	67% (2/3)	100% detection at 10-fold higher conc. (2×10^8 CFU/mL)
<i>Streptococcus criceti</i> ATCC19642	67% (2/3)	100% detection at 10-fold higher conc. (4×10^8 CFU/mL)
<i>Candida parapsilosis</i> ATCC90018	33% (1/3)	100% detection at 10-fold higher conc. (1×10^7 CFU/mL)
<i>Corynebacterium afermentans</i> subsp. <i>afermentans</i> ATCC51403	67% (2/3)	100% detection at 10-fold higher conc. (2×10^8 CFU/mL)
<i>Corynebacterium confusum</i> ATCC38268	67% (2/3)	100% detection at 10-fold higher conc. (2×10^8 CFU/mL)
<i>Streptococcus salivarius</i> ATCC13419	0%	100% detection at 10-fold higher conc. (4×10^8 CFU/mL)
<i>Streptococcus salivarius</i> ATCC31067	0%	100% detection at 10-fold higher conc. (4×10^8 CFU/mL)
<i>Corynebacterium timonense</i> CCUG64728	0%	100% detection at 10-fold higher conc. (2×10^8 CFU/mL)

Organism	Initial Detection Result (3 replicates)	Retest Result (3 replicates)
<i>Corynebacterium freneyi</i> ATCC64424	0%	100% detection at 100-fold higher conc. (2x10 ⁹ CFU/mL)
<i>Corynebacterium imitans</i> ATCC700354	0%	100% detection at 100-fold higher conc. (2x10 ⁹ CFU/mL)

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

Note: the performance of the ePlex BCID-GP Panel has not been established for all of the organisms listed in the tables below. See the Analytical Reactivity (Inclusivity) and Limit of Detection (Analytical Sensitivity) sections for data on organisms for which performance characteristics have been established (indicated with an asterisk in Tables 31-41). 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 31: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Bacillus cereus* group

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

Table 32: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Bacillus subtilis* group

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

Table 33: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Corynebacterium*

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

<i>Corynebacterium bovis</i>	<i>Corynebacterium glyciniphilum</i>	<i>Corynebacterium riegelii</i>
<i>Corynebacterium callunae</i>	<i>Corynebacterium kroppenstedtii</i>	<i>Corynebacterium sphenisci</i>
<i>Corynebacterium capitovis</i>	<i>Corynebacterium kutscheri</i>	<i>Corynebacterium spheniscorum</i>
<i>Corynebacterium caspium</i>	<i>Corynebacterium lactis</i>	<i>Corynebacterium stationis</i>
<i>Corynebacterium confusum</i>	<i>Corynebacterium lubricantis</i>	<i>Corynebacterium sundsvallense</i>
<i>Corynebacterium crenatum</i>	<i>Corynebacterium maris</i>	<i>Corynebacterium thomssenii</i>
<i>Corynebacterium cystitidis</i>	<i>Corynebacterium mastitidis</i>	<i>Corynebacterium tuberculostearicum</i>
<i>Corynebacterium deserti</i>	<i>Corynebacterium matruchotii</i>	<i>Corynebacterium uropygiale</i>
<i>Corynebacterium durum</i>	<i>Corynebacterium mustelae</i>	<i>Corynebacterium uterequi</i>
<i>Corynebacterium efficiens</i>	<i>Corynebacterium phocae</i>	

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

Table 34: Predicted (in silico) Reactivity (Inclusivity) Results for *Enterococcus*

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

Table 35: Predicted (in silico) Reactivity (Inclusivity) Results for *Lactobacillus*

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

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

Table 36: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Listeria*

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

Table 37: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Micrococcus*

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

Table 38: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Staphylococcus*

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

^A. Data for only one strain available in NCBI.

Table 39: Predicted (in silico) Reactivity (Inclusivity) Results for Streptococcus

Detection Predicted for $\geq 95\%$ of target sequences		
<i>Streptococcus agalactiae</i> *	<i>Streptococcus infantarius</i> *	<i>Streptococcus phocae</i>
<i>Streptococcus alactolyticus</i>	<i>Streptococcus infantis</i> *	<i>Streptococcus pneumoniae</i> *
<i>Streptococcus anginosus</i> *	<i>Streptococcus intermedius</i> *	<i>Streptococcus porcinus</i>
<i>Streptococcus australis</i>	<i>Streptococcus intestinalis</i>	<i>Streptococcus porcorum</i>
<i>Streptococcus caballi</i>	<i>Streptococcus lactarius</i>	<i>Streptococcus pseudopneumoniae</i>
<i>Streptococcus constellatus</i> *	<i>Streptococcus loxodonta salivarius</i>	<i>Streptococcus pseudoporcinus</i>
<i>Streptococcus criceti</i> *	<i>Streptococcus luteciae</i>	<i>Streptococcus pyogenes</i> *
<i>Streptococcus cristatus</i>	<i>Streptococcus lutetiensis</i>	<i>Streptococcus rifensis</i>
<i>Streptococcus danieliae</i>	<i>Streptococcus macedonicus</i>	<i>Streptococcus rubneri</i>
<i>Streptococcus dentasini</i>	<i>Streptococcus marimammalium</i>	<i>Streptococcus salivarius</i> *
<i>Streptococcus dentisani</i>	<i>Streptococcus massiliensis</i>	<i>Streptococcus saliviloxodontae</i>
<i>Streptococcus didelphis</i>	<i>Streptococcus mitis</i> *	<i>Streptococcus sanguinis</i> *
<i>Streptococcus difficilis</i>	<i>Streptococcus moroccensis</i>	<i>Streptococcus seminale</i>
<i>Streptococcus dysgalactiae</i> subsp. <i>dysgalactiae</i>	<i>Streptococcus oligofermentans</i>	<i>Streptococcus sinensis</i>
<i>Streptococcus dysgalactiae</i> subsp. <i>equisimilis</i>	<i>Streptococcus oralis</i> *	<i>Streptococcus suis</i>
<i>Streptococcus dysgalactiae</i> *	<i>Streptococcus oricebi</i>	<i>Streptococcus thermophilus</i>
<i>Streptococcus equi</i> *	<i>Streptococcus orisratti</i>	<i>Streptococcus thoraltensis</i> *
<i>Streptococcus equinus</i> *	<i>Streptococcus panodentis</i>	<i>Streptococcus tigurinus</i>
<i>Streptococcus fryi</i>	<i>Streptococcus parasanguinis</i> *	<i>Streptococcus troglodytae</i>
<i>Streptococcus gallolyticus</i> *	<i>Streptococcus parasuis</i>	<i>Streptococcus troglodytidis</i>
<i>Streptococcus gordonii</i> *	<i>Streptococcus parauberis</i>	<i>Streptococcus urinalis</i>
<i>Streptococcus himalayensis</i>	<i>Streptococcus pasteurii</i>	<i>Streptococcus ursoris</i>
<i>Streptococcus hongkongensis</i>	<i>Streptococcus pasteurianus</i>	<i>Streptococcus vestibularis</i>
<i>Streptococcus hyointestinalis</i>	<i>Streptococcus peroris</i> *	<i>Streptococcus waiu</i>
Detection Predicted for 85% -94% of target sequences		

<i>Streptococcus bovis</i> *	<i>Streptococcus uberis</i>	
Detection Predicted for <85% of target sequences		
<i>Streptococcus canis</i> (15.8%)	<i>Streptococcus henryi</i> (10.0%)	<i>Streptococcus ratti</i> (75.0%)
<i>Streptococcus halichoeri</i> (66.7%)	<i>Streptococcus iniae</i> (6.9%)	
Detection Not Predicted		
<i>Streptococcus acidominimus</i>	<i>Streptococcus entericus</i>	<i>Streptococcus orisasini</i>
<i>Streptococcus azizii</i>	<i>Streptococcus ferus</i>	<i>Streptococcus orisuis</i>
<i>Streptococcus cameli</i>	<i>Streptococcus gallinaceus</i>	<i>Streptococcus ovis</i>
<i>Streptococcus castoreus</i>	<i>Streptococcus hyovaginalis</i>	<i>Streptococcus pharyngis</i>
<i>Streptococcus cremoris</i>	<i>Streptococcus ictaluri</i>	<i>Streptococcus pluranimalium</i>
<i>Streptococcus criae</i>	<i>Streptococcus lactis</i>	<i>Streptococcus plurextorum</i>
<i>Streptococcus cuniculi</i>	<i>Streptococcus macacae</i>	<i>Streptococcus plutanimalium</i>
<i>Streptococcus dentapri</i>	<i>Streptococcus marmotae</i>	<i>Streptococcus porci</i>
<i>Streptococcus dentiloxodontae</i>	<i>Streptococcus merionis</i>	<i>Streptococcus rupicaprae</i>
<i>Streptococcus dentirousetti</i>	<i>Streptococcus milleri</i>	<i>Streptococcus sobrinus</i>
<i>Streptococcus devriesei</i>	<i>Streptococcus minor</i>	<i>Streptococcus tangierensis</i>
<i>Streptococcus downei</i>	<i>Streptococcus oriloxodontae</i>	

Table 40: Predicted (*in silico*) Reactivity (Inclusivity) Results for *Streptococcus anginosus* group

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

Table 41: Predicted (*in silico*) Reactivity (Inclusivity) Results for Pan *Candida*

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

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

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

g. Analytical specificity (Exclusivity):

Cross-reactivity of on-panel and off-panel analytes was evaluated with the BCID-GP Panel. Bacterial targets were tested in triplicate at a concentration of $\geq 1 \times 10^9$ CFU/mL while fungi were tested in triplicate at a concentration of $\geq 1 \times 10^7$ CFU/mL. If the target concentration could not be reached, the organism was diluted 2-fold from stock for use.

No cross reactivity was observed for any of the on-panel gram-positive organisms.

Three organisms showed cross-reactivity, *Burkholderia cepacia* cross reacts with the *Corynebacterium* assay at levels $\geq 1 \times 10^7$ CFU/mL, an unspciated *Rhodococcus* strain (ATCC 49988) cross reacts with the *Micrococcus* assay at levels $\geq 1 \times 10^7$ CFU/mL and *Bacillus badius* cross reacts with the *Bacillus subtilis* group assay at 7×10^7 CFU/mL. See Table 54 and Table 55 for summaries of the on-panel strains tested as a part of the Limit of Detection (Analytical Sensitivity) and Analytical Reactivity (Inclusivity) studies and Table 42 for a summary of off-panel strains tested.

Table 42: Targets Assessed for Cross-Reactivity with the ePlex BCID-GP Panel (Exclusivity)

Organism	Strain ID	Organism	Strain ID
<i>Abiotrophia defectiva</i>	ATCC 49176	<i>Granulicatella elegans</i>	ATCC 700633 ^C
<i>Actinomyces odontolyticus</i>	ATCC 17929	<i>Kocuria kristinae</i>	ATCC BAA-752
<i>Aerococcus sanguinicola</i>	ATCC BAA-465	<i>Kocuria rhizophila</i>	ATCC 9341
<i>Aerococcus urinae</i>	ATCC 700306	<i>Kytococcus sedentarius</i>	ATCC 27575
<i>Aerococcus viridans</i>	ATCC 10400	<i>Lactococcus garvieae</i>	ATCC 43921 ^D
<i>Anaerococcus prevotii</i>	ATCC 9321	<i>Lactococcus lactis</i>	ATCC 49032
<i>Arcanobacterium bernardiae</i>	ATCC 51728	<i>Leuconostoc carnosum</i>	ATCC 49367
<i>Arcanobacterium haemolyticum</i>	ATCC BAA-1784 ^A	<i>Leuconostoc citreum</i>	ATCC 13146
<i>Arthrobacter psychrolactophilus</i>	ATCC 700733	<i>Leuconostoc mesenteroides</i>	ATCC 8293
<i>Aspergillus fumigatus</i>	ATCC 204305 ^B	<i>Macrococcus caseolyticus</i>	ATCC 29750
<i>Bacillus badius</i>	ATCC 14574	<i>Macrococcus caseolyticus</i>	ATCC 51834
<i>Bacillus pumilus</i>	ATCC 14884	<i>Mycobacterium avium complex</i>	ATCC 15769
<i>Brochothrix thermosphacta</i>	ATCC 11509	<i>Mycobacterium fortuitum</i>	ATCC 6841
<i>Candida lusitanae</i>	ATCC 34449	<i>Mycobacterium mucogenicum</i>	ATCC 49650
<i>Candida metapsilosis</i>	ATCC 96144	<i>Mycobacterium tuberculosis</i>	ATCC 25177
<i>Candida orthopsilosis</i>	ATCC 96139	<i>Mycoplasma pneumoniae</i>	ATCC 39505
<i>Candida tropicalis</i>	ATCC 1369	<i>Pediococcus acidilactici</i>	ATCC 8042
<i>Carnobacterium divergens</i>	ATCC 35677	<i>Pediococcus pentosaceus</i>	ATCC 33316
<i>Carnobacterium maltaromaticum</i>	ATCC 27865 ^C	<i>Penicillium marneffei</i>	ATCC 200050
<i>Cellulomonas turbata</i>	ATCC 25835	<i>Peptostreptococcus anaerobius</i>	ATCC 27337
<i>Cellulosimicrobium cellulans</i>	ATCC 27402	<i>Planococcus species</i>	ATCC 35671
<i>Clostridium clostridioforme</i>	ATCC 25537	<i>Propionibacterium propionicum</i>	ATCC 14157
<i>Clostridium perfringens</i>	ATCC 13124	<i>Rhodococcus equi</i>	ATCC 6939
<i>Clostridium ramosum</i>	ATCC 25582	<i>Rhodococcus species</i>	ATCC 49988
<i>Cryptococcus gattii</i>	ATCC 76108	<i>Rhodotorula glutinis</i>	ATCC 32766
<i>Cryptococcus grubii</i>	ATCC 208821	<i>Rhodotorula minuta</i>	ATCC 36236
<i>Cryptococcus neoformans</i>	ATCC 14116	<i>Rhodotorula mucilaginosa</i>	ATCC 9449
<i>Cutibacterium granulosum</i>	ATCC 11829	<i>Rothia dentocariosa</i>	ATCC 31918
<i>Erysipelothrix rhusiopathiae</i>	ATCC 35457	<i>Rothia mucilaginosa</i>	ATCC 25296

Organism	Strain ID	Organism	Strain ID
<i>Gemella haemolysans</i>	ATCC 10379	<i>Saccharomyces cerevisiae</i>	ATCC 18824
<i>Gemella morbillorum</i>	ATCC 27824	<i>Trichosporon asahii</i>	ATCC 201110
<i>Geotrichum capitatum</i>	ATCC 10663	<i>Vagococcus fluvialis</i>	ATCC 49515
<i>Granulicatella adiacens</i>	ATCC 43205	<i>Weissella paramesenteroides</i>	ATCC 33313

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

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

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

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

Three off-panel organisms showed cross-reactivity, *Burkholderia cepacia* cross reacts with the *Corynebacterium* assay at levels $\geq 1 \times 10^7$ CFU/mL, an unspecified *Rhodococcus* strain (ATCC 49988) cross reacts with the *Micrococcus* assay at levels $\geq 1 \times 10^7$ CFU/mL and *Bacillus badius* cross reacts with the *Bacillus subtilis* group assay at 1×10^8 CFU/mL.

h. Assay cut-off:

Analytical studies were conducted to establish the signal boundaries for all targets and controls of the ePlex BCID-GP Panel.

A mixture of clinical samples, contrived bottle positives, and organisms spiked at or above the analytically determined limit of detection were used as samples for the study. Positive data points from samples at or greater than the determined LoD test concentration in the Limit of Detection study were used to supplement the Cutoff study data. Negative data points for all targets were obtained from the Limit of Blank study. Expected negative data points from replicates that were positive for other targets in the LoD and Cutoff studies were also combined to increase statistical power of the ROC analysis.

For each target, the signals for positive and negative tests were analyzed. An appropriate boundary was established wherein specificity and sensitivity were maximized. The analysis was verified by ROC analysis. The final boundary set points are listed in Table 43 below.

Table 43: Summary of BCID-GP Panel Boundary Set

Target Name	Boundary (nA)
<i>Bacillus cereus</i> group	20
<i>Bacillus subtilis</i> group	30
<i>Corynebacterium</i>	10
<i>Cutibacterium acnes</i> / <i>P. acnes</i>	50
<i>Enterococcus</i>	20
<i>Enterococcus faecalis</i>	15
<i>Enterococcus faecium</i>	20-400*
<i>Lactobacillus</i>	20
<i>Listeria</i>	20
<i>Listeria monocytogenes</i>	20

Target Name	Boundary (nA)
<i>Micrococcus</i>	30
<i>Staphylococcus</i>	20
<i>Staphylococcus aureus</i>	15
<i>Staphylococcus epidermidis</i>	20
<i>Staphylococcus lugdunensis</i>	20
<i>Streptococcus</i>	30
<i>Streptococcus agalactiae</i>	50
<i>Streptococcus anginosus</i> group	30
<i>Streptococcus pneumoniae</i>	20
<i>Streptococcus pyogenes</i>	30
Pan <i>Candida</i>	40
<i>Stenotrophomonas maltophilia</i>	20
Pan Gram-Negative	40
<i>mecA</i>	20
<i>mecC</i>	20
<i>vanA</i>	20
<i>vanB</i>	20
<i>Schizosaccharomyces pombe</i>	20
Synthetic Control	20

**Enterococcus faecium* is considered detected if the signal is ≥ 20 nA for both *Enterococcus faecium* and the *Enterococcus* genus call. *Enterococcus faecium* is considered detected independent of the *Enterococcus* species call if the signal is above 400 nA.

i. *Interference:*

Two organism mixes consisting of 9 on-panel organisms representing 14 targets and negative blood matrix were used to assess eighteen potentially interfering substances and thirteen bottle types for interference. Potentially interfering test substances were spiked at levels predicted to be above the concentration of the substance likely to be found in a blood culture specimen. The positivity of the organisms for each potentially interfering substance at the initial testing concentration is summarized in Table 44 and 45.

Table 44: Composition of Test Mixes

Mix	Primer Pool	Organism (Test Concentration)	BCID-GP Panel Expected Result
1	1, 7, 2	<i>Enterococcus faecalis</i> /vanB (4x10 ⁷ CFU/mL)	<i>Enterococcus faecalis</i> vanB
	3	<i>Lactobacillus casei</i> (4x10 ⁷ CFU/mL)	<i>Lactobacillus casei</i>
	6, 8	<i>Staphylococcus epidermidis</i> (2x10 ⁷ CFU/mL)	<i>Staphylococcus epidermidis</i>

Mix	Primer Pool	Organism (Test Concentration)	BCID-GP Panel Expected Result
	5	<i>Cutibacterium acnes</i> (3x10 ⁸ CFU/mL)	<i>Cutibacterium acnes</i>
2	5	<i>Streptococcus pneumoniae</i> (4x10 ⁷ CFU/mL)	<i>Streptococcus pneumoniae</i>
	1, 4, 3	<i>Enterococcus faecium/vanA</i> (4x10 ⁷ CFU/mL)	<i>Enterococcus faecium</i> <i>vanA</i>
	2	<i>Candida albicans</i> (1x10 ⁶ CFU/mL)	Pan <i>Canadida</i>
	7	<i>Klebsiella pneumoniae</i> (5x10 ⁸ CFU/mL)	Pan Gram-Negative
	6, 8	<i>Staphylococcus aureus</i> (2x10 ⁷ CFU/mL)	<i>Staphylococcus aureus</i>

Table 45: List of Potentially Interfering Substances

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

No false positives were detected in negative blood matrix runs without or with interfering substances.

Thirteen of 14 targets were detected in all conditions tested but *C. acnes* was detected in only 2 of 3 runs in the presence of γ-globulin. Upon retest with an additional 6 replicates per the rerun criteria for false negatives defined in the testing protocol, an

additional *C. acnes* false negative was observed. Therefore, γ -globulin was diluted and tested until all expected targets were detected.

k. *Mixed Culture Study (Microbial interference):*

A study was performed to evaluate whether the presence of high levels of organisms will interfere with detection of representative organisms at bottle positivity and bottle positivity +8 hours concentrations. The study evaluated the possibility of high concentration organisms interfering with detection of lower concentration targets in the same sample. Eight clinically-relevant co-infection organisms were selected for the study. Selection of the organisms in the mixes was based on those that have been identified in peer-reviewed literature as common polymicrobial co-infections. Testing was performed in triplicate on the BCID-GP Panel

Table 46: Co-Infections Mix Concentrations

Mix	Organisms	Bottle Positivity Concentration (CFU/mL)	Bottle Positivity +8 Hrs Concentration (CFU/mL)
1	<i>Staphylococcus epidermidis</i>	2 x 10 ⁷	1 x 10 ⁸ *
	<i>Streptococcus agalactiae</i>	4 x 10 ⁷	4 x 10 ⁸
2	<i>Streptococcus pneumoniae</i>	4 x 10 ⁷	4 x 10 ⁸
	<i>Staphylococcus aureus</i>	2 x 10 ⁷	1 x 10 ⁸ *
3	<i>Enterococcus faecium</i>	4 x 10 ⁷	1 x 10 ⁸ *
	<i>Cutibacterium granulosum</i> **	3 x 10 ⁸	1 x 10 ⁹ *
4	<i>Escherichia coli</i>	2 x 10 ⁸	1 x 10 ⁹
	<i>Candida albicans</i>	1 x 10 ⁶	1 x 10 ⁷ *

*Per Bottle Positivity Study, this organism concentration did not increase after 8 hours of culture post bottle ring. The concentration at bottle positivity was rounded up to the next integer log concentration to serve as a second (high) test concentration for this study.

***Cutibacterium granulosum* is an off-panel organism (not detected by BCID-GP Panel).

Study results demonstrated that high concentrations of the on-panel BCID-GP microorganisms spiked into blood culture samples produced positive results for the relevant assays on the BCID-GP Panel but did interfere with any expected results for other analytes. High concentrations of off-panel BCID-GP microorganisms also showed no interference with the detection of any ePlex BCID-GP organism with no unexpected false negative or false positive results observed.

l. Testing of Additional Blood Culture Bottle Types

Thirteen different blood culture bottle types from three different blood culture systems (BacT/Alert, BACTEC and VersaTREK) were evaluated analytically with the BCID-GP Panel. Blood culture bottles/media were tested with the recommended ratio of blood to media. Testing was performed using two organism mixes whose

members were present at a concentration approximating blood culture bottle positivity in a clinical sample. These organism mixes represent each of the eight multiplex amplification pools on the BCID-GP Panel and include common gram-positive bacteria, drug resistance genes, bottle contaminants (*Lactobacillus*, *Corynebacterium*, *Cutibacterium*), gram-negative (*Klebsiella pneumoniae*) and fungal (*Candida albicans*) targets. The 13 bottle types listed in the table below were evaluated and study results demonstrated correct positive and negative BCID-GP Panel results with each bottle type.

Table 47: Sample Matrix Equivalency (Bottle Evaluation) Bottle Types

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

Eleven of the bottle types tested showed no interference for any of the targets tested. BD Bactec Anaerobic/F had 95% detection of *C. acnes*; this organism was tested at Limit of Detection (LoD) concentration. BioMérieux BacT Alert Standard Aerobic observed false positives in the control runs in one of two tested lots. However, false positives were not detected in samples from seven bottle lots used in the clinical study. Together, this data suggest that the bottle is not inhibitory and it is considered acceptable for use with the BCID-GP Panel, but an elevated level of false positive results is possible with certain bottle lots. The appropriate limitation is included in the package insert. The BioMérieux BacT Alert FN bottle type may result in lower sensitivity for some targets. The appropriate limitation statement for this specific bottle type is included in the package insert.

m. Carryover Study:

The carryover/cross-contamination rate of the ePlex BCID-GP Panel and ePlex instrument was evaluated using a checkerboard approach by running high positive and negative samples interspersed in all bays of a four-tower ePlex instrument (i.e., 24 bays total) over five separate runs on five separate days. The positive sample was a multi-organism mix containing bacterial species at 1×10^9 CFU/mL and one fungal species at 1×10^7 CFU/mL. The organism levels were higher than typically found in positive blood cultures in order to challenge the system for potential cross contamination. On each round of testing, 24 ePlex BCID-GP Panel cartridges were evaluated. 100% of the positive sample runs resulted in detection of *S. aureus*, *mecA*, *E. faecium*, *vanA*, Pan Gram-Negative, and Pan *Candida*. No false positives were detected in the negative runs indicating no carryover or cross-contamination was observed between bays or within bays with the ePlex BCID-GP Panel when testing samples consecutively or in adjacent bays with an ePlex instrument.

2. Comparison studies:

a. *Method comparison with predicate device:*

Not applicable. Refer to the Clinical Studies Section of this document.

b. *Matrix comparison:*

Not applicable

3. Clinical studies:

The clinical performance of the ePlex BCID-GP Panel was established during multi-center clinical studies conducted at seven distinct U.S. test sites in two phases. Each test site was representative of the intended use setting (clinical laboratories) and testing was performed by trained clinical laboratory personnel. From June 2014 through July 2016, 400 samples were prospectively collected and frozen; from January through February 2018, 319 samples were prospectively collected and tested fresh (never frozen) for a total of 719 samples across the 2 phases. 8 of these samples were withdrawn; 5 due to the sample coming from a patient already enrolled; 1 was collected outside of the required timeframe; 1 was not viable upon subculture and 1 was from an autopsy. Samples with final, valid ePlex BCID-GP Panel results and valid comparator results were considered evaluable. Of the 711 prospectively-collected samples eligible for testing, all 711 were evaluable. Demographic information for prospectively collected samples is described in Table 48. Subjects enrolled in this study were from a diverse demographic distribution and represent the intended patient population.

To supplement the number of positives for low prevalence targets in the prospective collection, 586 samples were collected retrospectively and all 586 were evaluable. Demographic information for retrospectively collected samples is described in Table 49.

Table 48: Demographic Data for Clinical Samples by Collection Site (Prospective Collection)

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

Table 49: Demographic Data for Clinical Samples by Collection Site (Retrospective Collection)

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

Clinical performance of the ePlex BCID-GP was compared to standard laboratory procedures, including traditional and automated culture, MALDI-TOF IVD, and

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

The comparator method(s) results were used to determine the Detected/Not Detected status for each target organism on the ePlex BCID-GP Panel. The comparator methods for each target are summarized in Table 50.

Table 50: Comparator Method(s) by ePlex BCID-GP Panel Target

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

Target	Comparator Method
<i>vanA</i>	qPCR/sequencing in samples with <i>Enterococcus</i> identified
<i>vanB</i>	

*The *Corynebacterium* assay is not designed to detect the following *Corynebacterium* species: *C. amycolatum*, *C. argentoratense*, *C. bovis*, *C. durum*, *C. glucuronolyticum*, *C. macginleyi*, *C. propinquum*, *C. riegelii*, and *C. sundsvallens*

Sensitivity or positive percent agreement (PPA) was calculated by dividing the number of true positive (TP) results by the sum of TP and false negative (FN) results, while specificity or negative percent agreement (NPA) was calculated by dividing the number of true negative (TN) results by the sum of TN and false positive (FP) results. A TP result being defined as a sample where the detected ePlex BCID-GP Panel result matched the detected comparator method result, while a TN result was one where a negative ePlex BCID-GP Panel result matched a negative comparator method result. The two-sided 95% confidence interval was also calculated.

A total of 711 prospectively-collected samples (312 tested fresh and 399 tested after previously frozen) and 586 retrospectively collected samples as well as 565 contrived samples were evaluated for the ePlex BCID-GP Panel targets. Contrived samples were prepared by spiking an isolate into a blood culture bottle and growing until flagged positive by a continuously monitoring blood culture system. Samples were removed from the system within 8 hours of positivity and stored frozen until the time of testing. PPA and NPA results are summarized by target in Tables 51-74 and the strains used to contrive samples are summarized in Table 75.

Table 51: Clinical Performance for *Bacillus cereus* group

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

Table 52: Clinical Performance for *Bacillus subtilis* group

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

Table 53: Clinical Performance for *Corynebacterium*

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

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

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

Table 54: Clinical Performance for *Cutibacterium acnes*

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

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

Table 55: Clinical Performance for *Enterococcus*

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

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

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

Table 56: Clinical Performance for *Enterococcus faecalis*

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

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

Table 57: Clinical Performance for *Enterococcus faecium*

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

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

Table 58: Clinical Performance for *Lactobacillus*

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

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

Table 59: Clinical Performance for *Listeria*

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

Table 60: Clinical Performance for *Listeria monocytogenes*

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

Table 61: Clinical Performance for *Micrococcus*

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

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

Table 62: Clinical Performance for *Staphylococcus*

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

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

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

Table 63: Clinical Performance for *Staphylococcus aureus*

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

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

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

Table 64: Clinical Performance for *Staphylococcus epidermidis*

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

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

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

Table 65: Clinical Performance for *Staphylococcus lugdunensis*

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

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

Table 66: Clinical Performance for *Streptococcus*

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

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

Table 67: Clinical Performance for *Streptococcus agalactiae*

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

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

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

Table 68: Clinical Performance for *Streptococcus anginosus* group

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

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

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

Table 69: Clinical Performance for *Streptococcus pneumoniae*

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

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

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

Table 70: Clinical Performance for *Streptococcus pyogenes*

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

Table 71: Clinical Performance for *mecA*

Target	Sample Type	Sensitivity/PPA		Specificity/NP	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
<i>mecC</i> <i>Staphylococcus</i>	Prospective (Fresh)	0/0	---	182/182	100 (97.9-100)
	Prospective (Frozen)	0/0	---	274/274	100 (98.6-100)
	Prospective (All)	0/0	---	456/456	100 (99.2-100)
	Retrospective	0/0	---	191/191	100 (98.0-100)
	Prospective/Retrospective	0/0	---	647/647	100 (99.4-100)
	Contrived	49/49	100 (92.7-100)	56/56	100 (93.6-100)
	Overall	49/49	100 (92.7-100)	703/703	100 (99.5-100)
<i>mecC</i> <i>Staphylococcus aureus</i>	Prospective (Fresh)	0/0	---	65/65	100 (94.4-100)
	Prospective (Frozen)	0/0	---	101/101	100 (96.3-100)
	Prospective (All)	0/0	---	166/166	100 (97.7-100)
	Retrospective	0/0	---	125/125	100 (97.0-100)
	Prospective/Retrospective	0/0	---	291/291	100 (98.7-100)

Target	Sample Type	Sensitivity/PPA		Specificity/NP	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
	Contrived	49/49	100 (92.7-100)	10/10	100 (72.2-100)
	Overall	49/49	100 (92.7-100)	301/301	100 (98.7-100)
<i>mecC</i> <i>Staphylococcus epidermidis</i>	Prospective (Fresh)	0/0	---	63/63	100 (94.3-100)
	Prospective (Frozen)	0/0	---	58/58	100 (93.8-100)
	Prospective (All)	0/0	---	121/121	100 (96.9-100)
	Retrospective	0/0	---	38/38	100 (90.8-100)
	Prospective/Retrospective	0/0	---	159/159	100 (97.6-100)
	Contrived	0/0	---	1/1	100 (20.7-100)
	Overall	0/0	---	160/160	100 (97.7-100)
<i>mecC</i> <i>Staphylococcus lugdunensis</i>	Prospective (Fresh)	0/0	---	1/1	100 (20.7-100)
	Prospective (Frozen)	0/0	---	1/1	100 (20.7-100)
	Prospective (All)	0/0	---	2/2	100 (34.2-100)
	Retrospective	0/0	---	4/4	100 (51.0-100)
	Prospective/Retrospective	0/0	---	6/6	100 (61.0-100)
	Contrived	0/0	---	45/45	100 (92.1-100)
	Overall	0/0	---	51/51	100 (93.0-100)

Table 72: Clinical Performance for *vanA*

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

Table 74: Clinical Performance for *vanB*

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

In addition to the evaluable prospective and retrospective samples that contain gram-positive organisms, the clinical performance of the Pan *Candida* and Pan Gram-Negative

targets was evaluated by testing an additional 480 non-intended use retrospective samples with gram-negative or fungal organisms; these are denoted as Retrospective (Non-Intended Use) samples. Results from those samples are summarized in Table 74.

Table 74: Clinical Performance for Pan Targets

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

Table 75: Contrived Sample Summary

Target	Organism	Strain	Independent Contrived Samples Tested
<i>Bacillus cereus</i> group	<i>Bacillus cereus</i>	ATCC 10876	11
		ATCC 21769	10
		ATCC 31430	9
		ATCC 53522	10
	<i>Bacillus thuringiensis</i>	ATCC 33679	1
		ATCC 10792	2
		ATCC 55173	3
	<i>Bacillus cereus</i> group total		46
<i>Bacillus subtilis</i> group	<i>Bacillus amyloliquefaciens</i>	ATCC 23350	3
		ATCC 23845	4
		ATCC 53495	3
	<i>Bacillus atrophaeus</i>	ATCC 51189	4

Target	Organism	Strain	Independent Contrived Samples Tested
	<i>Bacillus licheniformis</i>	ATCC 6455	3
		ATCC 6537	4
		ATCC 21039	3
		ATCC 21667	3
		ATCC 53926	4
	<i>Bacillus subtilis</i>	ATCC 15040	5
		ATCC 15561	8
		ATCC 55614	6
	<i>Bacillus subtilis</i> group total		50
<i>Corynebacterium</i>	<i>Corynebacterium coyleae</i>	ATCC 700219	7
	<i>Corynebacterium falsenii</i>	ATCC BAA-596	9
	<i>Corynebacterium striatum</i>	ATCC BAA-1293	4
	<i>Corynebacterium</i> total		20
<i>Enterococcus</i>	<i>Enterococcus faecalis, vanA</i>	JMI 876745	10
	<i>Enterococcus faecalis, vanB</i>	ATCC 51299	11
		ATCC 51575	11
		ATCC 700802	10
		ATCC BAA-2365	10
	<i>Enterococcus faecium, vanA</i>	ATCC 51559	4
		ATCC 700221	3
		ATCC BAA-2316	5
		ATCC BAA-2317	3
		ATCC BAA-2318	5
		ATCC BAA-2319	5
		ATCC BAA-2320	3
		LMC 002867	3
		LMC 003921	4
		LMC 032261	4
		LMC 055971	3
		LMC 103676	5
		LMC 104266	3
	<i>Enterococcus faecium, vanB</i>	ATCC 51858	10
	<i>Enterococcus flavescens</i>	ATCC 49996	3
	<i>Enterococcus gallinarum</i>	ATCC 49610	1
		ATCC 700425	3
	<i>Enterococcus hirae</i>	ATCC 10541	1
	<i>Enterococcus malodoratus</i>	ATCC 43197	3
	<i>Enterococcus raffinosus</i>	ATCC 49464	2
	<i>Enterococcus saccharolyticus</i>	ATCC 43076	1
	<i>Enterococcus</i> total		126

Target	Organism	Strain	Independent Contrived Samples Tested
<i>Lactobacillus</i>	<i>Lactobacillus casei</i>	ATCC 25598	2
		ATCC 334	6
		ATCC 39392	4
	<i>Lactobacillus paracasei</i>	148-260 *	3
		ATCC 27092	2
		ATCC BAA-52	6
	<i>Lactobacillus rhamnosus</i>	ATCC 39595	3
		ATCC 53103	5
		ATCC 55915	2
	<i>Lactobacillus total</i>		33
<i>Listeria</i>	<i>Listeria innocua</i>	ATCC 33090	4
		NCTC 11288	5
	<i>Listeria ivanovii</i>	ATCC 19119	2
		ATCC 700402	4
		ATCC BAA-139	4
	<i>Listeria monocytogenes</i>	ATCC 13932	5
		ATCC 19111	3
		ATCC 19112	4
		ATCC 19114	5
		ATCC 19116	5
		ATCC 19117	5
		ATCC 19118	5
		ATCC 7644	5
		ATCC BAA-751	5
		NCTC 10890	4
	<i>Listeria seeligeri</i>	ATCC 35967	5
	<i>Listeria welshimeri</i>	ATCC 35897	5
	<i>Listeria total</i>		75
<i>Micrococcus</i>	<i>Micrococcus luteus</i>	ATCC 10240	3
		ATCC 19212	3
		ATCC 400	3
		ATCC 4698	3
		ATCC 49732	3
		ATCC 53598	4
	<i>Micrococcus lylae</i>	ATCC 27566	4
	<i>Micrococcus yunnanensis</i>	ATCC 7468	4
	<i>Micrococcus total</i>		27
<i>Cutibacterium acnes</i>	<i>Cutibacterium acnes</i>	ATCC 11827	8
		ATCC 11828	6
		ATCC 33179	4
		ATCC 6919	8
	<i>Cutibacterium acnes total</i>		26

Target	Organism	Strain	Independent Contrived Samples Tested
Staphylococcus	<i>Staphylococcus aureus, mecA</i>	ATCC 33591	3
		ATCC BAA-44	5
		NCTC 12493	2
	<i>Staphylococcus aureus, mecC</i>	ATCC BAA-2312	23
		ATCC BAA-2313	26
	<i>Staphylococcus epidermidis, mecA</i>	ATCC 35984	1
	<i>Staphylococcus lugdunensis</i>	ATCC 49576	9
		NRS 878	9
		NRS 879	9
		NRS 880	9
		NRS 881	9
	<i>Staphylococcus total</i>		105
Streptococcus	<i>Streptococcus agalactiae</i>	ATCC 12403	2
		ATCC 12973	2
		ATCC 13813	2
		ATCC 27956	2
	<i>Streptococcus anginosus</i>	ATCC 700231	5
		ATCC 9895	3
		NCTC 10713	5
	<i>Streptococcus constellatus</i>	ATCC 27513	4
		ATCC 27823	2
	<i>Streptococcus intermedius</i>	ATCC 27335	4
	<i>Streptococcus pyogenes</i>	ATCC 12344	5
		ATCC 12384	4
		ATCC 14289	4
		ATCC 19615	4
		ATCC 49399	5
		NCIMB 13285	4
	<i>Streptococcus total</i>		57

*Derived from clinical specimen

The ePlex BCID-GP Panel reports genus or group level results for *Bacillus cereus* group, *Bacillus subtilis* group, *Corynebacterium*, *Enterococcus*, *Lactobacillus*, *Listeria*, *Micrococcus*, *Staphylococcus*, *Streptococcus*, *Streptococcus anginosus* group, Pan Gram-Negative and Pan *Candida* targets. Sensitivity/PPA of these genus and group level targets for species as determined by comparator methods for all evaluable samples tested are summarized in Table 76.

Table 76: Species Detected in Genus and Group Assays by Comparator Methods

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

Target Species detected by Comparator Method	Sensitivity/PPA (Prospective)		Sensitivity/PPA (Retrospective)		Sensitivity/PPA (Contrived)		Sensitivity/PPA (Combined)	
	TP/ TP+F N	% (95% CI)	TP/ TP+F N	% (95% CI)	TP/ TP+F N	% (95% CI)	TP/ TP+F N	% (95% CI)
<i>Corynebacterium urealyticum</i>	-	-	0/1	0.0 (0.0-79.3)	-	-	0/1	0.0 (0.0-79.3)
Enterococcus	61/61	100 (94.1-100)	139/147	94.6 (89.6-97.2)	126/126	100 (97.0-100)	326/334	97.6 (95.3-98.8)
<i>Enterococcus</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Enterococcus avium</i>	1/1	100 (20.7-100)	2/3	66.7 (20.8-93.9)	-	-	3/4	75.0 (30.1-95.4)
<i>Enterococcus casseliflavus</i>	-	-	0/1	0.0 (0.0-79.3)	-	-	0/1	0.0 (0.0-79.3)
<i>Enterococcus casseliflavus/gallinarum</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Enterococcus faecalis</i>	49/49	100 (92.7-100)	85/90	94.4 (87.6-97.6)	52/52	100 (93.1-100)	186/191	97.4 (94.0-98.9)
<i>Enterococcus faecium</i>	12/12	100 (75.8-100)	52/53	98.1 (90.1-99.7)	60/60	100 (94.0-100)	124/125	99.2 (95.6-99.9)
<i>Enterococcus flavescens</i>	-	-	-	-	3/3	100 (43.9-100)	3/3	100 (43.9-100)
<i>Enterococcus gallinarum</i>	-	-	2/2	100 (34.2-100)	4/4	100 (51.0-100)	6/6	100 (61.0-100)
<i>Enterococcus hirae</i>	-	-	-	-	1/1	100 (20.7-100)	1/1	100 (20.7-100)
<i>Enterococcus malodoratus</i>	-	-	-	-	3/3	100 (43.9-100)	3/3	100 (43.9-100)
<i>Enterococcus raffinosus</i>	-	-	-	-	2/2	100 (34.2-100)	2/2	100 (34.2-100)
<i>Enterococcus saccharolyticus</i>	-	-	-	-	1/1	100 (20.7-100)	1/1	100 (20.7-100)
Lactobacillus	4/4	100 (51.0-100)	9/9	100 (70.1-100)	32/33	97.0 (84.7-99.5)	45/46	97.8 (88.7-99.6)
<i>Lactobacillus casei</i>	-	-	1/1	100 (20.7-100)	12/12	100 (75.8-100)	13/13	100 (77.2-100)
<i>Lactobacillus paracasei</i>	1/1	100 (20.7-100)	-	-	11/11	100 (74.1-100)	12/12	100 (75.8-100)
<i>Lactobacillus rhamnosus</i>	2/2	100 (34.2-100)	8/8	100 (67.6-100)	9/10	90.0 (59.6-98.2)	19/20	95.0 (76.4-99.1)
<i>Lactobacillus zeae</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
Listeria	-	-	2/2	100 (34.2-100)	74/75	98.7 (92.8-99.8)	76/77	98.7 (93.0-99.8)
<i>Listeria innocua</i>	-	-	-	-	9/9	100 (70.1-100)	9/9	100 (70.1-100)
<i>Listeria ivanovii</i>	-	-	-	-	9/10	90.0 (59.6-98.2)	9/10	90.0 (59.6-98.2)
<i>Listeria monocytogenes</i>	-	-	2/2	100 (34.2-100)	46/46	100 (92.3-100)	48/48	100 (92.6-100)

Target Species detected by Comparator Method	Sensitivity/PPA (Prospective)		Sensitivity/PPA (Retrospective)		Sensitivity/PPA (Contrived)		Sensitivity/PPA (Combined)	
	TP/TP+F N	% (95% CI)	TP/TP+F N	% (95% CI)	TP/TP+F N	% (95% CI)	TP/TP+F N	% (95% CI)
<i>Listeria seeligeri</i>	-	-	-	-	5/5	100 (56.6-100)	5/5	100 (56.6-100)
<i>Listeria welshimeri</i>	-	-	-	-	5/5	100 (56.6-100)	5/5	100 (56.6-100)
Micrococcus	19/21	90.5 (71.1-97.3)	20/23	87.0 (67.9-95.5)	27/27	100 (87.5-100)	66/71	93.0 (84.6-97.0)
<i>Micrococcus</i>	8/9	88.9 (56.5-98.0)	10/13	76.9 (49.7-91.8)	-	-	18/22	81.8 (61.5-92.7)
<i>Micrococcus luteus</i>	9/9	100 (70.1-100)	8/8	100 (67.6-100)	19/19	100 (83.2-100)	36/36	100 (90.4-100)
<i>Micrococcus luteus/lylae</i>	2/3	66.7 (20.8-93.9)	2/2	100 (34.2-100)	-	-	4/5	80.0 (37.6-96.4)
<i>Micrococcus lylae</i>	-	-	-	-	4/4	100 (51.0-100)	4/4	100 (51.0-100)
<i>Micrococcus yunnanensis</i>	-	-	-	-	4/4	100 (51.0-100)	4/4	100 (51.0-100)
Staphylococcus	447/456	98.0 (96.3-99.0)	185/191	96.9 (93.3-98.6)	105/105	100 (96.5-100)	737/752	98.0 (96.7-98.8)
<i>Coagulase-negative staphylococci (CoNS)</i>	18/18	100 (82.4-100)	-	-	-	-	18/18	100 (82.4-100)
<i>CoNS (Not S. epidermidis, S. lugdunensis)</i>	2/2	100 (34.2-100)	-	-	-	-	2/2	100 (34.2-100)
<i>Staphylococcus</i>	74/78	94.9 (87.5-98.0)	1/3	33.3 (6.1-79.2)	-	-	75/81	92.6 (84.8-96.6)
<i>Staphylococcus aureus</i>	158/160	98.8 (95.6-99.7)	121/123	98.4 (94.3-99.6)	59/59	100 (93.9-100)	338/342	98.8 (97.0-99.5)
<i>Staphylococcus aureus subsp. aureus</i>	6/6	100 (61.0-100)	2/2	100 (34.2-100)	-	-	8/8	100 (67.6-100)
<i>Staphylococcus auricularis</i>	2/2	100 (34.2-100)	2/2	100 (34.2-100)	-	-	4/4	100 (51.0-100)
<i>Staphylococcus capitis</i>	14/14	100 (78.5-100)	7/7	100 (64.6-100)	-	-	21/21	100 (84.5-100)
<i>Staphylococcus carnosus subsp. carnosus</i>	-	-	0/1	0.0 (0.0-79.3)	-	-	0/1	0.0 (0.0-79.3)
<i>Staphylococcus cohnii</i>	1/2	50.0 (9.5-90.5)	-	-	-	-	1/2	50.0 (9.5-90.5)
<i>Staphylococcus epidermidis</i>	117/121	96.7 (91.8-98.7)	37/38	97.4 (86.5-99.5)	1/1	100 (20.7-100)	155/160	96.9 (92.9-98.7)
<i>Staphylococcus haemolyticus</i>	6/6	100 (61.0-100)	2/2	100 (34.2-100)	-	-	8/8	100 (67.6-100)
<i>Staphylococcus hominis</i>	24/24	100 (86.2-100)	13/13	100 (77.2-100)	-	-	37/37	100 (90.6-100)
<i>Staphylococcus hominis subsp. hominis</i>	22/22	100 (85.1-100)	5/5	100 (56.6-100)	-	-	27/27	100 (87.5-100)
<i>Staphylococcus hominis subsp. novobiopeteticus</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)

Target Species detected by Comparator Method	Sensitivity/PPA (Prospective)		Sensitivity/PPA (Retrospective)		Sensitivity/PPA (Contrived)		Sensitivity/PPA (Combined)	
	TP/ TP+F N	% (95% CI)	TP/ TP+F N	% (95% CI)	TP/ TP+F N	% (95% CI)	TP/ TP+F N	% (95% CI)
<i>Staphylococcus lugdunensis</i>	2/2	100 (34.2-100)	4/4	100 (51.0-100)	45/45	100 (92.1-100)	51/51	100 (93.0-100)
<i>Staphylococcus pettenkoferi</i>	2/2	100 (34.2-100)	-	-	-	-	2/2	100 (34.2-100)
<i>Staphylococcus saccharolyticus</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Staphylococcus saprophyticus</i>	1/1	100 (20.7-100)	1/1	100 (20.7-100)	-	-	2/2	100 (34.2-100)
<i>Staphylococcus schleiferi</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Staphylococcus simulans</i>	3/3	100 (43.9-100)	-	-	-	-	3/3	100 (43.9-100)
<i>Staphylococcus warneri</i>	4/4	100 (51.0-100)	-	-	-	-	4/4	100 (51.0-100)
Streptococcus	103/110	93.6 (87.4-96.9)	171/173	98.8 (95.9-99.7)	57/57	100 (93.7-100)	331/340	97.4 (95.0-98.6)
<i>Alpha Hemolytic Streptococcus</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Gamma Hemolytic Streptococcus</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Streptococcus</i>	5/7	71.4 (35.9-91.8)	-	-	-	-	5/7	71.4 (35.9-91.8)
<i>Streptococcus (Group G)</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Streptococcus agalactiae</i>	10/11	90.9 (62.3-98.4)	37/37	100 (90.6-100)	8/8	100 (67.6-100)	55/56	98.2 (90.6-99.7)
<i>Streptococcus anginosus</i>	1/1	100 (20.7-100)	13/13	100 (77.2-100)	13/13	100 (77.2-100)	27/27	100 (87.5-100)
<i>Streptococcus anginosus group</i>	4/4	100 (51.0-100)	22/22	100 (85.1-100)	-	-	26/26	100 (87.1-100)
<i>Streptococcus bovis</i>	-	-	2/2	100 (34.2-100)	-	-	2/2	100 (34.2-100)
<i>Streptococcus bovis group</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Streptococcus constellatus</i>	-	-	-	-	6/6	100 (61.0-100)	6/6	100 (61.0-100)
<i>Streptococcus constellatus subsp. constellatus</i>	-	-	2/2	100 (34.2-100)	-	-	2/2	100 (34.2-100)
<i>Streptococcus constellatus subsp. pharyngis</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Streptococcus dysgalactiae</i>	-	-	2/2	100 (34.2-100)	-	-	2/2	100 (34.2-100)
<i>Streptococcus dysgalactiae (Group G)</i>	4/4	100 (51.0-100)	1/1	100 (20.7-100)	-	-	5/5	100 (56.6-100)
<i>Streptococcus gallolyticus</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)

Target Species detected by Comparator Method	Sensitivity/PPA (Prospective)		Sensitivity/PPA (Retrospective)		Sensitivity/PPA (Contrived)		Sensitivity/PPA (Combined)	
	TP/ TP+F N	% (95% CI)	TP/ TP+F N	% (95% CI)	TP/ TP+F N	% (95% CI)	TP/ TP+F N	% (95% CI)
<i>Streptococcus gordonii</i>	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)
<i>Streptococcus infantarius</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Streptococcus intermedius</i>	-	-	2/2	100 (34.2-100)	4/4	100 (51.0-100)	6/6	100 (61.0-100)
<i>Streptococcus mitis</i>	9/10	90.0 (59.6-98.2)	14/15	93.3 (70.2-98.8)	-	-	23/25	92.0 (75.0-97.8)
<i>Streptococcus mitis</i> group	10/10	100 (72.2-100)	-	-	-	-	10/10	100 (72.2-100)
<i>Streptococcus mutans</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Streptococcus oralis</i>	-	-	3/3	100 (43.9-100)	-	-	3/3	100 (43.9-100)
<i>Streptococcus parasanguinis</i>	2/2	100 (34.2-100)	4/4	100 (51.0-100)	-	-	6/6	100 (61.0-100)
<i>Streptococcus pneumoniae</i>	28/28	100 (87.9-100)	41/41	100 (91.4-100)	-	-	69/69	100 (94.7-100)
<i>Streptococcus pyogenes</i>	8/8	100 (67.6-100)	19/20	95.0 (76.4-99.1)	26/26	100 (87.1-100)	53/54	98.1 (90.2-99.7)
<i>Streptococcus salivarius</i>	4/4	100 (51.0-100)	5/5	100 (56.6-100)	-	-	9/9	100 (70.1-100)
<i>Streptococcus vestibularis</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Streptococcus viridans</i> group	14/17	82.4 (59.0-93.8)	2/2	100 (34.2-100)	-	-	16/19	84.2 (62.4-94.5)
<i>Streptococcus anginosus</i> group	4/5	80.0 (37.6-96.4)	38/40	95.0 (83.5-98.6)	23/23	100 (85.7-100)	65/68	95.6 (87.8-98.5)
<i>Streptococcus anginosus</i>	0/1	0.0 (0.0-79.3)	12/13	92.3 (66.7-98.6)	13/13	100 (77.2-100)	25/27	92.6 (76.6-97.9)
<i>Streptococcus anginosus</i> group	4/4	100 (51.0-100)	21/22	95.5 (78.2-99.2)	-	-	25/26	96.2 (81.1-99.3)
<i>Streptococcus constellatus</i>	-	-	-	-	6/6	100 (61.0-100)	6/6	100 (61.0-100)
<i>Streptococcus constellatus</i> spp <i>constellatus</i>	-	-	2/2	100 (34.2-100)	-	-	2/2	100 (34.2-100)
<i>Streptococcus constellatus</i> spp <i>pharynges</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Streptococcus intermedius</i>	-	-	2/2	100 (34.2-100)	4/4	100 (51.0-100)	6/6	100 (61.0-100)
Pan Candida	-	-	7/9	77.8 (45.3-93.7)	-	-	7/9	77.8 (45.3-93.7)
<i>Candida albicans</i>	-	-	4/4	100 (51.0-100)	-	-	4/4	100 (51.0-100)
<i>Candida glabrata</i>	-	-	1/2	50 (9.5-90.5)	-	-	1/2	50 (9.5-90.5)

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

Target Species detected by Comparator Method	Sensitivity/PPA (Prospective)		Sensitivity/PPA (Retrospective)		Sensitivity/PPA (Contrived)		Sensitivity/PPA (Combined)	
	TP/TP+F N	% (95% CI)	TP/TP+F N	% (95% CI)	TP/TP+F N	% (95% CI)	TP/TP+F N	% (95% CI)
<i>Pseudomonas</i>	-	-	1/1	100 (20.7-100)	-	-	1/1	100 (20.7-100)
<i>Pseudomonas aeruginosa</i>	1/1	100 (20.7-100)	1/2	50.0 (9.5-90.5)	-	-	2/3	66.7 (20.8-93.9)
<i>Serratia marcescens</i>	2/2	100 (34.2-100)	-	-	-	-	2/2	100 (34.2-100)
<i>Stenotrophomonas maltophilia</i>	1/1	100 (20.7-100)	1/1	100 (20.7-100)	-	-	2/2	100 (34.2-100)
<i>Veillonella</i> species	-	-	0/1	0.0 (0.0-79.3)	-	-	0/1	0.0 (0.0-79.3)
Non-fermenting gram-negative bacilli	1/1	100 (20.7-100)	-	-	-	-	1/1	100 (20.7-100)

The PPA and NPA of the BCID-GP Panel *mecA* target stratified by the *Staphylococcus* species identified by comparator methods for 647 prospective and retrospective samples and 105 contrived samples are shown in Table 77.

Table 77: Clinical Performance of *mecA* Target by *Staphylococcus* Species Detected by Comparator Methods

Species detected by Comparator Method		Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95% CI)	TN/TN+FP	% (95% CI)
Coagulase-negative <i>Staphylococci</i> (CoNS)	Prospective	12/12	100 (75.8-100)	6/6	100 (61.0-100)
	Retrospective	-	-	-	-
	Contrived	-	-	-	-
	Combined	12/12	100 (75.8-100)	6/6	100 (61.0-100)
CoNS (not <i>S. epidermidis</i> / <i>S. lugdunensis</i>)	Prospective	1/1	100 (20.7-100)	0/1	0.0 (0.0-79.3)
	Retrospective	-	-	-	-
	Contrived	-	-	-	-
	Combined	1/1	100 (20.7-100)	0/1	0.0 (0.0-79.3)
<i>Staphylococcus</i>	Prospective	49/52	94.2 (84.4-98.0)	24/26	92.3 (75.9-97.9)
	Retrospective	1/2	50.0 (9.5-90.5)	1/1	100 (20.7-100)
	Contrived	-	-	-	-
	Combined	50/54	92.6 (82.4-97.1)	25/27	92.6 (76.6-97.9)
<i>Staphylococcus aureus</i>	Prospective	80/83	96.4 (89.9-98.8)	74/77	96.1 (89.2-98.7)

Species detected by Comparator Method		Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95 % CI)	TN/TN+FP	% (95 % CI)
	Retrospective	105/106	99.1 (94.8-99.8)	16/17	94.1 (73.0-99.0)
	Contrived	10/10	100 (72.2-100)	49/49	100 (92.7-100)
	Combined	195/199	98.0 (94.9-99.2)	139/143	97.2 (93.0-98.9)
<i>Staphylococcus aureus</i> subsp. <i>aureus</i>	Prospective	3/3	100 (43.9-100)	3/3	100 (43.9-100)
	Retrospective	2/2	100 (34.2-100)	0/0	-
	Contrived	-	-	-	-
	Combined	5/5	100 (56.6-100)	3/3	100 (43.9-100)
<i>Staphylococcus auricularis</i>	Prospective	1/1	100 (20.7-100)	1/1	100 (20.7-100)
	Retrospective	0/0	-	2/2	100 (34.2-100)
	Contrived	-	-	-	-
	Combined	1/1	100 (20.7-100)	3/3	100 (43.9-100)
<i>Staphylococcus capitis</i>	Prospective	4/5	80.0 (37.6-96.4)	5/5	100 (56.6-100)
	Retrospective	4/4	100 (51.0-100)	7/7	100 (64.6-100)
	Contrived	-	-	-	-
	Combined	8/9	88.9 (56.5-98.0)	12/12	100 (75.8-100)
<i>Staphylococcus carnosus</i> subsp. <i>carnosus</i>	Prospective	-	-	-	-
	Retrospective	0/0	-	1/1	100 (20.7-100)
	Contrived	-	-	-	-
	Combined	0/0	-	1/1	100 (20.7-100)
<i>Staphylococcus cohnii</i>	Prospective	0/1	0.0 (0.0-79.3)	1/1	100 (20.7-100)
	Retrospective	-	-	-	-
	Contrived	-	-	-	-
	Combined	0/1	0.0 (0.0-79.3)	1/1	100 (20.7-100)

Species detected by Comparator Method		Sensitivity/PPA		Specificity/NPA	
		TP/TP+FN	% (95 % CI)	TN/TN+FP	% (95 % CI)
<i>Staphylococcus epidermidis</i>	Prospective	77/79	97.5 (91.2-99.3)	39/42	92.9 (81.0-97.5)
	Retrospective	30/30	100 (88.6-100)	7/8	87.5 (52.9-97.8)
	Contrived	1/1	100 (20.7-100)	0/0	-
	Combined	108/110	98.2 (93.6-99.5)	46/50	92.0 (81.2-96.8)
<i>Staphylococcus haemolyticus</i>	Prospective	4/4	100 (51.0-100)	2/2	100 (34.2-100)
	Retrospective	2/2	100 (34.2-100)	0/0	-
	Contrived	-	-	-	-
	Combined	6/6	100 (61.0-100)	2/2	100 (34.2-100)
<i>Staphylococcus hominis</i>	Prospective	12/13	92.3 (66.7-98.6)	10/11	90.9 (62.3-98.4)
	Retrospective	12/12	100 (75.8-100)	1/1	100 (20.7-100)
	Contrived	-	-	-	-
	Combined	24/25	96.0 (80.5-99.3)	11/12	91.7 (64.6-98.5)
<i>Staphylococcus hominis</i> subsp. <i>hominis</i>	Prospective	10/11	90.9 (62.3-98.4)	11/11	100 (74.1-100)
	Retrospective	2/2	100 (34.2-100)	3/3	100 (43.9-100)
	Contrived	-	-	-	-
	Combined	12/13	92.3 (66.7-98.6)	14/14	100 (78.5-100)
<i>Staphylococcus hominis</i> subsp. <i>novobiosepticus</i>	Prospective	1/1	100 (20.7-100)	0/0	-
	Retrospective	-	-	-	-
	Contrived	-	-	-	-
	Combined	1/1	100 (20.7-100)	0/0	-
<i>Staphylococcus lugdunensis</i>	Prospective	0/0	---	2/2	100 (34.2-100)
	Retrospective	1/1	100 (20.7-100)	3/3	100 (43.9-100)
	Contrived	0/0	---	45/45	100 (92.1-100)
	Combined	1/1	100 (20.7-100)	50/50	100 (92.9-100)

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

A comparison of specific *Staphylococcus* species and *mecA* identified by comparator methods versus the ePlex BCID-GP Panel results are shown in Table 78 and Table 79 for prospective and retrospective samples.

Table 78: Distribution of *mecA* Results in *Staphylococcus aureus* Prospective/Retrospective Samples

	Comparator Method			
BCID-GP	Org+/ARG+	Org+/ARG-	Org-	Total
Org+/ARG+	190	2	2	194
Org+/ARG-	2	88	4	94
Org-	2	7	1000	1009
Total	194	97	1006	1297

% Agreement (95% CI) for Org+/ARG+: 190/194=97.9 (94.8-99.2)

% Agreement (95% CI) for Org+/ARG-: 88/97=90.7 (83.3-95.0)

% Agreement (95% CI) for Org-: 1000/1006=99.4 (98.7-99.7)

Table 79: Distribution of *mecA* Results in *Staphylococcus* Species (Excluding Known *S. aureus*, *S. epidermidis*, *S. lugdunensis*) Prospective/Retrospective Samples

	Comparator Method			
BCID-GP	Org+/ARG+	Org+/ARG-	Org-	Total
Org+/ARG+	33	1	4	38
Org+/ARG-	3	45	8	56
Org-	10*	4	1091	1105
Total	46	50	1103	1199

% Agreement (95% CI) for Org+/ARG+: 33/46=71.7 (57.5-82.7)

% Agreement (95% CI) for Org+/ARG-: 45/50=90.0 (78.6-95.7)

% Agreement (95% CI) for Org-: 1091/1103=98.9 (98.1-99.4)

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

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

The PPA and NPA of the BCID-GP Panel vanA target stratified by the Enterococcus species identified by comparator methods for 208 clinical prospective/retrospective samples and 126 contrived samples are shown in Table 80.

Table 80: Clinical Performance of vanA Target by Enterococcus Species Detected by Comparator Methods

Species detected by Comparator Method		Sensitivity/PPA		Specificity/NPA	
		TP/TP+F N	% (95% CI)	TN/TN+ FP	% (95% CI)
<i>Enterococcus</i>	Prospective	0/0	-	1/1	100 (20.7-100)
	Retrospective	-	-	-	-
	Contrived	-	-	-	-
	Combined	0/0	-	1/1	100 (20.7-100)
<i>Enterococcus avium</i>	Prospective	0/0		1/1	100 (20.7-100)
	Retrospective	0/1	0.0 (0.0-79.3)	2/2	100 (34.2-100)
	Contrived	-	-	-	-
	Combined	0/1	0.0 (0.0-79.3)	3/3	100 (43.9-100)
<i>Enterococcus casseliflavus</i>	Prospective	-	-	-	-
	Retrospective	0/0	-	1/1	100 (20.7-100)
	Contrived	-	-	-	-
	Combined	0/0	-	1/1	100 (20.7-100)
<i>Enterococcus casseliflavus / E. gallinarum</i>	Prospective	-	-	-	-
	Retrospective	0/0	-	1/1	100 (20.7-100)
	Contrived	-	-	-	-
	Combined	0/0	-	1/1	100 (20.7-100)
<i>Enterococcus faecalis</i>	Prospective	1/1	100 (20.7-100)	48/48	100 (92.6-100)
	Retrospective	11/14	78.6 (52.4-92.4)	76/76	100 (95.2-100)
	Contrived	10/10	100 (72.2-100)	42/42	100 (91.6-100)
	Combined	22/25	88.0 (70.0-95.8)	166/166	100 (97.7-100)
<i>Enterococcus faecium</i>	Prospective	7/7	100 (64.6-100)	4/5	80.0 (37.6-96.4)
	Retrospective	44/44	100 (92.0-100)	8/9	88.9 (56.5-98.0)
	Contrived	50/50	100 (92.9-100)	10/10	100 (72.2-100)
	Combined	101/101	100 (96.3-100)	22/24	91.7 (74.2-97.7)
<i>Enterococcus flavescens</i>	Prospective	-	-	-	-
	Retrospective	-	-	-	-
	Contrived	0/0	-	3/3	100 (43.9-100)
	Combined	0/0	-	3/3	100 (43.9-100)
<i>Enterococcus gallinarum</i>	Prospective	-	-	-	-
	Retrospective	0/0	-	2/2	100 (34.2-100)
	Contrived	0/0	-	4/4	100 (51.0-100)
	Combined	0/0	-	6/6	100 (61.0-100)
<i>Enterococcus hirae</i>	Prospective	-	-	-	-
	Retrospective	-	-	-	-
	Contrived	0/0	-	1/1	100 (20.7-100)
	Combined	0/0	-	1/1	100 (20.7-100)
<i>Enterococcus malodoratus</i>	Prospective	-	-	-	-
	Retrospective	-	-	-	-
	Contrived	0/0	---	3/3	100 (43.9-100)

Species detected by Comparator Method		Sensitivity/PPA		Specificity/NPA	
		TP/TP+F N	% (95% CI)	TN/TN+ FP	% (95% CI)
	Combined	0/0	-	3/3	100 (43.9-100)
<i>Enterococcus raffinosus</i>	Prospective	-	-	-	-
	Retrospective	-	-	-	-
	Contrived	0/0	-	2/2	100 (34.2-100)
	Combined	0/0	-	2/2	100 (34.2-100)
<i>Enterococcus saccharolyticus</i>	Prospective	-	-	-	-
	Retrospective	-	-	-	-
	Contrived	0/0	-	1/1	100 (20.7-100)
	Combined	0/0	-	1/1	100 (20.7-100)

A comparison of *Enterococcus faecalis*/*Enterococcus faecium* and *vanA* identified by comparator methods versus the ePlex BCID-GP Panel results is shown in Table 81 and Table 82 for prospective and retrospective samples.

Table 81: Distribution of *vanA* Results in *Enterococcus faecalis* Prospective/Retrospective Samples

	Comparator Method			
BCID-GP	Org+/ARG+	Org+/ARG-	Org-	Total
Org+/ARG+	10	0	0	10
Org+/ARG-	1	120	1	122
Org-	4*	4	1157	1165
Total	15	124	1158	1297

% Agreement (95% CI) for Org+/ARG+: 10/15=66.7 (41.7-84.8)

% Agreement (95% CI) for Org+/ARG-: 120/124=96.8 (92.0-98.7)

% Agreement (95% CI) for Org-: 1157/1158=99.9 (99.5-100)

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

Table 82: Distribution of *vanA* Results in *Enterococcus faecium* Prospective/Retrospective Samples

	Comparator Method			
BCID-GP	Org+/ARG+	Org+/ARG-	Org-	Total
Org+/ARG+	51	2	3	56
Org+/ARG-	0	10	5	15
Org-	0	2	1224	1226
Total	51	14	1232	1297

% Agreement (95% CI) for Org+/ARG+: 51/51=100.0 (93.0-100)

% Agreement (95% CI) for Org+/ARG-: 0/14=0.0 (0.0-0.0)

% Agreement (95% CI) for Org-: 1224/1232=99.4 (98.7-99.7)

A table for *vanB* is not provided because *vanB* was only detected in 1 clinical sample and 52 contrived samples comprised of two species, *E. faecalis* (n=43) and *E. faecium* (n=10), resulting in PPA and NPA of 100%.

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

In prospective samples, the most common co-detection combination identified by the ePlex BCID-GP Panel was *Enterococcus faecalis* with Pan Gram-Negative which was detected in 6 samples. Pan Gram-Negative was identified in 17 co-detections, *Staphylococcus* was identified in 26 co-detections, *Enterococcus* was identified in 13 co-detections, and *Streptococcus* was identified in 12 co-detections. Results are summarized in Table 83.

Table 83: Co-Detections Identified by the ePlex BCID-GP Panel in Prospective Clinical Samples

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

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

* A discrepant result is one that was detected by the ePlex BCID-GP Panel but not by the comparator method(s). 7/16 discrepant organisms were detected using PCR/sequencing as shown: In 1/1 false positive *E. faecium* samples, *E. faecium* was detected. In 1/1 false positive *Lactobacillus* samples, *Lactobacillus* was detected. In 2/5 false positive *S. epidermidis* samples, *S. epidermidis* was detected. In 2/2 false positive *S. lugdunensis* samples, *S. lugdunensis* was detected. In 1/1 false positive *Streptococcus* samples, *Streptococcus* was detected.

In retrospective samples, the most common co-detection combination identified by the ePlex BCID-GP Panel was *Enterococcus faecalis* with Pan Gram-Negative which was detected in 9 samples, 2 of which also had *vanA* detected. Pan Gram-Negative was identified in 33 co-detections, *Staphylococcus* was identified in 22 co-detections, *Enterococcus* was identified in 34 co-detections, and *Streptococcus* was identified in 24 co-detections. Results are summarized in Table 84.

Table 84: Co-Detections Identified by the ePlex BCID-GP Panel in Retrospective Clinical Samples

Distinct Co-Detection Combinations Detected by the ePlex BCID-GP Panel in Retrospective Clinical Samples				Number Samples (Number Discrepant)	Discrepant Organism(s) / Resistance Marker(s)*
Target 1	Target 2	Target 3	Resistance Marker		
<i>Corynebacterium</i>	<i>S. epidermidis</i>	<i>S. lugdunensis</i>	<i>mecA</i>	1 (1)	<i>Corynebacterium</i> (1)
<i>Corynebacterium</i>	<i>Staphylococcus</i>			1 (0)	
<i>Corynebacterium</i>	<i>Staphylococcus</i>		<i>mecA</i>	1 (0)	
<i>E. faecalis</i>	<i>E. faecium</i>			4 (3)	<i>E. faecium</i> (3)
<i>E. faecalis</i>	<i>E. faecium</i>		<i>vanA</i>	3 (1)	<i>E. faecium</i> (1)
<i>E. faecalis</i>	Pan <i>Candida</i>			1 (0)	
<i>E. faecalis</i>	Pan GN			6 (0)	
<i>E. faecalis</i>	Pan GN		<i>vanA</i>	2 (0)	
<i>E. faecalis</i>	Pan GN	<i>S. aureus</i>		1 (0)	

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

Distinct Co-Detection Combinations Detected by the ePlex BCID-GP Panel in Retrospective Clinical Samples				Number Samples (Number)	Discrepant Organism(s) / Resistance
<i>S. aureus</i>	<i>Streptococcus</i>		<i>mecA</i>	2 (1)	<i>Streptococcus</i> (1)
<i>S. epidermidis</i>	<i>Streptococcus</i>		<i>mecA</i>	1 (0)	

* A discrepant result is one that was detected by the ePlex BCID-GP Panel but not by the comparator method(s). 6/18 discrepant organisms were detected using PCR/sequencing as shown: In 1/1 false positive *Corynebacterium* samples, *Corynebacterium* was detected. In 2/5 false positive *E. faecium* samples, *E. faecium* was detected. In 1/1 false positive *Staphylococcus* samples, *Staphylococcus* was detected. In 2/2 false positive *Streptococcus* samples, *Streptococcus* was detected.

Additional co-detection combinations identified by comparator method(s) are summarized in Table 85 and Table 86 for prospective and retrospective samples, respectively.

Table 85: Additional Co-Detections Identified by Comparator Method(s) in Prospective Clinical Samples by Organism

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

Distinct Co-Detection Combinations Detected by the Comparator Methods in Prospective Clinical Samples					Number Samples (Number Discrepant)	Discrepant Organism(s)/ Resistance Markers(s)*
Organism 1	Organism 2	Organism 3	Organism 4	Resistance Marker		
<i>E. coli</i>	<i>P. mirabilis</i>	<i>Providencia stuartii</i>	<i>S. anginosus</i> gp		1 (0)	
<i>E. faecalis</i>	<i>E. faecium</i>				1 (1)	<i>E. faecium</i> (1)
<i>E. faecalis</i>	<i>K. pneumoniae</i>				2 (0)	
<i>E. faecalis</i>	<i>P. mirabilis</i>				1 (0)	
<i>E. faecalis</i>	<i>S. aureus</i>			<i>mecA</i>	1 (1)	<i>S. aureus</i> (1), <i>mecA</i> (1)
<i>E. faecalis</i>	<i>S. marcescens</i>				1 (0)	
<i>E. faecalis</i>	<i>Staphylococcus</i> (CoNS)			<i>mecA</i>	1 (0)	
<i>E. faecium</i>	<i>S. epidermidis</i>	<i>Staphylococcus haemolyticus</i>		<i>mecA</i> , <i>vanA</i>	1 (0)	
<i>K. pneumoniae</i>	<i>Staphylococcus haemolyticus</i>	non-fermenting GN bacilli			1 (0)	
<i>P. aeruginosa</i>	<i>P. mirabilis</i>	<i>Streptococcus - viridans</i> group			1 (0)	
<i>P. mirabilis</i>	<i>Staphylococcus</i>			<i>mecA</i>	1 (1)	<i>Staphylococcus</i> (1), <i>mecA</i> (1)
<i>Peptostreptococcus</i> species ^A	<i>Staphylococcus</i>				1 (0)	
<i>Rothia</i> (stomatococcus) <i>mucilagenosus</i> ^A	<i>S. epidermidis</i>				1 (0)	
<i>Rothia mucilagenosa</i> ^A	<i>Streptococcus - viridans</i> group				1 (0)	
<i>S. agalactiae</i>	<i>S. aureus</i>	<i>Staphylococcus</i>		<i>mecA</i>	1 (1)	<i>S. aureus</i> (1), <i>Staphylococcus</i> (1), <i>mecA</i> (1)
<i>S. anginosus</i>	<i>Streptococcus mitis</i>				1 (1)	<i>S. anginosus</i> (1)
<i>S. epidermidis</i>	<i>Staphylococcus capitis</i>			<i>mecA</i>	1 (0)	
<i>S. epidermidis</i>	<i>Staphylococcus hominis</i>				2 (0)	
<i>S. epidermidis</i>	<i>Staphylococcus hominis</i>			<i>mecA</i>	4 (1)	<i>S. epidermidis</i> (1)
<i>S. epidermidis</i>	<i>Staphylococcus hominis</i>	<i>Staphylococcus warneri</i>			1 (0)	
<i>S. epidermidis</i>	<i>Streptococcus - viridans</i> group				1 (1)	<i>S. epidermidis</i> (1)

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

* A discrepant result is one that was detected by the comparator method(s) but not by the ePlex BCID-GP Panel (excludes organisms not targeted by the ePlex BCID-GP Panel). 16 discrepant organisms were investigated using PCR/sequencing; 1 discrepant organism was not detected: In 1/1 false negative *S. anginosus* group sample, PCR/Sequencing instead detected *Streptococcus dysgalactiae*.

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

Table 86: Additional Co-Detections Identified by Comparator Method(s) in Retrospective Clinical Samples by Organism

Distinct Co-Detection Combinations Detected by the Comparator Methods in Retrospective Clinical Samples					Number Samples (Number Discrepant)	Discrepant Organism(s)/ Resistance Markers(s)*
Organism 1	Organism 2	Organism 3	Organism 4	Resistance Marker		
<i>A. baumannii</i>	<i>E. faecalis</i>			<i>vanA</i>	2 (2)	<i>A. baumannii</i> (2)
<i>A. baumannii</i>	<i>E. faecalis</i>	<i>S. aureus</i>		<i>mecA</i>	1 (1)	<i>mecA</i> (1)
<i>A. baumannii</i>	<i>E. faecium</i>			<i>vanA</i>	1 (0)	
<i>Aerococcus sanguinicola</i> ^A	<i>Corynebacterium</i>	<i>Staphylococcus saprophyticus</i>			1 (0)	
<i>Aeromonas caviae</i>	<i>E. coli</i>	<i>Enterococcus casseliflavus</i>	<i>K. oxytoca</i>		1 (1)	<i>E. casseliflavus</i> (1)
<i>C. acnes</i>	<i>Enterococcus avium</i>			<i>vanA</i>	1 (1)	<i>E. avium</i> (1), <i>vanA</i> (1)
<i>C. albicans</i>	<i>E. faecalis</i>			<i>vanA</i>	1 (1)	<i>E. faecalis</i> (1)
<i>C. albicans</i>	<i>E. faecium</i>	<i>Staphylococcus hominis</i>		<i>mecA</i> , <i>vanA</i>	1 (0)	
<i>C. albicans</i>	<i>S. epidermidis</i>			<i>mecA</i>	1 (0)	
<i>C. glabrata</i>	<i>Lactobacillus rhamnosus</i>				1 (1)	<i>C. glabrata</i> (1)
<i>C. glabrata</i>	<i>S. pneumoniae</i>				1 (0)	
<i>C. krusei</i>	<i>S. epidermidis</i>			<i>mecA</i>	1 (0)	
<i>C. parapsilosis</i>	<i>E. faecalis</i>				1 (0)	

Distinct Co-Detection Combinations Detected by the Comparator Methods in Retrospective Clinical Samples					Number Samples (Number Discrepant)	Discrepant Organism(s)/ Resistance Markers(s)*
Organism 1	Organism 2	Organism 3	Organism 4	Resistance Marker		
<i>C. parapsilosis</i>	<i>E. faecalis</i>			<i>vanA</i>	1 (1)	<i>C. parapsilosis</i> (1)
<i>Citrobacter braakii</i>	<i>Streptococcus oralis</i>				1 (0)	
<i>E. cloacae</i>	<i>E. faecalis</i>				1 (0)	
<i>E. cloacae</i>	<i>E. faecium</i>			<i>vanA</i>	1 (0)	
<i>E. cloacae</i>	<i>E. faecium</i>	<i>Staphylococcus hominis</i>		<i>mecA</i> , <i>vanA</i>	1 (0)	
<i>E. cloacae</i>	<i>S. anginosus gp</i>				1 (0)	
<i>E. coli</i>	<i>E. faecalis</i>				3 (0)	
<i>E. coli</i>	<i>E. faecalis</i>	<i>K. pneumoniae</i>			1 (0)	
<i>E. coli</i>	<i>E. faecalis</i>	<i>P. mirabilis</i>			1 (0)	
<i>E. coli</i>	<i>E. faecium</i>				2 (0)	
<i>E. coli</i>	<i>K. oxytoca</i>	<i>Streptococcus infantarius</i>			1 (0)	
<i>E. coli</i>	<i>S. agalactiae</i>				1 (0)	
<i>E. coli</i>	<i>S. anginosus gp</i>				1 (0)	
<i>E. coli</i>	<i>S. aureus</i>			<i>mecA</i>	1 (0)	
<i>E. coli</i>	<i>S. pneumoniae</i>				1 (0)	
<i>E. coli</i>	<i>Streptococcus bovis</i>				1 (0)	
<i>E. faecalis</i>	<i>K. pneumoniae</i>			<i>vanA</i>	1 (1)	<i>E. faecalis</i> (1), <i>K. pneumoniae</i> (1)
<i>E. faecalis</i>	<i>M. morganii</i>			<i>vanA</i>	1 (0)	
<i>E. faecalis</i>	<i>M. morganii</i>	<i>Proteus vulgaris</i>		<i>vanA</i>	1 (1)	<i>E. faecalis</i> (1), <i>vanA</i> (1)
<i>E. faecalis</i>	<i>P. aeruginosa</i>	<i>S. aureus</i>		<i>mecA</i>	1 (1)	<i>E. faecalis</i> (1), <i>P. aeruginosa</i> (1)
<i>E. faecalis</i>	<i>P. mirabilis</i>				2 (2)	<i>E. faecalis</i> (1), <i>P. mirabilis</i> (1)
<i>E. faecalis</i>	<i>P. mirabilis</i>			<i>vanA</i>	1 (1)	<i>E. faecalis</i> (1), <i>vanA</i> (1)
<i>E. faecalis</i>	<i>Providencia stuartii</i>				1 (1)	<i>P. stuartii</i> (1)
<i>E. faecalis</i>	<i>S. maltophilia</i>			<i>vanA</i>	1 (0)	
<i>E. faecium</i>	<i>K. pneumoniae</i>				1 (0)	
<i>E. faecium</i>	<i>Moraxella (Branhamella) catarrhalis</i>	<i>Pediococcus pentosaceus</i>		<i>vanA</i>	1 (0)	

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

* A discrepant result is one that was detected by the comparator method(s) but not by the ePlex BCID-GP Panel (excludes organisms not targeted by the ePlex BCID-GP Panel). 24 discrepant organisms were investigated using PCR/sequencing; 2 discrepant organisms were not detected: In 2/6 false negative *E. faecalis* samples, PCR/Sequencing instead detected *Enterococcus faecium*.

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

External Control testing in the Clinical Study:

External controls used in the clinical study consisted of three positive controls (A, B, C) and 1 negative control. The positive controls together represent all the targets on the ePlex BCID-GP Panel. On each day of testing with the ePlex BCID-GP Panel, each site tested one positive and one negative control. Sites rotated through the 3 positive controls throughout the study.

Table 87: External Controls Utilized in the Clinical Evaluations

Mix ID	Organisms in Mix	Organism Strain ID	Concentration in Mix (CFU/mL)
Mix 1	<i>Enterococcus casseliflavus</i>	ATCC25788	1x10 ⁷
	<i>Micrococcus luteus</i>	ATCC19212	1x10 ⁷
	<i>Streptococcus agalactiae</i>	ATCC12401	1x10 ⁶
	<i>Bacillus cereus</i>	ATCC21769	1x10 ⁷
	<i>Staphylococcus lugdunensis</i>	NRS879	1x10 ⁷
Mix 2	<i>Staphylococcus aureus/mecC</i>	ATCCBAA-2313	1x10 ⁶
	<i>Candida albicans</i>	ATCC24433	1x10 ⁷
	<i>Cutibacterium acnes (P. acnes)</i>	ATCC6919	1x10 ⁸
	<i>Stenotrophomonas maltophilia</i>	ATCC13636	1x10 ⁷
Mix 3	<i>Staphylococcus epidermidis/MecA</i>	ATCC35983	1x10 ⁶
	<i>Candida glabrata</i>	ATCC66032	1x10 ⁷
	<i>Enterococcus faecium/VanA</i>	ATCCBAA-2317	1x10 ⁸
Mix 4	<i>Bacillus subtilis</i>	ATCC55614	1x10 ⁷
	<i>Listeria monocytogenes</i>	ATCC10890	1x10 ⁶
	<i>Streptococcus pneumoniae</i>	ATCCBAA-475	1x10 ⁶
	<i>Escherichia coli</i>	ATCC4157	1x10 ⁷
Mix 5	<i>Enterococcus faecalis/vanB</i>	ATCC51575	1x10 ⁷
	<i>Streptococcus anginosus</i>	ATCC9895	1x10 ⁶
	<i>Lactobacillus paracasei</i>	ATCC25598	1x10 ⁷
	<i>Streptococcus pyogenes</i>	ATCC12384	1x10 ⁶
	<i>Corynebacterium striatum</i>	ATCC43735	1x10 ⁷

A total of 110 control runs (55 negative and 55 positive) were tested across multiple testing days. All valid negative control runs generated the expected result on the BCID-GP Panel;

no targets were detected. All positive controls tested resulted in the correct targets detected with the exception of one run. This run failed to detect the *Cutibacterium acnes* (*C. acnes*) target. The concentration of *C. acnes* in this mix was noted to be at the Limit of Detection (LoD) and below the bottle positive concentration. Therefore, this result was expected and accepted.

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

A prospective, multicenter clinical study was conducted to evaluate the clinical performance of the ePlex BCID-GP Panel in positive blood culture samples. A total of 711 samples were prospectively collected at 7 clinical sites in 2 phases from patients of all ages and genders. In the first phase from June 2014 through July 2016, 399 samples were prospectively collected and frozen; from January through February 2018, 312 samples were prospectively collected and tested fresh (never frozen). The expected values of individual analytes based on the ePlex BCID-GP Panel results in prospective samples are summarized by age group and by site in Table 88 and Table 89, respectively.

Table 88: Expected Value by Age Group (Prospective Samples)

Target	All Ages (N=711)	Age <1 (N=27)	Age 1-17 (N=42)	Age 18-44 (N=121)	Age 45-64 (N=2500)	Age 65-84 (N=217)	Age 85+ (N=54)
<i>Bacillus cereus</i> group	5 (0.7)	0 (0.0)	0 (0.0)	3 (2.5)	2 (0.8)	0 (0.0)	0 (0.0)
<i>Bacillus subtilis</i> group	2 (0.3)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.9)
<i>Corynebacterium</i>	14 (2.0)	1 (3.7)	0 (0.0)	4 (3.3)	5 (2.0)	4 (1.8)	0 (0.0)
<i>Cutibacterium acnes</i> (<i>P. acnes</i>)	8 (1.1)	0 (0.0)	0 (0.0)	3 (2.5)	2 (0.8)	3 (1.4)	0 (0.0)
<i>Enterococcus</i>	62 (8.7)	0 (0.0)	6 (14.3)	8 (6.6)	20 (8.0)	24 (11.1)	4 (7.4)
<i>Enterococcus faecalis</i>	50 (7.0)	0 (0.0)	6 (14.3)	6 (5.0)	15 (6.0)	20 (9.2)	3 (5.6)
<i>Enterococcus faecium</i>	12 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	6 (2.4)	5 (2.3)	0 (0.0)
<i>Lactobacillus</i>	5 (0.7)	0 (0.0)	0 (0.0)	2 (1.7)	1 (0.4)	1 (0.5)	1 (1.9)
<i>Listeria</i>	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)
<i>Listeria monocytogenes</i>	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<i>Micrococcus</i>	19 (2.7)	0 (0.0)	3 (7.1)	2 (1.7)	8 (3.2)	5 (2.3)	1 (1.9)
<i>Staphylococcus</i>	452 (63.6)	23 (85.2)	23 (54.8)	78 (64.5)	154 (61.6)	139 (64.1)	35 (64.8)
<i>Staphylococcus aureus</i>	162 (22.8)	8 (29.6)	4 (9.5)	37 (30.6)	69 (27.6)	38 (17.5)	6 (11.1)
<i>Staphylococcus epidermidis</i>	182 (25.6)	10 (37.0)	11 (26.2)	26 (21.5)	54 (21.6)	62 (28.6)	19 (35.2)
<i>Staphylococcus lugdunensis</i>	5 (0.7)	1 (3.7)	0 (0.0)	0 (0.0)	3 (1.2)	0 (0.0)	1 (1.9)
<i>Streptococcus</i>	110 (15.5)	5 (18.5)	9 (21.4)	16 (13.2)	40 (16.0)	31 (14.3)	9 (16.7)

Target	All Ages (N=711)	Age <1 (N=27)	Age 1-17 (N=42)	Age 18-44 (N=121)	Age 45-64 (N=2500)	Age 65-84 (N=217)	Age 85+ (N=54)
<i>Streptococcus agalactiae</i>	12 (1.7)	1 (3.7)	0 (0.0)	1 (0.8)	5 (2.0)	5 (2.3)	0 (0.0)
<i>Streptococcus anginosus</i> group	10 (1.4)	0 (0.0)	0 (0.0)	2 (1.7)	3 (1.2)	3 (1.4)	2 (3.7)
<i>Streptococcus pneumoniae</i>	28 (3.9)	2 (7.4)	2 (4.8)	3 (2.5)	12 (4.8)	8 (3.7)	1 (1.9)
<i>Streptococcus pyogenes</i>	8 (1.1)	0 (0.0)	0 (0.0)	1 (0.8)	5 (2.0)	2 (0.9)	0 (0.0)
Pan <i>Candida</i>	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pan Gram-Negative	25 (3.5)	0 (0.0)	4 (9.5)	4 (3.3)	10 (4.0)	6 (2.8)	1 (1.9)
<i>mecA</i> (<i>Staphylococcus</i>)	261 (36.7)	14 (51.9)	10 (23.8)	41 (33.9)	83 (33.2)	94 (43.3)	19 (35.2)
<i>mecA</i> (<i>S. aureus</i>)	86 (12.1)	4 (14.8)	1 (2.4)	17 (14.0)	35 (14.0)	26 (12.0)	3 (5.6)
<i>mecA</i> (<i>S. epidermidis</i>)	137 (19.3)	8 (29.6)	9 (21.4)	19 (15.7)	38 (15.2)	48 (22.1)	15 (27.8)
<i>mecA</i> (<i>S. lugdunensis</i>)	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
<i>mecA</i> (CoNS excluding <i>S. epidermidis</i> / <i>S. lugdunensis</i>)	40 (5.6)	2 (7.4)	0 (0.0)	6 (5.0)	10 (4.0)	20 (9.2)	2 (3.7)
<i>mecC</i> (<i>Staphylococcus</i>)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<i>vanA</i> (<i>Enterococcus</i>)	9 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	6 (2.4)	3 (1.4)	0 (0.0)
<i>vanA</i> (<i>E. faecalis</i>)	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
<i>vanA</i> (<i>E. faecium</i>)	8 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	5 (2.0)	3 (1.4)	0 (0.0)
<i>vanB</i> (<i>Enterococcus</i>)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 89: Expected Value by Collection Site (Prospective Samples)

Target	All Sites (N=711)	Site 1 (N=161)	Site 2 (N=58)	Site 3 (N=164)	Site 4 (N=145)	Site 5 (N=77)	Site 6 (N=33)	Site 7 (N=73)
<i>Bacillus cereus</i> group	5 (0.7)	3 (1.9)	1 (1.7)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<i>Bacillus subtilis</i> group	2 (0.3)	0 (0.0)	1 (1.7)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)
<i>Corynebacterium</i>	14 (2.0)	2 (1.2)	2 (3.4)	0 (0.0)	6 (4.1)	2 (2.6)	0 (0.0)	2 (2.7)
<i>Cutibacterium acnes</i> (<i>P. acnes</i>)	8 (1.1)	1 (0.6)	0 (0.0)	1 (0.6)	2 (1.4)	0 (0.0)	0 (0.0)	4 (5.5)
<i>Enterococcus</i>	62 (8.7)	20 (12.4)	7 (12.1)	15 (9.1)	9 (6.2)	10 (13.0)	1 (3.0)	0 (0.0)
<i>Enterococcus faecalis</i>	50 (7.0)	14 (8.7)	6 (10.3)	13 (7.9)	8 (5.5)	8 (10.4)	1 (3.0)	0 (0.0)
<i>Enterococcus faecium</i>	12 (1.7)	6 (3.7)	1 (1.7)	1 (0.6)	2 (1.4)	2 (2.6)	0 (0.0)	0 (0.0)
<i>Lactobacillus</i>	5 (0.7)	1 (0.6)	1 (1.7)	2 (1.2)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)
<i>Listeria</i>	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
<i>Listeria monocytogenes</i>	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<i>Micrococcus</i>	19 (2.7)	2 (1.2)	2 (3.4)	5 (3.0)	6 (4.1)	0 (0.0)	0 (0.0)	4 (5.5)

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

N. Instrument Name :

GenMark's ePlex Instrument

O. System Descriptions :

1. Modes of Operation:

See Device Description (Section I) above

2. Software

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes X or No

3. Specimen Identification:

The Sample ID can be entered manually or scanned in by using barcode scanner.

4. Quality Control:

See Section M (1c) above

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Not Applicable

Q. Proposed Labeling:

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

R. Patient Perspectives:

This submission did not include specific information on patient perspectives for this device.

S. Conclusion:

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