510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number: k130914

B. Purpose for Submission:

To obtain clearance for the FilmArray® Blood Culture Identification (BCID) Panel

C. Measurand:

Enterococci, *Listeria monocytogenes*, Staphylococci (including specific differentiation of *Staphylococcus aureus*), Streptococci (with specific differentiation of *Streptococcus agalactiae*, *Streptococcus pneumoniae*, and *Streptococcus pyogenes*), *Acinetobacter baumannii*, Enterobacteriaceae (including specific differentiation of the *Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, Proteus, and *Serratia marcescens*), *Haemophilus influenzae*, *Neisseria meningitidis* (encapsulated), *Pseudomonas aeruginosa*, *Candida albicans*, *Candida glabrata*, *Candida krusei*, *Candida parapsilosis*, and *Candida tropicalis*.

D. Type of Test:

A multiplexed nucleic acid-based test intended for use with the FilmArray® 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 assay is performed directly on positive blood culture samples that demonstrate the presence of organisms as determined by Gram stain.

E. Applicant:

BioFire Diagnostics, Inc.

F. Proprietary and Established Names:

FilmArray® Blood Culture Identification (BCID) 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, OOI

4. Panel:

   83 (Microbiology)

H. Intended Use:

1. Intended use(s):

   The FilmArray Blood Culture Identification (BCID) Panel is a qualitative multiplexed nucleic acid-based *in vitro* 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: *Enterococci*, *Listeria monocytogenes*, commonly encountered *Staphylococci* (including specific differentiation of *Staphylococcus aureus)*, commonly encountered *Streptococci* (with specific differentiation of *Streptococcus agalactiae*, *Streptococcus pneumoniae*, and *Streptococcus pyogenes*), *Acinetobacter baumannii*, commonly encountered *Enterobacteriaceae* (including specific differentiation of the *Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus*, and *Serratia marcescens*), *Haemophilus influenzae*, *Neisseria meningitidis* (encapsulated), *Pseudomonas aeruginosa*, *Candida albicans*, *Candida glabrata*, *Candida krusei*, *Candida parapsilosis*, and *Candida tropicalis*.

   The FilmArray BCID Panel also contains assays for the detection of genetic determinants of resistance to methicillin (*mecA*), vancomycin (*vanA* and *vanB*), and carbapenems (bla_{KPC}) 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. 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.

2. Indication(s) for use:

   Same as Intended Use

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   For use with the FilmArray instrument

I. Device Description:

The FilmArray Blood Culture Identification (BCID) Panel is a multiplex nucleic acid test designed to be used with the FilmArray Instrument. The FilmArray BCID pouch contains freeze-dried reagents to perform nucleic acid purification and nested, multiplex PCR with DNA melt analysis. The BCID Panel simultaneously tests a single blood culture sample for 24 different organisms and organism groups that cause bloodstream infections and three genetic markers that are known to confer antimicrobial resistance. Targeted organisms and resistance genes are listed in the following table.

Gram-Positive Bacteria	**Gram-Negative Bacteria**	**Yeast**
Enterococcus	*Acinetobacter baumannii*	*Candida albicans*
Listeria monocytogenes	***Enterobacteriaceae***	*Candida glabrata*
Staphylococcus	*Enterobacter cloacae* complex	*Candida krusei*
Staphylococcus aureus	*Escherichia coli*	*Candida parapsilosis*
Streptococcus	*Klebsiella oxytoca*	*Candida tropicalis*
Streptococcus agalactiae	*Klebsiella pneumoniae*	**Antimicrobial resistance genes**
Streptococcus pneumoniae	*Proteus*	*mecA* – methicillin resistance
Streptococcus pyogenes	*Serratia marcescens*	*vanA/B* – vancomycin resistance
	Haemophilus influenzae	KPC – carbapenem resistance
	Neisseria meningitidis (encapsulated)	
	Pseudomonas aeruginosa	

A test is initiated by loading Hydration Solution and a positive blood culture sample mixed with the provided Sample Buffer into the FilmArray BCID pouch. The pouch contains all of the reagents required for specimen testing and analysis in a freeze-dried format; the addition of Hydration Solution and Sample/Buffer Mix rehydrates the reagents. After the pouch is

prepared, the FilmArray Software guides the user though the steps of placing the pouch into the instrument, scanning the pouch barcode, entering the sample identification, and initiating the run.

The FilmArray Instrument contains a coordinated system of inflatable bladders and seal points, which act on the pouch to control the movement of liquid between the pouch blisters. When a bladder is inflated over a reagent blister, it forces liquid from the blister into connecting channels. Alternatively, when a seal is placed over a connecting channel it acts as a valve to open or close a channel. In addition, electronically controlled pneumatic pistons are positioned over multiple plungers in order to deliver the rehydrated reagents into the blisters at the appropriate times. Two Peltier devices control heating and cooling of the pouch to drive the PCR reactions and the melt curve analysis.

Nucleic acid extraction occurs within the FilmArray pouch using mechanical lysis and standard magnetic bead technology. After extracting and purifying nucleic acids from the unprocessed sample, the FilmArray performs a nested multiplex PCR that is executed in two stages. During the first stage, the FilmArray performs a single, large volume, highly multiplexed PCR reaction which includes all primers of the outer primer sets. The products from first stage PCR are then diluted and combined with a fresh, primer-free master mix and a fluorescent double stranded DNA binding dye (LC Green® Plus+, BioFire Diagnostics). The solution is then distributed to each well of the array. Array wells contain sets of primers designed specifically to amplify sequences internal to the PCR products generated during the first stage PCR reaction. The 2nd stage PCR, or nested PCR, is performed in singleplex fashion in each well of the array. At the conclusion of the 2nd stage PCR, the array is interrogated by melt curve analysis for the detection of signature amplicons denoting the presence of specific targets. A digital camera placed in front of the 2nd stage PCR captures fluorescent images of the PCR reactions and software interprets the data. 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.

Test results for antimicrobial resistance genes are only reported when an associated organism (as shown in the following table) is detected in the same test.

Antimicrobial Resistance Genes and Associated Organisms

Antimicrobial Resistance Genes	Associated Organism
mecA	*Staphylococcus*
*vanA/B**	*Enterococcus*
KPC	Any *Enterobacteriaceae*, *A. baumannii*, and/or *P. aeruginosa*

While many of the individual assays within the BCID Panel detect one specific organism, the following BCID assays can detect multiple organisms within a genus or family:

- *Enterococcus*: Detects most species of Enterococcus (see analytical reactivity study below).

- *Staphylococcus*: The BCID Panel contains three assays for the detection of *Staphylococcus* species. The *Staphylococcus aureus* assay and two multi-species assays (Staphylococcus1 and Staphylococcus2). The Saureus assay detects all strains of *S. aureus* and does not cross-react with other organisms, including other species of *Staphylococcus*. The multi-species assays detect the most prevalent coagulase-negative *Staphylococcus* (CoNS) species encountered in blood culture specimens and can also react with high levels of *S. aureus*. The FilmArray Software integrates the results of the three *Staphylococcus* assays into a final *Staphylococcus* test result. If all three assays are negative, the test result will be *Staphylococcus* Not Detected. If any of the three assays is positive, the result will be *Staphylococcus* Detected. Results for the Saureus assay (positive or negative) determine the *Staphylococcus aureus* test result (Detected or Not Detected, respectively).

- *Streptococcus*: The BCID Panel contains four assays for the detection of *Streptococcus* species. Species-specific assays are included for the detection of Group A Strep (Spyogenes), Group B Strep (Sagalactiae), and Spneumoniae. The fourth assay is a multi-species assay (Streptococcus) designed to react with select Viridans group and other *Streptococcus* species encountered in blood culture specimens. However, the BCID Panel may not detect all *Streptococcus* species. The FilmArray Software integrates the results of all four *Streptococcus* assays into a final *Streptococcus* result as shown in the table below. If all of the assays are negative, the test result will be *Streptococcus* Not Detected. Alternatively, if any of the four assays are positive, the test result will be *Streptococcus* Detected. Results for each species-specific assay are also reported independently.

- *Enterobacteriaceae:* The BCID Panel includes seven assays to detect members of the *Enterobacteriaceae* family. Six genus/species specific assays are included for the detection of *Enterobacter cloacae* (and other *E. cloacae* complex species); *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus* spp., and *Serratia marcescens*. A seventh assay (the Enteric assay) will react with some (not all) species detected by the other six assays; however, its primary function is to detect other less common, but clinically relevant members of the *Enterobacteriaceae* family. Combined, these seven assays will detect many, but not all *Enterobacteriaceae* (see Analytical Reactivity section below). A positive result for any of the seven *Enterobacteriaceae*-associated assays will generate an *Enterobacteriaceae* Detected result. Each specific genus/species assay result will also be reported independently. Results for the Enteric assay are not reported independently, but are incorporated into the *Enterobacteriaceae* test result. Negative results for all seven assays will generate an *Enterobacteriaceae* Not Detected result.

- *Enterobacter cloacae complex*: The *Enterobacter cloacae* complex is comprised of six species (*E. asburiae*, *E. cloacae*, *E. hormaechei*, *E. kobei*, *E. ludwigii*, and *E. nimipressuralis*) that may all be identified as *E. cloacae* by phenotypic laboratory methods. Of the six species in the complex, the BCID Panel Ecloacae assay detects *E. cloacae* (subspecies *cloacae* and *dissolvens*), *E. asburiae*, and *E. hormaechei*.

- *Proteus*: The BCID Panel Proteus assay detects four of five characterized species

within the genus (*P. mirabilis*, *P. hauseri*, *P. penneri*, and *P. vulgaris*).

Materials provided in each kit:

- Individually packaged FilmArray BCID Panel Pouches: The BCID pouches are used to test the patient samples. Each reagent pouch is packaged in a metal canister under vacuum.
- Single-use Sample Buffer vials: The Sample Buffer serves to inactivate RNases in the sample and promote binding of nucleic acids to the magnetic beads for extraction.
- Single-use Hydration Solution vials: Each single use vial is used to rehydrate the freeze-dried reagents contained in the FilmArray BCID pouch.
- Individually packaged transfer pipettes: The Transfer Pipettes are used to mix the blood culture sample with Sample Buffer. An alternative workflow is also described whereby the Transfer Pipette is used to transfer approximately 100 µL of blood culture to the single use Sample Buffer vials prior to mixing.
- Individually packaged Sample Loading Syringes with attached cannula (red cap): Used for adding the patient sample/ buffer mixture to the pouch.
- Individually packaged Pouch Hydration Syringes with attached cannula (blue cap): Used for adding Hydration Solution to the pouch prior to testing.

Materials required but not provided:

- FilmArray® Instrument: The FilmArray System is composed of the FilmArray Instrument and a laptop computer loaded with FilmArray Software. The FilmArray Software controls the function of the instrument and collects, analyzes, and stores data generated by the instrument.
- FilmArray Pouch Loading Station: The FilmArray Pouch Loading Station is used for hydrating the BCID pouch and loading of the sample/Sample Buffer mixture.
- Syringes with a 28-gauge needle capable of measuring 0.1 mL (100 µl) sample volume.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Nanosphere Verigene® Gram-Positive Blood Culture Nucleic Acid Test

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

   k122514

3. Comparison with predicate:

Similarities		
Item	**Device: FilmArray BCID Panel**	**Predicate: Nanosphere Verigene® Gram-Positive Blood Culture Nucleic Acid Test**
Organisms and Resistance Markers Detected	*Enterococci*, *Staphylococci* (including specific differentiation of *Staphylococcus aureus*), *Streptococci* (with specific differentiation of *Streptococcus agalactiae*, *Streptococcus pneumoniae*, and *Streptococcus pyogenes*) and resistance markers *mecA*, *vanA*, and *vanB.*	Same See below for differences
Analyte	DNA	Same
Technological Principles	Multiplex nucleic acid-based	Same See below for differences
Sample Processing and Purification	Automated by instrument	Same
Controls	Two controls are included in each reagent pouch to control for sample processing and both stages of PCR and melt analysis.	Two Internal Processing Controls (whole organism complete assay control and single-stranded DNA Hybridization control)

Differences		
Item	**Device: FilmArray BCID Panel**	**Predicate: Nanosphere Verigene® Gram-Positive Blood Culture Nucleic Acid Test**
Specimen Types	Positive blood culture samples containing gram-positive bacteria, gram-negative bacteria, and/or yeast.	Positive blood culture bottles containing gram-positive bacteria.
Organisms and Resistance Markers Detected	Detection of additional targets: *Listeria monocytogenes*, *Acinetobacter baumannii*, *Enterobacteriaceae* (including specific differentiation of *Enterobacter cloacae* complex species, *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus*, and *Serratia marcescens*), *Haemophilus influenzae*, *Neisseria meningitidis*, *Pseudomonas aeruginosa*, *Candida albicans*, *Candida glabrata*, *Candida krusei*, *Candida parapsilosis*, *Candida tropicalis*, and resistance marker *bla*KPC	Tests for gram-positive bacteria. Tests for *Listeria* spp. rather than *Listeria monocytogenes*. Includes testing for additional *Staphylococcus* spp.: *Staphylococcus epidermidis*, *Staphylococcus lugdunensis*, as well as testing for specific *Enterococcus* spp.: *Enterococcus faecalis*, *Enterococcus faecium*. Includes testing for an additional *Streptococcus* spp.: *Streptococcus anginosus* group. Does not include testing for *bla*KPC. Specifically differentiates between *van*A and *van*B resistance markers.
Technological Principles	Nested multiplex PCR followed by high resolution melting analysis to confirm identity of amplified product.	Qualitative, multiplexed test for the detection of specific nucleic acid targets in a microarray format using capture and mediator oligonucleotides for gold nanoparticle probe-based endpoint detection.
Instrumentation	FilmArray Instrument	Verigene Reader and Processor *SP*
Time to result	Less than 1 hour	2.5 hours

K. Standard/Guidance Document Referenced

- Draft Guidance for Industry and Food and Drug Administration Staff - Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices, (November 9, 2012)
- Draft Guidance for Industry and FDA Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of methicillin-resistant Staphylococcus aureus (MRSA) for Culture Based Devices (June 15, 2011)
- Draft Guidance for Industry and Food and Drug Administration Staff - Establishing the Performance Characteristics of Nucleic Acid-Based In vitro Diagnostic Devices for the Detection and Differentiation of Methicillin-Resistant Staphylococcus aureus (MRSA) and Staphylococcus aureus (SA) (January 5, 2011)
- Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests, FDA Guidance Document (March 13, 2007)
- User Protocol for Evaluation of Qualitative Test Performance, Clinical and Laboratory Standards Institute (CLSI) Approved Guideline – Second Edition, EP12-A2 (January 2008)
- Molecular Diagnostic Methods for Infectious Diseases, CLSI Approved Guideline, MM3-A2 (February 2006)
- Interference Testing in Clinical Chemistry, CLSI Approved Guideline EP7-A2 (November 2005)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, FDA Guidance Document (May 11, 2005)
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices (September 9, 1999)
- General Principle of Software Validation; Final Guidance for Industry and FDA Staff (January 11, 2002)

L. Test Principle:

The FilmArray BCID pouch is a closed system that houses all the chemistry required to isolate, amplify, and detect nucleic acid from multiple bloodstream pathogens within a single blood culture sample. The user of the FilmArray BCID Panel loads the sample into the FilmArray BCID pouch, places the pouch into the FilmArray Instrument, and starts the run and the following processes occur automatically during the FilmArray run:

- **Nucleic Acid Purification -** Nucleic acid purification occurs in the first three blisters of the pouch. The sample is lysed by agitation (bead beating) and the liberated nucleic acid is captured, washed and eluted using magnetic bead technology. These steps require about ten minutes.

- **1st Stage Multiplex PCR** – After nucleic acid purification, the purified nucleic acid solution is combined with a preheated master mix to initiate thermocycling for multiplex PCR. During this stage, the FilmArray performs a single, large volume, highly multiplexed PCR reaction which includes all primers of the outer primer sets.

The effect of 1st stage PCR is to enrich for the target nucleic acids present in the sample.

- **2nd Stage PCR** - The products of 1st stage PCR are diluted and mixed with fresh PCR reagents containing a double stranded DNA binding dye (LCGreen® Plus, BioFire Diagnostics, Inc.). This solution is distributed over the 2nd stage PCR array. The individual wells of the array contain primers for different assays (each present in triplicate) that target specific nucleic acid sequences from each of the pathogens detected, as well as control template material. These primers are 'nested' or internal to the specific products of the 1st stage multiplex reaction, which enhances both the sensitivity and specificity of the reactions.
- **DNA Melting Analysis** – After 2nd stage PCR, the temperature is slowly increased and fluorescence in each well of the array is monitored and analyzed to generate a melt curve. The temperature at which a specific PCR product melts (melting temperature or Tm) is consistent and predictable and the FilmArray Software automatically evaluates the data from replicate wells for each assay to report results. The FilmArray Software controls the operation of the instrument, collects and analyzes data, and automatically generates a test report at the end of the run.

M. Performance Characteristics:

1. Analytical performance:

a. Reproducibility:

A multicenter reproducibility study was performed to determine between-site and overall reproducibility of the BCID Panel. Reproducibility testing occurred at three test sites using a panel of six simulated blood culture specimens, each spiked with various combinations of two different organisms. Specimens were prepared in a matrix of human whole blood and blood culture media. In total, 12 organisms were evaluated to generate positive data for 17 of the possible 27 BCID Panel test results, including antimicrobial resistance genes.

To best represent the composition of specimens likely to be tested by the BCID Panel, half of the replicates were at a concentration consistent with the level of organism in a blood culture bottle at the time of positivity, and half were at a concentration similar to that observed in bottles eight hours after positivity. The concentrations used were determined based on the results of the Growth and Detection Studies (see below). Final organism dilutions were plated to confirm the concentration of organism in each sample. A negative blood culture panel member was also included in the study.

The study incorporated potential variances: seven different operators, three

different pouch lots, and 10 different FilmArray Instruments. Over the course of four weeks, samples were tested on eight different days, for a total of 90 replicates per analyte and per concentration.

Valid results were attained for 540 of 547 runs (98.7%). The seven remaining runs included four runs with Instrument Communication Errors (4/547 = 0.73%) and three runs with control failures (3/547 = 0.55%). Expected positive (Detected) test results were obtained in all 540 completed test runs (1800/1800 = 100% agreement with the expected result). Expected negative (Not Detected) or N/A results were obtained in 539/540 pouch runs. Correct negative results were 12,776/12,780 or 99.97% agreement with the expected result. The four false positive results were generated from a single pouch run that was determined to be due to a pouch failure.

A summary of results (percent agreement with the expected result) for each analyte is provided in the following tables:

Summary of Reproducibility Results – Organism Assays

BCID Panel Test Result	Organism Tested Test Concentration	Test Site	Results		% Agreement with Expected Result
			Detected	Not Detected	
Enterococcus	*Enterococcus faecium* [*vanA*] JMI475 1.50E+08 CFU/mL	Site A	30/30	0/30	**180/180 100% [98.0% - 100%]**
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	**90/90**	**0/90**	
	Enterococcus faecalis [*vanB*] JMI 368 8.95E+08 CFU/mL	Site A	30/30	0/30	
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	**90/90**	**0/90**	
	Negative	Site A	0/120	120/120	**360/360 100% [99.0% - 100%]**
		Site B	0/120	120/120	
		Site C	0/120	120/120	
		All Sites	**0/360**	**360/360**	
Listeria monocytogenes	Negative	Site A	0/180	180/180	**540/540 100% [99.3% - 100%]**
		Site B	0/180	180/180	
		Site C	0/180	180/180	
		All Sites	**0/540**	**540/540**	
Staphylococcus	*Staphylococcus aureus* [MRSA] ATCC BAA-1747 8.60E+06 CFU/mL	Site A	30/30	0/30	**90/90 100% [96.0% - 100%]**
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	**90/90**	**0/90**	
	Negative	Site A	0/150	150/150	**449/450[a] 99.8% [98.8% - 100%]**
		Site B	1/150 [a]	149/150	
		Site C	0/150	150/150	
		All Sites	**1/450**	**449/450**	
Staphylococcus aureus	*Staphylococcus aureus* [MRSA] ATCC BAA-1747 8.60E+06 CFU/mL	Site A	30/30	0/30	**90/90 100% [96.0% - 100%]**
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	**90/90**	**0/90**	
	Negative	Site A	0/150	150/150	**450/450 100%**
		Site B	0/150	150/150	

BCID Panel Test Result	Organism Tested Test Concentration	Test Site	Results		% Agreement with Expected Result
			Detected	Not Detected	
		Site C	0/150	150/150	**[99.2% - 100%]**
		All Sites	**0/450**	**450/450**	
Streptococcus	*Streptococcus pyogenes* ATCC 19615 5.70E+08 CFU/mL	Site A	30/30	0/30	**90/90 100% [96.0% - 100%]**
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	**90/90**	**0/90**	
	Negative	Site A	0/150	150/150	**450/450 100% [99.2% - 100%]**
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	**0/450**	**450/450**	
Streptococcus agalactiae	Negative	Site A	0/180	180/180	**540/540 100% [99.3% - 100%]**
		Site B	0/180	180/180	
		Site C	0/180	180/180	
		All Sites	**0/540**	**540/540**	
Streptococcus pneumoniae	Negative	Site A	0/180	180/180	**540/540 100% [99.3% - 100%]**
		Site B	0/180	180/180	
		Site C	0/180	180/180	
		All Sites	**0/540**	**540/540**	
Streptococcus pyogenes	*Streptococcus pyogenes* ATCC 19615 5.70E+08 CFU/mL	Site A	30/30	0/30	**90/90 100% [96.0% - 100%]**
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	**90/90**	**0/90**	
	Negative	Site A	0/150	150/150	**450/450 100% [99.2% - 100%]**
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	**0/450**	**450/450**	
Acinetobacter baumannii	*Acinetobacter baumannii* ATCC 9955 2.00E+08 CFU/mL	Site A	30/30	0/30	**90/90 100% [96.0% - 100%]**
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	**90/90**	**0/90**	
	Negative	Site A	0/150	150/150	**450/450 100% [99.2% - 100%]**
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	**0/450**	**450/450**	
Enterobacteriaceae	*Klebsiella pneumoniae* [KPC] JMI 766 9.40E+08 CFU/mL	Site A	30/30	0/30	**180/180 100% [98.0% - 100%]**
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	**90/90**	**0/90**	
	Proteus mirabilis ATCC 29906 9.20E+08 CFU/mL	Site A	30/30	0/30	
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	**90/90**	**0/90**	
	Negative	Site A	0/120	120/120	**360/360 100% [99.0% - 100%]**
		Site B	0/120	120/120	
		Site C	0/120	120/120	
		All Sites	**0/360**	**360/360**	
Enterobacter cloacae complex	Negative	Site A	0/180	180/180	**540/540 100% [99.3% -**
		Site B	0/180	180/180	
		Site C	0/180	180/180	

BCID Panel Test Result	Organism Tested Test Concentration	Test Site	Results		% Agreement with Expected Result
			Detected	Not Detected	
		All Sites	**0/540**	**540/540**	**100%]**
Escherichia coli	Negative	Site A	0/180	180/180	**540/540 100% [99.3% - 100%]**
		Site B	0/180	180/180	
		Site C	0/180	180/180	
		All Sites	**0/540**	**540/540**	
Klebsiella oxytoca	Negative	Site A	0/180	180/180	**540/540 100% [99.3% - 100%]**
		Site B	0/180	180/180	
		Site C	0/180	180/180	
		All Sites	**0/540**	**540/540**	
Klebsiella pneumoniae	*Klebsiella pneumoniae* [KPC] JMI 766 9.40E+08 CFU/mL	Site A	30/30	0/30	**90/90 100% [96.0% - 100%]**
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	**90/90**	**0/90**	
	Negative	Site A	0/150	150/150	**450/450 100% [99.2% - 100%]**
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	**0/450**	**450/450**	
Proteus	*Proteus mirabilis* ATCC 29906 9.20E+08 CFU/mL	Site A	30/30	0/30	**90/90 100% [96.0% - 100%]**
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	**90/90**	**0/90**	
	Negative	Site A	0/150	150/150	**450/450 100% [99.2% - 100%]**
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	**0/450**	**450/450**	
Serratia marcescens	Negative	Site A	0/180	180/180	**540/540 100% [99.3% - 100%]**
		Site B	0/180	180/180	
		Site C	0/180	180/180	
		All Sites	**0/540**	**540/540**	
Haemophilus influenzae	Negative	Site A	0/180	180/180	**539/540 [a] 98.0% [99.0% - 100%]**
		Site B	1/180 [a]	179/180	
		Site C	0/180	180/180	
		All Sites	**1/540**	**539/540**	
Neisseria meningitidis	Negative	Site A	0/180	180/180	**540/540 100% [99.3% - 100%]**
		Site B	0/180	180/180	
		Site C	0/180	180/180	
		All Sites	**0/540**	**540/540**	
Pseudomonas aeruginosa	*Pseudomonas aeruginosa* ATCC 27853 1.40E+08 CFU/mL	Site A	30/30	0/30	**90/90 100% [96.0% - 100%]**
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	**90/90**	**0/90**	
	Negative	Site A	0/150	150/150	**450/450 100% [99.2% - 100%]**
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	**0/450**	**450/450**	
Candida albicans	*Candida albicans* ATCC 10231 3.10E+04	Site A	30/30	0/30	**90/90 100% [96.0% - 100%]**
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	**90/90**	**0/90**	

BCID Panel Test Result	Organism Tested Test Concentration	Test Site	Results		% Agreement with Expected Result
			Detected	Not Detected	
	Negative	Site A	0/150	150/150	**450/450 100% [99.2% - 100%]**
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	**0/450**	**450/450**	
Candida glabrata	*Candida glabrata* ATCC 15545 2.00E+07	Site A	30/30	0/30	**90/90 100% [96.0% - 100%]**
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	**90/90**	**0/90**	
	Negative	Site A	0/150	150/150	**450/450 100% [99.2% - 100%]**
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	**0/450**	**450/450**	
Candida krusei	*Candida krusei* ATCC 90878 3.20E+07	Site A	30/30	0/30	**90/90 100% [96.0% - 100%]**
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	**90/90**	**0/90**	
	Negative	Site A	0/150	150/150	**450/450 100% [99.2% - 100%]**
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	**0/450**	**450/450**	
Candida parapsilosis	Negative	Site A	0/180	180/180	**539/540 [a] 99.8% [99.0% - 100%]**
		Site B	1/180 [a]	179/180	
		Site C	0/180	180/180	
		All Sites	**1/540**	**539/540**	
Candida tropicalis	*Candida tropicalis* ATCC 66029 9.70E+05	Site A	30/30	0/30	**90/90 100% [96.0% - 100%]**
		Site B	30/30	0/30	
		Site C	30/30	0/30	
		All Sites	**90/90**	**0/90**	
	Negative	Site A	0/150	150/150	**450/450 100% [99.2% - 100%]**
		Site B	0/150	150/150	
		Site C	0/150	150/150	
		All Sites	**0/450**	**450/450**	

[a] A single pouch run at Site B generated four false positive results: *Staphylococcus*, *mecA* , *Haemophilus influenzae*, and *Candida parapsilosis*.

Summary of Reproducibility Results: Antimicrobial Resistance Assays

BCID Panel Test Result	Organism Tested Test Concentration	Test Site	Results			% Agreement with Expected Test Result
			Detected	Not Detected	N/A	
vanA/B	*Enterococcus faecium* [*vanA*] JMI475 1.50E+08 CFU/mL	Site A	30/30	0/30	0/30	**180/180 100% [98.0% - 100%]**
		Site B	30/30	0/30	0/30	
		Site C	30/30	0/30	0/30	
		All Sites	**90/90**	**0/90**	**0/90**	
	Enterococcus faecalis [*vanB*] JMI 368	Site A	30/30	0/30	0/30	
		Site B	30/30	0/30	0/30	
		Site C	30/30	0/30	0/30	

BCID Panel Test Result	Organism Tested Test Concentration	Test Site	Results			% Agreement with Expected Test Result
			Detected	Not Detected	N/A	
	8.95E+08 CFU/mL	**All Sites**	**90/90**	**0/90**	**0/90**	
	No Associated Organism	Site A	0/120	0/120	120/120	**360/360 100% [99.0% - 100%]**
		Site B	0/120	0/120	120/120	
		Site C	0/120	0/120	120/120	
		All Sites	**0/360**	**0/360**	**360/360**	
mecA	*Staphylococcus aureus* [MRSA] ATCC BAA-1747 8.60E+06 CFU/mL	Site A	30/30	0/30	0/30	**90/90 100% [96.0% - 100%]**
		Site B	30/30	0/30	0/30	
		Site C	30/30	0/30	0/30	
		All Sites	**90/90**	**0/90**	**0/90**	
	No Associated Organism	Site A	0/150	0/150	150/150	**449/450[a] 99.8% [98.8% - 100%]**
		Site B	1/150[a]	0/150	149/150	
		Site C	0/150	0/150	150/150	
		All Sites	**1/450**	**0/450**	**449/450**	
KPC	*Klebsiella pneumoniae* [KPC] JMI 766 9.40E+08	Site A	30/30	0/30	0/30	**90/90 100% [96.0% - 100%]**
		Site B	30/30	0/30	0/30	
		Site C	30/30	0/30	0/30	
		All Sites	**90/90**	**0/90**	**0/90**	
	Proteus mirabilis ATCC 29906 and *Pseudomonas aeruginosa* ATCC 27853	Site A	0/90	90/90	0/90	**270/270 100% [98.6% - 100%]**
		Site B	0/90	90/90	0/90	
		Site C	0/90	90/90	0/90	
		All Sites	**0/270**	**270/270**	**0/270**	
	No Associated Organism	Site A	0/60	0/60	60/60	**180/180 100% [98.0% - 100%]**
		Site B	0/60	0/60	60/60	
		Site C	0/60	0/60	60/60	
		All Sites	**0/180**	**0/180**	**180/180**	

[a] A single pouch run at Site B generated a false positive result for *mec*A.

The reproducibility of Tm values for each analyte was evaluated and a summary is provided in the following tables.

Summary of Tm Analysis for Positive Organism Assays

BCID Panel Assay	Organism Tested Test Concentration	Test Site	Reproducibility of Tm				
			Tm Mean	Tm Std Dev	Tm Minimum	Tm Maximum	Observed Range (Max-Min)
Gram-Positive Bacteria							
Enterococcus	*Enterococcus faecium* [*vanA*] JMI475	Site A	82.5	0.4	81.9	84.0	2.1
		Site B	82.6	0.2	82.3	83.0	0.7
		Site C	82.3	0.2	81.9	82.8	0.9

BCID Panel Assay	Organism Tested Test Concentration	Test Site	Reproducibility of Tm				
			Tm Mean	Tm Std Dev	Tm Minimum	Tm Maximum	Observed Range (Max-Min)
	1.50E+08 CFU/mL	**All Sites**	**82.5**	**0.3**	**81.9**	**84.0**	**2.1**
	Enterococcus faecalis [*vanB*] JMI 368 8.95E+08 CFU/mL	Site A	82.0	0.3	81.5	82.4	0.9
		Site B	82.2	0.2	81.8	82.8	1.0
		Site C	81.6	0.4	81.0	82.4	1.4
		All Sites	**81.9**	**0.4**	**81.0**	**82.8**	**1.8**
Saureus	*Staphylococcus aureus* [MRSA] ATCC BAA-1747 8.60E+06 CFU/mL	Site A	77.1	0.3	76.6	77.8	1.2
		Site B	77.3	0.3	76.8	77.8	1.0
		Site C	76.9	0.2	76.5	77.5	1.0
		All Sites	**77.1**	**0.3**	**76.5**	77.8	1.3
Streptococcus	*Streptococcus pyogenes* ATCC 19615 5.70E+08 CFU/mL	Site A	81.9	0.4	81.5	83.6	2.1
		Site B	82.1	0.1	81.8	82.3	0.5
		Site C	81.8	0.2	81.5	82.1	0.6
		All Sites	**81.9**	**0.3**	**81.5**	**83.6**	**2.1**
Spyogenes	*Streptococcus pyogenes* ATCC 19615 5.70E+08 CFU/mL	Site A	79.0	0.4	78.5	79.8	1.3
		Site B	79.2	0.3	78.7	79.8	1.1
		Site C	78.8	0.3	78.5	79.5	1.0
		All Sites	**79.0**	**0.3**	**78.5**	**79.8**	**1.3**
Gram-Negative Bacteria							
Abaumannii	*Acinetobacter baumannii* ATCC 9955 2.00E+08 CFU/mL	Site A	80.6	0.4	80.0	81.2	1.2
		Site B	80.8	0.2	80.4	81.2	0.8
		Site C	80.3	0.4	79.5	80.9	1.4
		All Sites	**80.5**	**0.4**	**79.5**	**81.2**	**1.7**
Enteric	*Klebsiella pneumoniae* [KPC] JMI 766 9.40E+08 CFU/mL	Site A	88.6	0.3	88.1	89.1	1.0
		Site B	88.8	0.1	88.6	89.2	0.5
		Site C	88.3	0.3	87.8	88.8	1.0
		All Sites	**88.6**	**0.3**	**87.8**	**89.2**	**1.4**
Kpneumoniae	*Klebsiella pneumoniae* [KPC] JMI 766 9.40E+08 CFU/mL	Site A	87.9	0.3	87.3	88.5	1.2
		Site B	88.1	0.2	87.8	88.4	0.6
		Site C	87.6	0.3	86.7	88.1	1.5
		All Sites	**87.8**	**0.4**	**86.7**	**88.5**	**1.8**
Proteus	*Proteus mirabilis* ATCC 29906 9.20E+08 CFU/mL	Site A	81.2	0.3	80.6	81.8	1.2
		Site B	81.4	0.2	81.2	81.9	0.7
		Site C	81.2	0.2	80.7	81.6	0.9
		All Sites	**81.3**	**0.3**	**80.6**	**81.9**	**1.2**
Paeruginosa	*Pseudomonas aeruginosa* ATCC 27853 1.40E+08 CFU/mL	Site A	87.9	0.3	87.3	88.5	1.2
		Site B	88.2	0.3	87.8	89.5	1.7
		Site C	88.5	0.2	88.1	89.1	1.0
		All Sites	**88.2**	**0.4**	**87.3**	**89.5**	**2.2**
Yeast							

BCID Panel Assay	Organism Tested Test Concentration	Test Site	Reproducibility of Tm				
			Tm Mean	Tm Std Dev	Tm Minimum	Tm Maximum	Observed Range (Max-Min)
Calbicans	*Candida albicans* ATCC 10231 3.10E+04	Site A	79.8	0.3	79.3	80.3	1.0
		Site B	80.1	0.2	79.7	80.5	0.8
		Site C	79.5	0.3	78.9	80.2	1.3
		All Sites	**79.8**	**0.4**	**78.9**	**80.5**	**1.7**
Cglabrata	*Candida glabrata* ATCC 15545 2.00E+07	Site A	75.3	0.3	74.7	76.1	1.3
		Site B	75.4	0.3	74.9	76.4	1.5
		Site C	75.7	0.2	75.4	76.1	0.7
		All Sites	**75.5**	**0.3**	**74.7**	**76.4**	**1.7**
Ckrusei	*Candida krusei* ATCC 90878 3.20E+07	Site A	84.5	0.4	84.1	85.2	1.2
		Site B	84.7	0.3	84.3	85.3	1.1
		Site C	85.0	0.3	84.6	85.8	1.3
		All Sites	**84.8**	**0.4**	**84.1**	**85.8**	**1.8**
Ctropicalis	*Candida tropicalis* ATCC 66029 9.70E+05	Site A	79.1	0.3	78.6	80.1	1.6
		Site B	79.2	0.2	78.8	79.6	0.8
		Site C	79.5	0.2	79.3	80.0	0.7
		All Sites	**79.3**	**0.3**	**78.6**	**80.1**	**1.6**

b. *Linearity/assay reportable range:*

Not applicable

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

Internal Controls: The following internal controls are included in each FilmArray BCID pouch:

- DNA Process Control: The DNA Process Control assay targets DNA from the yeast *Schizosaccharomyces pombe*. The yeast is present in the pouch in a freeze-dried form and is hydrated and introduced into the test when the sample is loaded. The control material is carried through all stages of the test process, including lysis, nucleic acid purification, 1st stage PCR, dilution, 2nd stage PCR, and DNA melting. A positive control result indicates that all steps carried out in the pouch were successful.

- PCR2 Control: The PCR2 Control assay detects a DNA target that is dried into the wells of the array along with the corresponding primers. A positive result indicates that the 2nd stage PCR was successful.

Both internal control assays must be positive for the test run to pass. When either control fails, the Controls field of the test report will display "Failed" and all results will be listed as Invalid. If the controls fail, the user is instructed to repeat the test using a new pouch.

Recommended External Controls: External controls are not provided with the BCID Panel, but are recommended in the package insert. Uninoculated blood culture media can be used as an external negative control and previously characterized positive samples or samples spiked with well characterized organisms can be used as external positive controls. External controls should be used in accordance with the appropriate accrediting organization requirements, as applicable.

External Controls used in clinical studies:

External controls used in the clinical study consisted of six different organism mixes spiked into a human blood and blood culture matrix. All BCID targets were represented in at least one external control mix. Testing of positive external controls was rotated, with one of the six controls tested each day.

Specimen Stability:

Testing with the FilmArray BCID Panel should be performed as soon as possible after a blood culture specimen is signaled as positive by a continuous monitoring instrument. As blood culture bottles are sometimes not removed from the instrument immediately (e.g., when microbiology laboratories are closed at night), testing of positive specimens is indicated up to eight hours after bottle ring. Testing with BCID Panel is indicated for both time frames. A "Growth and Detection" study (see below) was performed to validate the performance of the BCID Panel when testing immediately after bottle positivity as compared to testing after incubation for an additional eight hours.

d. Growth and Detection Study

A study was performed to establish the range of expected organism concentrations in positive blood cultures. Testing with the BCID Panel is indicated immediately after a blood culture specimen is indicated as positive for growth by a continuously monitoring blood culture system and subsequent Gram stain or up to eight hours after bottle positivity. This study included evaluated the FilmArray BCID Panel using blood cultures at both time points. All organism growth and testing was performed using seeded blood culture bottles (BACTEC™ Plus Aerobic/F Medium) incubated in the BACTEC™ 9050 continuously monitoring blood culture instrument. Each microorganism was mixed with human whole blood and seeded directly into blood culture bottles for growth. 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 FilmArray BCID testing. Three independent positive cultures (bottles) were evaluated for each organism at each time point and FilmArray testing was performed in triplicate for each bottle.

The following table summarizes the concentration of organism (CFU/mL) determined for a representative panel of 30 isolates. The number and percent of correct positive BCID Panel test results is provided for each isolate and overall (% Detected). A correct result means that both the correct organism and antimicrobial resistance gene (where applicable) were detected in the sample. The correct organism and antimicrobial resistance gene results were reported for all 540 samples tested (540/540, 100%). In addition to the correct results, 5 false positive results (*Streptococcus, Streptococcus agalactiae, Haemophilus influenzae, Neisseria meningitidis, and Candida krusei*) were observed in a single run (1/540; 0.2%). The correct results were obtained when the sample was retested.

Summary of Organism Concentration (CFU/mL) in Positive Blood Cultures and Correct Detection of Organisms in Positive Blood Cultures by the FilmArray BCID Panel

	At Positivity			8 Hours After Positivity		
Species/Isolate(s) Tested	**Per Bottle (CFU/mL)**	**Mean (CFU/mL)**	**# Detected/Total (% Detected)**	**Per Bottle CFU/mL**	**Mean CFU/mL**	**# Detected/Total (% Detected)**
Gram-Positive Bacteria						
Enterococcus faecalis [*vanB*] JMI 368	4.60E+08 1.80E+08 2.62E+08	3.01E+08	9/9 (100%)	7.25E+08 8.90E+08 1.07E+09	8.95E+08	9/9 (100%)
Enterococcus faecium [*vanA*] JMI 475	1.47E+08 1.53E+08 1.59E+08	1.53E+08	9/9 (100%)	2.23E+08 1.64E+08 1.55E+08	1.81E+08	9/9 (100%)
Enterococcus hirae ATCC 49135	1.26E+08 2.76E+08 3.25E+08	2.42E+08	9/9 (100%)	8.00E+08 6.60E+08 7.20E+08	7.27E+08	9/9 (100%)
Listeria monocytogenes CDC F2380 (ATCC 43256)	4.50E+08 1.22E+09 1.18E+09	9.50E+08	9/9 (100%)	1.76E+09 2.31E+09 1.67E+09	1.91E+09	9/9 (100%)
Staphylococcus aureus ATCC 11632	1.48E+08 2.00E+07 2.56E+07	6.45E+07	9/9 (100%)	8.75E+08 9.80E+08 1.21E+08	6.59E+08	9/9 (100%)
Staphylococcus aureus [MRSA/*mecA*] ATCC BAA-1747	1.41E+07 5.65E+06 6.05E+06	8.60E+06	9/9 (100%)	5.70E+07 3.85E+07 9.75E+07	6.43E+07	9/9 (100%)
Staphylococcus epidermidis ATCC 12228	1.38E+08 9.85E+07 1.16E+08	1.18E+08	9/9 (100%)	2.12E+08 3.95E+08 1.56E+09	7.22E+08	9/9 (100%)
Staphylococcus epidermidis [MRSE/*mecA*] ATCC 29887	3.60E+07 3.75E+07 1.56E+08	7.65E+07	9/9 (100%)	1.35E+09 6.80E+08 2.29E+09	1.44E+09	9/9 (100%)

Species/Isolate(s) Tested	At Positivity			8 Hours After Positivity		
	Per Bottle (CFU/mL)	Mean (CFU/mL)	# Detected/Total (% Detected)	Per Bottle CFU/mL	Mean CFU/mL	# Detected/Total (% Detected)
Streptococcus agalactiae ATCC 13813	4.50E+08 1.22E+08 9.15E+08	4.96E+08	9/9 (100%)	3.15E+08 5.80E+08 4.30E+08	4.42E+08	9/9 (100%)
Streptococcus mitis ATCC 15914	1.57E+08 1.51E+09 6.90E+08	7.86E+08	9/9 (100%)	1.50E+09 2.03E+09 2.91E+09	2.15E+09	9/9 (100%)
Streptococcus pneumoniae ATCC BAA-255	3.45E+08 2.67E+08 1.31E+09	6.41E+08	9/9 (100%)	1.03E+09 6.00E+08 1.37E+09	1.00E+09	9/9 (100%)
Streptococcus pyogenes ATCC 19615	2.53E+08 2.44E+08 3.80E+08	2.92E+08	9/9 (100%)	2.38E+08 5.70E+08 8.90E+08	5.66E+08	9/9 (100%)
Gram-Negative Bacteria						
Acinetobacter baumannii ATCC 9955	2.17E+08 1.44E+08 2.45E+08	2.02E+08	9/9 (100%)	4.85E+08 3.85E+08 4.35E+08	4.35E+08	9/9 (100%)
Enterobacter cloacae ATCC 13047	4.20E+08 3.95E+08 1.50E+08	3.22E+08	9/9 (100%)	2.23E+09 1.46E+09 2.19E+09	1.96E+09	9/9 (100%)
Escherichia coli ATCC 43888	9.80E+07 6.10E+07 1.93E+08	1.17E+08	9/9 (100%)	1.17E+09 1.39E+09 7.70E+07	8.79E+08	9/9 (100%)
Klebsiella oxytoca ATCC 13182	7.40E+08 6.85E+08 3.85E+08	6.03E+08	9/9 (100%)	3.05E+09 1.86E+09 1.20E+09	2.04E+09	9/9 (100%)
Klebsiella oxytoca [KPC] JMI 7818	6.15E+07 9.15E+07 3.05E+07	6.12E+07	9/9 (100%)	1.96E+09 2.00E+09 1.13E+09	1.70E+09	9/9 (100%)
Klebsiella pneumoniae ATCC 13883	4.35E+08 2.10E+08 9.15E+08	5.20E+08	9/9 (100%)	1.60E+09 1.65E+09 1.58E+09	1.61E+09	9/9 (100%)
Klebsiella pneumoniae [KPC] JMI 766	1.21E+08 2.50E+08 2.05E+08	1.92E+08	9/9 (100%)	1.14E+09 9.10E+08 7.70E+08	9.40E+08	9/9 (100%)
Proteus mirabilis ATCC 29906	3.25E+07 1.04E+08 9.10E+07	7.58E+07	9/9 (100%)	1.04E+09 9.80E+08 7.30E+08	9.17E+08	9/9a (100%)
Serratia marcescens ATCC 27137	8.35E+08 1.46E+09 4.90E+08	9.28E+08	9/9 (100%)	1.05E+09 1.37E+09 1.02E+09	1.15E+09	9/9 (100%)
Serratia marcescens [KPC] JMI 697	4.90E+08 3.90E+08 1.02E+08	3.27E+08	9/9 (100%)	2.19E+09 1.40E+09 2.42E+08	1.28E+09	9/9 (100%)
Haemophilus influenzae (type b) ATCC 10211	2.80E+08 3.60E+08 2.23E+08	2.88E+08	9/9 (100%)	3.25E+09 3.35E+09 2.74E+09	3.11E+09	9/9 (100%)
Neisseria meningitidis	2.07E+08	2.51E+08	9/9	6.65E+08	7.38E+08	9/9

Species/Isolate(s) Tested	At Positivity			8 Hours After Positivity		
	Per Bottle (CFU/mL)	Mean (CFU/mL)	# Detected/Total (% Detected)	Per Bottle CFU/mL	Mean CFU/mL	# Detected/Total (% Detected)
ATCC 43744	3.90E+08 1.55E+08		(100%)	7.65E+08 7.85E+08		(100%)
Pseudomonas aeruginosa ATCC 27853	1.34E+08 1.76E+08 9.75E+07	1.36E+08	9/9 (100%)	1.35E+09 1.39E+08 1.76E+09	1.08E+09	9/9 (100%)
Yeast						
Candida albicans ATCC 10231	9.05E+03 8.00E+04 4.65E+03	3.12E+04	9/9 (100%)	8.80E+04 1.03E+05 1.00E+05	9.70E+04	9/9 (100%)
Candida glabrata ATCC 15545	1.26E+06 1.11E+06 1.97E+06	1.45E+06	9/9 (100%)	1.47E+07 2.65E+07 1.91E+07	2.01E+07	9/9 (100%)
Candida krusei ATCC 90878	5.65E+06 2.47E+06 6.35E+06	4.82E+06	9/9 (100%)	2.68E+07 3.55E+07 3.25E+07	3.16E+07	9/9 (100%)
Candida parapsilosis ATCC 90875	2.56E+06 3.60E+06 3.20E+06	3.12E+06	9/9 (100%)	6.70E+07 3.80E+07 5.55E+07	5.35E+07	9/9 (100%)
Candida tropicalis *ATCC 66029*	1.50E+06 7.45E+05 6.65E+05	9.70E+05	9/9 (100%)	1.10E+07 2.04E+07 9.45E+06	1.36E+07	9/9 (100%)
Overall Correct Detection (Organism and Antimicrobial Resistance Genes)	**At Positivity:**		**270/270 (100%)**	**8 Hours After Positivity:**		**270/270 (100%)**

e. *Analytical Reactivity (Inclusivity):*

The analytical reactivity of the FilmArray BCID Panel was evaluated with a collection of 303 bacterial and yeast isolates that represent the diversity of the FilmArray BCID 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 FilmArray BCID 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). If an isolate was not detected initially, the sample was retested at 10-100 fold 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 FilmArray BCID Panel. Results are provided below for each FilmArray BCID Panel test result.

Results of *Enterococcus* Inclusivity Testing

***Enterococcus* Detected** [~1x10^8 CFU/mL]		***Enterococcus* Detected with Reduced Sensitivity** [~1x10^9 CFU/mL]		***Enterococcus* Not Detected**[a]	
Enterococcus avium	ATCC 49463	*Enterococcus saccharolyticus*	ATCC 43076	*Enterococcus pseudoavium*	ATCC 49372
Enterococcus casseliflavus	ATCC 700668	*Enterococcus dispar*	ATCC 51266	*Enterococcus raffinosus*	ATCC 49427
Enterococcus cecorum	ATCC 43198				
Enterococcus durans	ATCC 11576				
Enterococcus faecalis	ATCC 49532				
	ATCC 49533				
	JMI 12536				
	ATCC 51299				
	ATCC 700802				
	JMI 368				
Enterococcus faecium	ATCC 27270				
	ATCC 35667				
	ATCC BAA-2127				
	JMI 536				
	ATCC 700221				
	JMI 475				
Enterococcus flavescens	ATCC 49996				
Enterococcus gallinarum	ATCC 49608				
Enterococcus hirae	ATCC 8043				
Enterococcus malodoratus	ATCC 43197				
Enterococcus mundtii	ATCC 43187				

[a] Not detected at the highest test concentrations ~1x10^9-1x10^{10} CFU/mL.

Results of *Listeria monocytogenes* Inclusivity Testing

***Listeria monocytogenes* Detected**[a]		
Species	**Serotype**	**Isolate ID**
Listeria monocytogenes	1/2a	FSL-C1-056[b]
Listeria monocytogenes	1/2a	FSL-J2-020[b]
Listeria monocytogenes	1/2b	FSL-J2-064[b]
Listeria monocytogenes	1/2b	HUM-2009042206[c]

Listeria monocytogenes Detected[a]		
Species	**Serotype**	**Isolate ID**
Listeria monocytogenes	4b	ATCC 43256
Listeria monocytogenes	4b	ATCC 13932

[a] Estimated concentration in a positive blood culture is ~$5x10^8$ CFU/mL.
[b] Isolates obtained from Cornell University.
[c] Isolates obtained from the Colorado Department of Public Health (CDPH).

Results of *Staphylococcus aureus* Inclusivity Testing

Staphylococcus/*Staphylococcus aureus* Detected[a]			
Species	**Isolate ID**	**Strain Information**	**PFGE Type**
Methicillin-sensitive *S. aureus* (MSSA)			
Staphylococcus aureus	ATCC BAA-1749	96:308	USA 900
Staphylococcus aureus	ATCC BAA-1759	N7129	USA 900
Staphylococcus aureus	ATCC BAA-1765	102-04	USA 1200
Staphylococcus aureus[b]	ATCC 12600	NCTC 8532 Type strain	Unknown
Staphylococcus aureus[b]	ATCC 11632	S13	Unknown
Staphylococcus aureus	ATCC BAA-2419	Mass/2010	Unknown
Staphylococcus aureus	ATCC BAA-2420	Mass/2010	Unknown
Staphylococcus aureus	ATCC BAA-2421	Mass/2010	Unknown
Staphylococcus aureus	1060728	n/a[c]	Unknown
Staphylococcus aureus	Ant1	n/a[c]	Unknown
Staphylococcus aureus	Lem8	n/a[c]	Unknown
Staphylococcus aureus	MAL8134	n/a[c]	Unknown
Staphylococcus aureus	MAQ	n/a[c]	Unknown
Staphylococcus aureus	Per2	n/a[c]	Unknown
Staphylococcus aureus	RAR	n/a[c]	Unknown
Staphylococcus aureus	S313	n/a[c]	Unknown
Staphylococcus aureus	Sal3	n/a[c]	Unknown
Staphylococcus aureus	Ver2	n/a[c]	Unknown
Staphylococcus aureus ssp. *aureus*[b]	ATCC 10832	Wood 46	Unknown
Staphylococcus aureus ssp. *aureus*[b]	ATCC 14154	Rose	Unknown
Staphylococcus aureus ssp. *aureus*	ATCC 25923	Seattle/1945	Unknown
Borderline Oxacillin-resistant *S. aureus* (BORSA)			
Staphylococcus aureus	SUN1[d]	n/a	Unknown
Staphylococcus aureus	SUN2[d]	n/a	Unknown
Staphylococcus aureus	SUN3[d]	n/a	Unknown
Staphylococcus aureus	SUN4[d]	n/a	Unknown
Staphylococcus aureus	SUN5[d]	n/a	Unknown
Staphylococcus aureus	SUN6[d]	n/a	Unknown
Methicillin-resistant *S. aureus* (MRSA)			
Staphylococcus aureus ssp. *aureus*	ATCC BAA-38	E2125 Denmark	Unknown
Staphylococcus aureus ssp. *aureus*	ATCC 43300	F-182 Kansas	Unknown
Staphylococcus aureus ssp. *aureus*	ATCC 700698	Mu3 Japan/1996	Unknown
Staphylococcus aureus ssp. *aureus*	ATCC BAA-1720	MRSA252 UK	Unknown

***Staphylococcus*/*Staphylococcus aureus* Detected[a]**			
Species	**Isolate ID**	**Strain Information**	**PFGE Type**
Staphylococcus aureus ssp. *aureus*	ATCC BAA-39	HUSA304 Hungary/1993	Unknown
Staphylococcus aureus	NARSA NRS705	NY-12 New York/2005	USA 100
Staphylococcus aureus	NARSA NRS701	MN-082 Minn/2006	USA 200
Staphylococcus aureus ssp. *aureus*	ATCC BAA-1717	TCH1516 Texas	USA 300
Staphylococcus aureus	NARSA NRS703	MN-095 Minn/2006	USA 300
Staphylococcus aureus	NARSA NRS683	GA-298 Georgia/2005	USA 300
Staphylococcus aureus	NARSA NRS662	CO-34 Colorado/2005	USA 300
Staphylococcus aureus	NARSA NRS707	NY-155 New York/2005	USA 300
Staphylococcus aureus	ATCC BAA-1707	MW2 N. Dakota/1998	USA 400
Staphylococcus aureus	NARSA NRS691	GA-62 Georgia/2005	USA 500
Staphylococcus aureus	NARSA NRS648	CA-347 California/2005	USA 600
Staphylococcus aureus	NARSA NRS689	GA-442 Georgia/2006	USA 700
Staphylococcus aureus ssp. *aureus*	ATCC BAA-42	HDE288 Portugal/1996	USA 800
Staphylococcus aureus	NARSA NRS668	CO-72 Colorado/2005	USA 800
Staphylococcus aureus	ATCC BAA-1747	94:1013 Vermont/1993	USA 1000
Staphylococcus aureus	NARSA NRS676	CT-19 Conn/2005	USA 1000
Staphylococcus aureus	NARSA NRS745	CA-629 California/2006	USA 1000
Staphylococcus aureus	ATCC BAA-1764	7031 Alaska	USA 1100
Staphylococcus aureus	ATCC BAA-1691	HFH-30137 Michigan/2003	Not 100-1100
Staphylococcus aureus	ATCC BAA-1700	HFH-33798 Illinois/2004	Not 100-1100
Staphylococcus aureus	ATCC BAA-2312	M10/0061 Ireland/2010	Unknown
Staphylococcus aureus	ATCC BAA-2313	M10/0148 Ireland/2010	CC130
Staphylococcus aureus (VRSA)[e]	NARSA VRS5	HIP15178 Michigan/2005	Unknown

[a] Detected at the initial test concentration of $5x10^6$CFU/mL.
[b] Initial test concentration was $5x10^5$ CFU/mL.
[c] Isolates obtained from University of Rennes, Laboratory of Microbiology and Immunology, France.
[d] Isolates obtained from Sunnybrook Research Institute, affiliated with the University of Toronto.
[e] Tested as a seeded blood culture at the time of positivity.

Results of *Staphylococcus* (non-*S. aureus*) Inclusivity Testing[a]

***Staphylococcus* Detected** [~5x10^6 CFU/mL]		***Staphylococcus* Detected with Reduced Sensitivity** [~5x10^7 CFU/mL]		***Staphylococcus* Not Detected**[b]	
Coagulase-positive staphylococci (non-*S.aureus*)					
Staphylococcus lutrae	ATCC 700373			*Staphylococcus intermedius*[c]	ATCC 29663
				Staphylococcus pseudointermedius	ATCC 49444
				Staphylococcus schleiferi subsp. *coagulans*	ATCC 49545
Coagulase-negative staphylococci (CoNS)					
Staphylococcus caprae	ATCC 51548	*Staphylococcus capitis* subsp. *capitis*	ATCC 27842	*Staphylococcus auricularis*	Clinical isolate[d]
Staphylococcus cohnii	ATCC 29972	*Staphylococcus pasteuri*	ATCC 51127	*Staphylococcus carnosus*	ATCC 51365
Staphylococcus epidermidis	ATCC 12228	*Staphylococcus saprophyticus*	ATCC 15305	*Staphylococcus lentus*[e]	ATCC 700403
	ATCC 29886	*Staphylococcus simulans*	Clinical isolates[f]	*Staphylococcus pettenkoferi*	5 clinical isolates
	ATCC 55133	*Staphylococcus warneri*	ATCC 25614	*Staphylococcus schleiferi* subsp. *schleiferi*	ATCC 43808
	ATCC 29887			*Staphylococcus sciuri*	ATCC 29060
	ATCC 51625				
	ATCC 35984				
Staphylococcus equorum	ATCC 43958				
Staphylococcus haemolyticus	ATCC 29968				
Staphylococcus hominis ssp. hominis	ATCC 25615				
Staphylococcus lugdunensis	ATCC 43809				
Staphylococcus xylosus	ATCC 29966				

[a] All 54 *S. aureus* isolates (table above) received *Staphylococcus* Detected results.
[b] Not detected when tested at a concentration of ≥5x10^8 CFU/mL.
[c] Isolates identified as *Staphylococcus intermedius* by automated identification systems were detected in two clinical specimens.
[d] *Staphylococcus auricularis* was not tested in analytic studies, but was not detected in a clinical blood culture.
[e] An isolate identified as *Staphylococcus lentus* by an automated identification system was detected in one clinical specimen.
[f] *Staphylococcus simulans* was not tested in analytic studies, but was detected in three clinical blood cultures at unknown concentration.

Based on inclusivity testing results for staphylococci and *in silico* analysis of available sequences, the following predictions of reactivity (table below) are provided for less common CoNS species. Prediction of reactivity was based on the number and location of mismatches between the target sequence and the assay primer(s). Listed organisms were not tested by the FilmArray assay either in

analytical or clinical testing. **Performance of the FilmArray BCID Panel for these organisms has not been established.**

In silico Predictions of *Staphylococcus* Reactivity

Detection Predicted[a]	Detection Predicted with Reduced Sensitivity[b]	Detection Not Predicted[c]
Staphylococcus gallinarum	*Staphylococcus microti*	*Staphylococcus arlettae*
Staphylococcus kloosii	*Staphylococcus simiae*	*Staphylococcus chromogenes*
	Staphylococcus succinus	*Staphylococcus condimenti*
		Staphylococcus fleurettii
		Staphylococcus piscifermentans
		Staphylococcus pulvereri
		Staphylococcus rostri
		Staphylococcus saccharolyticus
		Staphylococcus vitulinus

[a] Predicted result of *Staphylococcus* Detected when present in a blood culture sample at a concentration of $\geq 5x10^6$ CFU/mL.
[b] Predicted result of *Staphylococcus* Detected when present in a blood culture sample at a concentration of $\geq 5x10^7$ CFU/mL.
[c] Predicted result of *Staphylococcus* Not Detected at relevant concentrations.

Results of *Streptococcus* Inclusivity Testing

***Streptococcus* Detected[a]**		
Species	**Isolate ID**	**Strain Information**
Streptococcus pyogenes	ATCC 19615	Group A (Pyogenic group)
Streptococcus pyogenes	PCMC 20100107CI02	
Streptococcus pyogenes	ATCC 49399	
Streptococcus pyogenes	ATCC 12344	
Streptococcus pyogenes	ATCC 12384	
Streptococcus agalactiae	ATCC 13813 Type strain – Serotype 1a/c	Group B (Pyogenic group)
Streptococcus agalactiae	PCMC 20100107CI03 Untyped clinical isolate	
Streptococcus agalactiae	ATCC 12403 Type III	
Streptococcus agalactiae	ATCC BAA-611 Serotype V	
Streptococcus agalactiae	NCTC 8017 Unknown serotype	
Streptococcus dysgalactiae ssp. equisimilis	ATCC 12388	Group C/G (Pyogenic group)
Streptococcus bovis	ATCC 33317	Group D (Bovis group)
Streptococcus equinis	ATCC 9812	
Streptococcus mutans	ATCC 25175	Group E (Mutans group)
Streptococcus anginosus	ATCC 33397	Group F (Anginosus group)
Streptococcus intermedius	ATCC 27335	
Streptococcus constellatus	ATCC 27513	
Streptococcus gordonii	ATCC 10558	Mitis group
Streptococcus parasanguinis	ATCC 31412	

***Streptococcus* Detected[a]**		
Species	**Isolate ID**	**Strain Information**
Streptococcus sanguinis	ATCC 10556	
Streptococcus mitis	ATCC 15914	
Streptococcus oralis	ATCC 10557	
Streptococcus pseudopneumoniae	ATCC BAA-960	
Streptococcus pneumoniae	ATCC BAA-255 Strain R6 (no capsule)	
Streptococcus pneumoniae	ATCC 700672 Serotype 14	
Streptococcus pneumoniae	ATCC BAA-334 Serotype 4	
Streptococcus pneumoniae	ATCC 700673 Serotype 19A	
Streptococcus pneumoniae	ATCC BAA-341 Serotype 5	
Streptococcus salivarius	ATCC 13419	Salivarius group
Streptococcus gallolyticus	ATCC BAA-2069	Uncertain grouping

[a] Detected at the initial test concentration of ~$1x10^8$ CFU/mL.

Results of *Streptococcus agalactiae* Inclusivity Testing

***Streptococcus/Streptococcus agalactiae* (Group B) Detected[a]**		
Species	**Isolate ID**	**Strain Information**
Streptococcus agalactiae	ATCC 13813 Type strain – Serotype 1a/c	
Streptococcus agalactiae	PCMC 20100107CI03 Untyped clinical isolate	
Streptococcus agalactiae	ATCC 12403 Type III	Group B (Pyogenic group)
Streptococcus agalactiae	ATCC BAA-611 Serotype V	
Streptococcus agalactiae	NCTC 8017 Unknown serotype	

[a] Detected at the initial test concentration of ~$1x10^8$ CFU/mL.

Results of *Streptococcus pneumoniae* Inclusivity Testing

***Streptococcus/Streptococcus pneumoniae* Detected[a,b]**		
Species	**Isolate ID**	**Strain Information**
Streptococcus pneumoniae	ATCC BAA-255 Strain R6 (no capsule)	
Streptococcus pneumoniae	ATCC 700672 Serotype 14	
Streptococcus pneumoniae	ATCC BAA-334 Serotype 4	Mitis group
Streptococcus pneumoniae	ATCC 700673 Serotype 19A	
Streptococcus pneumoniae	ATCC BAA-341 Serotype 5	

[a] Detected at the initial test concentration of ~$1x10^8$ CFU/mL.
[b] Based on sequence analysis, the BCID Panel may not detect *S. pneumoniae* serotypes 11A and 19, or may detect these serotypes with reduced sensitivity compared to other serotypes.

Results of *Streptococcus pyogenes* Inclusivity Testing

***Streptococcus/Streptococcus pyogenes* (Group A) Detected[a]**		
Species	**Isolate ID**	**Strain Information**
Streptococcus pyogenes	ATCC 19615	Group A (Pyogenic group)
Streptococcus pyogenes	PCMC 20100107CI02	
Streptococcus pyogenes	ATCC 49399	
Streptococcus pyogenes	ATCC 12344	
Streptococcus pyogenes	ATCC 12384	

[a] Detected at the initial test concentration of ~$1x10^8$ CFU/mL.

Based on results of inclusivity testing and *in silico* analysis of available sequences, predictions of reactivity are provided in the table below for less common *Streptococcus* species. Prediction of reactivity was based on the number and location of mismatches between the target sequence and the assay primer(s). The analysis predicts that many species may be detected at concentrations expected in positive blood cultures (10^8-10^9 CFU/mL), and others (particularly Mutans group species) will likely not be detected due to sequence mismatches with the assay primers. Listed organisms were not tested by the FilmArray assay either in analytical or clinical testing. **Performance of the FilmArray BCID Panel for these organisms has not been established.**

***In silico* Predictions of *Streptococcus* Reactivity**

Detection Predicted[a]	**Detection Predicted with Reduced Sensitivity[b]**	**Detection Not Predicted**
Streptococcus australis	*Streptococcus parauberis*	*Streptococcus criceti*[c]
Streptococcus equi		*Streptococcus downei*[c]
Streptococcus ictaluri		*Streptococcus macacae*[c]
Streptococcus infantis		*Streptococcus porcinus*
Streptococcus infantarius		*Streptococcus urialis*
Streptococcus pasteurianus		
Streptococcus perois		
Streptococcus suis		
Streptococcus thermophilus		
Streptococcus vestibularis		

[a] Predicted result of *Streptococcus* Detected when present in a blood culture sample at a concentration of ~$1x10^8$ CFU/mL.
[b] Predicted result of *Streptococcus* Detected when present in a blood culture sample at a concentration of $\geq 1x10^9$ CFU/mL.
[c] Mutans group streptococci.

Results of *Acinetobacter baumannii* Inclusivity Testing

***Acinetobacter baumannii* Detected[a]**	
Species	**Isolate ID**
Acinetobacter baumannii	ATCC 9955
Acinetobacter baumannii	ATCC BAA-1605
Acinetobacter baumannii	ATCC 17961

Acinetobacter baumannii	ATCC 19003
Acinetobacter baumannii	ATCC BAA-2093
Acinetobacter baumannii	ATCC 15308

[a] Detected at the initial test concentration of ~1x10^8 CFU/mL

Results of *Enterobacteriaceae* Inclusivity Testing

***Enterobacteriaceae* Detected** [~5×10^7 CFU/mL or 1×10^8 CFU/mL]		***Enterobacteriaceae* Detected with Reduced Sensitivity** [~5×10^8-1×10^9 CFU/mL]		***Enterobacteriaceae* Not Detected[a]**	
Cedeceae davisiae	ATCC 43023	*Edwardsiella tarda*	ATCC 15947	*Morganella morganii* subsp. *morganii*	ATCC 25829
Citrobacter freundii	ATCC 43864	*Enterobacter gergoviae*	ATCC 33028	*Pantoea (Enterobacter) agglomerans*[b]	ATCC 27155
Citrobacter koseri	ATCC 29223	*Hafnia alvei*	ATCC 51815	*Providencia (Proteus) acalifaciens*	ATCC 51902
Cronobacter muytjensii	ATCC 51329	*Salmonella bongori*	SGSC 3041	*Providencia (Proteus) rettgeri*	ATCC 9250
Cronobacter (Enterobacter) sakazakii	ATCC 29544	*Serratia fonticola*	ATCC 29844	*Providencia stuarti*	ATCC 33672
Enterobacter aerogenes	ATCC 13048	*Serratia odorifera*	ATCC 33077	*Rahnella aquatilis*	ATCC 33071
Enterobacter aerogenes	ATCC 29751	*Serratia rubidaea*	ATCC 27593	*Serratia liquefaciens*	ATCC 27592
Enterobacter amnigenus	ATCC 51816			*Serratia plymuthica*	ATCC 183
Enterobacterasburiae	ATCC 35953			*Tatumella ptyseos*	ATCC 33301
Enterobacter cloacae	9 isolates[c]			*Yersinia enterocolitica*	ATCC 6025
Enterobacter hormaechei	ATCC 49162				
Enterobacter kobei	ATCC BAA-260[d]				
Enterobacter nimipressuralis	ATCC 9912[d]				
Escherichia coli	5 isolates[e]				
Escherichia fergusonii	ATCC 35469				
Escherichia hermanii	ATCC 33650				
Escherichia vulneris	ATCC 33821				
Klebsiella oxytoca	11 isolates[f]				
Klebsiella pneumoniae	10 isolates[g]				
Klebsiella variicola	ATCC BAA-830				
Kluyvera ascorbata	ATCC 33433				
Kluyvera (Enterobacter) intermedius	ATCC 33110				
Leclercia adecarboxylata	ATCC 23216				
Proteus species	10 isolates[h]				
Raoultella ornithinolytica	ATCC 31898				
Raoultella planticola	ATCC 31900				
Raoultella terrigena	ATCC 33257				
Salmonella enterica-cholerasius	ATCC 10708				

***Enterobacteriaceae* Detected** [~5×10^7 CFU/mL or 1×10^8 CFU/mL]		***Enterobacteriaceae* Detected with Reduced Sensitivity** [~5×10^8-1×10^9 CFU/mL]	***Enterobacteriaceae* Not Detected**[a]
Salmonella enterica-heidelberg	ATCC 8326		
Salmonella enterica-paratyphi	SGSC 3222		
Salmonella enterica-typhimurium	ATCC 13311		
Serratia marcescens	6 isolates[i]		
Serratia entomophila	ATCC 43705		
Serratia ficaria	ATCC 33105		
Shigella boydii[j]	ATCC 8700		
Shigella dysenteriae[j]	PHM-2004008089		
Shigella flexneri[j]	ATCC 12022		
Shigella sonnei[j]	ATCC 11060		
Yokenella regensburgei	ATCC 35313		

[a] Not Detected at the highest test concentration of 1×10^9-1×10^{10}CFU/mL.
[b] Not Detected in this study, but *Pantoea agglomerans* was detected by the BCID Panel in a clinical blood culture.
[c] See *Enterobacter cloacae* complex table.
[d] Tested as purified nucleic acid at a concentration of 0.63µg/mL (equivalent to ~1.0×10^8 CFU/mL).
[e] See *Escherichia coli* table.
[f] See *Klebsiella oxytoca* table.
[g] See *Klebsiella pneumoniae* table.
[h] See *Proteus* table.
[i] See *Serratia marcescens* table.
[j] Tested as a seeded blood culture within 1 hour of positivity.

Based on results of inclusivity testing and *in silico* analysis of available sequences, predictions of reactivity are provided in the following table for less common members of the *Enterobacteriaceae* that were not tested. Prediction of reactivity was based on the number and location of mismatches between the target sequence and the assay primer(s). Listed organisms were not tested by the FilmArray assay either in the analytical or clinical testing. **The performance of the FilmArray BCID Panel for these organisms has not been established.**

In silico Predictions of Enterobacteriaceae Reactivity

Detection Predicted with Reduced Sensitivity[a]	Detection Not Predicted	Unknown Reactivity[b]
Brenneria spp.	*Photorhabdus* spp.	*Buttiauxella* spp.
Dickeya spp.	*Serratia grimesii*	*Ewingella americana*
Erwinia spp.	*Serratia proteamaculans*	*Leminorella* spp.
Pectobacterium spp.	*Xenorhabdus* spp.	*Moellerella* spp.
	Yersinia spp.	

[a] Predicted result of *Enterobacteriaceae* Detected when present in a blood culture sample at a concentration of $\geq 1x10^8$ CFU/mL

[b] Sequence data not available for *in silico* reactivity predictions

Results of *Enterobacter cloacae* complex Inclusivity Testing

***Enterobacter cloacae* complex Detected** [~1×10^8 CFU/mL]		***Enterobacter cloacae* complex Not Detected[a]**	
Enterobacter asburiae	ATCC 35953	*Enterobacter nimipressuralis*[b]	ATCC 9912
Enterobacter cloacae subsp. *cloacae*	ATCC BAA-1143	*Enterobacter kobei*	ATCC BAA-260
Enterobacter cloacae subsp. *cloacae*	ATCC 13047		
Enterobacter cloacae subsp. *cloacae*	NCTC 10005		
Enterobacter cloacae subsp. *cloacae*	ATCC 49141		
Enterobacter cloacae subsp. *dissolvens*[b]	ATCC 23373		
Enterobacter hormaechei	ATCC 49162		

[a] Not Detected at highest test concentration of 1×10^{10} CFU/mL.

[b] Tested as purified nucleic acid at a concentration of 0.63µg/mL (equivalent to ~1×10^8 CFU/mL).

Results of *Escherichia coli* Inclusivity Testing

***Escherichia coli* Detected[a]**		
Species	**Isolate ID**	**Strain Info**
Escherichia coli	ATCC 43888	CDC B6914-MS1 serotype O157:H7
Escherichia coli	ATCC 49105	7482-1-1 serotype O15
Escherichia coli	ATCC 25922	FDA-Seattle1946
Escherichia coli	ATCC 35401	H10407 serotype O78:H11
Escherichia coli	ATCC BAA-201	Produces ESBL TEM-3

[a] Detected at the initial test concentration of 5×10^7 CFU/mL.

Results of *Klebsiella oxytoca* Inclusivity Testing

***Klebsiella oxytoca* Detected[a]**			***Klebsiella oxytoca* Not Detected**		
Species	**Isolate ID**	**Strain Info**	**Species**	**Isolate ID**	**Strain Info**
Klebsiella oxytoca	ATCC 13182	n/a	*Klebsiella oxytoca*[b,c]	JMI 10678	MY/2011
Klebsiella oxytoca	ATCC 49131	n/a			
Klebsiella oxytoca	ATCC 700324	n/a			
Klebsiella oxytoca	ATCC 43086	n/a			

***Klebsiella oxytoca* Detected[a]**			***Klebsiella oxytoca* Not Detected**		
Species	**Isolate ID**	**Strain Info**	**Species**	**Isolate ID**	**Strain Info**
Klebsiella oxytoca	ATCC 8724	n/a			
Klebsiella oxytoca	JMI 14611	AR/2011			
Klebsiella oxytoca	JMI 12707	MA/2011			
Klebsiella oxytoca	JMI 7818	AR/2004			
Klebsiella oxytoca	JMI 2661	NY/2003			
Klebsiella oxytoca	JMI 2523	n/a			

[a] Detected at the initial test concentration of 5×10^7 CFU/mL.
[b] Detected as *Enterobacteriaceae* at the initial test concentration of 5×10^7 CFU/mL but Not Detected for *Klebsiella oxytoca* at the highest test concentration of 1×10^{10} CFU/mL.
[c] Sequence analysis confirmed this isolate as a variant *K. oxytoca* that will not be detected by the FilmArray BCID Panel Koxytoca assay.

Results of *Klebsiella pneumoniae* Inclusivity Testing

***Klebsiella pneumoniae* Detected[a]**		
Species	**Isolate ID**	**Strain Information**
Klebsiella pneumoniae	ATCC BAA-1706	n/a
Klebsiella pneumoniae ssp. *pneumoniae*	ATCC 13883	Type strain
Klebsiella pneumoniae ssp. *ozaenae*	ATCC 11296	NCTC 5050
Klebsiella pneumoniae ssp. *rhinoscleromatis*	ATCC 13884	NCTC 5046 Type strain
Klebsiella pneumoniae	ATCC 700603	n/a
Klebsiella pneumoniae	ATCC BAA-1705	n/a
Klebsiella pneumoniae	JMI 766	n/a
Klebsiella pneumoniae	JMI 328	n/a
Klebsiella pneumoniae	JMI 8091	n/a
Klebsiella pneumoniae	JMI 438	n/a
Klebsiella variicola[b]	ATCC BAA-830	F2R9/ 2001 Type strain

[a] Detected at the initial test concentration of 1×10^8 CFU/mL.
[b] Identical sequence to *K. pneumoniae* variant 342. Both *K. pneumoniae* variant 342 and *Klebsiella variicola* have been recovered from clinical specimens and will be identified by the BCID Panel and most standard laboratory methods as *Klebsiella pneumoniae*.

Results of *Proteus* Inclusivity Testing

***Proteus* Detected[a]**	
Species	**Isolate ID**
Proteus mirabilis	ATCC 29906
	JMI 10793
	ATCC 25933
	ATCC 33583
	ATCC 7002
Proteus hauseri	ATCC 13315
	ATCC 700826
Proteus penneri	ATCC 33519
Proteus vulgaris	ATCC 33420
	ATCC 27973

[a] Detected at the initial test concentration of 1×10^7 CFU/mL.

Results of *Serratia marcescens* Inclusivity Testing

***Serratia marcescens* Detected[a]**		
Species	**Isolate ID**	**Strain Information**
Serratia marcescens	ATCC 13880	Type strain
Serratia marcescens	ATCC 14756	n/a
Serratia marcescens	ATCC 27137	n/a
Serratia marcescens	ATCC 43297	n/a
Serratia marcescens	JMI 697	CT/2009
Serratia marcescens	JMI 8089	TX/2004

[a] Detected at the initial test concentration of 1×10^8CFU/mL.

Results of Inclusivity Testing for *Haemophilus influenzae*

Haemophilus influenzae Detected[a]		
Species	**Isolate ID**	**Strain Information**
Haemophilus influenzae	ATCC 33929	Non-typeable
Haemophilus influenzae	ATCC 51907	Non-typeable
Haemophilus influenzae ssp. *aegyptus*	ATCC 11116	Non-typeable
Haemophilus influenzae	ATCC 9006	Type a
Haemophilus influenzae	ATCC 31512	Type b
Haemophilus influenzae	ATCC 10211	Type b
Haemophilus influenzae	ATCC 49699	Type c
Haemophilus influenzae	ATCC 9008	Type d
Haemophilus influenzae	ATCC 8142	Type e
Haemophilus influenzae	ATCC 700223	Type f

[a] Detected as seeded positive blood cultures tested within 1 hour of positivity. The concentration of *H. influenzae* in a positive blood culture at the time of positivity is estimated to be ~1×10^8 CFU/mL

Results of *Neisseria meningitidis* Inclusivity Testing

***Neisseria meningitidis* Detected[a]**			***Neisseria meningitidis* Not Detected[b,c]**		
Species	**Isolate ID**	**Serogroup**	**Species**	**Isolate ID**	**Serogroup**
Neisseria meningitidis	ATCC 43744	W135	*Neisseria meningitidis* (unencapsulated)	Clinical isolate[c]	None
Neisseria meningitidis	ATCC 13077	A	*Neisseria meningitidis* (unencapsulated)	Clinical isolate[c]	None
Neisseria meningitidis	ATCC 13090	B	*Neisseria meningitidis* (unencapsulated)	Clinical isolate[c]	None
Neisseria meningitidis	ATCC 13102	C	*Neisseria meningitidis* (unencapsulated)	Clinical isolate[c]	None
Neisseria meningitidis	ATCC 13113	D	*Neisseria meningitidis*	Clinical isolate[d]	B
Neisseria meningitidis	ATCC 35561	Y			

[a] Detected in a seeded blood culture tested within 1 hour of positivity (estimated concentration ~1×10^8 CFU/mL).
[b] Not Detected in a seeded blood culture tested 1-5 hours after positivity.
[c] Clinical isolates of unencapsulated *N. meningitidis* were tested from seeded positive blood cultures to confirm that they would not be detected by the BCID Panel.
[d] DNA from a clinical isolate with a variant *ctrA* gene was tested and not detected at a concentration

equivalent to 2.5×10^9 CFU/mL.

Results of *Pseudomonas aeruginosa* Inclusivity Testing

***Pseudomonas aeruginosa* Detected[a]**	
Species	**Isolate ID**
Pseudomonas aeruginosa	ATCC 27853
Pseudomonas aeruginosa	ATCC 10145
Pseudomonas aeruginosa	ATCC 19429
Pseudomonas aeruginosa	ATCC 25619
Pseudomonas aeruginosa	ATCC BAA-1744
Pseudomonas aeruginosa	ATCC 35554

[a] Detected at the initial test concentration of 1×10^8CFU/mL

Results of *Candida albicans* Inclusivity Testing

***Candida albicans* Detected[a]**		
Species	**Isolate ID**	**Strain Info**
Candida albicans	ATCC 10231	Serotype A - 3147
Candida albicans	ATCC MYA-427	A39 [DUMC 136.97]
Candida albicans	ATCC MYA-2876	SC5314
Candida albicans	ATCC 11651	171D
Candida albicans	ATCC 22972	M 97
Candida albicans	ATCC 90028	NCCLS 11

[a] Detected at the initial test concentration of 1×10^4 CFU/mL.

Results of *Candida glabrata* Inclusivity Testing

***Candida glabrata* Detected[a]**		
Species	**Isolate ID**	**Strain Info**
Candida glabrata	ATCC 15545	NRRL YB-4025
Candida glabrata	ATCC 32554	26247-1
Candida glabrata	ATCC 2001	CBS138
Candida glabrata	ATCC 15126	CBS15126
Candida glabrata	ATCC MYA-2950	n/a

[a] Detected at the initial test concentration of 1×10^6 CFU/mL.

Results of *Candida krusei* Inclusivity Testing

***Candida krusei* Detected[a]**		
Species	**Isolate ID**	**Strain Info**
Candida krusei	ATCC 90878	B74
Candida krusei	ATCC 201748	89-08-008
Candida krusei	ATCC 14243	n/a
Candida krusei/*Issatchenkia orientalis*[b]	ATCC 28870	CBS 2052
Issatchenkia orientalis[b]	ATCC 6258	NRRL Y-413

[a] Detected at the initial test concentration of 1×10^6 CFU/mL.
[b] *Issatchenkia orientalis* and *Pichia kudriavzevii* are anamorphs of *C. krusei*.

Results of *Candida parapsilosis* Inclusivity Testing

***Candida parapsilosis* Detected[a]**		
Species	**Isolate ID**	**Strain Info**
Candida parapsilosis	ATCC 90875	B78
Candida parapsilosis	ATCC 34136	ST-89
Candida parapsilosis	ATCC 96142	MCO462 [UTHSC R-648]
Candida parapsilosis	ATCC 96138	MCO433
Candida parapsilosis	ATCC 22019	CBS604

[a] Detected at the initial test concentration of 1×10^6 CFU/mL.

Results of *Candida tropicalis* Inclusivity Testing

***Candida tropicalis* Detected[a]**		
Species	**Isolate ID**	**Strain Info**
Candida tropicalis	ATCC 66029	AmMS 227
Candida tropicalis	ATCC 750	Type Strain
Candida tropicalis	ATCC 90874	B79
Candida tropicalis	ATCC MYA-2734	508-12.1
Candida tropicalis[b]	ATCC 201380	API 9001 105(Vitek QC)

[a] Detected at the initial test concentration of 1×10^5 CFU/mL.
[b] Target concentration was 5×10^5 CFU/mL, final test concentration was 1×10^6 CFU/mL

Results of *mecA* Inclusivity Testing

***mecA* Detected[a,b]**			
Species	**Isolate ID**	**Strain Information**	**SCCmec Type**
Methicillin-sensitive *S. aureus* (MSSA) with SCCmec cassette (*mecA* positive)			
Staphylococcus aureus	ATCC BAA-2419	Mass/2010	II
Staphylococcus aureus	ATCC BAA-2420	Mass/2010	II
Staphylococcus aureus	ATCC BAA-2421	Mass/2010	II
Methicillin-resistant *S. epidermidis* (MRSE) (*mecA* positive)			
Staphylococcus epidermidis	ATCC 29887	255-01B	Unknown
Staphylococcus epidermidis[c]	ATCC 51625	CCF 15990	
Staphylococcus epidermidis	ATCC 35984	RP62A	
Methicillin-resistant *S. aureus* (MRSA) (*mecA* positive)			
Staphylococcus aureus ssp. *aureus*	ATCC BAA-38	E2125 Denmark	I
Staphylococcus aureus ssp. *aureus*	ATCC 43300	F-182 Kansas	II
Staphylococcus aureus ssp. *aureus*	ATCC 700698	Mu3 Japan/1996	II
Staphylococcus aureus ssp. *aureus*	ATCC BAA-1720	MRSA252 UK	II
Staphylococcus aureus	NARSA NRS705	NY-12 New York/2005	II
Staphylococcus aureus	NARSA NRS701	MN-082 Minn/2006	II
Staphylococcus aureus	NARSA NRS648	CA-347 California/2005	II
Staphylococcus aureus ssp. *aureus*	ATCC BAA-39	HUSA304 Hungary/1993	III 3A&5
Staphylococcus aureus	NARSA NRS703	MN-095 Minnesota/2006	IV
Staphylococcus aureus	NARSA NRS683	GA-298 Georgia/2005	IV
Staphylococcus aureus	NARSA NRS662	CO-34 Colorado/2005	IV
Staphylococcus aureus	NARSA NRS707	NY-155 New York/2005	IV
Staphylococcus aureus	ATCC BAA-1707	MW2 N. Dakota/1998	IV
Staphylococcus aureus	NARSA NRS691	GA-62 Georgia/2005	IV
Staphylococcus aureus	NARSA NRS689	GA-442 Georgia/2006	IV
Staphylococcus aureus	NARSA NRS668	CO-72 Colorado/2005	IV
Staphylococcus aureus	ATCC BAA-1747	94:1013 Vermont/1993	IV
Staphylococcus aureus	NARSA NRS676	CT-19 Conn/2005	IV

***mecA* Detected[a,b]**			
Species	**Isolate ID**	**Strain Information**	**SCCmec Type**
Staphylococcus aureus	ATCC BAA-1764	7031 Alaska	IV
Staphylococcus aureus	ATCC BAA-1691	HFH-30137 Mich/2003	IV
Staphylococcus aureus	ATCC BAA-1700	HFH-33798 Illinois/2004	IV
Staphylococcus aureus ssp. *aureus*	ATCC BAA-1717	TCH1516 Texas	IVa
Staphylococcus aureus	NARSA NRS745	CA-629 California/2006	V
Staphylococcus aureus ssp. *aureus*	ATCC BAA-42	HDE288 Portugal/1996	VI
Methicillin-resistant *S. aureus* with *mecA*$_{LGA251}$/*mecC* variant			
Staphylococcus aureus	ATCC BAA-2312	M10/0061 Ireland/2010	XI
Staphylococcus aureus	ATCC BAA-2313	M10/0148 Ireland/2010	XI

[a] Detected at the initial test concentration of 5×10^6CFU/mL.
[b] *Staphylococcus* Detected and/or *Staphylococcus aureus* Detected results also reported, as appropriate.
[c] Initial test concentration was 5 x10^5 CFU/mL.

Results of *vanA*/*B* Inclusivity Testing

***vanA/B* Detected[a,b]**		
Species	**Isolate ID**	**Strain Information**
Enterococcus faecium [*vanA*]	JMI 536	TX/2006
Enterococcus faecium [*vanA*]	ATCC 700221	Connecticut
Enterococcus faecium [*vanA*]	JMI 475	IN/2003
Enterococcus faecalis [*vanA*]	JMI 12536	Mass/2002
Enterococcus faecalis [*vanB*]	ATCC 51299	Missouri
Enterococcus faecalis [*vanB*]	ATCC 700802	Missouri/1987
Enterococcus faecalis [*vanB*]	JMI 368	VA/2003

[a] Detected at the initial test concentration of 1×10^8 CFU/mL.
[b] *Enterococcus* Detected results also reported.

Results of KPC Inclusivity Testing

KPC Detected[a, b]			
Species[c]	**Isolate ID**	**KPC Type**	**Strain Information**
Enterobacter cloacae	BAA-2341	Unknown	1101152
Enterobacter hormaechei	BAA-2082	Unknown	n/a
Escherichia coli	BAA-2340	Unknown	1101362
Klebsiella oxytoca	JMI 2523	Unknown	n/a
Escherichia coli	Clinical Isolate	KPC-2	n/a
Enterobacter cloacae	Clinical Isolate	KPC-2	n/a
Klebsiella oxytoca	JMI 7818	KPC-2	AR/2004
Klebsiella pneumoniae	JMI 328	KPC-2	n/a
Klebsiella pneumoniae	ATCC BAA-1705	KPC-2	Modified Hodge Test Control
Serratia marcescens	JMI 697	KPC-2	CT/2009
Enterobacter cloacae	Clinical Isolate	KPC-3	n/a

KPC Detected[a, b]			
Species[c]	**Isolate ID**	**KPC Type**	**Strain Information**
Klebsiella oxytoca	JMI 2661	KPC-3	NY/2003
Klebsiella pneumoniae	JMI 766	KPC-4	n/a
Klebsiella pneumoniae	JMI 8091	KPC-4	n/a
Klebsiella pneumoniae	JMI 438	KPC-4	n/a

[a] Detected at the initial test concentration of 5×10^7 CFU/mL for *K. oxytoca* isolates and 1×10^8 CFU/mL for *K. pneumoniae* and *S. marcescens* isolates. Detected in a seeded blood culture tested within 1 hour of positivity for *Enterobacter* spp. and *E. coli*.
[b] *Enterobacteriaceae* and corresponding species specific Detected results also reported.
[c] Other isolates which carry the KPC gene (i.e. *Acinetobacter baumannii, Pseudomonas aeruginosa,* and *Enterobacteriaceae* other than those listed above) were not evaluated.

Isolates of KPC-carrying organisms other than those listed in the above table (e.g., *Pseudomonas aeruginosa*, *Acinetobacter baumanii*, *Citrobacter spp*., *Salmonella spp*., *Enterobacter spp*. (other than *E. cloacae*)) were not evaluated in the inclusivity or clinical studies. In silico analysis of available KPC sequences of these organisms known to contain the KPC resistance marker demonstrated 100% homology with the BCID primers. Therefore detection of the KPC gene is predicted but has not been demonstrated for these organisms.

f. Analytical specificity (Exclusivity):

The potential for cross-reactivity between assays contained in the BCID Panel was evaluated by testing blood culture samples with concentrations equal to or greater than the level of organism estimated to be in a blood culture sample eight hours after positivity (approximately 10^9-10^{10} CFU/mL for bacteria and 10^7-10^8 CFU/mL for yeast), or the highest concentration possible based on the organism stock. Organisms were tested as either seeded blood cultures or contrived specimens at known concentrations. For blood culture samples, test organisms were seeded into blood culture bottles and grown to positivity on a continuous monitoring blood culture instrument. Bottles were removed from the instrument and tested with the BCID Panel after eight hours of being called positive. Contrived samples were prepared by spiking the organism into a simulated blood culture matrix (human whole blood in blood culture medium), and incubated on the blood culture instrument for ~24 hours to the final desired concentration. Target concentrations were confirmed by plating. Frozen quantified stocks were used to test the following organisms at the highest concentrations possible: *Mycoplasma hominis* (3.16×10^7 CFU/mL), *Ureaplasma urealyticum* (1.57×10^6 CFU/mL), *Mycobacterium tuberculosis* (7.33×10^6 CFU/mL), and *Legionella pneumophilia* (2.63×10^8 CFU/mL). In addition, extracted DNA was used for a vancomycin-resistant *E. faecium* isolate carrying the *vanM* gene (5ng/mL; ~1×10^6 CFU/mL).

The selection of organisms focused on species that may be found in positive blood cultures (clinically relevant) and/or those that are closely related to target organisms (nearest neighbors). Organisms were also selected based on antimicrobial resistance phenotypes and the presence or absence of the antimicrobial resistance genes identified by the BCID Panel. The tested organisms were divided into two categories:

on-panel organisms and off-panel organisms. On-panel exclusivity testing included a total of 141 isolates of gram-positive bacteria, gram-negative bacteria, and yeast representing 29 genera and 98 individual species. Off-panel organisms were expected to have negative test results for all of the assays on the FilmArray BCID Panel (or positive organism results but negative results for the antimicrobial resistance genes detected by the FilmArray BCID Panel). Off-panel testing included gram-positive bacteria, gram-negative bacteria, yeast, viruses and *Mycoplasmataceae*.

The following tables present both on-panel and off-panel organisms that were tested and yielded the expected negative FilmArray BCID Panel test results for all BCID targets (other than the targets for which the on-panel organism were expected to be positive).

Non-Cross Reactive Gram Positive Organisms

ON PANEL – Gram Positive Organisms			
***Enterococcus* Species**	***Staphylococcus aureus***	**Coagulase-Negative Staphylococci**	***Streptococcus* Species**
E. avium *E. casseliflavus* (2 isolates) *E. cecorum* *E. dispar* *E. durans* *E. faecalis* (3 isolates) *E. faecium* (2 isolates)[a] *E. gallinarium* (2 isolates) *E. hirae* *E. raffinosus*	MSSA (18 isolates) Resistant *S. aureus* – BORSA (6 isolates) MRSA *(mec*A*)* VRSA *(mec*A, *van*A)	*S. capitis* ssp. *capitis* *S. caprae* *S. cohnii* *S. epidermidis* (2 isolates) *S. haemolyticus* *S. hominis* *S. lugdunensis* *S. pasteuri* *S. saprophyticus* *S. schleiferi* ssp. *schleiferi* *S. sciuri* *S. warneri* *S. xylosus*	*S. agalactiae* *S. anginosus* *S. bovis* *S. dysgalactiae* *S. gallolyticus* *S. mitis* *S. mutans* *S. parasanguinis* *S. pneumoniae* *S. pseudopneumoniae* *S. pyogenes* *S. salivarius*
Listeria monocytogenes	**Coagulase-Positive Staphylococci**		
L. monocytogenes	*S. intermedius* *S. lutrae* *S. pseudointermedius* *S. schleiferi* ssp. *coagulans*		

OFF PANEL			
Gram-positive Cocci	**Gram-positive Bacilli**	***Listeria* Species**	**Gram-positive Anaerobes**
Granulicatella adiacens[b] *Gemella morbillorum* *Lactococcus lactis* *Macrococcus caseolyticus* *Micrococcus luteus* *Vagococcus fluvialis*	*Actinomyces odontolyticus* *Bacillus cereus* *Corynebacterium jeikeium* *Lactobacillus acidophilus* *Mycobacterium tuberculosis*[c] *Rhodococcus equi* *Rothia mucilaginosa*	*L. (murrayi) grayi* *L. innocua*[d] *L. ivanovii* ssp. *londoniensis* *L. seeligeri* *L. welshimeri*	*Clostridium perfringens* *Peptostreptococcus anaerobius* *Propionibacterium acnes*

[a] One isolate was tested at a concentration of 5ng/mL Extracted DNA; ~1×10^6 CFU/mL.
[b] A false positive *Streptococcus* result was observed in the initial test of this isolate. The expected negative results were observed in multiple subsequent tests. No cross-reactivity between *G. adiacens* and the BCID Panel *Streptococcus* assays is predicted by sequence analysis.

[c] Tested at a concentration of 7.33×10^{6} CFU/mL.
[d] *In silico* analysis predicts that cross-reactivity between the Lmonocytogenes assay and some atypical strains *of L. innocua* is possible, however, no cross-reactivity was observed in this testing.

Non-Cross Reactive Gram-Negative Organisms

ON PANEL			
Acinetobacter baumannii	***Enterobacteriaceae* Isolates[a]**		
A. baumannii (2 isolates)	*Cedeceae davisiae* *Citrobacter freundii* *Citrobacter koseri* *Cronobacter muytjensi* *Cronobacter sakazakii* *Enterobacter amnigenus* *Enterobacter asburiae* *Enterobacter cancerogenus* *Enterobacter cloacae* *Enterobacter hormaechei* *Enterobacter gergoviae* *Escherichia coli* (2 isolates)	*Escherichia hermanii* *Escherichia vulneris* *Hafnia alvei* *Klebsiella oxytoca* (3 isolates) *Klebsiella pneumoniae* (6 isolates) *Kluyvera ascorbata* Kluyvera *intermedius* *Leclercia adecarboxylata* *Morganella morganii* *Pantoea agglomerans*[a] *Proteus mirabilis* *Proteus penneri* *Proteus vulgaris*	*Providencia acalifaciens* *Providencia rettgeri* *Providencia stuarti* *Rahnella aquatilis* *Raoultella terrigena* *Raoultella planticola* *Salmonella enterica* *Serratia liquefaciens* *Serratia fonticola* *Serratia marcescens* (2 isolates) *Serratia plymuthica* *Tatumella ptyseos* *Yersinia enterocolitica* *Yokenella regensburgei*
Haemophilus influenzae			
H. influenzae (type b)			
Neisseria meningitidis			
N. meningitidis			
Pseudomonas aeruginosa			
P. aeruginosa			

OFF PANEL			
***Acinetobacter* Species**	***Haemophilus* Species**	***Pseudomonas* Species**	**Gram-negative Bacilli**
A. calcoaceticus *A. haemolyticus* *A. johnsonii* *A. junii* *A. lwoffii* *A. radioresistens* *A. schindleri* *A. ursingii* *A. nosocomialis (genomospecies* 13TU; 2 isolates)	*H. parahaemolyticus* *H. parainfluenzae* *H. parasuis* *H. somnus*	*P. fluorescens* *P. luteola* *P. nitroreducens* *P. oryzihabitans* *P. pertucinogena* *P. stutzeri*	*Aeromonas hydrophila* *Brevundimonasdiminuta* *Moraxella catarrhalis* (3 isolates) *Stenotrophomonas maltophila* *Vibrio parahaemolyticus*
	***Neisseria* Species**		
	N. sicca *N. elongate* *N. perflava* *N. mucosa* *N. lactamica*	**Gram-negative Anaerobes**	**Gram-negative Coccobacilli**
		Bacteroides fragilis *Veillonella parvula*	*Bordetella pertussis* *Campylobacter fetus* *Chlamydia trachomatis* *Legionella pneumophilia*[b]

[a] *In silico* analysis indicates that cross-reactivity between the *Enterobacter cloacae* complex assay and *Pantoea* (*Enterobacter*) *agglomerans* may be possible. However, no cross-reactivity was observed in this study.
[b] Tested at a concentration of 2.63×10^{8} CFU/mL.

Non-Cross-Reactive Fungi

ON PANEL	OFF PANEL		
***Candida* Species**	***Candida* Species**		**Non-*Candida* Fungi**
C. albicans	*C. dubliniensis*	*C. sojae*	*Aspergillus fumigatus*
C. glabrata	*C. lusitaniae*	*C. viswanathii*	*Debaryomyces hansenii*
C. krusei	*C. metapsilosis*	*C. guilliermondii*	*Kluyveromyces lactis*
C. parapsilosis	*C. multigemmis*[a]		*Saccharomyces cerevisiae*
C. tropicalis			*Schizosaccharomyces pombe*

[a] *In silico* analysis predicts that cross-reactivity between the Cparapsilosis assay and *C. multigemmis* is possible, however, no cross-reactivity was observed in this testing.

Non-Cross-Reactive Viruses and Mycoplasmataceae

OFF PANEL	
Mycoplasmataceae Isolates	**Viruses**
Mycoplasma hominis (3.16×10^7 CFU/mL)	Cytomegalovirus (1.67×10^4 $TCID_{50}$/mL)
Ureaplasma urealyticum (1.57×10^6 CFU/mL)	Epstein Barr Virus (1.00×10^5 $TCID_{50}$/mL)
	Herpes Simplex Virus - Type 1 (1:30 dilution of stock)
	Varicella Zoster Virus (8.17×10^3 $TCID_{50}$/mL)

Non-cross-reactive with Antimicrobial Resistance Gene Assays

ON PANEL		OFF PANEL[a]	
***mec*A**			
Methicillin Resistant Staphylococci (*mec*A)		**Borderline Oxacillin Resistant S. aureus (BORSA)**	
Staphylococcus epidermidis-MRSE	*mec*A	*Staphylococcus aureus*-BORSA (6 isolates)	
Staphylococcus aureus-MRSA	*mec*A	**Methicillin Sensitive Staphylococci**	
Staphylococcus aureus-VRSA	*mec*A/*van*A	*Staphylococcus aureus*-MSSA (18 isolates)[b]	
		Staphylococcus epidermidis-MRSE (1 isolate)	
		Staphylococcus spp. (16 isolates)	
***van*A/B**			
Vancomycin Resistant Enterococci (*van*A/B)		**Vancomycin Resistant Enterococci (non-*vanA/B*)**	
Enterococcus faecalis	*van*B	*Enterococcus casseliflavus*	*van*C
Enterococcus faecium	*van*A	*Enterococcus casseliflavus*	*van*C
		Enterococcus gallinarium	*van*C
		Enterococcus gallinarium	*van*C
		Vancomycin Sensitive Enterococci	
		Enterococcus spp. (8 isolates)	
KPC			
Carbapenem Resistant *Enterobacteriaceae* (KPC)		**Carbapenem Resistant *Enterobacteriaceae* (non-KPC)**	
Klebsiella oxytoca	KPC-2	*Klebsiella pneumoniae*	Unknown
Klebsiella pneumoniae	KPC-4	*Klebsiella pneumoniae*	NDM
Serratia marcescens	KPC-2	**Carbapenem Sensitive/Beta-lactam Resistant Isolates**	
		Klebsiella pneumoniae	AmpC
		Klebsiella pneumoniae	SHV
		Escherichia coli	TEM-3/CTX-1
		Acinetobacter baumannii	*bla*OXA
		Moraxella catarrhalis	*bla*OXA
		Moraxella catarrhalis	BRO-1(*bla*)/*orf3*
		Carbapenem Sensitive Isolates	

ON PANEL	OFF PANEL[a]
	Enterobacteriaceae (51 Isolates) *Acinetobacter baumannii* (1 isolate) *Pseudomonas aeruginosa* (2 isolates)

[a] Off-panel refers to the antimicrobial resistance gene. Organisms may be positive for organism assay(s).
[b] Ten Isolates known to harbor remnants of SCCmec cassette (empty cassette strains)

The following table includes organisms for which cross-reactivity was observed with one or more of the BCID Panel assays as well as any predicted cross-reactivity as determined by in silico analysis.

Predicted and Observed Cross-Reactivity with On-Panel or Off-Panel Organisms

BCID Panel Result	Cross-Reactive Organism(s)/Isolate(s)/Gene
Gram-positive Bacteria	
Enterococcus	Some coagulase-negative staphylococci[a]
Gram-negative Bacteria	
Acinetobacter baumannii	*Acinetobacter calcoaceticus-baumannii* (ACB) complex species: *Acinetobacter calcoaceticus* (ssp. *anitratus*) [b] *Acinetobacter pittii* (formerly *genomospecies* 3) [b]
Escherichia coli/ *Enterobacteriaceae*	*Shigella* species: *Shigella boydii* *Shigella dysenteriae* *Shigella flexneri* *Shigella sonnei* *Escherichia fergusonnii*
Klebsiella pneumoniae/ *Enterobacteriaceae*	*Klebsiella variicola* (aka *Klebsiella pneumoniae* variant 342) *Enterobacter aerogenes* *Raoultella ornithinolytica*[c]
Serratia marcescens/ *Enterobacteriaceae*	*Serratia* species (*S. entomophila*[e], *S. ficaria*, *S. odorifera*[d], and *S. rubidaea*[d]) *Raoultella ornithinolytica*[c] *Pseudomonas aeruginosa* (ATCC 25619)[f] *Pseudomonas putida*[e]
Haemophilus influenzae	*Haemophilus haemolyticus*[g]
Yeast	
Candida parapsilosis	*Candida orthopsilosis* (Group III *Candida parapsilosis*) [h]
Antimicrobial Resistance Genes	
vanA/B	*vanM* [i]

[a] Cross-reactivity was not observed in this study but is predicted by *in silico* analysis to occur only with some species (i.e. *S. epidermis*, *S. capitis* and *S. haemolyticus*) when present in a sample at very high levels. This cross-reactivity was observed infrequently in pre-analytical studies and the clinical evaluation (estimated occurrence of ~0.25% of all *Staphylococcus* positive patient samples).
[b] *Acinetobacter calcoaceticus-baumannii* (ACB) complex species are often mis-identified as *A. baumannii* by automated and manual microbial identification methods.
[c] Cross-reactivity was not observed when ATCC 31898 was tested in the inclusivity study at a concentration ~$1x10^8$ CFU/mL, but cross-reactivity was observed in clinical cultures containing *R. ornithinolytica*.
[d] Cross-reactivity was observed only at high organism concentration ($\geq 10^9$ CFU/mL); rare human pathogens.

[e] *Pseudomonas putida* is a rare opportunistic pathogen.
[f] No cross-reactivity observed with five other *Pseudomonas aeruginosa* isolates tested at $\geq 10^8$ CFU/mL.
[g] *Haemophilus haemolyticus* is a commensal organism of the respiratory tract that is rarely isolated from blood culture.
[h] *Candida orthopsilosis* is mis-identified as *C. parapsilosis* by automated and manual microbial identification methods.
[i] Vancomycin-resistant *Enterococcus faecium* isolated in Asia, 2011; *vanB* resistance phenotype.

g. Assay cut-off:

The BCID Melt Detector software determines whether a FilmArray BCID assay result is positive or negative using a predefined algorithm that includes Tm values, fluorescence values, and analysis of melting curves. For each BCID target sequence there is a mean Tm at which PCR2 products from the most similar isolates will melt. The range surrounding that mean is where amplicon from more diverse isolates are expected to melt. The location and width of each Tm range is assay specific and is used in the FA analysis software to ensure specificity in target detection. Due to the number of species, rarity of some strains, and variability of strain sequences detected by BCID assays, thousands of clinical samples would need to be tested from isolates spanning geography and time in order to estimate the Tm ranges for each target experimentally.

The Melt Detector software uses a mathematical model for Tm prediction that was developed and verified using database sequences, beta site testing, analytical studies, and reference runs. Melting ranges for all 31 pathogen, antibiotic resistance gene targets, and control assays were initially determined and subsequently validated. The validation of the BCID Melt Detector software was performed by comparing FilmArray BCID test results obtained from well-characterized clinical and analytical samples to expert annotation (review of melt curves and assay calls made by the Biofire software team). For individual melt curves, the observed sensitivity and specificity of the melt detector software as compared to expert annotation are greater than 98.5% and 99.9%, respectively. For the Analysis Software, the observed sensitivity and specificity as compared to expert annotation, of the assay calls are greater than 97.0% and 99.85%, respectively. The validation results surpassed the predefined acceptance criteria of >95% accuracy as compared to expert annotation.

h. Fresh versus Frozen Study:

In order to utilize frozen clinical blood culture samples in the evaluation of FilmArray BCID Panel, an analytical study was conducted to demonstrate that preservation of samples by freezing at ≤-70°C does not affect the accuracy of test results compared to freshly collected or freshly prepared samples.

A total of 62 FilmArray runs were attempted in this evaluation of 60 frozen specimens, 60 of which were completed. There was one run failure each for a software error and an instrument communication error. Of the 60 completed runs, no

control failures occurred. Specimens had been stored at ≤ 70°C for an average of 44 days before re-testing for this study. The median age was 47 days (Range: 9-83 days). All of the analytes that were originally detected in the specimens when tested fresh were also detected after storage at ≤ 70°C. Further, no additional analytes were detected in frozen specimens that had not been previously detected when they were tested fresh.

Analyte Detections in Frozen Specimens compared to Fresh Specimens

Analyte	Frozen/Fresh			
	PPA	%	NPA	%
Enterococcus	5/5	100%	55/55	100%
Listeria monocytogenes	2/2	100%	58/58	100%
Staphylococcus	11/11	100%	49/49	100%
Staphylococcus aureus	7/7	100%	53/53	100%
Streptococcus	9/9	100%	51/51	100%
Streptococcus agalactiae	3/3	100%	57/57	100%
Streptococcus pneumoniae	2/2	100%	58/58	100%
Streptococcus pyogenes	2/2	100%	58/58	100%
Acinetobacter baumannii	2/2	100%	58/58	100%
Enterobacteriaceae	18/18	100%	42/42	100%
Enterobacter cloacae complex	2/2	100%	58/58	100%
Escherichia coli	4/4	100%	56/56	100%
Klebsiella oxytoca	2/2	100%	58/58	100%
Klebsiella pneumoniae	5/5	100%	55/55	100%
Proteus	2/2	100%	58/58	100%
Serratia marcescens	2/2	100%	58/58	100%
Haemophilus influenzae	3/3	100%	57/57	100%
Neisseria meningitidis	2/2	100%	58/58	100%
Pseudomonas aeruginosa	3/3	100%	57/57	100%
Candida albicans	2/2	100%	58/58	100%
Candida glabrata	2/2	100%	58/58	100%
Candida krusei	2/2	100%	58/58	100%
Candida parapsilosis	2/2	100%	58/58	100%
Candida tropicalis	2/2	100%	58/58	100%
mecA	7/7	100%	53/53	100%
vanA/B	3/3	100%	57/57	100%
KPC	2/2	100%	58/58	100%

Additionally, A total of four (4) co-infections were identified when the specimens were originally tested fresh, all of which were also detected when the specimens were re-tested from frozen aliquots.

Co-infection Analysis

Coinfections	Frozen/Fresh	%
E. coli + *Enterococcus* + *vanA/B*	1/1	100%
S. aureus + *mecA* + *S. agalactiae*	1/1	100%
S. aureus + *mecA* + *P. aeruginosa* + *Enterococcus*	1/1	100%
Enterococcus + *K. pneumoniae*	1/1	100%
Total	4/4	100%

An analysis of Cp and Tm values was conducted to compare the performance of the BCID individual assays in the original, freshly tested specimens and the frozen specimens. The difference in average and median Cp values between the samples when tested fresh and frozen were typically within 2 cycles and the delta Cp were observed in both directions (both earlier and later relative to fresh testing. The largest variations were consistent with run-to-run variation in Cp values that were observed in the Reproducibility Study when the same samples were tested multiple times over several days. Similarly, the delta Tm values ranged from 0 to Tm 0.9ºC (median 0.4), which is consistent with the variation of Tm values observed in the Reproducibility Study. Tm changes were also observed in both directions.

i. Interference:

Substances that could be present in blood culture samples or introduced during sample handling were evaluated for potential interference. Potentially interfering substances were added to simulated positive blood culture samples which contained simulated blood culture matrix (human whole blood that had been incubated in a blood culture bottle) and one of six different organism mixes. Each organism mix contained two live pathogens at a concentration equivalent to the level determined to be present when a blood culture bottle is detected as positive by the blood culture instrument as shown in the following table. Twelve targeted organisms and four targeted resistance genes were evaluated.

Organism Mixes and Targeted Test Concentrations

Mixture ID	Organism	Source	Strain	IBR Level*
Mix 1	*Enterococcus faecium* (*vanA*)	JMI	475	1.53×10^{8} CFU/mL
	Streptococcus pneumoniae	ATCC	BAA-255	6.41×10^{8} CFU/mL
Mix 2	*Acinetobacter baumannii*	ATCC	9955	2.02×10^{8} CFU/mL
	Klebsiella pneumoniae (KPC)	JMI	766	1.92×10^{8} CFU/mL
Mix 3	*Candida tropicalis*	ATCC	66029	9.70×10^{5} CFU/mL
	Candida krusei	ATCC	90878	4.82×10^{6} CFU/mL
Mix 4	*Staphylococcus aureus* (MRSA)	ATCC	BAA-1747	8.60×10^{6} CFU/mL
	Proteus mirabilis	ATCC	29906	7.58×10^{7} CFU/mL
Mix 5	*Enterococcus faecalis* (*vanB*)	JMI	368	3.01×10^{8}CFU/mL
	Candida albicans	ATCC	10231	3.12×10^{4} CFU/mL
Mix 6	*Haemophilus influenzae* (type b)	ATCC	10211	2.88×10^{8} CFU/mL
	Candida glabrata	ATCC	15545	1.45×10^{6} CFU/mL

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. For most substances the concentration tested was up to three times the level expected to be found in patient blood/culture samples. The following tables list the test substances and final test concentrations used in this study.

Endogenous Substances

Test Substance	Test Concentration
Hemoglobin	2 mg/mL
Triglycerides	10 mg/mL
Bilirubin	0.20 mg/mL
γ-globulin	60 mg/mL
Human genomic DNA	0.2, 2, and 20 ng/µL

Exogenous Substances

Test Substance	Test Concentration
Fluconazole	75 µg/mL
Vancomycin	103 µg/mL
Ciprofloxacin	10 µg/mL
Gentamicin sulfate	10 µg/mL
Imipenem	900 µg/mL
Amoxicillin/Clavulanate	75 µg/mL/6.9 µg/mL
Ceftriaxone	966 µg/mL
Tetracycline	15 µg/mL
Sodium Polyanetholesulfonate (SPS)	0.25% w/v
Heparin	3 Units/mL
Bleach	1%
Ethanol	7%

On each day of testing, one specimen per organism mix was evaluated without any interfering substance to serve as a positive control (no interference) to which the test specimens were compared. For each endogenous and exogenous test substance, one specimen per organism mix was spiked with the appropriate amount of test substance.

Testing of specimens with the above described potential interfering substances produced the expected positive and negative results indicating that none of the endogenous or exogenous test substances compete or interfere with obtaining accurate test results with the FilmArray BCID system. In addition, there were no consistent trends for either Cp or Tm values when comparing the presence and absence of each endogenous or exogenous substance. In summary, study data suggests that higher than expected levels of the all evaluated substances will not interfere with obtaining

accurate test results with the FilmArray BCID Panel.

j. 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 ring" concentrations. Three bacteria (*Staphylococcus epidermidis, Escherichia coli*, and *Streptococcus mitis*) that can be detected by the FilmArray BCID Panel were tested at high levels. These organisms were selected for their high prevalence in mixed blood culture specimens. Five bacteria (*Propionibacterium acnes, Corynebacterium jeikeium, Bacillus cereus, Micrococcus luteus, and Clostridium perfringens)* that are not detected by assays in the FilmArray BCID Panel, but that can be found in blood cultures as contaminants, were also tested to determine if their presence interferes with the ability of the FilmArray BCID Panel to detect organisms targeted by the BCID Panel.

Testing was performed by spiking a high concentration of each potentially interfering bacteria (~1 x 10^{10} CFU/mL) into blood culture specimens that each contained 2 BCID organisms (Mix 1-6 described above for interference testing) at "bottle ring" concentrations. Study results demonstrated that high concentrations of the on-panel BCID microorganisms spiked into blood culture samples produced positive results for the relevant assays on the BCID Panel but did interfere with any expected results for other analytes. High concentrations of off-panel BCID microorganisms also showed no interference with the detection of any FilmArray BCID organism with no unexpected false negative or false positive results observed.

k. Testing of Additional Blood Culture Bottle Types

Fourteen different bottle types from three different blood culture systems (BacT/Alert, BACTEC and VersaTREK) were evaluated analytically with the FilmArray BCID panel. Blood culture bottles/media were tested with the recommended ratio of blood to media. The six organism mixes described above (see interference section) were separately spiked into each bottle type with final concentrations tested at "bottle ring" levels. Results were evaluated to determine if the bottle type provided the expected positive results. A negative control (simulated blood culture matrix) was also tested for each bottle type. The test results for the negative control (NC) and the positive mixes (which give negative results for many organisms on the panel) were evaluated to determine if the bottle type posed a risk of false positive test results due to presence of non-viable organism or organism nucleic acids in the culture media. The 14 bottle types listed in the table below were evaluated and study results demonstrated correct positive and negative FilmArray BCID results with each bottle type.

Blood Culture Bottle Types	
BacT/Alert SA Standard Aerobic	BACTEC Plus Aerobic/F
BacT/Alert SN Standard Anaerobic	BACTEC Plus Anaerobic/F
BacT/Alert FA Aerobic FAN	BACTEC Pediatric Plus

BacT/Alert FN Anaerobic FAN	BACTEC Lytic/10 Anaerobic/F
BacT/Alert PF Pediatric FAN	VersaTREK REDOX 1
BACTEC Standard Aerobic	VersaTREK REDOX 2
BACTEC Standard Anaerobic	BacT/ALERT FA Plus Aerobic

False positive test results were observed during development and beta testing of the FilmArray BCID panel when using BacT/ALERT FA FAN® Aerobic media. An investigation determined that these bottle types contain nucleic acids and/or non-viable organism that can be detected by FilmArray BCID Panel (multiple organisms could be detected in different test runs and media lots). It was confirmed that the charcoal used in FAN media can have a relatively high bio-burden; therefore false results could be generated from the media itself. Because of the potential for false positive results associated with charcoal-containing media, BacT/ALERT FAN media should not be used with the FilmArray BCID Panel. This information is presented in the package insert.

l. *Carryover Study*:

The potential for run-to-run carryover was evaluated by determining whether a high positive sample tested in one pouch would cause false positive results in subsequently tested pouches. Each high positive sample contained ~10^{10} CFU/mL of a unique on-panel bacteria and each negative sample contained a unique off-panel organism or no organism. For each set of samples the negative sample was loaded in the same workspace, using the same Pouch Loading Station and tested directly after the high positive sample using the same FilmArray instrument. No false positive results were observed during consecutive testing of 10 high positive samples alternating with negative samples, demonstrating that recommended sample handling and testing practices are effective in preventing false positive results due to carryover or cross-contamination between samples.

2. Comparison studies:

a. *Method comparison with predicate device:*

N/A

b. *Matrix comparison:*

N/A

3. Clinical studies:

The clinical performance of the FilmArray BCID Panel was established during a two armed clinical study which was conducted at eight U.S. clinical sites over an eight month time period. The study included a prospective residual blood culture arm and a seeded

blood culture arm. In the prospective arm, 1635 prospectively-collected residual blood culture samples (pediatric and adult) were initially included in the study. Only blood cultures collected in BD BACTEC Plus Aerobic/F blood culture bottles were included in the study. Sixty-seven (67) specimens were excluded from the study. The most common reasons for exclusion were when specimens were >8 hours past positivity, incomplete reference/comparator data were provided, or the specimen was from a subject who had a previous specimen included in the study. In the seeded culture arm, analytes proven to be of low prevalence in the prospective arm were evaluated by seeding previously characterized isolates into blood culture bottles and incubating until positivity. A total of 716 seeded cultures were initiated for the study. Seeded specimens were also prepared in BD BACTEC Plus Aerobic/F blood culture bottles. Seventy-seven (77) cultures were excluded from the study. The most common reasons for exclusion were that the specimens were >8 hours past positivity, the seeded culture was not called positive by the automated blood culture system, or the culture was contaminated or inconsistent with the intended seed organism. The final specimen set consisted of 2207 blood cultures (1568 prospective and 639 seeded). Specimens were tested by the FilmArray BCID Panel either from freshly positive blood cultures or from frozen blood culture aliquots. The following table provides a summary of demographic information for the 1568 specimens included in the prospective arm of the study.

Demographic Summary for Prospective Arm of FilmArray BCID Clinical Evaluation

Prospective Study Specimens: Total Specimens - 1568	
Sex	Number of Specimens
Male	917 (58%)
Female	651 (42%)
Age Group	Number of Specimens
≤ 1 year	57 (4%)
1 - 17 years	92 (6%)
18 - 44 years	281 (18%)
45 - 64 years	583 (37%)
65 - 84 years	442 (28%)
≥ 85 years	113 (7%)

Positive blood cultures (prospective and seeded) were tested with the FilmArray BCID Panel. The performance of FilmArray BCID was evaluated by comparing each FilmArray BCID Panel result with the appropriate comparator/reference methods shown in the following table.

Reference/Comparator Methods used to Assess FilmArray BCID Performance

Test Result	Reference/Comparator Method(s)
All organism detections except *Acinetobacter baumannii*	Standard manual and automated microbiological/biochemical identification methods [a]
Acinetobacter baumannii detection	Standard manual and automated microbiological/biochemical identification methods Plus 16S PCR with bi-directional sequencing of all *A. calcoaceticus-baumannii* complex isolates for characterization as *A. baumannii or* non-*A. baumannii* [a]
Antimicrobial resistance gene detections in specimens in which an associated organism was detected (*mecA* from *Staphylococcus*; *vanA/B* from *Enterococcus*, KPC from *Enterobacteriaceae*, *Acinetobacter baumannii*, and *Pseudomonas aeruginosa*)	Method 1: PCR with bi-directional sequencing for specific resistance gene direct from blood culture [b] Method 2: PCR with bi-directional sequencing for specific resistance gene from appropriate cultured isolates[b] Informational: Standard manual and automated phenotypic antimicrobial susceptibility testing of appropriate cultured isolates (methicillin resistance, vancomycin resistance, and carbapenem resistance (and/or carbapenemase production) according to current CLSI criteria) [c]

[a] Performance of FilmArray BCID detecting all organisms was compared to standard manual and automated microbiological/biochemical identification methods. Additionally, isolates identified as being members of the *A. calcoaceticus-baumannii* complex were subjected to 16S PCR and bi-directional sequencing to categorize the isolate as being *A. baumannii* or non-*A. baumannii* for final comparison to the FilmArray BCID *A. baumannii*-specific results. Positive results required a sequencing result of adequate quality to match sequences of *A. baumannii* or non-*A. baumannii* organisms deposited in the National Center for Biotechnology Information (NCBI) GenBank database (www.ncbi.nlm.nih.gov), with an acceptable E-value. This was required due to the inability of phenotypic identification methods to adequately discriminate between members of the *A. calcoaceticus-baumannii* complex.
[b] Performance of FilmArray BCID detecting antimicrobial resistance genes (*mecA*, *vanA/B*, and KPC) was compared to gene-specific PCR tests with bi-directional sequencing. The assays were designed to amplify different sequences than those targeted by FilmArray BCID.
[c] Performance of FilmArray BCID as compared to phenotypic antimicrobial susceptibility testing was performed for informational purposes. The phenotypic methods were performed in accordance with current CLSI criteria.

A total of 2207 specimens were tested in the clinical evaluation, of which 99% (2185/2207) were successful on the first test. Six (6) initial tests were incomplete due to instrument/software errors (5 tests) or a user aborted run (1 test). Sixteen (16) of the completed runs were invalid due to a pouch control failure. Valid results were achieved after a single retest for the 22 incomplete/invalid specimens, resulting in a final successful testing rate of 100%.

Clinical sensitivity or positive percent agreement (PPA) was calculated as 100% x (TP/TP + FN). True positive (TP) indicates that both FilmArray BCID and the reference/comparator method had a positive result for a specific analyte, and false negative (FN) indicates that the FilmArray BCID result was negative while the reference/comparator method was positive. Clinical specificity or negative percent agreement (NPA) was calculated as 100% x (TN/TN + FP). True negative (TN) indicates that both FilmArray BCID and the reference/comparator method had a negative result for a specific analyte, and false positive (FP) indicates that the FilmArray BCID result was positive while the reference/comparator method was negative. The exact binomial two-

sided 95% confidence interval was calculated. The results are summarized in the following tables.

FilmArray BCID Clinical Performance Summary – Gram-Positive Organism Results (Comparator Method: Standard Manual/Automated Microbiological/Biochemical Identification)

Gram-Positive Bacteria		Sensitivity/PPA [a]			Specificity/NPA [a]		
		TP/TP + FN	%	95% CI	TN/TN + FP	%	95% CI
Enterococcus	Prospective Fresh	55/55	100	93.5-100	762/766	99.5	98.7-99.9
	Prospective Frozen	43/46	93.5	82.1-98.6	701/701	100	99.5-100
	Seeded Fresh	12/12	100	73.5-100	407/407	100	99.1-100
	Seeded Frozen	17/17	100	80.5-100	203/203	100	98.2-100
	Overall	***127/130***	***97.7***	***93.4-99.5***	***2073/2077*** [b]	***99.8***	***99.5-99.9***
Listeria monocytogenes	Prospective Fresh	0/0	-	-	821/821	100	99.6-100
	Prospective Frozen	0/0	-	-	747/747	100	99.5-100
	Seeded Fresh	23/23	100	85.2-100	396/396	100	99.1-100
	Seeded Frozen	13/13	100	75.3-100	207/207	100	98.2-100
	Overall	***36/36***	***100***	***90.3-100***	***2171/2171***	***100***	***99.8-100***
Staphylococcus	Prospective Fresh	405/418	96.9	94.7-98.3	401/403	99.5	98.2-99.9
	Prospective Frozen	364/379	96.0	93.6-97.8	359/368	97.6	95.4-98.9
	Seeded Fresh	0/0	-	-	418/419	99.8	98.7-100
	Seeded Frozen	1/1	100	2.5-100	219/219	100	98.3-100
	Overall	***770/798*** [c]	***96.5***	***95.0-97.7***	***1397/1409*** [c]	***99.1***	***98.5-99.6***
Staphylococcus aureus	Prospective Fresh	133/136	97.8	93.7-99.5	685/685	100	99.5-100
	Prospective Frozen	120/121	99.2	95.5-100	622/626	99.4	98.4-99.8
	Seeded Fresh	0/0	-	-	419/419	100	99.1-100
	Seeded Frozen	0/0	-	-	220/220	100	98.3-100
	Overall	***253/257*** [d]	***98.4***	***96.1-99.6***	***1946/1950*** [d]	***99.8***	***99.5-99.9***
Streptococcus	Prospective Fresh	73/77	94.8	87.2-98.6	740/744	99.5	98.6-99.9
	Prospective Frozen	63/64	98.4	91.6-100	683/683	100	99.5-100
	Seeded Fresh	18/18	100	81.5-100	401/401	100	99.1-100
	Seeded Frozen	44/44	100	92.0-100	175/176	99.4	96.9-100
	Overall	***198/203***	***97.5***	***94.3-99.2***	***1999/2004*** [e]	***99.8***	***99.4-99.9***
***Streptococcus agalactiae* (Group B)**	Prospective Fresh	8/8	100	63.1-100	813/813	100	99.5-100
	Prospective Frozen	10/10	100	69.2-100	737/737	100	99.5-100
	Seeded Fresh	3/3	100	29.2-100	416/416	100	99.1-100
	Seeded Frozen	15/15	100	78.2-100	205/205	100	98.2-100
	Overall	***36/36***	***100***	***90.3-100***	***2171/2171***	***100***	***99.8-100***
Streptococcus pneumoniae	Prospective Fresh	15/15	100	78.2-100	805/806	99.9	99.3-100
	Prospective Frozen	10/10	100	69.2-100	737/737	100	99.5-100
	Seeded Fresh	4/5	80.0	28.4-99.5	413/414	99.8	98.7-100
	Seeded Frozen	7/7	100	59.0-100	213/213	100	98.3-100
	Overall	***36/37***	***97.3***	***85.8-99.9***	***2168/2170***	***99.9***	***99.7-100***
***Streptococcus pyogenes* (Group A)**	Prospective Fresh	5/5	100	47.8-100	815/816	99.9	99.3-100
	Prospective Frozen	2/2	100	15.8-100	745/745	100	99.5-100
	Seeded Fresh	9/9	100	66.4-100	410/410	100	99.1-100
	Seeded Frozen	22/22	100	84.6-100	198/198	100	98.2-100
	Overall	***38/38***	***100***	***90.7-100***	***2168/2169***	***99.9***	***99.7-100***

[a] Sensitivity and Specificity refer to performance with the prospective specimens only; Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) refer to performance with the seeded specimens.

[b] 3/4 false positive *Enterococcus* specimens contained *Staphylococcus*; the false positive results may be due to cross-reactivity.

[c] Isolates from 16/28 false negative *Staphylococcus* specimens were identified as the newly described species *S.*

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pettenkoferi by bi-directional sequencing. Bidirectional sequencing confirmed the presence of *Staphylococcus* in 10/12 false positive specimens; 2 were *S. aureus*, 6 were *S. epidermidis*, and 1 was *S. haemolyticus*.
[d] Bidirectional sequencing identified 2 isolates from *S. aureus* false negative specimens as *S. hominis* and *S. epidermidis;* they were not *S. aureus*. Bidirectional sequencing confirmed the presence of *S. aureus* in 1/4 false positive specimens. One false positive and one false negative *S. aureus* were consecutively tested specimens and may be due to sample mix-up.
[e] Bidirectional sequencing confirmed the presence of *S. mitis* in 1/5 false positive *Streptococcus* specimens.

FilmArray BCID Clinical Performance Summary – Gram-Negative Organism Results (Comparator Method: Standard Manual/Automated Microbiological/Biochemical Identification plus 16S Sequencing for Speciation for *A. baumannii*)

Gram-Negative Bacteria		Sensitivity/PPA [a]			Specificity/NPA [a]		
		TP/TP + FN	%	95% CI	TP/TP + FP	%	95% CI
Acinetobacter baumannii	Prospective Fresh	7/7	100	59.0-100	813/814	99.9	99.3-100
	Prospective Frozen	7/7	100	59.0-100	739/740	99.9	99.2-100
	Seeded Fresh	20/20	100	83.2-100	397/399	99.5	98.2-99.9
	Seeded Frozen	17/17	100	80.5-100	202/203	99.5	97.3-100
	Overall	***51/51***	***100***	***93.0-100***	***2151/2156 [b]***	***99.8***	***99.5-99.9***
Enterobacteriaceae	Prospective Fresh	153/156	98.1	94.5-99.6	665/665	100	99.4-100
	Prospective Frozen	150/154	97.4	93.5-99.3	589/593	99.3	98.3-99.8
	Seeded Fresh	93/93	100	96.1-100	326/326	100	98.9-100
	Seeded Frozen	94/95	98.9	94.3-100	125/125	100	97.1-100
	Overall	***490/498 [c]***	***98.4***	***96.9-99.3***	***1705/1709 [c]***	***99.8***	***99.4-99.9***
Enterobacter cloacae complex	Prospective Fresh	10/11	90.9	58.7-99.8	809/810	99.9	99.3-100
	Prospective Frozen	11/11	100	71.5-100	734/736	99.7	99.0-100
	Seeded Fresh	8/8	100	63.1-100	411/411	100	99.1-100
	Seeded Frozen	9/9	100	66.4-100	211/211	100	98.3-100
	Overall	***38/39***	***97.4***	***86.5-99.9***	***2165/2168***	***99.9***	***99.6-100***
Escherichia coli	Prospective Fresh	77/79	97.5	91.2-99.7	742/742	100	99.5-100
	Prospective Frozen	68/69	98.6	92.2-100	674/678	99.4	98.5-99.8
	Seeded Fresh	4/4	100	39.8-100	414/415	99.8	98.7-100
	Seeded Frozen	1/1	100	2.5-100	219/219	100	98.3-100
	Overall	***150/153 [d]***	***98.0***	***94.4-99.6***	***2049/2054 [d]***	***99.8***	***99.4-99.9***
Klebsiella oxytoca	Prospective Fresh	4/4	100	39.8-100	817/817	100	99.5-100
	Prospective Frozen	1/2	50	1.3-98.7	744/745	99.9	99.3-100
	Seeded Fresh	32/36	88.9	73.9-96.9	383/383	100	99.0-100
	Seeded Frozen	22/22	100	84.6-100	198/198	100	98.2-100
	Overall	***59/64 [e]***	***92.2***	***82.7-97.4***	***2142/2143***	***99.9***	***99.7-100***
Klebsiella pneumoniae	Prospective Fresh	33/34	97.1	84.7-99.9	786/787	99.9	99.3-100
	Prospective Frozen	35/37	94.6	81.8-99.3	705/710	99.3	98.4-99.8
	Seeded Fresh	13/13	100	75.3-100	403/406	99.3	97.9-99.8
	Seeded Frozen	21/21	100	83.9-100	199/199	100	98.2-100
	Overall	***102/105 [f]***	***97.1***	***91.9-99.4***	***2093/2102 [f]***	***99.6***	***99.2-99.8***
Proteus	Prospective Fresh	11/11	100	71.5-100	810/810	100	99.5-100
	Prospective Frozen	11/11	100	71.5-100	736/736	100	99.5-100
	Seeded Fresh	2/2	100	15.8-100	417/417	100	99.1-100
	Seeded Frozen	15/15	100	78.2-100	205/205	100	98.2-100
	Overall	***39/39***	***100***	***91.0-100***	***2168/2168***	***100***	***99.8-100***
Serratia marcescens	Prospective Fresh	14/14	100	76.8-100	807/807	100	99.5-100
	Prospective Frozen	8/8	100	63.1-100	739/739	100	99.5-100
	Seeded Fresh	28/28	100	87.7-100	390/391	99.7	98.6-100
	Seeded Frozen	26/27	96.3	81.0-99.9	193/193	100	98.1-100

Gram-Negative Bacteria		Sensitivity/PPA [a]			Specificity/NPA [a]		
		TP/TP + FN	%	95% CI	TP/TP + FP	%	95% CI
	Overall	***76/77*** [g]	***98.7***	***93.0-100***	***2129/2130*** [g]	***99.9***	***99.7-100***
Haemophilus influenzae	Prospective Fresh	5/5	100	47.8-100	816/816	100	99.5-100
	Prospective Frozen	3/3	100	29.2-100	744/744	100	99.5-100
	Seeded Fresh	29/29	100	88.1-100	390/390	100	99.1-100
	Seeded Frozen	6/6	100	54.1-100	214/214	100	98.3-100
	Overall	***43/43***	***100***	***91.8-100***	***2164/2164***	***100***	***99.8-100***
Neisseria meningitidis	Prospective Fresh	1/1	100	2.5-100	820/820	100	99.6-100
	Prospective Frozen	0/0	-	-	747/747	100	99.5-100
	Seeded Fresh	30/30	100	88.4-100	389/389	100	99.1-100
	Seeded Frozen	5/5	100	47.8-100	215/215	100	98.3-100
	Overall	***36/36***	***100***	***90.3-100***	***2171/2171***	***100***	***99.8-100***
Pseudomonas aeruginosa	Prospective Fresh	19/19	100	82.4-100	802/802	100	99.5-100
	Prospective Frozen	32/33	97	84.2-99.9	713/714	99.9	99.2-100
	Seeded Fresh	0/0	-	-	419/419	100	99.1-100
	Seeded Frozen	0/0	-	-	220/220	100	98.3-100
	Overall	***51/52*** [h]	***98.1***	***89.7-100***	***2154/2155***	***99.9***	***99.7-100***

[a] Sensitivity and Specificity refer to performance with the prospective specimens only; Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) refer to performance with the seeded specimens.
[b] Bidirectional sequencing identified isolates from 4 false positive specimens as *A. pittii* (genomospecies 3); this species cross-reacts with the *A. baumannii* assay. These four isolates were identified as *A. baumannii* by phenotypic methods. 6 other isolates originally identified as *A. baumannii* by phenotypic methods were identified by bidirectional sequencing as *A. nosocomialis* (genomospecies 13; 4 isolates), *A. bereziniae*, and *A. radioresistens*; these 6 isolates did not cross-react with the *A. baumannii* assay.
[c] One false positive and one false negative *Enterobacteriaceae* were consecutively tested specimens and may be due to sample mix-up. One isolate from another false negative specimen, identified as *E. coli* by phenotypic methods, was identified as *Pasteurella*, and not *E. coli*, by bidirectional sequencing.
[d] One false positive and one false negative *E. coli* were consecutively tested specimens and may be due to sample mix-up.
[e] Bidirectional sequencing identified 4/5 isolates from false negative *K. oxytoca* specimens as the closely related species, *Raoultella ornithinolytica*, and not *K. oxytoca*. The misidentification is a known limitation of phenotypic testing methods for this species.
[f] The isolate from one false negative *K. pneumoniae* specimen was identified as the closely related organism, *Raoultella planticola* and not *K. pneumoniae*. 6/9 false positive *K. pneumoniae* results appear to be due to cross-reactivity with *Enterobacter aerogenes* and *Raoultella ornithinolytica* (misidentified as *K. oxytoca* by phenotypic methods).
[g] Bidirectional sequencing identified the isolate from the one false negative *S. marcescens* specimen as being in the *S. proteomaculans/grimesii* group and not *S. marcescens.* The one false positive *S. marcescens* result appears to be due to cross-reactivity with *Raoultella ornithinolytica* (misidentified as *K. oxytoca* by phenotypic methods).
[h] Bidirectional sequencing identified the isolate from the one false negative *P. aeruginosa* specimen as the closely related species *Pseudomonas stutzeri* and not *P. aeruginosa*.

FilmArray BCID Clinical Performance Summary – Yeast Organism Results (Comparator Method: Standard Manual/Automated Microbiological/Biochemical Identification)

Yeast		Sensitivity/PPA [a]			Specificity/NPA [a]		
		TP/TP + FN	%	95% CI	TN/TN + FP	%	95% CI
Candida albicans	Prospective Fresh	12/12	100	73.5-100	808/809	99.9	99.3-100
	Prospective Frozen	4/4	100	39.8-100	740/743	99.6	98.8-99.9
	Seeded Fresh	47/47	100	92.5-100	372/372	100	99.0-100
	Seeded Frozen	1/1	100	2.5-100	219/219	100	98.3-100
	Overall	***64/64***	***100***	***94.4-100***	***2139/2143***	***99.8***	***99.5-99.9***

Yeast		Sensitivity/PPA [a]			Specificity/NPA [a]		
		TP/TP + FN	%	95% CI	TN/TN + FP	%	95% CI
Candida glabrata	Prospective Fresh	6/6	100	54.1-100	813/815	99.8	99.1-100
	Prospective Frozen	6/6	100	54.1-100	741/741	100	99.5-100
	Seeded Fresh	32/32	100	89.1-100	387/387	100	99.1-100
	Seeded Frozen	5/5	100	47.8-100	215/215	100	98.3-100
	Overall	***49/49***	***100***	***92.7-100***	***2156/2158***	***99.9***	***99.7-100***
Candida krusei	Prospective Fresh	2/2	100	15.8-100	819/819	100	99.6-100
	Prospective Frozen	2/2	100	15.8-100	745/745	100	99.5-100
	Seeded Fresh	28/28	100	87.7-100	391/391	100	99.1-100
	Seeded Frozen	5/5	100	47.8-100	215/215	100	98.3-100
	Overall	***37/37***	***100***	***90.5-100***	***2170/2170***	***100***	***99.8-100***
Candida parapsilosis	Prospective Fresh	3/3	100	29.2-100	818/818	100	99.6-100
	Prospective Frozen	4/4	100	39.8-100	742/743	99.9	99.3-100
	Seeded Fresh	47/49	95.9	86.0-99.5	370/370	100	99.0-100
	Seeded Frozen	5/5	100	47.8-100	214/215	99.5	97.4-100
	Overall	***59/61*** [b]	***96.7***	***88.7-99.6***	***2144/2146***	***99.9***	***99.7-100***
Candida tropicalis	Prospective Fresh	0/0	-	-	821/821	100	99.6-100
	Prospective Frozen	3/3	100	29.2-100	744/744	100	99.5-100
	Seeded Fresh	31/31	100	88.8-100	388/388	100	99.1-100
	Seeded Frozen	5/5	100	47.8-100	215/215	100	98.3-100
	Overall	***39/39***	***100***	***91.0-100***	***2168/2168***	***100***	***99.8-100***

[a] Sensitivity and Specificity refer to performance with the prospective specimens only; Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) refer to performance with the seeded specimens.
[b] Bidirectional sequencing identified the isolates from the two false negative *C. parapsilosis* specimens as being the closely related species *C. metapsilosis*. This misidentification is a known limitation of phenotypic identification methods.

Comparator testing for the antimicrobial resistance genes was performed with both the blood culture sample and with isolates recovered after subculture of the blood culture media. The results are presented in the tables below. The NPA for *mecA* and *vanA/B* are lower when comparing to PCR/sequencing from bacterial isolates than to PCR/sequencing directly from blood culture primarily due to the reference culture methods not isolating a resistant clone of an applicable organism. This may be due to heterogeneous resistance within a population of cultured organisms or co-culturing of multiple indistinguishable applicable organisms with different resistance profiles (e.g., mixed culture of a resistant *Staphylococcus* with sensitive *Staphylococcus*).

FilmArray BCID Clinical Performance Summary – Antimicrobial Resistance Genes (Comparator Method: PCR/Sequencing Direct from Blood Culture).

Antimicrobial Resistance Genes		Sensitivity /PPA [a]			Specificity /NPA [a]		
		TP/TP + FN	%	95% CI	TN/TN + FP	%	95% CI
***mecA* - Methicillin Resistance Gene**							
mecA All *Staphylococcus* Detected	Prospective Fresh	253/257	98.4%	96.1-99.6%	147/150	98.0%	94.3-99.6%
	Prospective Frozen	233/237	98.3%	95.7-99.5%	134/136	98.5%	94.8-99.8%
	Seeded Fresh	1/1	100%	n/a	0/0	-	-
	Seeded Frozen	1/1	100%	n/a	0/0	-	-
	Overall	***488/496***	***98.4%***	***96.8-99.3%***	***281/286***	***98.3%***	***96.0-99.4%***
mecA *Staphylococcus*	Prospective Fresh	67/69	97.1%	89.9-99.6%	64/64	100%	94.4-100%
	Prospective Frozen	70/70	100%	94.9-100%	54/54	100%	93.4-100%

Antimicrobial Resistance Genes		Sensitivity /PPA [a]			Specificity /NPA [a]		
		TP/TP + FN	%	95% CI	TN/TN + FP	%	95% CI
Detected; *S. aureus* Detected	Seeded Fresh	0/0	-	-	0/0	-	-
	Seeded Frozen	0/0	-	-	0/0	-	-
	Overall	***137/139***	***98.6%***	***94.9-99.8%***	***118/118***	***100%***	***96.9-100%***
mecA *Staphylococcus* Detected; *S. aureus* Not Detected	Prospective Fresh	186/188	98.9%	96.2-99.9%	83/86	96.5%	90.1-99.3%
	Prospective Frozen	163/167	97.6%	94.0-99.3%	80/82	97.6%	91.5-99.7%
	Seeded Fresh	1/1	100%	n/a	0/0	-	-
	Seeded Frozen	1/1	100%	n/a	0/0	-	-
	Overall	***351/357***	***98.3%***	***96.4-99.4%***	***163/168***	***97.0%***	***93.2-99.0%***
***vanA/B* - Vancomycin Resistance Genes**							
vanA/B *Enterococcus* Detected	Prospective Fresh	23/23	100%	85.2-100%	36/36	100%	90.3-100%
	Prospective Frozen	13/13	100%	75.3-100%	30/30	100%	88.4-100%
	Seeded Fresh	12/12	100%	73.5-100%	0/0	-	-
	Seeded Frozen	16/16	100%	79.4-100%	1/1	100%	n/a
	Overall	***64/64***	***100%***	***94.4-100%***	***67/67***	***100%***	***94.6-100%***
KPC - Carbapenem Resistance Gene (Carbapenemase)							
KPC *Enterobacteriaceae* and/or *A. baumannii* and/or *P. aeruginosa* Detected	Prospective Fresh	3/3	100%	29.2-100%	177/177	100%	97.9-100%
	Prospective Frozen	3/3	100%	29.2-100%	187/187	100%	98.0-100%
	Seeded Fresh	10/10	100%	69.2-100%	105/105	100%	96.5-100%
	Seeded Frozen	23/23	100%	85.2-100%	89/89	100%	95.9-100%
	Overall	***39/39***	***100%***	***91.0-100%***	***558/558***	***100%***	***99.3-100%***
KPC *Enterobacteriaceae* Detected	Prospective Fresh	3/3	100%	29.2-100%	150/150	100%	97.6-100%
	Prospective Frozen	3/3	100%	29.2-100%	151/151	100%	97.6-100%
	Seeded Fresh	10/10	100%	69.2-100%	83/83	100%	95.7-100%
	Seeded Frozen	23/23	100%	85.2-100%	71/71	100%	94.9-100%
	Overall	***39/39***	***100%***	***91.0-100%***	***455/455***	***100%***	***99.2-100%***
KPC *Enterobacteriaceae* Not Detected; *A. baumannii* and/or *P. aeruginosa* Detected	Prospective Fresh	0/0	-	-	27/27	100%	87.4-100%
	Prospective Frozen	0/0	-	-	36/36	100%	90.3-100%
	Seeded Fresh	0/0	-	-	22/22	100%	84.6-100%
	Seeded Frozen	0/0	-	-	18/18	100%	81.5-100%
	Overall	***0/0***	***-***	***-***	***103/103***	***100%***	***96.5-100%***

[a] Sensitivity and Specificity refer to performance with the prospective specimens only; Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) refer to performance with the seeded specimens.

FilmArray BCID Clinical Performance Summary – Antimicrobial Resistance Genes (Comparator Method: PCR/Sequencing of Cultured Isolates).

ANTIMICROBIAL RESISTANCE GENES		Positive Percent Agreement			Negative Percent Agreement[a]		
		TP/TP + FN	%	95% CI	TN/TN + FP	%	95% CI
***mecA* - Methicillin Resistance Gene**							
mecA All *Staphylococcus* Detected	Prospective Fresh	234/236	99.2%	97.0-99.9%	149/172	86.7%	80.6-91.3%
	Prospective Frozen	219/222	98.6%	96.1-99.7%	135/151	89.4%	83.4-93.8%
	Seeded Fresh	0/0	-	-	0/0	-	-
	Seeded Frozen	1/1	100%	n/a	0/0	-	-
	Overall	***454/459***	***98.9%***	***97.5-99.6%***	***284/323***	***87.9%***	***83.9-91.3%***
mecA *Staphylococcus* Detected; *S. aureus* Detected	Prospective Fresh	64/65	98.5%	91.7-100%	65/68	95.6%	87.6-99.1%
	Prospective Frozen	66/66	100%	94.6-100%	54/58	93.1%	83.3-98.1%
	Seeded Fresh	0/0	-	-	0/0	-	-
	Seeded Frozen	0/0	-	-	0/0	-	-

ANTIMICROBIAL RESISTANCE GENES		Positive Percent Agreement TP/TP + FN	%	95% CI	Negative Percent Agreement[a] TN/TN + FP	%	95% CI
	Overall	***130/131***	***99.2%***	***95.8-100%***	***119/126***	***94.4%***	***88.9-97.7%***
mecA *Staphylococcus* Detected; *S. aureus* Not Detected	Prospective Fresh	170/171	99.4%	96.8-100%	84/104	80.8%	71.9-87.8%
	Prospective Frozen	153/156	98.1%	94.5-99.6%	81/93	87.1%	78.6-93.2%
	Seeded Fresh	0/0	-	-	0/0	-	-
	Seeded Frozen	1/1	100%	n/a	0/0	-	-
	Overall	***324/328***	***98.8%***	***96.9-99.7%***	***165/197***	***83.8%***	***77.9-88.6%***
***vanA/B* - Vancomycin Resistance Genes**							
vanA/B *Enterococcus* Detected	Prospective Fresh	20/20	100%	83.2-100%	36/39	92.3%	79.1-98.4%
	Prospective Frozen	12/12	100%	73.5-100%	30/31	96.8%	83.3-99.9%
	Seeded Fresh	12/12	100%	73.5-100%	0/0	-	-
	Seeded Frozen	16/16	100%	79.4-100%	1/1	100%	n/a
	Overall	***60/60***	***100%***	***94.0-100%***	***67/71***	***94.4%***	***86.2-98.4%***
KPC - Carbapenem Resistance Gene (Carbapenemase)							
KPC *Enterobacteriaceae* and/or *A. baumannii* and/or *P. aeruginosa* Detected	Prospective Fresh	3/3	100%	29.2-100%	177/177	100%	97.9-100%
	Prospective Frozen	3/3	100%	29.2-100%	187/187	100%	98.1-100%
	Seeded Fresh	10/10	100%	69.2-100%	105/105	100%	96.5-100%
	Seeded Frozen	23/23	100%	85.2-100%	89/89	100%	95.9-100%
	Overall	***39/39***	***100%***	***91.0-100%***	***558/558***	***100%***	***99.3-100%***
KPC *Enterobacteriaceae* Detected	Prospective Fresh	3/3	100%	29.2-100%	151/151	100%	97.6-100%
	Prospective Frozen	3/3	100%	29.2-100%	152/152	100%	97.6-100%
	Seeded Fresh	10/10	100%	69.2-100%	83/83	100%	95.7-100%
	Seeded Frozen	23/23	100%	85.2-100%	71/71	100%	94.9-100%
	Overall	***39/39***	***100%***	***91.0-100%***	***457/457***	***100%***	***99.2-100%***
KPC *Enterobacteriaceae* Not Detected; *A. baumannii* and/or *P. aeruginosa* Detected	Prospective Fresh	0/0	-	-	26/26	100%	86.8-100%
	Prospective Frozen	0/0	-	-	35/35	100%	90.0-100%
	Seeded Fresh	0/0	-	-	22/22	100%	84.6-100%
	Seeded Frozen	0/0	-	-	18/18	100%	81.5-100%
	Overall	***0/0***	***-***	***-***	***101/101***	***100%***	***96.4-100%***

[a] Isolates for 12 Staphylococci, 4 Enterococci, and 7 *Enterobacteriaceae/A. baumannii/P. aeruginosa* did not grow from the subcultured blood culture and could therefore not be tested with the PCR/bi-directional sequencing comparator method. These blood cultures were considered negative for the antimicrobial resistance genes by comparator method, and FilmArray performance has been calculated as True Negative (when FilmArray is negative for the analyte) or False Positive (when FilmArray is positive for the analyte) for each of these isolates.

The performance of FilmArray BCID panel as compared to phenotypic antimicrobial susceptibility testing (AST) results was calculated for informational purposes. Results stratified by AST method are presented in the following three tables. Positive percent agreement is sometimes lower when comparing results from bacterial isolates than when comparing to PCR/sequencing directly from blood culture because phenotypic AST testing is capable of detecting antimicrobial resistance due to mechanisms other than acquisition of *mecA*, *vanA/B*, or KPC. AST results were not provided for all isolates.

***mecA* Performance – Comparison to Phenotypic Cefoxitin (Methicillin/Oxacillin Susceptibility) AST Methods.**

PHENOTYPIC METHODS		Positive Percent Agreement		Negative Percent Agreement	
		TP/TP + FN	% (95%CI)	TN/TN + FP	% (95%CI)
Prospective All *Staphylococcus*	Cefoxitin Disc Diffusion	22/22	100%	15/15	100%
	Chromogenic Agar	42/46	91.3%	25/32	78.1%
	Automated Antimicrobial Susceptibility Testing	366/380	96.3%	226/262	86.3%
	All Methods	***430/448***	***96.0% (93.7 - 97.6%)***	***266/309***	***86.1% (81.7 - 89.7%)***
Prospective *Staphylococcus*, *S. aureus* Detected	Chromogenic Agar	10/11	90.9%	8/8	100%
	Automated Antimicrobial Susceptibility Testing	117/119	98.3%	108/112	96.4%
	All Methods	***127/130***	***97.7% (93.4 - 99.5%)***	***116/120***	***96.7% (91.7 - 99.1%)***
Seeded *Staphylococcus*	Automated Antimicrobial Susceptibility Testing	1/1	100%	0/0	-

***vanA/B* Performance – Comparison to Phenotypic Vancomycin AST Methods.**

PHENOTYPIC METHODS		Positive Percent Agreement		Negative Percent Agreement	
		TP/TP + FN	% (95%CI)	TN/TN + FP	% (95%CI)
Prospective *Enterococcus*	Vancomycin Screen Agar	3/3	100%	5/5	100%
	Vancomycin Disc Diffusion	0/1	0.0%	-	-
	Automated Antimicrobial Susceptibility Testing	29/30	96.7%	55/58	94.8%
	All Methods	***32/34*** [a]	***94.1% (80.3 - 99.3%)***	***60/63***	***95.2% (86.7 - 99.0%)***
Seeded *Enterococcus*	Vancomycin Disc Diffusion	14/14	100%	1/1	100%
	Vancomycin Screen Agar	14/14	100%	-	-
	All Methods	***28/28***	***100% (87.7 - 100%)***	***1/1***	***100% (n/a)***
Combined Prospective and Seeded *Enterococcus*	***All Methods***	***60/62*** [a]	***96.8% (88.8 - 99.6%)***	***61/64***	***95.3% (86.9 - 99.0%***

[a] Two isolates (one *E. gallinarum* and one *E. faecalis*) that were vancomycin resistant by phenotypic AST testing were negative for the *vanA/B* genes by bi-directional sequence analysis.

KPC Performance – Comparison to Phenotypic Carbapenem AST Methods.

- AST results were not provided for several isolates.
- *Acinetobacter baumannii* and *Pseudomonas aeruginosa* are commonly resistant to carbapenems due to mechanisms other than acquisition of the KPC gene (bla_{KPC}). These bacteria very rarely carry the KPC gene.

PHENOTYPIC METHODS		Positive Percent Agreement		Negative Percent Agreement	
		TP/ TP + FN	% (95%CI)	TN/ TN + FP	% (95%CI)
Prospective ***A. baumannii***	Automated Antimicrobial Susceptibility Testing	0/10	0%	4/4	100%
Seeded ***A. baumannii***	Meropenem Disc Diffusion	0/30	0%	9/9	100%
***A. baumannii* – All Methods**		**0/40**	**0% (n/a)**	**13/13**	**100% (75.3-100%)**
Prospective ***P. aeruginosa***	Automated Antimicrobial Susceptibility Testing	0/10	0%	32/32	100%
	Meropenem Disc Diffusion	-	-	6/6	100%
	Meropenem/Ertapenem Disc Diffusion	0/1	0%	2/2	100%
***P. aeruginosa* – All Methods**		**0/11**	**0% (n/a)**	**40/40**	**100% (91.2-100%)**
Prospective ***K. pneumoniae***	Automated Antimicrobial Susceptibility Testing	6/6	100%	64/64	100%
Seeded ***K. pneumoniae***	Meropenem Disc Diffusion	19/19	100%	1/1	100%
	Modified Hodge Test (Meropenem)	11/11	100%	1/1	100%
***K. pneumoniae* – All Methods**		**36/36**	**100% (90.3-100%)**	**66/66**	**100% (94.6-100%)**
Prospective ***E. cloacae***	Automated Antimicrobial Susceptibility Testing	-	-	22/22	100%
Seeded ***E. cloacae***	Automated Antimicrobial Susceptibility Testing	-	-	3/3	100%
	Meropenem Disc Diffusion	0/1	0%	-	-
	Modified Hodge Test (Meropenem)	2/2	100%	11/11	100%
***E. cloacae* – All Methods**		**2/3[a]**	**66.7% (9.4-99.2%)**	**36/36**	**100% (90.3-100%)**
Prospective ***E. coli***	Automated Antimicrobial Susceptibility Testing	-	-	144/144	100%
Seeded ***E. coli***	Modified Hodge Test (Meropenem)	1/1	100%	4/4	100%

PHENOTYPIC METHODS		Positive Percent Agreement		Negative Percent Agreement	
		TP/ TP + FN	% (95%CI)	TN/ TN + FP	% (95%CI)
***E. coli* – All Methods**		**1/1**	**100% (n/a)**	**148/148**	**100% (97.5-100%)**
Prospective *P. mirabilis*	Automated Antimicrobial Susceptibility Testing	-	-	21/21	100%
Seeded *P. mirabilis*	Meropenem Disc Diffusion	-	-	4/4	100%
	Modified Hodge Test (Meropenem)	0/1	0%	11/11	100%
***P. mirabilis* – All Methods**		**0/1[a]**	**0% (n/a)**	**36/36**	**100% (90.3-100%)**
Prospective All Other *Enterobacteriaceae*	Automated Antimicrobial Susceptibility Testing	-	-	43/43	100%
Seeded All Other Enterobacteriaceae	Automated Antimicrobial Susceptibility Testing	-	-	42/42	100%
	Meropenem Disc Diffusion	-	-	13/13	100%
	Modified Hodge Test (Meropenem)	-	-	61/61	100%
All Other *Enterobacteriaceae* – All Methods		**-**	**-**	**159/159**	**100% (97.7-100%)**

[a] Two isolates (one *E. cloacae* and one *P. mirabilis*) that were carbapenem resistant by phenotypic AST testing were negative for the KPC gene by bi-directional sequence analysis.

The FilmArray BCID Panel reports genus or family level results for *Enterococcus*, *Staphylococcus*, *Streptococcus*, E*nterobacteriaceae*, and *Proteus*. Standard identification methods identified various genera/species within each of these groups during the clinical evaluation. Stratification of performance by species within the groups is presented below.

Stratification of *Enterococcus* Clinical Performance by Species. (Comparator Method: Standard Manual/Automated Microbiological/Biochemical Identification)

***Enterococcus* species**	Positive Agreement	
	Prospective	**Seeded**
E. avium	2/2 (100%)	-
E. casseliflavus	1/2 (50%)	1/1 (100%)
E. durans	1/1 (100%)	-
E. faecalis	55/56 (98.2%)	8/8 (100%)
E. faecalis + *E. faecium*	1/1 (100%)	-
E. faecium	36/37 (97.3%)	9/9 (100%)
E. gallinarum	2/2 (100%)	1/1 (100%)
Enterococcus sp. (not speciated)	-	10/10 (100%)
Overall *Enterococcus*	**98/101 (97.0%) 95%CI = 91.6-99.4%**	**29/29 (100%) 95%CI = 88.1-100%**

Stratification of *Staphylococcus* Clinical Performance by Species (Comparator Method: Standard Manual/Automated Microbiological/Biochemical Identification)

***Staphylococcus* species**	**Positive Agreement**	
	Prospective	**Seeded**
S. aureus	256/257 (99.6%)	-
S. auricularis	0/1 (0%)	-
S. capitis	15/17 (88.2%)	-
S. capitis + *S. epidermidis*	1/1 (100%)	-
S. capitis + *S. hominis*	1/1 (100%)	-
S. capitis + *S. lugdunensis*	1/1 (100%)	-
S. carnosus	0/1 (0%)	-
S. cohnii	1/1 (100%)	-
S. cohnii + *S. hominis*	1/1 (100%)	-
S. epidermidis	200/201 (99.5%)	1/1 (100%)
S. epidermidis + *S. hominis*	4/4 (100%)	-
S. epidermidis + *Staphylococcus* sp. (not speciated)	2/2 (100%)	-
S. haemolyticus	19/19 (100%)	-
S. haemolyticus + *S. hominis*	1/1 (100%)	-
S. hominis	65/65 (100%)	-
S. hominis + *Staphylococcus* sp. (not speciated)	1/1 (100%)	-
S. intermedius	2/2 (100%)	-
S. intermedius + *Staphylococcus* sp. (not speciated)	1/1 (100%)	-
S. lentus	1/1 (100%)	-
S. lugdunensis	5/5 (100%)	-
S. saprophyticus	2/2 (100%)	-
S. sciuri	0/1 (0%)	-
S. simulans	3/3 (100%)	-
S. warneri	4/5 (80%)	-
Staphylococcus sp. (not speciated)[a]	180/200 (90%)	-
Overall *Staphylococcus*	**769/797 (96.5%)** **95%CI = 95.0-97.7%**	**1/1 (100%)** **95%CI = n/a**

[a] Of the 20 unspeciated staphylococci not detected by FilmArray BCID, 16 were identified as *S. pettenkoferi*, 2 as *S. epidermidis*, 1 as *S. capitis*, and 1 as *S. caprae* by 16S sequence analysis. The 180 unspeciated Staphylococci that were detected by FilmArray BCID were not sequenced.

Stratification of *Streptococcus* Clinical Performance by Species. (Comparator Method: Standard Manual/Automated Microbiological/Biochemical Identification)

***Streptococcus* species**	**Positive Agreement**	
	Prospective	**Seeded**
Group A (Pyogenic)		
S. pyogenes	7/7 (100%)	31/31 (100%)
Group B (Pyogenic)		
S. agalactiae	18/18 (100%)	18/18 (100%)
Group C/G (Pyogenic)		

***Streptococcus* species**	**Positive Agreement**	
	Prospective	**Seeded**
S. canis	1/1 (100%)	-
S. equi/S. dysgalactiae	1/1 (100%)	-
Streptococcus group C	2/2 (100%)	-
Streptococcus group G	2/2 (100%)	-
Group D (Bovis Group)		
S. bovis	3/3 (100%)	-
S. equinus	1/1 (100%)	-
Group F (Anginosus Group)		
S. anginosus	4/4 (100%)	-
S. anginosus group	1/1 (100%)	-
S. intermedius	3/3 (100%)	-
S. constellatus	2/2 (100%)	-
Group H (Mitis Group)		
S. gordonii	1/1 (100%)	-
S. mitis	8/9 (88.9%)	-
S. mitis + viridans streptococci	1/1 (100%)	-
S. mitis/S. oralis	2/2 (100%)	-
S. mitis/S. oralis + viridans streptococci	1/1 (100%)	-
S. oralis	5/5 (100%)	-
S. parasanguinis	1/1 (100%)	-
S. parasanguinis + viridans streptococci	1/1 (100%)	-
S. pneumoniae	25/25 (100%)	12/12 (100%)
S. sanguinis	2/2 (100%)	-
Salivarius Group		
S. salivarius	1/2 (50%)	-
S. salivarius + *S. sanguinis* group	1/1 (100%)	-
Other		
S. vestibularis	1/1 (100%)	-
Viridans streptococci (not further speciated)	40/43 (93.0%)	1/1 (100%)
Streptococcus sp. (not speciated)	1/1 (100%)	-
Overall *Streptococcus*	**136/141 (96.5) 95%CI = 91.9-98.8%**	**62/62 (100%) 95%CI = 94.2-100%**

Stratification of *Enterobacteriaceae* Clinical Performance by Genus/Species. (Comparator Method: Standard Manual/Automated Microbiological/Biochemical Identification)

***Enterobacteriaceae* genus/species**	**Positive Agreement**	
	Prospective	**Seeded**
Citrobacter freundii	2/2 (100%)	-
Citrobacter freundii + *Escherichia coli*	1/1 (100%)	-
Citrobacter koseri	1/2 (50%)	-
Enterobacter aerogenes	5/5 (100%)	2/2 (100%)
Enterobacter aerogenes + *Klebsiella oxytoca*	1/1 (100%)	-
Enterobacter cloacae	19/19 (100%)	17/17 (100%)
Enterobacter cloacae complex	3/3 (100%)	-
Enterobacter gergoviae	1/1 (100%)	-

***Enterobacteriaceae* genus/species**	**Positive Agreement**	
	Prospective	**Seeded**
Enterobacter sakasakii	1/1 (100%)	-
Enterobacter sp.	1/1 (100%)	-
Escherichia coli	141/144 (98%)	5/5 (100%)
Escherichia coli + Klebsiella pneumoniae	2/2 (100%)	-
Escherichia coli + Providencia stuartii	1/1 (100%)	-
Escherichia hermannii	1/1 (100%)	-
Klebsiella oxytoca	5/5 (100%)	58/58 (100%)
Klebsiella pneumoniae	67/68 (99%)	34/34 (100%)
Klebsiella pneumoniae + Pantoea agglomerans	1/1 (100%)	-
Leclercia adacarboxylata	1/1 (100%)	-
Morganella morganii + Proteus mirabilis	1/1 (100%)	-
Pantoea agglomerans	1/1 (100%)	-
Pantoea sp.	0/2 (0%)	-
Proteus mirabilis	21/21 (100%)	15/15 (100%)
Proteus vulgaris	-	2/2 (100%)
Salmonella group B	1/1 (100%)	-
Salmonella group C	1/1 (100%)	-
Salmonella sp.	1/1 (100%)	-
Salmonella typhi	1/1 (100%)	-
Serratia marcescens	22/22 (100%)	54/55 (98%)
Overall *Enterobacteriaceae*	**303/310 (97.7%) 95%CI = 95.4-99.1%**	**187/188 (99.5%) 95%CI = 97.1-100%**

Stratification of *Proteus* Clinical Performance by Species. (Comparator Method: Standard Manual/Automated Microbiological/Biochemical Identification)

***Proteus* species**	**Positive Agreement**	
	Prospective	**Seeded**
Proteus mirabilis	22/22 (100%)	15/15 (100%)
Proteus vulgaris	-	2/2 (100%)
Overall *Proteus*	**22/22 (100%) 95%CI = 84.6-100%**	**17/17 (100%) 95%CI = 80.5-100%**

FilmArray BCID reported a total of 81 prospective specimens with discernible multiple organism detections (5.2% of all prospective specimens; 81/1568). The majority of multiple detections (74/81; 91.3%) contained two discernible organisms, while 6.2% (5/81) contained three discernible organisms, and 2.5% (2/81) contained four discernible organisms. The most prevalent multiple detection was *Enterococcus* with *Staphylococcus* (*S. aureus* not detected) (1.3% of all specimens; 20/1568). Out of the 81 polymicrobial specimens, 29 contained one or more analytes that had not been detected with the reference/comparator methods, i.e., discrepant result/false positive by FilmArray BCID.

Discernible Multiple Detection Combinations as Determined by FilmArray BCID

Distinct Multiple Detection Combinations as Determined by FilmArray BCID				Total Specimens	Discrepant Specimens	Discrepant Result(s) (Organism Not Detected by Reference Method)
Organism 1 Results	**Organism 2 Results**	**Organism 3 Results**	**Organism 4 Results**			
Enterobacter cloacae complex, Enterobacteriaceae	*Escherichia coli, Enterobacteriaceae*	*Klebsiella oxytoca, Enterobacteriaceae*	*Klebsiella pneumoniae, Enterobacteriaceae*	1	1	*E. cloacae, E. coli, K. oxytoca*
Candida albicans	*Candida glabrata*	*Staphylococcus*	*Streptococcus*	1	1	*C. albicans*
Candida albicans	*Candida parapsilosis*	*Enterococcus*		1	1	*C. parapsilosis*
Enterococcus	*Pseudomonas aeruginosa*	*Staphylococcus aureus, Staphylococcus*		1	0	
Enterococcus	*Proteus, Enterobacteriaceae*	*Staphylococcus*		1	0	
Enterococcus	*Staphylococcus*	*Streptococcus*		1	1	*Streptococcus*
Candida albicans	*Staphylococcus*	*Streptococcus*		1	0	
Staphylococcus	*Streptococcus agalactiae, Streptococcus*			1	0	
Proteus, Enterobacteriaceae	*Staphylococcus aureus, Staphylococcus*			1	1	*Staphylococcus, S. aureus*
Staphylococcus aureus, Staphylococcus	*Streptococcus agalactiae, Streptococcus*			1	0	
Staphylococcus aureus, Staphylococcus	*Streptococcus pneumoniae, Streptococcus*			1	1	*Streptococcus, S. pneumoniae*
Escherichia coli, Enterobacteriaceae	*Staphylococcus aureus, Staphylococcus*			3	0	
Enterococcus	*Staphylococcus aureus, Staphylococcus*			3	1	*Staphylococcus, S. aureus*
Candida albicans	*Staphylococcus aureus, Staphylococcus*			1	1	*C. albicans*
Acinetobacter baumannii	*Staphylococcus aureus, Staphylococcus*			1	0	
Staphylococcus aureus, Staphylococcus	*Pseudomonas aeruginosa*			1	1	*P. aeruginosa*
Staphylococcus aureus, Staphylococcus	*Streptococcus*			4	0	
Enterococcus	*Escherichia coli, Enterobacteriace*			1	1	*Enterobacteriaceae, E. coli*

Distinct Multiple Detection Combinations as Determined by FilmArray BCID				Total Specimens	Discrepant Specimens	Discrepant Result(s) (Organism Not Detected by Reference Method)
Organism 1 Results	**Organism 2 Results**	**Organism 3 Results**	**Organism 4 Results**			
	ae					
Acinetobacter baumannii	*Klebsiella pneumoniae, Enterobacteriaceae*			2	1	*A. baumannii*
Enterobacter cloacae complex	*Klebsiella pneumoniae, Enterobacteriaceae*			1	1	*E. cloacae complex*
Klebsiella pneumoniae, Enterobacteriaceae	*Enterococcus*			3	1	*K. pneumoniae, Enteric*
Klebsiella pneumoniae, Enterobacteriaceae	*Escherichia coli, Enterobacteriaceae*			5	3	*E. coli, K. pneumoniae* (2)
Candida glabrata	*Proteus, Enterobacteriaceae*			1	1	*C. glabrata*
Proteus, Enterobacteriaceae	*Enterococcus*			1	1	
Enterococcus	*Staphylococcus*			20	6	*Staphylococcus* (3), *Enterococcus* (3)
Staphylococcus	*Pseudomonas aeruginosa*			1	1	*Staphylococcus*
Escherichia coli, Enterobacteriaceae	*Streptococcus*			2	1	*Streptococcus*
Klebsiella pneumoniae, Enterobacteriaceae	*Streptococcus*			1	0	
Staphylococcus	*Streptococcus*			7	0	
Candida albicans	*Enterococcus*			2	0	
Candida krusei	*Enterococcus*			1	0	
Candida glabrata	*Enterococcus*			1	0	
Enterococcus	*Staphylococcus*			1	0	
Candida albicans	*Candida glabrata*			1	1	*C. glabrata*
Candida albicans	*Enterococcus*			1	1	*C. albicans*
Enterobacteriaceae	*Enterococcus*			1	0	
Acinetobacter baumannii	*Pseudomonas aeruginosa*			2	0	
Enterobacteriaceae	*Pseudomonas aeruginosa*			1	0	

Distinct Multiple Detection Combinations as Determined by FilmArray BCID				Total Specimens	Discrepant Specimens	Discrepant Result(s) (Organism Not Detected by Reference Method)
Organism 1 Results	**Organism 2 Results**	**Organism 3 Results**	**Organism 4 Results**			
Enterobacteriaceae	*Staphylococcus*			1	1	*Staphylococcus*
Total Specimens with Multiple Detections				**81**	**29**	

The following table lists 86 additional specimens with multiple species identified by the reference method. Of these additional 86 mixed cultures, 16 had organisms positive by the reference culture method but not detected (false negative) by FilmArray BCID.

Additional Specimens with Multiple Isolates Identified by Reference/Comparator Methods
Note: Organisms shaded gray are not targeted by FilmArray BCID (i.e., off-panel organisms). This list does not include multiple detection combinations already represented in the previous table of multiple detections by Film Array BCID.

Distinct Multiple Detections by Reference/Comparator methods				Total Specimens	Discrepant Specimens	Discrepant Result(s) (Targeted Organisms Not Detected by FilmArray BCID)
Isolate 1	**Isolate 2**	**Isolate 3**	**Isolate 4**			
Aeromonas sobria	*Pantoea agglomerans*	*Pantoea agglomerans*	*Pseudomonas aeruginosa*	1	0	
Enterococcus faecalis	*Flavobacterium* species	*Klebsiella pneumoniae*	*Staphylococcus* species	1	1	*Staphylococcus*
Klebsiella pneumoniae	*Staphylococcus* species	*Staphylococcus* species	Viridans streptococci	1	1	*Staphylococcus, Streptococcus*
Neisseria species	Viridans streptococci	Viridans streptococci	Viridans streptococci	1	0	
Acinetobacter lwoffii	*Corynebacterium* species	*Staphylococcus epidermidis*		1	0	
Coryneform bacterium species	*Staphylococcus* aureus	*Streptococcus oralis*		1	0	
Enterococcus casseliflavus	*Escherichia coli*	*Staphylococcus aureus*		1	1	*Enterococcus*
Klebsiella pneumoniae	*Klebsiella pneumoniae*	*Streptococcus mitis/oralis*		1	0	
Pantoea species	*Staphylococcus intermedius*	*Staphylococcus* species		1	1	*Enterobacteriaceae*
Staphylococcus aureus	*Staphylococcus haemolyticus*	*Streptococcus parasanguis*		1	0	
Staphylococcus capitis	*Staphylococcus epidermidis*	*Staphylococcus lugdunensis*		1	0	
Streptococcus mitis/oralis	Viridans streptococci	Viridans streptococci		1	0	
Viridans streptococci	Viridans streptococci	Viridans streptococci		1	0	

Distinct Multiple Detections by Reference/Comparator methods				Total Specimens	Discrepant Specimens	Discrepant Result(s) (Targeted Organisms Not Detected by FilmArray BCID)
Isolate 1	**Isolate 2**	**Isolate 3**	**Isolate 4**			
Abiotrophia defectiva	*Staphyloccocus* species			1	1	*Staphylococcus*
Acinetobacter baumannii (seq. = A. *nosocomialis/calcoaceticus*)	*Acinetobacter baumannii* (seq. = A. *nosocomialis/calcoaceticus*)			1	0	
Acinetobacter lwoffi	*Klebsiella pneumoniae*			1	0	
Acinetobacter lwoffi	Viridans streptococci			1	1	*Streptococcus*
Acinetobacter lwoffi	*Staphylococcus* species			1	1	*Staphylococcus*
Aerococcus viridans	*Klebsiella pneumoniae*			1	1	*K. pneumoniae, Enterobacteriaceae*
Aerococcus species	*Staphylococcus epidermidis*			1	1	*Staphylococcus*
Bacillus pumilus	*Pseudomonas fluorescens/putida*			1	0	
Brevundimonas diminuta	*Weeksella virosa*			1	0	
Candida parapsilosis	*Kocuria kristinae*			1	0	
Citrobacter freundii	*Escherichia coli*			1	0	
Citrobacter koseri	*Enterococcus faecium*			1	0	
Corynebacterium jeikeium	*Corynebacterium* species			1	0	
Corynebacterium species	*Corynebacterium* species			1	0	
Corynebacterium species	*Enterococcus faecalis*			1	0	
Corynebacterium species	*Micrococcus species*			1	0	
Corynebacterium species	*Staphylococcus aureus*			2	0	
Corynebacterium species	*Staphylococcus haemolyticus*			2	0	
Corynebacterium species	*Staphylococcus hominis*			2	0	
Corynebacterium species	*Staphylococcus* species			3	1	*Staphylococcus*
Diphtheroids	*Staphylococcus* species			1	0	
Enterobacter aerogenes	*Klebsiella oxytoca*			1	0	
Enterococcus	*Enterococcus*			1	0	

Distinct Multiple Detections by Reference/Comparator methods				Total Specimens	Discrepant Specimens	Discrepant Result(s) (Targeted Organisms Not Detected by FilmArray BCID)
Isolate 1	Isolate 2	Isolate 3	Isolate 4			
faecalis	*faecium*					
Enterococcus faecalis	*Stenotrophomonas maltophilia*			1	0	
Enterococcus faecalis	Viridans streptococci			1	1	*Enterococcus*
Enterococcus faecium	*Enterococcus faecium*			1	0	
Escherichia coli	*Escherichia coli*			3	0	
Escherichia coli	*Pasteurella multocida*			1	1	*E. coli, Enterobacteriaceae*
Escherichia coli	*Providencia stuartii*			1	0	
Escherichia coli	*Stenotrophomonas maltophilia*			1	0	
Haemophilus influenzae	*Moraxella catarrhalis*			1	0	
Klebsiella pneumoniae	*Pantoea agglomerans*			1	1	*K. pneumoniae*
Lactobacillus acidophilus	*Streptococcus* species			1	0	
Micrococcus species	*Staphylococcus epidermidis*			1	0	
Morganella morganii	*Proteus mirabilis*			1	0	
Neisseria species	*Staphylococcus hominis*			1	0	
Rhodococcus species	*Staphylococcus warneri*			1	1	*Staphylococcus*
Staphylococcus aureus	*Staphylococcus aureus*			2	0	
Staphylococcus aureus	*Staphylococcus caprae*			1	0	
Staphylococcus aureus	*Staphylococcus* species			2	0	
Staphylococcus aureus	Streptococcus salivarius			1	1	*Streptococcus*
Staphylococcus capitis	Staphylococcus capitis			1	0	
Staphylococcus capitis	*Staphylococcus epidermidis*			1	0	
Staphylococcus capitis	*Staphylococcus hominis*			1	0	
Staphylococcus capitis	*Streptococcus pneumoniae*			1	1	*Staphylococcus*
Staphylococcus cohnii	*Staphylococcus hominis*			1	0	
Staphylococcus epidermidis	*Staphylococcus hominis*			4	0	

Distinct Multiple Detections by Reference/Comparator methods				Total Specimens	Discrepant Specimens	Discrepant Result(s) (Targeted Organisms Not Detected by FilmArray BCID)
Isolate 1	**Isolate 2**	**Isolate 3**	**Isolate 4**			
Staphylococcus epidermidis	*Staphylococcus species*			2	0	
Staphylococcus haemolyticus	*Staphylococcus hominis*			1	0	
Staphylococcus hominis	*Staphylococcus hominis*			1	0	
Staphylococcus hominis	*Staphylococcus* species			1	0	
Staphylococcus species	*Staphylococcus* species			3	0	
Staphylococcus species	*Stenotrophomonas maltophilia*			1	0	
Streptococcus parasanguinis	Viridans streptococci			1	0	
Streptococcus salivarius	*Streptococcus sanguis* group			1	0	
Viridans streptococci	*Streptococcus mitis*			1	0	
Viridans streptococci	Viridans streptococci			3	0	
			Total	**86**	**16**	

The reference method detected 201 off-panel organism isolates (i.e., those not targeted by FilmArray BCID) from the 1568 prospective cultures. The majority of these isolates belong to groups of organisms commonly considered to be blood culture contaminants (49 *Corynebacterium*/Diphtheroids, 33 *Bacillus* sp., and 27 *Micrococcus* sp., among others). Occurrence of off-panel organisms in the prospective arm of the clinical evaluation is presented in the following table.

Occurrence of Off-Panel Organisms as Determined by Reference/Comparator Methods

Off-Panel Organism	Number Identified	Off-Panel Organism	Number Identified
Abiotrophia sp. or *Granulicatella* sp. (formerly nutritionally-deficient Streptococci)	7	*Flavobacterium* species	1
Achromobacter xylosoxidans	1	*Fusarium* species	1
Acinetobacter sp. (not *A. baumannii*)	23	*Kocuria kristinae*	1
Actinomyces odontolyticus	2	*Lactobacillus acidophilus*	1
Actinomyces species	1	*Lactobacillus* species	2
Aerococcus species	1	*Micrococcus luteus*	1
Aerococcus viridans	2	*Micrococcus luteus/lylae*	1
Aeromonas sobria	1	*Micrococcus* species	25

Off-Panel Organism	Number Identified	Off-Panel Organism	Number Identified
Bacillus cereus	19	*Moraxella catarrhalis*	1
Bacillus pumilus	1	*Moraxella osloensis*	1
Bacillus species	13	*Moraxella* species	1
Brevibacterium species	1	*Mycobacterium fortuitum* complex	1
Brevibacterium ensei	1	*Mycobacterium* species	1
Brevundimonas diminuta	1	*Neisseria* species	2
Brevundimonas vesicularis	1	*Paenibacillus* species	1
Burkholderia cepacia complex	2	*Pasteurella multocida*	2
Candida kefyr	1	*Pasteurella* species	1
Capnocytophaga species	1	*Propionibacterium* species	1
Chryseobacterium meningosepticum (Elizabethkingia/Flavobacterium)	1	*Pseudomonas fluorescens/putida*	2
Chryseobacterium indologenes	1	*Pseudomonas* species	3
Chryseomonas luteola	1	*Rhizobium radiobacter*	2
Corynebacterium jeikeium	1	*Rothia (Stomatococcus) mucilaginosa*	4
Corynebacterium mucifaciens	1	*Sphingomonas mucosissima*	1
Corynebacterium species/Diphtheroids	47	*Stenotrophomonas maltophilia*	10
Cryptococcus neoformans	2	*Weeksella virosa*	1

External Control testing in the Clinical Study:

Six frozen (-70°C) control mixes were provided to the study sites for daily testing. Five control mixes consisted of pooled blood and blood culture media containing whole bacteria/yeast at levels expected at culture positivity (bacteria at approximately 10^8 CFU/mL and yeast at approximately 10^6 CFU/mL). Combined, the five mixes covered all panel analytes. A sixth mix was negative for all panel members and only contained pooled blood and blood culture media. The operators were required to complete a valid control mix run with correct results obtained on each day of fresh specimen testing. A total of 403 control mix runs were attempted; two runs did not complete and two runs had failed internal control(s). Of the remaining 399 control runs, 396 (99.2%) were successful while 3 (0.8%) did not return the correct organism results either due to the detection of an extra analyte and/or the failure to detect one or more analytes. For each day that a control run was invalid or produced incorrect results, another control run was performed and valid results were required prior to testing any study specimens.

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

In the prospective arm of the FilmArray BCID clinical study, 1568 eligible blood cultures

were collected and tested at seven of eight study sites across the United States over eight months. The number and percentage of positive results as determined by FilmArray BCID, stratified by study site or age group, are presented in the following tables. Overall, FilmArray BCID detected at least one organism in 88.1% (1382/1568) of prospective positive blood cultures.

Expected Value (as Determined by FilmArray BCID) Summary by Study Site for the Prospective Arm of the Clinical Evaluation

FilmArray BCID Result	**Site 1 (n = 94)**	**Site 2 (n = 611)**	**Site 4 (n = 225)**	**Site 5 (n = 193)**	**Site 6 (n = 122)**	**Site 7 (n = 178)**	**Site 8 (n = 145)**	***Total (n = 1568)***
Gram-Positive Bacteria								
Enterococcus	4 (4%)	32 (5%)	17 (8%)	15 (8%)	6 (5%)	16 (9%)	12 (8%)	***102 (7%)***
Listeria monocytogenes	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	***0 (0%)***
Staphylococcus	47 (50%)	314 (51%)	108 (48%)	87 (45%)	74 (61%)	85 (48%)	65 (45%)	***780 (50%)***
Staphylococcus aureus	19 (20%)	84 (14%)	34 (15%)	35 (18%)	30 (25%)	34 (19%)	21 (14%)	***257 (16%)***
Streptococcus	13 (14%)	51 (8%)	22 (10%)	12 (6%)	7 (6%)	14 (8%)	21 (14%)	***140 (9%)***
Streptococcus agalactiae	1 (1%)	5 (1%)	4 (2%)	2 (1%)	3 (2%)	1 (1%)	2 (1%)	***18 (1%)***
Streptococcus pneumoniae	1 (1%)	8 (1%)	5 (2%)	2 (1%)	3 (2%)	4 (2%)	3 (2%)	***26 (2%)***
Streptococcus pyogenes	2 (2%)	3 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)	2 (1%)	***8 (1%)***
Gram-Negative Bacteria								
Acinetobacter baumannii	0 (0%)	9 (1%)	3 (1%)	0 (0%)	0 (0%)	3 (2%)	1 (1%)	***16 (1%)***
Enterobacteriaceae	14 (15%)	120 (20%)	33 (15%)	51 (26%)	22 (18%)	36 (20%)	31 (21%)	***307 (20%)***
Enterobacter cloacae complex	3 (3%)	9 (1%)	3 (1%)	3 (2%)	1 (1%)	2 (1%)	3 (2%)	***24 (2%)***
Escherichia coli	8 (9%)	53 (9%)	17 (8%)	21 (11%)	15 (12%)	22 (12%)	13 (9%)	***149 (10%)***
Klebsiella oxytoca	2 (2%)	0 (0%)	0 (0%)	3 (2%)	0 (0%)	1 (1%)	0 (0%)	***6 (0%)***
Klebsiella pneumoniae	1 (1%)	30 (5%)	7 (3%)	16 (8%)	2 (2%)	7 (4%)	11 (8%)	***74 (5%)***
Proteus	0 (0%)	14 (2%)	2 (1%)	1 (1%)	3 (2%)	1 (1%)	1 (1%)	***22 (1%)***
Serratia marcescens	0 (0%)	8 (1%)	4 (2%)	3 (2%)	1 (1%)	2 (1%)	4 (3%)	***22 (1%)***
Haemophilus influenzae	3 (3%)	2 (0%)	1 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (1%)	***8 (1%)***
Neisseria meningitidis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)	0 (0%)	***1 (0%)***
Pseudomonas aeruginosa	3 (3%)	19 (3%)	8 (4%)	11 (6%)	3 (2%)	6 (3%)	2 (1%)	***52 (3%)***
Yeast								

FilmArray BCID Result	Site 1 (n = 94)	Site 2 (n = 611)	Site 4 (n = 225)	Site 5 (n = 193)	Site 6 (n = 122)	Site 7 (n = 178)	Site 8 (n = 145)	***Total (n = 1568)***
Candida albicans	1 (1%)	7 (1%)	2 (1%)	3 (2%)	1 (1%)	3 (2%)	3 (2%)	***20 (1%)***
Candida glabrata	0 (0%)	2 (0%)	2 (1%)	7 (4%)	0 (0%)	1 (1%)	2 (1%)	***14 (1%)***
Candida krusei	0 (0%)	0 (0%)	1 (0%)	1 (1%)	0 (0%)	2 (1%)	0 (0%)	***4 (0%)***
Candida parapsilosis	0 (0%)	5 (1%)	0 (0%)	0 (0%)	0 (0%)	2 (1%)	1 (1%)	***8 (1%)***
Candida tropicalis	0 (0%)	2 (0%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	***3 (0%)***
Antimicrobial Resistance Genes								
mecA	28 (30%)	201 (33%)	70 (31%)	56 (29%)	43 (35%)	56 (32%)	37 (26%)	***491 (31%)***
vanA/B	0 (0%)	13 (2%)	8 (4%)	4 (2%)	0 (0%)	5 (3%)	6 (4%)	***36 (2%)***
KPC	0 (0%)	2 (<1%)	0 (0%)	1 (1%)	0 (0%)	1 (1%)	2 (1%)	***6 (<1%)***

Expected Value (as Determined by FilmArray BCID) Summary by Age Group for the Prospective Arm of the Clinical Evaluation

FilmArray BCID Result	<1 (n = 57)	1-17 (n = 92)	18-44 (n = 281)	45-64 (n = 583)	65-84 (n = 442)	85+ (n = 113)
Gram-Positive Bacteria						
Enterococcus	1 (2%)	4 (4%)	17 (6%)	42 (7%)	30 (7%)	8 (7%)
Listeria monocytogenes	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Staphylococcus	34 (60%)	40 (43%)	141 (50%)	304 (52%)	201 (45%)	60 (53%)
Staphylococcus aureus	7 (12%)	18 (20%)	43 (15%)	110 (19%)	62 (14%)	17 (15%)
Streptococcus	8 (14%)	13 (14%)	33 (12%)	44 (8%)	31 (7%)	11 (10%)
Streptococcus agalactiae (GBS)	2 (4%)	0 (0%)	3 (1%)	8 (1%)	3 (1%)	2 (2%)
Streptococcus pneumoniae	0 (0%)	3 (3%)	5 (2%)	9 (2%)	5 (1%)	4 (4%)
Streptococcus pyogenes (GAS)	1 (2%)	1 (1%)	2 (1%)	2 (0%)	2 (0%)	0 (0%)
Gram-Negative Bacteria						
Acinetobacter baumannii	0 (0%)	1 (1%)	2 (1%)	6 (1%)	6 (1%)	1 (1%)
Enterobacteriaceae	13 (23%)	14 (15%)	50 (18%)	112 (19%)	102 (23%)	16 (14%)
Enterobacter cloacae complex	2 (4%)	2 (2%)	6 (2%)	8 (1%)	6 (1%)	0 (0%)
Escherichia coli	10 (18%)	6 (7%)	25 (9%)	50 (9%)	48 (11%)	10 (9%)
Klebsiella oxytoca	0 (0%)	1 (1%)	1 (0%)	3 (1%)	1 (0%)	0 (0%)
Klebsiella pneumoniae	0 (0%)	5 (5%)	11 (4%)	32 (5%)	23 (5%)	3 (3%)
Proteus	0 (0%)	0 (0%)	2 (1%)	9 (2%)	7 (2%)	4 (4%)
Serratia marcescens	0 (0%)	1 (1%)	2 (1%)	9 (2%)	9 (2%)	1 (1%)
Haemophilus influenzae	1 (2%)	2 (2%)	0 (0%)	2 (0%)	2 (0%)	1 (1%)
Neisseria meningitidis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)

FilmArray BCID Result	<1 (n = 57)	1-17 (n = 92)	18-44 (n = 281)	45-64 (n = 583)	65-84 (n = 442)	85+ (n = 113)
Pseudomonas aeruginosa	0 (0%)	4 (4%)	9 (3%)	15 (3%)	18 (4%)	6 (5%)
Yeast						
Candida albicans	0 (0%)	1 (1%)	3 (1%)	11 (2%)	1 (0%)	4 (4%)
Candida glabrata	0 (0%)	0 (0%)	2 (1%)	7 (1%)	4 (1%)	1 (1%)
Candida krusei	0 (0%)	1 (1%)	0 (0%)	2 (0%)	1 (0%)	0 (0%)
Candida parapsilosis	0 (0%)	0 (0%)	2 (1%)	3 (1%)	3 (1%)	0 (0%)
Candida tropicalis	0 (0%)	0 (0%)	2 (1%)	1 (0%)	0 (0%)	0 (0%)
Antimicrobial Resistance Genes						
mecA	24 (42%)	22 (24%)	97 (35%)	175 (30%)	133 (30%)	40 (35%)
vanA/B	0 (0%)	0 (0%)	9 (3%)	14 (2%)	10 (2%)	3 (3%)
KPC	0 (0%)	0 (0%)	1 (<1%)	0 (0%)	5 (1%)	0 (0%)

N. Instrument Name:

FilmArray® 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 the FilmArray barcode scanner.

4. Specimen Sampling and Handling:

   N/A

5. Calibration:

   N/A

6. 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 is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

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