DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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BIOFIRE DIAGNOSTICS, LLC
KRISTEN KANACK, PHD
VICE PRESIDENT OF REGULATED PRODUCTS
390 WAKARA WAY
SALT LAKE CITY UT 84108

January 30, 2015

Re: K143171
Trade/Device Name: FilmArray Blood Culture Identification (BCID) Panel for use with the FilmArray 2.0
Regulation Number: 21 CFR 866.3365
Regulation Name: Multiplex nucleic acid assay for identification of microorganisms
Regulatory Class: II
Product Code: PEN, OOI, PAM
Dated: October 31, 2014
Received: November 4, 2014

Dear Dr. Kanack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally Hojvat, M. Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143171

Device Name
FilmArray Blood Culture Identifcation (BCID) Panel

Indications for Use *(Describe)*
The FilmArray Blood Culture Identification (BCID) Panel is a qualitative multiplexed nucleic acid-based in vitro 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 BCID assay is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system that demonstrate the presence of organisms as determined by Gram stain.

The following gram-positive bacteria, gram-negative bacteria, and yeast are identified using the FilmArray BCID Panel: Enterococci, Listeria monocytogenes, Staphylococci (including specific differentiation of Staphylococcus aureus), Streptococci (with specific differentiation of Streptococcus agalactiae, Streptococcus pneumoniae, and Streptococcus pyogenes), Acinetobacter baumannii, Enterobacteriaceae (including specific differentiation of the Enterobacter cloacae complex, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus, and Serratia marcescens), Haemophilus influenzae, Neisseria meningitidis (encapsulated), Pseudomonas aeruginosa, Candida albicans, Candida glabrata, Candida krusei, Candida parapsilosis, and Candida tropicalis.

The FilmArray BCID Panel also contains assays for the detection of genetic determinants of resistance to methicillin (mecA), vancomycin (vanA and vanB), and carbapenems (blaKPC) to aid in the identification of potentially antimicrobial resistant organisms in positive blood culture samples. The antimicrobial resistance gene detected may or may not be associated with the agent responsible for disease. Negative results for these select antimicrobial resistance gene assays do not indicate susceptibility, as multiple mechanisms of resistance to methicillin, vancomycin, and carbapenems exist.

FilmArray BCID is indicated as an aid in the diagnosis of specific agents of bacteremia and fungemia and results should be used in conjunction with other clinical and laboratory findings. Positive FilmArray results do not rule out co-infection with organisms not included in the FilmArray BCID Panel. FilmArray BCID is not intended to monitor treatment for bacteremia or fungemia.

Subculturing of positive blood cultures is necessary to recover organisms for susceptibility testing and epidemiological typing, to identify organisms in the blood culture that are not detected by the FilmArray BCID Panel, and for species determination of some Staphylococci, Enterococci, Streptococci, and Enterobacteriaceae that are not specifically identified by the FilmArray BCID Panel assays.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
BioFire Diagnostics, LLC

FilmArray Blood Culture Identification (BCID) Panel for use with FilmArray 2.0

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitted by:

BioFire Diagnostics, LLC
390 Wakara Way
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USA

Telephone: 801-736-6354
Facsimile: 801-588-0507

Contact: Kristen Kanack, ext. 330

Date Submitted: October 31, 2014

Device Name and Classification:

Trade Name: FilmArray Blood Culture Identification (BCID) Panel

Regulation Number: 21 CFR 866.3365

Classification Name: Multiplex devices that use DNA hybridization to detect bacteria and their resistance markers

Predicate Device:

K130914 – FilmArray BCID Panel

Intended Use:

The FilmArray Blood Culture Identification (BCID) Panel is a qualitative multiplexed nucleic acid-based *in vitro* 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 BCID assay is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system that demonstrate the presence of organisms as determined by Gram stain.

The following gram-positive bacteria, gram-negative bacteria, and yeast are identified using the FilmArray BCID Panel: *Enterococci*, *Listeria monocytogenes*, *Staphylococci* (including specific differentiation of *Staphylococcus aureus)*, *Streptococci* (with specific differentiation of

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

The FilmArray BCID Panel also contains assays for the detection of genetic determinants of resistance to methicillin (*mecA*), vancomycin (*vanA* and *vanB*), and carbapenems (bla_{KPC}) to aid in the identification of potentially antimicrobial resistant organisms in positive blood culture samples. The antimicrobial resistance gene detected may or may not be associated with the agent responsible for disease. Negative results for these select antimicrobial resistance gene assays do not indicate susceptibility, as multiple mechanisms of resistance to methicillin, vancomycin, and carbapenems exist.

FilmArray BCID is indicated as an aid in the diagnosis of specific agents of bacteremia and fungemia and results should be used in conjunction with other clinical and laboratory findings. Positive FilmArray results do not rule out co-infection with organisms not included in the FilmArray BCID Panel. FilmArray BCID is not intended to monitor treatment for bacteremia or fungemia.

Subculturing of positive blood cultures is necessary to recover organisms for susceptibility testing and epidemiological typing, to identify organisms in the blood culture that are not detected by the FilmArray BCID Panel, and for species determination of some *Staphylococci*, *Enterococci*, *Streptococci*, and *Enterobacteriaceae* that are not specifically identified by the FilmArray BCID Panel assays.

Device Description:

The FilmArray Blood Culture Identification (BCID) Panel is a multiplex nucleic acid test designed to be used with a FilmArray system. The FilmArray BCID pouch contains freeze-dried reagents to perform nucleic acid purification and nested, multiplex PCR with DNA melt analysis. The FilmArray Blood Culture Identification (BCID) Panel simultaneously tests a single positive blood culture sample to provide results for 24 different organisms and organism groups that cause bloodstream infections and three genetic markers that are known to confer antimicrobial resistance (see Table 1).

Table 1. FilmArray BCID Panel Test Results.

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

Gram-Positive Bacteria	Gram-Negative Bacteria	Yeast
	Neisseria meningitidis (encapsulated)	
	Pseudomonas aeruginosa	

A test is initiated by loading Hydration Solution and a positive blood culture sample mixed with the provided Sample Buffer into the FilmArray BCID pouch. The pouch contains all of the reagents required for specimen testing and analysis in a freeze-dried format; the addition of Hydration Solution and sample/Sample Buffer Mix rehydrates the reagents. After the pouch is prepared, the software guides the user though the steps of placing the pouch into the instrument, scanning the pouch barcode, entering the sample identification, and initiating the run.

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

Nucleic acid extraction occurs within the FilmArray pouch using mechanical lysis and standard magnetic bead technology. After extracting and purifying nucleic acids from the unprocessed sample, a nested multiplex PCR is executed in two stages. During the first stage, a single, large volume, highly multiplexed PCR reaction which includes all primers of the outer primer sets, is performed. 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 Defense, LLC). 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 array captures fluorescent images of the PCR reactions and software interprets the data.

The 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.

Substantial Equivalence:

The FilmArray BCID Panel for use with the FilmArray 2.0 is substantially equivalent to the FilmArray BCID Panel (K130914) for use with the FilmArray, which was cleared on June 21, 2013 and determined to be a Class II device.

The following table compares the FilmArray BCID Panel for use with the FilmArray 2.0to the previously cleared FilmArray BCID Panel (K130914). The table outlines the similarities and differences for the BCID Panel tested on the two devices.

Table 2. Comparison of the BCID Panel on FilmArray 2.0 (New) to the BCID Panel on FilmArray (Predicate).

Element	Predicate: BCID Panel - FilmArray (K130914)	New Device: BCID Panel FilmArray 2.0
Organisms Detected	*Enterococci*, *Listeria monocytogenes*, *Staphylococci* (including specific differentiation of *Staphylococcus aureus)*, *Streptococci* (with specific differentiation of *Streptococcus agalactiae*, *Streptococcus pneumoniae*, and *Streptococcus pyogenes*), *Acinetobacter baumannii*, *Enterobacteriaceae* (including specific differentiation of the *Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus*, and *Serratia marcescens*), *Haemophilus influenzae*, *Neisseria meningitidis* (encapsulated), *Pseudomonas aeruginosa*, *Candida albicans*, *Candida glabrata*, *Candida krusei*, *Candida parapsilosis*, *Candida tropicalis*, and resistance markers *mecA*, *vanA*, *vanB*, and bla_{KPC} (KPC)	Same
Analyte	RNA/DNA	Same
Specimen Types	Positive blood culture samples containing gram-positive or gram-negative bacteria and/or yeast.	Same
Technological Principles	Nested multiplex RT-PCR followed by high resolution melting analysis to confirm identity of amplified product.	Same
Instrumentation	FilmArray	FilmArray or FilmArray 2.0
Time to result	About 1 hour	Same
Test Interpretation	Automated test interpretation and report generation. User cannot access raw data.	Same
Reagent Hydration and Sample Loading	Syringe-based loading procedure	Syringe-based loading procedure or FilmArray Injection Vial-based loading procedure

Sample Preparation Method	Sample processing is automated in the FilmArray BCID pouch.	Same
Reagent Storage	Reagents are stored at room temperature.	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

Summary of Performance Data

Clinical Performance

The original FilmArray BCID Panel was developed for use with the current, single instrument FilmArray system. A clinical study was conducted to compare the performance observed when testing clinical specimens using the FilmArray BCID in its current configuration on the current system to results obtained when testing with the modified system using the current loading tools (platform comparison) as well as results on the modified platform when syringes or FilmArray Injection Vial (FAIV) loading tools are used (loading tools comparison). Data obtained with the current system/tools were also compared to the modified system with FAIVs (multifactor comparison).

Specimens previously obtained during the FilmArray BCID prospective clinical evaluation comprised the base of the specimen set used for testing. Seeded blood cultures (remnant from the prospective BCID clinical study) were used for rare BCID analytes. A total of 100 specimens were selected such that each analyte (and antibiotic resistance marker) was represented 3-5 times.

System performance for testing these 102 specimens on each platform was calculated. For the current system, a total of 102 runs were attempted, 100 of which were completed (98.8%; 100/102). There were two run failures for software errors (2.0%). No control failures were observed.

For the modified system (paired with syringe and FAIV loading) a total of 202 runs were attempted, 200 of which were completed (99.0%; 200/202). There were two run failures for software errors (1.0%). No control failures were observed. All specimens were of sufficient volume that retesting was possible in order to obtain valid runs for all testing configurations.

As shown in Table3, 100% concordance was observed for most analytes across all comparisons. Occasional discrepant results were observed where an analyte was detected by one or two out of three pouches; in all cases this was attributed to analyte levels well below what is typically seen in positive blood culture. Overall PPA for all three comparisons was 99.1% or greater, with the

lower bound of the two-sided 95% confidence interval (95% CI) at 95.3% or greater. Overall NPA for all three comparisons was 99.9% or greater with the lower bound of the two-sided 95% CI at 99.7% or greater

Table 3. Analyte Detections across all systems and loading tools. For all "X vs Y" headers, Y is the denominator. The number of PBC and SBC that comprised each analyte population are shown. Comparisons demonstrating performance less than 100% but are shaded in yellow. CS + S = Current System, Syringe; MS+S = Modified System, Syringe; MS+F = Modified System, FAIV

Analyte	Specimen Type		MS+S vs CS+S				MS+F vs MS+S				MS+F vs CS+S			
	PBC	SBC	PPA	%	NPA	%	PPA	%	NPA	%	PPA	%	NPA	%
Gram-Positive Bacteria														
Enterococcus	6	1	6/6	100%	93/94[a]	98.9%	6/7[a]	85.7%	93/93	100%	6/6	100%	94/94	100%
Listeria monocytogenes	0	4	4/4	100%	96/96	100%	4/4	100%	96/96	100%	4/4	100%	96/96	100%
Staphylococcus	11	0	10/10	100%	89/90[b]	98.9%	11/11	100%	89/89	100%	10/10	100%	89/90[b]	98.9%
Staphylococcus aureus	5	0	5/5	100%	95/95	100%	5/5	100%	95/95	100%	5/5	100%	95/95	100%
Streptococcus	15	0	15/15	100%	85/85	100%	15/15	100%	85/85	100%	15/15	100%	85/85	100%
Streptococcus agalactiae	3	0	3/3	100%	97/97	100%	3/3	100%	97/97	100%	3/3	100%	97/97	100%
Streptococcus pneumoniae	3	0	3/3	100%	97/97	100%	3/3	100%	97/97	100%	3/3	100%	97/97	100%
Streptococcus pyogenes	3	0	3/3	100%	97/97	100%	3/3	100%	97/97	100%	3/3	100%	97/97	100%
Gram-Negative Bacteria														
Acinetobacter baumannii	5	0	5/5	100%	95/95	100%	5/5	100%	95/95	100%	5/5	100%	95/95	100%
Enterobacteriaceae	22	1	23/23	100%	77/77	100%	23/23	100%	77/77	100%	23/23	100%	77/77	100%
Enterobacter cloacae complex	3	0	3/3	100%	97/97	100%	3/3	100%	97/97	100%	3/3	100%	97/97	100%
Escherichia coli	3	0	3/3	100%	97/97	100%	3/3	100%	97/97	100%	3/3	100%	97/97	100%
Klebsiella oxytoca	3	0	3/3	100%	97/97	100%	3/3	100%	97/97	100%	3/3	100%	97/97	100%
Klebsiella pneumoniae	3	1	4/4	100%	96/96	100%	4/4	100%	96/96	100%	4/4	100%	96/96	100%
Proteus	3	0	3/3	100%	97/97	100%	3/3	100%	97/97	100%	3/3	100%	97/97	100%
Serratia marcescens	3	0	3/3	100%	97/97	100%	3/3	100%	97/97	100%	3/3	100%	97/97	100%
Haemophilus influenzae	3	1	4/4	100%	96/96	100%	4/4	100%	96/96	100%	4/4	100%	96/96	100%
Neisseria meningitidis	1	3	4/4	100%	96/96	100%	4/4	100%	96/96	100%	4/4	100%	96/96	100%
Pseudomonas aeruginosa	4	0	4/4	100%	96/96	100%	4/4	100%	96/96	100%	4/4	100%	96/96	100%
Yeast														
Candida albicans	5	0	5/5	100%	95/95	100%	5/5	100%	95/95	100%	5/5	100%	95/95	100%
Candida glabrata	5	0	5/5	100%	95/95	100%	5/5	100%	95/95	100%	5/5	100%	95/95	100%
Candida krusei	3	2	5/5	100%	95/95	100%	5/5	100%	95/95	100%	5/5	100%	95/95	100%
Candida parapsilosis	5	0	5/5	100%	95/95	100%	5/5	100%	95/95	100%	5/5	100%	95/95	100%

Analyte	Specimen Type		MS+S vs CS+S				MS+F vs MS+S				MS+F vs CS+S			
	PBC	SBC	PPA	%	NPA	%	PPA	%	NPA	%	PPA	%	NPA	%
Candida tropicalis	3	2	5/5	100%	95/95	100%	5/5	100%	95/95	100%	5/5	100%	95/95	100%
Antimicrobial Resistance Genes														
mecA	6	0	5/5	100%	5/5[c]	100%	6/6	100%	5/5	100%	5/5[c]	100%	5/5[c]	100%
vanA/B	2	1	3/3	100%	3/3	100%	3/3	100%	3/3	100%	3/3	100%	3/3	100%
KPC	3	1	4/4	100%	28/28	100%	4/4	100%	28/28	100%	4/4	100%	28/28	100%
Overall agreement/			113/113	100%	1885/1887	99.9%	114/115	99.1%	1885/1885	100%	113/113	100%	1886/1887	100%
95% CI			96.8-100%		99.7-100%		95.3-100%		99.8-100%		96.8-100%		99.7-100%	

[a] Specimen 014111-BC-0043 was originally characterized as positive for *S. pneumoniae* and was unexpectedly positive for *Enterococcus* when tested on the MS+S but was not when tested on the CS+S or the MS+F.

[b] Specimen 014111-BC-0006 was originally characterized as positive for *S. capitis* which was detected when tested on the MS+S and MS+F but was not detected when tested on the CS+S. The BCID Panel is known to have reduced sensitivity for *S. capitis* as described in the package insert.

[c] Because *Staphylococcus* was not detected in specimen 014111-BC-0006 when tested with the CS+S as described in footnote "b", *mecA* was not reported (i.e., was reported as N/A) in this specimen and the specimen could not be used in performance calculations for *mecA* (however, the *mecA* assay was positive in all 3 testing configurations.

Selected Analytic Studies

Low Analyte

A comparison of performance between the current FilmArray system (one instrument to one computer configuration) and the FilmArray 2.0 system (up to eight instruments to one computer) was performed for the FilmArray Blood Culture Identification (BCID) Panel. Testing performed on the current system using the current syringe-based pouch loading procedure was compared to data collected on the modified system with both the syringe-based pouch loading procedure and a modified, injection vial-based pouch loading procedure.

Testing consisted of a dilution series of samples containing a mix of BCID analytes. The concentration of analyte in the samples started at the level known to be present in positive blood cultures (1×), followed by 10-fold serial dilutions (0.1× - 0.001× test levels).

In the titration series testing, detection of each analyte at all concentrations was found to be comparable between the current and modified FilmArray systems using either the syringe or injection vial pouch loading procedures (Table 4).

Table 4. Results of the Titration Testing for the Blood Culture Identification (BCID) Panel on Current and Modified FilmArray Systems with Syringe and/or Injection Vial Pouch Loading Procedures
At each test level, if the number of detected results on the modified system (syringe or injection vial) was the same as for the current system (syringe) the results are listed as 'Same'.

Organism	FilmArray BCID Test Result	Test Level	# Detected/Total (% Detected)		
			Current System (Syringe)	Modified System (Syringe)	Modified System (Injection Vial)
GRAM-POSITIVE BACTERIA					
Enterococcus faecalis (*vanB*) JMI 368	*Enterococcus*	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	**4/5 (80%)**	**3/5 (60%)**	**3/5 (60%)**
	vanA/B	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	**4/5 (80%)**	**3/5 (60%)**	**3/5 (60%)**
Enterococcus faecium (*vanA*) *JMI 475*	*Enterococcus*	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	**1/5 (20%)**	**5/5 (100%)**	**2/5 (40%)**
	vanA/B	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	**1/5 (20%)**	**5/5 (100%)**	**2/5 (40%)**
Listeria monocytogenes ATCC 43256	*Listeria monocytogenes*	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	5/5 (100%)		
Staphylococcus aureus (*mecA*) ATCC BAA-1747	Staphylococcus	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	**4/5 (80%)**	**5/5 (100%)**	**3/5 (60%)**
	mec A	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		

Organism	FilmArray BCID Test Result	Test Level	# Detected/Total (% Detected)		
			Current System (Syringe)	Modified System (Syringe)	Modified System (Injection Vial)
		0.001×	**4/5 (80%)**	**5/5 (100%)**	**3/5 (60%)**
Staphylococcus epidermidis ATCC 12228	Staphylococcus	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	**5/5 (100%)**	**4/5 (80%)**	
		0.001×	**4/5 (80%)**	**2/5 (40%)**	**2/5 (40%)**
Streptococcus mitis ATCC 15914	Streptococcus	1×	5/5 (100%)	Same	Same
		0.1×	**5/5 (100%)**		**4/5 (80%)**
		0.01×	**4/5 (80%)**	**5/5 (100%)**	**3/5 (60%)**
		0.001×	**0/5 (0%)**	**0/5 (0%)**	**0/5 (0%)**
Streptococcus agalactiae ATCC 13813	*Streptococcus*	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	5/5 (100%)		
	Streptococcus agalactiae	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	5/5 (100%)		
Streptococcus pneumoniae [a] ATCC BAA-255	*Streptococcus*	1× [a]	5/5 (100%)	Same	Same
		0.1× [a]	5/5 (100%)		
		0.01× [a]	5/5 (100%)		
		0.001× [a]	5/5 (100%)		
	Streptococcus pneumoniae	1× [a]	5/5 (100%)	Same	Same
		0.1× [a]	5/5 (100%)		
		0.01× [a]	5/5 (100%)		
		0.001× [a]	5/5 (100%)		
Streptococcus pyogenes ATCC 19615	*Streptococcus*	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	5/5 (100%)		
	Streptococcus pyogenes	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	5/5 (100%)		
GRAM-NEGATIVE BACTERIA					
Acinetobacter baumannii ATCC 9955	*Acinetobacter baumannii*	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	5/5 (100%)		
Enterobacter cloacae ATCC 13047	*Enterobacteriaceae*	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	5/5 (100%)		
	Enterobacter cloacae complex	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	**3/5 (60%)**	**3/5 (60%)**	**2/5 (40%)**
Escherichia coli ATCC 43888	*Enterobacteriaceae*	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	**4/5 (80%)**	**2/5 (40%)**	**1/5 (20%)**
	Escherichia coli	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	**4/5 (80%)**	**2/5 (40%)**	**0/5 (0%)**
Klebsiella oxytoca	*Enterobacteriaceae*	1×	5/5 (100%)	Same	Same

Organism	FilmArray BCID Test Result	Test Level	# Detected/Total (% Detected)		
			Current System (Syringe)	Modified System (Syringe)	Modified System (Injection Vial)
ATCC 13182		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	5/5 (100%)		
	Klebsiella oxytoca	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	5/5 (100%)		
Klebsiella pneumoniae (KPC) JMI 766	*Enterobacteriaceae*	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	5/5 (100%)		
	Klebsiella pneumoniae	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	5/5 (100%)		
	KPC	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	5/5 (100%)		
Proteus mirabilis ATCC 29906	*Enterobacteriaceae*	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	**4/5 (80%)**	**4/5 (80%)**	**1/5 (20%)**
	Proteus	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	**4/5 (80%)**	**4/5 (80%)**	**1/5 (20%)**
Serratia marcescens [a] ATCC 27137	*Enterobacteriaceae*	1× [a]	5/5 (100%)	Same	Same
		0.1× [a]	5/5 (100%)		
		0.01× [a]	5/5 (100%)		
		0.001× [a]	5/5 (100%)		
	Serratia marcescens	1× [a]	5/5 (100%)	Same	Same
		0.1× [a]	5/5 (100%)		
		0.01× [a]	5/5 (100%)		
		0.001× [a]	5/5 (100%)		
Haemophilus influenzae [a] ATCC 10211	*Haemophilus influenzae*	1× [a]	5/5 (100%)	Same	Same
		0.1× [a]	5/5 (100%)		
		0.01× [a]	5/5 (100%)		
		0.001× [a]	5/5 (100%)		
Neisseria meningitidis [b] ATCC 43744	*Neisseria meningitidis*	1× [b]	5/5 (100%)	Same	Same
		0.1× [b]	5/5 (100%)		
		0.01× [b]	5/5 (100%)		
		0.001× [b]	5/5 (100%)		
Pseudomonas aeruginosa ATCC 27853	*Pseudomonas aeruginosa*	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	5/5 (100%)		
YEAST					
Candida albicans ATCC 10231	*Candida albicans*	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	**4/5 (80%)**	**4/5 (80%)**	**3/5 (60%)**
		0.001×	**1/5 (20%)**	**1/5 (20%)**	**2/5 (40%)**
Candida glabrata ATCC 15545	*Candida glabrata*	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		

Organism	FilmArray BCID Test Result	Test Level	# Detected/Total (% Detected)		
			Current System (Syringe)	Modified System (Syringe)	Modified System (Injection Vial)
		0.001×	**4/5 (80%)**	**5/5 (100%)**	**4/5 (80%)**
Candida krusei ATCC 90878	*Candida krusei*	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	5/5 (100%)		
Candida parapsilosis ATCC 90875	*Candida parapsilosis*	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	**4/5 (80%)**	**5/5 (100%)**	**5/5 (100%)**
Candida tropicalis ATCC 66029	*Candida tropicalis*	1×	5/5 (100%)	Same	Same
		0.1×	5/5 (100%)		
		0.01×	5/5 (100%)		
		0.001×	5/5 (100%)		

[a] The starting 1× concentration is equivalent to half (0.5×) the concentration in a positive blood culture and the same adjustment applies to all dilutions (0.05×, 0.005×, and 0.0005× relative to blood culture level).
[b] The starting 1× concentration is equivalent to one-tenth (0.1×) the concentration in a positive blood culture and the same adjustment applies to all dilutions (0.01×, 0.001×, and 0.0001× relative to blood culture level).

Tm values from the titration series were compared to assess whether Tm data are equivalent between the current and modified FilmArray systems, the syringe and injection vial pouch loading procedures, and between the current and modified system/loading combined. Normal Tm variation of the current FilmArray configuration is ±0.5˚C and it was observed that mean Tm values for all FilmArray BCID assays on the modified configurations were ± 0.5°C or less compared to the same samples tested on the current configuration (ΔTm System, ΔTm Loading, and ΔTm Combined in Table 5).

Table 5. Comparison of Mean Tm Values for FilmArray BCID Panel Analytes on the Current and Modified Systems with Syringe or Injection Vial Pouch Loading Procedures

Organism	Assay		FilmArray System (Loading Procedure)	Mean Tm[a]	Δ Mean Tm		
					ΔTm System	ΔTm Loading	ΔTm Combined
Enterococcus faecium (*van*A)	Enterococcus		Current (Syringe)	82.6	0.0		0.0
			Modified (Syringe)	82.6		0.0	
			Modified (Injection Vial)	82.6			
	vanA/B		Current (Syringe)	85.6	0.2		0.0
			Modified (Syringe)	85.4		-0.2	
			Modified (Injection Vial)	85.6			
Enterococcus faecalis (*van*B)	Enterococcus		Current (Syringe)	82.2	0.1		-0.1
			Modified (Syringe)	82.1		-0.2	
			Modified (Injection Vial)	82.3			
	vanA/B	Tm 1	Current (Syringe)	81.6	0.1		0.0
			Modified (Syringe)	81.5		-0.1	
			Modified (Injection Vial)	81.6			
		Tm 2	Current (Syringe)	86.1	0.2		0.1
			Modified (Syringe)	85.9		-0.1	
			Modified (Injection Vial)	86.0			
Listeria monocytogenes	Lmonocytogenes		Current (Syringe)	80.2	0.2		0.1
			Modified (Syringe)	80.0		-0.1	
			Modified (Injection Vial)	80.1			
Staphylococcus aureus (*mec*A)	Saureus		Current (Syringe)	77.0	0.1		0.1
			Modified (Syringe)	76.9		0.0	
			Modified (Injection Vial)	76.9			

Organism	Assay	FilmArray System (Loading Procedure)	Mean Tm[a]	Δ Mean Tm		
				ΔTm System	ΔTm Loading	ΔTm Combined
	mecA	Current (Syringe)	73.5	0.1		0.0
		Modified (Syringe)	73.4		-0.1	
		Modified (Injection Vial)	73.5			
Streptococcus mitis	Streptococcus	Current (Syringe)	83.7	0.2		0.1
		Modified (Syringe)	83.5		-0.1	
		Modified (Injection Vial)	83.6			
Staphylococcus epidermidis	Staphylococcus 1	Current (Syringe)	79.3	0.1		-0.1
		Modified (Syringe)	79.2		-0.2	
		Modified (Injection Vial)	79.4			
	Staphylococcus 2	Current (Syringe)	79.0	0.2		0.0
		Modified (Syringe)	78.8		-0.2	
		Modified (Injection Vial)	79.0			
Streptococcus agalactiae	Streptococcus	Current (Syringe)	81.5	0.0		0.0
		Modified (Syringe)	81.5		0.0	
		Modified (Injection Vial)	81.5			
	Sagalactiae	Current (Syringe)	80.8	-0.1		0.1
		Modified (Syringe)	80.9		0.2	
		Modified (Injection Vial)	80.7			
Streptococcus pneumoniae	Spneumoniae	Current (Syringe)	82.9	0.1		0.1
		Modified (Syringe)	82.8		0.0	
		Modified (Injection Vial)	82.8			
	Streptococcus	Current (Syringe)	81.3	0.2		0.0
		Modified (Syringe)	81.1		-0.2	
		Modified (Injection Vial)	81.3			
Streptococcus pyogenes	Spyogenes	Current (Syringe)	78.9	0.2		0.0
		Modified (Syringe)	78.7		-0.2	
		Modified (Injection Vial)	78.9			
	Streptococcus	Current (Syringe)	82.1	0.2		0.1
		Modified (Syringe)	81.9		-0.1	
		Modified (Injection Vial)	82.0			
Acinetobacter baumannii	Abaumannii	Current (Syringe)	80.3	0.1		-0.1
		Modified (Syringe)	80.2		-0.2	
		Modified (Injection Vial)	80.4			
Enterobacter cloacae	Enteric	Current (Syringe)	87.6	0.2		0.0
		Modified (Syringe)	87.4		-0.2	
		Modified (Injection Vial)	87.6			
	Ecloacae	Current (Syringe)	83.8	0.2		0.0
		Modified (Syringe)	83.6		-0.2	
		Modified (Injection Vial)	83.8			
Escherichia coli	Enteric	Current (Syringe)	87.9	0.2		0.0
		Modified (Syringe)	87.7		-0.2	
		Modified (Injection Vial)	87.9			
	Ecoli	Current (Syringe)	87.2	0.2		0.1
		Modified (Syringe)	87.0		-0.1	
		Modified (Injection Vial)	87.1			
Klebsiella pneumoniae (KPC)	Enteric	Current (Syringe)	88.6	0.0		0.1
		Modified (Syringe)	88.6		0.1	
		Modified (Injection Vial)	88.5			
	Kpneumoniae	Current (Syringe)	87.7	0.0		0.2
		Modified (Syringe)	87.7		0.2	
		Modified (Injection Vial)	87.5			
	KPC	Current (Syringe)	86.0	-0.1		0.1
		Modified (Syringe)	86.1		0.2	
		Modified (Injection Vial)	85.9			

Organism	Assay	FilmArray System (Loading Procedure)	Mean Tm[a]	Δ Mean Tm		
				ΔTm System	ΔTm Loading	ΔTm Combined
Klebsiella oxytoca	Enteric	Current (Syringe)	87.3	0.2		0.0
		Modified (Syringe)	87.1		-0.2	
		Modified (Injection Vial)	87.3			
	Koxytoca	Current (Syringe)	83.1	0.2		0.0
		Modified (Syringe)	82.9		-0.2	
		Modified (Injection Vial)	83.1			
Proteus mirabilis	Proteus	Current (Syringe)	81.3	0.2		0.1
		Modified (Syringe)	81.1		-0.1	
		Modified (Injection Vial)	81.2			
Serratia marcescens	Smarcescens	Current (Syringe)	85.7	0.1		0.0
		Modified (Syringe)	85.6		-0.1	
		Modified (Injection Vial)	85.7			
Haemophilus influenzae	Hinfluenzae 1	Current (Syringe)	77.6	-0.1		0.0
		Modified (Syringe)	77.7		0.1	
		Modified (Injection Vial)	77.6			
	Hinfluenzae 2	Current (Syringe)	80.2	-0.1		0.0
		Modified (Syringe)	80.3		0.1	
		Modified (Injection Vial)	80.2			
Neisseria meningitidis	Nmeningitidis	Current (Syringe)	83.0	0.1		0.0
		Modified (Syringe)	82.9		-0.1	
		Modified (Injection Vial)	83.0			
Pseudomonas aeruginosa	Paeruginosa	Current (Syringe)	87.9	0.1		0.1
		Modified (Syringe)	87.8		0.0	
		Modified (Injection Vial)	87.8			
Candida albicans	Calbicans	Current (Syringe)	79.7	0.1		-0.1
		Modified (Syringe)	79.6		-0.2	
		Modified (Injection Vial)	79.8			
Candida glabrata	Cglabrata	Current (Syringe)	75.2	0.0		-0.1
		Modified (Syringe)	75.2		-0.1	
		Modified (Injection Vial)	75.3			
Candida krusei	Ckrusei	Current (Syringe)	84.5	0.1		0.0
		Modified (Syringe)	84.4		-0.1	
		Modified (Injection Vial)	84.5			
Candida parapsilosis	Cparapsilosis	Current (Syringe)	77.3	0.1		0.0
		Modified (Syringe)	77.2		-0.1	
		Modified (Injection Vial)	77.3			
Candida tropicalis	Ctropicalis	Current (Syringe)	78.8	0.1		0.0
		Modified (Syringe)	78.7		-0.1	
		Modified (Injection Vial)	78.8			

[a] Mean Tm calculated from all replicates at all concentrations.

Reproducibility

A multicenter reproducibility study was performed to determine between-site/system and overall reproducibility of the FilmArray Blood Culture Identification (BCID) Panel on multi-instrument FilmArray 2.0 systems using the current (syringe) and modified (injection vial) pouch loading procedures.

Reproducibility testing occurred at three test sites using a panel of contrived blood culture samples, each spiked with various concentrations of six different BCID organisms (some

containing antibiotic resistance genes). Each analyte was evaluated at two different concentrations (Negative and Positive).

The study incorporated a range of potential variation introduced by ten different operators, three different pouch lots, and 14 different FilmArray 2.0 instruments per loading procedure on three different systems. A system consisted of at least three instruments connected to a single computer. Samples were stored frozen and tested on five different days at three testing sites (one system, A, B, or C per site) for 90 data points per sample, per loading procedure.

A summary of results (percent (%) agreement with the expected result) for each analyte (by site/system and overall) is provided in Table 6 alongside the overall % Agreement with Expected Results originally obtained on the single-instrument system.

Table 6. Reproducibility of the FilmArray BCID Panel Test Results on Multi-instrument FilmArray 2.0 and Single-instrument FilmArray Systems

BCID Panel Test Result	Organism Tested	Test Level	Expected Test Result	% Agreement with Expected Result[a]								
				Multi-instrument FilmArray 2.0 System (Syringe)				Multi-instrument FilmArray 2.0 System (Injection Vial)				Single-instrument FilmArray System[b] (Syringe)
				Site/System			All Sites/Systems (95% CI)	Site/System			All Sites/Systems (95% CI)	All sites (95% CI)
				A	B	C		A	B	C		
Enterococcus	*Enterococcus faecalis* (*van*B) JMI 368	Positive	Detected	30/30 100%	30/30 100%	**29/30 96.7%**	**89/90 98.90% (94.0%-100%)**	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	180/180 100% (98.0%-100%)
		Negative	Not Detected	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	360/360 100% (99.0%-100%)
Listeria monocytogenes	N/A	Negative	Not Detected	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	540/540 100% (99.3%-100%)
Staphylococcus	*Staphylococcus aureus* (*mec*A) ATCC BAA-1747	Positive	Detected	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	90/90 100% (96.0%-100%)
		Negative	Not Detected	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	**449/450[c] 98.8% (98.8-100%)**
Staphylococcus aureus	*Staphylococcus aureus* (*mec*A) ATCC BAA-1747	Positive	Detected	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	90/90 100% (96.0%-100%)
		Negative	Not Detected	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	450/450 100% (99.2%-100%)
Streptococcus	N/A	Negative	Not Detected	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	450/450 100% (99.2%-100%)
Streptococcus agalactiae	N/A	Negative	Not Detected	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	540/540 100% (99.3%-100%)
Streptococcus pneumoniae	N/A	Negative	Not Detected	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	540/540 100% (99.3%-100%)
Streptococcus	N/A	Negative	Not	60/60	60/60	60/60	180/180	60/60	60/60	60/60	180/180	450/450

BCID Panel Test Result	Organism Tested	Test Level	Expected Test Result	% Agreement with Expected Result[a]								
				Multi-instrument FilmArray 2.0 System (Syringe)				Multi-instrument FilmArray 2.0 System (Injection Vial)				Single-instrument FilmArray System[b] (Syringe)
				Site/System			All Sites/Systems (95% CI)	Site/System			All Sites/Systems (95% CI)	All sites (95% CI)
				A	B	C		A	B	C		
pyogenes			Detected	100%	100%	100%	100% (98.0%-100%)	100%	100%	100%	100% (98.0%-100%)	100% (99.2%-100%)
Enterobacteriaceae	*Klebsiella pneumoniae* (KPC) JMI 7818	Positive	Detected	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	180/180 100% (98.0%-100%)
		Negative	Not Detected	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	360/360 100% (99.0%-100%)
Enterobacter cloacae complex	N/A	Negative	Not Detected	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	540/540 100% (99.3%-100%)
Escherichia coli	N/A	Negative	Not Detected	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	540/540 100% (99.3%-100%)
Klebsiella oxytoca	N/A	Negative	Not Detected	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	540/540 100% (99.3%-100%)
Klebsiella pneumoniae	*Klebsiella pneumoniae* (KPC) JMI 7818	Positive	Detected	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	90/90 100% (96.0%-100%)
		Negative	Not Detected	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	450/450 100% (99.2%-100%)
Proteus	N/A	Negative	Not Detected	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	450/450 100% (99.2%-100%)
Serratia marcescens	N/A	Negative	Not Detected	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	450/450 100% (99.2%-100%)
Haemophilus influenzae	N/A	Negative	Not Detected	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	**539/540[c] 99.8% (99.0%-100%)**
Neisseria	N/A	Negative	Not	60/60	60/60	60/60	180/180	60/60	60/60	60/60	180/180	540/540

BCID Panel Test Result	Organism Tested	Test Level	Expected Test Result	% Agreement with Expected Result[a]								
				Multi-instrument FilmArray 2.0 System (Syringe)				Multi-instrument FilmArray 2.0 System (Injection Vial)				Single-instrument FilmArray System[b] (Syringe)
				Site/System			All Sites/Systems (95% CI)	Site/System			All Sites/Systems (95% CI)	All sites (95% CI)
				A	B	C		A	B	C		
meningitidis			Detected	100%	100%	100%	100% (98.0%-100%)	100%	100%	100%	100% (98.0%-100%)	100% (99.3%-100%)
Pseudomonas aeruginosa	*Pseudomonas aeruginosa* ATCC 27853	Positive	Detected	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	90/90 100% (96.0%-100%)
		Negative	Not Detected	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	450/450 100% (99.2%-100%)
Candida albicans	*Candida albicans* ATCC 10231	Positive	Detected	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	90/90 100% (96.0%-100%)
		Negative	Not Detected	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	450/450 100% (99.2%-100%)
Candida glabrata	*N/A*	Negative	Not Detected	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	450/450 100% (99.2%-100%)
Candida krusei	*Candida krusei* ATCC 90878	Positive	Detected	**29/30 96.7%**	30/30 100%	**29/30 96.7%**	**88/90 97.80% (92.2%-99.7%)**	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	90/90 100% (96.0%-100%)
		Negative	Not Detected	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	450/450 100% (99.2%-100%)
Candida parapsilosis	N/A	Negative	Not Detected	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	59/60 98.3%	60/60 100%	60/60 100%	**179/180 99.4% (96.9%-99.9%)**	**539/540[c] 99.8% (99.0%-100%)**
Candida tropicalis	N/A	Negative	Not Detected	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	60/60 100%	60/60 100%	60/60 100%	180/180 100% (98.0%-100%)	450/450 100% (99.2%-100%)
***van*A/B**	*Enterococcus faecalis* (*van*B)	Positive	Detected	30/30 100%	30/30 100%	**29/30 96.7%**	**89/90 98.90% (94.0%-100%)**	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	180/180 100% (98.0%-100%)

BCID Panel Test Result	Organism Tested	Test Level	Expected Test Result	% Agreement with Expected Result[a]								
				Multi-instrument FilmArray 2.0 System (Syringe)				Multi-instrument FilmArray 2.0 System (Injection Vial)				Single-instrument FilmArray System[b] (Syringe)
				Site/System			All Sites/Systems (95% CI)	Site/System			All Sites/Systems (95% CI)	All sites (95% CI)
				A	B	C		A	B	C		
	JMI 368	Negative	N/A	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	360/360 100% (99.0%-100%)
***mec*A**	*Staphylococcus aureus* (*mec*A) ATCC BAA-1747	Positive	Detected	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	30/30 100%	30/30 100%	**29/30 96.7%**	**89/90 98.90% (94%-100%)**	90/90 100% (96.0%-100%)
		Negative	N/A	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	**449/450[c] 99.8% (98.8%-100%)**
KPC	*Klebsiella pneumoniae* (KPC) JMI 7818	Positive	Detected	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	90/90 100% (96.0%-100%)
		Negative	N/A	N/A[d]								270/270 100% (98.6%-100%)
			Not Detected	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	30/30 100%	30/30 100%	30/30 100%	90/90 100% (96.0%-100%)	180/180 100% (98.0%-100%)

[a] Performance calculations with lower than 100% agreement with expected results are indicated in bold font.
[b] Single-instrument FilmArray System (Syringe) data reproduced from SDY-007653, 'Evaluation of Reproducibility for the FilmArray Blood Culture Identification (BCID) System.'
[c] A single pouch run at Site B generated four false positive results: *Staphylococcus, mec*A, *Haemophilus influenzae*, and *Candida parapsilosis*.
[d] KPC test result of Not Detected instead of N/A due to the presence of *Pseudomonas aeruginosa* in the sample.

The test results obtained for the BCID Panel on the multi-instrument FilmArray 2.0 systems following the syringe and injection vial loading procedures were highly reproducible and are consistent with the data collected on the current, single-instrument FilmArray in the original BCID Panel Reproducibility evaluation.

The reproducibility of Tm for each positive assay was also evaluated by site/system and overall (all sites/systems) and a summary is provided in Table 7.

Table 7. Tm Reproducibility Analysis (Within Site/System and Overall) for Positive FilmArray BCID Panel Assays on Multi-instrument FilmArray 2.0 Systems

BCID Panel Assay	Organism Tested Test Concentration	Test Site/System	Reproducibility of Tm			
			Syringe		Injection Vial	
			Tm Mean	Tm StDev	Tm Mean	Tm StDev
Gram-Positive Bacteria						
Enterococcus	***Enterococcus faecalis* [*vanB*] JMI 368** 8.95E+08 CFU/mL	A	82.1	±0.3	82.0	±0.2
		B	81.9	±0.2	82.0	±0.3
		C	81.6	±0.3	81.4	±0.3
		All Sites/Systems	81.9	±0.3	81.8	±0.4
Saureus	***Staphylococcus aureus* [*mec*A] ATCC BAA-1747** 8.60E+06 CFU/mL	A	77.3	±0.2	77.3	±0.2
		B	77.2	±0.2	77.1	±0.2
		C	76.8	±0.2	76.7	±0.2
		All Sites/Systems	77.1	±0.3	77.0	±0.3
Gram-Negative Bacteria						
Enteric	***Klebsiella pneumoniae* [KPC] JMI 766** 9.40E+08 CFU/mL	A	89.0	±0.3	88.9	±0.2
		B	88.7	±0.2	88.8	±0.2
		C	88.3	±0.3	88.2	±0.3
		All Sites/Systems	88.7	±0.4	88.6	±0.4
Kpneumoniae		A	88.3	±0.2	88.2	±0.2
		B	88.0	±0.1	88.1	±0.2
		C	87.6	±0.3	87.5	±0.3
		All Sites/Systems	88.0	±0.3	87.9	±0.4
Paeruginosa	***Pseudomonas aeruginosa* ATCC 27853** 1.40E+08 CFU/mL	A	88.3	±0.2	88.3	±0.2
		B	88.1	±0.2	88.1	±0.2
		C	87.6	±0.3	87.5	±0.3
		All Sites/Systems	88.0	±0.4	88.0	±0.4
Yeast						
Calbicans	***Candida albicans* ATCC 10231** 3.10E+04 CFU/mL	A	80.1	±0.3	80.0	±0.3
		B	79.9	±0.2	79.9	±0.3
		C	79.5	±0.3	79.4	±0.3
		All Sites/Systems	79.9	±0.4	79.8	±0.4
Ckrusei	***Candida krusei* ATCC 90878** 3.20E+07 CFU/mL	A	84.6	±0.1	84.6	±0.2
		B	84.5	±0.2	84.5	±0.2
		C	84.1	±0.3	84.0	±0.3

BCID Panel Assay	Organism Tested Test Concentration		Test Site/System	Reproducibility of Tm			
				Syringe		Injection Vial	
				Tm Mean	Tm StDev	Tm Mean	Tm StDev
			All Sites/Systems	84.4	±0.3	84.4	±0.4
Antimicrobial Resistance Genes							
vanA/B	***Enterococcus faecium* [*vanA*] JMI475** 1.50E+08 CFU/mL	Tm1	A	81.8	±0.3	81.7	±0.2
			B	81.7	±0.2	81.7	±0.2
			C	81.3	±0.3	81.2	±0.2
			All Sites/Systems	81.6	±0.3	81.5	±0.3
		Tm2	A	86.5	±0.2	86.4	±0.2
			B	86.3	±0.2	86.3	±0.2
			C	85.9	±0.3	85.7	±0.3
			All Sites/Systems	86.2	±0.4	86.2	±0.4
mecA	***Staphylococcus aureus* [*mecA*] ATCC BAA-1747** 8.60E+06 CFU/mL		A	73.8	±0.2	73.7	±0.2
			B	73.7	±0.2	73.7	±0.2
			C	73.3	±0.3	73.2	±0.3
			All Sites/Systems	73.6	±0.3	73.5	±0.3
KPC	***Klebsiella pneumoniae* [KPC] JMI 766** 9.40E+08 CFU/mL		A	86.5	±0.2	86.5	±0.2
			B	86.3	±0.2	86.3	±0.2
			C	85.9	±0.3	85.8	±0.3
			All Sites/Systems	86.2	±0.4	86.2	±0.4