



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

I Background Information:

A 510(k) Number

K193519

B Applicant

BioFire Diagnostics, LLC

C Proprietary and Established Names

BioFire Blood Culture Identification 2 (BCID2) Panel

BioFire BCID2 Panel

BCID2 Panel

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PAM	Class II	21 CFR 866.3365 - Multiplex nucleic acid assay for identification of microorganisms and resistance markers from positive blood cultures	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain a substantial equivalence determination for the for the BioFire Blood Culture Identification 2 (BCID2) Panel.

B Measurand:

Gram Positive Bacteria:

Enterococcus faecalis, *Enterococcus faecium*, *Listeria monocytogenes*, *Staphylococcus* spp. (with specific differentiation of *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Staphylococcus lugdunensis*), *Streptococcus* spp. (with specific differentiation of *Streptococcus*

agalactiae (Group B), *Streptococcus pneumoniae*, and *Streptococcus pyogenes* (Group A))

Gram-negative Bacteria:

Acinetobacter calcoaceticus-baumannii complex, *Bacteroides fragilis*, *Haemophilus influenzae*, *Neisseria meningitidis* (encapsulated), *Pseudomonas aeruginosa*, *Stenotrophomonas maltophilia*, *Enterobacterales* (with specific differentiation of *Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae* group, *Proteus* spp., *Salmonella* spp., and *Serratia marcescens*)

Yeast:

Candida albicans, *Candida auris*, *Candida glabrata*, *Candida krusei*, *Candida parapsilosis*, *Candida tropicalis*, and *Cryptococcus neoformans/gatti*

Resistance Markers:

CTX-M, IMP, KPC, *mcr*-1, *mecA/C*, *mecA/C* and MREJ (MRSA), NDM, OXA-48-like, *vanA/B* and VIM

C Type of Test:

A multiplexed nucleic acid-based test intended for use with the FilmArray 2.0 or FilmArray Torch systems for the qualitative *in vitro* detection and identification of multiple bacterial and yeast nucleic acids and select genetic determinants of antimicrobial resistance. The BCID2 Panel is performed directly on positive blood culture samples identified as positive by a continuous monitoring blood culture system.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The BioFire Blood Culture Identification 2 (BCID2) Panel is a multiplexed nucleic acid test intended for use with FilmArray 2.0 or FilmArray Torch systems for the simultaneous qualitative detection and identification of multiple bacterial and yeast nucleic acids and select genetic determinants associated with antimicrobial resistance. The BioFire BCID2 Panel test is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system. Results are intended to be interpreted in conjunction with Gram stain results.

The following organism types and subtypes are identified using the BioFire BCID2 Panel:

Gram Positive Bacteria: *Enterococcus faecalis*, *Enterococcus faecium*, *Listeria monocytogenes*, *Staphylococcus* spp. (with specific differentiation of *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Staphylococcus lugdunensis*), *Streptococcus* spp. (with specific differentiation

of *Streptococcus agalactiae* (Group B), *Streptococcus pneumoniae*, and *Streptococcus pyogenes* (Group A))

Gram Negative Bacteria: *Acinetobacter calcoaceticus-baumannii* complex, *Bacteroides fragilis*, *Haemophilus influenzae*, *Neisseria meningitidis* (encapsulated), *Pseudomonas aeruginosa*, *Stenotrophomonas maltophilia*, *Enterobacteriales* (with specific differentiation of *Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae* group, *Proteus* spp., *Salmonella* spp., and *Serratia marcescens*)

Yeast: *Candida albicans*, *Candida auris*, *Candida glabrata*, *Candida krusei*, *Candida parapsilosis*, *Candida tropicalis*, and *Cryptococcus neoformans/gatti*

The BioFire BCID2 Panel contains assays for the detection of genetic determinants associated with resistance to methicillin (*mecA/C* and *mecA/C* in conjunction with MREJ), vancomycin (*vanA* and *vanB*), β -lactams including penicillins, cephalosporins, monobactams, and carbapenems (*bla*CTX-M, *bla*IMP, *bla*KPC, *bla*NDM, *bla*OXA48-like, *bla*VIM) to aid in the identification of potentially antimicrobial-resistant organisms in positive blood culture samples. In addition, the panel includes an assay for the detection of the mobilized colistin genetic determinant *mcr-1*, an emerging marker of public health importance. The antimicrobial resistance gene or marker detected may or may not be associated with the agent responsible for disease. Negative results for these select antimicrobial resistance gene and marker assays do not indicate susceptibility, as multiple mechanisms of resistance to methicillin, vancomycin, β -lactams, and colistin exist.

Antimicrobial Resistance Genes: CTX-M, IMP, KPC, *mcr-1*, *mecA/C*, *mecA/C* and MREJ (MRSA), NDM, OXA-48-like, *vanA/B* and VIM

The BioFire BCID2 Panel is indicated as an aid in the diagnosis of specific agents of bloodstream infection and results should be used in conjunction with other clinical and laboratory findings. Positive results do not rule out co-infection with organisms not included in the BioFire BCID2 Panel. The BioFire BCID2 Panel is not intended to monitor treatment for blood stream infection.

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 BioFire BCID2 Panel, and for determination of species detected but not identified within complexes, groups, or genera by the BioFire BCID2 Panel assays.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

For use with the FilmArray 2.0 or FilmArray Torch systems

IV Device/System Characteristics:

A Device Description:

The BioFire Blood Culture Identification 2 (BCID2) Panel is designed to simultaneously identify 43 bacteria, yeast, and select genetic determinants of antimicrobial resistance. The BioFire BCID2 Panel is performed directly on positive blood culture samples. BioFire BCID2 Panel is compatible with BioFire's PCR-based in vitro diagnostic FilmArray 2.0 and FilmArray Torch systems for infectious disease testing. A specific software module (i.e., BioFire BCID2 Panel Pouch Module) is used to perform BioFire BCID2 Panel testing on these systems.

B Principle of Operation:

A test is initiated by loading Hydration Solution into one port of the FilmArray pouch and positive blood culture specimen mixed with the provided Sample Buffer into the other port of the BioFire BCID2 Panel pouch and placing it in a FilmArray instrument. 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 through the steps of placing the pouch into the instrument, scanning the pouch barcode, entering the sample identification, and initiating the run.

The FilmArray instruments contain coordinated systems 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 and chemical lysis followed by purification using 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 reverse transcription PCR (rt-PCR) reaction. 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 on the panel.

V Substantial Equivalence Information:

A Predicate Device Name(s):

FilmArray Blood Culture Identification (BCID) Panel

B Predicate 510(k) Number(s):

K181493

C Comparison with Predicate(s):

Device & Predicate Device(s):	K193519	K181493
Device Trade Name	BioFire Blood Culture Identification 2 (BCID2) Panel	FilmArray Blood Culture Identification (BCID) Panel
General Device Characteristic Similarities		
Intended Use/ Indications for Use	The BioFire Blood Culture Identification 2 (BCID2) Panel is a multiplexed nucleic acid test intended for use with FilmArray 2.0 or FilmArray Torch systems for the simultaneous qualitative detection and identification of multiple bacterial and yeast nucleic acids and select genetic determinants associated with antimicrobial resistance. The BioFire BCID2 Panel test is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system. Results are intended to be interpreted in conjunction with Gram stain results. The following organism types and subtypes are identified using the BioFire BCID2 Panel: Gram-positive Bacteria: <i>Enterococcus faecalis</i>, <i>Enterococcus faecium</i>, <i>Listeria monocytogenes</i>, <i>Staphylococcus</i> spp. (with specific differentiation of <i>Staphylococcus aureus</i>, <i>Staphylococcus epidermidis</i>, and <i>Staphylococcus lugdunensis</i>), <i>Streptococcus</i> spp. (with specific differentiation of <i>Streptococcus agalactiae</i> (Group B), <i>Streptococcus pneumoniae</i>, and <i>Streptococcus pyogenes</i> (Group A)) Gram-negative Bacteria: <i>Acinetobacter calcoaceticus-baumannii</i> complex, <i>Bacteroides fragilis</i>, <i>Haemophilus influenzae</i>, <i>Neisseria meningitidis</i> (encapsulated), <i>Pseudomonas aeruginosa</i>, <i>Stenotrophomonas maltophilia</i>, <i>Enterobacterales</i> (with specific differentiation of <i>Enterobacter cloacae</i>	The FilmArray Blood Culture Identification (BCID) Panel is a qualitative multiplexed nucleic acid-based <i>in vitro</i> diagnostic test intended for use with FilmArray systems. 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 FilmArray BCID Panel assay is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system. Results are intended to be interpreted in conjunction with Gram stain results. The following gram-positive bacteria, gram-negative bacteria, and yeast are identified using the FilmArray BCID Panel: <i>Enterococci</i>, <i>Listeria monocytogenes</i>, <i>Staphylococci</i> (including specific differentiation of <i>Staphylococcus aureus</i>), <i>Streptococci</i> (with specific differentiation of <i>Streptococcus agalactiae</i>, <i>Streptococcus pneumoniae</i>, and <i>Streptococcus pyogenes</i>), <i>Acinetobacter baumannii</i>, <i>Enterobacteriaceae</i> (including specific differentiation of the <i>Enterobacter cloacae</i> complex, <i>Escherichia coli</i>, <i>Klebsiella oxytoca</i>, <i>Klebsiella pneumoniae</i>, <i>Proteus</i>, and <i>Serratia marcescens</i>), <i>Haemophilus influenzae</i>, <i>Neisseria meningitidis</i> (encapsulated), <i>Pseudomonas aeruginosa</i>, <i>Candida albicans</i>, <i>Candida glabrata</i>, <i>Candida krusei</i>, <i>Candida parapsilosis</i>, and <i>Candida tropicalis</i>.

Device & Predicate Device(s):	K193519	K181493
	<i>complex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae</i> group, <i>Proteus</i> spp., <i>Salmonella</i> spp., and <i>Serratia marcescens</i>) Yeast: <i>Candida albicans, Candida auris, Candida glabrata, Candida krusei, Candida parapsilosis, Candida tropicalis,</i> and <i>Cryptococcus neoformans/gatti</i> The BioFire BCID2 Panel contains assays for the detection of genetic determinants associated with resistance to methicillin (<i>mecA/C</i> and <i>mecA/C</i> in conjunction with <i>MREJ</i>), vancomycin (<i>vanA</i> and <i>vanB</i>), β-lactams including penicillins, cephalosporins, monobactams, and carbapenems (<i>bla</i>CTX-M, <i>bla</i>IMP, <i>bla</i>KPC, <i>bla</i>NDM, <i>bla</i>OXA48-like, <i>bla</i>VIM) to aid in the identification of potentially antimicrobial-resistant organisms in positive blood culture samples. In addition, the panel includes an assay for the detection of the mobilized genetic determinant <i>mcr</i>-1, an emerging marker of public health importance. The antimicrobial resistance gene or marker detected may or may not be associated with the agent responsible for disease. Negative results for these select antimicrobial resistance gene and marker assays do not indicate susceptibility, as multiple mechanisms of resistance to methicillin, vancomycin, β-lactams, and colistin exist. Antimicrobial Resistance Genes: CTX-M, IMP, KPC, <i>mcr</i>-1, <i>mecA/C</i>, <i>mecA/C</i> and <i>MREJ</i> (MRSA), NDM, OXA-48-like, <i>vanA/B</i>, VIM The BioFire BCID2 Panel is indicated as an aid in the diagnosis of specific agents of bloodstream infection and results should be used in conjunction with other clinical and laboratory findings. Positive results do not rule out co-infection with organisms not included in the BioFire BCID2 Panel. The BioFire BCID2 Panel is not intended to monitor treatment for blood stream infection. Subculturing of positive blood cultures is	The FilmArray BCID Panel also contains assays for the detection of genetic determinants of resistance to methicillin (<i>mecA</i>), vancomycin (<i>vanA</i> and <i>vanB</i>), and carbapenems (<i>bla</i>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. The FilmArray BCID Panel 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. The FilmArray BCID Panel 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 <i>Staphylococci</i>, <i>Enterococci</i>, <i>Streptococci</i>, and <i>Enterobacteriaceae</i> that are not specifically identified by the FilmArray BCID Panel assays.

Device & Predicate Device(s):	K193519	K181493
	necessary to recover organisms for susceptibility testing and epidemiological typing, to identify organisms in the blood culture that are not detected by the BioFire BCID2 Panel, and for determination of species detected but not identified within complexes, groups, or genera by the BioFire BCID2 Panel assays.	
Specimen Type	Blood culture samples identified as positive by a continuous monitoring blood culture system.	Same
Analyte	DNA	Same
Technological Principles	Highly-multiplexed nested nucleic acid amplification test with melt analysis	Same
Instrumentation	FilmArray 2.0 or FilmArray Torch	FilmArray, FilmArray 2.0, or FilmArray Torch
Time to result	About 1 hour	Same
Reagent Storage	Room temperature	Same
Test Interpretation	Automated test interpretation and report generation. User cannot access raw data.	Same
Controls	Two controls are included in each reagent pouch to control for sample processing and both stages of PCR and melt analysis.	Same
User Complexity	Moderate/Low	Same
General Device Characteristic Differences		
Organisms Detected	<u>Gram-positive Bacteria</u> <i>Enterococcus faecalis</i>, <i>Enterococcus faecium</i>, <i>Listeria monocytogenes</i>, <i>Staphylococcus</i> spp. (with specific differentiation of <i>Staphylococcus aureus</i>, <i>Staphylococcus epidermidis</i>, and <i>Staphylococcus lugdunensis</i>), <i>Streptococcus</i> spp. (with specific differentiation of <i>Streptococcus agalactiae</i> (Group B), <i>Streptococcus pneumoniae</i>, and <i>Streptococcus pyogenes</i> (Group A)) <u>Gram-negative Bacteria</u> <i>Acinetobacter calcoaceticus-baumannii</i> complex, <i>Bacteroides</i>	<u>Gram-positive Bacteria</u> <i>Enterococcus</i> spp., <i>Listeria monocytogenes</i>, <i>Staphylococcus</i> spp.(including specific differentiation of <i>Staphylococcus aureus</i>), <i>Streptococcus</i> spp. (with specific differentiation of <i>Streptococcus agalactiae</i>, <i>Streptococcus pneumoniae</i>, and <i>Streptococcus pyogenes</i>) <u>Gram-negative Bacteria</u> <i>Acinetobacter baumannii</i>, <i>Enterobacteriaceae</i> (including specific

Device & Predicate Device(s):	K193519	K181493
	<i>fragilis</i>, <i>Haemophilus influenzae</i>, <i>Neisseria meningitidis</i> (encapsulated), <i>Pseudomonas aeruginosa</i>, <i>Stenotrophomonas maltophilia</i>, <i>Enterobacterales</i> (with specific differentiation of <i>Enterobacter cloacae</i> complex, <i>Escherichia coli</i>, <i>Klebsiella aerogenes</i>, <i>Klebsiella oxytoca</i>, <i>Klebsiella pneumoniae</i> group, <i>Proteus</i> spp., <i>Salmonella</i> spp., and <i>Serratia marcescens</i>) <u>Yeast</u> <i>Candida albicans</i>, <i>Candida auris</i>, <i>Candida glabrata</i>, <i>Candida krusei</i>, <i>Candida parapsilosis</i>, <i>Candida tropicalis</i>, and <i>Cryptococcus neoformans/gatti</i> <u>Antimicrobial Resistance Genes</u> CTX-M, IMP, KPC, <i>mcr-1</i>, <i>mecA/C</i>, <i>mecA/C</i> and MREJ (MRSA), NDM, OXA-48-like, <i>vanA/B</i>, VIM The BioFire BCID2 Panel is indicated as an aid in the diagnosis of specific agents of bloodstream infection and results should be used in conjunction with other clinical and laboratory findings. Positive results do not rule out co-infection with organisms not included in the BioFire BCID2 Panel. The BioFire BCID2 Panel is not intended to monitor treatment for blood stream infection. 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 BioFire BCID2 Panel, and for determination of species detected but not identified within complexes, groups, or genera by the BioFire BCID2 Panel assays.	differentiation of the <i>Enterobacter cloacae</i> complex, <i>Escherichia coli</i>, <i>Klebsiella oxytoca</i>, <i>Klebsiella pneumoniae</i>, <i>Proteus</i>, and <i>Serratia marcescens</i>, <i>Haemophilus influenzae</i>, <i>Neisseria meningitidis</i> (encapsulated), <i>Pseudomonas aeruginosa</i> <u>Yeast</u> <i>Candida albicans</i>, <i>Candida glabrata</i>, <i>Candida krusei</i>, <i>Candida parapsilosis</i>, <i>Candida tropicalis</i> <u>Antimicrobial Resistance Genes</u> <i>mecA</i> (detects <i>mecA</i> and <i>mecC</i>), <i>vanA/B</i>, and KPC

VI Standards/Guidance Documents Referenced:

General

- Guidance for Industry and Food and Drug Administration Staff – Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices, (August 27, 2014)
- Guidance for Industry and Food and Drug Administrative Staff – Class II Special Control Guideline: Multiplex Nucleic Acid Assay for Identification of Microorganisms and Resistance Markers from Positive Blood Cultures (May 27, 2015)
- 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, Clinical and Laboratory Standards Institute (CLSI) Approved Guideline, MM3-A2 (February 2006)
- Interference Testing in Clinical Chemistry, 3rd Edition, Clinical and Laboratory Standards Institute (CLSI) Approved Guideline, EP07 (April 2018)

Software

- Guidance for Industry and FDA Staff, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- Off-The-Shelf Software Use in Medical Devices, Guidance for Industry and Food and Drug Administration Staff (September 27, 2019) General Principle of Software Validation; Final Guidance for Industry and FDA Staff (January 11, 2002)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Draft Guidance for Industry and Food and Drug Administration Staff (October 18, 2018)

Labeling

- Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use, FDA
- Guidance Document (November 30, 2004)
- Guidance for Industry and FDA on Alternative to Certain Prescription Device Labeling Requirements (January 1, 2000)

FDA-recognized Standards

- ISO 14971:2007 ‘Medical devices – Application of risk management to medical devices’
- EN 62366:2008/IEC 62366-1:2015, ‘Medical device – Application of usability engineering to medical devices’
- EN 13612:2002, ‘Performance evaluation of in vitro diagnostic devices’
- ISO 62304:2006, ‘Medical device software – Software life-cycle processes’ – IEC 62304:2006, November 27, 2008
- ISO 15223-1:2012, ‘Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements’

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

A multi-center study was performed to evaluate the reproducibility of analyte detection on the FilmArray 2.0 and FilmArray Torch systems. The study incorporated potential variation introduced by site (three), day (five), operator (at least two per site), system/module, and reagent kit lot (three). The contrived samples contained representative isolates of aerobic and anaerobic gram-positive and gram-negative bacteria, AMR genes, and yeast in simulated blood culture matrix. Each organism was present in a sample at a concentration consistent with what is observed in a positive blood culture (at positive bottle indication or up to 24 hours after positive bottle indication). Negative results were obtained from samples that were not spiked with the organism or AMR gene.

Each of the three sites tested 20 replicates per sample and system for a total of 120 valid runs per sample and 720 valid runs overall. A summary of the reproducibility of results (percent (%) agreement with the expected Detected, Not Detected or N/A result) for each analyte (by site and system) is provided in Table 1.

Table 1: Reproducibility of the BioFire BCID2 Panel Results on FilmArray 2.0 and FilmArray Torch Systems

Analyte (Type/Species) Source ID	Concentr ation Tested	Expected Result	Expected Result								All Sites/Syste ms [95% Confidence Interval]
			FilmArray 2.0				FilmArray Torch				
			Site A	Site B	Site C	System Total	Site A	Site B	Site C	System Total	
Gram Positive Bacteria											
<i>Enterococcus faecalis</i> ATCC 51299	7.65E+08 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	120/120 100% [97.0%- 100%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
<i>Enterococcus faecium</i> ATCC 27270	9.19E+08 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	120/120 100% [97.0%- 100%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
<i>Listeria monocytogenes</i>	Negative (no analyte)	Not Detected	120/120 (100%)	120/120 (100%)	120/120 (100%)	360/360 (100%)	120/120 (100%)	120/120 (100%)	120/120 (100%)	360/360 (100%)	720/720 100% [99.5%- 100%]
<i>Staphylococcus spp.</i>	Multiple ^a	Detected	59/60 (98.3%)	60/60 (100%)	60/60 (100%)	179/180 (99.4%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	180/180 (100%)	359/360 99.7% [98.5%- 99.9%]

Analyte (Type/Species) Source ID	Concentration Tested	Expected Result	Expected Result								
			FilmArray 2.0				FilmArray Torch				All Sites/Systems [95% Confidence Interval]
			Site A	Site B	Site C	System Total	Site A	Site B	Site C	System Total	
	Negative (no analyte)	Not Detected	60/60 (100%)	60/60 (100%)	60/60 (100%)	180/180 (100%)	60/60 (100%)	60/60 (100%)	60/60 (100%)	180/180 (100%)	360/360 100% [99.0%- 100%]
<i>Staphylococcus aureus</i> ATCC BAA-38	2.44E+08 CFU/mL	Detected	19/20 (95.0%)	20/20 (100%)	20/20 (100%)	59/60 (98.3%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	119/120 99.2% [95.4- 99.9%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
<i>Staphylococcus epidermidis</i> ATCC 12228	2.31E+06 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	19/20 (95.0%)	59/60 (98.3%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	119/120 99.2% [95.4- 99.9%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
<i>Staphylococcus lugdunensis</i> ATCC 43809	1.67E+07 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	120/120 100% [97.0%- 100%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
<i>Streptococcus spp.</i>	Multiple ^b	Detected	40/40 (100%)	40/40 (100%)	40/40 (100%)	120/120 (100%)	40/40 (100%)	40/40 (100%)	40/40 (100%)	120/120 (100%)	240/240 100% [98.4%- 100%]
	Negative (no analyte)	Not Detected	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (100%)	80/80 (100%)	80/80 (100%)	80/80 (100%)	240/240 (100%)	480/480 100% [99.2%- 100%]
<i>Streptococcus agalactiae</i>	Negative (no analyte)	Not Detected	120/120 (100%)	120/120 (100%)	120/120 (100%)	360/360 (100%)	120/120 (100%)	120/120 (100%)	120/120 (100%)	360/360 (100%)	720/720 100% [99.5%- 100%]
<i>Streptococcus pneumoniae</i> ATCC 6303	5.91E+07 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	120/120 100% [97.0%- 100%]

Analyte (Type/Species) Source ID	Concentration Tested	Expected Result	Expected Result								
			FilmArray 2.0				FilmArray Torch				All Sites/Systems [95% Confidence Interval]
			Site A	Site B	Site C	System Total	Site A	Site B	Site C	System Total	
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
<i>Streptococcus pyogenes</i> ATCC 49399	2.63E+07 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	120/120 100% [97.0%- 100%]
	None (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
Gram Negative Bacteria											
<i>Acinetobacter calcoaceticus- baumannii</i> complex (<i>Acinetobacter baumannii</i>) AR Bank 0033	7.36E+07 CFU/mL	Detected	19/20 (95.0%)	19/20 (95.0%)	20/20 (100%)	58/60 (96.7%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	118/120 98.3% [94.1%- 99.8%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
<i>Bacteroides fragilis</i> ATCC 25285	8.62E+08 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	120/120 100% [99.4%- 100%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
<i>Enterobacterales</i>	Multiple ^c	Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
	Negative (no analyte)	Not Detected	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	120/120 100% [97.0%- 100%]
<i>Enterobacter cloacae</i> complex	Negative (no analyte)	Not Detected	120/120 (100%)	120/120 (100%)	120/120 (100%)	360/360 (100%)	120/120 (100%)	120/120 (100%)	120/120 (100%)	360/360 (100%)	720/720 100% [99.5%- 100%]
<i>Escherichia coli</i> CDC-FDA AR Bank #0350	8.79E+08 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	19/20 (95.0%)	59/60 (98.3%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	119/120 99.2% [95.4- %99.9%]

Analyte (Type/Species) Source ID	Concentration Tested	Expected Result	Expected Result								
			FilmArray 2.0				FilmArray Torch				All Sites/Systems [95% Confidence Interval]
			Site A	Site B	Site C	System Total	Site A	Site B	Site C	System Total	
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
<i>Klebsiella aerogenes</i> CDC-FDA AR Bank #0161	9.29E+08 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	120/120 100% [97.0%- 100%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
<i>Klebsiella oxytoca</i> CDC-FDA AR Bank #0147	2.44E+07 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	120/120 100% [97.0%- 100%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
<i>Klebsiella pneumoniae</i> group	Negative (no analyte)	Not Detected	120/120 (100%)	120/120 (100%)	120/120 (100%)	360/360 (100%)	120/120 (100%)	120/120 (100%)	120/120 (100%)	360/360 (100%)	720/720 100% [99.5%- 100%]
<i>Proteus spp.</i> (<i>Proteus mirabilis</i>) GRE 1254053	1.68E+09 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	120/120 100% [97.0%- 100%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
<i>Salmonella spp.</i> (<i>Salmonella enterica</i>) ATCC 700720	1.74E+09 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	120/120 100% [97.0%- 100%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
<i>Serratia marcescens</i> GRE 1659004	3.05E+07 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	120/120 100% [97.0%- 100%]

Analyte (Type/Species) Source ID	Concentration Tested	Expected Result	Expected Result								
			FilmArray 2.0				FilmArray Torch				All Sites/Systems [95% Confidence Interval]
			Site A	Site B	Site C	System Total	Site A	Site B	Site C	System Total	
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
<i>Haemophilus influenzae</i> ATCC 10211	1.32E+08 CFU/mL	Detected	19/20 (95.0%)	20/20 (100%)	20/20 (100%)	59/60 (98.3%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	119/120 99.2% [99.4%- 99.9%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
<i>Neisseria meningitidis</i>	Negative (no analyte)	Not Detected	120/120 (100%)	120/120 (100%)	120/120 (100%)	360/360 (100%)	120/120 (100%)	120/120 (100%)	120/120 (100%)	360/360 (100%)	720/720 100% [99.5%- 100%]
<i>Pseudomonas aeruginosa</i> CDC-FDA AR Bank #0054	7.22E+07 CFU/mL	Detected	19/20 (95.0%)	20/20 (100%)	20/20 (100%)	59/60 (98.3%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	119/120 99.2% [95.4- 99.9%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
<i>Stenotrophomonas maltophilia</i> ATCC 700475	1.13E+09 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	120/120 100% [97.0%- 100%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
Antimicrobial Resistance Genes											
CTX-M (CTX-M- 22) (<i>Proteus mirabilis</i>) GRE 1254053	1.68E+09 CFU/mL	Detected	19/20 (95.0%)	20/20 (100%)	20/20 (100%)	59/60 (98.3%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	119/120 99.2% [95.4- %99.9%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
IMP (IMP-4) (<i>Klebsiella aerogenes</i>) CDC-	9.29E+08 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	120/120 100% [97.0%- 100%]

Analyte (Type/Species) Source ID	Concentration Tested	Expected Result	Expected Result								
			FilmArray 2.0				FilmArray Torch				All Sites/Systems [95% Confidence Interval]
			Site A	Site B	Site C	System Total	Site A	Site B	Site C	System Total	
FDA AR Bank #0161	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
KPC-3 (Klebsiella oxytoca) ATCC 10211	2.44E+07 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	120/120 100% [97.0%- 100%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
mcr-1 (Escherichia coli) CDC-FDA AR Bank #0350	8.79E+08 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	19/20d (95.0%)	59/60 (98.3%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	119/120 99.2% [95.4%- 99.9%]
	Negative (no analyte)	Not Detected or N/A	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
mecA/C	Negative (no analyte)	Not Detected or N/A	120/120 (100%)	120/120 (100%)	120/120 (100%)	360/360 (100%)	120/120 (100%)	120/120 (100%)	120/120 (100%)	360/360 (100%)	720/720 100% [99.5%- 100%]
mecA/C and MREJ (MRSA) (Staphylococcus aureus) ATCC BAA-38	2.44E+08 CFU/mL	Detected	19/20 (95.0%)	20/20 (100%)	20/20 (100%)	59/60 (98.3%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	119/120 99.2% [95.4- 99.9%]
	Negative (no analyte)	N/A	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
NDM (NDM-1)	7.36E+07 CFU/mL	Detected	19/20 (95.0%)	20/20 (100%)	20/20 (100%)	59/60 (98.3%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	119/120 99.2% [95.4- 99.9%]
(Acinetobacter baumannii) CDC-FDA AR Bank #0033	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
OXA-48-like (OXA-48)	3.05E+07 CFU/mL	Detected	19/20 (95.0%)	20/20 (100%)	20/20 (100%)	59/60 (98.3%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	119/120 99.2% [95.4- 99.9%]

Analyte (Type/Species) Source ID	Concentration Tested	Expected Result	Expected Result								
			FilmArray 2.0				FilmArray Torch				All Sites/Systems [95% Confidence Interval]
			Site A	Site B	Site C	System Total	Site A	Site B	Site C	System Total	
(Serratia marcescens) GRE 1659004	Negative (no analyte)	Not Detected or N/A	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
vanA/B (vanB) (Enterococcus faecalis) ATCC 51299	7.65E+08 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	120/120 100% [97.0%- 100%]
	Negative (no analyte)	N/A	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
VIM (VIM-4) (Pseudomonas aeruginosa) CDC-FDA AR Bank #0054	7.22E+07 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	120/120 100% [97.0%- 100%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
Yeast											
Candida albicans ATCC 90028	1.76E+05 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	19/20 (95.0%)	59/60 (98.3%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	119/120 99.2% [95.4%- 99.9%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
Candida auris CDC-FDA AR Bank #0381	3.49E+07 CFU/mL	Detected	19/20 (95.0%)	20/20 (100%)	20/20 (100%)	59/60 (98.3%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	119/120 99.2% [95.4%- 99.9%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
Candida glabrata ATCC 15545	3.82E+07 CFU/mL	Detected	20/20 (100%)	18/20 (90.0%)	20/20 (100%)	58/60 (96.7%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	118/120 98.3% [94.1%- 99.8%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]

Analyte (Type/Species) Source ID	Concentration Tested	Expected Result	Expected Result								
			FilmArray 2.0				FilmArray Torch				All Sites/Syste ms [95% Confidence Interval]
			Site A	Site B	Site C	System Total	Site A	Site B	Site C	System Total	
Candida krusei ATCC 6258	2.48E+05 CFU/mL	Detected	18/20 (90.0%)	20/20 (100%)	20/20 (100%)	58/60 (96.7%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	118/120 98.3% [94.1%- 99.8%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
Candida parapsilosis ATCC 34136	2.91E+05 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	120/120 100% [99.4%- 100%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
Candida tropicalis	Negative (no analyte)	Not Detected	120/120 (100%)	120/120 (100%)	120/120 (100%)	360/360 (100%)	120/120 (100%)	120/120 (100%)	120/120 (100%)	360/360 (100%)	720/720 100% [99.5%- 100%]
Cryptococcus neoformans/gattii (Cryptococcus neoformans) ATCC MYA-4564	1.20E+07 CFU/mL	Detected	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	60/60 (100%)	120/120 100% [99.4%- 100%]
	Negative (no analyte)	Not Detected	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	100/100 (100%)	100/100 (100%)	100/100 (100%)	300/300 (100%)	600/600 100% [99.4%- 100%]
Overall Agreement with the Expected Results (All Analytes/All Test Concentrations) [95% Confidence Interval]			5148/ 5160 99.8% [99.6%- 99.9%]	5157/ 5160 99.9% [99.8%- 99.9%]	5157/ 5160 99.9% [99.8%- 99.9%]	15461/ 15480 99.9% [99.8%- 99.9%]	5160/ 5160 100% [99.9%- 100%]	5160/ 5160 100% [99.9%- 100%]	5160/ 5160 100% [99.9%- 100%]	15480/ 15480 100% [99.9%- 100%]	30941/ 30960 99.94% [99.90%- 99.96%]

^a *Staphylococcus* spp. data are from samples containing *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Staphylococcus lugdunensis* at the concentrations listed in their respective sections.

^b *Streptococcus* spp. data are from samples containing *Streptococcus pneumoniae* and *Streptococcus pyogenes* at the concentrations listed in their respective sections.

^c *Enterobacteriales* data are from samples containing *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Proteus mirabilis*, *Salmonella enterica*, and *Serratia marcescens* at the concentrations listed in their respective sections.

^d One replicate of the *mcr-1* test result was reported as N/A. For this replicate, the MCR-1 assay was positive, but an applicable bacterium was not detected.

2. Linearity:

Not Applicable

3. Analytical Specificity/Interference:

Analytical Reactivity (Inclusivity)

The analytical reactivity of BioFire BCID2 Panel assays was assessed via a combination of *in silico* analysis of sequences available in public databases and testing of over 450 isolates representing the genetic, geographic, and temporal diversity of species, subspecies, and AMR gene types detected by the panel. Isolates were tested in triplicate at concentrations near LoD in simulated blood culture matrix.

Results for each isolate tested as well as *in silico* reactivity predictions for species or AMR gene types that were not tested are shown in Table 2 – Table 44. For isolates that were not detected at the initial near-LoD concentration, additional testing was performed at higher concentrations and the approximate concentration where detection was observed is indicated. In most cases, the detected concentration was equal to or less than the concentration expected in a positive blood culture. Alternately, a Not Detected result is indicated if the isolate was not detected at a concentration equivalent to a positive blood culture level. Additional limitations on reactivity predicted by *in silico* sequence analysis are noted.

Table 2: Results for *Enterococcus faecalis* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
<i>Enterococcus faecalis</i>	ATCC 19433	Type Strain	<i>Enterococcus faecalis</i> Detected
	ATCC 29212	Portland	
	ATCC 49533	UWH/1936	
	ATCC 51299	NJ-3	
	ATCC 700802	V583	
	ATCC BAA-2573	bMx 0502240	
	JMI 12536	MA/2002	

Table 3: Results for *Enterococcus faecium* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
<i>Enterococcus faecium</i>	ATCC 19434	Type Strain	<i>Enterococcus faecium</i> Detected
	ATCC 27270	X3 [F]	
	ATCC 51858	Vancomycin-dependent #4	
	ATCC 700221	-	
	ATCC BAA-2318	-	
	JMI 475	IN/2003	

Table 4: Results for *Listeria monocytogenes* Isolates Tested

Organism	Serotype ^a	Source ID	Strain/Location/Year	Result
<i>Listeria monocytogenes</i>	1/2a	ATCC 15313	Type Strain United Kingdom/1924	<i>Listeria monocytogenes</i> Detected
		ATCC 19111	Li 20 United Kingdom	
	1/2b	ATCC BAA-751	NSB 22072	
	4b	ATCC 13932	1071/53 Germany	
		ATCC 43256	CDC F2380	
	7	NCTC 10890	Li 2482 Germany	

^a Assay reactivity is not serotype dependent, the assay will react with all serotypes (1/2a, 1/2b, 1/2c, 3a, 3b, 3c, 4a, 4b, 4c, 4d, 4e, and 7)

Note: The BioFire BCID2 Panel may be able to detect strains of live, attenuated *Listeria monocytogenes* vaccines used in cancer immunotherapy.

Table 5: Results for Staphylococcus spp. Isolates Tested and Predicted Reactivity for Species Not Tested

Organism		Source ID	Strain/Location/Year	Result
Staphylococcus argensis		In silico prediction (not tested)		Staphylococcus spp. Detected
Staphylococcus arlettae		ATCC 43957	Type strain	
Staphylococcus auricularis		ATCC 33753	Type strain	
Staphylococcus capitis	ssp. capitis	ATCC 27842	-	
	ssp. urealyticus	ATCC 49326	Type strain	
Staphylococcus caprae		ATCC 55133	-	
Staphylococcus carnosus	ssp. carnosus	ATCC 51365	Type strain 1983	
	ssp. cohnii	ATCC 29972	-	
Staphylococcus cohnii	ssp. urealyticus	ATCC 49330	Type strain	
	Staphylococcus condimenti		CCUG 39902T	
Staphylococcus cornubiensis		In silico prediction (not tested)		
Staphylococcus delphini		ATCC 49171	Type strain Italy	
Staphylococcus devriesei		CCUG 58238T	Type Strain Belgium	
Staphylococcus edaphicus		In silico prediction (not tested)		
Staphylococcus epidermidis		ATCC 35984	Tennessee	
Staphylococcus felis		In silico prediction (not tested)		
Staphylococcus gallinarum		ATCC 700401	France	
Staphylococcus haemolyticus		ATCC 29968	-	
Staphylococcus hominis	ssp. hominis	ATCC 25615	-	
	ssp. novobiosepticus	ATCC 700236	Type strain New Jersey1992	
Staphylococcus hyicus		ATCC 11249	Type strain	
Staphylococcus intermedius		ATCC 29663	Type strain	
Staphylococcus kloosii		ATCC 43959	Type strain USA	
Staphylococcus lugdunensis		ATCC 43809	Type strain France	
Staphylococcus lutrae		ATCC 700373	Type strain	
Staphylococcus massiliensis		CCUG 55927T	Type strain France 2005	
Staphylococcus microti		In silico prediction (not tested)		
Staphylococcus nepalensis		CCUG 66326	Sweden 2014	
Staphylococcus pasteurii		ATCC 51127	France	
Staphylococcus petrasii	ssp. jettensis	CCUG 62657T	Type strain Belgium	

Organism		Source ID	Strain/Location/Year	Result
<i>Staphylococcus pettenkoferi</i>		CCUG 70234	Sweden 2017	
<i>Staphylococcus piscifermentans</i>		<i>In silico</i> prediction (not tested)		
<i>Staphylococcus pseudintermedius</i>		ATCC 49444	-	
<i>Staphylococcus pseudolugdunensis</i>		<i>In silico</i> prediction (not tested)		
<i>Staphylococcus saccharolyticus</i>		ATCC 14953	Type strain	
<i>Staphylococcus saprophyticus</i>	ssp. <i>saprophyticus</i>	ATCC 15305	Type strain 1935	
<i>Staphylococcus schleiferi</i>	ssp. <i>coagulans</i>	ATCC 49545	Type strain	
	ssp. <i>schleiferi</i>	ATCC 43808	Type strain France	
<i>Staphylococcus sciuri</i>	ssp. <i>sciuri</i>	ATCC 29061	-	
<i>Staphylococcus simiae</i>		GRE 1562010	Type strain Czech Republic	
<i>Staphylococcus simulans</i>		ATCC 27848	Type strain	
<i>Staphylococcus stepanovicii</i>		<i>In silico</i> prediction (not tested)		
<i>Staphylococcus warneri</i>		ATCC 25614	-	
<i>Staphylococcus xylosus</i>		ATCC 29966	-	
<i>Staphylococcus agnetis</i>		<i>In silico</i> prediction (not tested)		<i>Staphylococcus</i> spp. Detected (≥5.9E+06 CFU/mL)
<i>Staphylococcus argenteus</i> ^a		DSM 28299	Type strain Australia/2006	
<i>Staphylococcus aureus</i> ^a		Multiple isolates	-	
<i>Staphylococcus chromogenes</i>		ATCC 43764	Type strain	
<i>Staphylococcus sciuri</i>	ssp. <i>rodentium</i>	<i>In silico</i> prediction (not tested)		
<i>Staphylococcus succinus</i>	ssp. <i>succinus</i>	ATCC 700337	Type strain Dominican Republic	
<i>Staphylococcus schweitzeri</i> ^a		DSM 28300	Type strain Gabon/2010	
<i>Staphylococcus vitulinus</i>		ATCC 51145	Type strain	
<i>Staphylococcus equorum</i>		ATCC 43958	Type strain Belgium	Not Detected
<i>Staphylococcus fleurettii</i>		DSM 20047	-	
<i>Staphylococcus lentus</i>		ATCC 29070	Type strain France	
<i>Staphylococcus muscae</i>		<i>In silico</i> prediction (not tested)		
<i>Staphylococcus rostri</i>				

^a Also amplified by the *S. aureus* assay at lower concentrations. Will be reported as *Staphylococcus* spp. Detected and *Staphylococcus aureus* Detected

Table 6: Results for *Staphylococcus aureus* Isolates Tested

Organism		Source ID ^a	Strain/Location/Year	PFGE Type/PVL (if known)	Result
<i>Staphylococcus aureus</i>	<i>ssp. anaerobius</i>	ATCC 35844	MVF-7/Spain	unknown	Staphylococcus aureus Detected
	<i>ssp. aureus</i>	ATCC 10832	Wood 46	unknown	
		ATCC 12600	Type strain 1935	unknown	
		ATCC 14154	Rose	unknown	

Organism		Source ID ^a	Strain/Location/ Year	PFGE Type/ PVL (if known)	Result
<i>Staphylococcus aureus</i>		ATCC 25923	Seattle/1945	unknown	
		ATCC 43300	F182/Kansas	unknown	
		NARSA NRS705	NY-12	USA 100	
		ATCC BAA-41	New York/1994	USA 100/PVL-	
		NARSA NRS701	MN-082	USA 200	
		ATCC BAA-1720	MRSA252 United Kingdom	USA 200	
		ATCC BAA-1717	TCH1516/Texas	USA 300	
		NARSA NRS683	GA-298 Georgia/2005	USA 300/PVL+	
		NARSA NRS662	CO-34	USA 300/PVL+	
		NARSA NRS707	NY-155 New York/2005	USA 300/PVL+	
		ATCC BAA-1707	MW2 North Dakota/1998	USA 400	
		NARSA NRS691	GA-62	USA 500	
		NARSA NRS385	-	USA 500	
		NARSA NRS648	CA-347	USA 600	
		NARSA NRS689	GA-442	USA 700	
		NARSA NRS668	CO-72 Colorado/2005	USA 800	
		ATCC BAA-42	HDE288 Portugal/1996	USA 800	
		ATCC BAA-1749	96:308	USA 900	
		ATCC BAA-1759	N7129	USA 900	
		NARSA NRS745	CA-629	USA 1000	
		BEI NR-46081	HIP 12899	USA 1100/PVL+	
		ATCC BAA-1765	102-04	USA 1200	
		ATCC BAA-1700	HFH-33798 Illinois/2004	Not USA 100- 1100	
		ATCC BAA-1691	HFH-30137 Michigan/2003	Not USA 100- 1100	
		ATCC 29213	Wichita	unknown	
		ATCC BAA-38	E2125/Denmark	unknown	
		ATCC BAA-39	HUSA304 Hungary/1993	unknown	
		ATCC BAA-40	CPS22 Portugal/1994	unknown	
		ATCC BAA-44	HPV107 Portugal/1996	PVL-	
		ATCC BAA-2312	M10/0061 Ireland/2010	unknown	
		ATCC BAA-2313	M10/0148	unknown	

Organism	Source ID ^a	Strain/Location/ Year	PFGE Type/ PVL (if known)	Result
		Ireland/2010		
	ATCC BAA-2421	Massachusetts/2010	unknown	
	ATCC BAA-2422	Massachusetts/2010	unknown	<i>Staphylococcus aureus</i> Detected
	GRE 0759084	-	unknown	
	GRE 1055015	-	unknown	
	GRE 0860042	-	unknown	
	GRE 1052034	-	unknown	
	GRE 1151100	-	unknown	
	GRE 0960006	-	unknown	
	GRE 1055017	-	unknown	
	GRE 0759163	-	unknown	
	GRE 1062373	-	unknown	
	GRE 1057114	-	unknown	
	GRE 1062292	-	unknown	
	NARSA NRS686	-	unknown	
	Rennes 1060728	-	unknown	
	Sunnybrook SUN1	Toronto	unknown	
	GRE 1062264 ^b	-	unknown	<i>Staphylococcus aureus</i> Detected^b (≥6.3E+05 CFU/mL)

^a NARSA and BEI isolates sourced by the Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) for distribution by BEI Resources, NIAID, NIH

^b Isolate from private collection with variant sequence under assay primer(s). Similar variant sequences represent ~1% of over 10,000 *S. aureus* sequences evaluated

Table 7: Results for *Staphylococcus epidermidis* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
<i>Staphylococcus epidermidis</i>	ATCC 35984	RP62A Tennessee	<i>Staphylococcus epidermidis</i> Detected
	ATCC 12228	FDA strain/PCI 1200	
	ATCC 29887	255-01B	
	ATCC 35983	RP12 Tennessee	
	ATCC 51625	CCF 15990 Ohio	
	ATCC 700562	1191 Virginia/1997	

Table 8: Results for *Staphylococcus lugdunensis* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
<i>Staphylococcus lugdunensis</i>	ATCC 43809	Type strain France	<i>Staphylococcus lugdunensis</i> Detected
	NCTC 7990	Kelly United Kingdom/1949	
	ATCC 49576	LRA/260.05.79	
	ATCC 700328	6733	
	ATCC 700582	7829 Virginia/1997	

Table 9: Results for *Streptococcus* spp. Isolates Tested and Predicted Reactivity for Species Not Tested

Organism		Source ID	Strain/Location/Year	Result
<i>Streptococcus acidominimus</i>		In silico prediction (not tested)		Streptococcus spp. Detected
<i>Streptococcus agalactiae</i>		ATCC 13813	Type Strain	
<i>Streptococcus anginosus</i>		ATCC 33397	Havil	
<i>Streptococcus australis</i>		ATCC 700641	Type strain Australia/1987	
<i>Streptococcus azizii</i>		In silico prediction (not tested)		
<i>Streptococcus bovimastitidis</i>		In silico prediction (not tested)		
<i>Streptococcus bovis</i>		ATCC 33317	Pearl 11	
<i>Streptococcus caballi</i>		In silico prediction (not tested)		
<i>Streptococcus canis</i>		ATCC 43496	Type strain Belgium/1982	
<i>Streptococcus castoreus</i>		In silico prediction (not tested)		
<i>Streptococcus constellatus</i>		ATCC 27513	VPI 7712	
<i>Streptococcus criceti</i>		In silico prediction (not tested)		
<i>Streptococcus cristatus</i>		ATCC 51100	Type strain United Kingdom	
<i>Streptococcus cuniculi</i>		In silico prediction (not tested)		
<i>Streptococcus devriesei</i>		In silico prediction (not tested)		
<i>Streptococcus didelphis</i>		In silico prediction (not tested)		
<i>Streptococcus downei</i>		In silico prediction (not tested)		
Streptococcus dysgalactiae	ssp. <i>dysgalactiae</i>	ATCC 43078	Type strain United Kingdom/1970	
	ssp. <i>equisimilis</i>	ATCC 12388	Type strain United Kingdom/1970	
	ssp. <i>equisimilis</i>	NCTC 8543	LRA 06 11 76	
<i>Streptococcus equinus</i>		ATCC 9812	Type strain	Streptococcus spp. Detected
<i>Streptococcus ferus</i>		In silico prediction (not tested)		
Streptococcus gallolyticus	ssp. <i>gallolyticus</i>	ATCC BAA-2069	2001	
	ssp. <i>pasteurianus</i>	ATCC 700338	RG 1996	

Organism		Source ID	Strain/Location/Year	Result
Streptococcus gordonii		ATCC 10558	Type strain	
Streptococcus halotolerans		In silico prediction (not tested)		
Streptococcus henryi		In silico prediction (not tested)		
Streptococcus himalayensis		In silico prediction (not tested)		
Streptococcus hongkongensis		In silico prediction (not tested)		
Streptococcus hyointestinalis		In silico prediction (not tested)		
Streptococcus ictaluri		In silico prediction (not tested)		
Streptococcus infantarius	ssp. infantarius	ATCC BAA-102	HDP 90056	
Streptococcus iniae		In silico prediction (not tested)		
Streptococcus intermedius		ATCC 27335	1877	
Streptococcus lactarius		In silico prediction (not tested)		
Streptococcus lutetiensis		In silico prediction (not tested)		
Streptococcus macacae		In silico prediction (not tested)		
Streptococcus marimammalium		In silico prediction (not tested)		
Streptococcus marmotae		In silico prediction (not tested)		
Streptococcus massiliensis		In silico prediction (not tested)		
Streptococcus merionis		In silico prediction (not tested)		
Streptococcus milleri		In silico prediction (not tested)		
Streptococcus minor ^a		In silico prediction (not tested)		
Streptococcus mitis		ATCC 49456	Type strain	
Streptococcus mutans		ATCC 25175	Type Strain	
Streptococcus oligofermentans		In silico prediction (not tested)		
Streptococcus oralis ^a	-	ATCC 10557	SK2	
	ssp. tigurinus	DSM 24864	Type strain Switzerland	
Streptococcus orisasini		In silico prediction (not tested)		
Streptococcus orisratti		In silico prediction (not tested)		
Streptococcus ovis		In silico prediction (not tested)		
Streptococcus parasanguinis		ATCC 31412	Si-1	
Streptococcus parasuis		In silico prediction (not tested)		
Streptococcus parauberis		In silico prediction (not tested)		
Streptococcus pasteurianus		In silico prediction (not tested)		
Streptococcus penaeicida		In silico prediction (not tested)		
Streptococcus peroris		ATCC 700780	Type strain Japan/1990	
Streptococcus phocae		In silico prediction (not tested)		
Streptococcus pluranimalium		In silico prediction (not tested)		
Streptococcus plurextorum		In silico prediction (not tested)		
Streptococcus pneumoniae		ATCC 33400	Type strain	
Streptococcus porci		In silico prediction (not tested)		
Streptococcus porcinus		In silico prediction (not tested)		
Streptococcus pseudopneumoniae		ATCC BAA-960	Type strain Canada/2002	

Organism		Source ID	Strain/Location/Year	Result
<i>Streptococcus pseudoporcinus</i>		<i>In silico</i> prediction (not tested)		<i>Streptococcus</i> spp. Detected
<i>Streptococcus pyogenes</i>		ATCC 49399	QC A62	
<i>Streptococcus ratti</i>		In silico prediction (not tested)		
<i>Streptococcus respiraculi</i>		<i>In silico</i> prediction (not tested)		
<i>Streptococcus ruminantium</i>		<i>In silico</i> prediction (not tested)		
<i>Streptococcus salivarius</i>	-	ATCC 13419	C699	
	<i>ssp. thermophiles</i>	ATCC 19258	Type Strain	
<i>Streptococcus sanguinis</i>		ATCC 10556	Type strain	
<i>Streptococcus sinensis</i>		DSM 14990	HKU4 Hong Kong	
<i>Streptococcys sobrinus</i> ^a		ATCC 33478	Type strain	
<i>Streptococcus suis</i> ^a		ATCC 43765	Type strain	
<i>Streptococcus thoraltensis</i>		<i>In silico</i> prediction (not tested)		
<i>Streptococcus troglodytae</i>		<i>In silico</i> prediction (not tested)		
<i>Streptococcus uberisa</i>		<i>In silico</i> prediction (not tested)		
<i>Streptococcus urinalis</i>		<i>In silico</i> prediction (not tested)		
<i>Streptococcus vestibularis</i>		ATCC 49124	Type strain United Kingdom	
<i>Streptococcus equi</i>	<i>ssp. equi</i>	ATCC 33398	Type strain	<i>Streptococcus</i> spp. Detected (≥7.6E+06 CFU/mL)
	<i>ssp. zooepidemicus</i>	ATCC 43079	Type strain United Kingdom	
<i>Streptococcus entericus</i>		<i>In silico</i> prediction (not tested)		
<i>Streptococcus halitosis</i>				
<i>Streptococcus hyovaginalis</i>				
<i>Streptococcus pantholopis</i>				
Other <i>Streptococcus</i> species		No Sequence (not tested)		Unknown

^a A small percentage of publicly available sequences for this species have sequence variation under assay primer(s) that may have an impact on detection

Table 10: Results for *Streptococcus agalactiae* Isolates Tested

Organism	Serotype ^a	Source ID	Strain/Location/Year	Result
<i>Streptococcus agalactiae</i>	II	ATCC 13813	Type strain	<i>Streptococcus agalactiae</i> Detected
	III	ATCC 12403	Type strain	
	V	ATCC BAA-611	2603 V/R	
	VIII	ATCC BAA-2669	5030-08	
	Unknown	ATCC 12386	Grouping strain	
		NCTC 8017	MK 104 P	
		BF CI-2460	-	

^a Assay reactivity is not serotype-dependent, the assay will react with all serotypes

Table 11: Results for *Streptococcus pneumoniae* Isolates Tested

Organism	Serotype ^a	Source ID	Strain/Location/Year	Result
<i>Streptococcus pneumoniae</i>	3	ATCC 6303	-	<i>Streptococcus pneumoniae</i> Detected
	1	ATCC 33400	Type strain	
	5	ATCC BAA-341	SPN1439-106 Columbia/1995	
	14	ATCC 700672	VH14/Spain	
	11A	NCTC 11900	Gorman	
	19A	ATCC 700673	19A-6 Hungary/1989	
	Non-capsulated	ATCC BAA-255	R6 (non-virulent)	
	unknown	ATCC BAA-1409	62076 Canada/2005	

^a Assay reactivity is not serotype-dependent, the assay will react with all serotypes

Table 12: Results for *Streptococcus pyogenes* Isolates Tested

Organism	Serotype ^a	Source ID	Strain/Location/Year	Result
<i>Streptococcus pyogenes</i>	unknown	ATCC 49399	QC A62	<i>Streptococcus pyogenes</i> Detected
		ATCC 19615	Bruno	
	1	ATCC 12344	Type strain	
		ATCC 700294	SF370/M1 GAS	
		ATCC BAA-947	MGAS 5005 Canada/1996	
	3	ATCC 12384	C203	
		ATCC BAA-595	MGAS 315 Texas 1980's	
	6	ATCC 12348	S43	
	Unknown	Clinical Isolate ^b	Missouri/2019	Not Detected

^a Assay reactivity is not serotype-dependent, the assay will react with all serotypes

^b Isolate of *S. pyogenes* with partial gene deletion

Table 13: Results for *Acinetobacter calcoaceticus-baumannii* complex Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
<i>Acinetobacter baumannii</i>	CDC FDA AR BANK #0033	-	<i>Acinetobacter calcoaceticus-baumannii</i> complex Detected
	ATCC 9955	6-561/Italy	
	ATCC 19606	Type strain	
	ATCC 17961	CDC 7788	
	GRE 1153064	-	
	GRE 1062081	-	
	ATCC 15308	Biol 1 Maryland/1949	
	ATCC 51432	Pennsylvania	

Organism	Source ID	Strain/Location/Year	Result
<i>Acinetobacter calcoaceticus</i>	ATCC 23055	Type strain Netherlands	
	ATCC 14987	HO-1/Iowa	
<i>Acinetobacter nosocomialis</i> (formerly genomospecies 13TU)	ATCC 17903	2210 Rhode Island/1950	
	CCUG 57124	Sweden/2008	
<i>Acinetobacter pittii</i> (formerly genomospecies 3)	ATCC 19004	Type strain United Kingdom/1966	
	ATCC 17922	Pennsylvania	
<i>Acinetobacter seifertii</i>	CCUG 34785	Type strain Denmark	
<i>Acinetobacter nosocomialis</i>	ATCC 700472 ^a	France/1989	Not Detected
<i>Acinetobacter dikshoorniae</i>	No sequence (not tested)		Unknown

^a Sequence data from this isolate suggests that it has been mischaracterized. Sequence data are not consistent with other sequences of *A. nosocomialis* nor with sequences from other species within the *Acinetobacter calcoaceticus-baumannii* complex

Table 14: Results for *Bacteroides fragilis* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
<i>Bacteroides fragilis</i>	ATCC 25285	Type strain United Kingdom/1955	<i>Bacteroides fragilis</i> Detected
	ATCC 29771	2044 Florida/USA	
	ATCC 29768	12256	
	ATCC 43937	F1355	
	ATCC BAA-2283	2-1-56 FAA	

Table 15: Results for *Enterobacterales* Isolates Tested and Predicted Reactivity for Species Not Tested

Genus	Organism	Source ID	Strain/Location/Year	Result
<i>Cedeceae</i>	<i>Cedecea davisae</i>	ATCC 43023	CDC 2819-81 South Carolina	<i>Enterobacterales</i> Detected
	<i>Cedecea neteri</i>	ATCC 33855	Type strain California	
<i>Citrobacter</i>	<i>Citrobacter amalonaticus</i>	ATCC 25405	Type strain	
	<i>Citrobacter braakii</i>	ATCC 51113	Type strain France	
	<i>Citrobacter farmer</i>	ATCC 51112	Type strain New York	
	<i>Citrobacter freundii</i>	ATCC 8090	Type strain	
		CDC FDA AR Bank #0157	-	
	<i>Citrobacter koseri</i>	ATCC 27156	CDC 3613-63	
		ATCC 29223	CDC 1378/74	
	<i>Citrobacter murlinae</i>	ATCC 51118	Type strain	
	<i>Citrobacter sedlakii</i>	ATCC 51115	Type strain France	
	<i>Citrobacter rodentium</i>	<i>In silico</i> prediction (not tested)		
	<i>Citrobacter werkmanii</i>	ATCC 51114	Type strain Belgium	
	<i>Citrobacter youngae</i>	ATCC 29935	Type strain South Carolina	
<i>Cosenzaea</i>	<i>Cosenzaea (Proteus) myxofaciens</i>	ATCC 19692	Type strain	
<i>Cronobacter</i>	<i>Cronobacter condimenti</i>	<i>In silico</i> prediction (not tested)		
	<i>Cronobacter dublinensis</i>	DSM 18706	Type strain Switzerland/2004	
	<i>Cronobacter malonaticus</i>	DSM 18702	Type strain New York	
	<i>Cronobacter muytjensii</i>	DSM 51329	Type strain France	
	<i>Cronobacter sakazakii</i>	ATCC 29544	Type strain	
	<i>Cronobacter turicensis</i>	CCUG 55852	Type strain Switzerland 2005	
<i>Edwardsiella</i>	<i>Edwardsiella anguillarum</i>	<i>In silico</i> prediction (not tested)		<i>Enterobacterales</i> Detected
	<i>Edwardsiella hoshinae</i>	<i>In silico</i> prediction (not tested)		
	<i>Edwardsiella ictaluri</i>	<i>In silico</i> prediction (not tested)		
	<i>Edwardseilla piscicida</i>	<i>In silico</i> prediction (not tested)		
	<i>Edwardsiella tarda</i>	ATCC 15947	Type strain Kentucky	
<i>Enterobacter</i>	<i>Enterobacter bugandensis</i>	DSM 29888	Type strain Tanzania	

Genus	Organism		Source ID	Strain/Location/Year	Result
	<i>Enterobacter cancerogenus</i>		ATCC 35317	Type strain New York	
	<i>Enterobacter roggenkampii</i>		<i>In silico</i> prediction (not tested)		
	<i>Enterobacter soli</i>		ATCC BAA-2102	Type strain Peru	
<i>Escherichia</i>	<i>Escherichia albertii</i>		CCUG 46494	Type strain Bangladesh	
	<i>Escherichia fergusonii</i>		ATCC 35469	Type strain Missouri	
	<i>Escherichia hermanii</i>		ATCC 33650	Type strain Louisiana	
<i>Erwinia</i>	<i>Erwinia billingiae</i>		<i>In silico</i> prediction (not tested)		
<i>Hafnia</i>	<i>Hafnia alvei</i>		ATCC 51815	C2 Minnesota	
	<i>Hafnia paralvei</i>		ATCC 29927	Type strain	
<i>Klebsiella</i>	<i>Klebsiella grimontii</i>		DSM 105630	06D021	
	<i>Klebsiella michiganensis</i>		ATCC BAA-2403	Type strain Michigan	
<i>Kluyvera</i>	<i>Kluyvera ascorbate</i>		CDC FDA AR BANK #0144	-	
	<i>Kluyvera cryocrescens</i>		CCUG 18767T	Type strain	
	<i>Kluyvera georgiana</i>		<i>In silico</i> prediction (not tested)		
	<i>Kluyvera intermedia</i>		ATCC 33110	Type strain	
<i>Kosakonia</i>	<i>Kosakonia cowanii</i>		CCUG 62758	Sweden/2012	
	<i>Kosakonia oryzae</i>		<i>In silico</i> prediction (not tested)		
	<i>Kosakonia radicincitans</i>		<i>In silico</i> prediction (not tested)		
<i>Leclercia</i>	<i>Leclercia adecarboxylata</i>		ATCC 23216	1783	
<i>Lelliottia</i>	<i>Lelliottia amnigena</i>		ATCC 51816	C3	
	<i>Leliottia nimipressuralis</i>		<i>In silico</i> prediction (not tested)		
<i>Mixta</i>	<i>Mixta (Pantoea) gaviniae</i>		CCUG 66381	-	
<i>Morganella</i>	<i>Morganella morganii</i>	ssp. <i>morganii</i>	ATCC 25830	M11	
			CDC FDA AR BANK #0057	-	
		ssp. <i>sibonii</i>	ATCC 49948	CDC 8103-85	

Genus	Organism	Source ID	Strain/Location/Year	Result
<i>Pantoea</i>	<i>Pantoea agglomerans</i>	ATCC 27155	CDC 1461-67	<i>Enterobacterales</i> Detected
	<i>Pantoea ananatis</i>	<i>In silico</i> prediction (not tested)		
	<i>Pantoea septica</i>	CCUG 67124	-	
<i>Phytobacter</i>	<i>Phytobacter ursingii</i>	<i>In silico</i> prediction (not tested)		
<i>Plesiomonas</i>	<i>Plesiomonas shigelloides</i>	ATCC 51572	CIP 69.35	
<i>Pluralibacter</i>	<i>Pluralibacter (Enterobacter) gergoviae</i>	ATCC 33028	CDC 604-77	
<i>Providencia</i>	<i>Providencia alcalifaciens</i>	ATCC 51902	GNI 3	
	<i>Providencia rettgeri</i>	ATCC 9250	NCTC 1501	
	<i>Providencia stuartii</i>	CDC FDA AR Bank #0026	-	
<i>Pseudoescherichia</i>	<i>Pseudoescherichia (Escherichia) vulneris</i>	ATCC 33821	CDC 875-72	
<i>Rahnella</i>	<i>Rahnella aquatilis</i>	ATCC 33071	CUETM 77-115	
<i>Raoultella</i>	<i>Raoultella ornithinolytica</i>	ATCC 31898	AST 111-4	
	<i>Raoultella planticola</i>	ATCC 31900	AST 151-7	
	<i>Raoultella terrigena</i>	ATCC 33257	Type strain	
	<i>Serratia aquatilis</i>	DSM 100980	2015-2462-01	
<i>Serratia</i>	<i>Serratia entomophila</i>	ATCC 43705	Type strain	
	<i>Serratia ficaria</i>	<i>In silico</i> prediction (not tested)		
	<i>Serratia fonticola</i>	ATCC 29844	CUETM 77-165	
	<i>Serratia grimesii</i>	<i>In silico</i> prediction (not tested)		
	<i>Serratia liquefaciens</i>	ATCC 27592	CDC 1284-57	
	<i>Serratia odorifera</i>	ATCC 33077	1073	
	<i>Serratia plymuthica</i>	ATCC 183	K-7	
	<i>Serratia proteamaculans</i>	<i>In silico</i> prediction (not tested)		
	<i>Serratia rubidaea</i>	ATCC 27593	2199-72	
	<i>Sodalis</i>	<i>Sodalis praecaptivus</i>	<i>In silico</i> prediction (not tested)	
<i>Shigella</i>	<i>Shigella boydii</i>	ATCC 9207	AMC 43-G-58	
	<i>Shigella dysenteriae</i>	ATCC 13313	Strain Newcastle	
	<i>Shigella flexneri</i>	CDC FDA AR Bank #0421	-	
	<i>Shigella sonnei</i>	ATCC 29930	WRAIR I virulent	
<i>Tatumella</i>	<i>Tatumella ptyseos</i>	ATCC 33301	H36	
<i>Trabulsiella</i>	<i>Trabulsiella guamensis</i> ^a	ATCC 49490	Type strain	
<i>Yersinia</i>	<i>Yersinia aldovae</i>	<i>In silico</i> prediction (not tested)		
	<i>Yersinia aleksiciae</i>	<i>In silico</i> prediction (not tested)		
	<i>Yersinia enterocolitica</i>	ATCC 9610	33114	
	<i>Yersinia entomophage</i>	<i>In silico</i> prediction (not tested)		
	<i>Yersinia frederiksenii</i>	ATCC 33641	CDC 1461-81	
	<i>Yersinia intermedia</i>	ATCC 33647	CDC 870-77	

Genus	Organism	Source ID	Strain/Location/Year	Result
	<i>Yersinia kristensenii</i>	ATCC 33639	CDC 1459-81	
	<i>Yersinia massiliensis</i>	<i>In silico</i> prediction (not tested)		
	<i>Yersinia mollaretii</i>	ATCC 43969	CDC 2465-87	
	<i>Yersinia pestis</i>	<i>In silico</i> prediction (not tested)		
	<i>Yersinia rohdei</i>	<i>In silico</i> prediction (not tested)		
	<i>Yersinia ruckeri</i>	<i>In silico</i> prediction (not tested)		
	<i>Yersinia similis</i>	<i>In silico</i> prediction (not tested)		
<i>Yokenella</i>	<i>Yokenella regensburgei</i>	ATCC 35313	CDC 3349-72	Enterobacterales Detected
<i>Mixta</i>	<i>Mixta (Pantoea) calida</i>	CCUG 68064 -		Enterobacterales Detected (≥1.1E+07 CFU/mL)
<i>Yersinia</i>	<i>Yersinia pseudotuberculosis</i>	ATCC 29833	NCTC 10275	
<i>Photorabdus</i>	<i>Photorabdus asymbiotica</i>	ATCC 43950	3265-86	Not Detected
<i>Arsenophonus</i>	<i>Arsenophonus nasoniae</i>	<i>In silico</i> prediction (not tested)		
<i>Providencia</i>	<i>Providencia heimbachae</i>	<i>In silico</i> prediction (not tested)		
Other <i>Enterobacterales</i> species		<i>In silico</i> prediction (not tested) or No sequence (not tested)		Detected or Unknown

^a Only tested at high concentration (>1.0E+09 CFU/mL), expected to be detected at positive blood culture levels and lower

Table 16: Results for *Enterobacter cloacae* complex Isolates Tested

Organism		Source ID	Strain/Location/Year	Result
<i>Enterobacter asburiae</i>		GRE 1753006	-	<i>Enterobacter cloacae</i> complex Detected
<i>Enterobacter cloacae</i>	-	CDC FDA AR Bank #0154	-	
		CDC FDA AR Bank #0501	-	
		ATCC 49141	AmMS 204	
		ATCC BAA-2341	1101152	
		NCTC 13464	-	
	<i>ssp. cloacae</i>	ATCC 13047	Type strain	
		ATCC BAA-1143	Entb 55M	
	<i>spp. dissolvens</i>	ATCC 23373D	Type strain	
<i>Enterobacter hormaechei</i>	-	ATCC BAA-2082	-	
	<i>ssp. oharae</i>	CCUG 53905T	Type strain Germany	
	<i>ssp. steigerwaltii</i>	CCUG 53904T	Type strain Belgium	
	<i>ssp. xiangfangensis</i>	DSM 46348	1080M	
<i>Enterobacter kobei</i>		GRE 1753004	-	
<i>Enterobacter ludwigii</i>		CCUG 23050	Sweden	
<i>Enterobacter mori</i>		DSM 26271	Type strain/R18-2	

Organism		Source ID	Strain/Location/Year	Result
<i>Enterobacter asburiae</i>		ATCC 35953	CDC 1497-78 Rhode Island	<i>Enterobacter cloacae</i> complex Detected ($\geq 1.6 \times 10^7$ CFU/mL)
		ATCC 35954	Type strain Maryland	
		ATCC 35955	<i>In silico</i> prediction (not tested)	
		ATCC 35957	CDC 570-83 Hawaii	
		GRE 0758100	-	
<i>Enterobacter hormaechei</i>	<i>ssp. hormaechei</i>	ATCC 49162	Type strain California	

Table 17: Results for *Escherichia coli* Isolates Tested

Organism		Source ID	Strain/Location/Year	Result
<i>Escherichia coli</i>		CDC FDA AR BANK #0061	-	<i>Escherichia coli</i> Detected
		CDC FDA AR BANK #0086	-	
		CDC FDA AR BANK #0137	-	
		CDC FDA AR BANK #0149	-	
		CDC FDA AR BANK #0150	-	
		CDC FDA AR BANK #0346	-	
		CDC FDA AR BANK #0349	-	
		CDC FDA AR BANK #0350	-	
		CDC FDA AR BANK #0495	-	
		ATCC 11775	Type strain	
		ATCC 25922	DA strain Seattle 1946	
		GRE 1062016	-	
		GRE 1256018	-	

Table 18: Results for *Klebsiella aerogenes* Isolates Tested

Organism		Source ID	Strain/Location/Year	Result
<i>Klebsiella aerogenes</i>		CDC FDA AR Bank #0062	-	<i>Klebsiella aerogenes</i> Detected
		CDC FDA AR Bank #0074	-	
		CDC FDA AR Bank #0161	-	
		ATCC 13048	Type strain	
		ATCC 29751	MULB-250	
		GRE 1254066	-	

Table 19: Results for *Klebsiella oxytoca* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
<i>Klebsiella oxytoca</i>	CDC FDA AR Bank #0147	-	<i>Klebsiella oxytoca</i> Detected
	ATCC 8724	NRRL B-199	
	ATCC 13182	Type strain	
	ATCC 43086	Pasco 201 California	
	ATCC 49131	AmMS 101	
	ATCC 700324	LBM 90.11.033-	
	GRE 1254054		
	JMI 2523		
	JMI 7818		

Table 20: Results for *Klebsiella pneumoniae* group Isolates Tested

Organism		Source ID	Strain/Location/Year	Result
<i>Klebsiella pneumoniae</i>	-	GRE 1553001	-	<i>Klebsiella pneumoniae</i> group Detected
		CDC FDA AR Bank #0040	-	
		CDC FDA AR Bank #0068	-	
		CDC FDA AR Bank #0076	-	
		CDC FDA AR Bank #0079	-	
		CDC FDA AR Bank #0080	-	
		CDC FDA AR Bank #0107	-	
		CDC FDA AR Bank #0497	-	
		CDC FDA AR Bank #0525	-	
		ATCC BAA-1705	ART 2008133	
		GRE 1062084	-	
		GRE 1355030	-	
		JMI 766	-	
	ssp. <i>ozanae</i>	CDC FDA AR Bank #0051	-	
		CDC FDA AR Bank #0096	-	
		ATCC 11296	Type strain Sumatra/Indonesia	
	ssp. <i>pneumoniae</i>	ATCC 13883	Type strain	
	ssp. <i>rhinoscleromatis</i>	ATCC 13884	Type strain Sumatra/ Indonesia	

Organism		Source ID	Strain/Location/Year	Result
<i>Klebsiella quasipneumoniae</i>	ssp. <i>similipneumoniae</i>	ATCC 700603	K6	
		DSM 28212	Type strain Germany/1997	
	ssp. <i>quasipneumoniae</i>	DSM 28211	Type strain Austria/1997	
<i>Klebsiella variicola</i>		ATCC BAA-830	Type strain Mexico/2001	

Table 21: Results for *Proteus* spp. Isolates Tested and Predicted Reactivity for Species Not Tested

Organism	Source ID	Strain/Location/Year	Result
<i>Proteus alimentorum</i>	<i>In silico</i> prediction (not tested)		<i>Proteus</i> spp. Detected
<i>Proteus cibarius</i>	<i>In silico</i> prediction (not tested)		
<i>Proteus columbae</i>	<i>In silico</i> prediction (not tested)		
<i>Proteus hauseri</i>	ATCC 13315	strain Lehmann	
	ATCC 700826	Type strain Tennessee	
<i>Proteus mirabilis</i>	CDC FDA AR Bank #0155	-	
	CDC FDA AR Bank #0156	-	
	CDC FDA AR Bank #0159	-	
	ATCC 29906	Type strain	
	ATCC 33583	571101	
	GRE 1254053	-	
<i>Proteus penneri</i>	ATCC 33519	Type strain Illinois	
	ATCC 35197	CDC 1655-67 Maryland	
	ATCC 27973	CDC 1787-64-SC1 Connecticut	
<i>Proteus terrae</i>	<i>In silico</i> prediction (not tested)		
<i>Proteus vulgaris</i>	ATCC 29905	Type strain	

Table 22: Results for *Salmonella* spp. Isolates Tested

Organism (alternate ssp. designation)		Serotype	Source ID	Strain/Location/Year	Result
<i>Salmonella bongori</i> (V)		Brookfield	NCTC 10946	-	<i>Salmonella</i> spp. Detected
		-	SGSC 3100 SARC11	CDC 750-72 1972	
		-	ATCC 43975	Type strain	
<i>Salmonella enterica</i>	ssp. <i>arizonae</i> (IIIa)	-	ATCC 13314	Type strain	
	ssp. <i>diarizonae</i> (IIIb)	-	SGSC 3069 SARC8	CDC 678-94 California/1984	
	ssp. <i>enterica</i> (I)	Concord	CDC FDA AR Bank #0407	-	
		Enteritidis	ATCC BAA-708	-	
		Heidelberg	SGSC 2210 SARA30	Pennsylvania/1987	
		Infantis	ATCC BAA-1675	MZ1479 Senegal	
		Montevideo	ATCC BAA-710	G4639 1993	
		Newport	ATCC 27869	C487-69	
		Senftenberg	CDC FDA AR Bank #0127	-	
		Typhimurium	ATCC 700720	1948	
		Typhimurium	SGSC 3029 SARC1	England/1958	
	ssp. <i>houtenae</i> (IV)	45a,b:g, z51:-	SGSC 3074 SARC9	CDC 2584-68 Panama/1968	
	ssp. <i>indica</i> (VI)	45:a:e,n,x	SGSC 3116 SARC13	CDC 1363-65 India 1965	
	ssp. <i>salamae</i> (II)	42:f:g,t:-	SGSC 3047 SARC4	CDC3472-64 1964	

Table 23: Results for *Serratia marcescens* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
<i>Serratia marcescens</i>	CDC FDA AR Bank #0517	-	<i>Serratia marcescens</i> Detected
	ATCC 27137	CDC 3100-71 Colorado	
	GRE 1659004	-	
	GRE 1659006	-	
	JMI 697	-	
	ssp. <i>marcescens</i>	ATCC 13880 Type strain	
		ATCC 43297 3G Belgium	
	ssp. <i>sakuensis</i>	ATCC BAA-885 Type strain Japan 1992	

Table 24: Results for *Haemophilus influenzae* Isolates Tested

Organism	Serotype ^a	Source ID	Strain/Location/Year	Result
<i>Haemophilus influenzae</i>	Type a	ATCC 9006	AMC 36-A-3	<i>Haemophilus influenzae</i> Detected
	Type b	ATCC 10211	AMC 36-A-1	
	Type c	ATCC 49699	C 9007	
	Type d	ATCC 9008	AMC 36-A-6	
	Type e	ATCC 8142	AMC 36-A-7	
	Type f	ATCC 700223	GA1264/Georgia	
	Non-typeable	ATCC 33391	Type strain United Kingdom/1950	
		ATCC 51907	Rd [KW20]	
		ATCC 51997	INT 1 Missouri	
	Unknown	Clinical Isolate ^b	Utah/2012	Not Detected

^a Assay reactivity is not serotype-dependent, the assay will react with all types and non-typeable isolates

^b Clinical isolate of *H. influenzae* with partial gene deletion

Table 25: Results for *Neisseria meningitidis* Isolates Tested

Organism	Serotype ^a	Source ID	Strain/Location/Year	Result
<i>Neisseria meningitidis</i> (encapsulated)	A	ATCC 13077	M1027 Chicago/1937	<i>Neisseria meningitidis</i> Detected
	B	ATCC 13090	M2092 Massachusetts	
	C	ATCC 13102	M1628 Connecticut/1949	
	D	ATCC 13113	M158/[37A] 1955	
	W-135	ATCC 43744	M-1574 Illinois	
	Y	ATCC 35561	M-112/[BO-6]	

^a Assay reactivity is not serotype-dependent, the assay will react with all serotypes

NOTE: Unencapsulated strains of *Neisseria meningitidis* will not be detected.

Table 26: Results for *Pseudomonas aeruginosa* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
<i>Pseudomonas aeruginosa</i>	CDC FDA AR BANK #0092	-	<i>Pseudomonas aeruginosa</i> Detected
	CDC FDA AR BANK #0054	-	
	CDC FDA AR BANK #0100	-	
	CDC FDA AR BANK #0103	-	
	CDC FDA AR BANK #0239	-	
	ATCC 10145	Type strain Czechoslovakia/1963	
	ATCC 19429	Radlett Feb United Kingdom	
	ATCC 27853	41501 Boston	
	CUSM PS28	-	
	NCTC 13437	United Kingdom	
	ATCC 9027	IFO 13275	<i>Pseudomonas aeruginosa</i> Detected (3.1E+05 CFU/mL)
	ATCC 25619 ^a	-	Not Detected ^a

^a This isolate and a subset of *P. aeruginosa* sequences (<1% of total sequences) have critical mismatches to assay primer(s) and will not be detected

Table 27: Results for *Stenotrophomonas maltophilia* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
<i>Stenotrophomonas maltophilia</i>	ATCC 700475	CIP 104854	<i>Stenotrophomonas maltophilia</i> Detected
	ATCC 700269	WW Washington/1993	
	ATCC BAA-84	D457 Spain	
	ATCC 13637	Type strain United States/1961	
	ATCC BAA-2423	K279a	

Table 28: Results for CTX-M Isolates Tested and Predicted Reactivity for CTX-M Types^a

CTX-M Type	Organism	Source ID	Result
CTX-M-1	<i>Klebsiella oxytoca</i>	GRE 1254054	CTX-M Detected
CTX-M-3	<i>Shigella flexneri</i>	CDC FDA AR BANK #0421	
CTX-M-8	<i>Klebsiella aerogenes</i>	GRE 1254066	
CTX-M-9	<i>Enterobacter cloacae</i>	CDC FDA AR Bank #0501	
CTX-M-14	<i>Escherichia coli</i>	CDC FDA AR Bank #0086	
	<i>Klebsiella pneumoniae</i>	CDC FDA AR Bank #0079	
CTX-M-14, -55	<i>Escherichia coli</i>	CDC FDA AR Bank #0349	
CTX-M-15	<i>Escherichia coli</i>	CDC FDA AR BANK #0137	
	<i>Klebsiella pneumoniae</i> ssp. <i>ozaenae</i>	CDC FDA AR Bank #0051	
	<i>Klebsiella pneumoniae</i>	CDC FDA AR Bank #0068	
	<i>Klebsiella pneumoniae</i>	CDC FDA AR Bank #0040	
	<i>Serratia marcescens</i>	CDC FDA AR Bank #0517	
	<i>Salmonella enterica</i> ssp. <i>enterica</i>	CDC FDA AR Bank #0407	
	<i>Morganella morganii</i>	CDC FDA AR Bank #0057	
CTX-M-22	<i>Proteus mirabilis</i>	GRE 1254053	
	<i>Klebsiella pneumoniae</i>	CDC FDA AR Bank #0107	
CTX-M-25	<i>Enterobacter cloacae</i>	NCTC 13464	
CTX-M-55	<i>Escherichia coli</i>	CDC FDA AR Bank #0346	
CTX-M-124	<i>Kluyvera ascorbata</i>	CDC FDA AR Bank #0144	
In silico Reactivity Predictions			
Detected		Not Detected	Unknown (no sequence)
CTX-M-1 – CTX-M-69 CTX-M-71 – CTX-M-117 CTX-M-121 – CTX-M-127 CTX-M-129 – CTX-M-132 CTX-M-134 CTX-M-136 – CTX-M-139 CTX-M-141 – CTX-M-142 CTX-M-144 CTX-M-146 – CTX-M-148 CTX-M-150 CTX-M-152 CTX-M-155 – CTX-M-229		CTX-M-151	CTX-M-70 CTX-M-119 CTX-M-120 CTX-M-128 CTX-M-133 CTX-M-135 CTX-M-140 CTX-M-143 CTX-M-145 CTX-M-149 CTX-M-153 CTX-M-154

^a Isolates were tested at a concentration near the LoD for CTX-M.

Table 29: Results for IMP Isolates Tested and Predicted Reactivity for IMP Types^a

IMP Type	Organism	Source ID	Result
IMP-1	<i>Pseudomonas aeruginosa</i>	CDC FDA AR Bank #0103	IMP Detected
IMP-4	<i>Acinetobacter baumannii</i>	GRE 1062081	
IMP-4	<i>Escherichia coli</i>	GRE 1062016	
IMP-4	<i>Klebsiella pneumoniae</i>	CDC FDA AR Bank #0080	
IMP-4	<i>Klebsiella aerogenes</i>	CDC FDA AR Bank #0161	
IMP-8	<i>Klebsiella pneumoniae</i>	GRE 1062084	
IMP-14	<i>Pseudomonas aeruginosa</i>	CDC FDA AR Bank #0092	
In silico Reactivity Predictions			
Detected		Not Detected	Unknown (no sequences)
IMP-1 – IMP-30 ^b		IMP-10 ^b	IMP-36
IMP-32 – IMP-34			IMP-47
IMP-37 – IMP-45			IMP-50
IMP-48 – IMP-49			IMP-57
IMP-51 – IMP-56			IMP-65
IMP-58 – IMP-62			
IMP-64			
IMP-66 – IMP-84			

^a Isolates were tested at a concentration near the LoD for IMP.^b A subset of IMP-10 sequences (1/6) have mismatches to the assay primer(s) that may have an impact on detection.**Table 30: Results for KPC Isolates Tested and Predicted Reactivity for KPC Types^a**

KPC Type	Organism	Source ID	Strain/Location/Year	Result
KPC-2	<i>Klebsiella oxytoca</i>	JMI 7818	-	KPC Detected
	<i>Klebsiella pneumoniae</i>	ATCC BAA-1705	ART 2008133	
	<i>Proteus mirabilis</i>	CDC FDA AR Bank #0156	-	
	<i>Serratia marcescens</i>	JMI 697	-	
KPC-3	<i>Escherichia coli</i>	CDC FDA AR Bank #0061	-	
	<i>Klebsiella pneumoniae ssp. ozaenae</i>	CDC FDA AR Bank #0096	-	
	<i>Klebsiella oxytoca</i>	CDC FDA AR Bank #0147	-	
	<i>Serratia marcescens</i>	CDC FDA AR Bank #0517	-	
	<i>Kluyvera ascorbata</i>	CDC FDA AR Bank #0144	-	
KPC-4	<i>Klebsiella pneumoniae</i>	JMI 766	-	
KPC-5	<i>Pseudomonas aeruginosa</i>	Creighton University PS28	-	
KPC-6	<i>Proteus mirabilis</i>	CDC FDA AR Bank #0155	-	
KPC-11	<i>Klebsiella pneumoniae</i>	CDC FDA AR Bank #0525	-	
Unknown	<i>Enterobacter cloacae</i>	ATCC BAA-2341	1101152	
	<i>Enterobacter hormaechei</i>	ATCC BAA-2082	-	
	<i>Klebsiella oxytoca</i>	JMI 2523	-	
In silico Reactivity Predictions				
Detected				
KPC-1 – KPC-46				

^a Isolates were tested at a concentration near the LoD for KPC.

Table 31: Results for *mcr-1* Isolates Tested^a

Organism	Source ID	Result
<i>Escherichia coli</i>	CDC FDA AR Bank #0346	<i>mcr-1</i> Detected
	CDC FDA AR Bank #0349	
	CDC FDA AR Bank#0350	
	CDC FDA AR Bank#0495	
<i>Klebsiella pneumoniae</i>	CDC FDA AR Bank#0497	

Table 32: Results for *mecA/C* in Methicillin-resistant *Staphylococcus epidermidis* Isolates Tested^{a,b}

Organism	Source ID	Strain/Location/Year	Result
<i>Staphylococcus epidermidis</i> (MRSE)	ATCC 29887	255-01B	<i>mecA/C</i> Detected
	ATCC 35983	RP12 Tennessee	
	ATCC 35984	RP62A Tennessee	
	ATCC 51625	CCF 15990 Ohio	
	ATCC 700562	1191 Virginia/1997	

^a No methicillin-resistant isolates of *Staphylococcus lugdunensis* were available for testing.

^b Isolates were tested at a concentration near the LoD for *mecA/C*.

Table 33: Results for *mecA/C* and MREJ (MRSA) in *Staphylococcus aureus* Isolates Tested and Predicted Reactivity for MREJ Types^a

Organism	Source ID ^b	Strain/Location/Year	SCCmec Type/ MREJ Type	Result
<i>Staphylococcus aureus</i>	ATCC BAA-2421 ^c	Mass/2010	SCCmec Type II	<i>mecA/C</i> and MREJ (MRSA) Detected
	NARSA NRS705	NY-12	SCCmec Type II	
	NARSA NRS701	MN-082	SCCmec Type II	
	ATCC BAA-1717	TCH1516	SCCmec Type IV	
	NARSA NRS683	GA-298	SCCmec Type IV	
	NARSA NRS662	CO-34	SCCmec Type IV	
	NARSA NRS707	NY-155	SCCmec Type IV	
	ATCC BAA-1707	MW2	SCCmec Type IV	
	NARSA NRS691	GA-62	SCCmec Type IV	
	NARSA NRS648	CA-347	SCCmec Type II or IV	
	NARSA NRS689	GA-442	SCCmec Type IV	
	NARSA NRS668	CO-72	SCCmec Type IV	
	ATCC BAA-1700	HFH-33798	SCCmec Type IV	
	BEI NR-46081 (NARSA NRS484)	HIP12899	SCCmec Type IV	
	ATCC BAA-1691	HFH-30137	SCCmec Type IV	
	ATCC 43300	F182 Kansas	SCCmec Type II	
	ATCC BAA-2422	-	SCCmec Type II	
	ATCC BAA-1720	-	SCCmec Type II	
	NARSA NRS745	CA-629	SCCmec Type IV or V	
	ATCC BAA-38	-	MREJ Type i	
NARSA NRS686	-			

Organism	Source ID ^b	Strain/Location/Year	SCCmec Type/ MREJ Type	Result
	ATCC BAA-44	-	MREJ Type ii	
	ATCC BAA-41	-		
	NARSA NRS385	-		
	ATCC BAA-42	-		
	ATCC BAA-39	-	MREJ Type iii	
	ACC BAA-40	-	MREJ Type iv	
	GRE 1062264	-	MREJ Type iv	
	GRE 0759084	-	MREJ Type v	
	GRE 1055015	-	MREJ Type vi	
	GRE 0860042	-	MREJ Type vii	
	GRE 1052034	-	MREJ Type ix	
	GRE 1151100	-	MREJ Type xi	
	GRE 0960006	-	MREJ Type xii	
	GRE 1055017	-	MREJ Type xiii	
	GRE 0759163	-	MREJ Type xiv	
	GRE 1057114	-	MREJ Type xvii	
	ATCC BAA-2313 ^d	-	SCCmec Type XI	
	ATCC BAA-2312 ^d	-	SCCmec Type XI	
<i>Staphylococcus aureus</i>	Rennes 1060728 ^e	-	Empty SCCmec cassette	Not Detected
	GRE 1062519 ^e	-	MREJ Type xix	
	GRE 1062373 ^f	-	MREJ Type xv	
	GRE 1062292 ^f	-	MREJ Type xviii	
In silico Reactivity Predictions for MREJ Types				
Detected			Not Detected	Unknown (no sequence)
MREJ Type I,ia MREJ Type ii/xvi MREJ Type iii MREJ Type iv MREJ Type v	MREJ Type vi MREJ Type vii MREJ Type ixg MREJ Type xi MREJ Type xii	MREJ Type xiii MREJ Type xiv MREJ Type xvi MREJ Type xvii MREJ Type xxi	MREJ Type ix ^g MREJ Type xv MREJ Type xviii MREJ Type xix	MREJ Type viii MREJ Type x MREJ Type xx

^a Isolates were tested at a concentration near the LoD for *Staphylococcus aureus*.

^b NARSA/BEI isolates were sourced by the Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) for distribution by BEI Resources, NIAID, NIH.

^c Isolate is characterized as methicillin-sensitive *Staphylococcus aureus* (MSSA) with a non-functional *mecA* variant that is amplified by the *mecA/C* assay.

^d Isolate is characterized as methicillin-resistant *Staphylococcus aureus* (MRSA) with the *mecC* gene.

^e Isolate is characterized as MSSA, which matches the *mecA/C* and MREJ (MRSA) Not Detected result.

^f Isolate is characterized as MRSA, but the MREJ type is not detected by the assay.

^g A subset of MREJ Type ix sequences (2/8) have mismatches to the assay primer(s) that may have an impact on detection.

Table 34: Results for NDM Isolates Tested and Predicted Reactivity for NDM Types^a

NDM Type	Organism	Source ID	Result
NDM-1	<i>Acinetobacter baumannii</i>	CDC FDA AR Bank #0033	NDM Detected
	<i>Salmonella enterica</i>	CDC FDA AR Bank #0127	
	<i>Klebsiella pneumoniae</i>	CDC FDA AR Bank #0068	
	<i>Proteus mirabilis</i>	CDC FDA AR Bank #0159	
NDM-2	<i>Acinetobacter baumannii</i>	GRE 1153064	
NDM-5	<i>Escherichia coli</i>	CDC FDA AR Bank #0150	
NDM-6		CDC FDA AR Bank #0137	
NDM-7		CDC FDA AR Bank #0149	
In silico Reactivity Predictions			
Detected		Not Detected	
NDM-1 – NDM-24 ^{b,c,d}		NDM-1 ^b	
NDM-27 – NDM-29		NDM-4 ^c	
NDM-32		NDM-18 ^d	
NDM-40			

^a Isolates were tested at a concentration near the LoD for NDM.

^b A subset of NDM-1 sequences (5/753) have mismatches to assay primer(s) that may have an impact on detection.

^c A subset of NDM-4 sequences (1/57) have mismatches to assay primer(s) that may have an impact on detection.

^d A subset of NDM-18 sequences (1/3) have mismatches to assay primer(s) that may have an impact on detection.

Table 35: Results for OXA-48-like Isolates Tested and Predicted Reactivity for OXA-48-like Types^a

OXA-48 Like Type	Organism		Source ID		Result
OXA-48	Klebsiella aerogenes		CDC FDA AR Bank #0074		OXA-48-like Detected
OXA-48-like	Serratia marcescens		GRE 1659004		
OXA-162	Klebsiella pneumoniae		GRE 1355030		
OXA-181	Klebsiella pneumoniae		CDC FDA AR Bank #0051		
OXA-232	Klebsiella pneumoniae		CDC FDA AR Bank #0068		
In silico Reactivity Predictions					
Detected			Not Detected ^b		
OXA-48	OXA-244	OXA-515	OXA-54 ^c	OXA-439 ^d	OXA-551 ^d
OXA-48-like	OXA-245	OXA-519	OXA-163 ^d	OXA-517 ^d	OXA-552 ^d
OXA-162	OXA-252	OXA-546	OXA-247 ^d	OXA-535 ^d	OXA-553 ^d
OXA-181	OXA-370	OXA-547	OXA-405 ^d	OXA-538 ^d	OXA-567 ^d
OXA-199	OXA-484	OXA-566	OXA-416 ^c	OXA-548 ^d	OXA-731 ^d
OXA-204	OXA-505		OXA-436 ^d	OXA-549 ^d	
OXA-232	OXA-514		OXA-438 ^d	OXA-550 ^d	

^a Isolates were tested at a concentration near the LoD for OXA-48-like.

^b Non-OXA-48-like types (e.g. OXA-23-like, OXA-40/24-like, OXA-51-like, and OXA-58-like, OXA-143a-like, and OXA-143-like) will not be detected.

^c OXA-48-like progenitor found in *Shewanella* species. The OXAa assay was designed to exclude these types.

^d OXA-48-like types with altered carbapenem hydrolysis activity. The OXAa assay was designed to exclude these variants.

Table 36: Results for vanA/B in Vancomycin-resistant *Enterococcus faecium* and *Enterococcus faecalis* Isolates Tested^a

van Gene	Organism	Source ID	Strain/Location/Year	Result
vanA	<i>Enterococcus faecium</i>	ATCC 700221	-	vanA/B Detected
		JMI 475	IN/2003	
		ATCC BAA-2318		
		ATCC BAA-2573	bMx 0502240	

van Gene	Organism	Source ID	Strain/Location/Year	Result
	<i>Enterococcus faecalis</i>	JMI 12536	MA/2002	
		ATCC 700802	V583	
	<i>Enterococcus faecalis</i>	ATCC 51299	NJ-3	
vanB	<i>Enterococcus faecium</i>	ATCC 51858	Vancomycin- dependent #4	

^a Isolates were tested at a concentration near the LoD for *Enterococcus faecium* and *Enterococcus faecalis*.

Table 37: Results for VIM Isolates Tested and Predicted Reactivity for VIM Types^a

VIM Type	Organism	Source ID	Result
VIM-1	<i>Enterobacter cloacae</i>	CDC FDA AR Bank #0154	VIM Detected
	<i>Klebsiella pneumoniae</i>	CDC FDA AR Bank #0076	
	<i>Enterobacter cloacae</i>	CDC FDA AR Bank #0501	
VIM-2	<i>Pseudomonas aeruginosa</i>	CDC FDA AR Bank #0100	
VIM-4	<i>Pseudomonas aeruginosa</i>	CDC FDA AR-BANK #0054	
VIM-7	<i>Escherichia coli</i>	GRE 1256018	
VIM-10	<i>Pseudomonas aeruginosa</i>	NCTC 13437	
VIM-11	<i>Pseudomonas aeruginosa</i>	CDC FDA AR Bank #0239	
VIM-27	<i>Klebsiella pneumoniae</i>	CDC FDA AR Bank #0040	
In silico Reactivity Predictions			
Detected		Not Detected	Unknown (no sequences)
VIM-1 – VIM-20 ^b VIM-23 – VIM-38 VIM-40 – VIM-44 VIM-47 – VIM-64 VIM-66		VIM-2 ^b VIM-46 VIM-39 VIM-65 VIM-45 VIM-67	VIM-21 VIM-22

^a Isolates were tested at a concentration near the LoD for VIM.

^b A subset of VIM-2 sequences (3/182) have mismatches to assay primer(s) that may have an impact on detection.

Table 38: Results for *Candida albicans* Isolates Tested

Organism	Source ID	Strain	Result
<i>Candida albicans</i>	ATCC 11006	-	<i>Candida albicans</i> Detected
	ATCC 14053	NIH 3172	
	ATCC 22972	M 97	
	ATCC 10231	DSM 1386	
	ATCC 90028	NCCLS 11	
	ATCC MYA-2876	SC5314	

Note: The assay for detection of *C. albicans* amplifies a gene within the mitochondrial genome and 'petite' strains that have lost mitochondrial DNA will not be detected.

Table 39: Results for *Candida auris* Isolates Tested^a

Organism	Source ID	Strain/Location/Year	Result
<i>Candida auris</i>	CDC FDA AR Bank #0381	-	<i>Candida auris</i> Detected
	CDC FDA AR Bank #0383	-	
	CDC FDA AR Bank #0384	-	
	CDC FDA AR Bank #0385	-	

Organism	Source ID	Strain/Location/Year	Result
	CDC FDA AR Bank #0388	-	
	NCPF 8971	Strain 10 (non-aggregative) United Kingdom/2016	
	NCPF 8977	Strain 2 (aggregative) United Kingdom/2016	

^a A subset of *Candida auris* sequences (2/151) have mismatches to assay primer(s) that may have an impact on detection.

Table 40: Results for *Candida glabrata* Isolates Tested

Organism	Source ID	Strain/Year	Result
<i>Candida glabrata</i>	ATCC 2001	Type strain	<i>Candida glabrata</i> Detected
	ATCC 15545	-	
	ATCC 15126	Mutant TMAGR-23	
	ATCC 32554	26247-1	
	ATCC MYZ-2950	303542	
	Clinical Isolate ^a	2018	

^a Isolate characterized as 'petite mutant' with loss of mitochondrial function/mitochondrial DNA.

Note: The assay for detection of *C. glabrata* amplifies a gene within the mitochondrial genome and 'petite' strains that have lost mitochondrial DNA will not be detected.

Table 41: Results for *Candida krusei* Isolates Tested

Organism	Source ID	Strain	Result
<i>Candida krusei</i>	ATCC 6258	Type strain	<i>Candida krusei</i> Detected
	ATCC 14243	-	
	ATCC 28870	CBS 2052	
	ATCC 34135	ST-112	
	ATCC 90878	B74	
	ATCC 201748	89-08-008	

Table 42: Results for *Candida parapsilosis* Isolates Tested

Organism	Source ID	Strain	Result
<i>Candida parapsilosis</i>	ATCC 34136	ST-89	<i>Candida parapsilosis</i> Detected
	ATCC 22019	Type strain	
	ATCC 28475	CBS 2915	
	ATCC 90875	B78	
	ATCC 96138	MC0433	

Note: The assay for detection of *C. parapsilosis* amplifies a gene within the mitochondrial genome and 'petite' strains that have lost mitochondrial DNA will not be detected.

Table 43: Results for *Candida tropicalis* Isolates Tested

Organism	Source ID	Strain/Location	Result
<i>Candida tropicalis</i>	ATCC 750	Type strain	<i>Candida tropicalis</i> Detected
	ATCC 66029	AmMS 227	
	ATCC 90874	B79 Germany	
	ATCC 201380	API 90 01 105	
	ATCC MYA-2734	509-12.1	

Note: The assay for detection of *C. tropicalis* amplifies a gene within the mitochondrial genome and 'petite' strains that have lost mitochondrial DNA will not be detected.

Table 44: Results for *Cryptococcus neoformans/gattii* Isolates Tested

Organism	Serotype/Genotype ^a	Source ID	Strain	Result
<i>Cryptococcus gattii</i>	-	ATCC MYA-4071	WM 276	<i>Cryptococcus neoformans/gattii</i> Detected
	B/VGIIb	ATCC MYA-4094	R272	
	B/VGI	ATCC MYA-4560	WM179	
	B/VGIII	ATCC MYA-4562	WM161	
	C/VGIV	ATCC MYA-4563	WM779	
	VGIIc	ATCC MYA-4877	A6MR38	
<i>Cryptococcus neoformans</i>	-	ATCC 24067	52	
	-	ATCC 32045	Type strain	
	A/VNII	ATCC MYA-4564	WM148	
	AD/VNIII	ATCC MYA-4566	WM628	
	D/VNIV	ATCC MYA-4567	WM629	
	B	ATCC 24065	112	
	A	ATCC 208821b	Type strain	

^a Assay reactivity is not serotype/genotype-dependent, the assay will react with all serotypes and genotypes.

^b Described as *Cryptococcus neoformans* var. *grubii*.

Analytical Specificity (Cross-Reactivity and Exclusivity)

The potential for non-specific amplification and detection by the BioFire BCID2 Panel assays was evaluated by *in silico* analysis of available sequences and by testing of high concentrations of on-panel and off-panel organisms. Each organism was tested in triplicate with most bacteria tested at a concentration $>1.0E+09$ CFU/mL and most yeast tested at a concentration $>1.0E+08$ CFU/mL. Off-panel fungi, viruses, and parasites were tested at the highest cultured concentration possible.

The on-panel organisms tested to assess the potential for intra-panel cross-reactivity are listed in Table 45, with each observed or predicted cross-reactivity indicated. The off-panel organisms tested are listed in Table 46 and the list includes species genetically related to organisms or AMR genes detected by the panel (same genus or otherwise related) as well as unrelated organisms that may be found in blood and/or blood cultures as pathogens or contaminants (e.g. skin microorganisms, viruses, etc.). Off-panel AMR genes were also evaluated, and all observed or predicted cross-reactivities are indicated. Erroneous results due to cross-reactivity with organisms that were not evaluated or due to cross-reactivity with emerging or novel sequences are also possible.

Table 45: On-Panel Organisms and AMR Genes Tested for Evaluation of BioFire BCID2 Panel Analytical Specificity Elevated risk of cross-reactivity was observed for the species in bold.

ON-PANEL			
Gram Positive Bacteria			
<i>Enterococcus faecalis</i>	<i>Staphylococcus intermedius</i>	<i>Staphylococcus xylosus</i>	<i>Streptococcus mitis</i>
<i>Enterococcus faecium</i>	<i>Staphylococcus lentus</i>	<i>Streptococcus agalactiae</i>	<i>Streptococcus mutans</i>
<i>Listeria monocytogenes</i>	<i>Staphylococcus lugdunensis</i>	<i>Streptococcus anginosus</i>	<i>Streptococcus oralis</i>

ON-PANEL			
<i>Staphylococcus argenteus</i> ^a	<i>Staphylococcus lutrae</i>	<i>Streptococcus australis</i>	<i>Streptococcus parasanguinis</i>
<i>Staphylococcus aureus</i> (MRSA)	<i>Staphylococcus nepalensis</i>	<i>Streptococcus bovis</i>	<i>Streptococcus pneumoniae</i>
<i>Staphylococcus auricularis</i>	<i>Staphylococcus pasteurii</i>	<i>Streptococcus canis</i>	<i>Streptococcus pseudopneumoniae</i>
<i>Staphylococcus capitis</i>	<i>Staphylococcus pettenkoferi</i>	<i>Streptococcus constellatus</i>	<i>Streptococcus pyogenes</i>
<i>Staphylococcus caprae</i>	<i>Staphylococcus pseudintermedius</i>	<i>Streptococcus cristatus</i>	<i>Streptococcus salivarius</i>
<i>Staphylococcus carnosus</i>	<i>Staphylococcus saprophyticus</i>	<i>Streptococcus dysgalactiae</i>	<i>Streptococcus sanguinis</i>
<i>Staphylococcus cohnii</i>	<i>Staphylococcus schleiferi</i>	<i>Streptococcus equi</i>	<i>Streptococcus sobrinus</i>
<i>Staphylococcus epidermidis</i> (MRSE)	<i>Staphylococcus schweitzeri</i>^a	<i>Streptococcus equinus</i>	<i>Streptococcus suis</i>
<i>Staphylococcus equorum</i>	<i>Staphylococcus sciuri</i>	<i>Streptococcus gallolyticus</i>	<i>Streptococcus vestibularis</i>
<i>Staphylococcus haemolyticus</i>	<i>Staphylococcus simulans</i>	<i>Streptococcus gordonii</i>	
<i>Staphylococcus hominis</i>	<i>Staphylococcus warneri</i>	<i>Streptococcus intermedius</i>	
Gram Negative Bacteria			
<i>Acinetobacter baumannii</i>	<i>Enterobacter mori</i>	<i>Metakosakonia massiliensis</i>	<i>Salmonella typhimurium</i>
<i>Acinetobacter calcoaceticus</i>	<i>Enterobacter soli</i>	<i>Mixta calida</i>	<i>Serratia entomophila</i>
<i>Acinetobacter nosocomialis</i> ^b	<i>Erwinia billingiae</i>	<i>Mixta gaviniae</i>	<i>Serratia ficaria</i>
<i>Acinetobacter pittii</i>	<i>Escherichia albertii</i>^e	<i>Morganella morganii</i>	<i>Serratia fonticola</i>
<i>Acinetobacter seifertii</i>	<i>Escherichia coli</i>	<i>Neisseria meningitidis</i>	<i>Serratia liquefaciens</i>
<i>Bacteroides fragilis</i>	<i>Escherichia fergusonii</i>^f	<i>Pantoea agglomerans</i>	<i>Serratia marcescens</i>
<i>Cedecea davisae</i>	<i>Escherichia hermannii</i>	<i>Pantoea septica</i>	<i>Serratia odorifera</i>
<i>Citrobacter braakii</i>	<i>Haemophilus influenzae</i>	<i>Photorhabdus asymbiotica</i>	<i>Serratia plymuthica</i>
<i>Citrobacter freundii</i>	<i>Hafnia alvei</i>	<i>Plesiomonas shigelloides</i> ^h	<i>Serratia rubidaea</i>
<i>Citrobacter koseri</i>	<i>Hafnia paralvei</i>	<i>Pluralibacter gergoviae</i>	<i>Shigella boydii</i>^f
<i>Cosenzaea myxofaciens</i>^c	<i>Klebsiella aerogenes</i>	<i>Proteus hauseri</i>	<i>Shigella dysenteriae</i>^f
<i>Cronobacter malonaticus</i>	<i>Klebsiella grimontii</i>^g	<i>Proteus mirabilis</i>	<i>Shigella flexneri</i>^f
<i>Cronobacter sakazakii</i>	<i>Klebsiella michiganensis</i>^g	<i>Proteus penneri</i>	<i>Shigella sonnei</i>^f
<i>Cronobacter turicensis</i>	<i>Klebsiella oxytoca</i>	<i>Proteus vulgaris</i>	<i>Shimwellia blattae</i>
<i>Edwardsiella tarda</i>	<i>Klebsiella pneumoniae</i>	<i>Providencia stuartii</i>	<i>Stenotrophomonas maltophilia</i>
<i>Enterobacter asburiae</i>	<i>Klebsiella quasipneumoniae</i>	<i>Pseudoescherichia vulneris</i>	<i>Tatumella ptyseos</i>
<i>Enterobacter bugandensis</i>^d	<i>Klebsiella variicola</i>	<i>Pseudomonas aeruginosa</i>	<i>Trabulsiella guamensis</i>ⁱ
<i>Enterobacter cancerogenus</i>	<i>Kluyvera ascorbata</i>	<i>Rahnella aquatilis</i>	<i>Yersinia enterocolitica</i>

ON-PANEL			
<i>Enterobacter cloacae</i>	<i>Kluyvera intermedia</i>	<i>Raoultella ornithinolytica</i>	<i>Yersinia frederiksenii</i>
<i>Enterobacter hormaechei</i>	<i>Kosakonia cowanii</i>	<i>Raoultella planticola</i>	<i>Yersinia pestis</i>
<i>Enterobacter hormaechei</i> subsp. <i>xiangfangensis</i> (aka <i>Enterobacter xiangfangensis</i>)	<i>Leclercia adecarboxylata</i>	<i>Raoultella terrigena</i>	<i>Yersinia psuedotuberculosis</i>
<i>Enterobacter kobei</i>	<i>Lelliottia amnigena</i>	<i>Salmonella bongori</i>	<i>Yokenella regensburgei</i>
<i>Enterobacter ludwigii</i>	<i>Lelliottia nimipressuralis</i>	<i>Salmonella enterica</i>	
Yeast			
<i>Candida albicans</i>	<i>Candida glabrata</i>	<i>Candida parapsilosis</i>^j	<i>Cryptococcus gattii</i>
<i>Candida auris</i>	<i>Candida krusei</i>	<i>Candida tropicalis</i>^k	<i>Cryptococcus neoformans</i>
Antimicrobial Resistance Genes			
CTX-M	<i>mcr-1</i>	NDM	VIM
IMP	<i>mecA/C</i>	OXA-48-like	
KPC	<i>mecA/C</i> and MREJ (MRSA)	<i>vanA/B</i>	

^a Detected as *Staphylococcus aureus* (*mecA/C* and MREJ (MRSA) also detected for *S. argenteus*); members of the *Staphylococcus aureus* complex.

^b Risk of amplification by KPC assay predicted by sequence analysis; not observed when tested at 8.7E+09 CFU/mL.

^c Detected as *Proteus* spp. at $\geq 8.8E+06$ CFU/mL. Nonpathogenic bacterium isolated from gypsy moths; formerly classified as *Proteus*.

^d Detected as *Enterobacter cloacae* complex; newly described species.

^e Detected as *Escherichia coli* at $\geq 8.0E+08$ CFU/mL.

^f Detected as *Escherichia coli*.

^g Detected as *Klebsiella oxytoca*; *Klebsiella grimontii* was formerly classified as *K. oxytoca* phylogroup Ko6.

^h Risk of amplification by Salmonella assay predicted by sequence analysis; not observed when tested at 7.4E+09 CFU/mL.

ⁱ Detected as *Enterobacter cloacae* complex at $\geq 9.0E+07$ CFU/mL.

^j Detected as *Candida tropicalis* at $\geq 2.8E+07$ CFU/mL.

^k Detected as *Candida parapsilosis* at $\geq 6.3E+07$ CFU/mL.

Table 46: Off-Panel Organisms and AMR Genes Tested for Evaluation of BioFire BCID2
Panel Analytical Specificity Elevated risk of cross-reactivity was observed for the species in bold.

OFF-PANEL			
Gram Positive Bacteria			
<i>Acintomyces naeslundii</i>	<i>Corynebacterium jeikeium</i>	<i>Enterococcus raffinosus</i>	<i>Micrococcus luteus</i>
<i>Actinomyces israelii</i>	<i>Corynebacterium striatum</i>	<i>Gemella morbillorum</i>	<i>Mycoplasma hominis</i>
<i>Actinomyces odontolyticus</i>	<i>Corynebacterium urealyticum</i>	<i>Granulicatella adiacens^a</i>	<i>Mycoplasma pneumoniae</i>
<i>Aerococcus viridans^a</i>	<i>Cutibacterium acnes</i>	<i>Kocuria kristinae</i>	<i>Nocardia farcinica</i>
<i>Arcanobacterium haemolyticum</i>	<i>Enterococcus avium</i>	<i>Lactobacillus acidophilus</i>	<i>Peptostreptococcus anaerobius</i>
<i>Bacillus cereus</i>	<i>Enterococcus casseliflavus</i>	<i>Lactococcus lactis</i>	<i>Rhodococcus equi</i>
<i>Bacillus licheniformis</i>	<i>Enterococcus cecorum</i>	<i>Listeria grayi</i>	<i>Rothia mucilaginosa</i>
<i>Bacillus subtilis</i>	<i>Enterococcus dispar</i>	<i>Listeria innocua</i>	<i>Sarcina ventriculi</i>
<i>Clostridioides difficile</i>	<i>Enterococcus durans</i>	<i>Listeria ivanovii</i>	<i>Solibacillus silvestris</i>
<i>Clostridium perfringens</i>	<i>Enterococcus gallinarum</i>	<i>Listeria seeligeri</i>	<i>Ureaplasma parvum</i>
<i>Clostridium tetani</i>	<i>Enterococcus hirae</i>	<i>Listeria welsimeri</i>	<i>Ureaplasma urealyticum</i>

OFF-PANEL			
<i>Corynebacterium diphtheria</i>	<i>Enterococcus mundtii</i>	<i>Macrococcus caseolyticus</i>	<i>Vagococcus fluvialis</i>
Gram Negative Bacteria			
<i>Acinetobacter baylyi</i>	<i>Bacteroides uniformis</i>	<i>Kingella kingae</i>	<i>Pseudomonas fluorescens</i>
<i>Acinetobacter bereziniae</i>	<i>Bacteroides vulgatus</i>	<i>Kingella negevensis</i>	<i>Pseudomonas luteola</i>
<i>Acinetobacter guillouiae</i>	<i>Bordetella bronchiseptica</i>	<i>Kingella oralis</i>	<i>Pseudomonas nitroreducens</i>
<i>Acinetobacter haemolyticus</i>	<i>Bordetella parapertussis</i>	<i>Legionella pneumophila</i>	<i>Pseudomonas oleovorans</i>
<i>Acinetobacter johnsonii</i>	<i>Bordetella pertussis</i>	<i>Leptospira interrogans</i>	<i>Pseudomonas oryzihabitans</i>
<i>Acinetobacter junii</i>	<i>Burkholderia cepacia</i>	<i>Moraxella catarrhalis</i>	<i>Pseudomonas pertucinogena</i>
<i>Acinetobacter lwoffii</i>	<i>Burkholderia mallei</i>	<i>Moraxella osloensis</i>	<i>Pseudomonas putida</i>
<i>Acinetobacter parvus</i>	<i>Burkholderia multivorans</i>	<i>Mycobacterium tuberculosis</i>	<i>Pseudomonas stutzeri</i>
<i>Acinetobacter radioresistens</i>	<i>Burkholderia pseudomallei</i>	<i>Neisseria gonorrhoeae</i>	<i>Pseudomonas veronii</i>
<i>Acinetobacter schindleri</i>^b	<i>Campylobacter hominis</i>	<i>Neisseria lactamica</i>	<i>Psychrobacter cryohalolentis</i>
<i>Acinetobacter soli</i>	<i>Chlamydia trachomatis</i>	<i>Neisseria meningitidis</i> (unencapsulated)	<i>Psychrobacter immobilis</i>
<i>Acinetobacter ursingii</i>	<i>Chlamydophila pneumoniae</i>	<i>Neisseria mucosa</i>	<i>Ralstonia mannitolilytica</i>
<i>Acintobacillus ureae</i>	<i>Chromobacterium violaceum</i>	<i>Neisseria sicca</i>	<i>Ralstonia pickettii</i>
<i>Aggregatibacter actinomycetemcomitans</i>	<i>Eikenella corrodens</i>	<i>Parabacteroides distasonis</i>	<i>Stenotrophomonas acidiminiphila</i>
<i>Actinobacillus hominis</i>	<i>Haemophilus aegyptius</i>^d	<i>Pasteurella aerogenes</i>	<i>Stenotrophomonas nitritireducens</i>
<i>Aeromonas caviae</i>	<i>Haemophilus ducreyi</i>	<i>Pasteurella canis</i>	<i>Stenotrophomonas rhizophila</i>
<i>Aeromonas hydrophila</i>	<i>Haemophilus haemolyticus</i>	<i>Pasteurella multocida</i>	<i>Treponema pallidum</i>
<i>Aeromonas sobria</i>	<i>Haemophilus parahaemolyticus</i>	<i>Pasteurella stomatis</i>	<i>Veillonella parvula</i>
<i>Aggregatibacter aphrophilus</i>	<i>Haemophilus parainfluenzae</i>	<i>Prevotella melaninogenica</i>	<i>Vibrio alginolyticus</i>
<i>Bacteriodes xylanisolvens</i>^c	<i>Haemophilus parasuis</i>	<i>Prevotella oralis</i>	<i>Vibrio parahaemolyticus</i>
<i>Bacteroides caccae</i>	<i>Haemophilus quentini</i>	<i>Pseudomonas alcaligenes</i>	<i>Vibrio vulnificus</i>
<i>Bacteroides ovatus</i>	<i>Haemophilus sputorum</i>	<i>Pseudomonas citronellolis</i>	
<i>Bacteroides thetaiotaomicron</i>	<i>Kingella denitrificans</i>	<i>Pseudomonas mendocina</i>	
Yeast			
<i>Aspergillus flavus</i>	<i>Candida kefyr</i>	<i>Coccidioides posadasii</i>	<i>Millerozyma farinosa</i>

OFF-PANEL			
	(<i>Kluyveromyces marxianus</i>)		(<i>Candida cacaoi</i>)
<i>Aspergillus fumigatus</i> ^f	<i>Candida lusitaniae</i> (<i>Clavispora lusitaniae</i>)	<i>Cryptococcus amyloletus</i>^j	<i>Naganishia albida</i> (<i>Cryptococcus albidus</i>)
<i>Aspergillus niger</i>	<i>Candida metapsilosis</i>	<i>Cryptococcus uniguttulatus</i>	<i>Papiliotrema laurentii</i> (<i>Cryptococcus laurentii</i>)
<i>Aspergillus terreus</i>	<i>Candida multis-gemmis</i>	<i>Cutaneotrichosporon curvatum</i> (<i>Cryptococcus curvatus</i>)	<i>Penicillium chrysogenum</i>
<i>Blastomyces dermatitidis</i>	<i>Candida nivariensis</i>ⁱ	<i>Cyberlindnera fabianii</i> (<i>Candida fabianii</i>)	<i>Rhodotorula mucilaginosa</i>
<i>Candida dubliniensis</i>	<i>Candida norvegensis</i> (<i>Pichia norvegensis</i>) ^h	<i>Histoplasma capsulatum</i>	<i>Saccharomyces cerevisiae</i>
<i>Candida famata</i> (<i>Debaryomyces hansenii</i>) ^g	<i>Candida orthopsilosis</i>	<i>Kluyveromyces lactis</i>	<i>Schizosaccharomyces pombe</i>
<i>Candida guilliermondii</i> (<i>Meyerozyma guilliermondii</i> , <i>Pichia guilliermondii</i>)	<i>Candida sojae</i>	<i>Kodameae ohmeri</i>	<i>Talaromyces marneffeii</i>
<i>Candida haemulonii</i>	<i>Candida viswanthii</i>	<i>Lodderomyces elongisporus</i>	<i>Trichosporon asahii</i>
<i>Candida inconspicua</i> (<i>Pichia cactophila</i>) ^h	<i>Coccidioides immitis</i>	<i>Magnusiomyces capitatus</i>	<i>Wickerhamomyces anomalus</i>
Viruses			
Chikungunya Virus	Hepatitis B virus	Human Herpes Virus-7	Varicella Zoster Virus
Cytomegalovirus	Hepatitis C virus	Measles Virus	West Nile Virus
Dengue Virus	Human Immunodeficiency Virus	Mumps Virus	Zika Virus
Enterovirus	Herpes Simplex Virus Type 1	Parvovirus B19	
Epstein Barr Virus	Herpes Simplex Virus Type 2	Polyoma Virus	
Hepatitis A virus	Human Herpes Virus-6	Rubella Virus	
Parasites			
<i>Plasmodium falciparum</i>		<i>Trypanosoma cruzi</i>	

OFF-PANEL			
Antimicrobial Resistance Genes			
<i>AmpC</i>	<i>mcr-3</i>	<i>SHV</i>	<i>vanC</i>
<i>blaRAHN k</i>	<i>mcr-4</i>	<i>SME</i>	<i>vanD</i>
<i>CMY</i>	<i>ompK36</i>	<i>SPM</i>	<i>vanM</i>^l
<i>mcr-2</i>	<i>OXA-24/65</i>	<i>TEM</i>	

^a Risk of amplification by the Staphylococcus assay predicted by sequence analysis; not detected when tested at 3.0E+08 cells/mL (*G. adiacens*) or >6.0E+09 CFU/mL (*A. viridans* and *E. cecorum*). Similar risk predicted for *Aerococcus christensenii* and *Aerococcus sanguinicola*; not tested.

^b Risk of amplification by the CTX-M assay at ≥8.1E+09 CFU/mL; will not be detected unless an applicable bacterium is also detected.

^c Detected as *Bacteroides fragilis* at ≥8.2E+06 cells/mL. Similar risk predicted for *Bacteroides caccae*; not tested.

^d Detected as *Haemophilus influenzae*; also described as *Haemophilus influenzae* biogroup *aegyptius*.

^e Risk of amplification by KPC assay predicted by sequence analysis; not observed when tested at 7.8E+09 CFU/mL.

^f Risk of amplification by the Bfragilis assay predicted by sequence analysis; not observed when tested at 5.0E+08 CFU/mL. Similar risk predicted for *Aspergillus lentulus* and *Aspergillus viridinutans*; not tested.

^g Risk of amplification by the Ckrusei assay predicted by sequence analysis; not observed when tested at 8.9E+08 CFU/mL. Similar risk predicted for other yeast species; not tested.

^h Detected as *Candida krusei* at ≥3.7E+05 CFU/mL. Similar risk predicted for *Pichia pseudocactophila* and *Pichia cactophila*; not tested.

ⁱ Detected as *Candida glabrata* at ≥8.0E+06 CFU/mL. *Candida glabrata* complex species; similar risk predicted for *Candida bracarensis*; not tested.

^j Detected as *Cryptococcus neoformans/gattii*; nonpathogenic fungus isolated from beetles.

^k Risk of amplification by the CTX-M assay predicted by sequence analysis; not observed when *Rahnella aquatilis* was tested at 7.8E+09 CFU/mL. Similar risk predicted for *ampC* in *Leminorella* species, *blaOXY*, and *blaKLUC*; not tested.

^l Not tested; predicted to be detected as *vanA/B* if an applicable bacterium is also detected.

Interference

Potentially interfering substances that could be present in blood culture specimens were evaluated for their effect on BioFire BCID2 Panel performance. The substances tested included endogenous blood components (e.g. albumin, gamma-globulin, human genomic DNA), exogenous substances (e.g. prescribed or over-the-counter medications, blood anticoagulants, substances used to decontaminate or disinfect work areas, etc.), potentially competing commensal or infectious microorganisms, and various bottle/culture media.

Each substance was added to contrived samples containing representative panel organisms at concentrations near LoD (at least 10-fold lower than organism concentrations in a positive blood culture). The concentration of the substances or competing microorganisms added to the samples was equal to or greater than the highest level expected be in a blood culture. Valid and accurate results were obtained for each sample containing endogenous and exogenous substances as well as various anticoagulants and disinfectants at the concentrations indicated in Table 47.

Table 47: Interference Substance Test Concentrations

Substance Tested	Reference Range in Whole Blood ^a	Concentration Expected in Positive Blood Culture ^b	Test Concentration
Endogenous Substances			
Albumin	35 – 52 mg/mL	7.0 – 10.4 mg/mL	15 mg/mL ^c
Bilirubin (unconjugated)	0.0 – 0.2 mg/mL	0.00 – 0.04 mg/mL	0.40 mg/mL
Cholesterol	<2.0 mg/mL	<0.4 mg/mL	4.0 mg/mL
Fibrinogen	1.6 – 4.3 mg/mL ^d	0.32 – 0.86 mg/mL	4.3 mg/mL

Substance Tested	Reference Range in Whole Blood ^a	Concentration Expected in Positive Blood Culture ^b	Test Concentration
Gamma-globulin	7 – 16 mg/mL ^e	1.4 – 3.2 mg/mL	20 mg/mL
D-Glucose	0.74 – 1.00 mg/mL	0.15 – 0.20 mg/mL	10 mg/mL
Hemoglobin	<0.03 mg/mL	<0.006 mg/mL	10 mg/mL
Magnesium (MgSO ₄)	0.017 – 0.024 mg/mL	0.0034 – 0.0048 mg/mL	0.1 mg/mL
Triglycerides	<1.50 mg/mL	<0.30 mg/mL	15 mg/mL
Human Genomic DNA (e.g. nucleic acids from white blood cells)	4.0E+06 – 1.0E+07 cells/mL	8.0E+05 – 2.0E+06 cells/mL	0.07 mg/mL (1.0E+07 cells/mL) ^f
Exogenous Substances			
Over-the-Counter Medications and Supplements			
Acetaminophen	0.052 mg/mL	0.0104 mg/mL	0.156 mg/mL
Salicylic Acid	9.52 µg/mL	1.90 µg/mL	28.6 µg/mL
Ibuprofen	0.073 mg/mL	0.015 mg/mL	0.219 mg/mL
Biotin (Vitamin B7)	1.71 µg/mL	0.342 µg/mL	3.51 µg/mL
Chemotherapeutics			
Ara-C Triphosphate ^g (active metabolite of Cytarabine)	<i>C</i> _{max} = 13.2 µg/mL ^h	<i>C</i> _{max} = 2.64 µg/mL	2.64 µg/mL ⁱ

Anticoagulants	
Substance Tested	Test Concentration
Sodium Citrate	4× the vacutainer-specific ratio (anticoagulant: blood)
K2EDTA	4× the vacutainer-specific ratio (anticoagulant: blood)
K3EDTA	4× the vacutainer-specific ratio (anticoagulant: blood)
Lithium Heparin	4× the vacutainer-specific ratio (anticoagulant: blood)
Sodium Heparin	4× the vacutainer-specific ratio (anticoagulant: blood)
Acid Citrate Dextrose (ACD)	4× the vacutainer-specific ratio (anticoagulant: blood)
Sodium Polyethol Sulfate (SPS)	4× the vacutainer-specific ratio (anticoagulant: blood)

Disinfectants	
Bleach	5% v/v (3,000 ppm)
Ethanol	7% v/v
Povidone (iodinated)	1% v/v

^a EP37: Supplemental Table for Interference Testing in Clinical Chemistry – First Edition (2018), unless otherwise noted.

^b Calculated as a 5-fold dilution of the whole blood reference range (blood diluted in bottle media).

^c Albumin testing was performed over a range of concentrations; an effect on detection near LoD was observed at >15 mg/mL.

^d Wakeman, LJ et al, Fibrinogen reference range in adolescents. *Blood* 112, 4091 (2008).

^e EP07: Interference Testing in Clinical Chemistry; Approved Guideline—Third Edition (2018); values for IgG.

^f Cells/mL calculated from mass and human genome size.

^g Pyrimidine analog that inhibits DNA polymerase activity.

^h Liston, D.R. & Davis, M. Clinically relevant concentrations of anticancer drugs: a guide for nonclinical studies. *Clin Cancer Research* 23, 3489-3498 (2017).

ⁱ 20% of *C_{max}* represents the maximum expected concentration of drug metabolite in blood (McEvoy, G.K. (ed.). American Hospital Formulary Service. AHFS Drug Information. American Society of Health-System Pharmacists, Bethesda, MD. 2007, p. 994).

Mixed Culture Study (Microbial interference):

A study was performed to evaluate potential competitive inhibition or microbial interference on the BioFire BCID2 Panel. In Table 48, some polymicrobial blood culture samples contained high levels of a pathogenic or contaminating microorganism as well as low levels of another microorganism (e.g. a slower-growing yeast). A high level of on-panel or off-panel microorganism was added to contrived samples containing low levels (near LoD) of on-panel bacteria or yeast in order to assess the risk for interference that may result.

Table 48: Competing Microorganisms Tested

Substance Tested	Test Concentration
On-Panel	
<i>Staphylococcus epidermidis</i>	8.78E+08 CFU/mL
<i>Escherichia coli</i>	1.38E+09 CFU/mL
<i>Streptococcus mitis</i>	6.95E+08 CFU/mL
<i>Stenotrophomonas maltophilia</i>	7.40E+08 CFU/mL
<i>Bacteroides fragilis</i>	5.40E+07 cells/mL ^a
Off-Panel	
<i>Corynebacterium jeikeium</i>	8.70E+08 CFU/mL
<i>Bacillus cereus</i>	8.40E+08 CFU/mL
<i>Micrococcus luteus</i>	8.40E+08 CFU/mL
<i>Clostridium perfringens</i>	1.76E+08 cells/mL ^a
<i>Propionibacterium acnes</i>	1.12E+07 cells/mL ^a

^a Culture concentration in cells/mL determined via optical density (OD₆₀₀).

Study results demonstrated that high concentrations of the on-panel BioFire BCID2 microorganisms spiked into blood culture samples produced positive results for the relevant assays on the BCID2 Panel but did not interfere with any expected results for other analytes.

Testing of Additional Blood Culture Bottle Types

The BioFire BCID2 Panel was tested for compatibility with thirteen different blood culture bottle types. Approximately 35 different bacterial or yeast isolates were each mixed with human whole blood (acid citrate dextrose anticoagulant), seeded directly into a blood culture bottle (≤ 300 CFU/bottle), and incubated for growth in a continuous monitoring blood culture system (or standard incubator for the VersaTREK bottles) until indicated as positive for growth (i.e., bottle ring). For each positive bottle (note that some isolates did not grow to positivity in every bottle type), the sample was tested with the BioFire BCID2 Panel and was plate enumerated to determine the concentration of organism in the bottle. Samples were collected, tested, and enumerated within one hour of positive bottle indication and at 24 hours after positive bottle indication (+24h). The results are presented in the table below:

Table 49: Compatibility of the BioFire BCID2 Panel with Different Blood Culture Bottle Types

Manufacturer System	Bottle Type		Time Point	Seeded Organism		
				Gram-positive Bacteria	Gram-negative Bacteria	Yeast
bioMérieux BacT/ALERT VIRTUO	Aerobic	BacT/ALERT SA	Bottle Positive	11/11	18/18	8/8
			Positive +24h	11/11	18/18	8/8
		BacT/ALERT FA Plus	Bottle Positive	11/11	18/18	8/8
			Positive +24h	11/11	18/18	8/8
	Anaerobic	BacT/ALERT SN	Bottle Positive	11/11	19/19	7/7
			Positive +24h	11/11	19/19	7/7
		BacT/ALERT FN Plus	Bottle Positive	10/10	15/15	2/2
			Positive +24h	10/10	15/15	3/3
	Pediatric	BacT/ALERT PF Plus	Bottle Positive	11/11	18/18	8/8
			Positive +24h	11/11	18/18	8/8
Becton Dickinson BACTEC FX40	Aerobic	BACTEC Standard	Bottle Positive	11/11	18/18	7/7
			Positive +24h	11/11	18/18	7/7
		BACTEC Plus+	Bottle Positive	10/10	18/18	8/8
			Positive +24h	10/10	18/18	8/8
	Anaerobic	BACTEC Standard	Bottle Positive	9/9	13/13	1/1
			Positive +24h	9/9	13/13	1/1
		BACTEC Plus+	Bottle Positive	10/10	13/13	1/1
			Positive +24h	10/10	13/13	1/1
	Pediatric	BACTEC Peds Plus+	Bottle Positive	10/10	18/18	8/8
			Positive +24h	11/11	18/18	8/8
	Lytic	BACTEC Lytic	Bottle Positive	10/10	12/12	1/1
			Positive +24h	10/10	12/12	1/1
Thermo ^a	Aerobic	VersaTREK REDOX 1	Bottle Positive	9/9	18/18	4/4
			Positive +24h	9/9	18/18	4/4

Manufacturer System	Bottle Type		Time Point	Seeded Organism		
				Gram-positive Bacteria	Gram-negative Bacteria	Yeast
Scientific VersaTREK	Anaerobic	VersaTREK REDOX 2	Bottle Positive	9/9	13/13	0/0
			Positive +24h	9/9	13/13	1/1
# Correct Detected Results/Total Positive Bottles			265/265 100%	422/422 100%	128/128 100%	
			815/815 100%			

^a A VersaTREK system was not available for the evaluation. Seeded VersaTREK bottles were placed in a standard incubator (37°C, with or without agitation) for the average time to positivity required for the same isolate in the other bottles/systems.

The concentrations of each organism enumerated from bottles at the time of positivity and 24 hours after positivity are shown in Table 50; representing the approximate range of concentrations expected in a clinical setting for a mono-microbial blood culture

Table 50: Concentration of Organism in a Blood Culture at Positivity and 24 Hours After Positivity (+24h)

BioFire BCID2 Panel Analyte	Organism [AMR Gene]	Isolate ID	Concentration ^a	
			Positive Bottle (CFU/mL)	+24h (CFU/mL)
Gram Positive Bacteria				
<i>Enterococcus faecalis</i>	<i>Enterococcus faecalis</i> [vanA/B]	ATCC 51299	3.88E+08	1.16E+09
<i>Enterococcus faecium</i>	<i>Enterococcus faecium</i> [vanA/B]	ATCC 700221	1.37E+08	7.48E+08
<i>Listeria monocytogenes</i>	<i>Listeria monocytogenes</i>	ATCC 15313	9.28E+07	3.36E+08
<i>Staphylococcus</i> spp.	<i>Staphylococcus hominis</i>	ATCC 25615	3.02E+06	6.52E+07
<i>Staphylococcus aureus</i>	<i>Staphylococcus aureus</i> [mecA/C and MREJ]	ATCC BAA-38	2.88E+07	3.76E+08
<i>Staphylococcus epidermidis</i>	<i>Staphylococcus epidermidis</i>	ATCC 12228	1.34E+07	6.19E+08
<i>Staphylococcus lugdunensis</i>	<i>Staphylococcus lugdunensis</i>	ATCC 43809	7.05E+07	7.90E+08
<i>Streptococcus</i> spp.	<i>Streptococcus mitis</i>	ATCC 49456	2.29E+07	1.36E+08
<i>Streptococcus agalactiae</i>	<i>Streptococcus agalactiae</i>	ATCC 13813	3.82E+08	5.33E+08
<i>Streptococcus pneumoniae</i>	<i>Streptococcus pneumoniae</i>	ATCC 6303	6.86E+07	4.53E+07
<i>Streptococcus pyogenes</i>	<i>Streptococcus pyogenes</i>	ATCC 49399	2.04E+08	1.83E+08
Gram Negative Bacteria				
<i>Acinetobacter calcoaceticus-baumannii</i> complex	<i>Acinetobacter baumannii</i> [NDM]	CDC FDA AR Bank #0033	2.27E+08	4.22E+08
	<i>Acinetobacter calcoaceticus</i>	ATCC 23055	1.23E+07	5.46E+07
<i>Bacteroides fragilis</i>	<i>Bacteroides fragilis</i>	ATCC 25285	1.98E+08	3.00E+09
<i>Enterobacteriales</i>	<i>Citrobacter freundii</i>	ATCC 8090	1.57E+08	1.07E+09
	<i>Morganella morganii</i> [CTX-M, NDM]	CDC FDA AR Bank #0057	6.73E+08	1.66E+09

BioFire BCID2 Panel Analyte	Organism [AMR Gene]	Isolate ID	Concentration ^a	
			Positive Bottle (CFU/mL)	+24h (CFU/mL)
	<i>Raoultella ornithinolytica</i>	ATCC 31898	1.83E+08	1.18E+09
<i>Enterobacter cloacae</i> complex	<i>Enterobacter cloacae</i> [VIM]	CDC FDA AR Bank #0154	1.20E+08	9.89E+08
<i>Escherichia coli</i>	<i>Escherichia coli</i> [mcr-1]	CDC FDA AR Bank #0350	1.02E+08	1.25E+09
<i>Haemophilus influenzae</i>	<i>Haemophilus influenzae</i>	ATCC 10211	3.54E+08	2.60E+08
<i>Klebsiella aerogenes</i>	<i>Klebsiella aerogenes</i> [OXA-48-like]	CDC FDA AR Bank #0074	3.14E+08	1.63E+09
<i>Klebsiella oxytoca</i>	<i>Klebsiella oxytoca</i>	ATCC 13182	2.68E+08	1.33E+09
<i>Klebsiella pneumoniae</i> group	<i>Klebsiella pneumoniae</i>	CDC FDA AR Bank #0097	1.45E+08	4.31E+08
<i>Neisseria meningitidis</i>	<i>Neisseria meningitidis</i>	ATCC 13090	2.07E+08	9.30E+07
<i>Proteus</i> spp.	<i>Proteus mirabilis</i> [CTX-M]	GRE 1254053	1.26E+08	9.17E+08
<i>Pseudomonas aeruginosa</i>	<i>Pseudomonas aeruginosa</i> [IMP]	CDC FDA AR Bank #0092	9.75E+07	5.87E+08
	<i>Pseudomonas aeruginosa</i>	ATCC 10145	3.16E+08	9.00E+08
<i>Salmonella</i> spp.	<i>Salmonella enterica</i> [CTX-M]	CDC FDA AR Bank #0407	2.14E+08	1.33E+09
<i>Serratia marcescens</i>	<i>Serratia marcescens</i> [KPC]	JMI 697	9.09E+07	1.02E+09
<i>Stenotrophomonas maltophilia</i>	<i>Stenotrophomonas maltophilia</i>	ATCC 700475	2.80E+08	1.11E+09
Yeast				
<i>Candida albicans</i>	<i>Candida albicans</i>	ATCC 90028	4.28E+05	6.79E+06
<i>Candida auris</i>	<i>Candida auris</i>	CDC FDA AR Bank #0381	2.81E+06	2.49E+07
<i>Candida glabrata</i>	<i>Candida glabrata</i>	ATCC 15545	1.15E+06	3.68E+07
<i>Candida krusei</i>	<i>Candida krusei</i>	ATCC 6258	9.99E+05	1.57E+07
<i>Candida parapsilosis</i>	<i>Candida parapsilosis</i>	ATCC 34136	5.96E+05	1.39E+07
<i>Candida tropicalis</i>	<i>Candida tropicalis</i>	ATCC 201380	3.77E+05	1.19E+07
<i>Cryptococcus neoformans/gattii</i>	<i>Cryptococcus gattii</i>	ATCC MYA-4877	4.72E+05	2.83E+06
	<i>Cryptococcus neoformans</i>	ATCC MYA-4564	1.54E+06	9.24E+06

^a Mean concentration calculated from bottles cultured in the bioMerieux BacT/ALERT VIRTUO and Becton Dickinson BACTEC FX40 systems (VersaTREK bottle data excluded).

4. Assay Reportable Range:

Not applicable

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

Internal Controls

The following internal controls are included in each BioFire BCID2 Panel pouch:

- **DNA Process Control:** The DNA Process Control assay targets a DNA transcript from the yeast *Schizosaccharomyces pombe*. The yeast is present in the pouch in a freeze-dried form and becomes rehydrated when sample is loaded. The control material is carried through all stages of the test process, including lysis, nucleic acid purification, reverse transcription, PCR1, dilution, PCR2, and DNA melting. A positive control result indicates that all steps carried out in the BioFire BCID2 Panel 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 control assays must be positive for the test run to pass. If the controls fail, the sample should be retested using a new pouch. Table 51 below provides additional information for each of the possible control field results.

Table 51: Interpretation of Controls Field on the BioFire BCID2 Panel Test Report

Control Result	Explanation	Action
Passed	The run was successfully completed AND Both pouch controls were successful.	Report the results provided on the test report
Failed	The run was successfully completed BUT At least one of the pouch controls (DNA Process Control and/or PCR2 Control) failed.	Repeat the test using a new pouch. If the error persists, contact Technical Support for further instruction.
Invalid	The controls are invalid because the run did not complete. (Typically this indicates a software or hardware error).	Note any error codes displayed during the run and the Run Status field in the Run Details section of the report. Refer to the appropriate FilmArray Operator's Manual or contact Technical Support for further instruction. Once the error is resolved, repeat the test or repeat the test using another module.

Recommended External Controls

External controls are not provided with the BCID2 Panel but are recommended in the package insert.

External Controls should be used in accordance with laboratory protocols and the appropriate accrediting organization requirements, as applicable. Molecular grade water or saline can be used as an external negative control. Previously characterized positive samples or negative samples spiked with well-characterized organisms can be used as external positive controls.

Specimen Stability

Testing with the BioFire BCID2 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 24 hours after bottle ring in the blood culture system or kept at room temperature for up to 24 hours (15-25 °C) after positivity. Testing with BCID2 Panel is indicated for both time frames. A "Growth and Detection" study was performed to validate the performance of the BCID2 Panel when testing immediately after bottle positivity and testing after incubation for an additional 24 hours.

6. Detection Limit:

A limit of detection (LoD) was established for the bacteria and yeast detected by the BioFire BCID2 Panel. Contrived samples of representative isolates were prepared at a known concentration in a simulated blood culture matrix consisting of human whole blood incubated with blood culture media. LoD was estimated by serial dilution and confirmed by testing at least twenty replicates on the FilmArray 2.0 and FilmArray Torch systems. Confirmation of LoD required detection in at least 95% of replicates tested and the confirmed LoD concentrations are listed in Table 52. Testing also confirmed that each AMR gene can be detected at the LoD concentration of the applicable bacteria with which it may be reported. LoD concentrations are approximately 30 - 200,000-fold lower than the concentrations measured in positive blood cultures.

Table 52: Limit of Detection (LoD) for Analytes Detected by the BioFire BCID2 Panel

BioFire BCID2 Panel Analyte	Organism [AMR Gene] Tested	Isolate ID	LoD Concentration (CFU/mL)
Gram Positive Bacteria			
<i>Enterococcus faecalis</i>	<i>Enterococcus faecalis</i> [vanB]	ATCC 51299	1.0E+05
<i>Enterococcus faecium</i>	<i>Enterococcus faecium</i> [vanA]	ATCC 700221	1.0E+05
<i>Listeria monocytogenes</i>	<i>Listeria monocytogenes</i>	ATCC 15313	1.0E+04
<i>Staphylococcus spp.</i>	<i>Staphylococcus hominis</i>	ATCC 25615	1.0E+05
<i>Staphylococcus aureus</i>	<i>Staphylococcus aureus</i> [mecA]	ATCC BAA-38	1.0E+04 ^a
	<i>Staphylococcus aureus</i> [mecC]	ATCC BAA-2313	
<i>Staphylococcus epidermidis</i>	<i>Staphylococcus epidermidis</i> [mecA]	ATCC 35984	1.0E+05
<i>Staphylococcus lugdunensis</i>	<i>Staphylococcus lugdunensis</i>	ATCC 43809	1.0E+04
<i>Streptococcus spp.</i>	<i>Streptococcus mitis</i>	ATCC 49456	1.0E+04
<i>Streptococcus agalactiae</i>	<i>Streptococcus agalactiae</i>	ATCC 13813	5.0E+04
<i>Streptococcus pneumoniae</i>	<i>Streptococcus pneumoniae</i>	ATCC 6303	5.0E+03
<i>Streptococcus pyogenes</i>	<i>Streptococcus pyogenes</i>	ATCC 49399	5.0E+03

BioFire BCID2 Panel Analyte	Organism [AMR Gene] Tested	Isolate ID	LoD Concentration (CFU/mL)
Gram Negative Bacteria			
<i>Acinetobacter calcoaceticus-baumannii</i> complex	<i>Acinetobacter baumannii</i> [NDM]	CDC-FDA AR Bank #0033	5.0E+03
<i>Bacteroides fragilis</i>	<i>Bacteroides fragilis</i>	ATCC 25285	1.0E+04
<i>Enterobacterales</i>	<i>Citrobacter freundii</i>	ATCC 8090	1.0E+05
	<i>Morganella morganii</i>	ATCC 25830	
	<i>Serratia plymuthica</i>	ATCC 183	
<i>Enterobacter cloacae</i> complex	<i>Enterobacter cloacae</i> [VIM]	CDC-FDA AR Bank #0154	1.0E+05
<i>Escherichia coli</i>	<i>Escherichia coli</i> [mcr-1]	CDC-FDA AR Bank #0350	5.0E+05
<i>Haemophilus influenzae</i>	<i>Haemophilus influenzae</i>	ATCC 10211	1.0E+04
<i>Klebsiella aerogenes</i>	<i>Klebsiella aerogenes</i> [OXA-48-like]	CDC-FDA AR Bank #0074	1.0E+05
<i>Klebsiella oxytoca</i>	<i>Klebsiella oxytoca</i> [CTX-M]	GRE 1254054	1.0E+05
<i>Klebsiella pneumoniae</i> group	<i>Klebsiella pneumoniae</i>	ATCC 13883	5.0E+04
<i>Neisseria meningitidis</i>	<i>Neisseria meningitidis</i>	ATCC 13090	1.0E+03
<i>Proteus</i> spp.	<i>Proteus mirabilis</i>	ATCC 29906	5.0E+05
<i>Pseudomonas aeruginosa</i>	<i>Pseudomonas aeruginosa</i> [IMP]	CDC-FDA AR Bank #0092	1.0E+04
<i>Salmonella</i> spp.	<i>Salmonella enterica</i>	ATCC 700720	5.0E+04
<i>Serratia marcescens</i>	<i>Serratia marcescens</i> [KPC]	JMI 697	1.0E+05
<i>Stenotrophomonas maltophilia</i>	<i>Stenotrophomonas maltophilia</i>	ATCC 700475	1.0E+06
Yeast			
<i>Candida albicans</i>	<i>Candida albicans</i>	ATCC 90028	1.0E+03
<i>Candida auris</i>	<i>Candida auris</i>	CDC-FDA AR Bank #0381	1.0E+03
<i>Candida glabrata</i>	<i>Candida glabrata</i>	ATCC 15545	1.0E+02
<i>Candida krusei</i>	<i>Candida krusei</i>	ATCC 28870	5.0E+03
<i>Candida parapsilosis</i>	<i>Candida parapsilosis</i>	ATCC 34136	1.0E+04
<i>Candida tropicalis</i>	<i>Candida tropicalis</i>	ATCC 201380	1.0E+04
<i>Cryptococcus neoformans/gattii</i>	<i>Cryptococcus gattii</i>	ATCC MYA-4877	5.0E+02
	<i>Cryptococcus neoformans</i>	ATCC MYA-4564	

^a Confirmed LoD concentration for *Staphylococcus aureus* is the higher of the two LoD concentrations observed.

7. Assay Cut-Off:

The BioFire Blood Culture Identification 2 (BCID2) Panel is part of BioFire Diagnostics' (BFDX) FilmArray system. The FilmArray (FA) system is designed to interpret the test data and automatically report the test results to the operator. The FA system uses the results of the Melt Detector to determine each test result. The Melt Detector is part of the FilmArray Analysis Software and assigns a positive or negative result to each reaction on the array through analysis of the melt data collected during the test. These positive and negative results

are combined in the FilmArray Analysis Software (using the replicate, assay and interpretation rules) to report the presence or absence of each pathogen in the panel.

The purpose of this study was to validate the use of this Melt Detector with current optimization parameters with the BioFire BCID2 Panel. To evaluate the Melt Detector performance, the observed sensitivity and specificity rates for the individual melt curves and assay calls are reported. These sensitivity and specificity rates are determined by comparing the FilmArray test results obtained from well-characterized samples, collected as part of the clinical evaluation and analytic testing of the BCID2 panel, to expert annotation. Annotations (positive and negative calls) for all melt curves and assay calls were determined by the sponsor.

For individual melt curves, the observed sensitivity and specificity, as compared to expert annotation, of the Melt Detector is 99.63% and 99.81%, respectively. For the Analysis Software, the observed sensitivity and specificity, as compared to the expert annotation, of the assay calls are greater than 99.53% for sensitivity and 99.83% specificity. The validation results met the predefined acceptance criteria of >95% accuracy as compared to expert annotation.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Not Applicable

2. Matrix Comparison:

Not Applicable

C Clinical Studies:

1. Clinical Sensitivity:

The clinical performance of the Biofire BCID2 Panel was established with a prospective multi-center study that was further supplemented with archived and seeded positive blood culture (PBC) specimens.

Blood culture bottle types evaluated in the prospective clinical study included 11 different media from two different manufacturers as shown in Table 53. Equivalent performance was observed when results from the different media were compared; therefore, the data collected from all media types are combined for all analyses.

Table 53: Bottle Types Evaluated in the BioFire BCID2 Panel Prospective Clinical Evaluation

Blood Culture Media Type	Manufacturer and Product Name	Prospective Study			Seeded Study		
		N	Overall Performance ^a		N	Overall Performance ^a	
			Sensitivity/PPA	Specificity/NPA		Sensitivity/PPA	Specificity/NPA
Aerobic	BD Bactec Plus Aerobic/F	344	98.8%	99.8%	354	99.2%	100%
	BD Standard 10 Aerobic/F	3	100%	100%	0	-	-
	bioMérieux BacT/ALERT FA plus	264	98.8%	99.0%	168	99.0%	100%
	bioMérieux BacT/ALERT SA	21	100%	99.5%	0	-	-
Anaerobic	BD Bactec Plus Anaerobic/F	86	99.1%	99.9%	15 ^b	100%	100%
	BD Bactec Standard Anaerobic/F	1	100%	-	0	-	-
	BD Bactec Lytic/10 Anaerobic/F	187	99.6%	99.9%	0	-	-
	bioMérieux BacT/ALERT FN plus	40	100%	99.8%	15	100%	100%
	bioMérieux BacT/ALERT SN	83	97.9%	100%	0	-	-
Pediatric/ Low Volume	BD Bactec Peds Plus/F	13	100%	99.6%	0	-	-
	bioMérieux BacT/ALERT PF plus	32	95.8%	98.8%	0	-	-

^a Note that these calculations do not include the performance for the individual *Staphylococcus* species, individual *Streptococcus* species, or individual *Enterobacterales* interpretations, as the grouped *Staphylococcus* spp., *Streptococcus* spp., and *Enterobacterales* interpretations are included instead.

^b *Bacteroides fragilis* only

Nine geographically distinct study sites (seven in the US and two in the EU) participated in the prospective clinical evaluation from October 2018 to May 2019. A total of 11 pouch lots were used for testing.

A total of 1093 residual PBC specimens were acquired for the prospective clinical study. At two of the US sites, 69 specimens enrolled between October 2018 and February 2019 were collected and immediately frozen for later testing at the source laboratory. The remaining 1024 specimens were collected and tested fresh. No difference in performance was observed when fresh and frozen specimen results were compared. Therefore, the data collected from 69 valid frozen specimens are combined with data from the valid 1005 fresh specimens for all analyses.

Nineteen (19) specimens were excluded from the final data analysis. The most common reason for specimen exclusion was that the specimen was found to not meet the inclusion criteria after the specimen has been enrolled, most often due to the specimen being tested

with the BioFire BCID2 Panel outside of the 24 hour window following positive indication by the continuous monitoring blood culture system (CMBCS).

For the prospective study, the performance of the BioFire BCID2 Panel was evaluated by comparing the test result for each analyte with the appropriate comparator/reference methods shown in Table 54.

Table 54: Comparator Methods for the Prospective BioFire BCID2 Panel Clinical Evaluation

BioFire BCID2 Panel Result	Reference / Comparator Method(s)
All Bacteria and <i>Cryptococcus</i>	Standard manual and automated microbiological/biochemical identification methods according to site specific SOC methods; data was extracted from the subject medical chart
<i>Candida</i> species	SOC identification for genus level followed by PCR & sequencing of isolates for species identification
AMR Genes	Method 1 – Assessment of BioFire BCID2 Panel performance One PCR assay performed direct from PBC followed by sequencing of PCR amplicon (CTX-M, IMP, KPC, NDM, OXA-48 like, VIM, and <i>mcr-1</i>) Commercially available FDA-cleared and CE-marked molecular IVD assays performed on PBC (<i>mecA/C</i>, <i>mecA/C</i> and MREJ (MRSA), KPC, and <i>vanA/B</i>) Method 2 – Assessment of genotype concordance PCR & sequencing for specific resistance gene from applicable cultured isolates Method 3 – Assessment of phenotype concordance Phenotypic AST of applicable cultured isolates

To supplement the prospective study for low prevalence analytes, a total of 427 frozen archived PBC specimens were collected from 12 external laboratories and retrospectively tested. Of these, 395 were evaluable. Prior to testing with the BioFire BCID2 Panel, the composition/integrity of the specimens was first confirmed with confirmatory molecular methods; 370 specimens contained confirmed analytes of interest.

Table 55 provides a summary of demographic information for the 1074 specimens included in the prospective study and the 370 specimens included in the archived study.

Table 55: Demographic Data

		Prospective	Archived
Sex	Male	573 (53%)	205 (55%)
	Female	501 (47%)	156 (42%)
	Unknown	0 (0%)	9 (2%)
Age	<1 year	118 (11%)	22 (6%)
	1-17 years	143 (13%)	32 (9%)
	18-44 years	125 (12%)	44 (12%)
	45-64 years	257 (24%)	112 (30%)
	65-84 years	333 (31%)	132 (36%)
	85+ years	98 (9%)	27 (7%)
	Unknown	0 (0%)	1 (<1%)
Total		1074	370

A total of 552 seeded blood culture specimens were also evaluated to further supplement the prospective and archived studies for low prevalence analytes. Seeded PBC specimens were prepared by inoculating human whole blood with a variety of different isolates/strains for each analyte at low concentrations and growing to positivity in a CMBCS. The number of specimens tested per analyte is presented in Table 56.

Table 56: Seeded Specimen Analyte Composition

Purpose	Analyte	Number Tested ^a
Low Prevalence Analyte	<i>Listeria monocytogenes</i>	36
	<i>Staphylococcus lugdunensis</i>	30
	<i>Bacteroides fragilis</i>	30
	<i>Klebsiella aerogenes</i>	42
	<i>Neisseria meningitidis</i>	35
	<i>Salmonella</i> spp.	37
	<i>Stenotrophomonas maltophilia</i>	30
	<i>Candida auris</i>	30
	<i>Candida krusei</i>	33
	<i>Candida tropicalis</i>	35
	<i>Cryptococcus neoformans/gattii</i>	30
	IMP	30

Purpose	Analyte	Number Tested ^a
	KPC	45
	NDM	30
	OXA-48-like	30
	VIM	30
	<i>mcr-1</i>	30
Evaluation of Polymicrobial Specimens	<i>E. faecalis</i>	10
	<i>E. faecium</i>	10
	<i>S. aureus</i>	10
	<i>mecA/C</i> and MREJ	5
	<i>C. albicans</i>	10
AMR Gene Host and Evaluation of Polymicrobial Specimens	<i>A. calcoaceticus-baumannii</i> complex	19
	<i>K. pneumoniae</i> group	92
	<i>E. coli</i>	44
	<i>P. aeruginosa</i>	26
AMR Gene Host	<i>E. cloacae</i> complex	8
	<i>K. oxytoca</i>	6
	<i>Proteus</i>	9
Present in Host with other Rare AMR Genes	CTX-M	63

^a 552 seeded specimens total including some with polymicrobial composition or Detected results reporting both an AMR gene and host organism

Table 57: Strains and Replicates Tested in Seeded Specimens

Organism	AMR Gene(s)	Strain	Independent Specimens Tested
<i>Acinetobacter baumannii</i>	---	2 Individual clinical isolates	5 each (10)
	NDM-1	AR-BANK #0083	3
	NDM-1	AR-BANK #0088	3
	IMP-4	Individual clinical isolate	3
<i>Acinetobacter baumannii</i> total			19

Organism	AMR Gene(s)	Strain	Independent Specimens Tested
<i>Bacteroides fragilis</i>	---	ATCC 29771	3
	---	ATCC 23745	3
	---	ATCC 25285	3
	---	ATCC 29768	3
	---	ATCC 43858	3
	---	ATCC 43860	3
	---	ATCC 43936	3
	---	ATCC 43937	3
	---	ATCC BAA-2283	3
	---	Individual clinical isolate	3
<i>Bacteroides fragilis</i> total			30
<i>Candida albicans</i>	---	2 Individual clinical isolates	5 each (10)
<i>Candida albicans</i> total			10
<i>Candida auris</i>	---	AR-BANK #0381	3
	---	AR-BANK #0382	3
	---	AR-BANK #0383	3
	---	AR-BANK #0384	3
	---	AR-BANK #0385	3
	---	AR-BANK #0386	3
	---	AR-BANK #0387	3
	---	AR-BANK #0388	3
	---	AR-BANK #0389	3
	---	AR-BANK #0390	3
<i>Candida auris</i> total			30
<i>Candida krusei</i>	---	ATCC 14243	15
	---	ATCC 6258	3
	---	15 Individual clinical isolates	1 each (15)
<i>Candida krusei</i> total			33
<i>Candida tropicalis</i>	---	35 Individual clinical isolates	1 each (35)
<i>Candida tropicalis</i> total			35
<i>Cryptococcus gattii</i>	---	Individual clinical isolate	3
	---	ATCC 56989	3
	---	ATCC 56992	3
	---	ATCC 64062	3
	---	ATCC MYA-4560	3
<i>Cryptococcus gattii</i> total			15
<i>Cryptococcus neoformans</i>	---	4 Individual clinical isolates	3 each (12)
	---	ATCC 13690	3
<i>Cryptococcus neoformans</i> total			15

Organism	AMR Gene(s)	Strain	Independent Specimens Tested
<i>Enterobacter cloacae</i>	NDM-1, CTX-M-15	AR-BANK #0038	3
	VIM-1	AR-BANK #0154	3
	KPC	2 Individual clinical isolates	1 each (2)
<i>Enterobacter cloacae</i> total			8
<i>Enterococcus faecalis</i>	---	2 Individual clinical isolates	5 each (10)
<i>Enterococcus faecalis</i> total			10
<i>Enterococcus faecium</i>	---	2 Individual clinical isolates	5 each (10)
<i>Enterococcus faecium</i> total			10
<i>Escherichia coli</i>	NDM-1	AR-BANK #0069	3
	CTX-M-55, <i>mcr-1</i>	AR-BANK #0346	4
	CTX-M-14, CTX-M-55, <i>mcr-1</i>	AR-BANK #0349	4
	<i>mcr-1</i>	AR-BANK #0350	3
	<i>mcr-1</i>	AR-BANK #0493	4
	<i>mcr-1</i>	AR-BANK #0494	4
	CTX-M, <i>mcr-1</i>	AR-BANK #0495	3
	NDM-1	ATCC BAA-2452	3
	IMP-4	Individual clinical isolate	3
	IMP-3	Individual clinical isolate	3
	IMP-9	Individual clinical isolate	3
	VIM-7	Individual clinical isolate	3
	KPC	Individual clinical isolate	4
<i>Escherichia coli</i> total			44
<i>Klebsiella aerogenes</i>	---	10 Individual clinical isolates	3 each (30)
	---	2 Individual clinical isolates	1 each (2)
	OXA-48	AR-BANK #0074	3
	IMP-4	AR-BANK #0161	4
	CTX-M	Individual clinical isolate	3
<i>Klebsiella aerogenes</i> total			42
<i>Klebsiella oxytoca</i>	KPC-3	AR-BANK #0147	3
	CTX-M	Individual clinical isolate	3
<i>Klebsiella oxytoca</i> total			6

Organism	AMR Gene(s)	Strain	Independent Specimens Tested
<i>Klebsiella pneumoniae</i>	---	2 Individual clinical isolates	5 each (10)
	IMP-4	AR-BANK #0034	3
	OXA-181; CTX-M-15	AR-BANK #0039	3
	VIM-27; CTX-M-15	AR-BANK #0040	3
	VIM-27; CTX-M-15	AR-BANK #0046	3
	OXA-181, CTX-M-15	AR-BANK #0051	3
	OXA232; CTX-M-15	AR-BANK #0066	3
	OXA-232; CTX-M-15	AR-BANK #0075	3
	IMP-4	AR-BANK #0080	3
	VIM-1	AR-BANK #0135	3
	NDM-7; CTX-M-15	AR-BANK #0138	3
	OXA-181; CTX-M-15	AR-BANK #0140	3
	OXA-181; CTX-M-15	AR-BANK #0141	3
	OXA-181; CTX-M-15	AR-BANK #0142	3
	NDM-1; OXA-232; CTX-M-15	AR-BANK #0153	3
	OXA-48	AR-BANK #0160	3
	mcr-1	AR-BANK #0497	4
	NDM-1; CTX-M	ATCC BAA-2146	3
	KPC	Individual clinical isolate	8
	KPC	22 Individual clinical isolates	1 each (22)
<i>Klebsiella pneumoniae</i> total			92
<i>Listeria monocytogenes</i>	---	ATCC 19115	8
	---	ATCC 35152	1
	---	ATCC 43248	5
	---	ATCC 51779	5
	---	Individual clinical isolate	2
	---	7 Individual clinical isolates	1 each (7)
	---	NCTC 10890	8
<i>Listeria monocytogenes</i> total			36

Organism	AMR Gene(s)	Strain	Independent Specimens Tested
<i>Neisseria meningitidis</i>	---	ATCC 13077	10
	---	ATCC 13090	10
	---	ATCC 13102	4
	---	ATCC 13103	1
	---	ATCC 35561	4
	---	6 Individual clinical isolates	1 each (6)
<i>Neisseria meningitidis</i> total			35
<i>Proteus mirabilis</i>	KPC-6	AR-BANK #0155	3
	NDM-1	AR-BANK #0159	3
	CTX-M	Individual clinical isolate	3
<i>Proteus mirabilis</i> total			9
<i>Pseudomonas aeruginosa</i>	VIM-4	AR-BANK #0054	3
	KPC-5	AR-BANK #0090	3
	IMP-14	AR-BANK #0092	4
	VIM-2	AR-BANK #0100	3
	IMP-1	AR-BANK #0103	4
	VIM-2	AR-BANK #0108	3
	VIM-2	AR-BANK #0110	3
	VIM-2	AR-BANK #0111	3
<i>Pseudomonas aeruginosa</i> total			26
Salmonella sp.	---	3 Individual clinical isolates	3 each (9)
Salmonella enterica serogroup C	---	Individual clinical isolate	3
Salmonella enterica ser. Berta	---	Individual clinical isolate	3
Salmonella enterica ser. Enteritidis	---	Individual clinical isolate	3
	<i>mcr-1</i>	AR-BANK #0496	4
Salmonella enterica ser. Javiana	---	Individual clinical isolate	3
Salmonella enterica ser. Newport	---	Individual clinical isolate	3
Salmonella enterica ser. Senftenberg	NDM-1	AR-BANK #0127	3
Salmonella enterica ser. Typhi	---	Individual clinical isolate	3
Salmonella enterica ser. Typhimurium	---	Individual clinical isolate	3
<i>Salmonella</i> sp. total			37
<i>Staphylococcus aureus</i>	---	Individual clinical isolate	5
	<i>mecA</i> & MREJ	Individual clinical isolate	5
<i>Staphylococcus aureus</i> total			10

Organism	AMR Gene(s)	Strain	Independent Specimens Tested
<i>Staphylococcus lugdunensis</i>	---	5 Individual clinical isolates	3 each (15)
	---	ATCC 43809	3
	---	ATCC 49576	3
	---	ATCC 700328	3
	---	ATCC 700582	3
	---	NCTC 7990	3
<i>Staphylococcus lugdunensis</i> total			30
<i>Stenotrophomonas maltophilia</i>	---	10 Individual clinical isolates	3 each (30)
<i>Stenotrophomonas maltophilia</i> total			30

As additional supportive information in Table 58 is provided as evidence of a genetic determinant's association with phenotypic resistance. AMR Gene isolate(s) used in the seeded specimen study were compared to phenotypic antimicrobial susceptibility testing (AST) based on CLSI M100 breakpoints. Table 58 below is provided as supportive information only.

Table 58: Carbapenem AST Results for Strains with Relevant AMR Gene(s) Used in Seeded Specimens

Strain	AMR Gene(s)	Organism	Carbapenem AST ("—" = not tested)			
			Doripenem	Ertapenem	Imipenem	Meropenem
Individual clinical isolate	IMP-4	<i>Acinetobacter baumannii</i>	-	-	S	S
Individual clinical isolate	IMP-4	<i>Escherichia coli</i>	-	R	R	R
AR-BANK #0103	IMP-1	<i>Pseudomonas aeruginosa</i>	R	-	R	R
AR-BANK #0161	IMP-4	<i>Klebsiella aerogenes</i>	R	R	I	I
AR-BANK #0034	IMP-4	<i>Klebsiella pneumoniae</i>	I	R	S	I
AR-BANK #0080	IMP-4	<i>Klebsiella pneumoniae</i>	R	R	I	R
AR-BANK #0092	IMP-14	<i>Pseudomonas aeruginosa</i>	R	-	R	R
AR-BANK #0147	KPC-3	<i>Klebsiella oxytoca</i>	I	R	R	I
AR-BANK #0090	KPC-5	<i>Pseudomonas aeruginosa</i>	R	-	R	R
AR-BANK #0155	KPC-6	<i>Proteus mirabilis</i>	I	R	R	I
AR-BANK #0083	NDM-1	<i>Acinetobacter baumannii</i>	R	-	R	R
AR-BANK #0088	NDM-1	<i>Acinetobacter baumannii</i>	R	-	R	R
AR-BANK #0038 ^a	NDM-1	<i>Enterobacter cloacae</i>	R	R	R	R
AR-BANK #0069	NDM-1	<i>Escherichia coli</i>	R	R	R	R
AR-BANK #0159	NDM-1	<i>Proteus mirabilis</i>	R	R	R	R
AR-BANK #0127	NDM-1	<i>Salmonella enterica</i> ser. Senftenberg	R	R	R	R

Strain	AMR Gene(s)	Organism	Carbapenem AST ("–" = not tested)			
			Doripenem	Ertapenem	Imipenem	Meropenem
AR-BANK #0153 ^a	NDM-1, OXA-232	<i>Klebsiella pneumoniae</i>	R	R	R	R
AR-BANK #0138 ^a	NDM-7	<i>Klebsiella pneumoniae</i>	R	R	R	R
AR-BANK #0074	OXA-48	<i>Klebsiella aerogenes</i>	I	R	R	I
AR-BANK #0160	OXA-48	<i>Klebsiella pneumoniae</i>	R	R	R	R
AR-BANK #0039 ^a	OXA-181	<i>Klebsiella pneumoniae</i>	R	R	R	I
AR-BANK #0051 ^a	OXA-181	<i>Klebsiella pneumoniae</i>	R	R	R	R
AR-BANK #0140 ^a	OXA-181	<i>Klebsiella pneumoniae</i>	R	R	I	R
AR-BANK #0141 ^a	OXA-181	<i>Klebsiella pneumoniae</i>	R	R	I	R
AR-BANK #0142 ^a	OXA-181	<i>Klebsiella pneumoniae</i>	I	R	R	I
AR-BANK #0066 ^a	OXA-232	<i>Klebsiella pneumoniae</i>	R	R	R	R
AR-BANK #0075 ^a	OXA-232	<i>Klebsiella pneumoniae</i>	R	R	R	R
AR-BANK #0154	VIM-1	<i>Enterobacter cloacae</i>	R	R	R	I
AR-BANK #0135	VIM-1	<i>Klebsiella pneumoniae</i>	R	R	R	R
AR-BANK #0100	VIM-2	<i>Pseudomonas aeruginosa</i>	R	-	R	R
AR-BANK #0108	VIM-2	<i>Pseudomonas aeruginosa</i>	R	-	R	R
AR-BANK #0110	VIM-2	<i>Pseudomonas aeruginosa</i>	R	-	R	R
AR-BANK #0111	VIM-2	<i>Pseudomonas aeruginosa</i>	R	-	R	R
AR-BANK #0054	VIM-4	<i>Pseudomonas aeruginosa</i>	I	-	R	R
AR-BANK #0040 ^a	VIM-27	<i>Klebsiella pneumoniae</i>	R	R	R	R
AR-BANK #0046 ^a	VIM-27	<i>Klebsiella pneumoniae</i>	R	R	R	R
Unknown Source for Breakpoints or No AST Information Available						
Individual clinical isolate	IMP-3	<i>Escherichia coli</i>	-	-	-	-
Individual clinical isolate	IMP-9	<i>Escherichia coli</i>	-	-	-	-
ATCC BAA-2452	NDM-1	<i>Escherichia coli</i>	-	R	R	-
ATCC BAA-2146 ^{a,b}	NDM-1	<i>Klebsiella pneumoniae</i>	-	-	-	-
Individual clinical isolate	VIM-7	<i>Escherichia coli</i>	-	-	-	-

^a Also carries CTX-M gene.

^b Presence of CTX-M gene verified by independent molecular method.

Table 59: ESBL AST Results for Strains with Relevant AMR Gene(s) Used in Seeded Specimens

Strain	AMR Gene(s)	Organism	ESBL AST ("–" = not tested)							
			Ampicillin	Aztreonam	Cefazolin	Cefepime	Cefotaxime	Cefoxitin	Ceftazidime	Ceftriaxone
CLSI M100 ED30:2020 Used for Breakpoints										
Individual clinical isolate	CTX-M	<i>Klebsiella aerogenes</i>	R	R	-	S	R	R	R	R
Individual clinical isolate	CTX-M	<i>Klebsiella oxytoca</i>	R	R	-	S	R	S	S	R
Individual clinical isolate	CTX-M	<i>Proteus mirabilis</i>	R	S	-	S	R	S	S	R
CLSI 2018 M100 S28 Used for Breakpoints										
AR-BANK #0495 ^{a,e}	CTX-M	<i>Escherichia coli</i>	R	R	R	R	R	S	R	R
AR-BANK #0497 ^{a,e}	CTX-M	<i>Klebsiella pneumoniae</i>	R	R	R	R	R	I	R	R
AR-BANK #0349 ^a	CTX-M-14, CTX-M-55	<i>Escherichia coli</i>	R	R	R	R	R	I	R	R
AR-BANK #0038 ^b	CTX-M-15	<i>Enterobacter cloacae</i>	R	R	R	R	R	R	R	R
AR-BANK #0039 ^c	CTX-M-15	<i>Klebsiella pneumoniae</i>	R	R	R	R	R	R	R	R
AR-BANK #0040 ^d	CTX-M-15	<i>Klebsiella pneumoniae</i>	R	R	R	R	R	R	R	R
AR-BANK #0046 ^d	CTX-M-15	<i>Klebsiella pneumoniae</i>	R	R	R	R	R	R	R	R
AR-BANK #0051 ^c	CTX-M-15	<i>Klebsiella pneumoniae</i>	R	R	R	R	R	R	R	R
AR-BANK #0066 ^c	CTX-M-15	<i>Klebsiella pneumoniae</i>	R	R	R	R	R	R	R	R
AR-BANK #0075 ^c	CTX-M-15	<i>Klebsiella pneumoniae</i>	R	R	R	R	R	R	R	R
AR-BANK #0138 ^b	CTX-M-15	<i>Klebsiella pneumoniae</i>	R	R	R	R	R	R	R	R
AR-BANK #0140 ^c	CTX-M-15	<i>Klebsiella pneumoniae</i>	R	R	R	R	R	R	R	R
AR-BANK #0141 ^c	CTX-M-15	<i>Klebsiella pneumoniae</i>	R	R	R	R	R	I	R	R
AR-BANK #0142 ^c	CTX-M-15	<i>Klebsiella pneumoniae</i>	R	R	R	R	R	R	R	R
AR-BANK #0153 ^{b,c}	CTX-M-15	<i>Klebsiella pneumoniae</i>	R	R	R	R	R	R	R	R

Strain	AMR Gene(s)	Organism	ESBL AST (“-“ = not tested)							
			Ampicillin	Aztreonam	Cefazolin	Cefepime	Cefotaxime	Cefoxitin	Ceftazidime	Ceftriaxone
AR-BANK #0346 ^a	CTX-M-55	<i>Escherichia coli</i>	R	R	R	R	R	R	R	R

^a Also carries *mcr-1* gene.

^b Also carries NDM gene.

^c Also carries OXA-48-like gene.

^d Also carries VIM gene.

^e Presence of CTX-M gene verified by independent molecular method.

Table 60: Colistin MIC for Strains with Relevant AMR Gene(s) Used in Seeded Specimens

Strain	AMR Gene(s)	Organism	Colistin MIC (µg/ml) ^d
AR-BANK #0346 ^a	<i>mcr-1</i>	<i>Escherichia coli</i>	4
AR-BANK #0349 ^a	<i>mcr-1</i>	<i>Escherichia coli</i>	2-4
AR-BANK #0350	<i>mcr-1</i>	<i>Escherichia coli</i>	4
AR-BANK #0493	<i>mcr-1</i>	<i>Escherichia coli</i>	8
AR-BANK #0494	<i>mcr-1</i>	<i>Escherichia coli</i>	8
AR-BANK #0495 ^{a,b}	<i>mcr-1</i>	<i>Escherichia coli</i>	4
AR-BANK #0497 ^{a,b}	<i>mcr-1</i>	<i>Klebsiella pneumoniae</i>	8
AR-BANK #0496	<i>mcr-1</i>	<i>Salmonella</i> sp.	8

^a Also carries CTX-M gene.

^b Presence of CTX-M gene verified by independent molecular method.

^c As of February 2020, the United States Food and Drug Administration has not established or recognized minimum inhibitory concentration (MIC) breakpoints for colistin antimicrobial susceptibility testing (AST) related to *mcr-1*.

^d Isolates were acquired through the CDC's outbreak response and surveillance programs, validated and sequenced for testing, and then curated to increase lab efficiencies and public health innovations. More information about these isolates and the AR Bank can be found here <https://www.cdc.gov/drugresistance/resistance-bank/index.html>

Table 61: Methicillin AST Result for Strain with Relevant AMR Gene(s) Used in Seeded Specimens

Strain	Organism	AMR Gene(s)	Methicillin AST
Individual clinical isolate ^a	<i>Staphylococcus aureus</i>	<i>mecA</i> & MREJ	R

^a CLSI 2012 M100 S22 used for breakpoints.

The results from all three clinical studies are summarized for each organism in Table 62 through Table 74. Performance is based on comparison of the BioFire BCID2 Panel results to the results from comparator methods for prospective specimens (Table 54), the confirmed analyte of interest for archived specimens, and to the known analyte composition for seeded specimens. Positive Percent Agreement (PPA) or Sensitivity for each analyte was calculated as $100\% \times (TP / (TP + FN))$. True positive (TP) indicates that both the BioFire BCID2 Panel and the comparator method (or known analyte composition) had a positive result for the specific analyte, and false negative (FN) indicates that the BioFire BCID2 Panel was negative while the comparator result was positive. Negative Percent Agreement (NPA) or

Specificity was calculated as $100\% \times (TN / (TN + FP))$. True negative (TN) indicates that both the BioFire BCID2 Panel and the comparator method (or known analyte composition) had negative results, and false positive (FP) indicates that the BioFire BCID2 Panel was positive while the comparator result was negative. The exact binomial two-sided 95% confidence interval (95%CI) was calculated. Investigations of discrepant results are summarized in the footnotes.

Table 62: BioFire BCID2 Panel Clinical Performance Summary, *Enterococcus* spp.

Analyte	Study ^a	Sensitivity			Specificity		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>Enterococcus faecalis</i>	Prospective	31/33	93.9	80.4-98.3%	1040/1041	99.9	99.5-100%
	Seeded	10/10	100	72.2-100%	542/542	100	99.3-100%
	Overall	41/43^b	95.3	84.5-98.7%	1582/1583^c	99.9	99.6-100%
<i>Enterococcus faecium</i>	Prospective	27/27	100	87.5-100%	1044/1047	99.7	99.2-99.9%
	Seeded	10/10	100	72.2-100%	542/542	100	99.3-100%
	Overall	37/37	100	90.6-100%	1586/1589^d	99.8	99.4-99.9%

^a Archived testing not performed for *E. faecalis* or *E. faecium*

^b *E. faecalis* was detected in both FN specimens using an additional molecular method

^c The single FP specimen was negative for *E. faecalis* when tested with additional molecular methods

^d *E. faecium* was detected in all three FP specimens using an additional molecular method

Table 63: BioFire BCID2 Panel Clinical Performance Summary, *Listeria monocytogenes*

Analyte	Study	Sensitivity			Specificity		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>Listeria monocytogenes</i>	Prospective	3/3	100	43.9-100%	1071/1071	100	99.6-100%
	Archived	5/5	100	56.6-100%	231/231	100	98.4-100%
	Seeded	36/36	100	90.4-100%	516/516	100	99.3-100%
	Overall	44/44	100	92.0-100%	1818/1818	100	99.8-100%

Table 64: BioFire BCID2 Panel Clinical Performance Summary, *Staphylococcus* spp.

Analyte	Study ^a	Sensitivity			Specificity		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>Staphylococcus</i> spp.	Prospective	471/472	99.8	98.8-100%	589/602	97.8	96.3-98.7%
	Seeded	40/40	100	91.2-100%	512/512	100	99.3-100%
	Overall	511/512	99.8	98.9-100%	1101/1114^b	98.8	98.0-99.3%
<i>Staphylococcus aureus</i>	Prospective	149/149	100	97.5-100%	923/925	99.8	99.2-99.9%
	Seeded	10/10	100	72.2-100%	542/542	100	99.3-100%
	Overall	159/159	100	97.6-100%	1465/1467^c	99.9	99.5-100%
<i>Staphylococcus epidermidis</i>	Prospective	221/229	96.5	93.3-98.2%	816/845	96.6	95.1-97.6%
	Overall	221/229^d	96.5	93.3-98.2%	816/845^e	96.6	95.1-97.6%

Analyte	Study ^a	Sensitivity			Specificity		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>Staphylococcus lugdunensis</i>	Prospective	4/4	100	51.0-100%	1067/1070	99.7	99.2-99.9%
	Archived	16/16	100	80.6-100%	125/125	100	97.0-100%
	Seeded	30/30	100	88.6-100%	522/522	100	99.3-100%
	Overall	50/50	100	92.9-100%	1714/1717^f	99.8	99.5-99.9%

^a Archived testing not performed for *Staphylococcus* spp., *S. aureus*, or *S. epidermidis*; seeded testing not performed for *S. epidermidis*

^b *Staphylococcus* spp. was detected in all 13 FP specimens using an additional molecular method

^c *S. aureus* was detected in both FP specimens using an additional molecular method

^d *S. epidermidis* was detected in 3/8 FN specimens using an additional molecular method; sequencing of the remaining five FN specimens and their isolates identified them as other *Staphylococcus* spp.

^e *S. epidermidis* was detected in all 29 FP specimens using an additional molecular method

^f *S. lugdunensis* was detected in all three FP specimens using an additional molecular method

Table 65: BioFire BCID2 Panel Clinical Performance Summary, *Streptococcus* spp.

Analyte	Study ^a	Sensitivity			Specificity		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>Streptococcus</i> spp.	Prospective	121/123	98.4	94.3-99.6%	949/951	99.8	99.2-99.9%
	Overall	121/123^b	98.4	94.3-99.6%	949/951^c	99.8	99.2-99.9%
<i>Streptococcus agalactiae</i> (Group B)	Prospective	9/9	100	70.1-100%	1065/1065	100	99.6-100%
	Archived	16/16	100	80.6-100%	220/220	100	98.3-100%
	Overall	25/25	100	86.7-100%	1285/1285	100	99.7-100%
<i>Streptococcus pneumoniae</i>	Prospective	26/26	100	87.1-100%	1048/1048	100	99.6-100%
	Overall	26/26	100	87.1-100%	1048/1048	100	99.6-100%
<i>Streptococcus pyogenes</i> (Group A)	Prospective	13/14	92.9	68.5-98.7%	1060/1060	100	99.6-100%
	Archived	16/16	100	80.6-100%	220/220	100	98.3-100%
	Overall	29/30	96.7	83.3-99.4%	1280/1280	100	99.7-100%

^a Archived testing not performed for *Streptococcus* spp. or *S. pneumoniae*; seeded testing not performed for *Streptococcus* spp., *S. agalactiae*, *S. pneumoniae*, or *S. pyogenes*.

^b *Streptococcus* spp. was detected in 1/2 FN specimens using an additional molecular method.

^c *Streptococcus* spp. was detected in both FP specimens using an additional molecular method.

Table 66: BioFire BCID2 Panel Clinical Performance Summary, *Acinetobacter calcoaceticus-baumannii* complex

Analyte	Study	Sensitivity			Specificity		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>Acinetobacter calcoaceticus-baumannii</i> complex	Prospective	12/13	92.3	66.7-98.6%	1060/1061	99.9	99.5-100%
	Archived	34/35	97.1	85.5-99.5%	102/103	99.0	94.7-99.8%
	Seeded	19/19	100	83.2-100%	533/533	100	99.3-100%
	Overall	65/67^a	97.0	89.8-99.2%	1695/1697^b	99.9	99.6-100%

^a ACB complex was detected in both FN specimens; one was detected using an additional molecular method and one was detected upon BioFire BCID2 Panel retest.

^b ACB complex was detected in both FP specimens using an additional molecular method.

Table 67: BioFire BCID2 Panel Clinical Performance Summary, *Bacteroides fragilis*

Analyte	Study	Sensitivity			Specificity		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>Bacteroides fragilis</i>	Prospective	6/6	100	61.0-100%	1065/1068	99.7	99.2-99.9%
	Archived	16/16	100	80.6-100%	125/125	100	97.0-100%
	Seeded	30/30	100	88.6-100%	522/522	100	99.3-100%
	Overall	52/52	100	93.1-100%	1712/1715^a	99.8	99.5-99.9%

^a *B. fragilis* was detected in all three FP specimens using an additional molecular method.

Table 68: BioFire BCID2 Panel Clinical Performance Summary, *Enterobacterales*

Analyte	Study ^a	Sensitivity			Specificity		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>Enterobacterales</i>	Prospective	269/270	99.6	97.9-99.9%	750/804	93.3	91.3-94.8%
	Seeded	228/228	100	98.3-100%	324/324	100	98.8-100%
	Overall	497/498	99.8	98.9-100%	1074/1128^b	95.2	93.8-96.3%
<i>Enterobacter cloacae</i> complex	Prospective	16/16	100	80.6-100%	1058/1058	100	99.6-100%
	Archived	16/16	100	80.6-100%	219/219	100	98.3-100%
	Seeded	8/8	100	67.6-100%	544/544	100	99.3-100%
	Overall	40/40	100	91.2-100%	1821/1821	100	99.8-100%
<i>Escherichia coli</i>	Prospective	158/159	99.4	96.5-99.9%	913/915	99.8	99.2-99.9%
	Seeded	44/44	100	92.0-100%	508/508	100	99.2-100%
	Overall	202/203^c	99.5	97.3-99.9%	1421/1423^d	99.9	99.5-100%
<i>Klebsiella aerogenes</i>	Prospective	2/2	100	34.2-100%	1072/1072	100	99.6-100%
	Archived	16/16	100	80.6-100%	125/125	100	97.0-100%
	Seeded	42/42	100	91.6-100%	510/510	100	99.3-100%
	Overall	60/60	100	94.0-100%	1707/1707	100	99.8-100%

Analyte	Study ^a	Sensitivity			Specificity		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>Klebsiella oxytoca</i>	Prospective	8/8	100	67.6-100%	1066/1066	100	99.6-100%
	Archived	16/16	100	80.6-100%	219/219	100	98.3-100%
	Seeded	6/6	100	61.0-100%	546/546	100	99.3-100%
	Overall	30/30	100	88.6-100%	1831/1831	100	99.8-100%
<i>Klebsiella pneumoniae</i> group	Prospective	55/56	98.2	90.6-99.7%	1018/1018	100	99.6-100%
	Seeded	92/92	100	96.0-100%	460/460	100	99.2-100%
	Overall	147/148^e	99.3	96.3-99.9%	1478/1478	100	99.7-100%
<i>Proteus</i> spp.	Prospective	14/14	100	78.5-100%	1059/1060	99.9	99.5-100%
	Archived	16/16	100	80.6-100%	208/208	100	98.2-100%
	Seeded	9/9	100	70.1-100%	543/543	100	99.3-100%
	Overall	39/39	100	91.0-100%	1810/1811^f	99.9	99.7-100%
<i>Salmonella</i> spp.	Prospective	5/5	100	56.6-100%	1069/1069	100	99.6-100%
	Archived	16/16	100	80.6-100%	125/125	100	97.0-100%
	Seeded	37/37	100	90.6-100%	515/515	100	99.3-100%
	Overall	58/58	100	93.8-100%	1709/1709	100	99.8-100%
<i>Serratia marcescens</i>	Prospective	11/11	100	74.1-100%	1063/1063	100	99.6-100%
	Archived	16/16	100	80.6-100%	220/220	100	98.3-100%
	Overall	27/27	100	87.5-100%	1283/1283	100	99.7-100%

^a Archived testing not performed for *Enterobacteriales*, *E. coli*, or *K. pneumoniae* group; seeded testing not performed for *S. marcescens*.

^b Fifty-three (53) of 54 FP *Enterobacteriales* results were attributed to the presence of nucleic acid from non-viable *E. coli* in specific lots of blood culture bottles. The remaining FP specimen was observed in a blood culture bottle from a different manufacturer; an *Enterobacteriales* organism (*E. coli*) was detected in this specimen using an additional molecular method.

^c The single FN specimen was negative for *E. coli* when tested with Luminex Verigene BC-GN test.

^d The two FP specimens were attributed to the presence of nucleic acid from non-viable *E. coli* in the blood culture bottles.

^e *K. pneumoniae* group was detected in the single FN specimen using an additional molecular method.

^f *Proteus* spp. was detected in the single FP specimen using an additional molecular method.

Table 69: BioFire BCID2 Panel Clinical Performance Summary, *Haemophilus influenzae*

Analyte	Study ^a	Sensitivity			Specificity		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>Haemophilus influenzae</i>	Prospective	8/8	100	67.6-100%	1066/1066	100	99.6-100%
	Archived	24/25	96.0	80.5-99.3%	211/211	100	98.2-100%
	Overall	32/33^b	97.0	84.7-99.5%	1277/1277	100	99.7-100%

^a Seeded testing not performed for *H. influenzae*.

^b The single FN specimen was determined to contain a novel deletion in the BioFire BCID2 Panel assay target gene region.

Table 70: BioFire BCID2 Panel Clinical Performance Summary, *Neisseria meningitidis*

Analyte	Study	Sensitivity			Specificity		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>Neisseria meningitidis</i>	Prospective	0/0	-	-	1074/1074	100	99.6-100%
	Archived	3/3	100	43.9-100%	233/233	100	98.4-100%
	Seeded	35/35	100	90.1-100%	517/517	100	99.3-100%
	Overall	38/38	100	90.8-100%	1824/1824	100	99.8-100%

Table 71: BioFire BCID2 Panel Clinical Performance Summary, *Pseudomonas aeruginosa*

Analyte	Study ^a	Sensitivity			Specificity		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>Pseudomonas aeruginosa</i>	Prospective	29/29	100	88.3-100%	1043/1045	99.8	99.3-99.9%
	Seeded	24/26	92.3	75.9-97.9%	526/526	100	99.3-100%
	Overall	53/55^b	96.4	87.7-99.0%	1569/1571^c	99.9	99.5-100%

^a Archived testing not performed for *P. aeruginosa*.

^b 16/16 single seeded specimens were TP, and 8/10 specimens that were co-seeded with *E. faecalis* were detected. *E. faecalis* was detected in 10/10 of the co-seeded specimens.

^c *P. aeruginosa* was detected in both FP specimens using an additional molecular method.

Table 72: BioFire BCID2 Panel Clinical Performance Summary, *Stenotrophomonas maltophilia*

Analyte	Study	Sensitivity			Specificity		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>Stenotrophomonas maltophilia</i>	Prospective	7/8	87.5	52.9-97.8%	1066/1066	100	99.6-100%
	Archived	22/23	95.7	79.0-99.2%	116/116	100	96.8-100%
	Seeded	25/30 ^a	83.3	66.4-92.7%	522/522	100	99.3-100%
	Overall	54/61^b	88.5	78.2-94.3%	1704/1704	100	99.8-100%

^a 20/20 single seeded specimens were TP, and 5/10 specimens that were co-seeded with *S. aureus* were detected. *S. aureus* was detected in 10/10 of the co-seeded specimens.

^b *S. maltophilia* was detected in 2/7 FN specimens: one was detected using an additional molecular method and one was detected upon BioFire BCID2 Panel retest; the remaining five FN specimens were polymicrobial seeded specimens.

Table 73: BioFire BCID2 Panel Clinical Performance Summary, *Candida* spp.

Analyte	Study ^a	Sensitivity			Specificity		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>Candida albicans</i>	Prospective	12/12	100	75.8-100%	1061/1062	99.9	99.5-100%
	Archived	16/16	100	80.6-100%	218/218	100	98.3-100%
	Seeded	10/10	100	72.2-100%	542/542	100	99.3-100%
	Overall	38/38	100	90.8-100%	1821/1822^b	99.9	99.7-100%
<i>Candida auris</i>	Prospective	0/0	-	-	1074/1074	100	99.6-100%
	Archived	1/1	100	-	13/13	100	77.2-100%

Analyte	Study ^a	Sensitivity			Specificity		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
	Seeded	30/30	100	88.6-100%	522/522	100	99.3-100%
	Overall	31/31	100	89.0-100%	1609/1609	100	99.8-100%
<i>Candida glabrata</i>	Prospective	10/10	100	72.2-100%	1063/1064	99.9	99.5-100%
	Archived	16/16	100	80.6-100%	217/218	99.5	97.4-99.9%
	Overall	26/26	100	87.1-100%	1280/1282^c	99.8	99.4-100%
<i>Candida krusei</i>	Prospective	2/2	100	34.2-100%	1072/1072	100	99.6-100%
	Archived	9/9	100	70.1-100%	227/227	100	98.3-100%
	Seeded	33/33	100	89.6-100%	519/519	100	99.3-100%
	Overall	44/44	100	92.0-100%	1818/1818	100	99.8-100%
<i>Candida parapsilosis</i>	Prospective	8/8	100	67.6-100%	1065/1066	99.9	99.5-100%
	Archived	22/23	95.7	79.0-99.2%	211/211	100	98.2-100%
	Overall	30/31^d	96.8	83.8-99.4%	1276/1277^e	99.9	99.6-100%
<i>Candida tropicalis</i>	Prospective	5/5	100	56.6-100%	1069/1069	100	99.6-100%
	Archived	15/15	100	79.6-100%	219/220	99.5	97.5-99.9%
	Seeded	35/35	100	90.1-100%	517/517	100	99.3-100%
	Overall	55/55	100	93.5-100%	1805/1806^f	99.9	99.7-100%

^a Seeded testing was not performed for *C. glabrata* or *C. parapsilosis*.

^b *C. albicans* was detected in the single FP specimen using an additional molecular method.

^c *C. glabrata* was detected in both FP specimens using an additional molecular method.

^d The single FN specimen was misidentified as *C. parapsilosis* by the source laboratory; molecular testing of the specimen identified it as *C. orthopsilosis*.

^e *C. parapsilosis* was detected in the single FP specimen using an additional molecular method.

^f The single FP specimen was identified as a cross-reactivity between the BioFire BCID2 Panel *C. tropicalis* assay and high titer *C. parapsilosis* (refer to Analytical Specificity section for additional information regarding this cross-reactivity).

Table 74: BioFire BCID2 Panel Clinical Performance Summary, *Cryptococcus neoformans/gattii*

Analyte	Study	Sensitivity			Specificity		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>Cryptococcus neoformans/gattii</i>	Prospective	0/0	-	-	1074/1074	100	99.6-100%
	Archived	6/6	100	61.0-100%	135/135	100	97.2-100%
	Seeded	30/30	100	88.6-100%	522/522	100	99.3-100%
	Overall	36/36	100	90.4-100%	1731/1731	100	99.8-100%

BioFire BCID2 Panel assay performance stratified by species for *Staphylococcus* spp., *Streptococcus* spp., *Enterobacterales*, *Enterobacter cloacae* complex, *Klebsiella pneumoniae* group, *Proteus* spp., *Salmonella* spp., and *Cryptococcus neoformans/gattii* BioFire BCID2 Panel genus and group level organism results are presented in Table 75 through Table 78. Note: multiple organisms from a group may be detected in a single specimen, therefore the “Total” values in these Tables may not match the performance values presented above, which are reported per specimen.

Table 75: Stratification of *Staphylococcus* spp. Assay Performance by Species

Species	Sensitivity		
	Prospective	Archived	Seeded
<i>S. aureus</i>	149/149 (100%)	-	10/10 (100%)
<i>S. auricularis</i>	1/1 (100%)	-	-
<i>S. capitis</i>	19/19 (100%)	-	-
<i>S. caprae</i>	4/4 (100%)	-	-
<i>S. epidermidis</i>	229/229 (100%)	-	-
<i>S. haemolyticus</i>	24/24 (100%)	-	-
<i>S. hominis</i>	52/53 (98.1%)	-	-
<i>S. lentus</i>	1/1 (100%)	-	-
<i>S. lugdunensis</i>	4/4 (100%)	16/16 (100%)	30/30 (100%)
<i>S. pettenkoferi</i>	10/10 (100%)	-	-
<i>S. simulans</i>	3/3 (100%)	-	-
<i>S. warneri</i>	2/2 (100%)	-	-
Total <i>Staphylococcus</i> spp.	498/499 (99.8%) 95%CI: 98.9-100%	16/16 (100%) 95%CI: 80.6-100%	40/40 (100%) 95% CI: 91.2-100%

Table 76: Stratification of *Streptococcus* spp. Assay Performance by Species

Species	Sensitivity		
	Prospective	Archived	Seeded
Group A (Pyogenic)			
<i>S. pyogenes</i>	13/14 (92.9%)	16/16 (100%)	-
Group B (Pyogenic)			
<i>S. agalactiae</i>	9/9 (100%)	16/16 (100%)	-
Group C/G (Pyogenic)			
<i>S. canis</i>	1/1 (100%)	-	-
<i>S. dysgalactiae</i>	5/5 (100%)	-	-
Group D (Bovis)			
<i>S. bovis</i> group	2/2 (100%)	-	-
<i>S. gallolyticus</i>	2/2 (100%)	-	-
<i>S. lutetiensis</i>	1/1 (100%)	-	-
Group F (Anginosus)			
<i>S. anginosus</i>	3/4 (75.0%)	-	-
<i>S. anginosus</i> group	3/3 (100%)	-	-
<i>S. constellatus</i>	2/2 (100%)	-	-
<i>S. intermedius</i>	2/2 (100%)	-	-
<i>S. vestibularis</i>	2/2 (100%)	-	-
Mitis Group			
<i>S. gordonii</i>	1/1 (100%)	-	-
<i>S. mitis</i>	10/10 (100%)	-	-

Species	Sensitivity		
	Prospective	Archived	Seeded
<i>S. mitis/oralis</i>	7/7 (100%)	-	-
<i>S. oralis</i>	1/1 (100%)	-	-
<i>S. parasanguinis</i>	6/6 (100%)	-	-
<i>S. pneumoniae</i>	26/26 (100%)	-	-
Mutans Group			
<i>S. mutans</i>	2/2 (100%)	-	-
Salivarius Group			
<i>S. salivarius</i>	8/8 (100%)	-	-
Other			
Viridans streptococci	19/19 (100%)	-	-
Total Streptococcus spp.	125/127 (98.4%) 95%CI: 94.4-99.6%	32/32 (100%) 95%CI: 89.3-100%	-

Table 77: Stratification of *Enterobacterales* Assay Performance by Species

Species	Sensitivity		
	Prospective	Archived	Seeded
<i>Enterobacter cloacae</i> complex			
<i>Enterobacter cloacae</i>	10/10 (100%)	14/14 (100%)	8/8 (100%)
<i>Enterobacter cloacae</i> complex	3/3 (100%)	2/2 (100%)	-
<i>Enterobacter hormaechei</i>	2/2 (100%)	-	-
<i>Enterobacter kobei</i>	1/1 (100%)	-	-
Total	16/16 (100%) 95%CI: 80.6-100%	16/16 (100%) 95%CI: 80.6-100%	8/8 (100%) 95%CI: 67.6-100%
<i>Klebsiella pneumoniae</i> group			
<i>Klebsiella pneumoniae</i>	51/51 (100%)	-	92/92 (100%)
<i>Klebsiella pneumoniae</i> group	3/3 (100%)	-	-
<i>Klebsiella variicola</i>	2/2 (100%)	-	-
Total	56/56 (100%) 95%CI: 93.6-100%	-	92/92 (100%) 95%CI: 96.0-100%
<i>Proteus</i> spp.			
<i>Proteus mirabilis</i>	13/13 (100%)	14/14 (100%)	9/9 (100%)
<i>Proteus penneri</i>	1/1 (100%)	-	-
<i>Proteus vulgaris</i>	-	1/1 (100%)	-
<i>Proteus</i> sp.	-	1/1 (100%)	-
<i>Salmonella</i> spp			
<i>Salmonella enterica</i> sv. <i>Berta</i>	-	-	3/3 (100%)
<i>Salmonella enterica</i> sv. <i>Enteritidis</i>	-	-	7/7 (100%)
<i>Salmonella enterica</i> sv. <i>Javiana</i>	-	-	3/3 (100%)

Species	Sensitivity		
	Prospective	Archived	Seeded
<i>Salmonella enterica</i> sv. <i>Newport</i>	-	1/1 (100%)	3/3 (100%)
<i>Salmonella enterica</i> sv. <i>Paratyphi</i>	-	1/1 (100%)	-
<i>Salmonella enterica</i> sv. <i>Senftenberg</i>	-	-	3/3 (100%)
<i>Salmonella enterica</i> sv. <i>Tel-el-kebir</i>	1/1 (100%)	-	-
<i>Salmonella enterica</i> sv. <i>Typhi</i>	-	1/1 (100%)	3/3 (100%)
<i>Salmonella enterica</i> sv. <i>Typhimurium</i>	-	-	3/3 (100%)
<i>Salmonella enterica</i> serogroup B	-	1/1 (100%)	-
<i>Salmonella enterica</i> serogroup C	-	-	3/3 (100%)
<i>Salmonella enterica</i>	2/2 (100%)	-	-
<i>Salmonella</i> spp.	2/2 (100%)	12/12 (100%)	9/9 (100%)
Total	5/5 (100%) 95% CI: 56.6-100%	16/16 (100%) 95% CI: 80.6-100%	37/37 (100%) 95% CI: 90.6-100%
Other			
<i>Citrobacter amalonaticus</i>	1/1 (100%)	-	-
<i>Citrobacter freundii</i>	1/1 (100%)	-	-
<i>Enterobacter amnigenus</i>	1/1 (100%)	-	-
<i>Escherichia coli</i>	159/159 (100%)	-	44/44 (100%)
<i>Hafnia alvei</i>	1/1 (100%)	-	-
<i>Klebsiella aerogenes</i>	2/2 (100%)	16/16 (100%)	42/42 (100%)
<i>Klebsiella oxytoca</i>	8/8 (100%)	16/16 (100%)	6/6 (100%)
<i>Pantoea septica/agglomerans</i>	1/1 (100%)	-	-
<i>Providencia stuartii</i>	2/3 (66.7%)	-	-
<i>Serratia liquefaciens</i> complex	1/1 (100%)	-	-
<i>Serratia marcescens</i>	11/11 (100%)	16/16 (100%)	-
Total Enterobacterales	279/280 (99.6%) 95% CI: 98.0-99.9%	96/96 (100%) 95% CI: 96.2-100%	238/238 (100%) 95% CI: 98.4-100%

Table 78: Stratification of *Cryptococcus neoformans/gattii* Assay Performance by Species

Species	Sensitivity		
	Prospective	Archived	Seeded
<i>C. gattii</i>	-	-	15/15 (100%)
<i>C. neoformans</i>	-	6/6 (100%)	15/15 (100%)
Total <i>Cryptococcus neoformans/gattii</i>	-	6/6 (100%) 95% CI: 61.0-100%	30/30 (100%) 95% CI: 88.6-100%

Antimicrobial resistance (AMR) gene results are reported only when one or more applicable bacteria that may carry the gene are also detected in the sample. If no applicable bacteria are detected, the AMR gene results are reported as Not Applicable (N/A). The results are summarized for each AMR gene in Table 79 through Table 108. Note: the “Performance Summary” Tables below do not include specimens for which a potential host organism was not reported (i.e. the AMR gene was reported as N/A); these specimens are instead accounted for in the “Distribution of Clinical Specimens” Tables below.

Table 79: BioFire BCID2 Panel Clinical Performance Summary, CTX-M

Analyte	Study ^a	Positive Percent Agreement			Negative Percent Agreement		
		TP/ (TP + FN)	%	95% CI	TN/ (TN + FP)	%	95% CI
CTX-M	Prospective	46/47	97.9	88.9-99.6%	312/312	100	98.8-100%
	Seeded	63/63	100	94.3-100%	198/198	100	98.1-100%
	Overall	109/110	99.1	95.0-99.8%	510/510	100	99.3-100%

^a Archived testing was not performed for CTX-M.

Table 80: Distribution of CTX-M in Prospective Clinical Specimens

CTX-M		SOC: any associated organism PCR/seq: CTX-M			
		Org+ / Res+	Org+ / Res-	Org -	Total
BCID2 Panel Result	Org+ / Res+	46	0	0	46
	Org+ / Res-	1	258	54a	313
	Org -	0	2	713	715
	Total	47	260	767	1074
Performance		Agreement		%	95% CI
Org+ / Res+		46/47		97.9	88.9-99.6%
Org+ / Res-		258/260		99.2	97.2-99.8%
Org -		713/767a		93.0	90.9-94.6%

^a Fifty-three (53) FP results due to the presence of nucleic acid from non-viable *E. coli* in the blood culture bottles.

Table 81: Stratification of CTX-M Clinical Performance by Associated Host Organism

Analyte	Study ^a	Positive Percent Agreement			Negative Percent Agreement		
		TP/ (TP + FN)	%	95% CI	TN/ (TN + FP)	%	95% CI
Overall (any associated organism identified)	Prospective	46/47	97.9	88.9-99.6%	312/312	100	98.8-100%
	Seeded	63/63	100	94.3-100%	198/198	100	98.1-100%
	Overall	109/110	99.1	95.0-99.8%	510/510	100	99.3-100%
	Prospective	1/1	100	-	12/12	100	75.8-100%

Analyte	Study ^a	Positive Percent Agreement			Negative Percent Agreement		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>Acinetobacter calcoaceticus-baumannii</i> complex	Seeded	0/0	-	-	19/19	100	83.2-100%
	Overall	1/1	100	-	31/31	100	89.0-100%
<i>Enterobacterales</i>	Prospective	46/47	97.9	88.9-99.6%	276/276	100	98.6-100%
	Seeded	63/63	100	94.3-100%	165/165	100	97.7-100%
	Overall	109/110	99.1	95.0-99.8%	441/441	100	99.1-100%
<i>Enterobacter cloacae</i> complex	Prospective	0/0	-	-	16/16	100	80.6-100%
	Seeded	3/3	100	43.9-100%	5/5	100	56.6-100%
	Overall	3/3	100	43.9-100%	21/21	100	84.5-100%
<i>Escherichia coli</i>	Prospective	30/30	100	88.6-100%	130/130	100	97.1-100%
	Seeded	11/11	100	74.1-100%	33/33	100	89.6-100%
	Overall	41/41	100	91.4-100%	163/163	100	97.7-100%
<i>Klebsiella aerogenes</i>	Prospective	1/1	100	-	1/1	100	-
	Seeded	3/3	100	43.9-100%	39/39	100	91.0-100%
	Overall	4/4	100	51.0-100%	40/40	100	91.2-100%
<i>Klebsiella oxytoca</i>	Prospective	0/0	-	-	8/8	100	67.6-100%
	Seeded	3/3	100	43.9-100%	3/3	100	43.9-100%
	Overall	3/3	100	43.9-100%	11/11	100	74.1-100%
<i>Klebsiella pneumoniae</i> group	Prospective	12/12	100	75.8-100%	43/43	100	91.8-100%
	Seeded	40/40	100	91.2-100%	52/52	100	93.1-100%
	Overall	52/52	100	93.1-100%	95/95	100	96.1-100%
<i>Proteus</i> spp.	Prospective	4/4	100	51.0-100%	11/11	100	74.1-100%
	Seeded	3/3	100	43.9-100%	6/6	100	61.0-100%
	Overall	7/7	100	64.6-100%	17/17	100	81.6-100%
<i>Salmonella</i> spp.	Prospective	0/0	-	-	5/5	100	56.6-100%
	Seeded	0/0	-	-	37/37	100	90.6-100%
	Overall	0/0	-	-	42/42	100	91.6-100%
<i>Serratia marcescens</i>	Prospective	0/1	0	-	10/10	100	72.2-100%
	Overall	0/1	0	-	10/10	100	72.2-100%
<i>Pseudomonas aeruginosa</i>	Prospective	2/2	100	34.2-100%	29/29	100	88.3-100%
	Seeded	0/0	-	-	24/24	100	86.2-100%
	Overall	2/2	100	34.2-100%	53/53	100	93.2-100%

^a Archived testing not performed for CTX-M; seeded testing not performed for CTX-M with *S. marcescens*.

Table 82: BioFire BCID2 Panel Clinical Performance Summary, IMP

Analyte	Study ^a	Positive Percent Agreement			Negative Percent Agreement		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
IMP	Prospective	0/0	-	-	359/359	100	98.9-100%
	Seeded	29/29	100	88.3-100%	232/232	100	98.4-100%
	Overall	29/29	100	88.3-100%	591/591	100	99.4-100%

^a Archived testing not performed for IMP.

Table 83: Distribution of IMP in Prospective Clinical Specimens

IMP		SOC: any associated organism PCR/seq: IMP			
		Org+ / Res+	Org+ / Res-	Org -	Total
BCID2 Panel Result	Org+ / Res+	0	0	0	46
	Org+ / Res-	0	305	54 ^a	359
	Org -	0	2	713	715
	Total	0	307	767	1074
Performance		Agreement		%	95%CI
Org+ / Res+		0/0		-	-
Org+ / Res-		305/307		99.3	97.7-99.8%
Org -		713/767 ^a		93.0	90.9-94.6%

^a Fifty-three (53) FP results due to the presence of nucleic acid from non-viable *E. coli* in the blood culture bottles.

Table 84: Stratification of IMP Clinical Performance by Associated Host Organism, Seeded Study^a

Analyte	Positive Percent Agreement			Negative Percent Agreement		
	TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
Overall (any associated organism identified)	29/29	100	88.3-100%	232/232	100	98.4-100%
<i>Acinetobacter calcoaceticus- baumannii</i> complex	3/3	100	43.9-100%	16/16	100	80.6-100%
<i>Enterobacterales</i>	19/19	100	83.2-100%	209/209	100	98.2-100%
<i>Enterobacter cloacae</i> complex	0/0	-	-	8/8	100	67.6-100%
<i>Escherichia coli</i>	9/9	100	70.1-100%	35/35	100	90.1-100%
<i>Klebsiella aerogenes</i>	4/4	100	51.0-100%	38/38	100	90.8-100%
<i>Klebsiella oxytoca</i>	0/0	-	-	6/6	100	61.0-100%
<i>Klebsiella pneumoniae</i> group	6/6	100	61.0-100%	86/86	100	95.7-100%
<i>Proteus</i> spp.	0/0	-	-	9/9	100	70.1-100%
<i>Salmonella</i> spp.	0/0	-	-	37/37	100	90.6-100%
<i>Pseudomonas aeruginosa</i>	7/7	100	64.6-100%	17/17	100	81.6-100%

^a No observations for IMP in the prospective evaluation; archived testing not performed; seeded testing not performed for IMP with *S. marcescens*.

Table 85: BioFire BCID2 Panel Clinical Performance Summary, KPC

Analyte	Study	Positive Percent Agreement			Negative Percent Agreement		
		TP/ (TP + FN)	%	95% CI	TN/ (TN + FP)	%	95% CI
KPC	Prospective ^a	4/4	100	51.0-100%	328/328	100	98.8-100%
	Archived	14/14	100	78.5-100%	5/5	100	56.6-100%
	Seeded	45/45	100	92.1-100%	216/216	100	98.3-100%
	Overall	63/63	100	94.3-100%	549/549	100	99.3-100%

^a Twenty-seven (27) specimens were FN for an associated host organism by the molecular comparator method, thus providing an “N/A” result for KPC.

Table 86: Distribution of KPC in Prospective Clinical Specimens

KPC		SOC: any associated organism FDA-cleared test: KPC			
		Org+ / Res+	Org+ / Res-	Org -	Total
BCID2 Panel Result	Org+ / Res+	4	0	0	4
	Org+ / Res-	0	298	54 ^a	352
	Org -	0	0	713	713
	Total	4	298	767	1069 ^b
Performance		Agreement		%	95% CI
Org+ / Res+		4/4		100	51.0-100%
Org+ / Res-		298/298		100	98.7-100%
Org -		713/767 ^a		93.0	90.9-94.6%

^a Fifty-three (53) FP results due to the presence of nucleic acid from non-viable *E. coli* in the blood culture bottles.

^b Five specimens were FN for the associated host organism by the molecular comparator method, thus providing an “N/A” result for KPC.

Table 87: Stratification of KPC Clinical Performance by Associated Host Organism

Analyte	Study ^a	Positive Percent Agreement			Negative Percent Agreement		
		TP/ (TP + FN)	%	95% CI	TN/ (TN + FP)	%	95% CI
<i>Overall</i> (any associated organism identified)	Prospective	4/4	100	51.0-100%	328/328	100	98.8-100%
	Archived	14/14	100	78.5-100%	5/5	100	56.6-100%
	Seeded	45/45	100	92.1-100%	216/216	100	98.3-100%
	Overall	63/63	100	94.3-100%	549/549	100	99.3-100%
<i>Acinetobacter calcoaceticus-baumannii</i> complex	Prospective	0/0	-	-	13/13	100	77.2-100%
	Archived	0/0	-	-	5/5	100	56.6-100%
	Seeded	0/0	-	-	19/19	100	83.2-100%
	Overall	0/0	-	-	37/37	100	90.6-100%

Analyte	Study ^a	Positive Percent Agreement			Negative Percent Agreement		
		TP/ (TP + FN)	%	95% CI	TN/ (TN + FP)	%	95% CI
<i>Enterobacterales</i>	Prospective	4/4	100	51.0-100%	292/292	100	98.7-100%
	Archived	14/14	100	78.5-100%	0/0	-	-
	Seeded	42/42	100	91.6-100%	186/186	100	98.0-100%
	Overall	60/60	100	94.0-100%	478/478	100	99.2-100%
<i>Enterobacter cloacae</i> complex	Prospective	0/0	-	-	16/16	100	80.6-100%
	Archived	2/2	100	34.2-100%	0/0	-	-
	Seeded	2/2	100	34.2-100%	6/6	100	61.0-100%
	Overall	4/4	100	51.0-100%	22/22	100	85.1-100%
<i>Escherichia coli</i>	Prospective	0/0	-	-	159/159	100	97.6-100%
	Seeded	4/4	100	51.0-100%	40/40	100	91.2-100%
	Overall	4/4	100	51.0-100%	199/199	100	98.1-100%
<i>Klebsiella aerogenes</i>	Prospective	0/0	-	-	2/2	100	34.2-100%
	Seeded	0/0	-	-	42/42	100	91.6-100%
	Overall	0/0	-	-	44/44	100	92.0-100%
<i>Klebsiella oxytoca</i>	Prospective	0/0	-	-	8/8	100	67.6-100%
	Archived	1/1	100	-	0/0	-	-
	Seeded	3/3	100	43.9-100%	3/3	100	43.9-100%
	Overall	4/4	100	51.0-100%	11/11	100	74.1-100%
<i>Klebsiella pneumoniae</i> group	Prospective	4/4	100	51.0-100%	51/51	100	93.0-100%
	Archived	11/11	100	74.1-100%	0/0	-	-
	Seeded	30/30	100	88.6-100%	62/62	100	94.2-100%
	Overall	45/45	100	92.1-100%	113/113	100	96.7-100%
<i>Proteus</i> spp.	Prospective	0/0	-	-	15/15	100	79.6-100%
	Seeded	3/3	100	43.9-100%	6/6	100	61.0-100%
	Overall	3/3	100	43.9-100%	21/21	100	84.5-100%
<i>Salmonella</i> spp.	Prospective	0/0	-	-	5/5	100	56.6-100%
	Seeded	0/0	-	-	37/37	100	90.6-100%
	Overall	0/0	-	-	42/42	100	91.6-100%
<i>Serratia marcescens</i>	Prospective	0/0	-	-	11/11	100	74.1-100%
	Overall	0/0	-	-	11/11	100	74.1-100%
<i>Pseudomonas aeruginosa</i>	Prospective	0/0	-	-	31/31	100	89.0-100%
	Seeded	3/3	100	43.9-100%	21/21	100	84.5-100%
	Overall	3/3	100	43.9-100%	52/52	100	93.1-100%

^a Archived testing not performed for KPC with *E. coli*, *K. aerogenes*, *Proteus* spp., *Salmonella* spp., *S. marcescens*, or *P. aeruginosa*; seeded testing not performed for KPC with *S. marcescens*.

Table 88: BioFire BCID2 Panel Clinical Performance Summary, NDM

Analyte	Study	Positive Percent Agreement			Negative Percent Agreement		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
NDM	Prospective	1/1	100	-	358/358	100	98.9-100%
	Archived	5/5	100	56.6-100%	5/5	100	56.6-100%
	Seeded	30/30	100	88.6-100%	231/231	100	98.4-100%
	Overall	36/36	100	90.4-100%	594/594	100	99.4-100%

Table 89: Distribution of NDM in Prospective Clinical Specimens

NDM		SOC: any associated organism PCR/Seq: NDM			
		Org+ / Res+	Org+ / Res-	Org -	Total
BCID2 Panel Result	Org+ / Res+	1	0	0	1
	Org+ / Res-	0	304	54 ^a	358
	Org -	0	2	713	715
	Total	1	306	767	1074
Performance		Agreement		%	95%CI
Org+ / Res+		1/1		100	-
Org+ / Res-		304/306		99.3	97.6-99.8%
Org -		713/767 ^a		93.0	90.9-94.6%

^a Fifty-three (53) FP results due to the presence of nucleic acid from non-viable *E. coli* in the blood culture bottles.

Table 90: Stratification of NDM Clinical Performance by Associated Host Organism

Analyte	Study ^a	Positive Percent Agreement			Negative Percent Agreement		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
Overall (any associated organism identified)	Prospective	1/1	100	-	358/358	100	98.9-100%
	Archived	5/5	100	56.6-100%	5/5	100	56.6-100%
	Seeded	30/30	100	88.6-100%	231/231	100	98.4-100%
	Overall	36/36	100	90.4-100%	594/594	100	99.4-100%
<i>Acinetobacter calcoaceticus-baumannii</i> complex	Prospective	0/0	-	-	13/13	100	77.2-100%
	Archived	0/0	-	-	5/5	100	56.6-100%
	Seeded	6/6	100	61.0-100%	13/13	100	77.2-100%
	Overall	6/6	100	61.0-100%	31/31	100	89.0-100%
<i>Enterobacterales</i>	Prospective	1/1	100	-	322/322	100	98.8-100%
	Archived	5/5	100	56.6-100%	0/0	-	-
	Seeded	24/24	100	86.2-100%	204/204	100	98.2-100%
	Overall	30/30	100	88.6-100%	526/526	100	99.3-100%

Analyte	Study ^a	Positive Percent Agreement			Negative Percent Agreement		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>Enterobacter cloacae</i> complex	Prospective	0/0	-	-	16/16	100	80.6-100%
	Seeded	3/3	100	43.9-100%	5/5	100	56.6-100%
	Overall	3/3	100	43.9-100%	21/21	100	84.5-100%
<i>Escherichia coli</i>	Prospective	0/0	-	-	160/160	100	97.7-100%
	Archived	1/1	100	-	0/0	-	-
	Seeded	6/6	100	61.0-100%	38/38	100	90.8-100%
	Overall	7/7	100	64.6-100%	198/198	100	98.1-100%
<i>Klebsiella aerogenes</i>	Prospective	0/0	-	-	2/2	100	34.2-100%
	Seeded	0/0	-	-	42/42	100	91.6-100%
	Overall	0/0	-	-	44/44	100	92.0-100%
<i>Klebsiella oxytoca</i>	Prospective	0/0	-	-	8/8	100	67.6-100%
	Seeded	0/0	-	-	6/6	100	61.0-100%
	Overall	0/0	-	-	14/14	100	78.5-100%
<i>Klebsiella pneumoniae</i> group	Prospective	1/1	100	-	54/54	100	93.4-100%
	Archived	4/4	100	51.0-100%	0/0	-	-
	Seeded	9/9	100	70.1-100%	83/83	100	95.6-100%
	Overall	14/14	100	75.8-100%	137/137	100	97.3-100%
Proteus spp.	Prospective	0/0	-	-	15/15	100	79.6-100%
	Seeded	3/3	100	43.9-100%	6/6	100	61.0-100%
	Overall	3/3	100	43.9-100%	21/21	100	84.5-100%
Salmonella spp.	Prospective	0/0	-	-	5/5	100	56.6-100%
	Seeded	3/3	100	43.9-100%	34/34	100	89.8-100%
	Overall	3/3	100	43.9-100%	39/39	100	91.0-100%
Serratia marcescens	Prospective	0/0	-	-	11/11	100	74.1-100%
	Overall	0/0	-	-	11/11	100	74.1-100%
Pseudomonas aeruginosa	Prospective	1/1	100	-	30/30	100	88.6-100%
	Seeded	0/0	-	-	24/24	100	86.2-100%
	Overall	1/1	100	-	54/54	100	93.4-100%

^a Archived testing not performed for NDM with *E. cloacae* complex, *K. aerogenes*, *K. oxytoca*, *Proteus* spp., *Salmonella* spp., *S. marcescens*, or *P. aeruginosa*; seeded testing not performed for NDM with *S. marcescens*

Table 91: BioFire BCID2 Panel Clinical Performance Summary, OXA-48-like

Analyte	Study ^a	Positive Percent Agreement			Negative Percent Agreement		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
OXA-48-like	Prospective	0/0	-	-	323/323	100	98.8-100%
	Seeded	30/30	100	88.6-100%	198/198	100	98.1-100%
	Overall	30/30	100	88.6-100%	521/521	100	99.3-100%

^a Archived testing not performed for OXA-48-like.

Table 92: Distribution of OXA-48-like in Prospective Clinical Specimens

OXA-48-like		SOC: any associated organism PCR/seq: OXA-48-like			
		Org+ / Res+	Org+ / Res-	Org -	Total
BCID2 Panel Result	Org+ / Res+	0	0	0	0
	Org+ / Res-	0	269	54a	323
	Org -	0	1	750	751
	Total	0	270	804	1074
Performance		Agreement		%	95%CI
Org+ / Res+		0/0		-	-
Org+ / Res-		269/270		99.6	97.9-99.9%
Org -		750/804a		93.3	91.3-94.8%

^a Fifty-three (53) FP results due to the presence of nucleic acid from non-viable *E. coli* in the blood culture bottles.

Table 93: Stratification of OXA-48-like Clinical Performance by Associated Host Organism, Seeded Study^a

Analyte	Positive Percent Agreement			Negative Percent Agreement		
	TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
Overall (any associated organism identified)	30/30	100	88.6-100%	198/198	100	98.1-100%
<i>Enterobacterales</i>	30/30	100	88.6-100%	198/198	100	98.1-100%
<i>Enterobacter cloacae</i> complex	0/0	-	-	8/8	100	67.6-100%
<i>Escherichia coli</i>	0/0	-	-	44/44	100	92.0-100%
<i>Klebsiella aerogenes</i>	3/3	100	43.9-100%	39/39	100	91.0-100%
<i>Klebsiella oxytoca</i>	0/0	-	-	6/6	100	61.0-100%
<i>Klebsiella pneumoniae</i> group	27/27	100	87.5-100%	65/65	100	94.4-100%
<i>Proteus</i> spp.	0/0	-	-	9/9	100	70.1-100%
<i>Salmonella</i> spp.	0/0	-	-	37/37	100	90.6-100%

^a No observations for OXA-48-like in prospective evaluation; archived testing not performed; seeded testing not performed for OXA-48-like with *S. marcescens*.

Table 94: BioFire BCID2 Panel Clinical Performance Summary, VIM

Analyte	Study	Positive Percent Agreement			Negative Percent Agreement		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
VIM	Prospective	4/4	100	51.0-100%	355/355	100	98.9-100%

Analyte	Study	Positive Percent Agreement			Negative Percent Agreement		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
	Archived	1/1	100	-	5/5	100	56.6-100%
	Seeded	29/29	100	88.3-100%	232/232	100	98.4-100%
	Overall	34/34	100	89.8-100%	592/592	100	99.4-100%

Table 95: Distribution of VIM in Prospective Clinical Specimens

VIM		SOC: any associated organism PCR/seq: VIM			
		Org+ / Res+	Org+ / Res-	Org -	Total
BCID2 Panel Result	Org+ / Res+	4a	0	0	4
	Org+ / Res-	0	301	54b	355
	Org -	0	2	713	715
	Total	4	303	767	1074
Performance			Agreement	%	95%CI
Org+ / Res+			4/4	100	51.0-100%
Org+ / Res-			301/303	99.3	97.6-99.8%
Org -			713/767b	93.0	90.9-94.6%

^a One specimen had co-detection of *Klebsiella pneumoniae* group with *Pseudomonas aeruginosa*.

^b Fifty-three (53) FP results due to the presence of nucleic acid from non-viable *E. coli* in the blood culture bottles.

Table 96: Stratification of VIM Clinical Performance by Associated Host Organism

Analyte	Study ^a	Positive Percent Agreement			Negative Percent Agreement		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
Overall (any associated organism identified)	Prospective	4/4 ^b	100	51.0-100%	355/355	100	98.9-100%
	Archived	1/1	100	-	5/5	100	56.6-100%
	Seeded	29/29	100	88.3-100%	232/232	100	98.4-100%
	Overall	34/34	100	89.8-100%	592/592	100	99.4-100%
<i>Acinetobacter</i> <i>calcoaceticus-baumannii</i> complex	Prospective	0/0	-	-	13/13	100	77.2-100%
	Archived	0/0	-	-	5/5	100	56.6-100%
	Seeded	0/0	-	-	19/19	100	83.2-100%
	Overall	0/0	-	-	37/37	100	90.6-100%
<i>Enterobacterales</i>	Prospective	2/2	100	34.2-100%	321/321	100	98.8-100%
	Archived	1/1	100	-	0/0	-	-
	Seeded	15/15	100	79.6-100%	213/213	100	98.2-100%
	Overall	18/18	100	82.4-100%	534/534	100	99.3-100%
	Prospective	0/0	-	-	16/16	100	80.6-100%

Analyte	Study ^a	Positive Percent Agreement			Negative Percent Agreement		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>Enterobacter cloacae</i> complex	Seeded	3/3	100	43.9-100%	5/5	100	56.6-100%
	Overall	3/3	100	43.9-100%	21/21	100	84.5-100%
<i>Escherichia coli</i>	Prospective	0/0	-	-	160/160	100	97.7-100%
	Seeded	3/3	100	43.9-100%	41/41	100	91.4-100%
	Overall	3/3	100	43.9-100%	201/201	100	98.1-100%
<i>Klebsiella aerogenes</i>	Prospective	0/0	-	-	2/2	100	34.2-100%
	Seeded	0/0	-	-	42/42	100	91.6-100%
	Overall	0/0	-	-	44/44	100	92.0-100%
<i>Klebsiella oxytoca</i>	Prospective	0/0	-	-	8/8	100	67.6-100%
	Archived	1/1	100	-	0/0	-	-
	Seeded	0/0	-	-	6/6	100	61.0-100%
	Overall	1/1	100	-	14/14	100	78.5-100%
<i>Klebsiella pneumoniae</i> group	Prospective	2/2	100	34.2-100%	53/53	100	93.2-100%
	Seeded	9/9	100	70.1-100%	83/83	100	95.6-100%
	Overall	11/11	100	74.1-100%	136/136	100	97.3-100%
<i>Proteus</i> spp.	Prospective	0/0	-	-	15/15	100	79.6-100%
	Seeded	0/0	-	-	9/9	100	70.1-100%
	Overall	0/0	-	-	24/24	100	86.2-100%
<i>Salmonella</i> spp.	Prospective	0/0	-	-	5/5	100	56.6-100%
	Seeded	0/0	-	-	37/37	100	90.6-100%
	Overall	0/0	-	-	42/42	100	91.6-100%
<i>Serratia marcescens</i>	Prospective	0/0	-	-	11/11	100	74.1-100%
	Overall	0/0	-	-	11/11	100	74.1-100%
<i>Pseudomonas aeruginosa</i>	Prospective	3/3	100	43.9-100%	28/28	100	87.9-100%
	Seeded	14/14	100	78.5-100%	10/10	100	72.2-100%
	Overall	17/17	100	81.6-100%	38/38	100	90.8-100%

^a Archived testing not performed for VIM with *E. cloacae* complex, *E. coli*, *K. aerogenes*, *K. pneumoniae* group, *Proteus* spp., *Salmonella* spp., *S. marcescens*, or *P. aeruginosa*; seeded testing not performed for VIM with *S. marcescens*.

^b One specimen had co-detection of *Klebsiella pneumoniae* group with *Pseudomonas aeruginosa*.

Table 97: BioFire BCID2 Panel Clinical Performance Summary, *mecA/C*, Prospective Study

Analyte	Positive Percent Agreement			Negative Percent Agreement		
	TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>mecA/C</i>	195/195	100	98.1-100%	60/60	100	94.0-100%

^a Archived and seeded testing not performed for *mecA/C*

Table 98: Distribution of *mecA/C* in Prospective Clinical Specimens

<i>mecA/C</i>		SOC: any associated organism FDA-cleared test: <i>mecA</i>			
		Org+ / Res+	Org+ / Res-	Org -	Total
BCID2 Panel Result	Org+ / Res+	171 ^a	0	24	195
	Org+ / Res-	0	54	6	60
	Org -	4	3	811	818
	Total	175	57	841	1073 ^b
Performance		Agreement		%	95%CI
Org+ / Res+		171/175		97.7	94.3-99.1%
Org+ / Res-		54/57		94.7	85.6-98.2%
Org -		811/841		96.4	95.0-97.5%

^a Two specimens had co-detections of *Staphylococcus epidermidis* with *Staphylococcus lugdunensis*.

^b One specimen was FN for the associated host organism by the molecular comparator method, thus providing an "N/A" result for *mecA/C*.

Table 99: Stratification of *mecA/C* Clinical Performance by Associated Host Organism, Prospective Study^a

Analyte	Positive Percent Agreement			Negative Percent Agreement		
	TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
Overall (any associated organism identified)	195/195 ^b	100	98.1-100%	60/60	100	94.0-100%
<i>Staphylococcus epidermidis</i>	194/194	100	98.1-100%	56/56	100	93.6-100%
<i>Staphylococcus lugdunensis</i>	3/3 ^c	100	43.9-100%	4/4	100	51.0-100%

^a Archived and seeded testing not performed for *mecA/C*.

^b Two specimens had co-detections of *Staphylococcus epidermidis* with *Staphylococcus lugdunensis*.

^c All three specimens were identified as mixed cultures with *mecA* present in a different *Staphylococcus* species.

Table 100: BioFire BCID2 Panel Clinical Performance Summary, *mecA/C* and MREJ (MRSA)

Analyte	Study ^a	Positive Percent Agreement			Negative Percent Agreement		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>mecA/C</i> and MREJ (MRSA)	Prospective	52/57	91.2	81.1-96.2%	92/94	97.9	92.6-99.4%
	Seeded	5/5	100	56.6-100%	5/5	100	56.6-100%
	Overall	57/62 ^b	91.9	82.5-96.5%	97/99 ^c	98.0	92.9-99.4%

^a Archived testing not performed for *mecA/C* and MREJ (MRSA).

^b Isolates recovered from the five FN specimens were identified as MSSA by SOC phenotypic AST methods.

^c Isolates recovered from the two FP specimens were identified as MRSA by SOC phenotypic AST methods.

Table 101: Distribution of *mecA/C* and MREJ (MRSA) in Prospective Clinical Specimens

<i>mecA/C</i> and MREJ (MRSA)		SOC: any associated organism FDA-cleared test: MRSA			
		Org+ / Res+	Org+ / Res-	Org -	Total
BCID2 Panel Result	Org+ / Res+	50	2	2	54
	Org+ / Res-	5	92	0	97
	Org -	0	0	923	923
	Total	55	94	925	1074
Performance			Agreement	%	95% CI
Org+ / Res+			50/55	90.9	80.4-96.1%
Org+ / Res-			92/94	97.9	92.6-99.4%
Org -			923/925	99.8	99.2-99.9%

The nature of the seven discrepant results for *mecA/C* and MREJ (MRSA) between the BioFire BCID2 Panel and the reference method (Cepheid Xpert MRSA/SA BC) was investigated using various methods. As shown in Table 102, all *S. aureus* isolates recovered from the five false negative (FN) specimens were negative for the *mecA/C* genes by PCR/sequencing and had a methicillin sensitive antimicrobial susceptibility testing (AST) phenotype, indicating MSSA rather than MRSA. From three of these specimens, the laboratory also isolated a coagulase negative *Staphylococcus* (CoNS) that was methicillin resistant (i.e. carrying the *mecA* or *mecC* gene). Three of the five FN specimens were reported as SA (negative for MRSA) by the Cepheid Xpert MRSA/SA BC test when residual specimen was retested.

Similarly, *S. aureus* isolates from both false positive (FP) specimens were positive for the *mecA/C* genes by PCR/sequencing and had a methicillin resistant AST phenotype. Additionally, one of the specimens had a result of MRSA when retested by the Cepheid Xpert MRSA/SA BC test (Table 97).

In all cases, the BioFire BCID2 Panel *mecA/C* and MREJ (MRSA) results (Detected or Not Detected) were concordant with the AST phenotype of the *S. aureus* isolated from the blood culture, including instances where methicillin resistant CoNS were also present in the specimen.

Table 102: Investigation of Specimens with Discrepant *mecA/C* and MREJ (MRSA) Results

Discrepancy Type ^a	Laboratory Information	BioFire BCID2 Panel	Cepheid Xpert MRSA/SA BC	Investigation Summary		
	Additional <i>Staphylococci</i> Isolated	<i>mecA/C</i> and MREJ (MRSA) Results (associated with TP <i>S. aureus</i>) ^b	MRSA/SA Results ^c	Cepheid Xpert MRSA/SA BC Retest ^c	<i>mecA/C</i> Isolate PCR/sequencing Result	SOC Isolate AST Result (methicillin resistance phenotype) ^d
FN	-	Not Detected	MRSA	SA	Negative	MSSA
FN	<i>S. haemolyticus</i> (methicillin resistant)	Not Detected	MRSA	SA	Negative	MSSA
FN	<i>S. epidermidis</i> (methicillin resistant)	Not Detected	MRSA	MRSA	Negative	MSSA
FN	-	Not Detected	MRSA	SA	Negative	MSSA
FN	<i>S. epidermidis</i> (methicillin resistant)	Not Detected	MRSA	MRSA	Negative	MSSA
FP	-	Detected	SA	MRSA	Positive	MRSA
FP	-	Detected	SA	SA	Positive	MRSA

^a FN = false negative; FP = false positive

^b TP = true positive

^c MRSA = methicillin resistant *Staphylococcus aureus*; SA = *Staphylococcus aureus*

^d SOC = standard of care; MSSA = methicillin sensitive *Staphylococcus aureus*; MRSA = methicillin resistant *Staphylococcus aureus*

Table 103: BioFire BCID2 Panel Clinical Performance Summary, *mcr-1*

Analyte	Study ^a	Positive Percent Agreement			Negative Percent Agreement		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
<i>mcr-1</i>	Prospective	0/0	-	-	240/240	100	98.4-100%
	Seeded	30/30	100	88.6-100%	189/189	100	98.0-100%
	Overall	30/30	100	88.6-100%	429/429	100	99.1-100%

^a Archived testing not performed for *mcr-1*.

Table 104: Distribution of *mcr-1* in Prospective Clinical Specimens

<i>Mcr-1</i>		SOC: any associated organism PCR/seq: <i>mcr-1</i>			
		Org+ / Res+	Org+ / Res-	Org -	Total
BCID2 Panel Result	Org+ / Res+	0	0	0	0
	Org+ / Res-	0	238	2	240
	Org -	0	0	834	834
	Total	0	238	836	1074
Performance		Agreement		%	95% CI
Org+ / Res+		0/0		-	-
Org+ / Res-		238/238		100	98.4-100%
Org -		834/836		99.8	99.1-99.9%

Table 105: Stratification of *mcr-1* Clinical Performance by Associated Host Organism, Seeded Study^a

Analyte	Positive Percent Agreement			Negative Percent Agreement		
	TP/ (TP + FN)	%	95% CI	TN/ (TN + FP)	%	95% CI
Overall (any associated organism identified)	30/30	100	88.6-100%	189/189	100	98.0-100%
<i>Enterobacter cloacae</i> complex	0/0	-	-	8/8	100	67.6-100%
<i>Escherichia coli</i>	22/22	100	85.1-100%	22/22	100	85.1-100%
<i>Klebsiella aerogenes</i>	0/0	-	-	42/42	100	91.6-100%
<i>Klebsiella oxytoca</i>	0/0	-	-	6/6	100	61.0-100%
<i>Klebsiella pneumoniae</i> group	4/4	100	51.0-100%	88/88	100	95.8-100%
<i>Salmonella</i> spp.	4/4	100	51.0-100%	33/33	100	89.6-100%

^a No observations for *mcr-1* in prospective evaluation; no archived testing performed.

Table 106: BioFire BCID2 Panel Clinical Performance Summary, *vanA/B*

Analyte	Study ^a	Positive Percent Agreement			Negative Percent Agreement		
		TP/ (TP + FN)	%	95% CI	TN/ (TN + FP)	%	95% CI
<i>vanA/B</i>	Prospective	23/24	95.8	79.8-99.3%	38/38	100	90.8-100%
	Archived	16/16	100	80.6-100%	0/0	-	-
	Overall	39/40 ^b	97.5	87.1-99.6%	38/38	100	90.8-100%

^a Seeded testing not performed for *vanA/B*.

^b *vanA/B* was detected in the single FN specimen upon BioFire BCID2 Panel retest; the isolate recovered from this specimen was vancomycin resistant by SOC phenotypic AST methods.

Table 107: Distribution of *vanA/B* in Prospective Clinical Specimens

<i>vanA/B</i>		SOC: any associated organism FDA-cleared test: <i>vanA/B</i>			
		Org+ / Res+	Org+ / Res-	Org -	Total
BCID2 Panel Result	Org+ / Res+	22	0	1	23
	Org+ / Res-	1	35	3	39
	Org -	0	0	1010	1010
	Total	23	35	1014	1072a
Performance			Agreement	%	95%CI
Org+ / Res+			22/23	95.7	79.0-99.2%
Org+ / Res-			35/35	100	90.1-100%
Org -			1010/1014	99.6	99.0-99.8%

^a Two specimens were FN for the associated host organism by the molecular comparator method, thus providing an “N/A” result for *vanA/B*.

Table 108: Stratification of *vanA/B* Clinical Performance by Associated Host Organism

Analyte	Study ^a	Positive Percent Agreement			Negative Percent Agreement		
		TP/ (TP + FN)	%	95%CI	TN/ (TN + FP)	%	95%CI
Overall (any associated organism identified)	Prospective	23/24	95.8	79.8-99.3%	38/38	100	90.8-100%
	Archived	16/16	100	80.6-100%	0/0	-	-
	Overall	39/40	97.5	87.1-99.6%	38/38	100	90.8-100%
<i>Enterococcus faecalis</i>	Prospective	1/1	100	-	31/31	100	89.0-100%
	Archived	2/2	100	34.2-100%	0/0	-	-
	Overall	3/3	100	43.9-100%	31/31	100	89.0-100%
<i>Enterococcus faecium</i>	Prospective	22/23	95.7	79.0-99.2%	7/7	100	64.6-100%
	Archived	14/14	100	78.5-100%	0/0	-	-
	Overall	36/37	97.3	86.2-99.5%	7/7	100	64.6-100%

^a Seeded testing not performed for *vanA/B*.

For prospective specimens only, correlation of the AMR gene results reported in the specimen by the BCID2 Panel to identification of the gene in the cultured isolates from that particular specimen was assessed using one polymerase chain reaction (PCR) assay followed by bidirectional sequencing, performed directly on the isolate. The results are shown only for isolates recovered from specimens with true positive results (i.e. concordant results between BCID2 Panel and culture), and further stratified by each applicable host organism recovered from that specimen. There were no observations by either the BioFire BCID2 Panel or the reference/comparator methods for IMP, OXA-48-like, and *mcr-1*; therefore, performance Tables are not shown for these analytes. Performance for the remaining analytes is presented in Table 109 through Table 112.

Table 109: CTX-M and Select Carbapenem Resistance Genes Performance Table (as compared to PCR/seq on cultured isolate(s) from prospective PBC specimens)

Organism Identified by SOC and Detected by the BCID2 Panel	N	CTX-M		KPC		NDM		VIM		Overall (any resistance gene)	
		PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
Overall (any associated organism identified)	317	46/46 (100%)	267/271 (98.5%)	4/4 (100%)	313/313 (100%)	1/1 (100%)	315/316 (99.7%)	4/4 (100%)	312/313 (99.7%)	53/53 (100%) [93.2-100%]	261/264 (98.9%) [96.7-99.6%]
<i>Acinetobacter calcoaceticus-baumannii</i> complex	12	0/0 (-)	11/12 (91.7%)	0/0 (-)	12/12 (100%)	0/0 (-)	12/12 (100%)	0/0 (-)	12/12 (100%)	0/0 (-)	11/12 (91.7%)
<i>Enterobacterales</i>	276	46/46 (100%)	229/230 (99.6%)	4/4 (100%)	272/272 (100%)	1/1 (100%)	275/275 (100%)	1/1 (100%)	274/275 (99.6%)	50/50 ^a (100%)	225/226 (99.6%)
<i>Enterobacter cloacae</i> complex	16	0/0 (-)	16/16 (100%)	0/0 (-)	16/16 (100%)	0/0 (-)	16/16 (100%)	0/0 (-)	16/16 (100%)	0/0 (-)	16/16 (100%)
<i>Escherichia coli</i>	158	30/30 (100%)	128/128 (100%)	0/0 (-)	158/158 (100%)	0/0 (-)	158/158 (100%)	0/0 (-)	158/158 (100%)	30/30 (100%)	128/128 (100%)
<i>Klebsiella aerogenes</i>	2	0/0 (-)	1/2 (50.0%)	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	0/0 (-)	1/2 (50.0%)
<i>Klebsiella oxytoca</i>	8	0/0 (-)	8/8 (100%)	0/0 (-)	8/8 (100%)	0/0 (-)	8/8 (100%)	0/0 (-)	8/8 (100%)	0/0 (-)	8/8 (100%)
<i>Klebsiella pneumoniae</i> group	55	12/12 (100%)	43/43 (100%)	4/4 (100%)	51/51 (100%)	1/1 (100%)	54/54 (100%)	1/1 (100%)	53/54 (98.1%)	16/16 ^a (100%)	39/39 (100%)
<i>Proteus</i> spp.	14	4/4 (100%)	10/10 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	4/4 (100%)	10/10 (100%)
<i>Salmonella</i> spp.	5	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)
<i>Serratia marcescens</i>	11	0/0 (-)	11/11 (100%)	0/0 (-)	11/11 (100%)	0/0 (-)	11/11 (100%)	0/0 (-)	11/11 (100%)	0/0 (-)	11/11 (100%)

Organism Identified by SOC and Detected by the BCID2 Panel	N	CTX-M		KPC		NDM		VIM		Overall (any resistance gene)	
		PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
<i>Pseudomonas aeruginosa</i>	29	0/0 (-)	27/29 (93.1%)	0/0 (-)	29/29 (100%)	0/0 (-)	28/29 (96.6%)	3/3 (100%)	26/26 (100%)	3/3 (100%)	25/26 (96.2%)

^a Two *K. pneumoniae* group isolates had presence of dual AMR genes as determined by PCR (one CTX-M and NDM; one CTX-M and VIM).

Table 110: *mecA/C* Performance Table (as compared to PCR/seq on cultured isolate(s) from prospective PBC specimens)

Organism Identified by SOC and Detected by the BCID2 Panel	Positive Percent Agreement			Negative Percent Agreement		
	TP/ (TP + FN)	%	95% CI	TN/ (TN + FP)	%	95% CI
Overall (any associated organism identified)	162/165	98.2	94.8-99.4%	51/60	85.0	73.9-91.9%
<i>Staphylococcus epidermidis</i>	162/165	98.2	94.8-99.4%	47/56	83.9	72.2-91.3%
<i>Staphylococcus lugdunensis</i>	0/0	-	-	4/4	100	51.0-100%

Table 111: *mecA/C* and MREJ (MRSA) Performance Table (as compared to PCR/seq on cultured isolate(s) from prospective PBC specimens)

Organism Identified by SOC and Detected by the BCID2 Panel	Positive Percent Agreement			Negative Percent Agreement		
	TP/ (TP + FN)	%	95% CI	TN/ (TN + FP)	%	95% CI
<i>Staphylococcus aureus</i>	52/52	100	93.1-100%	97/97	100	96.2-100%

Table 112: *vanA/B* Performance Table (as compared to PCR/seq on cultured isolate(s) from prospective PBC specimens)

Organism Identified by SOC and Detected by the BCID2 Panel	Positive Percent Agreement			Negative Percent Agreement		
	TP/ (TP + FN)	%	95% CI	TN/ (TN + FP)	%	95% CI
Overall (any associated organism identified)	22/23	95.7	79.0-99.2%	35/35	100	90.1-100%
<i>Enterococcus faecalis</i>	1/1	100	-	30/30	100	88.6-100%
<i>Enterococcus faecium</i>	21/22	95.5	78.2-99.2%	5/5	100	56.6-100%

For prospective specimens, the BioFire BCID2 Panel AMR gene reporting in the specimen was also compared to phenotypic antimicrobial susceptibility testing (AST) methods performed on organism isolates recovered from those specimens. The results presented in Table 113 through Table 118 are only for specimens with concordant (true positive) results and are further stratified by each applicable host organism recovered from that specimen. Note that antimicrobial resistance, particularly extended-spectrum β -lactamase (ESBL) activity and, carbapenem resistance, may be due to mechanisms other than the presence of the AMR genes detected by the

BioFire BCID2 Panel; conversely, detection of these genes may not always confer an antimicrobial resistance phenotype. Additionally, discordant results between mecA/C detection in a blood culture specimen by the BioFire BCID2 Panel and the observed methicillin (oxacillin/cefoxitin) resistance of cultured Staphylococcus isolates may be due to polymicrobial Staphylococcus cultures containing a mixture of resistant and sensitive organisms.

Table 113: CTX-M Performance Table (as compared to phenotypic AST methods for ESBL activity on cultured isolate(s) from prospective PBC specimens)

Organism Identified by SOC and Detected by the BCID2 Panel	N		Positive Percent Agreement			Negative Percent Agreement		
	ESBL	Non-ESBL	TP/ (TP + FN)	%	95% CI	TN/ (TN + FP)	%	95% CI
<i>Overall</i> (any associated organism identified)	313		43/46	93.5	82.5-97.8%	260/267	97.4	94.7-98.7%
	46	267						
<i>Acinetobacter calcoaceticus-baumannii</i> complex	12		0/0	-	-	11/12	91.7	64.6-98.5%
	0	12						
<i>Enterobacterales</i>	273		43/46	93.5	82.5-97.8%	223/227	98.2	95.6-99.3%
	46	227						
<i>Enterobacter cloacae</i> complex	16		0/0	-	-	16/16	100	80.6-100%
	0	16						
<i>Escherichia coli</i>	157		30/30	100	88.6-100%	127/127	100	97.1-100%
	30	127						
<i>Klebsiella aerogenes</i>	2		0/0	-	-	1/2	50.0	-
	0	2						
<i>Klebsiella oxytoca</i>	8		0/1	0	-	7/7	100	64.6-100%
	1	7						
<i>Klebsiella pneumoniae</i> group	54		10/11	90.9	62.3-98.4%	41/43	95.3	84.5-98.7%
	11	43						
<i>Proteus</i> spp.	14		3/4	75.0	30.1-95.4%	9/10	90.0	59.6-98.2%
	4	10						
<i>Salmonella</i> spp.	5		0/0	-	-	5/5	100	56.6-100%
	0	5						
<i>Serratia marcescens</i>	11		0/0	-	-	11/11	100	74.1-100%
	0	11						
<i>Pseudomonas aeruginosa</i>	28		0/0	-	-	26/28	92.9	77.4-98.0%
	0	28						

Table 114: Carbapenem Resistance Genes Performance Table (as compared to phenotypic AST methods for carbapenem resistance on cultured isolate(s) from prospective PBC specimens)

Organism Identified by SOC and Detected by BioFire BCID2 Panel	N		IMP		KPC		NDM		OXA-48-like		VIM		Overall (any resistance gene)	
	R	S	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
Overall (any associated organism identified)	313		0/25 (0%)	288/288 (100%)	4/25 (16.0%)	288/288 (100%)	2/25 (8.0%)	288/288 (100%)	0/6 (0%)	267/267 (100%)	4/25 (16.0%)	287/288 (99.7%)	8/25 (32.0%) [17.2-51.6%]	287/288 (99.7%) [98.1-99.9%]
	25	288												
<i>Acinetobacter calcoaceticus -baumannii</i> complex	12		0/12 (0%)	0/0 (-)	0/12 (0%)	0/0 (-)	0/12 (0%)	0/0 (-)	N/A	N/A	0/12 (0%)	0/0 (-)	0/12 (0%)	0/0 (-)
	12	0												
<i>Enterobacter</i> <i>ales</i>	273		0/6 (0%)	267/267 (100%)	4/6 (66.7%)	267/267 (100%)	1/6 (16.7%)	267/267 (100%)	0/6 (0%)	267/267 (100%)	1/6 (16.7%)	266/267 (99.6%)	5/6 ^a (83.3%)	266/267 (99.6%)
	6	267												
<i>Enterobacter cloacae</i> complex	16		0/0 (-)	16/16 (100%)	0/0 (-)	16/16 (100%)	0/0 (-)	16/16 (100%)	0/0 (-)	16/16 (100%)	0/0 (-)	16/16 (100%)	0/0 (-)	16/16 (100%)
	0	16												
<i>Escherichia coli</i>	157		0/0 (-)	157/157 (100%)	0/0 (-)	157/157 (100%)	0/0 (-)	157/157 (100%)	0/0 (-)	157/157 (100%)	0/0 (-)	157/157 (100%)	0/0 (-)	157/157 (100%)
	0	157												
<i>Klebsiella aerogenes</i>	2		0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)
	0	2												
<i>Klebsiella oxytoca</i>	8		0/0 (-)	8/8 (100%)	0/0 (-)	8/8 (100%)	0/0 (-)	8/8 (100%)	0/0 (-)	8/8 (100%)	0/0 (-)	8/8 (100%)	0/0 (-)	8/8 (100%)
	0	8												
<i>Klebsiella pneumoniae</i> group	54		0/6 (0%)	48/48 (100%)	4/6 (66.7%)	48/48 (100%)	1/6 (16.7%)	48/48 (100%)	0/6 (0%)	48/48 (100%)	1/6 (16.7%)	47/48 (97.9%)	5/6 ^a (83.3%)	47/48 (97.9%)
	6	48												
<i>Proteus</i> spp.	14		0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)	0/0 (-)	14/14 (100%)
	0	14												

Organism Identified by SOC and Detected by BioFire BCID2 Panel	N		IMP		KPC		NDM		OXA-48-like		VIM		Overall (any resistance gene)	
	R	S	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
<i>Salmonella</i> spp.	5		0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)	0/0 (-)	5/5 (100%)
	0	5												
<i>Serratia marcescens</i>	11		0/0 (-)	11/11 (100%)	0/0 (-)	11/11 (100%)	0/0 (-)	11/11 (100%)	0/0 (-)	11/11 (100%)	0/0 (-)	11/11 (100%)	0/0 (-)	11/11 (100%)
	0	1												
<i>Pseudomonas aeruginosa</i>	28		0/7 (0%)	21/21 (100%)	0/7 (0%)	21/21 (100%)	1/7 (14.3%)	21/21 (100%)	N/A	N/A	3/7 (42.9%)	21/21 (100%)	3/7 ^b (42.9%)	21/21 (100%)

^a One *K. pneumoniae* group isolate had presence of dual AMR genes as determined by the BCID2 Panel (NDM and VIM).

^b One *P. aeruginosa* isolate had presence of dual AMR genes as determined by the BCID2 Panel (NDM and VIM).

Table 115: *mecA/C* Performance Table (as compared to phenotypic AST methods for methicillin (oxacillin/cefoxitin) resistance on cultured isolate(s) from prospective PBC specimens)

Organism Identified by SOC and Detected by the BCID2 Panel	N		Positive Percent Agreement			Negative Percent Agreement		
	R	S	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall (any associated organism identified)	225		160/164	97.6	93.9-99.0%	50/61	82.0	70.5-89.6%
	164	61						
<i>Staphylococcus epidermidis</i>	221		160/163	98.2	94.7-99.4%	47/58	81.0	69.1-89.1%
	163	58						
<i>Staphylococcus lugdunensis</i>	4		0/1	0	-	3/3	100	43.9-100%
	1	3						

Table 116: *mecA/C* and MREJ (MRSA) Performance Table (as compared to phenotypic AST methods for methicillin (oxacillin/cefoxitin) resistance on cultured isolate(s) from prospective PBC specimens)

Organism Identified by SOC and Detected by the BCID2 Panel	N		Positive Percent Agreement			Negative Percent Agreement		
	R	S	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
<i>Staphylococcus aureus</i>	149		52/52	100	93.1-100%	97/97	100	96.2-100%
	52	97						

Table 117: *mcr-1* Performance Table (as compared to phenotypic AST methods for colistin on cultured isolate(s) from prospective PBC specimens)^a

Organism Identified by SOC and Detected by FilmArray BCID2 Panel	MIC (µg/mL)	N
<i>Overall</i> (any associated organism identified)	0.25	242
	0.5	241
	1	112
	2	21
	4	8
	>4	6
<i>Enterobacter cloacae</i> complex	0.25	16
	0.5	15
	1	12
	2	5
	4	2
	>4	2
<i>Escherichia coli</i>	0.25	157
	0.5	157
	1	60
	2	7
	4	3
	>4	2
<i>Klebsiella aerogenes</i>	0.25	2
	0.5	2
	1	1
	2	1
	4	0
	>4	0
<i>Klebsiella oxytoca</i>	0.25	8
	0.5	8
	1	5
	2	1
	4	1
	>4	1
<i>Klebsiella pneumoniae</i> group	0.25	54
	0.5	54
	1	29
	2	6
	4	1
	>4	1

Organism Identified by SOC and Detected by FilmArray BCID2 Panel	MIC (µg/mL)	N
<i>Salmonella</i> spp.	0.25	5
	0.5	5
	1	5
	2	1
	4	1
	>4	0

^a No *mcr-1* specimens were identified by the BioFire BCID2 Panel in the prospective clinical evaluation.

^b Minimum inhibitory concentration (MIC) values were determined using microbroth dilution. As of February 2020, the United States Food and Drug Administration has not established or recognized MIC breakpoints for colistin antimicrobial susceptibility testing (AST) related to *mcr-1*.

Table 118: *vanA/B* Performance Table (as compared to phenotypic AST methods for vancomycin

Organism Identified by SOC and Detected by the BCID2 Panel	N		Positive Percent Agreement			Negative Percent Agreement		
	R	S	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
<i>Overall</i> (any associated organism identified)	58		21/22	95.5	78.2-99.2%	35/36	97.2	85.8-99.5%
	22	36						
<i>Enterococcus faecalis</i>	31		1/1	100	-	30/30	100	88.6-100%
	1	30						
<i>Enterococcus faecium</i>	27		20/21	95.2	77.3-99.2%	5/6	83.3	43.6-97.0%
	21	6						

The overall success rate for initial specimen tests in all three clinical studies was 99.4% (2042/2055). Eight tests (8/2055; 0.4%) did not complete on the initial test attempt, resulting in an instrument success rate of 99.6% (2047/2055) for initial specimen tests. Seven of the eight specimens were able to be retested and valid results were produced after a single retest. Of the 2047 tests that successfully produced a completed run on the initial test, 2042 had valid pouch controls. This represents a 99.8% (2042/2047) success rate for pouch controls in completed runs in the initial specimen tests. The five specimens with invalid control(s) were able to be retested and valid results were produced on the first retest.

2. Clinical Specificity:

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

D Clinical Cut-Off:

E Expected Values/Reference Range:

In the prospective clinical evaluation of the BioFire BCID2 Panel, 1074 positive blood culture (PBC) specimens were collected and tested at nine study sites across the United States and Europe over approximately eight months (October 2018 to May 2019). Expected value

summaries (as determined by the BioFire BCID2 Panel) are stratified by specimen enrollment site in Table 114 and by subject age in Table 115.

Table 119: Expected Value (as determined by the BioFire BCID2 Panel) Summary by Site for PBC Specimens Collected during the BioFire BCID2 Panel Prospective Clinical Evaluation (October 2018 to May 2019)

BioFire BCID2 Panel Result	Overall (N=1074)		Site 1 (N=117)		Site 2 (N=98)		Site 3 (N=191)		Site 4 (N=84)		Site 5 (N=106)		Site 6 (N=118)		Site 7 (N=146)		Site 8 (N=104)		Site 9 (N=110)	
	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV
Gram-Positive Bacteria																				
<i>Enterococcus faecalis</i>	32	3.0%	2	1.7%	1	1.0%	3	1.6%	5	6.0%	7	6.6%	6	5.1%	2	1.4%	5	4.8%	1	0.9%
<i>Enterococcus faecium</i>	30	2.8%	0	0%	4	4.1%	5	2.6%	9	10.7%	0	0%	4	3.4%	0	0%	2	1.9%	6	5.5%
<i>Listeria monocytogenes</i>	3	0.3%	0	0%	1	1.0%	0	0%	1	1.2%	0	0%	0	0%	0	0%	1	1.0%	0	0%
<i>Staphylococcus</i> spp.	484	45.1%	57	48.7%	29	29.6%	93	48.7%	31	36.9%	54	50.9%	58	49.2%	85	58.2%	43	41.3%	34	30.9%
<i>Staphylococcus aureus</i>	151	14.1%	17	14.5%	9	9.2%	14	7.3%	14	16.7%	19	17.9%	22	18.6%	24	16.4%	18	17.3%	14	12.7%
<i>Staphylococcus epidermidis</i>	250	23.3%	30	25.6%	14	14.3%	59	30.9%	12	14.3%	27	25.5%	28	23.7%	43	29.5%	23	22.1%	14	12.7%
<i>Staphylococcus lugdunensis</i>	7	0.7%	0	0%	0	0%	2	1.0%	1	1.2%	1	0.9%	2	1.7%	1	0.7%	0	0%	0	0%
<i>Streptococcus</i> spp.	123	11.5%	23	19.7%	12	12.2%	8	4.2%	6	7.1%	18	17.0%	8	6.8%	26	17.8%	9	8.7%	13	11.8%
<i>Streptococcus agalactiae</i> (Group B)	9	0.8%	0	0%	1	1.0%	2	1.0%	0	0%	3	2.8%	0	0%	1	0.7%	2	1.9%	0	0%
<i>Streptococcus pneumoniae</i>	26	2.4%	9	7.7%	1	1.0%	0	0%	0	0%	3	2.8%	3	2.5%	4	2.7%	5	4.8%	1	0.9%
<i>Streptococcus pyogenes</i> (Group A)	13	1.2%	7	6.0%	1	1.0%	0	0%	0	0%	2	1.9%	0	0%	2	1.4%	0	0%	1	0.9%
Gram-Negative Bacteria																				
<i>Acinetobacter calcoaceticus-baumannii</i> complex	13	1.2%	0	0%	0	0%	10	5.2%	0	0%	0	0%	1	0.8%	0	0%	2	1.9%	0	0%
<i>Bacteroides fragilis</i>	9	0.8%	0	0%	0	0%	2	1.0%	1	1.2%	1	0.9%	1	0.8%	0	0%	0	0%	4	3.6%
<i>Enterobacteriales</i>	323	30.1%	19	16.2%	33	33.7%	50	26.2%	32	38.1%	34	32.1%	35	29.7%	44	30.1%	43	41.3%	33	30.0%
<i>Enterobacter cloacae</i> complex	16	1.5%	0	0%	4	4.1%	4	2.1%	1	1.2%	0	0%	1	0.8%	1	0.7%	3	2.9%	2	1.8%
<i>Escherichia coli</i>	160	14.9%	14	12.0%	20	20.4%	26	13.6%	8	9.5%	9	8.5%	17	14.4%	12	8.2%	27	26.0%	27	24.5%
<i>Klebsiella aerogenes</i>	2	0.2%	0	0%	0	0%	0	0%	0	0%	0	0%	1	0.8%	0	0%	0	0%	1	0.9%
<i>Klebsiella oxytoca</i>	8	0.7%	1	0.9%	0	0%	1	0.5%	3	3.6%	0	0%	1	0.8%	1	0.7%	1	1.0%	0	0%
<i>Klebsiella pneumoniae</i> group	55	5.1%	1	0.9%	4	4.1%	13	6.8%	7	8.3%	6	5.7%	12	10.2%	1	0.7%	5	4.8%	6	5.5%
<i>Proteus</i> spp.	15	1.4%	0	0%	3	3.1%	4	2.1%	0	0%	3	2.8%	0	0%	0	0%	5	4.8%	0	0%
<i>Salmonella</i> spp.	5	0.5%	2	1.7%	1	1.0%	0	0%	1	1.2%	0	0%	0	0%	1	0.7%	0	0%	0	0%
<i>Serratia marcescens</i>	11	1.0%	1	0.9%	1	1.0%	1	0.5%	0	0%	1	0.9%	0	0%	2	1.4%	3	2.9%	2	1.8%
<i>Haemophilus influenzae</i>	8	0.7%	4	3.4%	1	1.0%	0	0%	0	0%	1	0.9%	0	0%	2	1.4%	0	0%	0	0%
<i>Neisseria meningitidis</i>	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
<i>Pseudomonas aeruginosa</i>	31	2.9%	1	0.9%	2	2.0%	5	2.6%	1	1.2%	2	1.9%	7	5.9%	4	2.7%	6	5.8%	3	2.7%
<i>Stenotrophomonas maltophilia</i>	7	0.7%	1	0.9%	0	0%	2	1.0%	2	2.4%	0	0%	1	0.8%	1	0.7%	0	0%	0	0%
AMR Genes																				
CTX-M	46	4.3%	2	1.7%	7	7.1%	8	4.2%	7	8.3%	1	0.9%	3	2.5%	2	1.4%	10	9.6%	6	5.5%

BioFire BCID2 Panel Result	Overall (N=1074)		Site 1 (N=117)		Site 2 (N=98)		Site 3 (N=191)		Site 4 (N=84)		Site 5 (N=106)		Site 6 (N=118)		Site 7 (N=146)		Site 8 (N=104)		Site 9 (N=110)	
	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV
IMP	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
KPC	4	0.4%	0	0%	0	0%	4	2.1%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
NDM	1	0.1%	0	0%	0	0%	1	0.5%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
OXA-48-like	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
VIM	4	0.4%	0	0%	0	0%	4	2.1%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
<i>mecA/C</i>	195	18.2%	23	19.7%	10	10.2%	50	26.2%	9	10.7%	19	17.9%	24	20.3%	30	20.5%	19	18.3%	11	10.0%
<i>mecA/C</i> and MREJ (MRSA)	54	5.0%	3	2.6%	4	4.1%	9	4.7%	5	6.0%	5	4.7%	8	6.8%	11	7.5%	2	1.9%	7	6.4%
<i>mcr-1</i>	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
<i>vanA/B</i>	23	2.1%	0	0%	3	3.1%	2	1.0%	9	10.7%	1	0.9%	4	3.4%	0	0%	0	0%	4	3.6%
Yeast																				
<i>Candida albicans</i>	13	1.2%	1	0.9%	3	3.1%	5	2.6%	0	0%	0	0%	0	0%	1	0.7%	2	1.9%	1	0.9%
<i>Candida auris</i>	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
<i>Candida glabrata</i>	11	1.0%	0	0%	3	3.1%	0	0%	3	3.6%	0	0%	1	0.8%	0	0%	0	0%	4	3.6%
<i>Candida krusei</i>	2	0.2%	0	0%	0	0%	2	1.0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
<i>Candida parapsilosis</i>	9	0.8%	1	0.9%	0	0%	4	2.1%	0	0%	1	0.9%	0	0%	0	0%	2	1.9%	1	0.9%
<i>Candida tropicalis</i>	5	0.5%	0	0%	1	1.0%	1	0.5%	0	0%	0	0%	0	0%	0	0%	3	2.9%	0	0%
<i>Cryptococcus neoformans/gattii</i>	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%

Table 120: Expected Value (as determined by the BioFire BCID2 Panel) Summary by Age Group for PBC Specimens Collected during the BioFire BCID2 Panel Prospective Clinical Evaluation (October 2018 to May 2019)

BioFire BCID2 Panel Result	Overall (N=1074)		<1 year (N=118)		1-17 years (N=143)		18-44 years (N=125)		45-64 years (N=257)		65-84 years (N=333)		85+ years (N=98)	
	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV
Gram-Positive Bacteria														
<i>Enterococcus faecalis</i>	32	3.0%	4	3.4%	1	0.7%	4	3.2%	8	3.1%	14	4.2%	1	1.0%
<i>Enterococcus faecium</i>	30	2.8%	0	0%	0	0%	3	2.4%	10	3.9%	15	4.5%	2	2.0%
<i>Listeria monocytogenes</i>	3	0.3%	0	0%	0	0%	1	0.8%	1	0.4%	0	0%	1	1.0%
<i>Staphylococcus</i> spp.	484	45.1%	70	59.3%	68	47.6%	67	53.6%	111	43.2%	137	41.1%	31	31.6%
<i>Staphylococcus aureus</i>	151	14.1%	13	11.0%	28	19.6%	20	16.0%	35	13.6%	41	12.3%	14	14.3%
<i>Staphylococcus epidermidis</i>	250	23.3%	46	39.0%	25	17.5%	35	28.0%	58	22.6%	74	22.2%	12	12.2%
<i>Staphylococcus lugdunensis</i>	7	0.7%	0	0%	0	0%	1	0.8%	3	1.2%	3	0.9%	0	0%
<i>Streptococcus</i> spp.	123	11.5%	25	21.2%	28	19.6%	10	8.0%	23	8.9%	30	9.0%	7	7.1%
<i>Streptococcus agalactiae</i> (Group B)	9	0.8%	1	0.8%	0	0%	0	0%	1	0.4%	7	2.1%	0	0%
<i>Streptococcus pneumoniae</i>	26	2.4%	7	5.9%	7	4.9%	2	1.6%	3	1.2%	5	1.5%	2	2.0%
<i>Streptococcus pyogenes</i> (Group A)	13	1.2%	0	0%	10	7.0%	2	1.6%	0	0%	1	0.3%	0	0%
Gram-Negative Bacteria														
<i>Acinetobacter calcoaceticus-baumannii</i> complex	13	1.2%	0	0%	0	0%	2	1.6%	4	1.6%	7	2.1%	0	0%
<i>Bacteroides fragilis</i>	9	0.8%	0	0%	0	0%	0	0%	2	0.8%	5	1.5%	2	2.0%
<i>Enterobacteriales</i>	323	30.1%	32	27.1%	30	21.0%	32	25.6%	78	30.4%	109	32.7%	42	42.9%
<i>Enterobacter cloacae</i> complex	16	1.5%	1	0.8%	0	0%	0	0%	5	1.9%	7	2.1%	3	3.1%
<i>Escherichia coli</i>	160	14.9%	16	13.6%	10	7.0%	13	10.4%	36	14.0%	61	18.3%	24	24.5%
<i>Klebsiella aerogenes</i>	2	0.2%	0	0%	0	0%	0	0%	2	0.8%	0	0%	0	0%
<i>Klebsiella oxytoca</i>	8	0.7%	1	0.8%	2	1.4%	0	0%	3	1.2%	1	0.3%	1	1.0%
<i>Klebsiella pneumoniae</i> group	55	5.1%	2	1.7%	1	0.7%	5	4.0%	20	7.8%	22	6.6%	5	5.1%
<i>Proteus</i> spp.	15	1.4%	0	0%	0	0%	0	0%	3	1.2%	8	2.4%	4	4.1%
<i>Salmonella</i> spp.	5	0.5%	2	1.7%	2	1.4%	0	0%	0	0%	1	0.3%	0	0%

BioFire BCID2 Panel Result	Overall (N=1074)		<1 year (N=118)		1-17 years (N=143)		18-44 years (N=125)		45-64 years (N=257)		65-84 years (N=333)		85+ years (N=98)	
	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV
<i>Serratia marcescens</i>	11	1.0%	0	0%	3	2.1%	2	1.6%	2	0.8%	2	0.6%	2	2.0%
<i>Haemophilus influenzae</i>	8	0.7%	2	1.7%	4	2.8%	0	0%	1	0.4%	1	0.3%	0	0%
<i>Neisseria meningitidis</i>	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
<i>Pseudomonas aeruginosa</i>	31	2.9%	0	0%	3	2.1%	4	3.2%	8	3.1%	11	3.3%	5	5.1%
<i>Stenotrophomonas maltophilia</i>	7	0.7%	2	1.7%	0	0%	0	0%	1	0.4%	4	1.2%	0	0%
AMR Genes														
CTX-M	46	4.3%	3	2.5%	1	0.7%	5	4.0%	9	3.5%	20	6.0%	8	8.2%
IMP	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
KPC	4	0.4%	0	0%	0	0%	0	0%	2	0.8%	1	0.3%	1	1.0%
NDM	1	0.1%	0	0%	0	0%	0	0%	1	0.4%	0	0%	0	0%
OXA-48-like	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
VIM	4	0.4%	1	0.8%	0	0%	0	0%	2	0.8%	1	0.3%	0	0%
<i>mecA/C</i>	195	18.2%	34	28.8%	19	13.3%	25	20.0%	44	17.1%	64	19.2%	9	9.2%
<i>mecA/C</i> and MREJ (MRSA)	54	5.0%	3	2.5%	9	6.3%	8	6.4%	12	4.7%	14	4.2%	8	8.2%
<i>mcr-1</i>	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
<i>vanA/B</i>	23	2.1%	0	0%	0	0%	3	2.4%	5	1.9%	13	3.9%	2	2.0%
Yeast														
<i>Candida albicans</i>	13	1.2%	2	1.7%	1	0.7%	0	0%	2	0.8%	6	1.8%	2	2.0%
<i>Candida auris</i>	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
<i>Candida glabrata</i>	11	1.0%	0	0%	0	0%	1	0.8%	4	1.6%	5	1.5%	1	1.0%
<i>Candida krusei</i>	2	0.2%	0	0%	0	0%	0	0%	0	0%	2	0.6%	0	0%
<i>Candida parapsilosis</i>	9	0.8%	0	0%	1	0.7%	1	0.8%	4	1.6%	3	0.9%	0	0%
<i>Candida tropicalis</i>	5	0.5%	0	0%	0	0%	0	0%	2	0.8%	3	0.9%	0	0%
<i>Cryptococcus neoformans/gattii</i>	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%

VIII Proposed Labeling:

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

IX Conclusion:

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