REF HTFA-ASY-0102
HTFA-SUB-0103
HTFA-ASY-0104

Operator's Manual

For *In Vitro* Diagnostic Use

IVD

CE

BIOFIRE®

A BIOMÉRIEUX COMPANY

This document is used solely for the purpose of FilmArray Torch operation.

Always maintain the FilmArray Torch in good working order. If used in a manner not specified by BioFire Diagnostics, LLC, then protection provided by the equipment may be impaired.

A printed version of this manual is available upon request.

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EC REP

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FilmArray® Torch Operator's Manual IVD HTFA-PRT-0001-03 June 2017

E-Labeling

The manual for this product can be accessed online at www.online-ifu.com/KEY-CODE. The product KEY-CODE is provided on the outer box label at the end of the URL. The KEY-CODE for this operator's manual is also listed below. Additionally, a paper copy is available upon request by contacting customer service via phone, fax, e-mail, or regular mail.

FilmArray Torch Operator's Manual	http://www.online-ifu.com/ITI0066
FilmArray Torch Information Quick Guide	http://www.online-ifu.com/ITI0077

Customer and Technical Support

Customer and Technical Support for U.S. Customers

Reach Us on the Web
www.biofiredx.com

Reach Us by E-mail
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Reach Us by Phone
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(801) 588-0507

Customer and Technical Support Outside of the U.S.

Contact the local bioMérieux sales representative or an authorized distributor for Customer Support.

Symbols Glossary

The following symbols can be found on the FilmArray Torch Modules, the System Base, the Duplex(es), the FilmArray pouches, or throughout this manual. Use the definitions below as a guideline to interpreting the symbols.

ISO 15223-1:2012 **Medical devices - Symbols to be used with medical devices labels, labeling and information to be supplied**					
5.1.1 	Manufacturer	5.1.2 	Authorized representative in the European Community	5.1.4 	Use By (YYYY-MM-DD)
5.1.5 	Batch Code (Lot Number)	5.1.6 	Catalog Number	5.1.7 	Serial Number
5.2.8 	Do Not Use if Package Is Damaged	5.3.4 	Keep Dry	5.3.7 	Temperature Limit
5.4.1 	Biological Risks	5.4.3 	Consult Instructions for Use	5.4.4 	Caution
5.5.1 	*In vitro* Diagnostic Medical Device				
IEC 60417 **Graphical Symbols for Use on Equipment**					
5007	On	5008 	Off	5019 	Protective Ground
5032 	Alternating current	5988 	Computer Network		
ISO 7000		**Underwriter's Laboratory Listing Mark for Canada and the United States**		**USB Implementers Forum**	
1027 	Reset		Underwriter's Laboratory Listing Mark		USB Cable
European Union Directive 98/79/EC of the European Parliament and of the Council on in vitro Diagnostic Medical Device			**European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)**		
	European Union Conformity		WEEE - Do not throw in trash		
Manufacture Symbols (BioFire Diagnostics, LLC)					
	Consult Instructions for Use - Online		Consult Instructions for Use - Phone		NOTE - explains how to operate the instrument more efficiently

Abbreviation of Terms

A	amp (ampere)
cm	centimeters
DNA	deoxyribonucleic acid
dNTP	deoxyribonucleotide triphosphate
kg	kilograms
Hz	hertz
in	inches
IVD	*in vitro* diagnostic
lbs	pounds
m	meters
nmPCR	nested multiplex PCR
PCR	polymerase chain reaction
PPE	personal protective equipment
RNA	ribonucleic acid
RT	reverse transcription
Taq	enzyme from Thermus aquaticus
Tm	melting temperature
VAC	volt, alternating current

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CHAPTER 1: FILMARRAY TORCH

FilmArray Torch Intended Use

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The FilmArray Torch is an automated *in vitro* diagnostic (IVD) device intended for use with FDA cleared or approved IVD FilmArray panels. The FilmArray Torch is intended for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray Torch interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR (nmPCR) in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The FilmArray Torch software automatically determines the results and provides a test report.

The FilmArray Torch is a modification of FilmArray 2.0 and is composed of two to twelve FilmArray Torch Modules connected to a FilmArray Torch System Base running FilmArray Torch software. The FilmArray Torch System Base houses two FilmArray Torch Modules. Up to five Duplex Module enclosures, each capable of housing two additional Torch Modules, may be added on top of the FilmArray Torch System Base. Each FilmArray Torch Module can be randomly and independently accessed to run a reagent pouch. The FilmArray Torch software controls the function of each FilmArray Torch Module and collects, analyzes, and stores data generated by each FilmArray Torch Module.

Limitations of Use

- This product can be used only with FilmArray pouches.
- For prescription use only.
- The FilmArray Torch is intended to be used in combination with FilmArray panels that have been FDA cleared for use on the FilmArray Torch.
- Do not remove the FilmArray Torch Module(s) front cover during a run.
- Use only the supplied cables when connecting any FilmArray Torch Module to the FilmArray Torch System Base.
- Do not use cable extenders to increase cable length.
- Do not install any software other than the BioFire Diagnostics FilmArray Torch software on the System Base unless required by peripheral devices (printers, removable drives, other USB devices).
- Do not enable Windows Automatic Updates on the System Base.
- Do not remove the default Windows user accounts
- Do not change screensaver settings on the System Base.
- Do not modify the FilmArray Torch software or configuration settings.
- Do not adjust system settings (such as date/time) while FilmArray Torch Modules are running.
- Do not re-run a pouch associated with an error, incomplete run, or invalid result.
- Only authorized service personnel should install and perform service or repairs on the FilmArray Torch.

FilmArray Pouch

Atitiktis_2.1

Each FilmArray pouch is a self-contained, closed-system disposable that houses all the chemistry required to isolate, amplify, and detect nucleic acid from a sample. The reservoirs in the rigid plastic component, or fitment, of the pouch (A) contain freeze-dried reagents. The flexible plastic film portion of the pouch (B) is divided into discrete segments (blisters) which, via interactions with actuators and sensors in the FilmArray Torch Module, are where the following chemical processes are performed:

(C) Extraction and purification of nucleic acids from a clinical sample using mechanical lysis (bead beating) and magnetic bead technology

(D) First-stage multiplex PCR (including reverse transcription of target RNAs when appropriate)

(E) Second-stage singleplex PCR and melting analysis within a multi-well array

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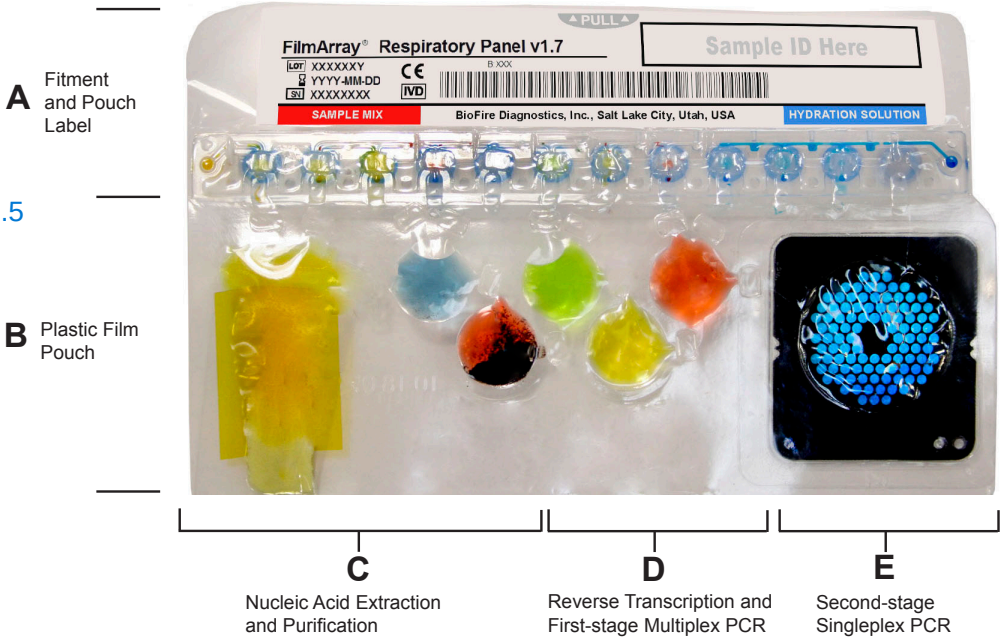
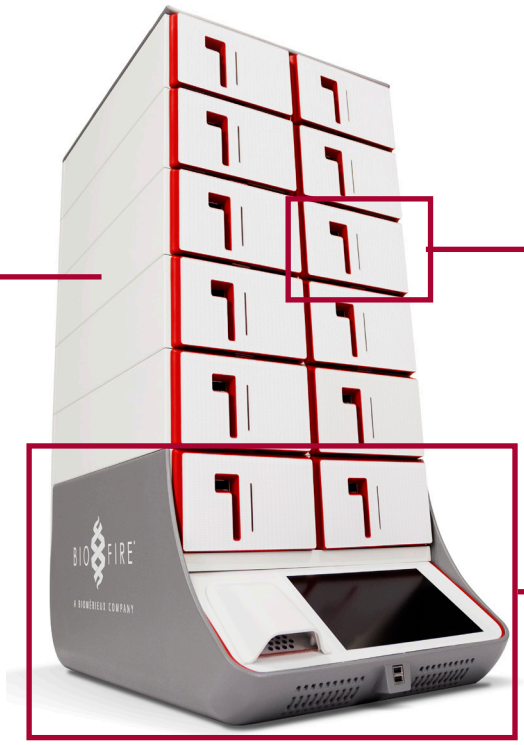


NOTE: The colored liquid in this image of a FilmArray pouch is for visualization only. FilmArray pouches do not contain any colored fluid.

Each pouch contains at least one internal process control. Control material is lysed and the nucleic acids of the control material are extracted along with that of the organisms contained in the sample. When the internal control is positive, proper operation of the FilmArray Torch Module and chemical processes have been demonstrated.

FilmArray Torch

Major components and operations of the FilmArray Torch are described below. A full list of components can be found in *Chapter 2* and specific step-by-step operating instructions can be found in *Chapter 5*.



FilmArray Torch Duplex
Module enclosure; houses two FilmArray Torch Modules

FilmArray Torch Module
Interacts with the reagent pouch to purify and amplify targeted nucleic acid sequences using nmPCR; includes pouch slot and LED status light

Atitiktis_2.2

FilmArray Torch System Base
Includes barcode scanner, touch screen, and USB ports

FilmArray Pouch Modules

Each FilmArray reagent pouch requires a pouch specific software called a pouch module to be installed on the FilmArray Torch in order to perform a test. These pouch modules contain definitions, protocols, analysis and reporting for specific FilmArray reagent kits. See the *Pouch Modules* section in *Chapter 6* for more information.

FilmArray Pouch Preparation

Refer to the *Procedure* section of the appropriate FilmArray reagent kit instruction booklet for step-by-step instructions for sample and pouch preparation.

FilmArray Torch Runs

The FilmArray Torch is used in combination with FilmArray reagent pouches to perform tests, also known as runs, that detect multiple nucleic acid targets contained in clinical specimens. The FilmArray Torch interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nmPCR in a closed system.

The FilmArray Torch software includes a detailed workflow that guides the operator on how to perform a run. Once a pouch has been prepared for testing, on-screen instructions prompt the operator to enter pouch and sample information, insert the pouch into an available Torch Module and start the run. For more information on starting a FilmArray Torch run, see *Chapter 5.*

FilmArray Torch Module and Pouch Interaction

After the run is started, a series of plungers, pneumatic actuators, and hard seals work together to move and mix liquid reagents between the blisters of the pouch. The FilmArray Torch Module controls these functions automatically based on the pouch module run protocol selected for a specific pouch and sample type in the FilmArray Torch software.

Mechanical Lysis

The first step in processing a sample is to break the outer membrane of the target cells or organisms contained in the sample using a device called a bead-beater. A sensor detects the speed and operation of the bead-beater motor and aborts the run if the bead-beater is not working properly.

Nucleic Acid Extraction

Following bead-beating, the nucleic acids contained in the sample are purified by magnetic bead technology. A retractable magnet is used to capture or release the magnetic beads during washes.

Thermal Control

The purified nucleic acids are mixed with PCR reagents, which amplify all of the targets identified by the pouch as well as the control material. A Peltier device drives the thermocycling (heating and cooling of the solution) of the reverse transcription and/or first-stage PCR reactions. A second Peltier device controls thermocycling for second-stage PCR and DNA melting. These reactions take place in the array located in the final pouch blister. The thermocycling conditions are controlled by the run protocol associated with each specific reagent pouch and sample type.

Optics and Imaging

To identify targets from positive PCR reactions, DNA melting curve analysis is performed. The fluorescence emitted by the LCGreen® Plus dye is imaged by a camera. DNA melting curves are captured by slowly increasing the temperature of the PCR array and capturing the fluorescent signal. These images are processed automatically by the System Base, and the data is analyzed to determine if the control reactions passed and which targets were detected in the sample.

The optics system contained in the FilmArray Torch Module is aligned, focused, and calibrated at the factory. Proper operation and calibration of FilmArray Torch Module optics is monitored by the FilmArray Torch Module self-tests and internal pouch controls.

FilmArray Torch software

The FilmArray Torch software manages and controls the operation of each FilmArray Torch Module. The software also collects, stores, and analyzes data generated by the FilmArray Torch Module. Results of analyses are presented in a test report. A brief overview of major software components are described below. For more detailed information about the features and operation of the FilmArray Torch software, see *Chapter 6, FilmArray Torch software*.

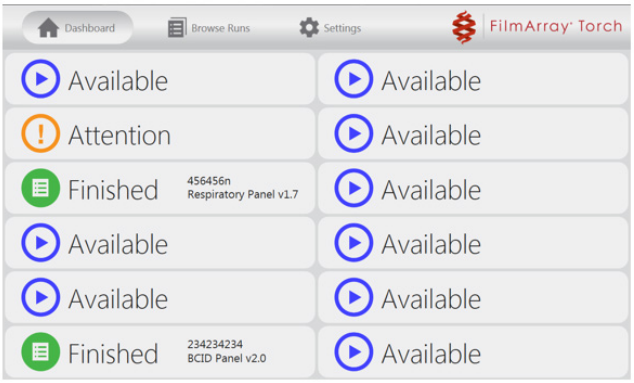
Toolbar

The toolbar always displays at the top of the screen and consists of three options:

- Dashboard
- Browse Runs
- Settings

Dashboard

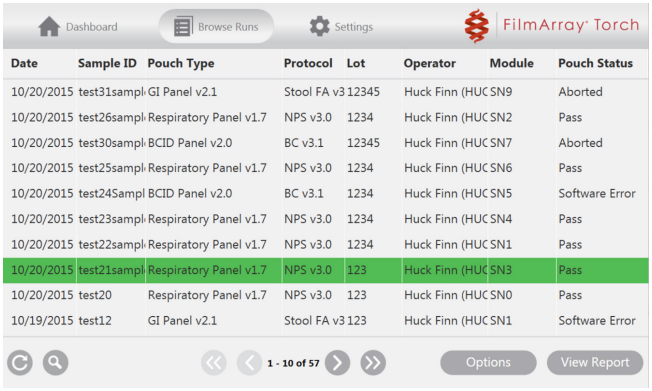
Displays the status of each FilmArray Torch Module within the FilmArray Torch and guides the operator through the process of operating the Modules.



NOTE: The Dashboard display may be different dependent upon the number of Modules configured.

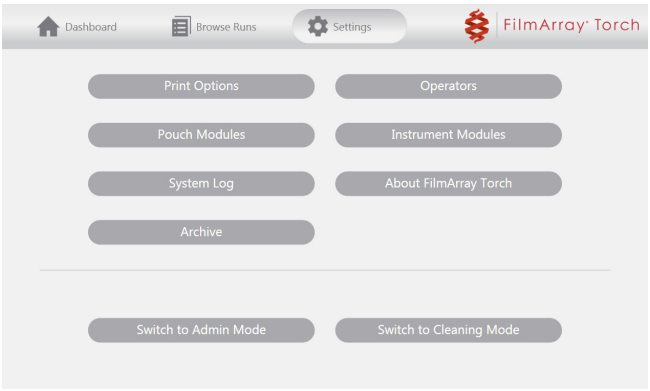
Browse Runs

Allows operators to search for runs and perform operations on individual runs or on groups of runs.



Settings

Allows users to perform administrative type tasks, such as managing operators (adding and updating), view system logs, etc.



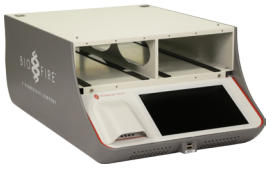
CHAPTER 2: FILMARRAY TORCH COMPONENTS AND SETUP

FilmArray Torch Components

Each FilmArray Torch comes with a FilmArray Torch System Base, two or more FilmArray Torch Modules, and accessories. Optional Duplexes are available to house additional Modules (up to 12 total). The FilmArray Torch ships in a minimum of three boxes and a maximum of 18 boxes; one System Base box, two to twelve Module boxes (one box per Module), and up to five Duplex boxes (one for every two Modules after the first two Modules).

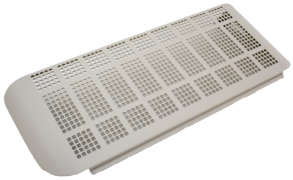
FilmArray Torch System Base Box Contents

NOTE: The FilmArray Torch System Base comes pre-loaded with the FilmArray Torch software



FilmArray Torch System Base

Top Cover



System Base Cable Shroud

FilmArray Pouch Loading Station

EU Power Cable

US Power Cable

Ethernet Cable

FilmArray Torch Information CD

FilmArray Torch Module Box Contents

FilmArray Torch Module

Module Front Cover

Filter

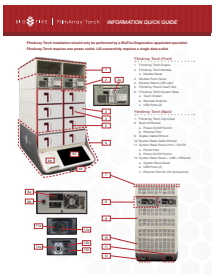
Long Ethernet Cable

Long Power Cable

Spare Filters (2x)

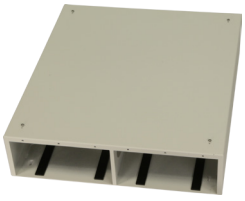
Short Ethernet Cable

Short Power Cable



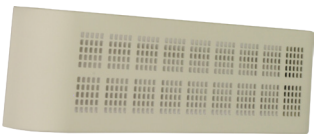
Information Quick Guide

FilmArray Duplex Box Contents (Optional)



FilmArray Torch Duplex

FilmArray Pouch Loading Station



Duplex Cable Shroud

NOTE: Duplexes ship separately in their own boxes.

Setup Requirements

Select a clean, well-ventilated area that is large enough to fit the FilmArray Torch.

- There must be at least 1 inch (2.6 cm) between the rear panels and any other surface (such as the wall) to allow for proper air flow.
- The depth of the bench-top space should be at least 30 in (77 cm).
- The width of the bench-top space should be at least 19 in (49 cm).
- The height of the space required depends on the number of Modules installed:
  - System Base – 11.5 in (30 cm)
  - System Base + 1 Duplex – 16 in (41 cm)
  - System Base + 2 Duplexes – 20.5 in (53 cm)
  - System Base + 3 Duplexes – 25 in (64 cm)
  - System Base + 4 Duplexes – 29.5 in (75 cm)
  - System Base + 5 Duplexes – 34 in (87 cm)

NOTE: One Duplex holds two FilmArray Torch Modules.

- Power Specifications:

Qty. of Modules	Voltage	Frequency	AC Current at 120V*	AC Current at 240V*
2	100-240VAC	50-60Hz	3.2 A	1.7 A
4			5.0 A	2.8 A
6			6.9 A	3.8 A
8			8.8 A	4.8 A
10			10.6 A	5.8 A
12			12.5 A	6.9 A

*Grounded outlet required

NOTE: FilmArray Torch requires one dedicated circuit. A single data outlet is sufficient for optional LIS connectivity.

The FilmArray Torch complies with the emission and immunity requirements in IEC 61326. It is advisable to evaluate the electromagnetic environment prior to operating the device.

CAUTION: Do not use this device in close proximity to sources of strong electromagnetic radiation (unshielded intentional radio frequency sources, for example) because these may interfere with the operation of the FilmArray Torch.

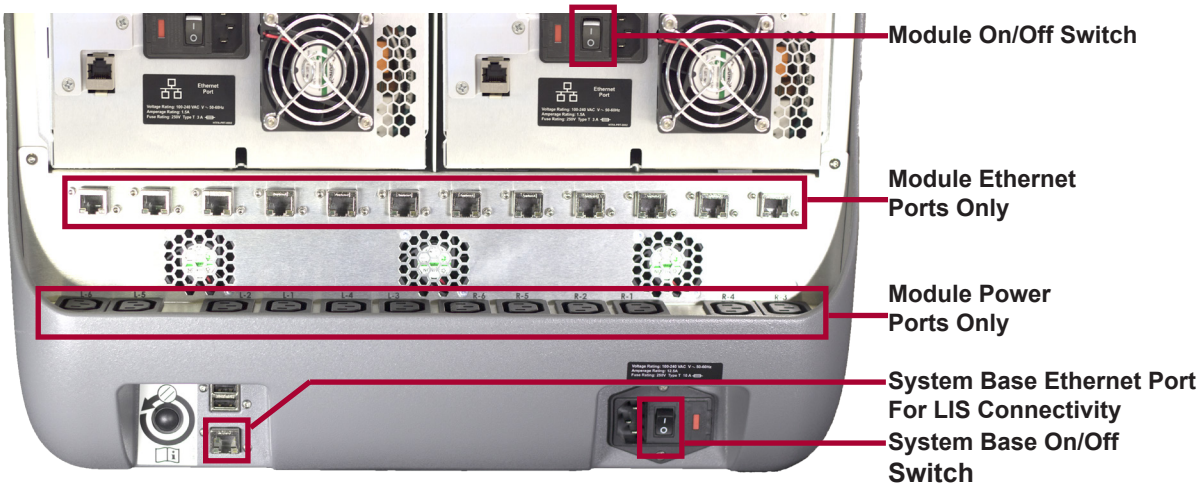
FilmArray Torch Installation

⚠CAUTION: FilmArray Torch installation should only be performed by a BioFire Diagnostics appointed specialist. A brief description of the installation process is provided below.

FilmArray Torch System Base Setup

⚠CAUTION: Use only the supplied cables when connecting the FilmArray Torch Modules to the FilmArray Torch System Base. Do not use cable extenders to increase cable length.

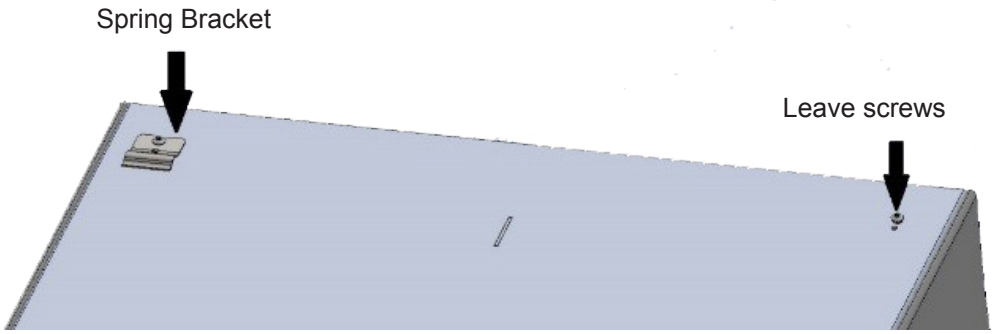
1. Remove all components in the System Base box.
2. Place the System Base in desired location.
3. Plug in power and ethernet cord from the System Base to the wall.
4. Turn on power to the System Base; then check that the FilmArray Torch software powers on.



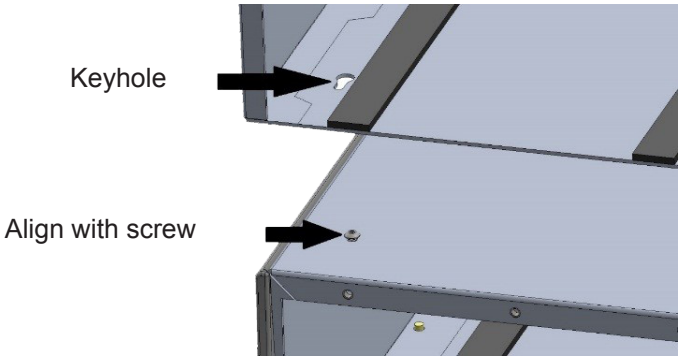
FilmArray Torch Duplex Installation

NOTE: Duplex installation is performed if more than two Modules need to be installed. If not, continue on to the *FilmArray Torch Module Installation* section in this chapter.

1. Remove all components from the Duplex box(es).
2. Loosen screw to remove the spring brackets at the rear of the top cover (leave the screw threaded in below).

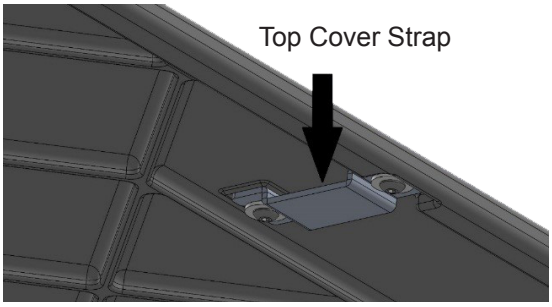


3. Stack a Duplex Module enclosure on top of the System Base/lower Duplex and align the key-holes with the screws in the base/Duplex below.

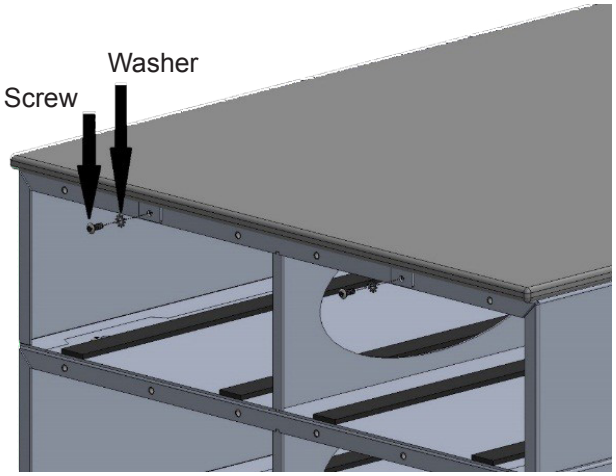


4. Slide the new Duplex back until the front edge is aligned with the Duplex below it; then tighten the fasteners.
5. Repeat steps 3 – 4 until all Duplexes are installed (up to five Duplexes).
6. Reinstall the top cover spring brackets on the top Duplex (at the rear holes) and tighten the screws.

7. Align the top cover straps with the spring brackets; then slide the top cover back until the tabs align with the front of the top Duplex.



8. Fasten with washers and screws.

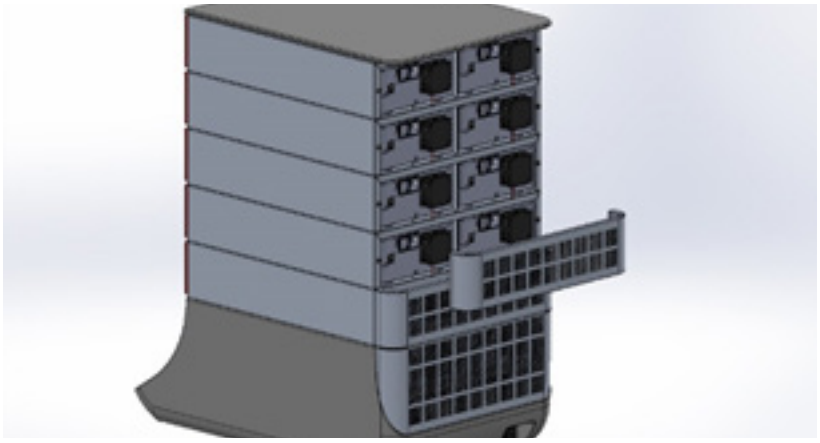


FilmArray Torch Module Installation

Unplug the FilmArray Torch before beginning.

1. Remove all contents from the Module boxes.
2. If necessary, install all Duplexes (see the *FilmArray Duplex Installation* section previously in this chapter for instructions).
3. Loosen the two screws on the front of the preinstalled tabs.
4. Starting at the bottom and working up, install Modules into the front of each Duplex opening and secure each with washers and screws.
5. Using the power and ethernet cables, connect each Module to the back of the System Base. The labels next to the AC power connectors on the System Base will indicate the optimal cable routing order.
6. Turn on power to each Module using the power switch on the back of each Module (see image in the *FilmArray Torch System Base Setup* section previously in this chapter for more information).

7. Install cable shrouds over the electrical cables. The shrouds attach by aligning the magnets on the back of each Duplex with the holes in the strikers.



8. Ensure the filters are in place on the back of each Module front cover; then attach a front cover to each Module by aligning the mounting posts with the alignment holes in the plastic.
9. Plug the System Base power cord into a power source; then plug the System Base Ethernet cable into desired Ethernet port.
10. Turn the FilmArray Torch on using the power switch on the back of the System Base near the power cord.

NOTE: Routine shutdown is not required for FilmArray Torch. To properly turn off, first press the reset button on the back of the System Base until the screen goes black; then turn off the main power switch near the System Base power cord.

FilmArray Torch Module Removal

1. Remove the cable shroud from the back of the Module and turn off the Module to be replace.
2. Disconnect the cables and remove the Module front cover.
3. Unscrew the washers and screws on the front of the Module; then carefully slide the Module out of its Duplex.

NOTE: If installing a replacement Module, install using the steps in the previous section.

Instrument Configuration Application for FilmArray Torch

The FilmArray Torch System Base is preinstalled with the Instrument Configuration application. Once connected physically to the System Base, the Instrument Configuration application allows an operator to add or remove Modules to the FilmArray Torch software.

NOTE: A Module must be added to the FilmArray Torch before the software can be used to initiate and perform runs.

Start Instrument Configuration Application

To access to the application from the FilmArray Torch software:

1. Navigate to the Settings toolbar and select **Switch to Admin Mode**.

   A confirmation message will appear.

2. Select **Yes** on the message to exit the FilmArray Torch software.

   A Windows login screen will appear after the software closes.

3. Log into Admin Mode by entering a valid username and password (see the *Switch to Admin Mode* section in *Chapter 6* for more information).

4. When the Windows desktop displays, double-tap the icon.

Instrument Configuration Grid

The Instrument Configuration grid is broken into 12 box*es* that represent the physical locations for all 12 potential Modules. Each Module that is currently configured to the FilmArray Torch displays within a box. Any boxes that have not had a Module configured to them contain a plus icon .

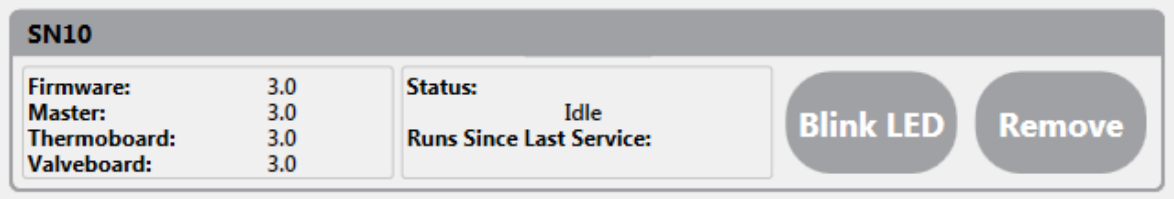
NOTE: Start initial configuration from the bottom and work up. Modules should be configured to correspond with the physical location(s) on the FilmArray Torch.

Grid Box

The grid box represents a single location within the FilmArray Torch.

Each Module configured to the FilmArray Torch displays the following:

- **Serial Number** displayed as a title
- **Firmware** version
- **Master** version
- **Thermoboard** version
- **Valveboard** version
- **Status**
- **Runs Since Last Service**
- **Blink LED** identifies which physical Module is linked to the appropriate location. The Module LED blinks white when the Blink LED option is selected. The Blink LED option is unavailable if the Module is disconnected.
- **Remove** (see the *Remove FilmArray Torch Module* section below)

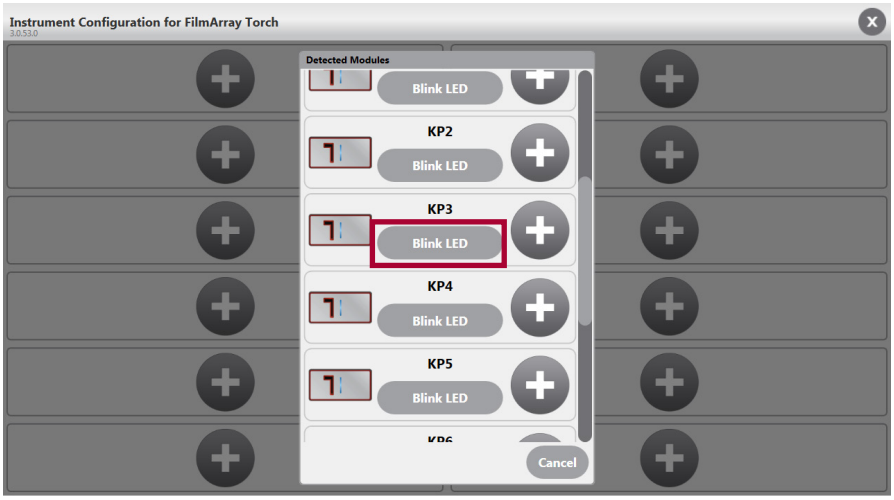


Add FilmArray Torch Module

To add a Module to the FilmArray Torch software:

1. Select the plus icon for the appropriate location.

The application presents the Detected Modules dialog.



2. Use the scroll bar to locate the applicable Module Serial Number and select **Blink LED**.
3. Use the plus icon to add the appropriate Module.
4. Select **Save** to save all changes made during this operation.

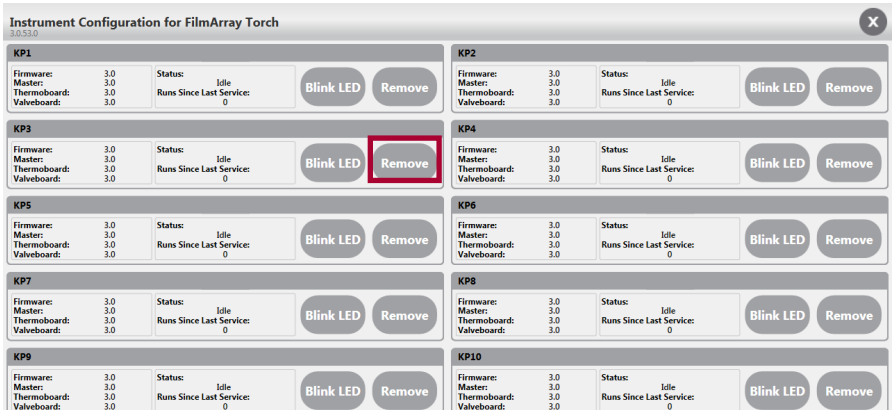
Remove FilmArray Torch Module

To remove a Module from the FilmArray Torch software:

1. Identify the location configured to Module and check that its status is **Idle**.

NOTE: There is no warning presented for removal of a FilmArray Torch Module that is currently in a running status.

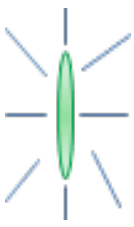
2. Select **Remove** on the applicable location.

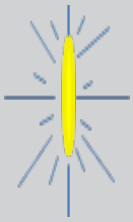


3. Select the **Save** option to save all changes made during this operation.

FilmArray Torch Module Status

The front of each FilmArray Torch Module is equipped with an LED light that shows the specific status of that Module.

LED	Color	Status	Meaning
	White	Solid	Module initializing.
	Yellow	Solid	Warning - e.g., Module not connected.
	Blue	Solid	Module idle and available to run a pouch.
	Blue	Blink	Module waiting for operator to insert a pouch.
	Green	Fast Blink	pouch inserted and seated, but pouch run not started.
	Green	Solid	pouch run in progress.
	Green	Slow Blink	Run complete - remove pouch

LED	Color	Status	Meaning
	Yellow	Blink	Warning – Operator action required - e.g., unknown insertion, double insertion, pouch jam Follow on-screen instructions.
	Purple	Blink	Error. Operator intervention or maintenance required. Module must be reset. Remove the front cover of the affected Module and reset the Module, or power off then power on the Module.
	Red	Solid	Error. Operator intervention or maintenance required. Module must be reset. Remove the front cover of the affected Module and reset the Module, or power off then power on the Module.

Connecting a Printer to FilmArray Torch

The FilmArray Torch can be configured to print to any printer compatible with a Windows 7 operating system.

Add or Update Printer

1. Navigate to the **Settings** toolbar.
2. Select **Switch to Admin Mode**. A warning message informs the operator that switching to Admin Mode will close the application and log off.
3. Select **Yes** to confirm the switch.
4. Enter the appropriate user name and password to log in. The standard Windows desktop lay-out will display.
5. Navigate to the Control Panel to manipulate printer details for the FilmArray Torch.
6. Restart the System Base when printer maintenance is complete. The FilmArray Torch software will automatically load.

CHAPTER 3: PRINCIPLES OF OPERATION

FilmArray is an automated *in vitro* diagnostic (IVD) system that utilizes nmPCR and high-resolution melting analysis to detect and identify multiple nucleic acid targets from clinical specimens. The user of the FilmArray Torch loads the sample into a reagent pouch, places the pouch into the FilmArray Torch Module, and starts the run. The FilmArray Torch Module interacts with the reagent pouch to extract nucleic acids from the sample and to amplify pathogen specific DNA sequences that are targeted by the assays. The resulting PCR products are evaluated using DNA melting analysis and the results are automatically determined and presented by the FilmArray software in a test report.

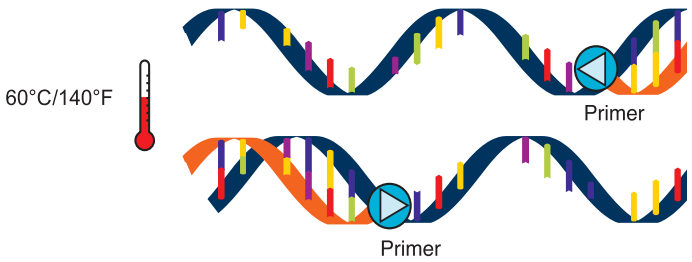
PCR Basics

Polymerase chain reaction (PCR) is the process of making billions of copies of DNA. Copies are made by melting the DNA into separate strands and using each strand as a template for generation of a new strand. To identify specific pathogens using PCR, primers (short pieces of a specific DNA sequence) are included in the PCR reaction to target unique segments of the pathogen genome. If the organism of interest has an RNA genome, a process called reverse transcription (RT) is performed prior to PCR in order to convert the RNA template into a DNA template (RT-PCR).

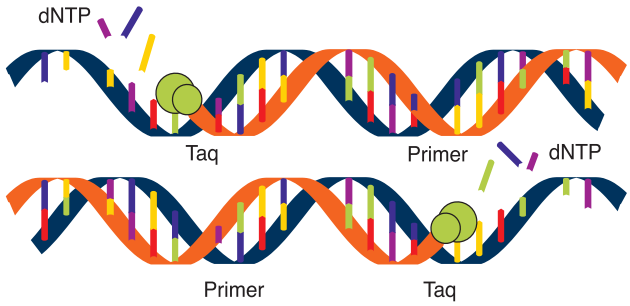
There are 3 steps to a PCR cycle:

Step 1: Denaturation - The sample is heated to about 94°C to denature or 'melt' the double-stranded target DNA into single strands.

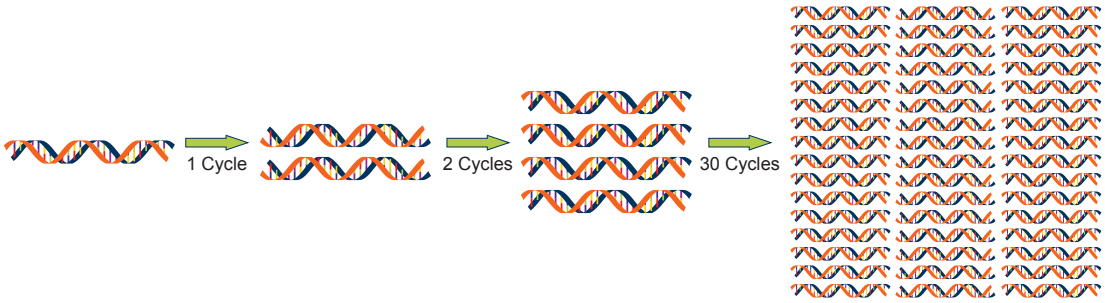
Step 2: Primer annealing - The sample is cooled to about 60°C, allowing the primers to bind or "anneal" to the target DNA strands at a specific site.



Step 3: Primer extension - an enzyme (Taq DNA polymerase) binds to the DNA/primer complex and makes a copy of the original double stranded DNA by adding nucleotides (dNTPs A, G, T or C) that are complementary to the nucleotide sequence of the target DNA.



At the end of a cycle, each piece of double-stranded target DNA has been duplicated. The new DNA copies act as templates in the next cycles, so after 30 cycles, as many as 1 billion copies of a single piece of DNA can be produced. With this duplication process, it becomes possible to detect DNA or RNA from even a low concentration of pathogens in the original sample.



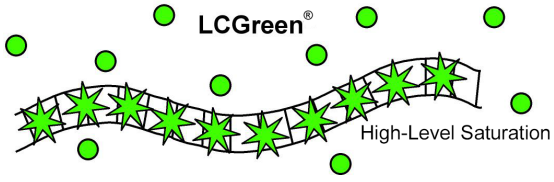
Nested Multiplex PCR

nmPCR uses two stages of PCR. During the first-stage PCR, multiple “outer primers” are used to perform multiplex PCR on the target templates present in the sample.

Second-stage PCR is performed in a singleplex format to further amplify the DNA copies generated during the first-stage PCR. The “inner primers” used in second-stage PCR are made up of sequences “nested” within the first-stage PCR product(s).

High Resolution Melting Analysis

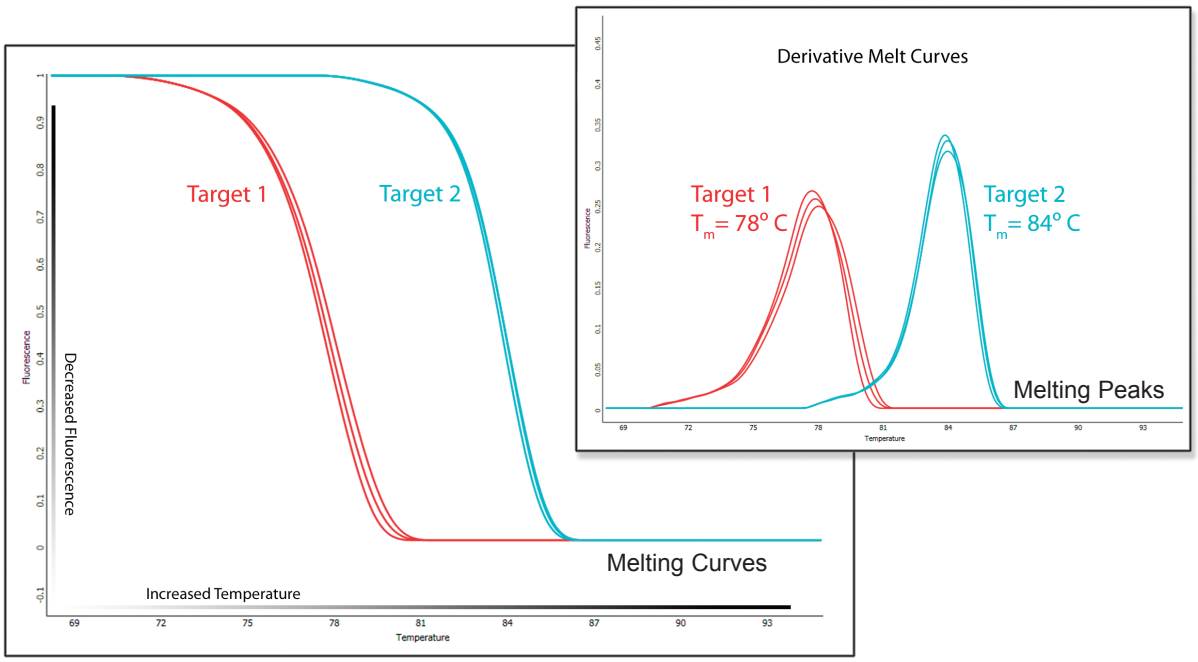
FilmArray PCR reactions contain the DNA binding dye LCGreen® Plus. LCGreen Plus is incorporated into the copies of DNA as they are made during each PCR cycle. When bound to double-stranded DNA, the dye fluoresces and the fluorescence is detected by the FilmArray Torch Module. As the temperature is increased and the copies of double-stranded DNA melt, the LCGreen Plus dye is released and a reduction in fluorescence is detected.



Copies of double-stranded DNA generated during PCR (called PCR products or amplicon) will have unique sequences based on the template that was amplified. Amplicon length and sequence determines the temperature at which the double-stranded DNA will melt apart, which is known as the melting temperature (Tm) of the amplicon. PCR products made from different targets will have different sequences and, therefore, different Tms.

After the last cycle of PCR, the FilmArray Torch Module gradually raises the temperature of the reaction from approximately 60°C to 94°C. As the temperature reaches the Tm of an amplicon, the amplicon denatures and fluorescence drops, releasing LCGreen Plus. This produces a melting curve, seen in the graph below, which shows the rapid decline in fluorescence. A melting peak with a specific Tm is generated for each amplicon by plotting the negative derivative of the melting curve.

Melting Curves for two Different Targets with Unique Amplicon Sequences



The FilmArray uses melting curve analysis to identify pathogen specific PCR product. Since the sequence and Tm of an amplicon from a specific target is known and consistent, pathogen specific PCR product can be identified as being copied from that target. Non-specific PCR products with different Tms are excluded.

CHAPTER 4: PERFORMANCE SPECIFICATIONS

FilmArray Torch System Specifications

<table>
<tr><td>Sample Description</td><td>• One sample capacity per FilmArray Torch Module (with up to 12 samples per FilmArray Torch)</td></tr>
<tr><td>Run Time</td><td>• Sample run time about one hour</td></tr>
<tr><td>User Interface</td><td>• System Base with touch screen and barcode scanner</td></tr>
<tr><td>Data Output</td><td>• Automatic analysis with end-of-run result reports</td></tr>
<tr><td>Fluorescence Acquisition</td><td>• Single color optics module: 475nm excitation, 545nm emission, and sensor imaging</td></tr>
<tr><td>Temperature Control</td><td>• Operating temperature 15°C to 30°C
• Peltier devices:
  • Ambient to 100°C
  • Ramp rate from 0.1–0.5°C /sec on melt</td></tr>
<tr><td>Operations Specification</td><td>• 15°C to 30°C @ 20 to 80% relative humidity (non-condensing)
• -16m to 3048m
• Indoor use only</td></tr>
<tr><td>Shipping Specifications</td><td>• -30°C to 38°C @ 5 to 85% relative humidity (non-condensing)
• -16m to 10,600m</td></tr>
<tr><td>Power Requirements</td><td>
<table>
<tr><th>Qty. of Modules</th><th>Voltage</th><th>Frequency</th><th>AC Current at 120V</th><th>AC Current at 240V</th></tr>
<tr><td>2</td><td rowspan="6">100-240VAC</td><td rowspan="6">50-60Hz</td><td>3.2 A</td><td>1.7 A</td></tr>
<tr><td>4</td><td>5.0 A</td><td>2.8 A</td></tr>
<tr><td>6</td><td>6.9 A</td><td>3.8 A</td></tr>
<tr><td>8</td><td>8.8 A</td><td>4.8 A</td></tr>
<tr><td>10</td><td>10.6 A</td><td>5.8 A</td></tr>
<tr><td>12</td><td>12.5 A</td><td>6.9 A</td></tr>
</table>
</td></tr>
<tr><td>Fuse</td><td>• 250V 3.15A Type T (Modules)
• 250V 10A Type T (System Base)</td></tr>
</table>

Dimensions and Weight	• 18 x 29 x 11.5 in (45.8 x 73.66 x 29.21 cm) (W x D x H; System Base only)
	  • 4.5 in (11.43 cm) (H; Modules only)
	  • 34 in (86.36 cm) max height (12 Modules)
	• Weight: Approximately 268 lbs (121.6 kg) maximum:
	  • System Base – 36 lbs (16.3 kg)
	  • Modules – 15 lbs (6.8 kg) each
	  • Duplex (Module enclosure) – 6.5 lbs (2.95 kg) each

EMC Requirements	• The FilmArray Torch complies with the emission and immunity requirements in IEC 61326: Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements.
Safety Requirements	• The FilmArray Torch complies with IEC 61010-2-101: Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.
CPU	• Intel® Core™ i7 4770S 3.1 GHz or faster
Storage and Memory	• 512 GB hard drive or greater • 16 GB RAM or greater
Interfaces and Peripherals	System Base • 12+1 Ethernet network interfaces • 4 USB connections or more
	Module • One Ethernet network interface
Display	• LCD • 10.6” diagonal (26.9 cm) • 1280 x 768 resolution • Capacitive touch screen interface
Operating System	• Microsoft® Windows® 7 Embedded OS

CHAPTER 5: FILMARRAY TORCH OPERATING INSTRUCTIONS

NOTE: Pouch preparation may vary depending on the pouch type used. Please consult the instruction booklet for each FilmArray reagent kit for specific preparation steps.

Using the FilmArray Torch involves three main steps:

1. Adding a patient sample to the FilmArray pouch.
2. Performing a run within a FilmArray Torch Module.
3. Viewing and/or printing a report.

FilmArray Reagent Kits

FilmArray reagent kits include FilmArray pouches and all components required to run tests on the FilmArray Torch. Components will vary based on the type of FilmArray reagent kit. Refer to the instruction booklet or Quick Guide for specific preparation and testing procedures.

CAUTION: Do not attempt to use components from one reagent kit to prepare a different pouch type. Components are pouch specific.

Each FilmArray pouch is labeled with:

LOT Batch Code

SN Serial Number

This information is both human-readable and contained in the barcode. The pouch also includes a space to write the Sample ID or affix a Sample ID barcode.

FilmArray Test Procedure

General Precautions

BIOLOGICAL RISKS: When working with the FilmArray Torch and clinical specimens, personnel may come in contact with contaminants or potentially infectious material. Appropriate biohazard guidelines for working with potentially infectious samples should be followed. Refer to the *Safety Precautions* section of the appropriate FilmArray reagent kit instruction booklet for additional safety information.

It is recommended that the handling of potentially infectious samples be performed in a biological safety cabinet or hood, or behind a protective shield. Once a sample has been added to the FilmArray pouch, move the pouch to a separate area to perform the test.

One of the most important guidelines for a test using PCR is to avoid contamination. Some important rules to follow are:

- Sample collection, pouch loading, and FilmArray Torch operation should each be performed in separate locations or work areas.
- Do not leave a work area or return to a previous work area without first completing decontamination procedures (i.e., washing the area and changing protective clothing and gloves).
- Prepare and load only one pouch at a time.
- Always dispose of used pouches, or pouches that have come in contact with a sample, in a biohazard waste container. Change gloves after handling a used pouch.

FilmArray pouches are stored under vacuum in individually-wrapped canisters. To preserve the integrity of the pouch vacuum for proper operation, be sure that a FilmArray Torch Module will be available and operational before unwrapping any pouches for loading.

Initiate Run

Refer to the *Procedure* section of the appropriate FilmArray reagent kit instruction booklet for step-by-step instructions for sample and pouch preparation.

The FilmArray Torch software includes a detailed workflow that guides the operator on how to perform a run.

Once a pouch has been prepared for testing, follow the on-screen instructions to enter pouch and sample information. Insert the pouch into an available FilmArray Torch Module and start the run.

The operator cannot start a run until one FilmArray Torch Module has been added to the FilmArray Torch software. Please see the *Instrument Configuration* section in *Chapter 2* for more information about adding a FilmArray Torch Module. In addition, the appropriate pouch module must be installed on the FilmArray Torch in order to start a run (see the *Pouch Module* section in *Chapter 6*).

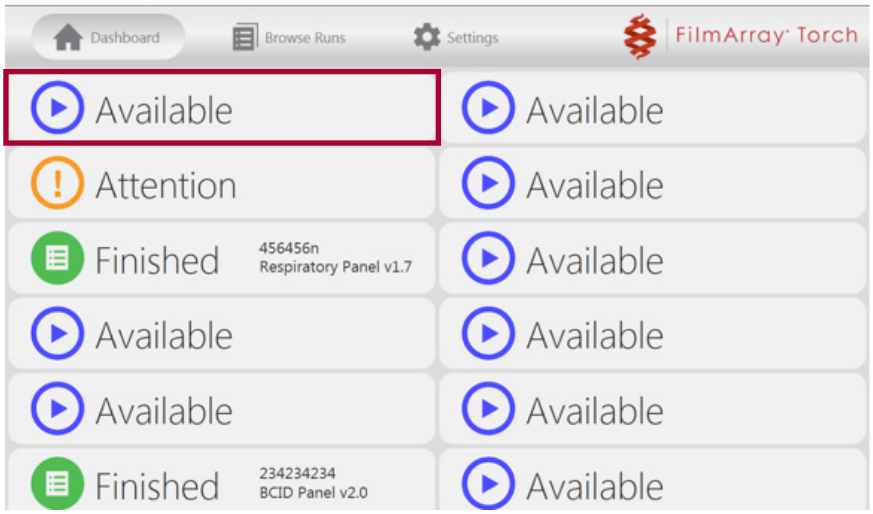
Initiate a FilmArray Torch run by Manual Initiation or Scan Initiation.

Manual Initiation

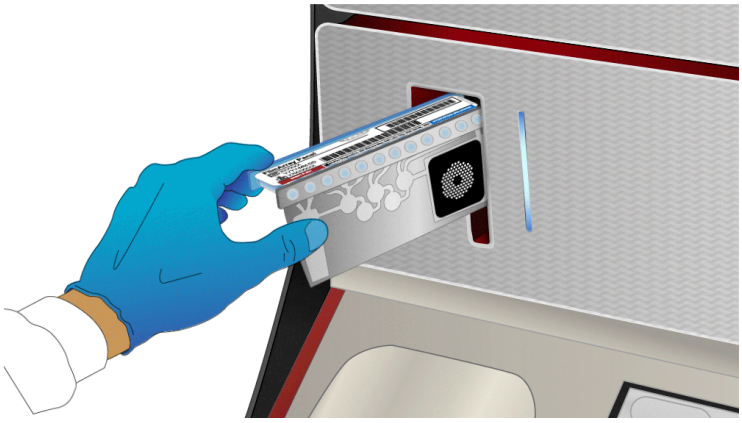
The operator selects a specific FilmArray Torch Module from the Dashboard using the touch screen. To initiate a run manually:

1. Select an **Available** Module on the Dashboard and scan the pouch barcode on the fitment label. Then scan or manually enter the Sample ID.

NOTE: If the barcode scanner is not available or the barcode is unreadable, manually enter the lot number and serial number printed on the pouch label.



2. Insert the pouch into the selected FilmArray Torch Module. The Module's LED will blink blue. Ensure that the pouch fitment label is lying flat on top of the pouch and not folded over. As the pouch is inserted, the Module will grab onto the pouch and pull it into the chamber.



CAUTION: Do not insert sharp objects to remove a jammed pouch. In the event of a jammed pouch, contact BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor for Customer Support.

Scan Initiation

The operator scans the fitment label on the pouch while the Dashboard is displayed on the touch screen. To initiate a run by scanning:

1. Scan the pouch barcode on the fitment label. Then scan or manually enter the Sample ID.
2. Insert the pouch into any Available FilmArray Torch Module. All available Module's LED will blink blue. Ensure that the pouch fitment label is lying flat on top of pouch and not folded over. As the pouch is inserted, the Module will grab onto the pouch and pull it into the chamber.

Start Run

After the pouch is correctly inserted into the FilmArray Torch Module, the LED will blink green to indicate that the pouch has been seated but the run has not yet started. To continue the run after Manual or Scan Initiation:

1. Select the correct pouch protocol for the pouch and sample type.

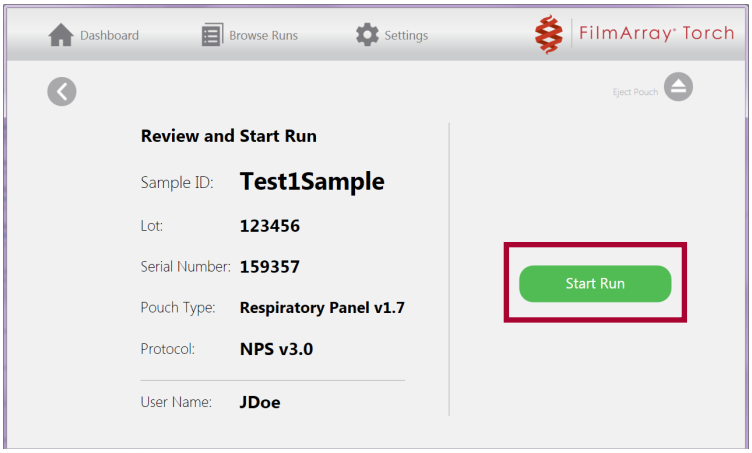
NOTE: If only one protocol is available, it will be automatically selected.

2. Enter operator username and password, then select **Next**.

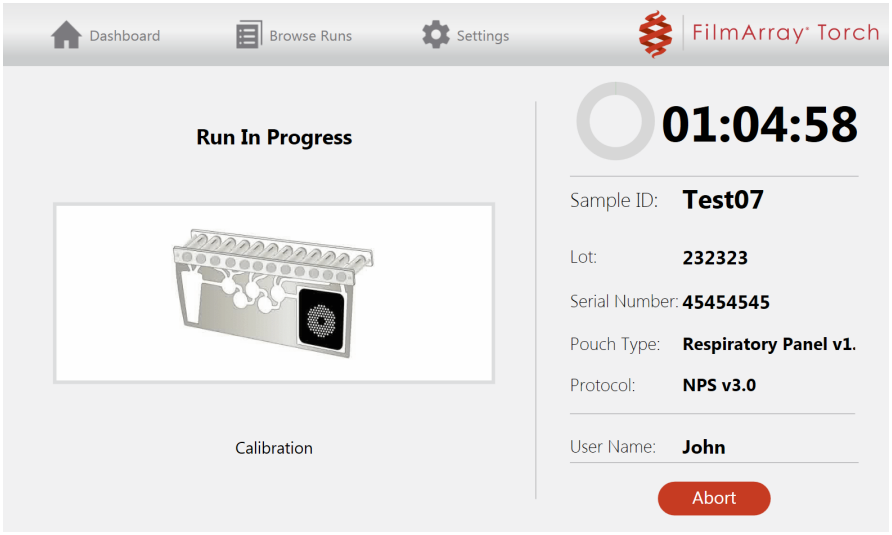
   The Next key will only become available when a correct username and password is entered. See the *Create New Operator(s)* section in *Chapter 6* for more information on how to create a new operator's username and password.

NOTE: The font color of the username and password is red until the user name is recognized by the FilmArray Torch software.

3. Review run information on the screen and if correct, select **Start Run.**



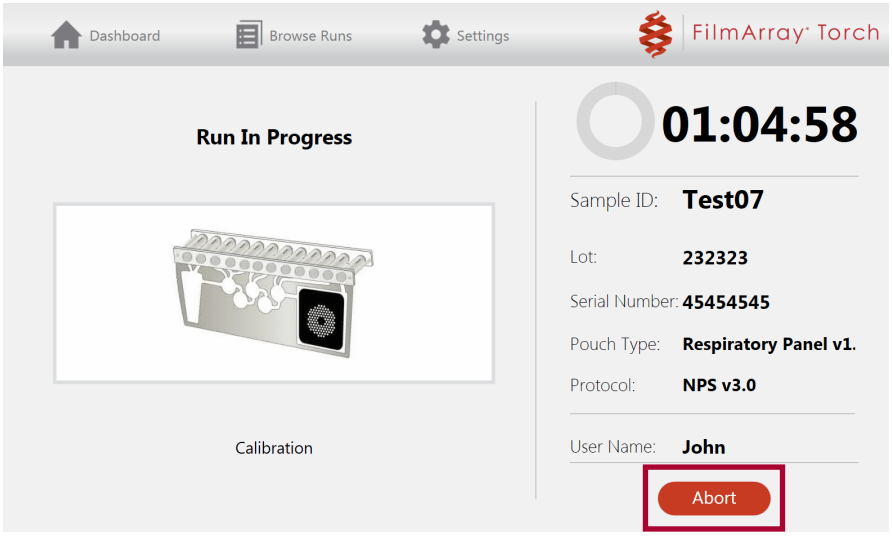
Once the run has been started, the selected Module's LED will turn solid green, indicating the run is in progress. The display also changes to the Run In Progress screen and shows the steps that the Module is currently performing and the approximate remaining run time. The operator may navigate to the Dashboard to perform other tasks.



Abort Run

If a run needs to be stopped before it is finished, select the applicable FilmArray Torch Module from the Dashboard. The Run In Progress screen will display the current run information; select **Abort**. Any data that has been generated for the aborted run will not be available for analysis. An aborted run cannot be restarted and the pouch must not be re-run.

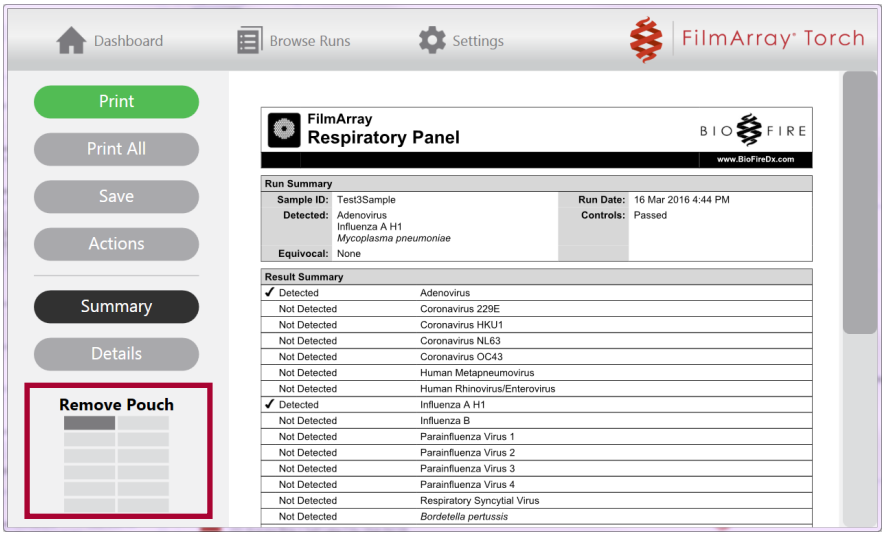
NOTE: Aborting a run may take up to five minutes to complete.



Finish Run

At the end of the run, the Dashboard changes the status of the Module to Finished and the pouch is partially ejected. To finish a run:

1. Select the **Finished** Module on the Dashboard to view the report.



2. Remove the pouch from the Module as shown in the diagram in the lower left corner of the display. The Module LED is solid blue indicating that the Module is ready for a new run

NOTE: Once the pouch has been removed, the report can only be viewed through the Browse Runs feature.

View Report

When a run is finished the report can be viewed on the:

- Run In Progress screen - the run report displays once the run is complete.
- Dashboard screen - a report icon appears and the status changes to Finished. Selecting the Module box displays the run report. Once the pouch is removed from the FilmArray Torch Module, the status changes to Available.
- Browse Runs screen - the run reports are accessible from the table.

Refer to the instruction booklet for the appropriate FilmArray reagent kit for more details about the information provided in the report.

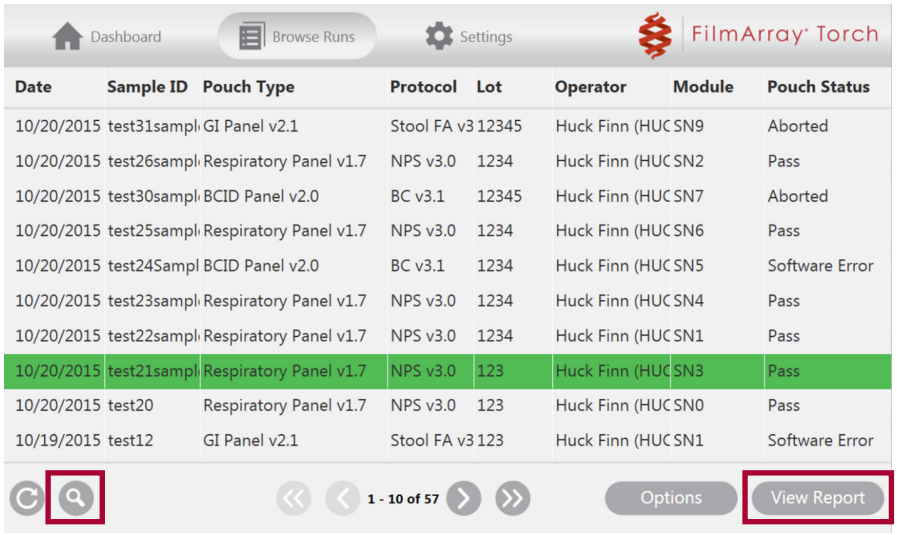
Print Report

Reports will always be printed to the default printer. The FilmArray Torch software can be configured to automatically print the report at the end of the run (see the *Print Options* section within *Settings* in *Chapter 6, FilmArray Torch software*).

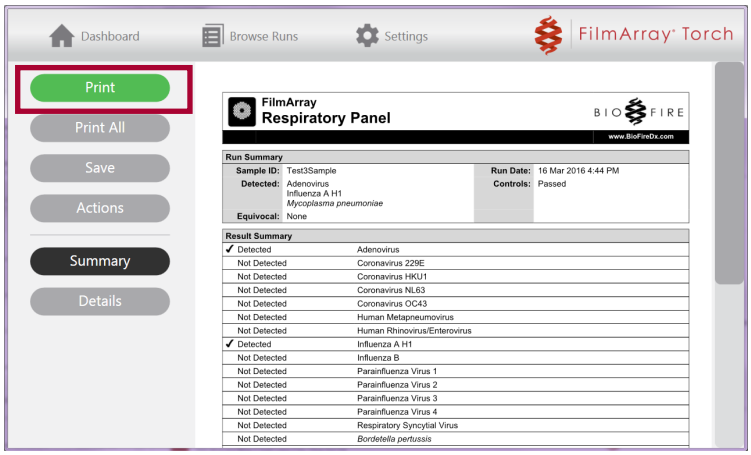
To print a report from a previous FilmArray pouch run:

1. Select **Browse Runs** in the top menu on the touch screen.
2. Use the search icon to search for runs.
3. Select a single desired run from the table.
4. Select **View Report** to open the report page.

NOTE: If no runs or multiple runs are selected, the View Report option is disabled.



5. Select **Print.**



Error Messages

If errors occur, see *Chapter 8, Preventative Maintenance and Troubleshooting*, for more information on viewing and handling error messages.

CHAPTER 6: FILMARRAY TORCH SOFTWARE

This chapter explains how to use the FilmArray Torch software and manage the database. The FilmArray Torch software automatically starts when the FilmArray Torch is powered on – no login is required.

FilmArray Torch Toolbar

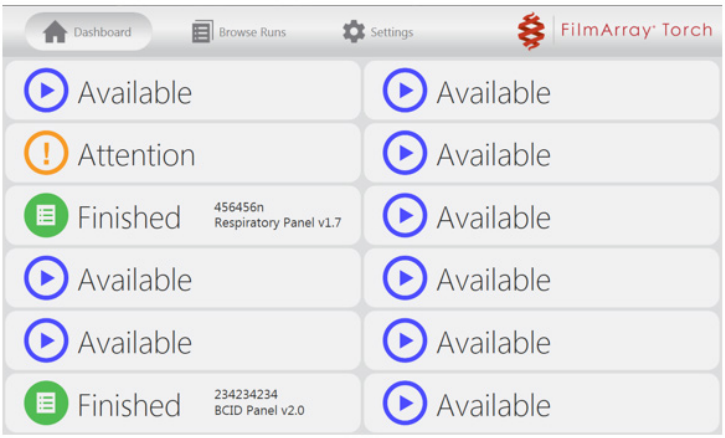
The table below lists the features available in the FilmArray Torch toolbar:

FilmArray Torch Toolbar	Description
Dashboard	The Dashboard allows the operator to do the following: • View the status of each FilmArray Torch Module in the system on a display that can be seen from a distance. • View the status of all runs that are in progress, along with the Sample ID, Pouch Type, and time remaining until completion. • Start a run by using the Start Run Workflow.
Browse Runs	Browse Runs allows the operator to review Run Results for runs performed on all FilmArray Torch Modules within the FilmArray Torch. The Browse Runs feature displays all the runs and allows access to the following actions: • View Report – This option is inactive until a specific report is selected. • Options – Allows access to additional features. • Run Table – Allows the operator to perform the following actions: a. View and sort runs in the database. b. Filter the database by run criteria. c. Page through the runs using the paging navigation at the bottom of the screen.
Settings	Settings allows the operator to perform basic configuration and management of the FilmArray Torch. See the Settings section for details.

Dashboard

The Dashboard option is always accessible from the toolbar. To access the Dashboard from any screen, select the **Dashboard** option on the toolbar. The FilmArray Torch Dashboard allows the operator to interact with several FilmArray Torch Modules from one System Base. Each FilmArray Torch Module is represented by a box displayed on the touch screen. Until at least one Module has been added to the FilmArray Torch software, the Dashboard will be blank. The number of boxes on the Dashboard mirrors the number of Modules that are configured.

Any FilmArray Torch Module box on the Dashboard can be selected to display additional details about the FilmArray Torch Module status.



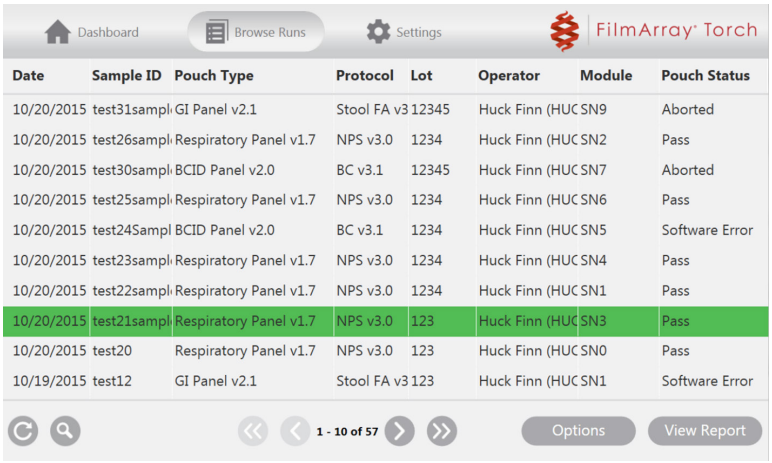
The details for each FilmArray Torch Module include the following:

Status Icon	Status	Description
Available	Available	The Module is available for a new run. The operator can initiate a new run (Manual Initiation of workflow)
01:04:43 test27sample GI Panel v2.1	Run In Progress	Module is performing a run and displays the Time Remaining.
Overtime test27sample GI Panel v2.1	Overtime	Module is performing a run and has gone over the expected run time for the pouch and displays Overtime.
Finished test21sample Respiratory Panel v1.7	Finished	Run has finished, pouch is ejected, run report is ready for viewing.
Attention	Attention	Module has lost connection with the software as a result of one of the following: • Module is initializing or is not connected. • There is an unknown pouch in the Module.
Attention	Attention	The Module needs to be reset. Module has an error on it as a result of one of the following: • Pouch jam • Stalled • Module error

Browse Runs

The Browse Runs option is always accessible from the toolbar. To access Browse Runs from any screen, select the **Browse Runs** option on the toolbar. When a run is completed on a Module, the software generates a report with the results of the run. Upon initial entry into the Browse Runs screen, all the runs within the database are displayed.

The runs are presented as a table that lists the date of the run, the Sample ID, and other information about the run. Selecting an individual run enables the View Report option, which can be selected to display the run report. For more information on viewing a report, see *Chapter 5, FilmArray Torch Operating Instructions.*



View Report Menu

The table below lists the features available on the View Report menu:

Menu Item	Description
Print	Prints the run report. See *Chapter 5, FilmArray Torch Operating Instructions* for more information about printing a report.
Save	Opens a dialog that enables the operator to save the run report to a chosen location.
Actions	Allows for the following actions to be performed for the selected report: 1. **Edit Sample ID**: If a mistake was made during run setup when entering the Sample ID, the operator can make the necessary corrections. A history is recorded of all changes and will be added to the run report. 2. **Show Run Details**: Allows the operator to view system details, messages and errors associated with a run. 3. **Create Error Bundle**: If an error associated with a FilmArray run occurs, a Customer Support representative may request that the operator create an error bundle for that run and send it to BioFire Diagnostics. For more information on creating an error bundle, see the *Error Bundle* section in *Chapter 8*.

Save Report

Run reports can be saved as a PDF file for future use. To save reports as PDF file:

1. Insert a removable drive into an available USB port on the front of the System Base. One or more removable drives, including USB flash drives, external CD/DVD drives, and external hard drives, can be connected to the USB ports on the System Base.

NOTE: Reports can only be saved to an removable drive.

2. Select **Save** on the View Report page.
3. Choose location and filename; then select **Save**. If multiple removable drives are connected to the USB ports on the System Base, select a destination device.
4. After save completion, select **OK** to close the dialog. It is now safe to remove the removable drive(s) from the front of the System Base.

Edit Sample ID

To change the Sample ID if a mistake was made during run set up:

1. Select **Actions** in the View Report page; then select **Edit Sample ID**.

   The operator is presented with a table that lists any previous change history.

2. Update the current Sample ID; then enter Username and Password.

   The save option is not enabled until the operator has entered their Username and Password. This tracks the changes to a specific user and meets the electronic signature and records requirements required in laboratories.

3. Select **Save**.

   After saving the changes, the report reflects the new Sample ID and displays the Change History.

Show Run Details

To see details of the run:

1. Select **Actions** on the View Report page; then select **Show Run Details** from the menu.

   The operator is presented with a list of the system details, messages, and errors associated with that run.

Create Error Bundle

For more information on creating an Error Bundle, see the *Error Bundle* section in *Chapter 8.*

Search Run Data

Search

The search icon on the Browse Runs page contains multiple search criteria the operator can use to locate desired runs. The following table describes the search criteria options:

Criteria	How to Search
Date	Select the date or date range of interest.
Sample ID	Enter the Sample ID of interest.
Pouch Type	Select the panel of interest.
Operator	Select the operator of interest.
Module	Select the Module serial number of interest.
Pouch Status	Select the pouch outcome of interest: Pass, Fail or Invalid, Completed, Incomplete, Aborted, Instrument Error, or Software Error.

To clear Search Criteria and view all of the runs saved in the database, select **Clear All** on the search screen or the **X** on the search results page.

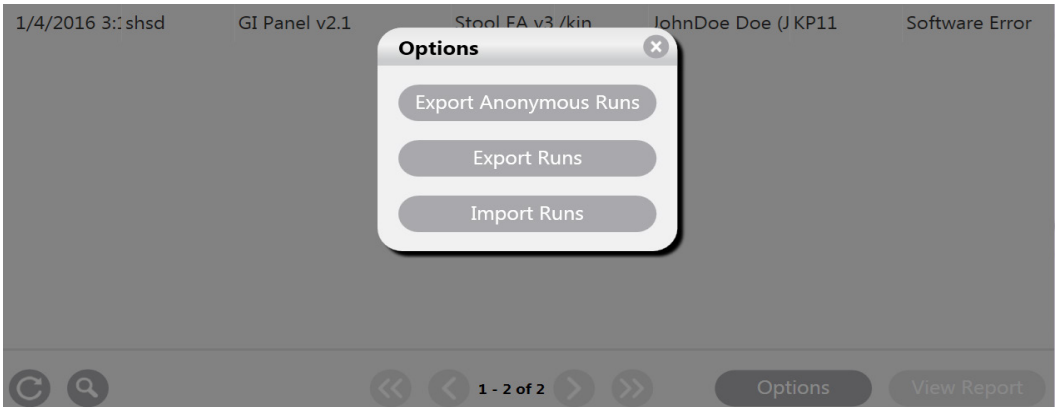
To retain the search criteria and update the search results to include recent runs, select **Refresh**.

Browse Runs Options Menu

The Browse Runs options menu presents a list of actions the operator can use on FilmArray Torch runs. The following table describes the available Browse Runs options:

Menu Item	Description
Export Runs	Enables the operator to write runs to a file while leaving the original runs in the FilmArray database.
Import Runs	Enables the operator to import FilmArray runs from a separate FilmArray database into the database on the FilmArray System Base being used.
Export Anonymous Runs	Works like the Export Runs option, but replaces the Sample ID in the run files with Anonymous.

To access the Browse Runs options menu, select **Options** to bring up the Options menu.



Export Runs

When exporting runs, database files are saved with the extension .db. To export runs to a file:

1. Insert removable drive(s) into an available USB port on the front of the System Base. One or more removable drives, including USB flash drives, external CD/DVD drives, and external hard drives, can be connected to the USB ports on the System Base.
2. Select **Browse Runs** from the toolbar to display a list of runs in the database. Runs can be searched and filtered by selecting the search icon  . See the *Search Run Data* section in this chapter for more information.
3. Select **Options** to view the Options menu; then select **Export Runs**.
4. Select one or more desired runs on the Browse Runs page; then select **OK**.
5. Select a location and filename for the .db file within the Specify Filename dialog. If multiple removable drives are connected to the USB ports on the System Base, select a destination device.
6. Select **Save** to start the export process. The message **Exporting Runs...** appears during the exporting process.

   The operator can cancel the export process before it completes by selecting **Cancel** on the export process dialog. Any runs that were exported before selecting Cancel will be saved to the chosen location.
7. After export completion, a **Successfully Exported [n] Runs to File** message appears. Select **OK** to close the export process dialog.

   It is now safe to remove the removable drive(s) from the front of the System Base.

Import Runs

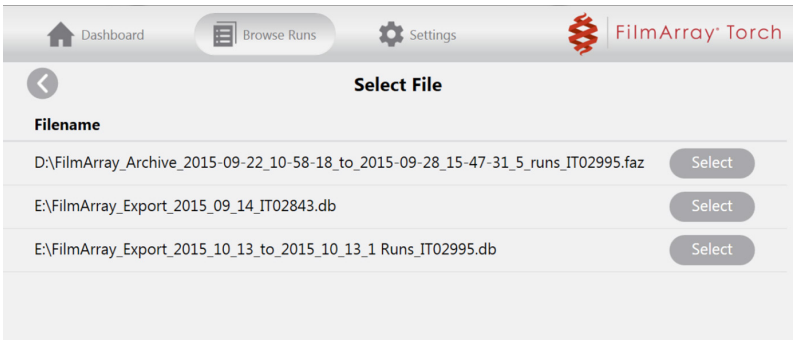
When importing runs, database files with the extension .db are added.

This process can also be used to restore any archived files with the extension .faz. Prior to restoring archived runs, verify that there is sufficient room in the database. If the database is approaching 5,000 runs, see the *Archive Runs* section in this chapter for more information.

To import runs from a file:

1. Insert the removable drive(s) containing the files into an available USB port on the front of the System Base. If multiple removable drives are connected to the USB ports on the System Base, select a destination device.
2. On the Browse Runs page, select **Options** to display the Options menu; then select **Import Runs**.

   The software searches the root level of all connected removable drives for any files that contain run data (both .db and .faz) and displays these files on the Select File page.



3. Select the runs needing to be imported (or restored) to start the import process.

   The operator can stop the import process before it completes by selecting **Stop**. Any runs that were imported before selecting Stop will be saved in the database.

4. After import completion, select **OK** to close the dialog. It is now safe to remove the removable drive(s) from the front of the System Base.

Export Anonymous Runs

Anonymous run files are saved with extension .adb. If a copy of run files must be sent to an external site, this option protects patient confidentiality. To prevent operators from overwriting a run file with an anonymous run file, these files cannot be imported back into the database

To export anonymous runs to a file:

1. Insert removable drive(s) into an available USB port on the front of the System Base.
2. Select **Browse Runs** from the toolbar to display a list of runs in the database. Runs can be searched and filtered by selecting the search icon . See the *Search Run Data* section in this chapter for more information.
3. Select **Options** to view the Options menu; then select **Export Anonymous Runs**.
4. Select one or more desired runs on the Browse Runs page; then select **OK**.
5. Select a location and filename for the .db file within the Specify Filename dialog. If multiple removable drives are connected to the USB ports on the System Base, select a destination device.
6. Select **Save** to start the export process. The message **Exporting Runs...** appears during the exporting process.

   The operator can cancel the export process before it completes by selecting **Cancel** on the export process dialog. Any runs that were exported before selecting Cancel will be saved to the chosen location.

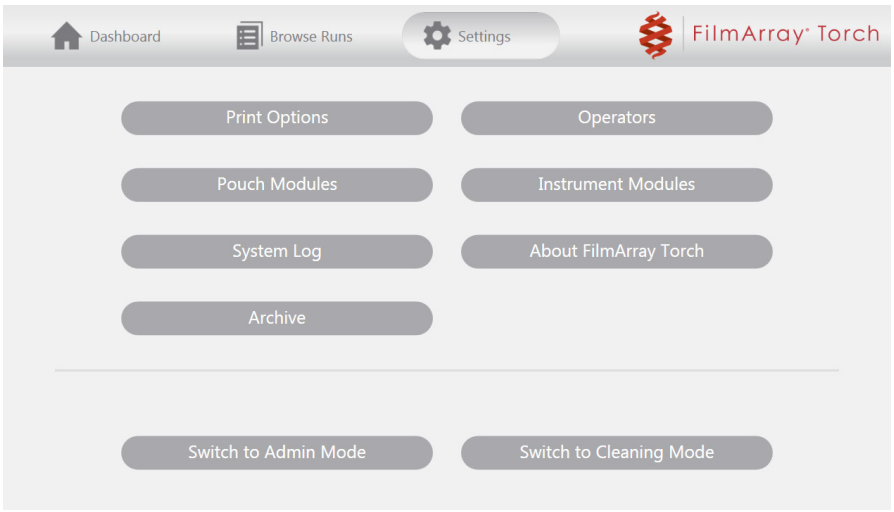
7. After export completion, a **Successfully Exported [n] Runs to File** message appears. Select **OK** to close the export process dialog.

   It is now safe to remove the removable drive(s) from the front of the System Base.

Settings

The Settings option is always accessible from the toolbar. To access Settings, select the **Settings** option on the toolbar. The Settings option allows users to perform the following administrative type tasks:

- **Print Options** - Allows the operator to set or change a default printer as well as the option to have reports automatically printed.
- **Operators** - Displays all operators currently recognized in the software and allows for addition and modification of operators within the system.
- **Pouch Modules** - Displays all currently installed pouch modules within the software and allows for installation of new pouch modules, modification of their status (active/inactive), and removal.
- **Instrument Modules** - Displays high level information for all Modules connected to FilmArray Torch.
- **Archive** - Allows operators to archive old runs off FilmArray Torch to an removable drive.
- **System Log** - Allows access to system logs for all Modules.
- **About FilmArray** - Displays details about FilmArray Torch installation.
- **Switch to Admin Mode** - Allows an administrator to log out of the FilmArray Torch software and access the Windows OS to perform administrative tasks (such as software/firmware updates, printer maintenance, and Instrument Configuration).
- **Switch to Cleaning Mode** - Allows an operator to temporarily freeze the touch screen so the surface can be cleaned without activating any actions (see *Chapter 8, Preventative Maintenance and Troubleshooting*).



Print Options

Any printer that has been configured to FilmArray Torch can be selected as the default.

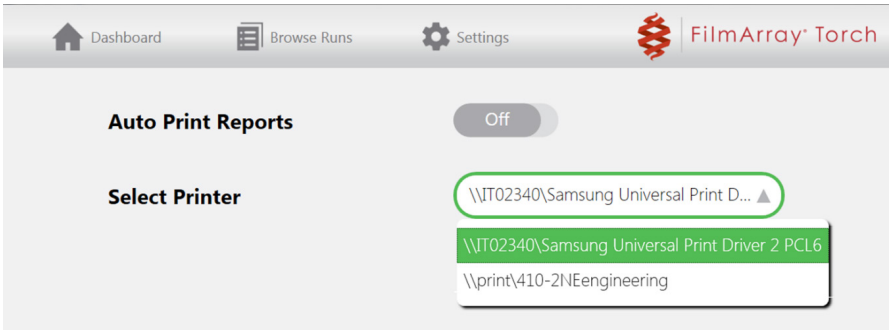
To set a default printer:

1. Select the **Select Printer** drop down box to display all printers configured to the System Base. The current default printer is highlighted green.

2. Select the applicable printer to set it as the default.

   The software updates the default printer and displays the new default within the Select Printer display box.

   To Auto Print Reports after a run, toggle the Auto Print Reports setting to On or Off.



Operators

An operator username and password are required to run a pouch on FilmArray Torch.

The FilmArray Torch software prompts the operator to enter these credentials after a pouch has been inserted into an available Module and pouch information has been captured.

The Operators feature displays all current operators on FilmArray Torch. This feature allows for the addition, modification, and/or deletion of operators.

Create New Operator(s)

New operators are created in two ways:

- Within the Settings toolbar Operators menu option within the Settings toolbar.
- Before starting a run during the Enter Operator Information step.

Operators menu option:

1. Select the **Settings** options from the toolbar; then select **Operators**.
2. Select **Add Operator** at the bottom of the screen when the list of current operators display.
3. Enter the new operator's information in the following fields:
   - **First Name**
   - **Last Name**
   - **Username**
   - **Password**
   - **Confirm**.

   The Confirm field will always display the password dots in red until the Password and Confirm fields match.
4. Select **Save** when complete.

Enter Operator Information step:

1. Select **Add/Edit Operator**.
2. Follow steps 3 and 4 in the previous instructions, *Create New Operator(s)*.

Pouch Modules

This feature enables the operator to install, and inactivate/uninstall pouch modules. These pouch modules contain definitions, protocols, analysis and reporting for specific FilmArray reagent kits.

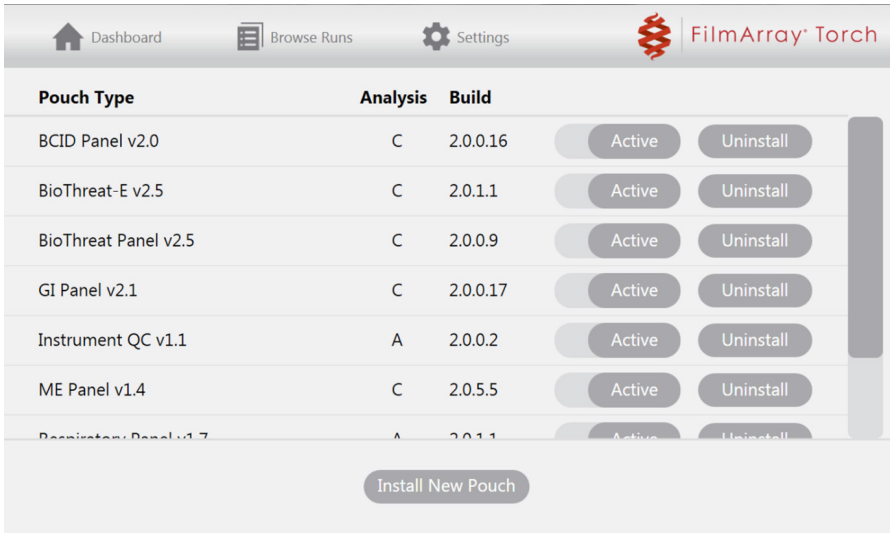
Install Pouch Modules

When new pouch modules are received from BioFire Diagnostics, the Pouch Modules option must be used on the FilmArray Torch. For information on receiving new pouch modules, contact Customer Support (see *page i*).

To install a new pouch module:

1. Insert removable drive containing the pouch module software. One or more removable drives, including USB flash drives, external CD/DVD drives, and external hard drives, can be connected to the USB ports on the System Base.
2. Navigate to the Settings menu from the toolbar.
3. Select **Pouch Modules**.

   All pouch modules currently installed display as Active.



4. Select **Install New Pouch** The software searches the root level of all connected removable drives and displays any detected pouch modules.
5. Select **Install** next to the desired pouch module. The new pouch module then displays with an Active status in the list of installed pouch modules to indicate that it is ready for use.

Inactivate/Uninstall Pouch Module

To inactivate a pouch module:

- Toggle the **Active** slider next to the pouch name to **Inactive**.

To uninstall a pouch module:

- Select **Uninstall** next to the pouch module name.

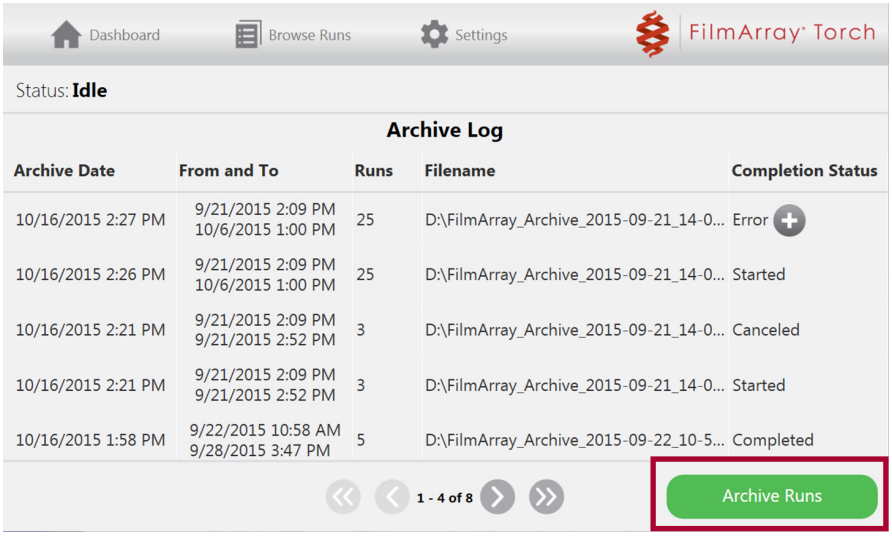
  When a pouch module in uninstalled, it is no longer available for selection when starting a run. To re-activate an uninstalled pouch module, it must be installed again.

Archive Runs

To archive runs stored in the FilmArray database:

1. Insert removable drive(s) into an available USB port on the front of the System Base. One or more removable drives, including USB flash drives, external CD/DVD drives, and external hard drives, can be connected to the USB ports on the System Base.
2. Navigate to the Settings menu from the toolbar.
3. Select **Archive**.

   The Archive Log will display the current status of archives and a log of all previous archiving tasks.



4. Select **Archive Runs** to display a calendar.
5. Select a date parameter on the calendar. This parameter means that all runs on or before that date will be archived.

   If more than 100 runs are selected, archived runs are sorted into files containing 100 runs each.

6. Select **Next** to choose the location and filename for the archived runs. It multiple removable drives are connected to the USB ports on the System Base, select a destination device.

   By default, runs are saved to a file with the extension .faz. Filenames default to a name containing the date parameter and the name of the System Base being used.

   After selecting the file name, a message displays indicating that the selected runs will be deleted from the database.

7. Select **Yes** to launch the archiving process. The date and time of the start will be recorded in the Archive Log.

   The archive process executes in the background and the status of the archive is seen in the status message on the Archive Log page. The operator may navigate to the Dashboard to perform other tasks.

NOTE: The software verifies that all runs have been saved to the file, and then deletes each run from the database one at a time.

When the archiving is complete, the date and time of the completion is logged and the archiving Status is set to Idle.

8. Remove the removable drive on which the .faz file was saved from the System Base and store according to institutional data retention policies.

Abort Archive Process

It is safe to abort the archive process while runs are being saved. To abort:

- Select the **Cancel** status message; then select **Confirm**.

  The status message changes to Canceling Archive. The archive stalls and all runs remain in the database.

  When archive cancellation is complete, the date and time of the completion is recorded in the Archive Log and the archiving Status is set to Idle.

NOTE: It is not safe to abort the archiving process while runs are being removed from the database. During this time, the software will not allow the operator to cancel the process.

CAUTION: Do not attempt to shut down the System Base or switch to Admin Mode during the archiving process. Wait until the process is complete before shutting down the System Base or performing other tasks.

Restore Runs

If a run file must be accessed after it has been removed from the database, the runs stored in the .faz file can be restored to the database by using Import Runs (see the *Import Runs* section in this chapter for more information).

Switch to Admin Mode

Admin Mode tasks are specific to the Windows application; these include:

- Installing printers
- Adding and removing Modules
- Updating software and applying security patches.

Please see Microsoft help for instructions on adding and deleting printers and changing the date and time. For further assistance, please contact Customer Support (see *page i*).

NOTE: Do not perform administrative tasks on the System Base—including setting the System Base's date/time—while a run is in progress on any Module.

To access the main Windows application:

- Select **Settings** from the toolbar; then select **Switch to Admin Mode**.

  This logs the user out of the FilmArray Torch software and allows for the admin user to log in to Windows. Once logged in as the admin user, the normal Windows desktop is displayed with limited access to Windows tools and the Instrument Configuration application.

NOTE: Logging into Admin Mode requires an administrative password. The FilmArray Torch is pre-configured with an administrative user account. The Windows user name is "LabAdmin" and the default password is "Lab_Admin". It is recommended that local IT personnel change the default password for the LabAdmin user account. Do not delete or modify the groups associated with the LabAdmin user account.

Instrument Configuration

Details of instrument configuration, including how to add and remove individual FilmArray Torch Modules, is done through Admin Mode using a separate application. Please see the *Instrument Configuration* section in *Chapter 2* for more information about adding a Module.

Printer Configuration

Adding and configuring printers to the FilmArray Torch is done through Admin Mode using the standard Windows features. For more information, see the *Switch to Admin Mode* section in this chapter.

Database Management

A local database on the System Base stores all run data generated by the FilmArray Torch. The runs saved in the database are listed in a table within Browse Runs toolbar. For more information on the function and use of the Browse Runs toolbar, see the *Browse Runs* section in this chapter.

The database stores up to 12,000 runs reliably. A warning appears when 5,000 runs is reached to encourage frequent archiving of data. For more information on archiving runs, see the *Archive Runs* section in this chapter.

CHAPTER 7: PRECAUTIONS WHEN WORKING WITH THE FILMARRAY SYSTEM

Laboratory Safety and Biohazards

General Safety Precautions

Please note that while the FilmArray pouches and the FilmArray Torch Modules are not themselves biohazardous, it is good laboratory procedure to handle all waste materials as potentially biohazardous material.

a. Follow all safety instructions printed on, or attached to, the FilmArray Torch.

b. Observe all general safety precautions that apply to electrical instruments.

c. Never touch switches or power cords with wet hands.

CAUTION: Do not attempt to lift or carry the FilmArray Torch while Modules are installed. Remove all Modules prior to lifting or carrying the FilmArray Torch System Base and always lift from the bottom.

NOTE: Only authorized service personnel should perform service or repairs required for this unit.

Laboratory Precautions

Handle all samples and waste materials as if they were capable of transmitting infectious agents. Refer to Biosafety in Microbiological and Biomedical Laboratories (Centers for Disease Control and Prevention and National Institutes of Health; available online at http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm) or other appropriate Biosafety procedures.

Observe safety guidelines found in the Clinical and Laboratory Standards Institute (CLSI) Protection of Laboratory Workers from Occupationally Acquired Infections, Approved Guideline M29 or other appropriate safety guidelines.

Wear personal protective equipment (PPE) and disposable powder-free gloves while handling reagents or samples and change gloves often. Wash hands thoroughly after performing a run.

Refer to the FilmArray reagent kit instruction booklets for assay-specific safety precautions.

CAUTION: A tear in the pouch could contaminate the Module and the surrounding area. Carefully dispose of pouches in a biohazard waste container.

General PCR Precautions

One of the most important guidelines when performing PCR is to avoid contamination. Some important rules to follow are:

a. Perform sample collection, pouch preparation, and running the FilmArray Torch in separate locations.

b. Load the pouch with sample behind a protective shield (or in a biological safety cabinet or hood whenever possible).

c. Do not leave a laboratory area without first completing decontamination procedures (i.e., washing and changing protective clothing and gloves).

Decontamination and Cleaning Procedures

The decontamination and cleaning procedures listed are intended to limit spread of contaminants as a result of a broken or leaked pouch. Decontamination is necessary to prevent false-positive results in subsequent runs.

If a pouch leak or breakage occurs, change gloves and other potentially contaminated personal protective equipment (PPE). Change gloves often during the decontamination process, especially during the first steps of decontamination and before touching any clean surface. All PPE should be disposed of after decontamination.

CAUTION: It is important that contamination from leaking and/or punctured pouches be contained and cleaned immediately. Pouches that break after PCR can contaminate future pouch runs. This material, although noninfectious, is easily spread by normal human activity. Treat all broken pouches as capable of contaminating the work area. Very small (molecular) quantities can be amplified by PCR in future runs, which can then be identified as a false positive by the FilmArray Torch.

BIOLOGICAL RISKS: If the pouch contains potentially infectious material, the risk of biohazard contamination exists in addition to sample contamination.

Cleaning Materials

This list provides items that are necessary in a laboratory to keep contamination to a minimum:

- 10% bleach solution in a squeeze or spray bottle (1 part bleach to 9 parts water)
- Distilled water in a squeeze or spray bottle
- DNAZap™ or equivalent DNA degrading system
- Paper towels
- Bleach wipes

Pouch Loading Station Decontamination

Routine cleaning of the Pouch Loading Station includes a 10% bleach wipe followed by two water wipes before each new pouch is loaded.

In the event of a sample spill or pouch leak, perform the following decontamination procedures.

1. Put on clean PPE, such as lab coat and gloves.
2. Fill a sink or bin with water and add bleach to create a 10% bleach solution.
3. Submerge the Pouch Loading Station until completely covered with bleach solution. Soak for 15 minutes.
4. Remove Pouch Loading Station from sink or bin. Replace bleach solution with distilled water.
5. Rinse the Pouch Loading Station by completely submerging in distilled water two additional times.

Contact BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor to obtain a replacement Pouch Loading Station, if necessary.

Decontamination Related to Pouch Leakage

If a pouch leaks, take the following precautions to avoid contamination:

1. Put on clean PPE, such as a lab coat and gloves.
2. Ensure no one uses the FilmArray Torch Module or potentially contaminated areas until the decontamination is complete.
3. Decontaminate the FilmArray Torch Module and work area and dispose of the pouch using the following steps:
    a. Dispose leaking pouch in a biohazard container.
    b. Dispose of potentially contaminated gloves and put on clean gloves.
    c. Dispose of the potentially contaminated lab coat.
    d. Put on clean PPE, such as a lab coat and gloves.
    e. Clean the Module and affected work areas following the guidelines below in Module Decontamination.

⚠ CAUTION: Use only 10% bleach solution, distilled water, and/or DNAZap to decontaminate the FilmArray Torch Module and Pouch Loading Station.

FilmArray Torch Module Decontamination

1. Put on clean PPE, such as a lab coat and gloves.
2. Remove pouch from Module and dispose in biohazard waste container.
3. Dispose of potentially contaminated gloves and lab coat and put on clean gloves and lab coat.
4. Wet a paper towel with the 10% bleach solution and wipe all exterior surfaces of the FilmArray Torch, including the bottom and the bench top where the FilmArray Torch Module had contact. Let it stand for at least 3 minutes to allow the bleach solution to react with any contaminants. Discard paper towel in biohazard waste. Change gloves.

NOTE: When cleaning the touch screen, put the FilmArray Torch into Cleaning Mode. The Cleaning Mode allows 30 seconds for the touch screen to be cleaned. Access this features from the Settings toolbar (see *Chapter 8, Preventative Maintenance and Troubleshooting* for more information).

CAUTION: The interior of the pouch slot and Module(s) should not be cleaned. Do not spray or insert any cleaning materials into the Module.

5. Repeat Step 4 twice with fresh paper towels for a total of three bleach wipes.
6. Change gloves, then wet a new paper towel with distilled water and wipe the all exterior surfaces of the FilmArray Torch. Dispose of paper towel in biohazard waste. Change gloves.
7. Repeat Step 6 with a new paper towel.
8. Remove Module front cover. Repeat Steps 3 through 7 for inner front cover surfaces and pouch slots.

Decontamination of Bench Tops and Other Areas

1. Put on clean PPE, such as a lab coat and gloves.
2. Spray the 10% bleach solution on the area that may have been contaminated. Let it stand for at least three minutes to allow the bleach solution to react with any contaminants on the surface.
3. Wipe the area with a clean paper towel. Change gloves.
4. Repeat Steps 2 and 3 twice, for a total of three wipes.
5. Change gloves. Spray the area with distilled water.
6. Wipe the area dry with a new paper towel. Change gloves.
7. Spray the area with DNAZap or an equivalent product. Follow the product's instructions for correct use. Change gloves.
8. Rinse the area by spraying it with distilled water and wiping it dry.

Check Function of Decontaminated FilmArray Torch Module

1. Test a negative sample by preparing a pouch according to instructions in *Chapter 5*, using water as the sample. Use distilled, sterile or molecular grade water for this test.
2. If the run is successful and all results are negative, continue using the Module as normal.
3. If unexpected positive results are obtained, or the run fails, please contact BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor for further instructions.

CHAPTER 8: PREVENTATIVE MAINTENANCE AND TROUBLESHOOTING

Introduction

This chapter provides step-by-step instructions for operators performing basic maintenance and troubleshooting for the FilmArray Torch.

The tasks performed in this chapter are the only tasks that should be performed by the operator. Do not attempt to perform any additional maintenance without the guidance and direction of a specialist from BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor.

In the event that an individual Module or the entire FilmArray Torch is taken out of service, follow the *FilmArray Torch Return Procedure* in *Appendix A*.

General Maintenance

There is no general maintenance needed for the FilmArray Torch other than the periodic cleaning steps listed below:

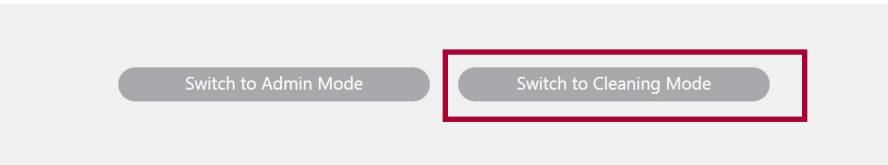
1. Wipe down all outside surfaces of the FilmArray Torch with a cloth or paper towel and a freshly prepared 10% bleach solution (one part bleach to nine parts water), followed by a water wipe.

NOTE: Do not remove the Module front cover and clean underneath it, except in the case of a contamination event.

2. Periodically check and clean the FilmArray Torch Module's air filters for any build up and debris. Air filters can also be swapped out with the spare filters included with the FilmArray Torch Module box (see *Chapter 2, FilmArray Torch Setup*).

3. When cleaning the touch screen of the FilmArray Torch, it is recommended that the FilmArray Torch software be put into cleaning mode in order to avoid any accidental selections.

   This can be done by navigating to the Settings toolbar and selecting the **Switch to Cleaning Mode** option. After selecting a confirmation for this action, the screen will display a timer for 30 seconds that will temporarily freeze the screen and allow for cleaning of the surface.



System Base Shutdown

It is not necessary to shut down and restart the System Base. If facility policy requires regular shut-down, select the reset button on the back of the System Base, wait for the screen to go black, then switch off the power. Switching the power back on will then restart the System Base and start the software automatically.

Troubleshooting

Pouch Troubleshooting

For problems encountered while using a FilmArray pouch, see the possible solutions below. If pouch leakage occurs, refer to Chapter 7 for proper decontamination procedures.

Problem	Possible Error Cause	Solution
Pouch packaging is not sealed tightly around pouch canister	Loss of vacuum in pouch packaging	Attempt to hydrate. If pouch hydration is successful, continue the run. Otherwise, discard the pouch and use a new pouch to test the sample.
Pouch does not automatically draw Hydration Solution or sample mix into pouch when loading	Loss of vacuum in pouch	Discard the pouch and use a new pouch to test the sample.
Failed controls	Hydration Solution not added or drawn into pouch	Retest sample in a new pouch.
	Sample mix not added or drawn into pouch	Retest sample in a new pouch.
	pouch and/or FilmArray Torch Module are not functioning properly	Retest sample in a new pouch.
		If controls continue to fail contact Customer Support.
Inadequate volume in Hydration Solution or Sample Buffer vials/ampoules	Evaporation or leakage	Discard vials/ampoules and obtain new ones.

Warning Messages

Warning Messages may originate in a FilmArray Torch Module, in the software, or in communication between the two. These messages and the suggested actions are reported in the table that follows.

Warning Message	Possible Solution
The pouch has already been run - a pouch can only be used once.	Dispose of any pouch that has already been run in a FilmArray Torch Module.
An attempt to leave the workflow has been made. If a pouch has been inserted the pouch will be ejected and Run Setup will have to be restarted. Do you wish to continue?	Select **Yes** to end the workflow. If a pouch has been inserted, it will eject from the Module. The ejected pouch may be used to begin another workflow.
FilmArray Torch database has more than 5,000 runs on it. Please use the Archive feature within Settings to remove runs from the database and store them according to your data retention policy. Please contact FilmArray Customer Support if you require assistance.	Use the Archive Runs feature in the Settings tab to remove run files from the database. Contact Customer Support if the problem persists.
Auto Print Error. There is an error auto printing reports. See the System Log for details of affected runs.	The FilmArray Torch software could not find the default printer. Ensure printer is properly connected. Use Print Options on the Settings toolbar to select a new default printer or Admin Mode to add a new default printer. For more information see *Chapter 6*.
Printer Error. The report could not be printed	

Hardware Troubleshooting

The table below lists potential symptoms and possible solutions for troubleshooting hardware issues with the FilmArray Torch. If the issue(s) persists after applying the recommended solutions, contact Customer Support for further assistance (see page i).

Symptom	Possible Solution
FilmArray Torch Module status lights are not on	• Turn Module on • Check power cord • Try different outlet • If problem persists, contact Customer Support
FilmArray Torch Module status light is red	• Reset system using the reset button located on the rear of the System Base • Check and reconnect cables • If problem persists, contact Customer Support
FilmArray Torch Module status light is blinking purple	• Remove and discard the pouch • Remove the front cover of the affected Module and reset the Module • If problem persists, contact Customer Support
Software will not connect to FilmArray Torch Module	• Check cable connections • Turn off system and disconnect all cables • Reconnect all cables and turn system on • If problem persists, contact Customer Support

Symptom	Possible Solution
Pouch not recognized when inserted into or removed from FilmArray Torch Module	• Remove the front cover of the affected Module and reset the Module • If problem persists, contact Customer Support
Pouch not recognized when inserted into FilmArray Torch Module, due to jam	• Follow the software's on-screen instructions for recovery • If problem persists, contact Customer Support
Pouch is ejected immediately after insertion	• Remove the front cover of the affected Module and reset the Module • Check and reconnect cables • If problem persists, contact Customer Support
Pouch is difficult to insert into FilmArray Torch Module	• Remove the front cover of the affected Module and reset the Module • If problem persists, contact Customer Support
Pouch does not eject from Module after run	• Remove the front cover of the affected Module and reset the Module • If problem persists, contact Customer Support
Software on the System Base crashes	• Reset the System Base using the reset button on the back of the System Base. • If problem persists, contact Customer Support
Barcode will not scan	• Manually input the pouch serial number and lot number

Module Reset

If a Module needs to be reset, remove the magnetic front cover; then press and hold the Reset button until the light turns off.

Error Messages

Errors in the FilmArray Torch may originate in a Module, in the software, or in communication between the two. In each case, the software reports a clear message with instructions that the operator can follow to resolve the issue. These messages and the suggested actions are reported in the table that follows.

The FilmArray Torch performs self-diagnostics with every run. Malfunctions are reported as errors to the operator with instructions on how to correct them. Record any error messages to assist in troubleshooting. Questions should be directed to BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor.

If communication is lost between the Module and System Base during a run, the run will continue and data will be uploaded when communication is re-established.

Error Message	Possible Solution
Remove the magnetic front cover from the Module and press the Reset button. A white light on the Module indicates initialization which may take up to 2 minutes. If the problem persists, contact FilmArray Customer Support for assistance.	Follow the error message as directed. Contact Customer Support if the problem persists.
The FilmArray Torch encountered an error during the run. The test results are invalid. Please see the System Log for details. If the problem persists, contact FilmArray Customer Support for assistance.	Discard the pouch and follow the error message as directed. The message should be accompanied by a fast blinking green light on the Module. The light indicates that the pouch can be removed. Removing the pouch sets the Module into an Available state. Contact Customer Support if the problem persists.
Data Recovered. Data has been recovered from a FilmArray Torch Module that could not be processed. Please see the System Log for details. Please contact Customer Support for assistance.	Follow the error message as directed. Contact Customer Support if the problem persists.
Run data was retrieved but cannot be analyzed because the <pouch type> pouch module was not installed in the software. For assistance, please contact FilmArray Customer Support.	
The software for the scanned pouch is not installed or is inactive. Please install or activate the required pouch module.	Verify the correct pouch module is installed and the correct barcode has been scanned for the pouch.

Diagnostic Errors

Diagnostic errors are used by Customer Support representatives to troubleshoot FilmArray Torch problems. See the *System Log* section in this chapter for details on accessing diagnostic error information.

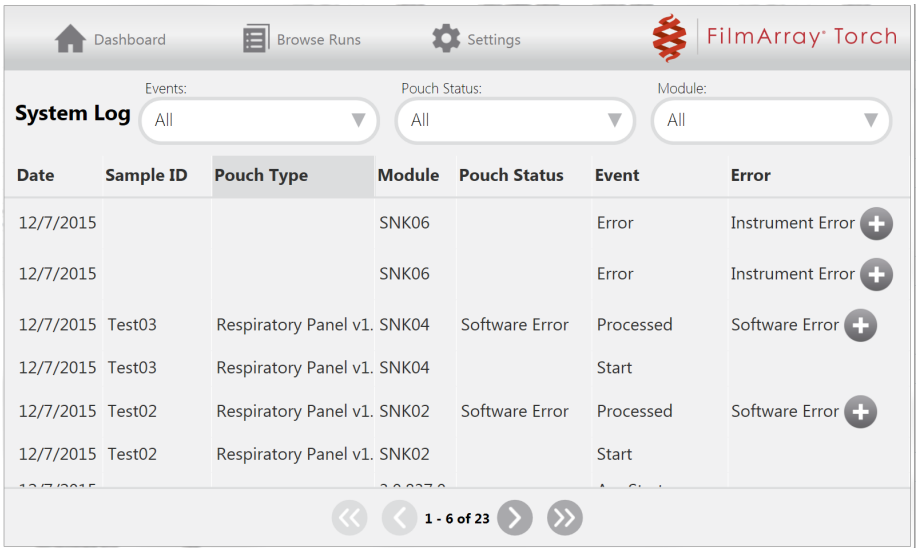
The table that follows lists potential error messages and possible solutions. If the error(s) persists after applying the recommended solutions, contact Customer Support for further assistance. Before contacting Customer Support, write down all error messages, the serial numbers of the System Base, affected Module(s), and pouch lot numbers. Customer Support will use this information to identify and resolve the error(s).

Error Message	Possible Solution
1012 Pouch Not Present	• Remove the magnetic front cover and press and hold the Reset button until the light turns off. • A white light on the Module indicates initialization which may take up to 2 minutes. • If the problem continues, please contact Customer Support for assistance.
1014 Failed to Find Run Data	
1015 Failed to Read Run Data	
2003 Thermoboard is not present	
2004 Valve board is not present	
3001 Valve Board Response Timeout	
3002 Valve Board Malformed Response	• Remove the magnetic front cover and press and hold the Reset button until the light turns off. • A white light on the Module indicates initialization which may take up to 2 minutes. • If the problem continues, please contact Customer Support for assistance.
3003 Valve Board Command Error Response	
3004 Thermocycler Board Response Timeout	
3005 Thermocycler Board Malformed Response	
3006 Thermocycler Board Command Error Response	
4001 Pressurization failed	
7001 Camera Initialization Error	
7003 Failed Excitation Check	

Error Reporting Tools

System Log

The error messages may refer to the System Log for details depending on the error and is accessed via the Settings option. When the System Log is opened, the following displays. Select the plus icon to view additional information regarding the error.

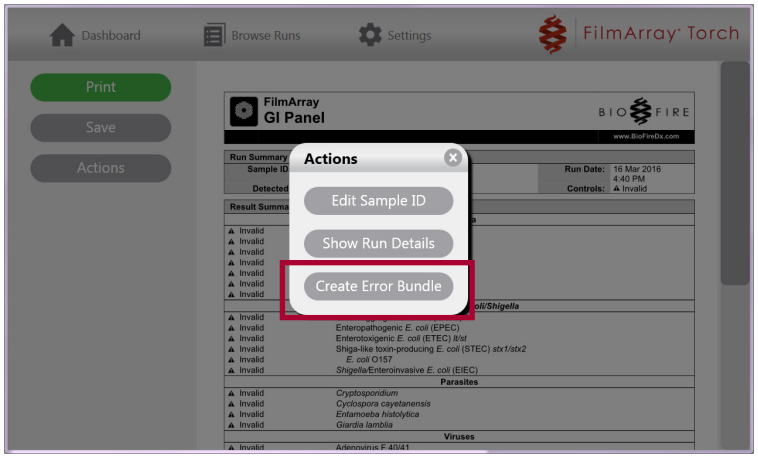


Error Bundle

A Customer Support representative may request the operator to create and provide an error bundle to assist in troubleshooting.

To create an error bundle:

1. Insert a removable drive into a USB port located on the front of the System Base.
2. Select the **Browse Runs** option from the toolbar.
3. Select the desired run.
4. Select **View Report** to open the report page; then select **Actions**.



5. Select **Create Error Bundle** menu item. A dialog displays the drive path and file name.
6. Navigate to a file location to save the zipped error bundle.
7. Select **Save**.
8. When the error bundle is complete, a message will indicate that the error bundle has been created.
9. Remove the removable drive.
10. Email this file to the Customer Support representitive to diagnose errors.

APPENDIX A: FILMARRAY SUPPORT INFORMATION

FilmArray Torch Module problems may be reported by contacting BioFire Diagnostics Customer Support, the local bioMérieux sales representative, or an authorized distributor.

FilmArray Torch Module Return Procedure

If returning a FilmArray Torch Module from within the United States, visit the Return Forms and Decontamination Procedures webpage:

- http://www.biofiredx.com/support/return-forms/

If returning a FilmArray Torch Module from outside the United States, contact the local bioMérieux sales representative or an authorized distributor for detailed instructions.

Disposal Recommendation

Components of the FilmArray Torch such as the FilmArray Torch Module, the FilmArray Torch System Base, etc., which are marked with the crossed-out wheeled bin symbol are covered by the European Directive 2012/19/EU.

These items must be disposed of via designated collection facilities appointed by government or local authorities.

For more information about disposal of old product, please contact local city office or waste disposal service; or BioFire Diagnostics Customer Support Department, a local bioMérieux sales representative, or an authorized distributor.

FilmArray Ordering Instructions

Customers inside the United States should contact BioFire Diagnostics to order any FilmArray equipment, accessories, and/or supplies.

BioFire Diagnostics accepts purchase orders and credit cards (Visa®, MasterCard®, and American Express®) as methods of payment.

Orders can be made via:

- E-mail: salesorders@biofiredx.com
- Fax: 801-588-0507
- Phone: 800-735-6544 or 801-736-6354
    - Payment is by credit card only for phone orders.

If ordering from outside the United States, contact the local bioMérieux sales representative or an authorized distributor for detailed instructions.

Warranty Information

Product warranty information is available online at:

- http://www.biofiredx.com/support/

For warranty information for customers outside the United States, contact the local bioMérieux sales representative or an authorized distributor.

APPENDIX B: BARCODE CALIBRATION

If the barcode scanner is not functioning, calibrate it by scanning the barcode shown below to program the barcode scanner. The scanner should sound as the code is scanned.

FilmArrayCR8000Config

A BIOMÉRIEUX COMPANY

For additional information regarding our products and applications, please contact BioFire Diagnostics Customer Support Department, local bioMérieux sales representative or an authorized distributor.

BioFire® Joint Infection (JI) Panel

IVD *Rx Only*

CE 2797 UKCA

Instructions for Use	https://www.biofiredx.com/e-labeling/ITI0017
Quick Guide	https://www.biofiredx.com/e-labeling/ITI0047
Safety Data Sheet (SDS)	https://www.biofiredx.com/e-labeling/ITI0097
Panel Software	https://www.biofiredx.com/e-labeling/ITIFA20JI10
Summary of Safety and Performance (Applicable for EU Customers)	https://ec.europa.eu/tools/eudamed

Customer and Technical Support Information *For more information on how to contact Customer and Technical Support, refer to Appendix B.	Phone: 1-800-735-6544 (toll free) E-mail: support@BioFireDX.com Website: www.biofiredx.com Or contact the local bioMérieux sales representative or an authorized distributor.

INTENDED PURPOSE

Intended Use

The BioFire® Joint Infection (JI) Panel is a multiplexed nucleic-acid-based, *in vitro* diagnostic test intended for use with BioFire® FilmArray® 2.0 and BioFire® FilmArray® Torch Systems for the simultaneous qualitative detection and identification of multiple bacterial and yeast nucleic acids and select antimicrobial resistance genes from synovial fluid obtained from individuals suspected to have a joint infection.

The following organisms are identified using the BioFire JI Panel:

Gram Positive Bacteria		
Anaerococcus prevotii/vaginalis	*Finegoldia magna*	*Streptococcus* spp.
Clostridium perfringens	*Parvimonas micra*	*Streptococcus agalactiae*
Cutibacterium avidum/granulosum	*Peptoniphilus*	*Streptococcus pneumoniae*
Enterococcus faecalis	*Peptostreptococcus anaerobius*	*Streptococcus pyogenes*
Enterococcus faecium	*Staphylococcus aureus*	
	Staphylococcus lugdunensis	
Gram Negative Bacteria		
Bacteroides fragilis	*Kingella kingae*	*Proteus* spp.
Citrobacter	*Klebsiella aerogenes*	*Pseudomonas aeruginosa*
Enterobacter cloacae complex	*Klebsiella pneumoniae* group	*Salmonella* spp.
Escherichia coli	*Morganella morganii*	*Serratia marcescens*
Haemophilus influenzae	*Neisseria gonorrhoeae*	
Yeast		
Candida *Candida albicans*		

The BioFire JI Panel contains assays for the detection of genetic determinants associated with *S. aureus* resistance to methicillin (*mecA/C* in conjunction with the SCCmec right extremity junction (MREJ)), enterococcal resistance to vancomycin (*vanA* and *vanB*) and some mechanisms of gram-negative bacterial resistance to ß-lactams including penicillins, cephalosporins, monobactams, and carbapenems (*bla*$_{CTX-M}$, *bla*$_{IMP}$, *bla*$_{KPC}$, *bla*$_{NDM}$, *bla*$_{OXA-48-like}$, *bla*$_{VIM}$). Detection of these genetic determinants can aid in the identification of potentially antimicrobial-resistant organisms in synovial fluid samples. 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 assays do not indicate susceptibility, as multiple mechanisms of resistance to methicillin, vancomycin, and ß-lactams exist.

Atitiktis_2.3

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

The BioFire JI Panel is indicated as an aid in the diagnosis of specific agents of joint infection and results should be used in conjunction with other clinical and laboratory findings. Negative results may be due to infection with pathogens that are not detected by this test, pathogens present below the limit of detection of the assay, or infection that may not be detected in a synovial fluid specimen. Positive results do not rule out co-infection with other organisms. The BioFire JI Panel is not intended to monitor treatment for joint infections.

Culture of synovial fluid is necessary to recover organisms for susceptibility testing and epidemiological typing, to identify organisms in the synovial fluid that are not detected by the BioFire JI Panel, and to further identify species in the genus, complex or group results.

Intended User and Use Environment

The BioFire JI Panel is intended for use by trained medical and laboratory professionals in a laboratory setting or under the supervision of a trained laboratory professional.

SUMMARY AND EXPLANATION OF THE TEST

Joint infections (JIs) occur when pathogens access bones and joints via hematogenous spread, contiguous spread of pathogens from an adjacent infection, or direct implantation (e.g., open fracture, surgery, implanted medical devices). JI broadly encompasses multiple types of infections including, but not limited to, septic arthritis (SA), and prosthetic joint infection (PJI). These infections are commonly diagnosed by a combination of laboratory results, microbiological data, histological evaluation of tissue, intraoperative inspection, and in some cases radiographic results.[1] JIs are most often caused by bacterial pathogens, though yeasts are also a significant cause. Serious morbidity can arise from JIs, resulting in significant pain, permanent disability, or death.[2] Additionally, JIs are often complicated and result in increased hospital stay length as well as higher rates of long-term rehabilitation and rehospitalization.[3,4] Globally, the prevalence of JI is estimated to be four to ten per 100,000 people in developed countries, with the economic impact of such infections totaling hundreds of millions of dollars per year.[4,5]

Timely diagnosis of JI and administration of effective treatment can significantly reduce the rates of serious complications, duration of hospital stays, and costs. The BioFire JI Panel tests a single synovial fluid sample to simultaneously provide results for multiple aerobic and anaerobic bacteria and yeast that cause JI as well as genetic markers associated with antimicrobial resistance. Although JI is a broad category that includes multiple types of infections, the BioFire JI Panel was primarily designed to detect organisms associated with SA and PJI. Rapid identification of the organism(s) in synovial fluid, along with information about antimicrobial resistance gene status for select microorganisms, may aid the physician in making timely and appropriate treatment and management decisions.

Summary of Detected Organisms

Gram-Positive Bacteria

Anaerococcus prevotii* and *vaginalis are gram-positive, rod-shaped, anaerobic bacteria, previously classified as *Peptostreptococcus* species, that are commonly found as normal skin, oral, and gut flora.[6] These organisms are fastidious and slow growers in culture, making them difficult to isolate.[7]

Clostridium perfringens is a gram-positive, spore-forming, anaerobic, rod-shaped bacterium found throughout the environment and in the gastrointestinal (GI) tract of humans and animals. *C. perfringens* is a common cause of food poisoning.[8] Although JIs caused by *Clostridium* species are rare, *C. perfringens* is the most common JI -causing species within this genus.[9–12] Knee, hip, and shoulder joints are the most commonly affected by *C. perfringens* infection.[13] Underlying malignancies, such as preexisting musculoskeletal infection, trauma, or biliary sepsis, may be risk factors [9–11,13] and serious complications such as necrosis, cartilage destruction, gas gangrene, or bacteremia, can arise from JI caused by *C. perfringens.*[11,13]

Cutibacterium avidum* and *granulosum are gram-positive, aerotolerant, anaerobic bacteria formerly known respectively as *Propionibacterium avidum* and *Propionibacterium granulosum*. These organisms are commensal organisms of the skin[14–16] but are also known to cause a number of infections including abscesses, lesions, endocarditis, prostate infection, and JI.[16] Although both species are rare, one study evaluated prevalence of all *Cutibacterium* species isolated in their institution over a nine-year period and found *C. avidum* to be nearly twice as prevalent as *C. granulosum*, with half of the total isolates originating from orthopedic and trauma surgery departments.[17] *Cutibacterium avidum* is responsible for approximately 1%[18] of all PJI, and the majority of these are opportunistic infections in the hip and occur shortly after surgery.[19–22] *Cutibacterium avidum* can form biofilms[19] which may increase the difficulty of treatment. Additionally, the onset of disease expression of PJI caused by *Cutibacterium* species can be significantly delayed after surgery, further complicating prevention and treatment.[16,23] Orthopedic specimens are often incubated for up to 14 days[24] and interpreting a culture positive as a true pathogen versus a contaminant is a major challenge for clinicians.[16]

Enterococcus faecalis* and *faecium are gram-positive facultative anaerobes that normally inhabit the GI tract of humans and are among the most common nosocomial pathogens.[25] There are 28 species of *Enterococcus*[25] and *E. faecalis* (80-

90%) and *E. faecium* (5-15%) cause the majority of enterococcal clinical infections, including PJI.[26,27] Enterococci make up approximately 12-15% of PJI and they are frequently associated with early-onset, polymicrobial infections of the joint.[1] Outcomes of PJI caused by *Enterococcus* species are typically poor, with a high rate of prosthetic failure within two years post-surgery (20-50%).[27,28] Enterococci can carry vancomycin resistance genes such as *vanA* and *vanB* (vancomycin-resistant enterococci (VRE)). Although *E. faecalis* is more pathogenic than *E. faecium,* the latter exhibits more resistance and is responsible for the majority of VRE infections.[29]

Finegoldia magna is a gram-positive, anaerobic bacterium formerly classified as *Peptococcus magnus* or *Peptostreptococcus magnus*. This species is a commensal organism in the GI tract, urogenital tract, and skin. *F. magna* is difficult to identify by routine microbiology and is usually identified by MALDI-TOF mass spectrometry or molecular methods. An opportunistic pathogen, *F. magna* is among the most common anaerobic causes of human infections, identified in 5-12% of all anaerobic infections and up to 40% of all gram-positive anaerobic cocci (GPAC) infections[30,31]. *F. magna* is commonly associated with wound, bone, and prosthetic joint infections and has been implicated in SA.[10] Hips and knees are the most commonly affected joints when prostheses are involved.[10]

Parvimonas micra is a gram-positive, anaerobic bacterium that is part of the normal commensal flora of the GI tract and the oral cavity.[31] *P. micra* infections include periodontitis, chronic wounds, diabetic foot infections, burn wounds, leg ulcers, PJIs, and native joint SA.[6,32–34] Due to the difficulty in culture and identification of anaerobic bacteria, *P. micra* may be underreported as a JI pathogen.[34] In several published case reports of JI, *P. micra* has been linked to potential risk factors including underlying crystal-induced arthritis, multiple myeloma, or dental problems.[33–35]

Peptoniphilus species are gram-positive, anaerobic cocci and were formerly members of the genus *Peptostreptococcus*. Organisms in this genus have been found in the normal flora of the armpit, but have also been identified as causative pathogens in chronic wounds, diabetic skin infections, bacterial vaginosis, surgical site infections, and JI (including PJI and SA).[6,36,37]

Peptostreptococcus anaerobius is a gram-positive, non-spore-forming, anaerobic bacterium that is commonly found in the gut and vaginal flora. Though rare, *P. anaerobius* has been identified a cause of PJI, with hip and knee prostheses the most commonly affected joints.[10] A published analysis of case studies suggests a *P. anaerobius* prevalence of approximately 0.1% in PJI, representing approximately 2% of anaerobic PJI.[38]

Staphylococcus aureus is a gram-positive coccus that tends to appear as irregular, grape-like clusters on a Gram stain. A common, opportunistic pathogen, *S. aureus* is capable of causing a wide range of diseases and is considered the most clinically relevant coagulase-positive human pathogen in the *Staphylococcus* genus. *S. aureus* is the most common cause of SA with one study reporting a prevalence of 46.3%.[39,40] Additionally, *S. aureus* is among the most common cause of chronic, early post-interventional, and acute hematogenous PJI.[38] The presence of *S. aureus* is frequently associated with treatment failure, possibly due to biofilm formation and small colony variants which allow the organisms to persist in the host.[41] *S. aureus* possesses extensive virulence factors, has various strategies to evade the host immune response, and has become resistant to many therapeutic agents.[42] It is estimated that approximately 40% of *S. aureus* isolates may be methicillin resistant (MRSA).[43,44] The primary mediator of methicillin resistance in staphylococci is the acquisition of the *mecA* or *mecC* genes encoded on the staphylococcal chromosome cassette *mec* (SCC*mec*), a mobile genetic element that can transfer between *Staphylococcus* spp.[45]

Staphylococcus lugdunensis is a gram-positive coagulase-negative *Staphylococcus* (CoNS) and an integral part of the normal skin flora.[46] It is more similar to *S. aureus* than to other CoNS, in terms of pathogenicity and virulence.[1,47,48] Fulminant cases of native valve endocarditis, characterized by an aggressive clinical course with high mortality and septic shock, have been attributed to *S. lugdunensis* and speak to its virulence.[49] In addition, skin and soft tissue infections also represent a significant portion of the total infections caused by *S. lugdunensis*[50] and *S. lugdunensis* is a frequent cause of PJI.[51] For example, a case series of PJI due to *S. lugdunensis* included 28 episodes of PJI in 22 patients over a nine year period at the Mayo Clinic in the Minnesota.[51] Additionally, a large, multicenter cohort study of PJI identified *S. lugdunensis* as the second most prevalent CoNS species isolated from patients over a ten year period.[38] *S. lugdunensis* is known to form biofilms similar to *S. aureus.*[52] Unlike most other CoNS, *S. lugdunensis* remains susceptible to a wide array of antimicrobial agents, although evidence from around the world suggests emerging resistance in *S. lugdunensis*, particularly to penicillin.[49,53]

Streptococcus* spp.* are gram-positive, catalase-negative cocci that grow in chains or pairs, as seen on a Gram stain. *Streptococcus* species are frequently found as commensal bacteria on mucous membranes and are occasionally present as transient skin microbiota.[42] Streptococci have historically been grouped as β-hemolytic or non-β-hemolytic, pyogenic (pus-forming) or non-pyogenic, and also divided according to the presence of specific surface antigens (i.e., Lancefield grouping). Of these, the Group A streptococci (represented primarily by *S. pyogenes*) and the Group B streptococci (*S. agalactiae*) are the most common in SA and PJI.[54,55] Streptococci may be responsible for up to 10% of PJIs[37,38] and up to 18% of SA cases.[56] SA due to streptococci is more common in older patients (>60) and infection is most often localized in the knees, hips, shoulders.[56] Additionally, streptococcal SA can result in persistent joint abnormalities due to deterioration of the cartilage.[56]

Streptococcus agalactiae (Lancefield Group B *Streptococcus* or GBS) is found as a commensal bacterium on mucous membranes and is occasionally present as transient skin microbiota.[42] *S. agalactiae* causes SA in children less than three months of age as well as in the older adult population.[56,57] Prevalence in SA has been reported in the range of 4%-22%.[56] It can manifest as multiple joint infections and presents as a systemic infection.[56,58] Disease caused by *S. agalactiae* is typically less severe than that of *S. pyogenes* with little involvement of fever or leukocytes.[56,58] Mortality rate of SA caused by *S. agalactiae* is lower than with other bacterial causes of SA.[58] In addition, *S. agalactiae* is one of the most common *Streptococcus* species involved in PJI (isolated in 2-6% of cases), primarily in hematogenous PJI.[38,59] Though generally susceptible to antimicrobial treatments, multiple studies have reported increasing resistance to some antibacterial classes among *S. agalactiae* clinical isolates.[60–63]

Streptococcus pneumoniae is a fastidious autolytic gram-positive bacterium that colonizes the upper respiratory tract. There are two licensed, multivalent pneumococcal vaccines in the US (PPV23 and PCV13) that help reduce the risk of both invasive disease and pneumococcal pneumonia by 50-80% and are recommended for neonates, the immunocompromised, and those over the age of 65.[64] SA associated with *S. pneumoniae* generally occurs in children less than two years of age without known risk factors and can be caused by serotypes not covered by the vaccine(s).[65–67] Pneumococcal SA infection in adults primarily occurs in middle-aged or elderly patients, and is often associated with underlying illnesses such as pneumococcal pneumonia, rheumatoid arthritis, diabetes mellitus, and HIV.[65,68–71] Overall, prevalence of *S. pneumoniae* in SA infections is between 3% and 10%, while PJI caused by *S. pneumoniae* are rare.[68,70,71] Knee joints are the joints most frequently affected by *S. pneumoniae*, though evidence suggests that SA infections may be more likely to present as polyarticular when *S. pneumoniae* is the cause than when other pathogens are the cause.[65,68]

Streptococcus pyogenes (Lancefield Group A *Streptococcus* or GAS) colonizes the human skin and upper respiratory tract. *S. pyogenes* possesses complex virulence mechanisms to avoid host defenses[72,73] and is responsible for BSI, sepsis, and deep soft tissue infections as well as JI.[74] Overall, *S. pyogenes* is among the most common streptococcal species associated with native joint infections, particularly in children and the elderly.[75–78] Among pediatric JI, *S. pyogenes* accounts for approximately 10% of all cases.[78] SA caused by *S. pyogenes* is often rapid onset and can be severe.[56]

Gram-Negative Bacteria

Bacteroides fragilis is a gram-negative, rod-shaped, anaerobic bacterium found as part of the commensal flora in the GI tract. *B. fragilis* accounts for only 0.5% of the total bacterial community in the lower intestine, however, *B. fragilis* can become an opportunistic pathogen when released into a sterile environment.[79,80] JI caused by *B. fragilis* is rare and most cases reported in the literature had concurrent BSI suggesting the organism seeded into the joint.[10] SA caused by *B. fragilis* is more common in patients with chronic joint disease.[79,80]

Citrobacter species are gram-negative, facultatively anaerobic, motile bacilli.[81] In the environment, *Citrobacter* species are commonly found in water, soil, food, and as occasional colonizers of the GI tract of animals and humans. *Citrobacter* strains are traditionally considered to have low virulence, however they can be the source of several types of infections such as urinary tract, respiratory, intra-abdominal, wound, bone, bloodstream, and CNS.[81] PJI and SA caused by *Citrobacter* species are rare and these opportunistic infections have typically been attributed to *C. koseri* and *C. freundii.*[82,83]

***Enterobacter cloacae* complex** (ECC) organisms (*Enterobacter cloacae* (and subspecies), *Enterobacter asburiae*,

Enterobacter hormaechei (and subspecies), *Enterobacter kobei*, *Enterobacter ludwigii*, *Enterobacter mori*, and *Enterobacter roggenkampii*[84–88]) are gram-negative, rod-shaped bacteria. Members of the complex are generally identified as '*E. cloacae*' by standard methods, though the group is genetically heterogeneous and descriptions of the complex members vary between analysis methods. Additional genetically similar *Enterobacter* species and subspecies (*Enterobacter bugandensis*, *Enterobacter cancerogenus*, *Enterobacter chengduensis*, *Enterobacter soli*, and *Enterobacter hormaechei ssp. xiangfangensis* (also described as *E. xiangfangensis*), among others) have been discussed in the context of the ECC or recently identified as potential new ECC members by comprehensive whole genome evaluations, but there is inconsistency in the literature as to which species should be considered species within the complex.[87,89–93] In clinical settings, *E. cloacae*, *E. hormaechei*, and *E. asburiae* are the members of the complex most commonly isolated, while there are currently no clinical reports for *E. mori* and *E. soli*. *Enterobacter cloacae* complex species are known to cause SA in children following an open wound or penetrating trauma.[94] One study found *E. cloacae* to be the most frequent gram-negative bacterium isolated from PJI, noting that infection usually occurred soon after a surgical event and was most common in patients with complex surgical histories.[95] High rates of resistance to β-lactam antibiotics is a global concern for these and other *Enterobacter* species.[96–98]

Escherichia coli is an enteric, gram-negative bacterium that is part of the normal flora of the intestines of humans and animals. While most pathogenic *E. coli* infections are associated with GI illness, certain strains may cause extraintestinal infections in healthy and immunocompromised individuals. Such infections include urinary tract infection, BSI, and meningitis, as well as SA and PJI. *E. coli* is one of the most common gram-negative bacteria isolated from PJI[38,99,100] and patients with SA.[101] As with other *Enterobacterales*, extended-spectrum β-lactamases (ESBLs) including CTX-M, AmpC β-lactamases, and *Klebsiella pneumoniae* carbapenemase (KPC) pose a significant antibiotic resistance problem.[74]

Haemophilus influenzae is a gram-negative coccobacillus, isolated exclusively from humans.[102] Strains of *H. influenzae* are divided into two groups based on the presence or absence of a capsular polysaccharide.[103,104] Encapsulated strains are further divided into six serotypes (a through f). Prior to the widespread use of the *H. influenzae* type b (Hib) conjugate vaccines, Hib caused greater than 80% of invasive *H. influenzae* infections, predominantly in children under the age of five.[103,104] In areas of routine vaccination, the majority of invasive *H. influenzae* infections are now caused by non-typeable strains and predominantly affect children under the age of one and the elderly.[103] In areas of low vaccination rates or incomplete vaccination status, Hib is a well-known, gram-negative cause of osteomyelitis and SA.[105,106] PJIs associated with *H. influenzae* are rare.[106,107]

Kingella kingae is a gram-negative, facultatively anaerobic, coccobacillus that is part of the normal flora found in the oral cavity and pharynx of young children. *K. kingae* is increasingly recognized as a major bacterial cause of SA in children under 4 years old, while children who are infected later on in life typically have an underlying medical condition.[108–115] This organism has been identified in 20% to 50% of positive cultures from children with SA.[108,109,114,116,117] SA caused by *K. kingae* most often affects the knee and hip joints, and osteomyelitis caused by *K. kingae* is localized in the lower limbs.[109] Evidence suggests that infections caused by *K. kingae* result in shorter hospital stays and fewer adverse complications than JI caused by other pathogens.[118,119]

Klebsiella aerogenes, previously classified as *Enterobacter aerogenes*, is a gram-negative, facultatively anaerobic, rod-shaped bacterium that is commensal in the GI tract.[120] *K. aerogenes* is an important pathogen responsible for nosocomial infections and is the eighth most common pathogen associated with hospital acquired infections in the United States.[121,122] Specific antibiotic treatments, venous catheter insertions, and surgical procedures are all risk factors associated with *K. aerogenes* infection.[123] Though rare, descriptions of JI caused by *K. aerogenes* are increasing in the literature. Specifically, *K. aerogenes* has been implicated in severe SA in children and prosthetic hip infections in adults.[96,124–126] As a widespread cause of nosocomial infections, carbapenem-resistance in *K. aerogenes* is an emerging concern.[127]

***Klebsiella pneumoniae* group** are a group of closely-related gram-negative, rod-shaped bacteria that are found as part of the normal flora of the human mouth and skin.[128] The *Klebsiella pneumoniae* group includes three species, previously described as *K. pneumoniae* (KP) phylogroups: *K. pneumoniae* (KPI), *K. quasipneumoniae* (KPII), and *K. variicola* (KPIII).[129] All three species have many of the same virulence factors and share biochemical and genetic similarities, which makes it difficult to distinguish *K. quasipneumoniae* and *K. variicola* from *K. pneumoniae* clinically or by standard culture methods.[129] *Klebsiella pneumoniae* group species are opportunistic pathogens accounting for approximately 8% of all nosocomial

bacterial infections in the United States and in Europe, primarily in the elderly or immunocompromised.[130,131] *K. pneumoniae* is one of the most common gram-negative pathogens associated with PJI, accounting for 21% of all gram-negative PJI in one eight-year study.[132] SA caused by *K. pneumoniae* group species is rare, though PJI and SA caused by resistant *K. pneumoniae* group strains often result in serious complications and often require aggressive medical and surgical interventions.[133,134] *K. pneumoniae* group species may carry the *Klebsiella pneumoniae* carbapenemase gene, *bla*$_{KPC}$, which confers resistance to carbapenem antibiotics[135], as well as several other genetic determinants of resistance to various classes of antibiotics

Morganella morganii is a facultatively anaerobic, gram-negative bacillus commonly found in the environment and the human GI tract. On rare occasions, *M. morganii* can become an opportunistic pathogen among postoperative, immunocompromised, and ICU patients.[136] *M. morganii*-caused infections represent about 1% to 3.5% of PJI cases and they are most often described in late-onset PJI localized in the knee joints.[100,137]

Neisseria gonorrhoeae is a gram-negative, diplococcic bacterium that causes sexually transmitted infection (STI) as well as other disseminated gonococcal disease, including SA.[138] This organism is an important cause of SA in newborns and sexually active adolescents.[139] Disseminated gonococcal infection occurs in 0.5% to 3% of young, previously healthy patients infected with *N. gonorrhoeae* and is comprised of two major clinical syndromes: arthritis-dermatitis syndrome and localized SA. Arthritis-dermatitis syndrome typically involves tenosynovitis, dermatitis, and polyarthralgia (multiple joints affected). In 75% of the cases skin lesions will develop. Localized SA usually only involves one joint and patients do not necessarily present with systemic symptoms such as fever and chills.[138] In North America and Europe, *N. gonorrhoeae* is the causative agent in 0.6% to 1.2% of SA cases.[140] *N. gonorrhoeae* has developed widespread resistance to cephalosporin.

***Proteus* spp**. are gram-negative, facultatively anaerobic, rod-shaped bacteria commonly isolated in the clinical laboratory, with *Proteus mirabilis* being the most prevalent species. *Proteus* species are opportunistic pathogens, responsible for urinary tract, wound, and nosocomial infections.[141] SA caused by *Proteus* species is rare and has a poor prognosis with respect to mortality and morbidity.[142] *Proteus* species are also a rare cause of PJI.[38,99] Antimicrobial resistance has become an increasing problem in *Proteus* infections, with approximately 32% of isolates producing extended-spectrum β-lactamases.[143]

Pseudomonas aeruginosa is an encapsulated, gram-negative, rod-shaped bacterium that commonly causes human disease. It can be found in man-made environments, soil, and water and is a normal part of the human skin microbiota. *P. aeruginosa* can cause SA in patients that have puncture wounds, are immunocompromised, or use intravenous drugs.[144,145] In one study of intravenous drug abusers, *P. aeruginosa* was found to cause 13% of all SA incidents.[146] Due to the ubiquitous nature of the organism and its ability to form biofilms, *P. aeruginosa* can cause PJI that are difficult to treat.[99] One study found that *P. aeruginosa* was responsible for approximately 3.6% of culture-positive PJI.[99]

***Salmonella* spp.** are motile, gram-negative, facultatively anaerobic rods that are associated with infection following the consumption of contaminated meat, fresh produce, and manufactured products.[147] Strains of *Salmonella* are categorized as typhoidal and non-typhoidal, corresponding to the particular disease syndromes they are related to. Strains of non-typhoidal *Salmonella* can be transferred from animals to humans and from humans to humans and usually cause GI infections. Approximately 5% of individuals with GI infections caused by non-typhoidal *Salmonella* will develop BSIs, especially in immunocompromised patients.[148] SA is rare and occurs in less than 1% of cases of salmonellosis.[149,150] PJI caused by *Salmonella* are also rare, the majority of which are caused by non-typhoidal *Salmonella.*[151]

Serratia marcescens is a gram-negative, red-pigmented, motile bacteria belonging to the *Yersiniaceae* family. Originally believed to be non-pathogenic, *S. marcescens* is now recognized as the primary pathogenic species of the *Serratia* genus. *S. marcescens* is an opportunistic and common nosocomial pathogen responsible for a wide range of infections. Transmission may occur from person-to-person contact, through a medical apparatus, or through intravenous fluids or other solutions.[152] Although rare, *S. marcescens* is known to cause both SA and PJI.[153–156] SA caused by *S. marcescens* is most likely acquired via hematogenous spread or routine medical procedures such as joint injections.[155,156] Non-pigmented *S. marcescens* are more resistant to antibiotics and are associated with most outbreaks.[157] *S. marcescens* is of particular concern due to its emerging antibiotic resistance to commonly used agents like β-lactams, aminoglycosides, carbapenems, and fluoroquinolones.[153]

Yeast

Candida* species are yeasts that are ubiquitous in the environment. They are also members of the normal human microbiota, especially in the digestive tract and on mucous membranes. These fungi are important causative agents of opportunistic nosocomial infections ranging from superficial (e.g. oral thrush) to systemic (e.g. septicemia). *Candida* infections in SA and PJI are generally rare. The majority of these are due to *C. albicans*, however *C. tropicalis, C. parapsilosis, C. glabrata* or *C. krusei* also cause infections, but at lower frequency.[158] Less common *Candida* species may be misidentified as one of the several common species using standard laboratory culture methods as well as some molecular methods. The emergence of mass spectrometry using MALDI-TOF technology has shown promising results for yeast identification. However, the lack of sufficient mass spectrometry spectra of closely related species and of unusual species from suitable reference strains limits the ability of MALDI-TOF MS database for accurate identification of these species.[159] SA due to *Candida* infection is typically de novo, monoarticular, and most cases involve the hip and knee.[158] PJI due to *Candida* infection is typically, but not always, monomicrobial and most cases involve the hip or knee.[160]

> ***Candida albicans*** is a common commensal organism, but also the most common human fungal pathogen.[161] This organism is an opportunistic pathogen of the immunocompromised, causing a range of infections that can involve any organ.[162,163] Biofilm formation is present in the majority of *C. albicans* infections, and can significantly complicate treatment as the biofilms often increase resistance to antifungal treatments.[164] JI caused by *C. albicans* often develops in the knees and hips from hematogenous spread post-surgery and diagnosis and treatment of these infections can be difficult.[158,160] Many patients with *C. albicans* JI experience indolent symptoms such as mild arthritis or systemic symptoms and these symptoms can present up to three years after the initial BSI.[165,166] Although fewer than 1% of PJI cases are caused by fungi, *C. albicans* is responsible for the majority of those cases.[158,167,168]

***Note:** In recent years there have been many taxonomic revisions of medically important yeast and *Candida* species names may have been revised to alternate genera such as *Clavispora, Debaryomyces, Kluyveromyces, Meyerozyma, Nakaseomyces, Pichia, and Wickerhamomyces,* among others.[169,170]

Antimicrobial Resistance Genes

CTX-M is a class A extended-spectrum β-lactamase (ESBL) that originated due to a mobilization of chromosomal genes (*bla*) from *Kluyvera* spp. and confers resistance to a broad spectrum of cephalosporins. This group of β-lactamases can be plasmid-borne and the *bla*$_{\text{CTX-M}}$ gene may be found in multiple copies per cell within a variety of gram-negative hosts. Phylogenetic analyses of CTX-M describes five main lineages or phylogroups (CTX-M groups 1, 2, 8, 9, and 25) and over 200 types or variants.[171] CTX-M ESBLs are predominantly found in species of the order *Enterobacterales*, but they have also been reported in other non-enteric, gram-negative bacteria such as *Pseudomonas aeruginosa*, *Stenotrophomonas maltophilia*, *Acinetobacter baumannii, Vibrio* spp. and *Aeromonas* spp. Over the last decade, CTX-M enzymes have overtaken other ESBLs, including TEM and SHV ESBL variants, in prevalence.[172]

IMP β-lactamases are plasmid-borne metallo-β-lactamases (MBLs) belonging to Ambler class B1 MBLs. More than 80 distinct IMP types have been identified which have the potential to confer different levels of antibiotic resistance to broad-spectrum β-lactams like carbapenems, cephamycins, and oxymino cephalosporins.[173,174] MBLs hydrolyze almost all β-lactams, rendering ineffective products, resulting in bacterial resistance to this class of antibiotics.[175] Carriage of a *bla*$_{\text{IMP}}$ gene has been detected in strains of *Serratia marcescens, Klebsiella pneumoniae, P. aeruginosa, Escherichia coli, and Enterobacter cloacae* and others.[176]

KPC – The *Klebsiella pneumoniae* carbapenemase gene (*bla*$_{\text{KPC}}$ or referred to here as KPC), confers resistance to the carbapenem class of β-lactams and currently is thought to be the most common and rapidly emerging carbapenemase in the United States. KPCs are frequently carried on mobile genetic elements with the potential to spread to other organisms. Though originally isolated from *Klebsiella pneumonia*e, the gene has since disseminated to other genera/species including *Acinetobacter*, *Pseudomonas*, and *Enterobacterales* (e.g. *Enterobacter, Serratia, Salmonella, Escherichia coli,* and *Klebsiella oxytoca*). There are more than 40 known KPC variants that have been identified, with the most commonly isolated types being KPC-2 and KPC-3.[177] Carbapenem-resistant *Enterobacterales* (CRE) are increasingly important pathogens in the hospital setting. Limited treatment options exist for CRE and they are associated with high mortality rates. Those most

at risk include patients receiving long courses of antibiotics and those with indwelling devices (e.g. ventilators, urinary catheters, or intravenous catheters).[178] Detection of KPCs using phenotypic susceptibility testing (e.g., MIC breakpoints or Modified Hodge Test) is very difficult, not only because other mechanisms of carbapenem-resistance exist, but also because KPC activity is regulated by multiple mechanisms that may not be accurately assessed *in vitro* resulting in incorrect susceptibility reporting.[179,180] Alternatively, molecular methods (e.g., PCR) are increasingly being used to specifically identify KPC genes in clinical isolates.[181]

mecA/C* and MREJ (MRSA) –** Methicillin-resistant (MR) staphylococci are a serious concern in both hospital-acquired and community-acquired infections. Few options exist for the treatment of these infections because the bacteria are resistant to both natural and semi-synthetic β-lactam antibiotics (e.g. oxacillin/methicillin)[74]. The primary mechanism of methicillin resistance is through the acquisition of the ***mecA gene that encodes a penicillin-binding protein (PBP2a) that has a low affinity for β-lactams. The *mecA* gene is carried on a chromosomally integrated mobile genetic element called the staphylococcal cassette chromosome *mec* (*SCCmec*). In 2011, an *SCCmec* type XI cassette carrying a divergent *mecA* homologue (***mecC***), which also confers methicillin resistance, was identified in Europe.[182]

The *SCCmec* cassette integrates into a specific region in the *Staphylococcus* genome.[183,184] In *S. aureus,* this insertion creates **MREJ** (*SCCmec* right-extremity junction), and molecular identification of this junction region provides specific identification of an *S. aureus* that carries the *SCCmec* cassette. The junction, or point of insertion of the *SCCmec* cassette, can lead to a variety of MREJ types (i-xxi). A combined molecular detection of *mecA/C,* MREJ, and *S. aureus* indicates MRSA. However, it is possible for *S. aureus* to carry *SCCmec* that has a non-functional *mecA* or *mecC* gene, or that has lost the *mecA/C* gene (an 'empty cassette', estimated to be 3.9-5% of methicillin-susceptible *S. aureus*[185,186]); such a strain would be a methicillin-susceptible *S. aureus* but could be misidentified by molecular methods, particularly if another *Staphylococcus* spp. that carries the *mecA/C* gene is in the sample.

NDM – The New Delhi metallo-β-lactamase (NDM) is a plasmid-mediated enzyme that confers resistance to all current β-lactam antibiotics, with the exception of aztreonam.[187,188] There are currently close to 40 different NDM types that may be found in a variety of gram-negative species, with NDM-1 recognized throughout the world. NDM is widely and rapidly disseminated throughout the *Enterobacteriaceae*, as well as other gram-negative bacteria.[188–192] The plasmids encoding NDM are easily transferable and capable of rearrangement, suggestive of extensive transmission, as well as plasticity, amongst bacterial populations.[189] Multi-drug resistant NDM-producing bacteria are now the most prevalent carbapenemase producers in Europe, and this trend is expected to continue worldwide.

OXA-48-like describes as group of oxacillinase (OXA) β-lactamases that are part of a group of primarily plasmid-mediated enzymes that confer resistance to penicillins, cephalosporins, and carbapenems. The *bla*$_{\text{OXA-48}}$ gene and its variants have been identified in various gram-negative bacteria in the *Enterobacterales* order.[193,194] OXA-48 hydrolyzes penicillins at a high level and carbapenems at a low level, with greater activity against imipenem than meropenem,[193] and demonstrates extremely weak activity against expanded-spectrum cephalosporins.[194] Several OXA-48-like variants maintain the hydrolytic properties and substrate profile of OXA-48 (-162, -181, -199, -204, -232, -244, -245, -252, -370, -484, -505, -514, -515, -519, -546, -547, and -566). Other variants retain activity against extended-spectrum cephalosporins but do not have the carbapenemase activity of OXA-48 (-163, -247, -405, -436, -438, -439, -517, -535, -538, -548, -549, -550, -551, -552, -553, -567, and -731).

vanA/B – Vancomycin resistance in *Enterococcus* spp. is conferred by the *vanA* and *vanB* genes. The prevalence of vancomycin-resistant enterococcus (VRE) has increased rapidly and infection with a VRE increases the risk of serious illness.[195] Nine gene clusters associated with vancomycin resistance have been identified to date (*vanA*, *vanB*, *vanC*, *vanD*, *vanE*, *vanG*, *vanL*, *vanM,* and *vanN*), with *vanA* and *vanB* being the most common in clinical isolates.[196] Both the *vanA* and *vanB* gene clusters are borne on mobile genetic elements (transposons) and can be located either on the chromosome or carried on a plasmid. Enterococci carrying *vanA* or *vanB* are resistant to high levels of vancomycin. Isolates carrying *vanA* are also resistant to high levels of teicoplanin.[197]

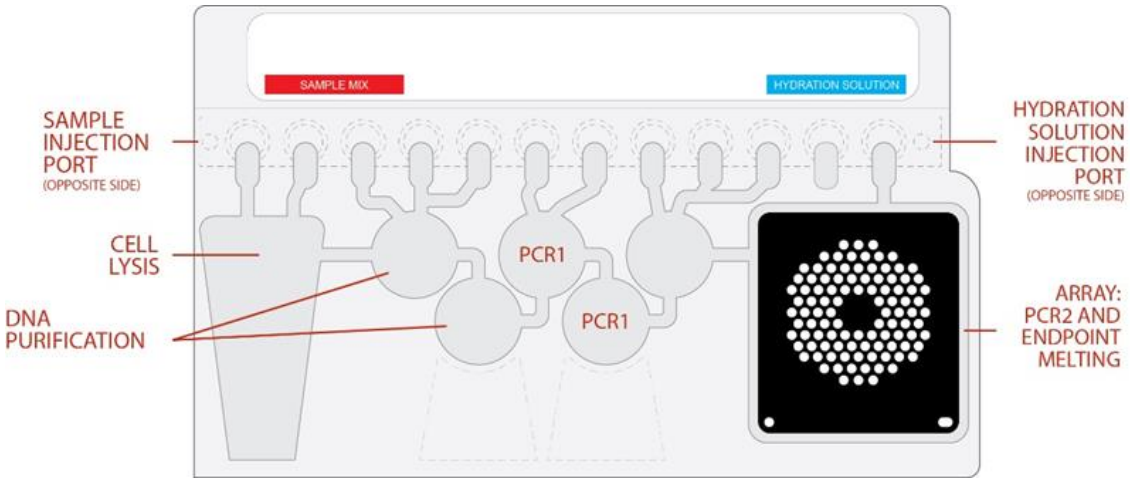
VIM – Verona Integron-Encoded Metallo-β-Lactamase (VIM) is an integron-encoded carbapenemase. There are reports of both plasmid and chromosomal localization of the *bla*$_{\text{VIM}}$ integron;[198] however, the majority of *bla*$_{\text{VIM}}$ alleles are found on plasmids. There are over 60 distinct VIM types. VIMs are found mainly in gram-negative bacteria, including *Enterobacterales*, with a vast majority associated with various species of *Pseudomonas*.

PRINCIPLE OF THE PROCEDURE

The BioFire® JI Panel pouch is a closed system disposable that stores all the necessary reagents for sample preparation, polymerase chain reaction (PCR), and detection in order to isolate, amplify, and detect nucleic acid from multiple organisms and antimicrobial resistance genes within a single synovial fluid specimen. After sample collection, the user injects hydration solution and sample combined with BioFire® FilmArray® Sample Buffer into the pouch, places the pouch into a BioFire® FilmArray® System Instrument module, and starts a run. The entire run process takes about one (1) hour. Additional detail can be found in the appropriate BioFire® FilmArray® System Operator's Manual.

During a run, the BioFire system:

- Lyses the sample by agitation (bead beating) in addition to chemical lysis mediated by the Sample Buffer.
- Extracts and purifies all nucleic acids from the sample using magnetic bead technology.
- Performs nested multiplex PCR by:
    - First performing a single, large volume, massively multiplexed reaction (PCR1).
    - Then performing multiple simultaneous second-stage PCR reactions (PCR2) in the array to amplify sequences within the PCR1 products.
- Uses endpoint melting curve data to detect and generate a result for each target on the BioFire JI Panel array.



MATERIALS PROVIDED

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The BioFire JI Panel contains materials consisting of primers, buffers, dNTPs, polymerase, molecular grade water, guanidinium chloride (50 - < 60%), Triton-X 100 (10 - < 20%), and LCGreen® Plus.

Each kit contains sufficient reagents to test 30 samples (30-test kit – REF# RFIT-ASY-0138):

- Individually packaged BioFire JI Panel pouches
- Single-use (1 mL) Sample Buffer ampoules
- Single-use pre-filled (1.5 mL) Hydration Injection Vials (blue)
- Single-use Sample Injection Vials (red)
- Individually packaged Transfer Pipettes
- BioFire® Joint Infection (JI) Panel Software

  This software is required to run the BioFire JI Panel and can be downloaded at www.biofiredx.com/e-labeling/ITIFA20JI10 if not already installed on the BioFire 2.0 or BioFire Torch Systems.

MATERIALS REQUIRED BUT NOT PROVIDED

- BioFire® FilmArray® System including:
  - BioFire 2.0 or BioFire Torch Systems
    - including accompanying system-specific core software and panel-specific software
  - BioFire® FilmArray® Pouch Loading Station
- 10% bleach solution or a similar disinfectant

WARNINGS AND PRECAUTIONS

General Precautions

1. For *in vitro* diagnostic use.
2. A trained healthcare professional should carefully interpret the results from the BioFire JI Panel in conjunction with a patient's signs and symptoms, results from other diagnostic tests, and relevant epidemiological information.
3. BioFire JI Panel pouches are only for use with BioFire 2.0 and BioFire Torch systems.
4. Always check the expiration date on the pouch. Do not use a pouch after its expiration date.
5. BioFire JI Panel pouches are stored under vacuum in individually wrapped canisters. To preserve the integrity of the pouch vacuum for proper operation, be sure that an instrument module will be available and operational before unwrapping any pouches for loading.

Safety Precautions

1. Wear appropriate Personal Protective Equipment (PPE), including (but not limited to) disposable clean powder-free gloves and lab coats. Protect skin, eyes, and mucus membranes. Change gloves often when handling reagents or samples.

2. Handle all samples and waste materials as if they were capable of transmitting infectious agents. Observe safety guidelines such as those outlined in:
    - CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*[199]
    - CLSI Document M29 *Protection of Laboratory Workers from Occupationally Acquired Infections*[200]
3. Follow your institution's safety procedures for handling biological samples.
4. Dispose of materials used in this assay, including reagents, samples, and used buffer vials, according to federal, state, and local regulations.
5. Sample Buffer contains Guanidinium chloride and Triton X100.

The following statements apply.

- Health Hazards
    - Acute Toxicity, oral (Category 4)
        - H302 – Harmful if swallowed.
    - Skin corrosion/irritation (Category 2)
        - H315 - Causes skin irritation.
    - Serious eye damage/eye irritation (Category 1)
        - H318 - Causes serious eye damage.
- Environment Hazards
    - Hazardous to the aquatic environment, acute aquatic hazard (Category 1)
        - H400 - Very toxic to aquatic life.
    - Hazardous to the aquatic environment, long-term aquatic hazard (Category 1)
        - H410 - Very toxic to aquatic life with long lasting effects.
- Precautionary Statements
    - Prevention
        - P273 – Avoid release to the environment.
        - P280 – Wear protective gloves/protective clothing/eye protections/face protection.
- Response
        - P332 + P313 - If skin irritation occurs: Get medical advice/attention.
        - P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
        - P301 + P312 - IF SWALLOWED: Call a POISON CENTRE/doctor if you feel unwell.
        - P337 + P313 - If eye irritation persists: Get medical advice/attention.

Please refer to the BioFire JI Panel Safety Data Sheet (SDS) for more information.

6. Sample Buffer will form hazardous compounds and fumes when mixed with bleach or other disinfectants.

WARNING: Never add Bleach to Sample Buffer or sample waste.

7. Bleach, a recommended disinfectant, is corrosive and may cause severe irritation or damage to eyes and skin. Vapor or mist may irritate the respiratory tract. Bleach is harmful if swallowed or inhaled.
    - Eye contact: Hold eye open and rinse with water for 15-20 minutes. Remove contact lenses after the first 5 minutes and continue rinsing eye. Seek medical attention.

- Skin contact: Immediately flush skin with plenty of water for at least 15 minutes. If irritation develops, seek medical attention.
- Ingestion: Do not induce vomiting. Drink a glassful of water. If irritation develops, seek medical attention.
- Please refer to the appropriate Safety Data Sheet (SDS) for more information.

Laboratory Precautions

1. **Preventing organism contamination**

   Due to the sensitive nature of the BioFire JI Panel, it is important to guard against contamination of the sample and work area by carefully following the testing process outlined in this instruction document, including these guidelines:

   - It is recommended to avoid handling specimens or pouches in an area used to routinely process primary samples for bacterial or fungal stains, rapid antigen testing, and/or cultures, unless the area is thoroughly cleaned first.
   - Careful adherence to the sample processing steps described in this document is recommended to avoid possible contamination. Samples should be processed in a clean biosafety cabinet if available, or according to local laboratory guidelines. If a biosafety cabinet is not used, a dead air box (e.g., AirClean PCR workstation), a splash shield (e.g., Bel-Art Scienceware Splash Shields), or a face shield can be used when preparing samples instead.
   - Prior to processing specimens, thoroughly clean both the work area and the BioFire Pouch Loading Station using a suitable cleaner such as freshly prepared 10% bleach or a similar disinfectant. To avoid residue build-up and potential damage to the specimen or interference from disinfectants, wipe disinfected surfaces with water.
   - Specimens and pouches should be handled and/or tested one-at-a-time. Always change gloves and clean the work area between each pouch and specimen.
   - Use clean gloves when removing Sample Buffer ampoules and Sample/Hydration Injection Vials from bulk packaging bags and reseal bulk packaging bags when not in use.

2. **Preventing amplicon contamination**

   A common concern with PCR-based assays is false positive results caused by contamination of the work area with PCR amplicon. Because the BioFire JI Panel pouch is a closed system, the risk of amplicon contamination is low provided that pouches remain intact after the test is completed. Adhere to the following guidelines, in addition to those above, to prevent amplicon contamination:

   - Discard used pouches in a biohazard container immediately after the run has completed.
   - Avoid excessive handling of pouches after test runs.
   - Change gloves after handling a used pouch.
   - Avoid exposing pouches to sharp edges or anything that might cause a puncture.

WARNING: If liquid is observed on the exterior of a pouch, the liquid and pouch should be immediately contained and discarded in a biohazard container. The instrument and workspace must be decontaminated as described in the appropriate BioFire System Operator's Manual.

DO NOT PERFORM ADDITIONAL TESTING UNTIL THE AREA HAS BEEN DECONTAMINATED.

Precautions Related to Public Health Reporting

Local, state, and federal/national regulations for notification of reportable disease are continually updated and include a number of organisms for surveillance and outbreak investigations.[201,202] Several initiatives are also in place worldwide for notification and surveillance of antibiotic resistance, including carbapenemase-producing *Enterobacterales* (CPE)/carbapenem-resistant *Enterobacterales* (CRE).

The Centers for Disease Control and Prevention (CDC) recommends that when pathogens from reportable diseases are detected by a culture independent diagnostic test (CIDT), the laboratory should facilitate obtaining the isolate or clinical materials for submission to the appropriate public health laboratory to aid in outbreak detection and epidemiological investigations.

Laboratories are responsible for following their state and/or local regulations and should consult their local, state and/or national public health laboratories for reporting as well as isolate and/or clinical sample submission guidelines.

Precaution Related to REACH Regulation (EC 1907/2006)

This statement only applies to countries within the European Union (EU) with regard to the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC 1907/2006):

It is recommended that all material associated with the test, including the material used to clean up spills, contaminated packaging, and/or unused and expired IVD tests, is incinerated. Please ensure that you follow local regulations regarding disposal.

REAGENT STORAGE, HANDLING, AND STABILITY

1. Store the test kit, including reagent pouches and buffers, at room temperature (15–25 ºC).
2. Avoid storage of any materials near heating or cooling vents or in direct sunlight.
3. All kit components should be stored and used together. Do not use components from one kit with those of another kit. Discard any extra components from the kit after all pouches have been consumed.
4. Do not remove pouches from their packaging until a sample is ready to be tested. Once the pouch packaging has been opened, the pouch should be loaded as soon as possible (within approximately 30 minutes).
5. Once a pouch has been loaded, the test run should be started as soon as possible (within approximately 60 minutes). Do not expose a loaded pouch to temperatures above 40°C (104°F) prior to testing.

SAMPLE REQUIREMENTS

The following table describes the requirements for specimen collection, preparation, and handling that will help ensure accurate test results.

Table 1. Sample Requirements for the BioFire JI Panel

Specimen Type	**Synovial Fluid** (SF) collected according to standard technique.
Minimum Sample Volume	0.2 mL (200 µL)
Transport and Storage	Specimens should be tested with the BioFire JI Panel as soon as possible[a]. If transport or storage is required, specimens can be held: • Refrigerated for up to 7 days (2-8 °C)

[a] The performance validation included the evaluation of clinical synovial fluid specimens frozen for up to 20 months. However, longer frozen storage may be acceptable. Please follow your institutions rules and protocols regarding sample storage validation.

NOTE: Storage of SF specimen at room temperature is not recommended.

NOTE: SF specimens should <u>not</u> be centrifuged, pre-processed, or placed into transport media or treated with anticoagulants before testing. The panel is not intended for use with synovial fluid in media/broths as these solutions may contain contaminating nucleic acids (bioburden) that can generate false positive results.

NOTE: Bleach can damage organisms/nucleic acids within the specimen, potentially causing false negative results. Contact between bleach and specimens during collection, disinfection, and testing procedures should be avoided.

PROCEDURE

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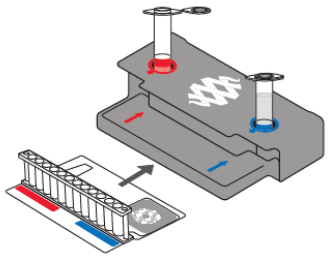
Use clean gloves and other Personal Protective Equipment (PPE) when handling pouches and samples. Only prepare one BioFire JI Panel pouch at a time and change gloves between samples and pouches. Once sample is added to the pouch, promptly transfer to the instrument to start the run. After the run is complete, discard the pouch in a biohazard container.

Step 1: Prepare Pouch

1. Thoroughly clean the work area and the BioFire Pouch Loading Station with freshly prepared 10% bleach (or suitable disinfectant) followed by a water rinse.
2. Remove the pouch from its vacuum-sealed package by tearing or cutting the notched outer packaging and opening the protective canister.

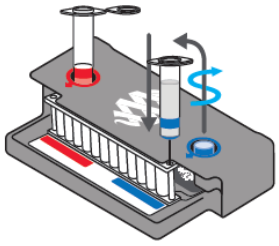
NOTE: The pouch may still be used even if the vacuum seal of the pouch is not intact. Attempt to hydrate the pouch using the steps in the Hydrate Pouch section. If hydration is successful, continue with the run. If hydration fails, discard the pouch and use a new pouch to test the sample.

3. Check the expiration date on the pouch. Do not use expired pouches.
4. Insert the pouch into the Pouch Loading Station, aligning the red and blue labels on the pouch with the red and blue arrows on the Pouch Loading Station.
5. Place a red-capped Sample Injection Vial into the red well of the Pouch Loading Station.
6. Place a blue-capped Hydration Injection Vial into the blue well of the Pouch Loading Station.



Step 2: Hydrate Pouch

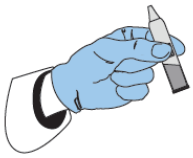
1. Unscrew the Hydration Injection Vial from the blue cap.
2. Remove the Hydration Injection Vial, leaving the blue cap in the BioFire Pouch Loading Station.
3. Insert the cannula tip of the Hydration Injection Vial into the pouch hydration port located directly below the blue arrow of the Pouch Loading Station.
4. Forcefully push down in a firm and quick motion to puncture seal until a faint “pop” is heard and there is an ease in resistance. Wait as the correct volume of Hydration Solution is pulled into the pouch by vacuum.



   - If the hydration solution is not automatically drawn into the pouch, repeat Step 2 to verify that the seal of the pouch hydration port was broken. If hydration solution is again not drawn into the pouch, discard the current pouch, retrieve a new pouch, and repeat from *Step 1: Prepare Pouch*.
5. Verify that the pouch has been hydrated.
   - Flip the barcode label down and check to see that fluid has entered the reagent wells (located at the base of the rigid plastic part of the pouch). Small air bubbles may be seen.
   - If the pouch fails to hydrate (dry reagents appear as white pellets), repeat Step 2 to verify that the seal of the pouch hydration port was broken. If hydration solution is still not drawn into the pouch, discard the current pouch, retrieve a new pouch, and repeat from *Step 1: Prepare Pouch*.

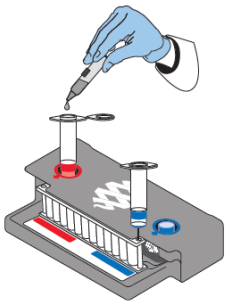
Step 3: Prepare Sample Mix

1. Add Sample Buffer to the Sample Injection Vial.
    - Hold the Sample Buffer ampoule with the tip facing up.



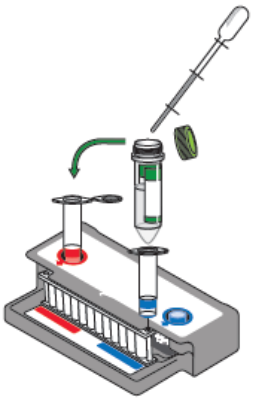
NOTE: Avoid touching the ampoule tip during handling, as this may introduce contamination.

- Firmly pinch at textured plastic tab on the side of the ampoule until the seal snaps.
- Invert the ampoule over the red-capped Sample Injection Vial and dispense Sample Buffer using a slow, forceful squeeze followed by a second squeeze.



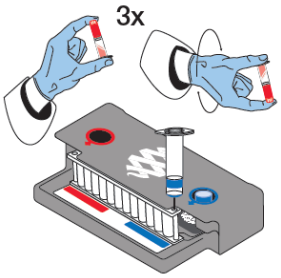
NOTE: Avoid squeezing the ampoule additional times. This will generate foam, which should be avoided.

WARNING: The Sample Buffer is harmful if swallowed and can cause serious eye damage and skin irritation.



2. Mix the synovial fluid specimen by inversion.
3. Use the transfer pipette provided in the test kit to draw specimen to the second line (approximately 0.2 mL) of the transfer pipette.
4. Add the specimen to the Sample Buffer in the Sample Injection Vial.
5. Tightly close the lid of the Sample Injection Vial and discard the transfer pipette in a biohazard waste container.

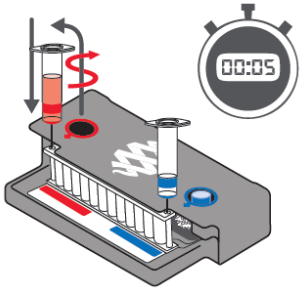
NOTE: DO NOT use the Transfer Pipette to mix the sample once it is loaded into the Sample Injection Vial.



6. Remove the Sample Injection Vial from the Pouch Loading Station and invert the vial at least 3 times to mix.
7. Return the Sample Injection Vial to the red well of the Pouch Loading Station.

Step 4: Load Sample Mix

1. Slowly twist to unscrew the Sample Injection Vial from the red cap and wait for 5 seconds with the vial resting in the cap.



NOTE: Waiting 5 seconds decreases the risk of dripping and contamination from the sample.

2. Lift the Sample Injection Vial, leaving red cap in the well of the Pouch Loading Station, and insert the Sample Injection Vial cannula tip into the pouch sample port located directly below the red arrow of the Pouch Loading Station.
3. Forcefully push down in a firm and quick motion to puncture seal (a faint “pop” is heard) and sample is pulled into the pouch by vacuum.
4. Verify that the sample has been loaded.

- Flip the barcode label down and check to see that fluid has entered the reagent well next to the sample loading port.
- If the pouch fails to pull sample from the Sample Injection Vial, the pouch should be discarded. Retrieve a new pouch and repeat from *Step 1: Prepare Pouch*.

5. Discard the Sample Injection Vial and the Hydration Injection Vial in appropriate biohazard sharps container.
6. Record the Sample ID in the provided area on the pouch label (or affix a barcoded Sample ID) and remove the pouch from the Pouch Loading Station.

Step 5: Run Pouch

The BioFire Software includes step-by-step, on-screen instructions that guide the operator through performing a run. Brief instructions for BioFire 2.0 and BioFire Torch Systems are given below. Refer to the appropriate BioFire System Operator's Manual for more detailed instructions.

BioFire 2.0

1. Ensure that the system (instrument and computer) is powered on and the software is launched.
2. Follow on-screen instructions and procedures described in the Operator's Manual to place the pouch in a module, enter pouch, sample, and operator information.
3. Pouch identification (Lot Number and Serial Number), Pouch Type and Protocol information will be automatically entered when the barcode is scanned. If it is not possible to scan the barcode, the pouch Lot Number, Serial Number, Pouch Type, and Protocol can be manually entered from the information provided on the pouch label into the appropriate fields. To reduce data entry errors, it is strongly recommended that the pouch information be entered by scanning the barcode.

NOTE: When selecting a Pouch Type manually, ensure that the Pouch Type matches the label on the BioFire JI Panel pouch.

4. Enter the Sample ID. The Sample ID can be entered manually or scanned in by using the barcode scanner when a barcoded Sample ID is used.
5. If necessary, select and/or confirm the appropriate protocol for your sample type from the Protocol drop down list. The BioFire JI Panel has a single protocol available in the drop down list.
6. Enter a username and password in the Name and Password fields.

NOTE: The font color of the username is red until the username is recognized by the software.

7. Review the entered run information on the screen. If correct, select Start Run.

   Once the run has started, the screen displays a list of the steps being performed by the instrument and the number of minutes remaining in the run.

NOTE: The bead-beater apparatus makes an audible, high-pitched noise during the first minute of operation.

8. When the run is finished, follow the on-screen instructions to remove the pouch, then immediately discard it in a biohazard waste container.
9. The run file is automatically saved in the BioFire Software database, and the test report can be viewed, printed, and/or saved as a PDF file.

BioFire Torch

1. Ensure that the system is powered on.
2. Select an available module on the touch screen or scan the barcode on the pouch using the barcode scanner.
3. Pouch identification (Lot Number and Serial Number), Pouch Type and Protocol information will be automatically entered when the barcode is scanned. If it is not possible to scan the barcode, the pouch Lot Number, Serial Number, Pouch Type, and Protocol can be manually entered from the information provided on the pouch label into the appropriate fields. To reduce data entry errors, it is strongly recommended that the pouch information be entered by scanning the barcode.

NOTE: When selecting a Pouch Type manually, ensure that the Pouch Type matches the label on the BioFire JI Panel pouch.

4. Enter the Sample ID. The Sample ID can be entered manually or scanned in by using the barcode scanner when a barcoded Sample ID is used.
5. Insert the pouch into the available module.
    - Ensure that the pouch fitment label is lying flat on top of pouch and not folded over. As the pouch is inserted, the module will grab onto the pouch and pull it into the chamber.
6. If necessary, select and/or confirm the appropriate protocol for your sample type from the Protocol drop down list. The BioFire JI Panel has a single protocol available in the drop down list.
7. Enter a username and password, then select Next.

NOTE: The font color of the username is red until the username is recognized by the software.

8. Review the entered run information on the screen. If correct, select Start Run.

    Once the run has started, the screen displays a list of the steps being performed by the module and the number of minutes remaining in the run.

NOTE: The bead-beater apparatus can be heard as a high-pitched noise during the first minute of operation.

9. At the end of the run, remove the partially ejected pouch, then immediately discard it in a biohazard waste container.
10. The run file is automatically saved in the BioFire Software database, and the test report can be viewed, printed, and/or saved as a PDF file.

QUALITY CONTROL

Process Controls

Two process controls are included in each pouch:

1. **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, PCR1, dilution, PCR2, and DNA melting. A positive control result indicates that all steps carried out in the BioFire JI Panel pouch were successful.

2. **PCR2 Control**

   The PCR2 Control assay detects a DNA target that is dried into wells of the array along with the corresponding primers. A positive result indicates that PCR2 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.

Monitoring Test System Performance

The software will automatically fail the run if the melting temperature (Tm) for either the DNA Process Control or the PCR2 Control is outside of an acceptable range (77.6 - 81.6°C for the DNA Process Control and 74.2-78.2°C for the PCR2 Control). If required by local, state, or accrediting organization quality control requirements, users can monitor the system by trending Tm values for the control assays and maintaining records according to standard laboratory quality control practices.[56,57] Refer to the appropriate BioFire FilmArray System Operator's Manual for instructions on obtaining control assay Tm values. The PCR2 Control is used in several BioFire pouch types and can, therefore, be used to monitor the system when multiple pouch types are used on the same BioFire System.

External Controls

External controls should be used in accordance with laboratory protocols and the appropriate accrediting organization requirements, as applicable. Previously characterized positive samples or negative samples spiked with well-characterized organisms can be used as external positive controls. Commercial external control materials may be available from other manufacturers; these should be used in accordance with the manufacturers' instructions and appropriate accrediting organization requirements, as applicable.

INTERPRETATION OF RESULTS

Assay Interpretation

When PCR2 is complete, the instrument performs a high-resolution DNA melting analysis on the PCR products and records the change in fluorescence signal generated in each well (for more information see appropriate BioFire System Operator's Manual). The BioFire Software then performs several analyses and assigns a final assay result. The steps in the analyses are described below.

Analysis of melt curves. The BioFire Software evaluates the DNA melt curve for each well of the PCR2 array to determine if a PCR product was present in that well. If the melt profile indicates the presence of a PCR product, then the analysis software calculates the melting temperature (Tm) of the curve and compares it against the expected Tm range for the assay. If the software determines that the Tm value falls inside the assay-specific Tm range, the melt curve is called positive. If the software determines that the melt curve is not in the appropriate Tm range, the melt curve is called negative.

Analysis of replicates. Once positive melt curves have been identified, the software evaluates the replicates for each assay to determine the assay result. For an assay to be called positive, two of the associated melt curves must be called positive, and both Tm values must be similar. Assays that do not meet these criteria are called negative.

Organism and Antimicrobial Resistance Gene Interpretation

Each positive and negative assay result is interpreted by the BioFire Software to provide results for the identification of specific bacteria, yeast, and antimicrobial resistance (AMR) genes as shown inTable 2.

For most of the organism results reported by the BioFire JI Panel, the result is qualitatively reported as Detected or Not Detected based on one assay. However, in some cases, determination of Detected and Not Detected results requires interpretation of more than one assay. Reporting of AMR genes with one or more applicable bacteria also requires interpretation based on more than one assay result, as discussed below.

NOTE: Polymicrobial specimens with four or more distinct organisms are possible but rare. If Detected results are reported for four or more organisms in a sample, a retest of the sample is recommended to confirm the polymicrobial result.

Table 2. Analytes Detected by the BioFire JI Panel

Gram Positive Bacteria		
Anaerococcus prevotii/vaginalis	*Finegoldia magna*	*Streptococcus* spp.
Clostridium perfringens	*Parvimonas micra*	*Streptococcus agalactiae*
Cutibacterium avidum/granulosum	*Peptoniphilus*	*Streptococcus pneumoniae*
Enterococcus faecalis	*Peptostreptococcus anaerobius*	*Streptococcus pyogenes*
Enterococcus faecium	*Staphylococcus aureus*	
	Staphylococcus lugdunensis	
Gram Negative Bacteria		
Bacteroides fragilis	*Kingella kingae*	*Proteus* spp.
Citrobacter	*Klebsiella aerogenes*	*Pseudomonas aeruginosa*
Enterobacter cloacae complex	*Klebsiella pneumoniae* group	*Salmonella* spp.
Escherichia coli	*Morganella morganii*	*Serratia marcescens*
Haemophilus influenzae	*Neisseria gonorrhoeae*	
Yeast		
Candida *Candida albicans*		

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

Results Interpretation for Gram-Positive Bacteria

The BioFire JI Panel contains assays for the specific detection of several species of gram-positive anaerobic cocci (GPAC), and gram-positive anaerobic rod-shaped bacteria, the major *Enterococcus* species associated with joint infections (*Enterococcus faecium* and *Enterococcus faecalis*), two clinically important Staphylococci (*S. aureus* and *S. lugdunensis*) and nearly all *Streptococcus* species, including specific identification of *S. agalactiae*, *S. pneumoniae*, and *S. pyogenes*.

Information about detection of specific species, subspecies, strains, isolates, or serotypes of gram-positive bacteria is provided in the Analytical Reactivity (Inclusivity) section (Table 53 - Table 67). Note that only a subset of *Peptoniphilus* species* will be detected (*P. assacharolyticus*, *P. gorbachii*, *P. harei*, *P. indolicus*, *P. lacrimalis*, and *P. senegalensis*) but that nearly all species within the *Streptococcus* genus (*Streptococcus* spp.) are predicted to be detected by the panel (exceptions include *Streptococcus entericus*, *S. halitosis*, *S.hyovaginalis*, *S. minor* and *S. pantholopis* and variant sequences identified as *S. equi*, *S. minor*, *S. oralis*, *S. sobrinus*, *S. suis,* and *S. uberis* that may be amplified less efficiently than others).

***Note:** *Peptoniphilus* reactivity testing also included isolates described as *Peptoniphilus allenii* and *Peptoniphilus grossensis* (both detected), though neither is currently listed as a validly published species name.

Based on *in silico* analysis and empirical testing (see Analytical Specificity (Cross-Reactivity) section (Table 93)), each of the assays for detection of gram-positive bacteria is specific for detection of the indicated species with the exception of cross-reactivity with some rare near-neighbor species of *Anaerococcus* (multiple species), *Clostridium* (*C. baratii*, *C. cadaveris*, *C. disporicum C. fallax*, and *C. grantii*), and species of the *S. aureus* complex (*S. argenteus* and *S. schweitzeri*).

Results for most gram-positive bacteria are reported as Detected or Not Detected based on one corresponding assay result. If the assay is positive the test result will be Detected, and if the assay is negative, the test result will be Not Detected. Detection of gram-positive bacteria that is based on interpretation of more than one assay is described below.

Cutibacterium avidum/granulosum

The BioFire JI Panel contains two assays (Cutibacterium1 and Cutibacterium2) for the detection of these two specific *Cutibacterium* species. A positive result for one or both assays will generate a *Cutibacterium avidum/granulosum* Detected test result. *Cutibacterium avidum/granulosum* will be reported as Not Detected when both assays are negative.

Staphylococcus aureus

The BioFire JI Panel contains two assays (Saureus1 and Saureus2) for the detection of *Staphylococcus aureus*. A positive result for one or both assays will generate a *Staphylococcus aureus* Detected test result. *Staphylococcus aureus* will be reported as Not Detected when both assays are negative.

Streptococcus spp.

The BioFire JI Panel contains four assays for the detection of *Streptococcus* species. Species-specific assays are included for the detection of *Streptococcus pyogenes* (Spyogenes), *Streptococcus agalactiae* (Sagalactiae), and *Streptococcus pneumoniae* (Spneumoniae). The fourth assay is a genus level assay (Streptococcus) designed to react with most Viridans group and other *Streptococcus* species that are not specifically identified by one of the other assays on the panel. The software integrates the results of all four *Streptococcus* assays into a *Streptococcus* spp. result as shown in Table 3. If all four assays are negative, the test result will be *Streptococcus* spp. Not Detected. Alternatively, if any of the four assays are positive, the test result will be *Streptococcus* spp. Detected and results for each species-specific assay will also be reported independently.

Table 3. Assay and Results Interpretation for the *Streptococcus* spp., *Streptococcus agalactiae*, *Streptococcus pneumoniae*, and *Streptococcus pyogenes* Test Results

BioFire JI Panel Results	Streptococcus Assay	Sagalactiae Assay	Spneumoniae Assay	Spyogenes Assay	Description
Streptococcus spp. Not Detected *Streptococcus agalactiae* Not Detected *Streptococcus pneumoniae* Not Detected *Streptococcus pyogenes* Not Detected	Negative	Negative	Negative	Negative	No *Streptococcus* species detected in the sample
***Streptococcus* spp. Detected** *Streptococcus agalactiae* Not Detected *Streptococcus pneumoniae* Not Detected *Streptococcus pyogenes* Not Detected	**Positive**	Negative	Negative	Negative	One or more *Streptococcus* species detected in the sample (not *S. agalactiae*, *S. pneumoniae*, or *S. pyogenes*)
***Streptococcus* spp. Detected** ***Streptococcus agalactiae* Detected** *Streptococcus pneumoniae* Not Detected *Streptococcus pyogenes* Not Detected	Any result	**Positive**	Negative	Negative	*Streptococcus agalactiae* detected in the sample. Note: additional *Streptococcus* species (not *S. pneumoniae* or *S. pyogenes*) may also be in the sample
***Streptococcus* spp. Detected** *Streptococcus agalactiae* Not Detected ***Streptococcus pneumoniae* Detected** *Streptococcus pyogenes* Not Detected	Any result	Negative	**Positive**	Negative	*Streptococcus pneumoniae* detected in the sample Note: additional *Streptococcus* species (not *S. agalactiae* or *S. pyogenes*) may also be in the sample
***Streptococcus* spp. Detected** *Streptococcus agalactiae* Not Detected *Streptococcus pneumoniae* Not Detected ***Streptococcus pyogenes* Detected**	Any result	Negative	Negative	**Positive**	*Streptococcus pyogenes* detected in the sample Note: additional *Streptococcus* species (not *S. agalactiae* or *S. pneumoniae*) may also be in the sample

NOTE: Multiple Streptococcus species assays may be positive in a single sample. If this occurs, the test result for each species with a positive assay will be reported as Detected.

Results Interpretation for Gram-Negative Bacteria

The BioFire JI Panel contains assays for the specific detection of many gram-negative aerobic and anaerobic species associated with joint infections. Species are identified individually (*Bacteroides fragilis, Escherichia coli, Haemophilus influenzae, Kingella kingae, Klebsiella aerogenes, Morganella morganii, Neisseria gonorrhoeae, Pseudomonas aeruginosa, Serratia marcescens*), or as multi-species complex, group, or genus results (*Enterobacter cloacae* complex, *Klebsiella pneumoniae* group, *Citrobacter, Proteus* spp., and *Salmonella* spp.). Each species, complex, group, or genus result is reported as Detected or Not Detected based on an individual corresponding assay result. If the assay is positive, the result will be Detected; if the assay is negative, the result will be Not Detected.

Information about detection of specific species, subspecies, strains, isolates, or serotypes of gram-negative bacteria is provided in the Analytical Reactivity (Inclusivity) section (Table 68 - Table 81). Note that only a subset of species within the *Citrobacter* genus are expected to be detected as *Citrobacter* by the panel, including: *C. braakii*, *C. europaeus, C. freundii*, *C. koseri*, *C. murliniae*, C. *pasteurii, C. portucalensis, C. werkmanii* and *C. youngae.*

Based on testing and *in silico* analysis, the assays for gram-negative bacteria are specific for detection of the indicated genus, complex, group or species, with the exception of the cross-reactivities with closely-related species described below

and noted in the Analytical Specificity (Cross-Reactivity) section (Table 93).

- *Bacteroides xylanisolvens*, a commensal species that naturally resides in the human intestine, can be mis-identified as *Bacteroides fragilis* due to non-specific interaction with the Bfragilis assay.
- The *Enterobacter cloacae* complex (ECC) is comprised of multiple species that may all be identified as *E. cloacae* by phenotypic laboratory methods. The Ecloacae assay will detect species and subspecies within the complex and may also react with other genetically related species (e.g. *E. bugandensis* and *E. chengduensis*) that have been more recently identified and may not be consistently designated as species of the ECC.
- The Ecoli assay cross-reacts with *Shigella* species (*S. boydii*, *S. dysenteriae*, *S. flexneri*, and *S. sonnei*); which are practically indistinguishable from *E. coli* by both phenotypic and genetic analyses but are not generally associated with JI. Cross-reactivity has also been observed with *Escherichia fergusonii*, a rare but emerging veterinary and human pathogen, and *Escherichia albertii* (only at high concentration), a species more typically associated with gastrointestinal infections.
- *Haemophilus aegyptius*, a species formerly described as a subgroup or biotype of *Haemophilus influenzae*, is difficult to differentiate from *H. influenzae* by most laboratory methods and will be detected as *Haemophilus influenzae* by the BioFire JI Panel due to cross-reactivity.
- *Kingella negevensis*, a recently identified species linked to pediatric joint infections and that is closely related to, and likely to be mis-identified by standard laboratory methods as, *K. kingae* will also be detected as *Kingella kingae* by the BioFire JI Panel due to cross-reactivity.
- The Proteus assay can cross-react with an insect-associated species (*Cosenzaea myxofaciens*) that was formerly classified as *Proteus myxofaciens*.

Results Interpretation for Antimicrobial Resistance (AMR) Genes

The BioFire JI Panel contains assays for the specific detection of several genetic determinants of resistance to multiple classes of antibiotics found in select gram-positive bacteria (*mecA/C* and MREJ (MRSA) and *vanA/B*) or gram-negative bacteria (CTX-M, IMP, KPC, NDM, OXA-48-like, and VIM). Results for the AMR genes are not reported unless an applicable bacterium (Table 4) is also detected, therefore the results are based on multiple assays, as described below.

The results for each of the antimicrobial resistance genes will be listed as:

- Detected – when an applicable bacterium is detected AND the antimicrobial resistance gene assay(s) are positive.
- Not Detected – when an applicable bacterium is detected AND the antimicrobial resistance gene assay(s) are negative.
- N/A – when all applicable bacteria are Not Detected, regardless of the result for the antimicrobial resistance gene assay(s).

Table 4. Antimicrobial Resistance (AMR) Genes and Applicable Bacteria

BioFire JI Panel AMR Gene Result	*Enterococcus faecalis*	*Enterococcus faecium*	*Staphylococcus aureus*	*Staphylococcus lugdunensis*	*Citrobacter*	*Enterobacter cloacae* complex	*Escherichia coli*	*Klebsiella aerogenes*	*Klebsiella pneumoniae* group	*Morganella morganii*	*Proteus* spp.	*Pseudomonas aeruginosa*	*Salmonella* spp.	*Serratia marcescens*
vanA/B	×	×												
***mecA/C* and MREJ (MRSA)**			×											
CTX-M					×	×	×	×	×	×	×	×	×	×

BioFire JI Panel AMR Gene Result	*Enterococcus faecalis*	*Enterococcus faecium*	*Staphylococcus aureus*	*Staphylococcus lugdunensis*	*Citrobacter*	*Enterobacter cloacae complex*	*Escherichia coli*	*Klebsiella aerogenes*	*Klebsiella pneumoniae group*	*Morganella morganii*	*Proteus* spp.	*Pseudomonas aeruginosa*	*Salmonella* spp.	*Serratia marcescens*
IMP					×	×	×	×	×	×	×	×	×	×
KPC					×	×	×	×	×	×	×	×	×	×
NDM					×	×	×	×	×	×	×	×	×	×
OXA-48-like					×	×	×	×	×	X	×		×	×
VIM					×	×	×	×	×	×	×	×	×	×

NOTE: Antimicrobial resistance can occur via multiple mechanisms. A Not Detected result for a genetic marker of antimicrobial resistance does not indicate susceptibility to associated antimicrobial drugs or drug classes. A Detected result for a genetic marker of antimicrobial resistance cannot be definitively linked to the microorganism(s) detected. Culture is required to obtain isolates for antimicrobial susceptibility testing, and BioFire JI Panel results should be used in conjunction with culture results for the determination of susceptibility or resistance.

Information about the detection of specific AMR gene types is provided in the Analytical Reactivity (Inclusivity) section (Table 84 - Table 91). Overall, testing and analysis of available sequence data demonstrate that each AMR gene assay will detect the majority of AMR gene types. However, there are some types and variant sequences that may be amplified less efficiently or may not be detected (MREJ types xv, xviii, xix, and xx; CTX-M-74, CTX-M-75, CTX-M-113, and CTX-M-151; IMP-31, IMP-35, and IMP-46; OXA-54, OXA-416 and several OXA-48-like types that lack carbapenemase activity; VIM-7, VIM-39, VIM-45, VIM-46, VIM-61, VIM-65, and VIM-67).

Information on cross-reactivity of AMR gene assays is described in the Analytical Specificity (Cross-Reactivity) section (Table 93). Most AMR gene assays are specific for detection of the indicated AMR genes; however, cross-reactivity may be observed between AMR gene assays and related AMR genes (CTX-M with related *bla*$_{OXY}$, *bla*$_{RAHN}$, *bla*$_{KLU}$ genes or some *ampC* sequences and vanA/B with *vanM*).

Each AMR gene result is associated with a single corresponding AMR gene assay (with the exception of the *mecA/C* and MREJ (MRSA) result) and one or more assay(s) for the detection of applicable bacteria. Table 5 - Table 7 describe how to interpret results for AMR genes and applicable bacteria. Table 5 describes how to interpret the mecA/C and MREJ assays in conjunction with detection of *S. aureus* for the *mecA/C* and MREJ (MRSA) result, Table 6 describes how to interpret a *vanA/B* AMR gene result with corresponding detection of enterococci, and Table 7 gives an example of how to interpret the KPC AMR gene result with various corresponding gram-negative bacteria. All other AMR genes that are reported with gram-negative bacteria follow the same interpretation rules as indicated for KPC, according to the applicable bacteria indicated in Table 4.

mecA/C and MREJ (MRSA)

The *mecA/C* and MREJ (MRSA) result is intended to aid in the identification of methicillin-resistant *Staphylococcus aureus* (MRSA). When the Saureus1 and/or Saureus2 assay(s) are positive, the *mecA/C* and MREJ (MRSA) result will be reported as Detected or Not Detected based on whether the mecA/C and MREJa assays are positive or negative, respectively. If both Saureus1 and Saureus2 are negative, the *mecA/C* and MREJ (MRSA) results will be reported as N/A.

Table 5. Possible *mecA/C* and MREJ (MRSA) Results with Different Saureus, mecA/C, and MREJ Assay Combinations

BioFire JI Panel Test Result		Saureus1 assay	Saureus2 Assay	mecA/C assay	MREJa assay
Staphylococcus aureus *mecA/C* and MREJ (MRSA)	Not Detected N/A	Negative	Negative	Any Result	Any Result

BioFire JI Panel Test Result		Saureus1 assay	Saureus2 Assay	mecA/C assay	MREJa assay
Staphylococcus aureus mecA/C and MREJ (MRSA)	**Detected** **Detected**[a]	**Positive**	Any Result	**Positive**	**Positive**
Staphylococcus aureus mecA/C and MREJ (MRSA)	**Detected** **Detected**[a]	Any Result	**Positive**	**Positive**	**Positive**
Staphylococcus aureus mecA/C and MREJ (MRSA)	**Detected** Not Detected	**Positive**	Any Result	Negative	Negative
Staphylococcus aureus mecA/C and MREJ (MRSA)	**Detected** Not Detected	Any Result	**Positive**	Negative	Negative
Staphylococcus aureus mecA/C and MREJ (MRSA)	**Detected** Not Detected	**Positive**	Any Result	**Positive**	Negative
Staphylococcus aureus mecA/C and MREJ (MRSA)	**Detected** Not Detected	**Positive**	Any Result	Negative	**Positive**
Staphylococcus aureus mecA/C and MREJ (MRSA)	**Detected** Not Detected	Any Result	**Positive**	**Positive**	Negative
Staphylococcus aureus mecA/C and MREJ (MRSA)	**Detected** Not Detected	Any Result	**Positive**	Negative	**Positive**

[a] Subculturing and AST testing is required in order to assign a resistant and/or susceptible phenotype to isolates recovered from the sample.

vanA/B

The *vanA/B* result is intended to aid in the identification of vancomycin-resistant enterococci (VRE). When either or both *Enterococcus faecium* or *Enterococcus faecalis* are detected, the *vanA/B* result will be reported as Detected or Not Detected based on whether the vanA/B assay is positive or negative, respectively. If both the Efaecium and Efaecalis assays are negative, the *vanA/B* results will be reported as N/A.

Table 6 . Possible *vanA/B* Test Results with Different Efaecium, Efaecalis and vanA/B Assay Results

BioFire JI Panel Test Result		Efaecium assay	Efaecalis assay	vanA/B assay
Enterococcus faecium *Enterococcus faecalis* *vanA/B*	Not Detected Not Detected N/A	Negative	Negative	Any Result
Enterococcus faecium *Enterococcus faecalis* *vanA/B*	**Detected** Not Detected Not Detected	**Positive**	Negative	Negative
Enterococcus faecium *Enterococcus faecalis* *vanA/B*	Not Detected **Detected** Not Detected	Negative	**Positive**	Negative
Enterococcus faecium *Enterococcus faecalis* *vanA/B*	**Detected** **Detected** Not Detected	**Positive**	**Positive**	Negative
Enterococcus faecium *Enterococcus faecalis* *vanA/B*	**Detected** Not Detected **Detected**[a]	**Positive**	Negative	**Positive**
Enterococcus faecium *Enterococcus faecalis* *vanA/B*	Not Detected **Detected** **Detected**[a]	Negative	**Positive**	**Positive**
Enterococcus faecium *Enterococcus faecalis* *vanA/B*	**Detected** **Detected** **Detected** [a,b]	**Positive**	**Positive**	**Positive**

[a] Subculturing and AST testing is required in order to assign a resistant and/or susceptible phenotype to isolates recovered from the sample.
[b] It is not possible to determine which species the *vanA/B* gene is associated with.

CTX-M, IMP, KPC, NDM, OXA-48-like and VIM

Detection and reporting of AMR genes with select gram-negative bacteria is intended to aid in the identification of bacteria with resistance to various antibiotics. When one or more of the applicable bacteria are detected, the AMR gene result will be reported as Detected or Not Detected based on whether the AMR gene assay is positive or negative. If all the assays for applicable bacteria are negative, the AMR gene results will be reported as N/A. An example of various assay combinations and KPC reporting is provided in Table 7 and similar interpretation is applicable to the other AMR genes.

Table 7. Possible KPC Test Results with Different Combinations of KPC and Applicable Bacterial Assay Results (Example for Gram-Negative Antimicrobial Resistance Gene Result Interpretation)

BioFire JI Panel Test Results		Citrobacter assay	Ecloacae assay	Ecoli assay	Kaerogenes assay	Kpneumoniae assay	Mmorganii assay	Proteus assay	Paeruginosa assay	Salmonella assay	Smarcescens assay	KPC Assay	Description
Citrobacter	Not Detected	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Any result	No applicable bacteria detected in the sample KPC results not applicable
Enterobacter cloacae complex	Not Detected												
Escherichia coli	Not Detected												
Klebsiella aerogenes	Not Detected												
Klebsiella pneumoniae group	Not Detected												
Morganella morganii	Not Detected												
Proteus spp.	Not Detected												
Pseudomonas aeruginosa	Not Detected												
Salmonella spp.	Not Detected												
Serratia marcescens	Not Detected												
KPC	N/A												
Citrobacter	**Detected**	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Neg	Multiple gram-negative bacteria detected in the sample AND KPC not detected
***Enterobacter cloacae* complex**	**Detected**												
Escherichia coli	**Detected**												
Klebsiella aerogenes	**Detected**												
***Klebsiella pneumoniae* group**	**Detected**												
Morganella morganii	**Detected**												
***Proteus* spp.**	**Detected**												
Pseudomonas aeruginosa	**Detected**												
***Salmonella* spp.**	**Detected**												
Serratia marcescens	**Detected**												
KPC	Not Detected												
Citrobacter	**Detected**	Pos	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Pos	*Citrobacter* detected in the sample AND KPC detected
Enterobacter cloacae complex	Not Detected												
Escherichia coli	Not Detected												
Klebsiella aerogenes	Not Detected												
Klebsiella pneumoniae group	Not Detected												
Morganella morganii	Not Detected												
Proteus spp.	Not Detected												
Pseudomonas aeruginosa	Not Detected												
Salmonella spp.	Not Detected												
Serratia marcescens	Not Detected												
KPC	**Detected**												
Citrobacter	Not Detected	Neg	Pos	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Pos	One or more species of the *Enterobacter cloacae* complex detected in the sample AND KPC detected
***Enterobacter cloacae* complex**	**Detected**												
Escherichia coli	Not Detected												
Klebsiella aerogenes	Not Detected												
Klebsiella pneumoniae group	Not Detected												
Morganella morganii	Not Detected												
Proteus spp.	Not Detected												
Pseudomonas aeruginosa	Not Detected												
Salmonella spp.	Not Detected												
Serratia marcescens	Not Detected												
KPC	**Detected**												

BioFire JI Panel Test Results		Citrobacter assay	Ecloacae assay	Ecoli assay	Kaerogenes assay	Kpneumoniae assay	Mmorganii assay	Proteus assay	Paeruginosa assay	Salmonella assay	Smarcescens assay	KPC Assay	Description
Citrobacter	Not Detected	Neg	Neg	Pos	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Pos	*Escherichia coli* detected in the sample AND KPC detected
Enterobacter cloacae complex	Not Detected												
Escherichia coli	**Detected**												
Klebsiella aerogenes	Not Detected												
Klebsiella pneumoniae group	Not Detected												
Morganella morganii	Not Detected												
Proteus spp.	Not Detected												
Pseudomonas aeruginosa	Not Detected												
Salmonella spp.	Not Detected												
Serratia marcescens	Not Detected												
KPC	**Detected**												
Citrobacter	Not Detected	Neg	Neg	Neg	Pos	Neg	Neg	Neg	Neg	Neg	Neg	Pos	*Klebsiella aerogenes* detected in the sample AND KPC detected
Enterobacter cloacae complex	Not Detected												
Escherichia coli	Not Detected												
Klebsiella aerogenes	**Detected**												
Klebsiella pneumoniae group	Not Detected												
Morganella morganii	Not Detected												
Proteus spp.	Not Detected												
Pseudomonas aeruginosa	Not Detected												
Salmonella spp.	Not Detected												
Serratia marcescens	Not Detected												
KPC	**Detected**												
Citrobacter	Not Detected	Neg	Neg	Neg	Neg	Pos	Neg	Neg	Neg	Neg	Neg	Pos	One or more species in the *Klebsiella pneumoniae* group detected in the sample AND KPC detected
Enterobacter cloacae complex	Not Detected												
Escherichia coli	Not Detected												
Klebsiella aerogenes	Not Detected												
***Klebsiella pneumoniae* group**	**Detected**												
Morganella morganii	Not Detected												
Proteus spp.	Not Detected												
Pseudomonas aeruginosa	Not Detected												
Salmonella spp.	Not Detected												
Serratia marcescens	Not Detected												
KPC	**Detected**												
Citrobacter	Not Detected	Neg	Neg	Neg	Neg	Neg	Pos	Neg	Neg	Neg	Neg	Pos	*Morganella morganii* detected in the sample AND KPC detected
Enterobacter cloacae complex	Not Detected												
Escherichia coli	Not Detected												
Klebsiella aerogenes	Not Detected												
Klebsiella pneumoniae group	Not Detected												
Morganella morganii	**Detected**												
Proteus spp.	Not Detected												
Pseudomonas aeruginosa	Not Detected												
Salmonella spp.	Not Detected												
Serratia marcescens	Not Detected												
KPC	**Detected**												

BioFire JI Panel Test Results		Citrobacter assay	Ecloacae assay	Ecoli assay	Kaerogenes assay	Kpneumoniae assay	Mmorganii assay	Proteus assay	Paeruginosa assay	Salmonella assay	Smarcescens assay	KPC Assay	Description
Citrobacter	Not Detected	Neg	Neg	Neg	Neg	Neg	Neg	Pos	Neg	Neg	Neg	Pos	*Pseudomonas aeruginosa* detected in the sample AND KPC detected
Enterobacter cloacae complex	Not Detected												
Escherichia coli	Not Detected												
Klebsiella aerogenes	Not Detected												
Klebsiella pneumoniae group	Not Detected												
Morganella morganii	Not Detected												
***Proteus* spp.**	**Detected**												
Pseudomonas aeruginosa	Not Detected												
Salmonella spp.	Not Detected												
Serratia marcescens	Not Detected												
KPC	**Detected**												
Citrobacter	Not Detected	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Pos	Neg	Neg	Pos	One or more *Proteus* species detected in the sample AND KPC detected
Enterobacter cloacae complex	Not Detected												
Escherichia coli	Not Detected												
Klebsiella aerogenes	Not Detected												
Klebsiella pneumoniae group	Not Detected												
Morganella morganii	Not Detected												
Proteus spp.	Not Detected												
Pseudomonas aeruginosa	**Detected**												
Salmonella spp.	Not Detected												
Serratia marcescens	Not Detected												
KPC	**Detected**												
Citrobacter	Not Detected	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Pos	Neg	Pos	One or more *Salmonella* species detected in the sample AND KPC detected
Enterobacter cloacae complex	Not Detected												
Escherichia coli	Not Detected												
Klebsiella aerogenes	Not Detected												
Klebsiella pneumoniae group	Not Detected												
Morganella morganii	Not Detected												
Proteus spp.	Not Detected												
Pseudomonas aeruginosa	Not Detected												
***Salmonella* spp.**	**Detected**												
Serratia marcescens	Not Detected												
KPC	**Detected**												
Citrobacter	Not Detected	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Pos	Pos	*Serratia marcescens* detected in the sample AND KPC detected
Enterobacter cloacae complex	Not Detected												
Escherichia coli	Not Detected												
Klebsiella aerogenes	Not Detected												
Klebsiella pneumoniae group	Not Detected												
Morganella morganii	Not Detected												
Proteus spp.	Not Detected												
Pseudomonas aeruginosa	Not Detected												
Salmonella spp.	Not Detected												
Serratia marcescens	**Detected**												
KPC	**Detected**												

Results Interpretation for Yeast

The BioFire JI Panel pouch contains two assays for the detection of *Candida** species. One species-specific assay (Calbicans) is included for the detection of *Candida albicans*. The second assay (Candida) is designed to detect some of the most clinically relevant *Candida* species, including *C. albicans*, *C. dubliniensis*, *C. glabrata*, *C. krusei*, *C. parapsilosis, C. orthopsilosis, C. metapsilosis*, and *C. tropicalis*. Additional information about the detection of specific species or isolates of *Candida* yeast is provided in the Analytical Reactivity (Inclusivity) section (Table 82 – Table 83). Based on *in silico* analysis and empirical testing, each assay is specific with no known cross-reactivity (see Analytical Specificity (Cross-Reactivity) section (Table 93)).

The software integrates the results of the Candida and Calbicans assays into the *Candida* test result, while the result for the species-specific Calbicans assay will be reported independently. If either of the two assays are positive, the test results will be *Candida* Detected (and *Candida albicans* Detected or Not Detected) and if both assays are negative, the result will be *Candida* Not Detected and *Candida albicans* Not Detected, as shown in Table 8.

Table 8. Assay and Results Interpretation for the *Candida* and *Candida albicans* Test Results

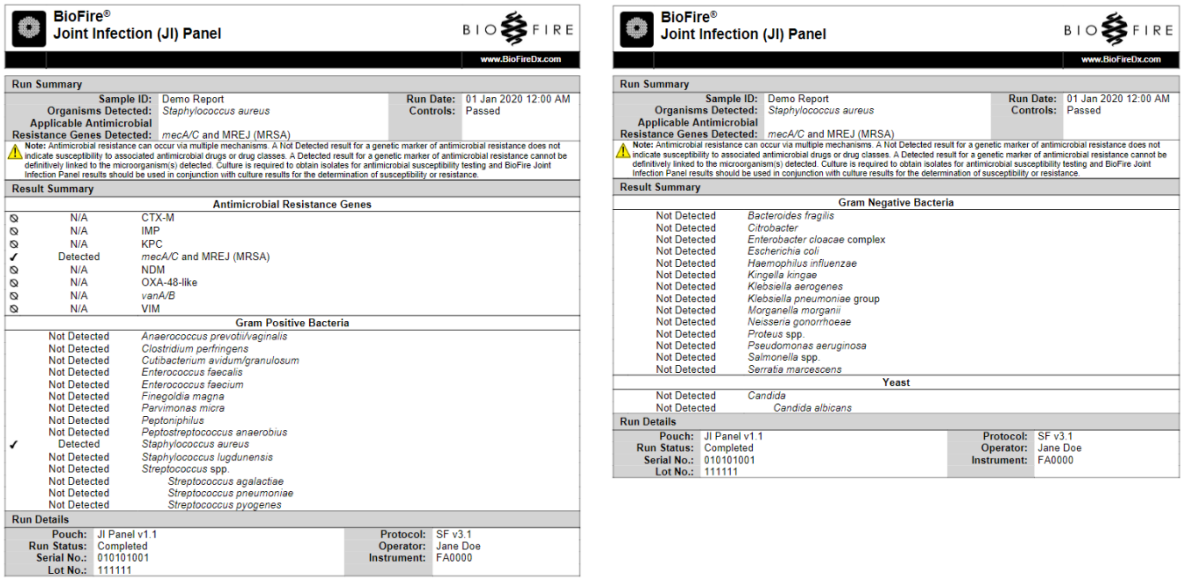
BioFire JI Panel Test Result		Candida assay	Calbicans assay
Candida *Candida albicans*	Not Detected Not Detected	Negative	Negative
Candida *Candida albicans*	**Detected** **Detected**	Any Result	**Positive**
Candida *Candida albicans*	**Detected** Not Detected	**Positive**	Negative

*Note: According to recent taxonomic revisions, several *Candida* species are now classified in different genera, including *Clavispora, Debaryomyces, Kluyveromyces, Meyerozyma, Nakaseomyces, Pichia, and Wickerhamomyces*.[169,170]

BioFire JI Panel Test Report

Atitiktis_4

The two-page BioFire JI Panel test report (Figure 1) is automatically displayed upon completion of a run and can be printed or saved as a PDF file. Each report contains a Run Summary, a Result Summary, and a Run Details section.



BioFire® Joint Infection (JI) Panel — www.BioFireDx.com

Run Summary

Sample ID:	Demo Report	Run Date:	01 Jan 2020 12:00 AM
Organisms Detected:	*Staphylococcus aureus*	Controls:	Passed
Applicable Antimicrobial Resistance Genes Detected:	*mecA/C* and MREJ (MRSA)		

Note: Antimicrobial resistance can occur via multiple mechanisms. A Not Detected result for a genetic marker of antimicrobial resistance does not indicate susceptibility to associated antimicrobial drugs or drug classes. A Detected result for a genetic marker of antimicrobial resistance cannot be definitively linked to the microorganism(s) detected. Culture is required to obtain isolates for antimicrobial susceptibility testing and BioFire Joint Infection Panel results should be used in conjunction with culture results for the determination of susceptibility or resistance.

Result Summary

Antimicrobial Resistance Genes	
N/A	CTX-M
N/A	IMP
N/A	KPC
Detected	*mecA/C* and MREJ (MRSA)
N/A	NDM
N/A	OXA-48-like
N/A	*vanA/B*
N/A	VIM

Gram Positive Bacteria	
Not Detected	*Anaerococcus prevotii/vaginalis*
Not Detected	*Clostridium perfringens*
Not Detected	*Cutibacterium avidum/granulosum*
Not Detected	*Enterococcus faecalis*
Not Detected	*Enterococcus faecium*
Not Detected	*Finegoldia magna*
Not Detected	*Parvimonas micra*
Not Detected	*Peptoniphilus*
Not Detected	*Peptostreptococcus anaerobius*
Detected	*Staphylococcus aureus*
Not Detected	*Staphylococcus lugdunensis*
Not Detected	*Streptococcus* spp.
Not Detected	*Streptococcus agalactiae*
Not Detected	*Streptococcus pneumoniae*
Not Detected	*Streptococcus pyogenes*

Run Details

Pouch:	JI Panel v1.1	Protocol:	SF v3.1
Run Status:	Completed	Operator:	Jane Doe
Serial No.:	010101001	Instrument:	FA0000
Lot No.:	111111		

BioFire® Joint Infection (JI) Panel — www.BioFireDx.com

Run Summary

Sample ID:	Demo Report	Run Date:	01 Jan 2020 12:00 AM
Organisms Detected:	*Staphylococcus aureus*	Controls:	Passed
Applicable Antimicrobial Resistance Genes Detected:	*mecA/C* and MREJ (MRSA)		

Note: Antimicrobial resistance can occur via multiple mechanisms. A Not Detected result for a genetic marker of antimicrobial resistance does not indicate susceptibility to associated antimicrobial drugs or drug classes. A Detected result for a genetic marker of antimicrobial resistance cannot be definitively linked to the microorganism(s) detected. Culture is required to obtain isolates for antimicrobial susceptibility testing and BioFire Joint Infection Panel results should be used in conjunction with culture results for the determination of susceptibility or resistance.

Result Summary

Gram Negative Bacteria	
Not Detected	*Bacteroides fragilis*
Not Detected	*Citrobacter*
Not Detected	*Enterobacter cloacae* complex
Not Detected	*Escherichia coli*
Not Detected	*Haemophilus influenzae*
Not Detected	*Kingella kingae*
Not Detected	*Klebsiella aerogenes*
Not Detected	*Klebsiella pneumoniae* group
Not Detected	*Morganella morganii*
Not Detected	*Neisseria gonorrhoeae*
Not Detected	*Proteus* spp.
Not Detected	*Pseudomonas aeruginosa*
Not Detected	*Salmonella* spp.
Not Detected	*Serratia marcescens*

Yeast	
Not Detected	*Candida*
Not Detected	*Candida albicans*

Run Details

Pouch:	JI Panel v1.1	Protocol:	SF v3.1
Run Status:	Completed	Operator:	Jane Doe
Serial No.:	010101001	Instrument:	FA0000
Lot No.:	111111		

Figure 1. BioFire JI Panel Example Test Report (Page 1 – on left; Page 2 – on right)

Run Summary

The **Run Summary** section of the test report provides the Sample ID, time and date of the run, control results and an overall summary of the test results. Any organism with a Detected result will be listed in the corresponding field of the summary. If all of the organism assays were negative then 'None' will be displayed in the Organisms Detected field. If an organism was detected and an applicable antimicrobial resistance gene assay was positive, the applicable antimicrobial resistance gene will be listed as Detected in the corresponding field of the summary. If all of the applicable antimicrobial resistance gene assays were negative then 'None' will be displayed in the Applicable Antimicrobial Resistance Genes Detected field. Controls are listed as Passed, Failed, or Invalid. Table 9 provides additional information for each of the possible control field results.

Table 9. Interpretation of Controls Field on the BioFire JI Panel Test Report

Control Result	Explanation	Action
Passed	The run was successfully completed AND Both pouch controls were successful.	None. 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 the Run Status field in the Run Details section of the report. Refer to the appropriate BioFire 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, if available.

Result Summary

The **Result Summary** section of the test report lists the result for each target tested by the panel. Possible results for each organism are Detected, Not Detected, or Invalid. Possible results for each antimicrobial resistance gene are Detected, Not Detected, N/A, or Invalid. Table 10 provides an explanation for each interpretation and any follow-up necessary to obtain a final result.

Table 10. Reporting of Results and Required Actions

Result	Explanation	Action
Detected[a]	The run was successfully completed AND The pouch controls were successful (Passed) AND The assay(s) for the organism (or antimicrobial resistance gene) were POSITIVE[a]	Report results.
Not Detected	The run was successfully completed AND The pouch controls were successful (Passed) AND The assay(s) for the organism (or antimicrobial resistance gene) were NEGATIVE	Report results.
Invalid	The pouch controls were not successful (Failed) OR The run did not complete successfully (Run Status displayed as: Aborted, Incomplete, Instrument Error, or Software Error)	See Table 9 for instruction.
N/A (Antimicrobial Resistance Genes only)	The run was successfully completed AND The pouch controls were successful (Passed) AND The assay(s) for the organism(s) that are applicable to the antimicrobial resistance gene were NEGATIVE so the results of the antimicrobial resistance gene are not applicable to the test results.	Report Results

[a] If four or more organisms are detected in a specimen, retesting is recommended to confirm the polymicrobial result.

Run Details

The **Run Details** section provides additional information about the run including: pouch information (type, lot number, and serial number), Run Status (Completed, Incomplete, Aborted, Instrument Error, or Software Error), the protocol that was used to perform the test, the identity of the operator that performed the test, and the instrument used to perform the test.

Change Summary

It is possible to edit the Sample ID once a run has completed. If this information has been changed, an additional section called **Change Summary** will be added to the test report. This Change Summary section lists the field that was changed, the revised entry, the original entry, the operator that made the change, and the date that the change was made. Sample ID is the only field of the report that can be changed.

Change Summary				
Field	**Changed To**	**Changed From**	**Operator**	**Date**
[1]Sample ID	New Example Id	Old Example Id	Anonymous	06 Apr 2020

LIMITATIONS

1. For prescription use only.
2. BioFire JI Panel performance has only been established on the BioFire FilmArray 2.0 and BioFire FilmArray Torch systems.
3. The BioFire JI Panel is a qualitative test and does not provide a quantitative value for the organism(s) or antimicrobial resistance genes detected in the specimen.
4. Results from this test must be correlated with clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
5. The BioFire JI Panel is intended to be used in conjunction with clinical history, signs and symptoms, and results of other diagnostic tests, including culture and anti-microbial susceptibility testing.
6. The performance of the BioFire JI Panel has been evaluated for use with human specimen material only.
7. The BioFire JI Panel has not been validated for testing of specimens other than synovial fluid specimens.
8. The performance of BioFire JI Panel has not been established for testing of homogenized human tissue nor sonicated or vortexed prostheses.
9. The BioFire JI Panel is not intended for use with synovial fluid in media. Media/broths may contain contaminating nucleic acids (bioburden) that can generate false positive results.
10. The performance of BioFire JI Panel has not been established for pooled synovial fluid specimens.
11. The performance of BioFire JI Panel has not been established for specimens collected from individuals without signs or symptoms of a joint infection.
12. The performance of the BioFire JI Panel has not been specifically evaluated for synovial fluid specimens from immunocompromised individuals.
13. The performance of the BioFire JI Panel has not been specifically evaluated for synovial fluid specimens collected from patients being treated with antibiotics.
14. The performance of the BioFire JI Panel has not been established for monitoring treatment of infection with any of the panel organisms.
15. If four or more organisms are detected in a specimen, retesting is recommended to confirm the polymicrobial result.
16. Bacterial and yeast nucleic acids may persist in vivo independent of organism viability. Detection of organism nucleic acid does not imply that the corresponding organisms are infectious or are the causative agents for clinical symptoms.
17. The detection of bacterial, yeast, and antimicrobial resistance gene nucleic acid is dependent upon proper sample collection, handling, transportation, and storage. Failure to observe proper procedures in any one of these steps can lead to incorrect results. There is a risk of false positive or false negative results from improperly collected, transported, or handled samples.
18. There is a risk of false positive results due to cross-contamination by target organisms, their nucleic acids or amplified product, or from non-specific signals in the assay. Particular attention should be given to the Laboratory Precautions noted under the Warnings and Precautions section.
19. Discrepancies between the BioFire JI Panel test result and other microbial identification methods may be due to the inability to reliably differentiate closely related species using standard phenotypic microbial identification methods or the design of other molecular assays.
20. False positive and false negative results can be the result of a variety of sources and causes; it is important that

results be used in conjunction with other clinical, epidemiological, or laboratory information.

21. Negative results do not exclude the possibility of infection and should not be used as the sole basis for diagnosis, treatment, or other management decisions. Negative test results may be due to sequence variants in the region targeted by the assay, the presence of inhibitors in the sample, technical error, or sample mix-up. See the Analytical Reactivity (Inclusivity) section for known sequence variation predicted to impact detection by the panel. Negative results may also be due to infection with organism(s) not identified by the BioFire JI Panel or due to an organism concentration in the sample that is below the limit of detection for the test. Organism levels may be influenced by concurrent antibacterial/antifungal therapy, which could lead to organism levels below the limit of detection for the test.
22. The results for the antimicrobial resistance gene assays do not specifically link the resistance gene to the applicable bacteria detected. In polymicrobial specimens, the resistance gene may be associated with any of the applicable bacteria detected or an organism that was not detected by the panel.
23. Antimicrobial resistance can occur via multiple mechanisms. A Not Detected result for the antimicrobial resistance gene assays does not indicate antimicrobial susceptibility. Subculturing and standard susceptibility testing of isolates are required to determine antimicrobial susceptibility.
24. Borderline oxacillin-resistant *Staphylococcus aureus* (BORSA) and moderately resistant *S. aureus* (MODSA) strains demonstrate reduced susceptibility to oxacillin due to hyperproduction of β-lactamases or modification of penicillin-binding proteins respectively. BORSA and MODSA strains do not contain the *mecA* or *mecC* gene. A *mecA/C* and MREJ (MRSA) Not Detected result will be reported by the BioFire JI Panel for these strains.
25. Cross-reactivity or non-specific amplification may lead to erroneous (false positive) results. Testing and sequence analysis has confirmed that some BioFire JI Panel assays can cross-react with closely related or near-neighbor species or antimicrobial resistance genes. Confirmed or predicted cross-reactivity is identified in Table 93 in the Analytical Specificity (Cross-Reactivity) section. Additional cross-reactivity with organisms or antimicrobial resistance genes other than those listed in the Analytical Specificity (Cross-Reactivity) section may be identified and could lead to erroneous results.
26. The potential for erroneous results due to interference from substances or competing microorganisms has only been evaluated for those listed in Table 95 in the Interference section. Interference or inhibition from substances or concentrations other than those described in the Interference section could lead to erroneous results.
27. Due to the small number of positive specimens collected for certain organisms during the prospective clinical study, performance characteristics for several analytes were primarily established using archived and/or contrived specimens as detailed in the Clinical Performance section.

EXPECTED VALUES

In the prospective clinical evaluation of the BioFire JI Panel, 1544 synovial fluid (SF) specimens were collected and tested at 13 study sites across the United States and Europe over approximately two years (May 2018 to March 2020). Expected values (as determined by the BioFire JI Panel) are stratified by enrollment site in Table 11. Expected values are stratified by subject age, SF collection method, and presence/absence of a prosthesis in Table 12 through Table 14, respectively.

Table 11. Expected Value (As Determined by BioFire JI Panel) Summary by Site for SF Specimens Collected During the BioFire JI Panel Prospective Clinical Evaluation (May 2018 to March 2020)

BioFire JI Panel Result	Overall (N=1544)		Site 1 (N=352)		Site 2 (N=88)		Site 3 (N=201)		Site 4 (N=89)		Site 5 (N=102)		Site 6 (N=87)		Site 7 (N=197)		Site 8 (N=66)		Site 9 (N=146)		Site 10 (N=136)		Site 11 (N=17)		Site 12 (N=49)		Site 13 (N=14)	
	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV
Gram-Positive Bacteria																												
Anaerococcus prevotii/vaginalis	***1***	*0.1%*	0	0%	0	0%	1	0.5%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Clostridium perfringens	***0***	*0%*	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Cutibacterium avidum/granulosum	***0***	*0%*	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Enterococcus faecalis	***15***	*1.0%*	4	1.1%	0	0%	6	3.0%	0	0%	0	0%	1	1.1%	1	0.5%	1	1.5%	2	1.4%	0	0%	0	0%	0	0%	0	0%
Enterococcus faecium	***3***	*0.2%*	1	0.3%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	1	1.5%	1	0.7%	0	0%	0	0%	0	0%	0	0%
Finegoldia magna	***4***	*0.3%*	0	0%	0	0%	2	1.0%	0	0%	0	0%	0	0%	1	0.5%	1	1.5%	0	0%	0	0%	0	0%	0	0%	0	0%
Parvimonas micra	***0***	*0%*	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Peptoniphilus	***2***	*0.1%*	0	0%	0	0%	1	0.5%	0	0%	0	0%	1	1.1%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Peptostreptococcus anaerobius	***3***	*0.2%*	1	0.3%	0	0%	1	0.5%	0	0%	0	0%	0	0%	0	0%	0	0%	1	0.7%	0	0%	0	0%	0	0%	0	0%
Staphylococcus aureus	***120***	*7.8%*	19	5.4%	8	9.1%	16	8.0%	4	4.5%	13	12.7%	20	23.0%	6	3.0%	3	4.5%	12	8.2%	4	2.9%	3	17.6%	9	18.4%	3	21.4%
Staphylococcus lugdunensis	***5***	*0.3%*	0	0%	0	0%	3	1.5%	0	0%	0	0%	1	1.1%	0	0%	0	0%	1	0.7%	0	0%	0	0%	0	0%	0	0%
Streptococcus spp.	***50***	*3.2%*	6	1.7%	6	6.8%	3	1.5%	3	3.4%	7	6.9%	9	10.3%	4	2.0%	3	4.5%	4	2.7%	2	1.5%	1	5.9%	1	2.0%	1	7.1%
Streptococcus agalactiae	***11***	*0.7%*	0	0%	2	2.3%	1	0.5%	1	1.1%	0	0%	1	1.1%	2	1.0%	1	1.5%	2	1.4%	1	0.7%	0	0%	0	0%	0	0%
Streptococcus pneumoniae	***3***	*0.2%*	1	0.3%	0	0%	0	0%	0	0%	1	1.0%	1	1.1%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Streptococcus pyogenes	***11***	*0.7%*	2	0.6%	1	1.1%	0	0%	2	2.2%	0	0%	1	1.1%	0	0%	2	3.0%	0	0%	0	0%	1	5.9%	1	2.0%	1	7.1%

BioFire JI Panel Result	Overall (N=1544)		Site 1 (N=352)		Site 2 (N=88)		Site 3 (N=201)		Site 4 (N=89)		Site 5 (N=102)		Site 6 (N=87)		Site 7 (N=197)		Site 8 (N=66)		Site 9 (N=146)		Site 10 (N=136)		Site 11 (N=17)		Site 12 (N=49)		Site 13 (N=14)	
	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV
Gram-Negative Bacteria																												
Bacteroides fragilis	***1***	*0.1%*	1	0.3%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Citrobacter	***2***	*0.1%*	0	0%	0	0%	0	0%	0	0%	0	0%	1	1.1%	1	0.5%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Enterobacter cloacae complex	***4***	*0.3%*	1	0.3%	0	0%	0	0%	0	0%	0	0%	1	1.1%	1	0.5%	0	0%	1	0.7%	0	0%	0	0%	0	0%	0	0%
Escherichia coli	***15***	*1.0%*	3	0.9%	1	1.1%	4	2.0%	0	0%	1	1.0%	5	5.7%	0	0%	0	0%	1	0.7%	0	0%	0	0%	0	0%	0	0%
Haemophilus influenzae	***2***	*0.1%*	1	0.3%	0	0%	0	0%	0	0%	0	0%	1	1.1%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Kingella kingae	***7***	*0.5%*	1	0.3%	0	0%	1	0.5%	0	0%	1	1.0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	4	8.2%	0	0%
Klebsiella aerogenes	***0***	*0%*	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Klebsiella pneumoniae group	***5***	*0.3%*	0	0%	0	0%	1	0.5%	0	0%	1	1.0%	3	3.4%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Morganella morganii	***3***	*0.2%*	0	0%	0	0%	1	0.5%	0	0%	0	0%	2	2.3%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Neisseria gonorrhoeae	***5***	*0.3%*	2	0.6%	0	0%	0	0%	2	2.2%	0	0%	1	1.1%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Proteus spp.	***8***	*0.5%*	1	0.3%	0	0%	5	2.5%	0	0%	0	0%	2	2.3%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Pseudomonas aeruginosa	***5***	*0.3%*	1	0.3%	0	0%	2	1.0%	0	0%	0	0%	0	0%	1	0.5%	0	0%	1	0.7%	0	0%	0	0%	0	0%	0	0%
Salmonella spp.	***0***	*0%*	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Serratia marcescens	***3***	*0.2%*	1	0.3%	0	0%	0	0%	0	0%	0	0%	1	1.1%	0	0%	0	0%	1	0.7%	0	0%	0	0%	0	0%	0	0%
AMR Genes																												
CTX-M	***5***	*0.3%*	0	0%	0	0%	0	0%	0	0%	1	1.0%	4	4.6%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
IMP	***0***	*0%*	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
KPC	***0***	*0%*	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
mecA/C and MREJ (MRSA)	***23***	*1.5%*	4	1.1%	3	3.4%	0	0%	0	0%	0	0%	4	4.6%	0	0%	1	1.5%	6	4.1%	2	1.5%	0	0%	2	4.1%	1	7.1%
NDM	***0***	*0%*	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
OXA-48-like	***1***	*0.1%*	0	0%	0	0%	0	0%	0	0%	0	0%	1	1.1%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
vanA/B	***3***	*0.2%*	1	0.3%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	1	1.5%	1	0.7%	0	0%	0	0%	0	0%	0	0%

BioFire JI Panel Result	Overall (N=1544)		Site 1 (N=352)		Site 2 (N=88)		Site 3 (N=201)		Site 4 (N=89)		Site 5 (N=102)		Site 6 (N=87)		Site 7 (N=197)		Site 8 (N=66)		Site 9 (N=146)		Site 10 (N=136)		Site 11 (N=17)		Site 12 (N=49)		Site 13 (N=14)	
	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV
VIM	***0***	*0%*	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Yeast																												
Candida	***5***	*0.3%*	0	0%	1	1.1%	3	1.5%	0	0%	0	0%	0	0%	0	0%	0	0%	1	0.7%	0	0%	0	0%	0	0%	0	0%
Candida albicans	***3***	*0.2%*	0	0%	0	0%	2	1.0%	0	0%	0	0%	0	0%	0	0%	0	0%	1	0.7%	0	0%	0	0%	0	0%	0	0%

Table 12. Expected Value (As Determined by BioFire JI Panel) Summary by Age Group for SF Specimens Collected During the BioFire JI Panel Prospective Clinical Evaluation (May 2018 to March 2020)

BioFire JI Panel Result	Overall (N=1544)		<91 Days (N=1)		91 days - 4 years (N=22)		5 - 15 years (N=75)		16 - 25 years (N=35)		26 - 64 years (N=774)		65+ years (N=637)	
	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV
Gram-Positive Bacteria														
Anaerococcus prevotii/vaginalis	***1***	*0.1%*	0	0%	0	0%	0	0%	0	0%	0	0%	1	0.2%
Clostridium perfringens	***0***	*0%*	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Cutibacterium avidum/granulosum	***0***	*0%*	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Enterococcus faecalis	***15***	*1.0%*	0	0%	0	0%	0	0%	0	0%	3	0.4%	12	1.9%
Enterococcus faecium	***3***	*0.2%*	0	0%	0	0%	0	0%	0	0%	3	0.4%	0	0%
Finegoldia magna	***4***	*0.3%*	0	0%	0	0%	0	0%	0	0%	2	0.3%	2	0.3%
Parvimonas micra	***0***	*0%*	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Peptoniphilus	***2***	*0.1%*	0	0%	0	0%	0	0%	0	0%	1	0.1%	1	0.2%
Peptostreptococcus anaerobius	***3***	*0.2%*	0	0%	0	0%	0	0%	0	0%	2	0.3%	1	0.2%
Staphylococcus aureus	***120***	*7.8%*	1	100%	2	9.1%	15	20.0%	2	5.7%	53	6.8%	47	7.4%
Staphylococcus lugdunensis	***5***	*0.3%*	0	0%	0	0%	0	0%	0	0%	3	0.4%	2	0.3%
Streptococcus spp.	***50***	*3.2%*	0	0%	1	4.5%	4	5.3%	0	0%	17	2.2%	28	4.4%
Streptococcus agalactiae	***11***	*0.7%*	0	0%	0	0%	0	0%	0	0%	4	0.5%	7	1.1%
Streptococcus pneumoniae	***3***	*0.2%*	0	0%	0	0%	0	0%	0	0%	2	0.3%	1	0.2%
Streptococcus pyogenes	***11***	*0.7%*	0	0%	1	4.5%	4	5.3%	0	0%	6	0.8%	0	0%
Gram-Negative Bacteria														
Bacteroides fragilis	***1***	*0.1%*	0	0%	0	0%	0	0%	0	0%	1	0.1%	0	0%
Citrobacter	***2***	*0.1%*	0	0%	0	0%	0	0%	0	0%	0	0%	2	0.3%
Enterobacter cloacae complex	***4***	*0.3%*	0	0%	0	0%	0	0%	0	0%	3	0.4%	1	0.2%
Escherichia coli	***15***	*1.0%*	0	0%	1	4.5%	0	0%	0	0%	7	0.9%	7	1.1%

BioFire JI Panel Result	Overall (N=1544)		<91 Days (N=1)		91 days - 4 years (N=22)		5 - 15 years (N=75)		16 - 25 years (N=35)		26 - 64 years (N=774)		65+ years (N=637)	
	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV	#	EV
Haemophilus influenzae	***2***	*0.1%*	0	0%	0	0%	0	0%	0	0%	2	0.3%	0	0%
Kingella kingae	***7***	*0.5%*	0	0%	6	27.3%	0	0%	0	0%	1	0.1%	0	0%
Klebsiella aerogenes	***0***	*0%*	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Klebsiella pneumoniae group	***5***	*0.3%*	0	0%	0	0%	0	0%	0	0%	0	0%	5	0.8%
Morganella morganii	***3***	*0.2%*	0	0%	0	0%	0	0%	0	0%	0	0%	3	0.5%
Neisseria gonorrhoeae	***5***	*0.3%*	0	0%	0	0%	0	0%	0	0%	5	0.6%	0	0%
Proteus spp.	***8***	*0.5%*	0	0%	0	0%	1	1.3%	0	0%	1	0.1%	6	0.9%
Pseudomonas aeruginosa	***5***	*0.3%*	0	0%	0	0%	0	0%	0	0%	1	0.1%	4	0.6%
Salmonella spp.	***0***	*0%*	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Serratia marcescens	***3***	*0.2%*	0	0%	0	0%	0	0%	0	0%	1	0.1%	2	0.3%
AMR Genes														
CTX-M	***5***	*0.3%*	0	0%	0	0%	0	0%	0	0%	0	0%	5	0.8%
IMP	***0***	*0%*	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
KPC	***0***	*0%*	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
mecA/C and MREJ (MRSA)	***23***	*1.5%*	0	0%	0	0%	3	4.0%	0	0%	11	1.4%	9	1.4%
NDM	***0***	*0%*	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
OXA-48-like	***1***	*0.1%*	0	0%	0	0%	0	0%	0	0%	0	0%	1	0.2%
vanA/B	***3***	*0.2%*	0	0%	0	0%	0	0%	0	0%	3	0.4%	0	0%
VIM	***0***	*0%*	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Yeast														
Candida	***5***	*0.3%*	0	0%	0	0%	0	0%	0	0%	1	0.1%	4	0.6%
Candida albicans	***3***	*0.2%*	0	0%	0	0%	0	0%	0	0%	1	0.1%	2	0.3%

Table 13. Expected Value (As Determined by BioFire JI Panel) Summary by Collection Method for SF Specimens Collected During the BioFire JI Panel Prospective Clinical Evaluation (May 2018 to March 2020)

BioFire JI Panel Result	Overall (N=1544)		Intraoperative (N=295)		Arthrocentesis (N=1226)		Unknown (N=23)	
	#	EV	#	EV	#	EV	#	EV
Gram-Positive Bacteria								
Anaerococcus prevotii/vaginalis	***1***	*0.1%*	1	0.3%	0	0%	0	0%
Clostridium perfringens	***0***	*0%*	0	0%	0	0%	0	0%
Cutibacterium avidum/granulosum	***0***	*0%*	0	0%	0	0%	0	0%
Enterococcus faecalis	***15***	*1.0%*	8	2.7%	6	0.5%	1	4.3%
Enterococcus faecium	***3***	*0.2%*	0	0%	3	0.2%	0	0%
Finegoldia magna	***4***	*0.3%*	2	0.7%	2	0.2%	0	0%
Parvimonas micra	***0***	*0%*	0	0%	0	0%	0	0%
Peptoniphilus	***2***	*0.1%*	2	0.7%	0	0%	0	0%
Peptostreptococcus anaerobius	***3***	*0.2%*	1	0.3%	2	0.2%	0	0%
Staphylococcus aureus	***120***	*7.8%*	38	12.9%	80	6.5%	2	8.7%
Staphylococcus lugdunensis	***5***	*0.3%*	2	0.7%	3	0.2%	0	0%
Streptococcus spp.	***50***	*3.2%*	16	5.4%	33	2.7%	1	4.3%
Streptococcus agalactiae	***11***	*0.7%*	6	2.0%	5	0.4%	0	0%
Streptococcus pneumoniae	***3***	*0.2%*	0	0%	2	0.2%	1	4.3%
Streptococcus pyogenes	***11***	*0.7%*	0	0%	10	0.8%	1	4.3%
Gram-Negative Bacteria								
Bacteroides fragilis	***1***	*0.1%*	0	0%	1	0.1%	0	0%
Citrobacter	***2***	*0.1%*	0	0%	2	0.2%	0	0%
Enterobacter cloacae complex	***4***	*0.3%*	1	0.3%	2	0.2%	1	4.3%
Escherichia coli	***15***	*1.0%*	9	3.1%	6	0.5%	0	0%
Haemophilus influenzae	***2***	*0.1%*	1	0.3%	0	0%	1	4.3%
Kingella kingae	***7***	*0.5%*	4	1.4%	2	0.2%	1	4.3%
Klebsiella aerogenes	***0***	*0%*	0	0%	0	0%	0	0%
Klebsiella pneumoniae group	***5***	*0.3%*	3	1.0%	2	0.2%	0	0%
Morganella morganii	***3***	*0.2%*	3	1.0%	0	0%	0	0%
Neisseria gonorrhoeae	***5***	*0.3%*	0	0%	5	0.4%	0	0%
Proteus spp.	***8***	*0.5%*	5	1.7%	3	0.2%	0	0%
Pseudomonas aeruginosa	***5***	*0.3%*	2	0.7%	3	0.2%	0	0%
Salmonella spp.	***0***	*0%*	0	0%	0	0%	0	0%
Serratia marcescens	***3***	*0.2%*	2	0.7%	1	0.1%	0	0%
AMR Genes								
CTX-M	***5***	*0.3%*	2	0.7%	3	0.2%	0	0%
IMP	***0***	*0%*	0	0%	0	0%	0	0%
KPC	***0***	*0%*	0	0%	0	0%	0	0%
mecA/C and MREJ (MRSA)	***23***	*1.5%*	9	3.1%	14	1.1%	0	0%
NDM	***0***	*0%*	0	0%	0	0%	0	0%
OXA-48-like	***1***	*0.1%*	1	0.3%	0	0%	0	0%
vanA/B	***3***	*0.2%*	0	0%	3	0.2%	0	0%
VIM	***0***	*0%*	0	0%	0	0%	0	0%
Yeast								
Candida	***5***	*0.3%*	4	1.4%	1	0.1%	0	0%
Candida albicans	***3***	*0.2%*	3	1.0%	0	0%	0	0%

Table 14. Expected Value (As Determined by BioFire JI Panel) Summary by Presence or Absence of a Prosthesis for SF Specimens Collected During the BioFire JI Panel Prospective Clinical Evaluation (May 2018 to March 2020)

BioFire JI Panel Result	Overall (N=1544)		Prosthesis (N=442)		Native (N=850)		Unknown (N=252)	
	#	EV	#	EV	#	EV	#	EV
Gram-Positive Bacteria								
Anaerococcus prevotii/vaginalis	***1***	*0.1%*	1	0.2%	0	0%	0	0%
Clostridium perfringens	***0***	*0%*	0	0%	0	0%	0	0%
Cutibacterium avidum/granulosum	***0***	*0%*	0	0%	0	0%	0	0%
Enterococcus faecalis	***15***	*1.0%*	8	1.8%	5	0.6%	2	0.8%
Enterococcus faecium	***3***	*0.2%*	0	0%	3	0.4%	0	0%
Finegoldia magna	***4***	*0.3%*	3	0.7%	0	0%	1	0.4%
Parvimonas micra	***0***	*0%*	0	0%	0	0%	0	0%
Peptoniphilus	***2***	*0.1%*	2	0.5%	0	0%	0	0%
Peptostreptococcus anaerobius	***3***	*0.2%*	1	0.2%	2	0.2%	0	0%
Staphylococcus aureus	***120***	*7.8%*	56	12.7%	56	6.6%	8	3.2%
Staphylococcus lugdunensis	***5***	*0.3%*	2	0.5%	3	0.4%	0	0%
Streptococcus spp.	***50***	*3.2%*	25	5.7%	21	2.5%	4	1.6%
Streptococcus agalactiae	***11***	*0.7%*	7	1.6%	2	0.2%	2	0.8%
Streptococcus pneumoniae	***3***	*0.2%*	0	0%	2	0.2%	1	0.4%
Streptococcus pyogenes	***11***	*0.7%*	2	0.5%	8	0.9%	1	0.4%
Gram-Negative Bacteria								
Bacteroides fragilis	***1***	*0.1%*	0	0%	1	0.1%	0	0%
Citrobacter	***2***	*0.1%*	0	0%	1	0.1%	1	0.4%
Enterobacter cloacae complex	***4***	*0.3%*	0	0%	2	0.2%	2	0.8%
Escherichia coli	***15***	*1.0%*	7	1.6%	8	0.9%	0	0%
Haemophilus influenzae	***2***	*0.1%*	0	0%	1	0.1%	1	0.4%
Kingella kingae	***7***	*0.5%*	0	0%	6	0.7%	1	0.4%
Klebsiella aerogenes	***0***	*0%*	0	0%	0	0%	0	0%
Klebsiella pneumoniae group	***5***	*0.3%*	4	0.9%	1	0.1%	0	0%
Morganella morganii	***3***	*0.2%*	3	0.7%	0	0%	0	0%
Neisseria gonorrhoeae	***5***	*0.3%*	0	0%	5	0.6%	0	0%
Proteus spp.	***8***	*0.5%*	6	1.4%	2	0.2%	0	0%
Pseudomonas aeruginosa	***5***	*0.3%*	4	0.9%	1	0.1%	0	0%
Salmonella spp.	***0***	*0%*	0	0%	0	0%	0	0%
Serratia marcescens	***3***	*0.2%*	3	0.7%	0	0%	0	0%
AMR Genes								
CTX-M	***5***	*0.3%*	3	0.7%	2	0.2%	0	0%
IMP	***0***	*0%*	0	0%	0	0%	0	0%
KPC	***0***	*0%*	0	0%	0	0%	0	0%
mecA/C and MREJ (MRSA)	***23***	*1.5%*	12	2.7%	11	1.3%	0	0%
NDM	***0***	*0%*	0	0%	0	0%	0	0%
OXA-48-like	***1***	*0.1%*	1	0.2%	0	0%	0	0%
vanA/B	***3***	*0.2%*	0	0%	3	0.4%	0	0%
VIM	***0***	*0%*	0	0%	0	0%	0	0%

BioFire JI Panel Result	Overall (N=1544)		Prosthesis (N=442)		Native (N=850)		Unknown (N=252)	
	#	EV	#	EV	#	EV	#	EV
Yeast								
Candida	***5***	*0.3%*	4	0.9%	1	0.1%	0	0%
Candida albicans	***3***	*0.2%*	2	0.5%	1	0.1%	0	0%

In addition, the observed multiple detections (as determined by the BioFire JI Panel) during the prospective clinical evaluation are presented in Table 15. At least one organism was detected in a total of 242 SF specimens (15.7% positivity rate; 242/1544). Polymicrobial detections of up to seven organisms were observed.

Table 15. Expected Values (Multiple Detections as Determined by the BioFire JI Panel) for the BioFire JI Panel Clinical Evaluation (May 2018 to March 2020)

BioFire JI Panel Organism Result	Expected Value (as determined by testing of 1544 prospective SF specimens)	
	Number Detected and Reported	% of Total (% of Positives)
Detected (at least one result)	242	15.7% (100%)
One organism result	226	14.6% (93.4%)
Two organism results	12	0.8% (5.0%)
Three organism results	2	0.1% (0.8%)
More than three organism results	2[a]	0.1% (0.8%)

[a] One specimen had six organisms and one specimen has seven organisms observed

The BioFire JI Panel reported a total of 16 specimens with discernible detection of multiple organisms (1.0% of all specimens, 16/1544; and 6.6% of positive specimens, 16/242). The different types of co-detections (categorized by gram stain classification) as reported by the BioFire JI Panel are presented in Table 16. The resulting co-detection analyte combinations are presented in Table 17. This table also indicates the number of specimens with false positive (FP) results for each co-detection combination, as well as the specific analytes that were discrepant. FP results were determined by comparison only to the primary comparator method (e.g. standard of care (SOC) culture for organisms, and molecular comparator for the antimicrobial resistance (AMR) genes, irrespective of host organism SOC culture results).

Table 16. Expected Values (Co-detection Types as Determined by the BioFire JI Panel) for the BioFire JI Panel Prospective Clinical Evaluation (May 2018 to March 2020)

BioFire JI Panel Co-Detection Type	Positive Specimens (N=16)	
	#	EV
Gram Positive + Gram Positive	4	25.0%
Gram Positive + Gram Negative	9	56.3%
Gram Positive + Yeast	0	0%
Gram Negative + Gram Negative	2	12.5%
Gram Negative + Yeast	1	6.3%
Gram Positive + Gram Negative + Yeast	0	0%

Table 17. Co-Detection Combinations as Determined by the BioFire JI Panel, Prospective Study

Distinct Co-Detection Combinations								Total Specimens with Co-Detection	Number of Specimens with FP Co-Detections[a]	False Positive Analyte(s)
Analyte 1	Analyte 2	Analyte 3	Analyte 4	Analyte 5	Analyte 6	Analyte 7	AMR Gene(s)			
E. faecalis	*F. magna*	*K. pneumoniae* group	*M. morganii*	*Peptoniphilus*	*Proteus* spp.	*P. anaerobius*	-	1	1	*F. magna*, *M. morganii*, *Peptoniphilus*, *P. anaerobius*
E. cloacae complex	*E. faecalis*	*H. influenzae*	*K. kingae*	*Streptococcus* spp., *S. pneumoniae*	*Streptococcus* spp., *S. pyogenes*	-	-	1	1	*H. influenzae*, *K. kingae*
A. prevotii/ vaginalis	*F. magna*	*Streptococcus* spp.	-	-	-	-	-	1	0	-
E. coli	*E. faecium*	*Proteus* spp.	-	-	-	-	*vanA/B*	1	1	*E. faecium*, *Proteus* spp.
B. fragilis	*P. anaerobius*	-	-	-	-	-	-	1	1	*B. fragilis*, *P. anaerobius*
Candida, *C. albicans*	*E. cloacae* complex	-	-	-	-	-	-	1	1	*E. cloacae* complex
E. faecalis	*Proteus* spp.	-	-	-	-	-	-	1	1	*E. faecalis*, *Proteus* spp.
E. faecalis	*S. aureus*	-	-	-	-	-	*mecA/C* and MREJ (MRSA)	1	0	-
E. coli	*Proteus* spp.	-	-	-	-	-	-	1	0	-
E. coli	*S. aureus*	-	-	-	-	-	CTX-M, *mecA/C* and MREJ (MRSA)	1	1	*S. aureus*
K. kingae	*S. aureus*	-	-	-	-	-	-	1	1	*K. kingae*, *S. aureus*
K. pneumoniae group	*M. morganii*	-	-	-	-	-	-	1	1	*K. pneumoniae* group, *M. morganii*
Proteus spp.	*S. lugdunensis*	-	-	-	-	-	-	1	1	*Proteus* spp., *S. lugdunensis*
S. marcescens	*S. aureus*	-	-	-	-	-	-	1	1	*S. marcescens*

Distinct Co-Detection Combinations								Total Specimens with Co-Detection	Number of Specimens with FP Co-Detections[a]	False Positive Analyte(s)
Analyte 1	Analyte 2	Analyte 3	Analyte 4	Analyte 5	Analyte 6	Analyte 7	AMR Gene(s)			
S. aureus	*Streptococcus* spp., *S. agalactiae*	-	-	-	-	-	-	1	0	-
S. aureus	*Streptococcus* spp., *S. pyogenes*	-	-	-	-	-	-	1	0	-
Total Co-Detections								**16**	**11**	**21/43[b]**
Total Double Detections								**12**	**8**	**13/24**
Total Triple Detections								**2**	**1**	**2/6**
Total Sextuple Detections								**1**	**1**	**2/6**
Total Septuple Detections								**1**	**1**	**4/7**

[a] Determined by comparison to SOC culture for organisms, and molecular methods for AMR genes, irrespective of host organism SOC culture results
[b] Of the 21 discrepant analytes (out of 43 total analytes), 20 (95.2%) were confirmed as being present in the specimen during discrepancy investigation: 2/20 (10.0%) were identified from additional laboratory testing performed as SOC and 18/20 (90.0%) were observed using an independent molecular method

PERFORMANCE CHARACTERISTICS

Clinical Performance

The clinical performance of the BioFire JI Panel was established during a prospective, multi-center study conducted at 13 geographically distinct study sites (10 in the US and three in the EU) from May 2018 to March 2020. Specimens enrolled between May 2018 and August 2019 were collected and immediately frozen for later testing at the source laboratory.

A total of 1591 SF specimens were acquired for the clinical study; 47 of these were excluded. The most common reasons for specimen exclusion were that the specimen was found to not meet the inclusion criteria after the specimen had been enrolled, that a valid BioFire JI Panel test was not obtained, or that the study site was unable to complete the case report form (CRF). The final data set consisted of 1544 specimens, of which 771 (49.9%) had been previously frozen before testing. No difference in performance was observed when fresh and frozen specimen results were compared. Therefore, the data collected from both are combined for all analyses.

Table 18 provides a summary of demographic information for the 1544 specimens included in the study.

Table 18. Demographic Data

Category		Prospective
Sex	Male	878 (56.9%)
	Female	666 (43.1%)
Age	≤ 90 days	1 (0.1%)
	91 days - 4 years	22 (1.4%)
	5 - 15 years	75 (4.9%)
	16 - 25 years	35 (2.3%)
	26 - 64 years	774 (50.1%)
	≥ 65 years	637 (41.3%)
Total		**1544**

The performance of the BioFire JI Panel was evaluated by comparing the test result for each analyte with the appropriate comparator/reference methods shown in Table 19.

Table 19. Comparator Methods for the BioFire JI Panel Clinical Evaluation

JI Panel Result	Reference / Comparator Method(s)	Reference / Comparator Test Location(s)
Bacteria and Yeast	Standard manual and automated microbiological/biochemical identification methods[a] (performed for SOC and abstracted from the subjects' medical records)	Study Site
Antimicrobial Resistance Genes	Method 1 – Assessment of BioFire JI Panel performance Molecular comparator for specific resistance gene direct from specimen	Method 1: BioFire Laboratory
	Method 2 – Assessment of genotype concordance Molecular comparator for specific resistance gene from applicable cultured isolates	Method 2: BioFire Laboratory
	Method 3 – Assessment of phenotype concordance Standard automated phenotypic AST of applicable cultured isolates performed for SOC	Method 3: Study Site

[a] Organism isolates with incomplete identification by the study site (n=4) were characterized at BioFire using additional molecular methods

The performance for bacteria and yeast is summarized in Table 20. Sensitivity or Positive Percent Agreement (PPA) for each analyte was calculated as 100% × (TP / (TP + FN)). True positive (TP) indicates that both the BioFire JI Panel and the comparator method had a positive result for the specific analyte, and false negative (FN) indicates that the BioFire JI Panel was negative while the comparator result was positive. Specificity or Negative Percent Agreement (NPA) was calculated as 100% × (TN / (TN + FP)). True negative (TN) indicates that both the BioFire JI Panel and the comparator method had negative results, and false positive (FP) indicates that the BioFire JI 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 20. BioFire JI Panel Clinical Performance Summary – Bacteria and Yeast

Analyte	Sensitivity			Specificity		
	TP/(TP + FN)	%	95% CI	TN/(TN + FP)	%	95% CI
Gram Positive Bacteria						
Anaerococcus prevotii/vaginalis	1/1	100	-	1543/1543	100	99.8-100%
Clostridium perfringens	0/0	-	-	1544/1544	100	99.8-100%
Cutibacterium avidum/granulosum	0/0	-	-	1544/1544	100	99.8-100%
Enterococcus faecalis[a]	10/10	100	72.2-100%	1529/1534	99.7	99.2-99.9%
Enterococcus faecium[b]	1/1	100	-	1541/1543	99.9	99.5-100%
Finegoldia magna[c]	3/3	100	43.9-100%	1540/1541	99.9	99.6-100%
Parvimonas micra[d]	0/1	0	-	1543/1543	100	99.8-100%
Peptoniphilus[e]	1/1	100	-	1542/1543	99.9	99.6-100%
Peptostreptococcus anaerobius[f]	0/0	-	-	1541/1544	99.8	99.4-99.9%
Staphylococcus aureus[g]	98/105	93.3	86.9-96.7%	1417/1439	98.5	97.7-99.0%
Staphylococcus lugdunensis[h]	2/2	100	34.2-100%	1539/1542	99.8	99.4-99.9%
Streptococcus spp.[i]	38/44	86.4	73.3-93.6%	1488/1500	99.2	98.6-99.5%
Streptococcus agalactiae[j]	10/11	90.9	62.3-98.4%	1532/1533	99.9	99.6-100%
Streptococcus pneumoniae	3/3	100	43.9-100%	1541/1541	100	99.8-100%
Streptococcus pyogenes[k]	11/12	91.7	64.6-98.5%	1532/1532	100	99.7-100%
Gram Negative Bacteria						
Bacteroides fragilis[l]	0/0	-	-	1543/1544	99.9	99.6-100%
Citrobacter	2/2	100	34.2-100%	1542/1542	100	99.8-100%
Enterobacter cloacae complex[m]	2/4	50.0	15.0-85.0%	1538/1540	99.9	99.5-100%
Escherichia coli[n]	14/14	100	78.5-100%	1529/1530	99.9	99.6-100%
Haemophilus influenzae[o]	1/1	100	-	1542/1543	99.9	99.6-100%
Kingella kingae[p]	1/1	100	-	1537/1543	99.6	99.2-99.8%
Klebsiella aerogenes	0/0	-	-	1544/1544	100	99.8-100%
Klebsiella pneumoniae group[q]	4/5	80.0	37.6-96.4%	1538/1539	99.9	99.6-100%
Morganella morganii[r]	1/1	100	-	1541/1543	99.9	99.5-100%
Neisseria gonorrhoeae[s]	2/2	100	34.2-100%	1539/1542	99.8	99.4-99.9%
Proteus spp.[t]	4/4	100	51.0-100%	1536/1540	99.7	99.3-99.9%
Pseudomonas aeruginosa[u]	2/2	100	34.2-100%	1539/1542	99.8	99.4-99.9%
Salmonella spp.	0/0	-	-	1544/1544	100	99.8-100%
Serratia marcescens[v]	2/2	100	34.2-100%	1541/1542	99.9	99.6-100%
Yeast						
Candida[w]	4/7	57.1	25.0-84.2%	1536/1537	99.9	99.6-100%
Candida albicans[x]	3/5	60.0	23.1-88.2%	1539/1539	100	99.8-100%

[a] *E. faecalis* was detected in all five FP specimens using an additional molecular method.
[b] *E. faecium* was detected in both FP specimens using an additional molecular method.
[c] *F. magna* was detected in the single FP specimen using an additional molecular method.

[d] *P. micra* was detected in the single FN specimen using an additional molecular method.
[e] *Peptoniphilus* was detected in the single FP specimen using an additional molecular method.
[f] *P. anaerobius* was detected in all three FP specimens using an additional molecular method.
[g] *S. aureus* was detected in 5/7 FN specimens using an additional molecular method; molecular testing of one of the remaining two FN specimens and its isolate identified it as *S. argenteus*. *S. aureus* was detected in 19/22 FP specimens using an additional molecular method.
[h] *S. lugdunensis* was detected in all three FP specimens using an additional molecular method.
[i] *Streptococcus* spp. was detected in 4/7 FN specimens and in all 12 FP specimens using an additional molecular method.
[j] *S. agalactiae* was detected in the single FN specimen and in the single FP specimen using an additional molecular method.
[k] The single FN specimen was negative for *S. pyogenes* when tested with additional molecular methods.
[l] *B. fragilis* was detected in the single FP specimen using an additional molecular method.
[m] *E. cloacae* complex was detected in 1/2 FN specimens using an additional molecular method; molecular testing of the remaining FN specimen and its isolate identified it as *E. bugandensis*. *E. cloacae* complex was detected in both FP specimens using an additional molecular method.
[n] *E. coli* was detected in the single FP specimen using an additional molecular method.
[o] *H. influenzae* was detected in the single FP specimen using an additional molecular method.
[p] *K. kingae* was detected in all six FP specimens using an additional molecular method.
[q] *K. pneumoniae* group was detected in the single FN specimen and in the single FP specimen using an additional molecular method.
[r] *M. morganii* was detected in both FP specimens using an additional molecular method.
[s] *N. gonorrhoeae* was detected in all three FP specimens using an additional molecular method.
[t] *Proteus* spp. was detected in all four FP specimens using an additional molecular method.
[u] *P. aeruginosa* was detected in all three FP specimens using an additional molecular method.
[v] *S. marcescens* was detected in the single FP specimen using an additional molecular method.
[w] *Candida* was detected in 2/3 FN specimens and in the single FP specimen using an additional molecular method.
[x] *Candida albicans* was detected in 1/2 FN specimens using an additional molecular method.

BioFire JI Panel Genus and Group level organism assay performance is stratified by species for *Anaerococcus prevotii/vaginalis*, *Peptoniphilus*, *Streptococcus* spp., *Citrobacter*, *Enterobacter cloacae* complex, *Klebsiella pneumoniae* group, *Proteus* spp., and *Candida* in Table 21. 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 21. Sensitivity of the BioFire JI Panel Genus and Group Assays Stratified by Species

Species	BioFire JI Panel Sensitivity
Anaerococcus prevotii/vaginalis	
A. vaginalis	1/1 (100%)
***Peptoniphilus* Species**	
P. asaccharolyticus	1/1 (100%)
***Streptococcus* Species**	
S. agalactiae	10/11 (90.9%)
S. anginosus	1/1 (100%)
S. anginosus group	1/1 (100%)
S. constellatus	1/1 (100%)
S. dysgalactiae	7/8 (85.7%)
S. gallolyticus	0/1 (0%)
S. gordonii	2/2 (100%)
S. mitis	1/1 (100%)
S. oralis	1/1 (100%)
S. pneumoniae + *S. pyogenes*	1/1 (100%)
S. pneumoniae	2/2 (100%)
S. pyogenes	10/11 (90.9%)
S. salivarius/vestibularis group	0/1 (100%)
Viridans streptococci	1/2 (50.0%)
Total *Streptococcus* species	38/44 (86.4%)
***Citrobacter* Species**	
C. freundii	1/1 (100%)
C. koseri	1/1 (100%)
Total *Citrobacter* species	2/2 (100%)
***Enterobacter cloacae* complex**	

Species	BioFire JI Panel Sensitivity
E. cloacae	1/2 (50.0%)
E. cloacae complex	1/2 (50.0%)
Total *E. cloacae* complex	2/4 (50.0%)
***Klebsiella pneumoniae* group**	
K. pneumoniae	4/5 (80.0%)
***Proteus* Species**	
P. mirabilis	4/4 (100%)
***Candida* Species**	
C. albicans	3/5 (60.0%)
C. parapsilosis	1/2 (50.0%)
Total *Candida* species	4/7 (57.1%)

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 22 through Table 38.

Note: The 'Performance Summary' tables below do not include specimens for which an applicable bacterium 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 22. BioFire JI Panel Clinical Performance Summary – AMR Genes

Analyte	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
CTX-M	5/5	100	56.6-100%	33/33	100	89.6-100%
IMP	0/0	-	-	38/38	100	90.8-100%
KPC	0/0	-	-	40/40	100	91.2-100%
mecA/C and MREJ (MRSA)	19/19	100	83.2-100%	90/94[a]	95.7	89.6-98.3%
NDM	0/0	-	-	40/40	100	91.2-100%
OXA-48-like	1/1	100	-	33/33	100	89.6-100%
vanA/B	3/3	100	43.9-100%	14/14	100	78.5-100%
VIM	0/0	-	-	38/38	100	90.8-100%

[a] *mecA/C* and MREJ (MRSA) was detected in 1/4 FP specimens using an additional molecular method; isolates recovered from the remaining three FP specimens were identified as MRSA by SOC phenotypic AST methods

Table 23. Distribution of CTX-M in Clinical Specimens

CTX-M		SOC: any applicable bacteria Molecular comparator: CTX-M			
		Org+ / Res+	Org+ / Res-	Org -	*Total*
BioFire JI Panel Result	Org+ / Res+	5	0	0	*5*
	Org+ / Res-	0	23[a]	10	*33*
	Org -	0	3	1472	*1475*
	Total	*5*	*26*	*1482*	*1513*[b]
Performance			**Agreement**	**%**	**95%CI**
		Org+ / Res+	5/5	100%	56.6-100%
		Org+ / Res-	23/26	88.5%	71.0-96.0%
		Org -	1472/1482	99.3%	98.8-99.6%

[a] Two specimens had co-detection of *Escherichia coli* with *Proteus* spp.; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii*; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii* and *Proteus* spp.
[b] Thirty-one (31) specimens excluded from molecular analysis for CTX-M due to volume constraints either initially or following a failure during comparator testing.

Table 24. Stratification of CTX-M Clinical Performance by Applicable Host Organism

Applicable Bacteria Result	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall *(any applicable bacteria Detected)*	***5/5***	***100***	***56.6-100%***	***33/33***[a]	***100***	**89.6-100%**
Citrobacter	0/0	-	-	2/2	100	34.2-100%
Enterobacter cloacae complex	0/0	-	-	4/4	100	51.0-100%
Escherichia coli	2/2	100	34.2-100%	13/13	100	77.2-100%
Klebsiella aerogenes	0/0	-	-	0/0	-	-
Klebsiella pneumoniae group	3/3	100	43.9-100%	2/2	100	34.2-100%
Morganella morganii	0/0	-	-	3/3	100	43.9-100%
Proteus spp.	0/0	-	-	8/8	100	67.6-100%
Pseudomonas aeruginosa	0/0	-	-	4/4	100	51.0-100%
Salmonella spp.	0/0	-	-	0/0	-	-
Serratia marcescens	0/0	-	-	2/2	100	34.2-100%

[a] Two specimens had co-detection of *Escherichia coli* with *Proteus* spp.; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii*; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii* and *Proteus* spp.

Table 25. Distribution of IMP in Clinical Specimens

IMP		SOC: any applicable bacteria Molecular comparator: IMP			
		Org+ / Res+	Org+ / Res-	Org -	*Total*
BioFire JI Panel Result	Org+ / Res+	0	0	0	*0*
	Org+ / Res-	0	28[a]	10	*38*
	Org -	0	3	1472	*1475*
	Total	*0*	*31*	*1482*	*1513*[b]
		Performance	**Agreement**	**%**	**95%CI**
		Org+ / Res+	0/0	-	-
		Org+ / Res-	28/31	90.3%	75.1-96.7%
		Org -	1472/1482	99.3%	98.8-99.6%

[a] Two specimens had co-detection of *Escherichia coli* with *Proteus* spp.; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii*; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii* and *Proteus* spp.
[b] Thirty-one (31) specimens excluded from molecular analysis for IMP due to volume constraints either initially or following a failure during comparator testing

Table 26. Stratification of IMP Clinical Performance by Applicable Host Organism

Applicable Bacteria Result	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall *(any applicable bacteria Detected)*	***0/0***	**-**	**-**	***38/38***[a]	***100***	**90.8-100%**
Citrobacter	0/0	-	-	2/2	100	34.2-100%
Enterobacter cloacae complex	0/0	-	-	4/4	100	51.0-100%
Escherichia coli	0/0	-	-	15/15	100	79.6-100%

Applicable Bacteria Result	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Klebsiella aerogenes	0/0	-	-	0/0	-	-
Klebsiella pneumoniae group	0/0	-	-	5/5	100	56.6-100%
Morganella morganii	0/0	-	-	3/3	100	43.9-100%
Proteus spp.	0/0	-	-	8/8	100	67.6-100%
Pseudomonas aeruginosa	0/0	-	-	4/4	100	51.0-100%
Salmonella spp.	0/0	-	-	0/0	-	-
Serratia marcescens	0/0	-	-	2/2	100	34.2-100%

[a] Two specimens had co-detection of *Escherichia coli* with *Proteus* spp.; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii*; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii* and *Proteus* spp.

Table 27. Distribution of KPC in Clinical Specimens

KPC		SOC: any applicable bacteria Molecular comparator: KPC			
		Org+ / Res+	Org+ / Res-	Org -	*Total*
BioFire JI Panel Result	Org+ / Res+	0	0	0	*0*
	Org+ / Res-	0	29[a]	11	*40*
	Org -	1	2	1488	*1491*
	Total	*1*	*31*	*1499*	*1531*[b]
		Performance	**Agreement**	**%**	**95%CI**
		Org+ / Res+	0/1	0%	-
		Org+ / Res-	29/31	93.5%	79.3-98.2%
		Org -	1488/1499	99.3%	98.7-99.6%

[a] Two specimens had co-detection of *Escherichia coli* with *Proteus* spp.; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii*; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii* and *Proteus* spp.
[b] Thirteen (13) specimens were excluded from molecular analysis for KPC due to volume constraints during comparator testing

Table 28. Stratification of KPC Clinical Performance by Applicable Host Organism

Applicable Bacteria Result	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall *(any applicable bacteria Detected)*	***0/0***	***-***	***-***	***40/40***[a]	***100***	***91.2-100%***
Citrobacter	0/0	-	-	2/2	100	34.2-100%
Enterobacter cloacae complex	0/0	-	-	4/4	100	51.0-100%
Escherichia coli	0/0	-	-	15/15	100	79.6-100%
Klebsiella aerogenes	0/0	-	-	0/0	-	-
Klebsiella pneumoniae group	0/0	-	-	5/5	100	56.6-100%
Morganella morganii	0/0	-	-	3/3	100	43.9-100%
Proteus spp.	0/0	-	-	8/8	100	67.6-100%
Pseudomonas aeruginosa	0/0	-	-	5/5	100	56.6-100%
Salmonella spp.	0/0	-	-	0/0	-	-
Serratia marcescens	0/0	-	-	3/3	100	43.9-100%

[a] Two specimens had co-detection of *Escherichia coli* with *Proteus* spp.; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii*; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii* and *Proteus* spp.

Table 29. Distribution of *mecA/C* and MREJ (MRSA) in Clinical Specimens

***mecA/C* and MREJ (MRSA)**		**SOC: *S. aureus* Molecular comparator: *mecA/C* and MREJ (MRSA)**			
		Org+ / Res+	**Org+ / Res-**	**Org -**	***Total***
BioFire JI Panel Result	**Org+ / Res+**	15	3	5	*23*
	Org+ / Res-	0	73	17	*90*
	Org -	0	7	1393	*1400*
	Total	*15*	*83*	*1415*	*1513*[a]
Performance			**Agreement**	**%**	**95%CI**
Org+ / Res+			15/15	100%	79.6-100%
Org+ / Res-			73/83	88.0%	79.2-93.3%
Org -			1393/1415	98.4%	97.7-99.0%

[a]Thirty-one (31) specimens excluded from molecular analysis for *mecA/C* and MREJ (MRSA) due to volume constraints either initially or following a failure during comparator testing

Table 30. Stratification of *mecA/C* and MREJ (MRSA) Clinical Performance by Applicable Host Organism

Applicable Bacteria Result	**Positive Percent Agreement**			**Negative Percent Agreement**		
	TP/(TP + FN)	**%**	**95%CI**	**TN/(TN + FP)**	**%**	**95%CI**
Staphylococcus aureus	19/19	100	83.2-100%	90/94	95.7	89.6-98.3%

Table 31. Distribution of NDM in Clinical Specimens

NDM		**SOC: any applicable bacteria Molecular comparator: NDM**			
		Org+ / Res+	**Org+ / Res-**	**Org -**	***Total***
BioFire JI Panel Result	**Org+ / Res+**	0	0	0	*0*
	Org+ / Res-	0	29[a]	11	*40*
	Org -	0	3	1488	*1491*
	Total	*0*	*32*	*1499*	*1531*[b]
Performance			**Agreement**	**%**	**95%CI**
Org+ / Res+			0/0	-	-
Org+ / Res-			29/32	90.6%	75.8-96.8%
Org -			1488/1499	99.3%	98.7-99.6%

[a] Two specimens had co-detection of *Escherichia coli* with *Proteus* spp.; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii*; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii* and *Proteus* spp.
[b] Thirteen (13) specimens were excluded from molecular analysis for NDM due to volume constraints during comparator testing

Table 32. Stratification of NDM Clinical Performance by Applicable Host Organism

Applicable Bacteria Result	**Positive Percent Agreement**			**Negative Percent Agreement**		
	TP/(TP + FN)	**%**	**95%CI**	**TN/(TN + FP)**	**%**	**95%CI**
Overall *(any applicable bacteria Detected)*	***0/0***	**-**	**-**	***40/40***[a]	***100***	***91.2-100%***
Citrobacter	0/0	-	-	2/2	100	34.2-100%
Enterobacter cloacae complex	0/0	-	-	4/4	100	51.0-100%
Escherichia coli	0/0	-	-	15/15	100	79.6-100%
Klebsiella aerogenes	0/0	-	-	0/0	-	-

Applicable Bacteria Result	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Klebsiella pneumoniae group	0/0	-	-	5/5	100	56.6-100%
Morganella morganii	0/0	-	-	3/3	100	43.9-100%
Proteus spp.	0/0	-	-	8/8	100	67.6-100%
Pseudomonas aeruginosa	0/0	-	-	5/5	100	56.6-100%
Salmonella spp.	0/0	-	-	0/0	-	-
Serratia marcescens	0/0	-	-	3/3	100	43.9-100%

[a]Two specimens had co-detection of *Escherichia coli* with *Proteus* spp.; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii*; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii* and *Proteus* spp.

Table 33. Distribution of OXA-48-like in Clinical Specimens

OXA-48-like		SOC: any applicable bacteria Molecular Comparator: OXA-48-like			
		Org+ / Res+	Org+ / Res-	Org -	*Total*
BioFire JI Panel Result	Org+ / Res+	1	0	0	*1*
	Org+ / Res-	0	25[a]	8	*33*
	Org -	0	3	1476	*1479*
	Total	*1*	*28*	*1484*	*1513*[b]
		Performance	Agreement	%	95%CI
		Org+ / Res+	1/1	100%	-
		Org+ / Res-	25/28	89.3%	72.8-96.3%
		Org -	1476/1484	99.5%	98.9-99.7%

[a] Two specimens had co-detection of *Escherichia coli* with *Proteus* spp.; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii*; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii* and *Proteus* spp.
[b] Thirty-one (31) specimens excluded from molecular analysis for OXA-48-like due to volume constraints either initially or following a failure during comparator testing.

Table 34. Stratification of OXA-48-like Clinical Performance by Applicable Host Organism

Applicable Bacteria Result	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall *(any applicable bacteria Detected)*	***1/1***	***100***	***-***	***33/33***[a]	***100***	***89.6-100%***
Citrobacter	0/0	-	-	2/2	100	34.2-100%
Enterobacter cloacae complex	0/0	-	-	4/4	100	51.0-100%
Escherichia coli	0/0	-	-	15/15	100	79.6-100%
Klebsiella aerogenes	0/0	-	-	0/0	-	-
Klebsiella pneumoniae group	1/1	100	-	4/4	100	51.0-100%
Morganella morganii	0/0	-	-	3/3	100	43.9-100%
Proteus spp.	0/0	-	-	8/8	100	67.6-100%
Salmonella spp.	0/0	-	-	0/0	-	-
Serratia marcescens	0/0	-	-	2/2	100	34.2-100%

[a] Two specimens had co-detection of *Escherichia coli* with *Proteus* spp.; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii*; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii* and *Proteus* spp.

Table 35. Distribution of *vanA/B* in Clinical Specimens

vanA/B		SOC: any applicable bacteria Molecular comparator: *vanA/B*			
		Org+ / Res+	Org+ / Res-	Org -	*Total*
BioFire JI Panel Result	Org+ / Res+	1	0	2	*3*
	Org+ / Res-	0	9	5	*14*
	Org -	0	0	1496	*1496*
	Total	*1*	*9*	*1503*	*1513*[a]
		Performance	**Agreement**	**%**	**95%CI**
		Org+ / Res+	1/1	100%	-
		Org+ / Res-	9/9	100%	70.1-100%
		Org -	1496/1503	99.5%	99.0-99.8%

[a]Thirty-one specimens excluded from molecular analysis for *vanA/B* due to volume constraints either initially or following a failure during comparator testing

Table 36. Stratification of *vanA/B* Clinical Performance by Applicable Host Organism

Applicable Bacteria Result	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall *(any applicable bacteria Detected)*	***3/3***	***100***	***43.9-100%***	***14/14***	***100***	***78.5-100%***
Enterococcus faecalis	0/0	-	-	14/14	100	78.5-100%
Enterococcus faecium	3/3	100	43.9-100%	0/0	-	-

Table 37. Distribution of VIM in Clinical Specimens

VIM		SOC: any applicable bacteria Molecular comparator: VIM			
		Org+ / Res+	Org+ / Res-	Org -	*Total*
BioFire JI Panel Result	Org+ / Res+	0	0	0	*0*
	Org+ / Res-	0	28[a]	10	*38*
	Org -	0	3	1472	*1475*
	Total	*0*	*31*	*1482*	*1513*[b]
		Performance	**Agreement**	**%**	**95%CI**
		Org+ / Res+	0/0	-	-
		Org+ / Res-	28/31	90.3%	75.1-96.7%
		Org -	1472/1482	99.3%	98.8-99.6%

[a] Two specimens had co-detection of *Escherichia coli* with *Proteus* spp.; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii*; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii* and *Proteus* spp.
[b] Thirty-one (31) specimens were excluded from molecular analysis for VIM due to volume constraints either initially or following a failure during comparator testing

Table 38. Stratification of VIM Clinical Performance by Applicable Host Organism

Applicable Bacteria Result	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall *(any applicable bacteria Detected)*	***0/0***	**-**	**-**	***38/38***[a]	***100***	***90.8-100%***
Citrobacter	0/0	-	-	2/2	100	34.2-100%
Enterobacter cloacae complex	0/0	-	-	4/4	100	51.0-100%

Applicable Bacteria Result	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Escherichia coli	0/0	-	-	15/15	100	79.6-100%
Klebsiella aerogenes	0/0	-	-	0/0	-	-
Klebsiella pneumoniae group	0/0	-	-	5/5	100	56.6-100%
Morganella morganii	0/0	-	-	3/3	100	43.9-100%
Proteus spp.	0/0	-	-	8/8	100	67.6-100%
Pseudomonas aeruginosa	0/0	-	-	4/4	100	51.0-100%
Salmonella spp.	0/0	-	-	0/0	-	-
Serratia marcescens	0/0	-	-	2/2	100	34.2-100%

[a]Two specimens had co-detection of *Escherichia coli* with *Proteus* spp.; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii*; one specimen had co-detection of *Klebsiella pneumoniae* group with *Morganella morganii* and *Proteus* spp.

Correlation of the AMR gene results reported in the specimen by the BioFire JI Panel to identification of the gene in the cultured isolates from that particular specimen was assessed using a molecular comparator performed directly on the isolate. The results are shown only for isolates recovered from specimens with true positive results (i.e. concordant results between the BioFire JI Panel and culture), and further stratified by each applicable host organism recovered from that specimen. Performance is presented in Table 39 through Table 42; there were no observations by either the BioFire JI Panel or the reference/comparator methods for IMP, KPC, NDM, and VIM.

Table 39. CTX-M and Select Carbapenem Resistance Genes Performance (as compared to molecular comparator on cultured isolate(s) from SF specimens)

Organism Identified by SOC and Detected by the BioFire JI Panel	N	CTX-M		IMP		KPC		NDM		VIM		*Overall (any resistance gene)*	
		PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
Overall *(any applicable bacteria identified)*	**29**	**5/5 (100%)**	**24/24 (100%)**	**0/0 (-)**	**29/29 (100%)**	**0/0 (-)**	**29/29 (100%)**	**0/0 (-)**	**29/29 (100%)**	**0/0 (-)**	**29/29 (100%)**	**5/5 (100%) [56.6-100%]**	**24/24 (100%) [86.2-100%]**
Citrobacter	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%)
Enterobacter cloacae complex	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%)
Escherichia coli	13	2/2 (100%)	11/11 (100%)	0/0 (-)	13/13 (100%)	0/0 (-)	13/13 (100%)	0/0 (-)	13/13 (100%)	0/0 (-)	13/13 (100%)	2/2 (100%)	11/11 (100%)
Klebsiella aerogenes	0	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)
Klebsiella pneumoniae group	4	3/3 (100%)	1/1 (100%)	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)	3/3 (100%)	1/1 (100%)

Organism Identified by SOC and Detected by the BioFire JI Panel	N	CTX-M		IMP		KPC		NDM		VIM		*Overall (any resistance gene)*	
		PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA	PPA	NPA
Morganella morganii	1	0/0 (-)	1/1 (100%)	0/0 (-)	1/1 (100%)	0/0 (-)	1/1 (100%)	0/0 (-)	1/1 (100%)	0/0 (-)	1/1 (100%)	0/0 (-)	1/1 (100%)
Proteus spp.	4	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)
Pseudomonas aeruginosa	1	0/0 (-)	1/1 (100%)	0/0 (-)	1/1 (100%)	0/0 (-)	1/1 (100%)	0/0 (-)	1/1 (100%)	0/0 (-)	1/1 (100%)	0/0 (-)	1/1 (100%)
Salmonella spp.	0	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)
Serratia marcescens	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%)

Table 40. *mecA/C* and MREJ (MRSA) Performance (as compared to molecular comparator on cultured isolate(s) from SF specimens)

Organism Identified by SOC and Detected by the BioFire JI Panel	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Staphylococcus aureus	15/16	93.8	71.7-98.9%	71/72	99.0	92.5-99.8%

Table 41. OXA-48-like Performance (as compared to molecular comparator on cultured isolate(s) from SF specimens)

Organism Identified by SOC and Detected by BioFire JI Panel	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall *(any applicable bacteria identified)*	***1/1***	***100***	***-***	***27/27***	***100***	***87.5-100%***
Citrobacter	0/0	-	-	2/2	100	34.2-100%
Enterobacter cloacae complex	0/0	-	-	2/2	100	34.2-100%
Escherichia coli	0/0	-	-	13/13	100	77.2-100%
Klebsiella aerogenes	0/0	-	-	0/0	-	-
Klebsiella pneumoniae group	1/1	100	-	3/3	100	43.9-100%
Morganella morganii	0/0	-	-	1/1	100	-
Proteus spp.	0/0	-	-	4/4	100	51.0-100%
Salmonella spp.	0/0	-	-	0/0	-	-
Serratia marcescens	0/0	-	-	2/2	100	34.2-100%

Table 42. *vanA/B* Performance (as compared to molecular comparator on cultured isolate(s) from SF specimens)

Organism Identified by SOC and Detected by the BioFire JI Panel	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall *(any applicable bacteria identified)*	***0/0***	***-***	***-***	***10/11***	***90.9***	***62.3-98.4%***
Enterococcus faecalis	0/0	-	-	10/10	100	72.2-100%
Enterococcus faecium	0/0	-	-	0/1	0	-

The BioFire JI 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 43 through Table 46 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 JI Panel; conversely, detection of these genes may not always confer an antimicrobial resistance phenotype. Additionally, discordant results between *mecA/C* and MREJ (MRSA) detection in a SF specimen by the BioFire JI Panel and the observed methicillin (oxacillin/cefoxitin) resistance of cultured *Staphylococcus aureus* isolates may be due to polymicrobial *Staphylococcus aureus* cultures containing a mixture of resistant and sensitive organisms.

Table 43. CTX-M Performance (as compared to phenotypic AST methods for ESBL activity on cultured isolate(s) from SF specimens)

Organism Identified by SOC and Detected by the BioFire JI Panel	N		Positive Percent Agreement			Negative Percent Agreement		
	ESBL	Non-ESBL	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall *(any applicable bacteria identified)*	***7***	***24***	***5/7***	***71.4***	***35.9-91.8%***	***24/24***	***100***	***86.2-100%***
Citrobacter	0	2	0/0	-	-	2/2	100	34.2-100%
Enterobacter cloacae complex	0	2	0/0	-	-	2/2	100	34.2-100%
Escherichia coli	2	12	2/2	100	34.2-100%	12/12	100	75.8-100%
Klebsiella aerogenes	0	0	0/0	-	-	0/0	-	-
Klebsiella pneumoniae group	4	0	3/4	75.0	30.1-95.4%	0/0	-	-
Morganella morganii	0	1	0/0	-	-	1/1	100	-
Proteus spp.	1	3	0/1	0	-	3/3	100	43.9-100%
Pseudomonas aeruginosa	0	2	0/0	-	-	2/2	100	34.2-100%
Salmonella spp.	0	0	0/0	-	-	0/0	-	-
Serratia marcescens	0	2	0/0	-	-	2/2	100	34.2-100%

Table 44. Carbapenem Resistance Genes Performance (as compared to phenotypic AST methods for carbapenem resistance on cultured isolate(s) from SF specimens)

Organism Identified by SOC and Detected by JI 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)*	31		**0/1 (0%)**	**30/30 (100%)**	**0/1 (0%)**	**30/30 (100%)**	**0/1 (0%)**	**30/30 (100%)**	**1/1 (100%)**	**28/28 (100%)**	**0/1 (0%)**	**30/30 (100%)**	**1/1 (100%) [-]**	**30/30 (100%) [88.6-100%]**
	1	***30***												
Citrobacter	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												
Enterobacter cloacae complex	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												
Escherichia coli	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												
Klebsiella aerogenes	0		0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)
	0	0												
Klebsiella pneumoniae group	4		0/1 (0%)	3/3 (100%)	0/1 (0%)	3/3 (100%)	0/1 (0%)	3/3 (100%)	1/1 (100%)	3/3 (100%)	0/1 (0%)	3/3 (100%)	1/1 (100%)	3/3 (100%)
	1	3												
Morganella morganii	1		0/0 (-)	1/1 (100%)	0/0 (-)	1/1 (100%)	0/0 (-)	1/1 (100%)	0/0 (-)	1/1 (100%)	0/0 (-)	1/1 (100%)	0/0 (-)	1/1 (100%)
	0	1												
Proteus spp.	4		0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)	0/0 (-)	4/4 (100%)
	0	4												
Pseudomonas aeruginosa	2		0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)	N/A	N/A	0/0 (-)	2/2 (100%)	0/0 (-)	2/2 (100%)
	0	2												
Salmonella spp.	0		0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)	0/0 (-)
	0	0												
Serratia marcescens	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												

Table 45. *mecA/C* and MREJ (MRSA) Performance (as compared to phenotypic AST methods for methicillin (oxacillin/cefoxitin) resistance on cultured isolate(s) from SF specimens)

Organism Identified by SOC and Detected by the BioFire JI Panel	N		Positive Percent Agreement			Negative Percent Agreement		
	R	S	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Staphylococcus aureus	98		18/22	81.8	61.5-92.7%	76/76	100	95.2-100%
	22	76						

Table 46. *vanA/B* Performance (as compared to phenotypic AST methods for vancomycin resistance on cultured isolate(s) from SF specimens)

Organism Identified by SOC and Detected by the BioFire JI Panel	N		Positive Percent Agreement			Negative Percent Agreement		
	R	S	TP/(TP + FN)	%	95%CI	TN/(TN + FP)	%	95%CI
Overall *(any applicable bacteria identified)*	***11***		***0/0***	**-**	**-**	***10/11***	***90.9***	***62.3-98.4%***
	0	***11***						
Enterococcus faecalis	10		0/0	-	-	10/10	100	72.2-100%
	0	10						
Enterococcus faecium	1		0/0	-	-	0/1	0	-
	0	1						

The overall success rate for initial specimen tests was 99.6% (1554/1561). Six tests (6/1561; 0.4%) did not complete on the

initial test attempt, resulting in an instrument success rate of 99.6% (1555/1561) for initial specimen tests. Retests were not possible due to insufficient specimen volume. Of the 1555 tests that successfully produced a completed run on the initial test, 1554 had valid pouch controls. This represents a 99.9% (1554/1555) success rate for pouch controls in completed runs in the initial specimen tests.

Testing of Preselected Archived Specimens

Many analytes on the BioFire JI Panel were of low prevalence during the prospective study and were not encountered in large enough numbers to adequately demonstrate system performance. To supplement the results of the prospective clinical study, an evaluation of preselected archived retrospective synovial fluid specimens was performed at BioFire.

A total of 134 frozen archived specimens were obtained from external laboratories for testing in this evaluation; 107 specimens were expected to contain a single analyte of interest, 14 specimens were expected to contain two analytes of interest, and 13 specimens were expected to be negative for all analytes of interest. Twenty-five (25) specimens were excluded from performance analysis due to low volume (23), because they were found to be the wrong specimen type (1), or because they were discovered to be a duplicated specimen (1). The remaining 97 expected positives and 12 expected negatives were further analyzed.

Prior to testing with the BioFire JI Panel, the composition/integrity of the laboratory-identified analytes in archived specimens was first confirmed with confirmatory molecular methods. Confirmation testing verified the presence of 93 out of 109 expected analytes (93/109; 85.3%) in a total of 88 of the 97 expected positive specimens. Specimens with unconfirmed (or unexpected) analytes were excluded from performance calculations for that particular analyte. Table 47 summarizes the number of expected and confirmed analytes that were evaluated in this study.

Table 47. Laboratory-Identified Archived Synovial Fluid Specimen Analyte Composition Summary

Tested Analyte	Number of Expected Analytes in 97 Specimens[a]	Number of Confirmed Analytes
Gram Positive Bacteria		
Cutibacterium avidum/granulosum	3	3
Enterococcus faecalis	8	8
Enterococcus faecium	2	1
Staphylococcus lugdunensis	8	8
Streptococcus agalactiae	18	16
Streptococcus pneumoniae	1	1
Streptococcus pyogenes	3	3
Gram Negative Bacteria		
Citrobacter	2	0
Enterobacter cloacae complex	13	9
Escherichia coli	10	9
Haemophilus influenzae	1	1
Kingella kingae	2	1
Klebsiella aerogenes	1	1
Klebsiella pneumoniae group	4	3
Morganella morganii	1	0
Neisseria gonorrhoeae	2	2
Proteus spp.	4	3
Pseudomonas aeruginosa	14	13
Salmonella spp.	4	3
Serratia marcescens	2	2
Yeast		
Candida	2	2
Candida albicans	1	1

Tested Analyte	Number of Expected Analytes in 97 Specimens[a]	Number of Confirmed Analytes
Antimicrobial Resistance		
Extended spectrum beta-lactamase (*bla*$_{CTX-M}$)	3	3

[a] Some specimens contained multiple analytes.

The specimens were randomized such that the users performing both the confirmation and the BioFire JI Panel testing were blinded to the expected test result. A summary of the available demographic information of the tested specimens is provided in Table 48, and the results of the BioFire JI Panel performance for analyte-confirmed archived specimens is shown in Table 49.

Table 48. Demographic Summary for All Confirmed, Valid Archived Specimens

Total Specimens		N=88
Sex	Male (%)	37 (42%)
	Female (%)	23 (26%)
	Unknown	28 (32%)
Age Range	≤ 90 days	-
	91 days - 4 years	1 (1%)
	5 - 15 years	1 (1%)
	16 - 25 years	1 (1%)
	26 - 64 years [a]	23 (26%)
	≥ 65 years	31 (35%)
	Unknown	31 (35%)

[a] One specimen included in this group has a reported age range of "45-65".

Table 49. BioFire JI Panel Performance Summary for All Confirmed, Valid Archived Specimens

Analyte	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95% CI	TN/(TN + FP)	%	95% CI
Gram Positive Bacteria						
Cutibacterium avidum/granulosum	3/3	100	43.9-100%	4/4	100	51.0-100%
Enterococcus faecalis	8/8	100	67.6-100%	92/92	100	96.0-100%
Enterococcus faecium	1/1	100	-	100/100	100	96.3-100%
Staphylococcus lugdunensis	8/8	100	67.6-100%	94/94	100	96.1-100%
Streptococcus agalactiae	15/16	93.8	71.7-98.9%	81/81	100	95.5-100%
Streptococcus pneumoniae	1/1	100	-	101/101	100	96.3-100%
Streptococcus pyogenes	3/3	100	43.9-100%	98/98	100	96.2-100%
Gram Negative Bacteria						
Enterobacter cloacae complex	8/9	88.9	56.5-98.0%	86/86	100	95.7-100%
Escherichia coli	9/9	100	70.1-100%	91/91	100	95.9-100%
Haemophilus influenzae	1/1	100	-	6/6	100	61.0-100%
Kingella kingae	1/1	100	-	100/100	100	96.3-100%
Klebsiella aerogenes	1/1	100	-	101/101	100	96.3-100%
Klebsiella pneumoniae group	3/3	100	43.9-100%	98/98	100	96.2-100%
Neisseria gonorrhoeae	2/2	100	34.2-100%	100/100	100	96.3-100%
Proteus spp.	3/3	100	43.9-100%	97/97	100	96.2-100%
Pseudomonas aeruginosa	13/13	100	77.2-100%	87/87	100	95.8-100%

Analyte	Positive Percent Agreement			Negative Percent Agreement		
	TP/(TP + FN)	%	95% CI	TN/(TN + FP)	%	95% CI
Salmonella spp.	3/3	100	43.9-100%	98/98	100	96.2-100%
Serratia marcescens	2/2	100	34.2-100%	99/99	100	96.3-100%
Yeast						
Candida	2/2	100	34.2-100%	100/100	100	96.3-100%
Candida albicans	1/1	100	-	101/101	100	96.3-100%
Antimicrobial Resistance Genes						
CTX-M	3/3	100	43.9-100%	32/32	100	89.3-100%

Testing of Contrived Specimens

Some analytes were of insufficient prevalence in the prospective and archived specimen evaluations to adequately demonstrate system performance. Therefore, contrived clinical specimens were created to evaluate the performance of the BioFire JI Panel assays for these rare analytes. Note that results for *mecA/C* and MREJ (MRSA) was not rare in the prospective study, but was included in this study for the evaluation of the rare antimicrobial gene *mecC*. Contrived specimens (N=1235) were spiked using residual clinical samples that were pre-screened and characterized as negative for the analytes of interest. Specimens were spiked with a variety of different isolates/strains for each organism at concentrations that spanned the detection range of each assay such that approximately 50% of specimens were spiked at a near-LoD test level (i.e. within ~2-fold of the assay LoD). Due to changes in the methods used for organism quantification over the course of the study, specimens were also spiked with analytes at levels below the established LoD for each assay. Different isolates of organisms were used from those used in analytical testing when possible. Samples positive for one analyte served as negatives for other analytes. Eighty-one (81) negative (unspiked) samples were also randomized with the spiked specimens to facilitate specimen blinding.

The results of the 1235 specimens tested in this study are summarized in Table 50 below.

Table 50. JI Panel Contrived Specimen Performance Summary. Rows labeled "Overall" include all specimens; rows labeled "≥ LoD" include only specimens spiked at the established assay LoD or higher.

Analyte	Level Tested	PPA			NPA		
		TP/(TP + FN)	%	95% CI	TN/(TN + FP)	%	95% CI
Gram Positive Bacteria							
Anaerococcus prevotii/vaginalis[a,b]	**≥ LoD**	**83/93**	**89.2**	**81.3-94.1%**	1125/1125	100	99.7-100%
	Overall	83/95	87.4	79.2-92.6%			
Clostridium perfringens[c]	**≥ LoD**	**92/102**	**90.2**	**82.9-94.6%**	1101/1101	100	99.7-100%
	Overall	113/134	84.3	77.2-89.5%			
Cutibacterium avidum/granulosum[d]	**≥ LoD**	**74/82**	**90.2**	**81.9-95.0%**	1128/1128	100	99.7-100%
	Overall	80/107	74.8	65.8-82.0%			
Enterococcus faecalis	**≥ LoD**	**51/51**	**100**	**93.0-100%**	1182/1182	100	99.7-100%
	Overall	53/53	100	93.2-100%			
Enterococcus faecium[e]	**≥ LoD**	**63/65**	**96.9**	**89.5-99.2%**	1169/1170[f]	99.9	99.5-100%
	Overall	63/65	96.9	89.5-99.2%			
Finegoldia magna[g]	**≥ LoD**	**78/87**	**89.7**	**81.5-94.5%**	1142/1142	100	99.7-100%
	Overall	82/93	88.2	80.1-93.3%			
Parvimonas micra[h]	**≥ LoD**	**52/57**	**91.2**	**81.1-96.2%**	1158/1158	100	99.7-100%
	Overall	54/77	70.1	59.2-79.2%			
Peptoniphilus[i]	**≥ LoD**	**56/61**	**91.8**	**82.2-96.4%**	1173/1173	100	99.7-100%

Analyte	Level Tested	PPA			NPA		
		TP/(TP + FN)	%	95% CI	TN/(TN + FP)	%	95% CI
	Overall	57/62	91.9	82.5-96.5%			
Peptostreptococcus anaerobius[j]	**≥ LoD**	**91/91**	**100**	**95.9-100%**	1135/1135	100	99.7-100%
	Overall	98/100	98.0	93.0-99.4%			
Staphylococcus lugdunensis[k]	**≥ LoD**	**46/48**	**95.8**	**86.0-98.8%**	1184/1185[f]	99.9	99.5-100%
	Overall	48/50	96.0	86.5-98.9%			
Streptococcus agalactiae	**≥ LoD**	**58/58**	**100**	**93.8-100%**	1175/1175	100	99.7-100%
	Overall	59/59	100	93.9-100%			
Streptococcus pneumoniae[l]	**≥ LoD**	**70/76**	**92.1**	**83.8-96.3%**	1152/1157[f]	99.6	99.0-99.8%
	Overall	70/78	89.7	81.0-94.7%			
Streptococcus pyogenes[m]	**≥ LoD**	**64/65**	**98.5**	**91.8-99.7%**	1170/1170	100	99.7-100%
	Overall	64/65	98.5	91.8-99.7%			
Gram Negative Bacteria							
Bacteroides fragilis[n]	**≥ LoD**	**95/95**	**100**	**96.1-100%**	1125/1125	100	99.7-100%
	Overall	98/100	98.0	93.0-99.4%			
Citrobacter[o]	**≥ LoD**	**67/69**	**97.1**	**90.0-99.2%**	1165/1165	100	99.7-100%
	Overall	67/70	95.7	88.1-98.5%			
Enterobacter cloacae complex	**≥ LoD**	**48/48**	**100**	**92.6-100%**	1185/1185	100	99.7-100%
	Overall	50/50	100	92.9-100%			
Escherichia coli	**≥ LoD**	**75/75**	**100**	**95.1-100%**	1158/1158	100	99.7-100%
	Overall	75/75	100	95.1-100%			
Haemophilus influenzae[p]	**≥ LoD**	**52/53**	**98.1**	**90.1-99.7%**	1180/1180	100	99.7-100%
	Overall	53/55	96.4	87.7-99.0%			
Kingella kingae	**≥ LoD**	**48/48**	**100**	**92.6-100%**	1185/1185	100	99.7-100%
	Overall	50/50	100	92.9-100%			
Klebsiella aerogenes[q]	**≥ LoD**	**97/97**	**100**	**96.2-100%**	1135/1135	100	99.7-100%
	Overall	99/100	99.0	94.6-99.8%			
Klebsiella pneumoniae group	**≥ LoD**	**93/93**	**100**	**96.0-100%**	1141/1141	100	99.7-100%
	Overall	94/94	100	96.1-100%			
Morganella morganii[r]	**≥ LoD**	**59/63**	**93.7**	**84.8-97.5%**	1171/1171	100	99.7-100%
	Overall	59/64	92.2	83.0-96.6%			
Neisseria gonorrhoeae[s]	**≥ LoD**	**46/48**	**95.8**	**86.0-98.8%**	1178/1179[f]	99.9	99.5-100%
	Overall	47/50	94.0	83.8-97.9%			
Proteus spp.[t]	**≥ LoD**	**52/52**	**100**	**93.1-100%**	1182/1182	100	99.7-100%
	Overall	52/53	98.1	90.1-99.7%			
Pseudomonas aeruginosa[u]	**≥ LoD**	**117/119**	**98.3**	**94.1-99.5%**	1105/1105	100	99.7-100%
	Overall	121/125	96.8	92.1-98.7%			
Salmonella spp.[v]	**≥ LoD**	**57/60**	**95.0**	**86.3-98.3%**	1173/1173	100	99.7-100%
	Overall	59/62	95.2	86.7-98.3%			
Serratia marcescens[w]	**≥ LoD**	**53/54**	**98.1**	**90.2-99.7%**	1179/1179	100	99.7-100%
	Overall	54/56	96.4	87.9-99.0%			
Yeast							
Candida[x]	**≥ LoD**	**102/105**	**97.1**	**91.9-99.0%**	1126/1126	100	99.7-100%
	Overall	105/109	96.3	90.9-98.6%			
Candida albicans[y]	**≥ LoD**	**50/51**	**98.0**	**89.7-99.7%**	1182/1182	100	99.7-100%
	Overall	52/53	98.1	90.1-99.7%			
AMR Genes							
CTX-M[z]	**≥ LoD**	**149/150**	**99.3**	**96.3-99.9%**	544/544	100	99.3-100%

Analyte	Level Tested	PPA			NPA		
		TP/(TP + FN)	%	95% CI	TN/(TN + FP)	%	95% CI
	Overall	152/153	99.3	96.4-99.9%			
IMP	**≥ LoD**	**90/90**	**100**	**95.9-100%**	603/603	100	99.4-100%
	Overall	93/93	100	96.0-100%			
KPC	**≥ LoD**	**77/77**	**100**	**95.2-100%**	618/618	100	99.4-100%
	Overall	79/79	100	95.4-100%			
mecA/C and MREJ (MRSA)[aa,ab]	**≥ LoD**	**48/48**	**100**	**92.6-100%**	46/53[f]	86.8	75.2-93.5%
	Overall	49/49	100	92.7-100%			
NDM[ac]	**≥ LoD**	**66/67**	**98.5**	**92.0-99.7%**	629/629	100	99.4-100%
	Overall	66/68	97.1	89.9-99.2%			
OXA-48-like	**≥ LoD**	**64/64**	**100**	**94.3-100%**	532/532	100	99.3-100%
	Overall	65/65	100	94.4-100%			
vanA/B	**≥ LoD**	**96/96**	**100**	**96.2-100%**	18/19[f]	94.7	75.4-99.1%
	Overall	98/98	100	96.2-100%			
VIM	**≥ LoD**	**79/79**	**100**	**95.4-100%**	614/614	100	99.4-100%
	Overall	83/83	100	95.6-100%			

[a] Sequence variation in *A. vaginalis* isolates result in impaired detection near the LoD of the assay, See Table 53.
[b] Ten *Anaerococcus prevotii/vaginalis* FN were observed at or above LoD and two FN were observed below LoD.
[c] Ten *Clostridium perfringens* FN were observed at or above LoD and 11 FN were observed below LoD.
[d] Eight *Cutibacterium avidum/granulosum* FN were observed at or above LoD and 19 FN were observed below LoD.
[e] Both *Enterococcus faecium* FN were observed at or above LoD.
[f] FP results due to background contamination in the matrix used for spiking.
[g] Nine *Finegoldia magna* FN were observed at or above LoD and two FN were observed below LoD.
[h] Five *Parvimonas micra* FN were observed at or above LoD and 18 FN were observed below LoD.
[i] Five *Peptoniphilus* FN were observed at or above LoD.
[j] Both *Peptostreptococcus anaerobius* FN were observed below LoD.
[k] Both *Staphylococcus lugdunensis* FN were observed at or above LoD.
[l] Six *Streptococcus pneumoniae* FN were observed at or above LoD and two FN were observed below LoD.
[m] The *Streptococcus pyogenes* FN was observed above LoD.
[n] Both *Bacteroides fragilis* FN were observed below LoD.
[o] Two *Citrobacter* FN were observed at or above LoD and one FN was observed below LoD.
[p] One *Haemophilus influenzae* FN was observed above LoD and one FN was observed below LoD.
[q] The *Klebsiella aerogenes* FN was observed below LoD.
[r] Four *Morganella morganii* FN were observed at or above LoD and one FN was observed below LoD.
[s] Two *Neisseria gonorrhoeae* FN were observed at or above LoD and one FN was observed below LoD.
[t] The *Proteus* spp. FN was observed below LoD.
[u] Two *Pseudomonas aeruginosa* FN were observed at or above LoD and two FN were observed below LoD.
[v] Three *Salmonella* spp. FN were observed at or above LoD.
[w] One *Serratia marcescens* FN was observed at or above LoD and one FN was observed below LoD.
[x] Three *Candida* FN were observed at or above LoD and one FN was observed below LoD.
[y] The *Candida albicans* FN was observed above LoD.
[z] The CTX-M FN was observed above the host organism's LoD.
[aa] Results were reported as N/A for the resistance marker because the host organism was reported as Not Detected.
[ab] Two different strains of *Staphylococcus aureus* containing *mecC* were used for spiking 50 contrived specimens.
[ac] One NDM FN was observed at or above the host organism's LoD and one FN was observed below the host organism's LoD.

Limit of Detection

A limit of detection (LoD) was established for the bacteria and yeast detected by the BioFire JI Panel. Contrived samples were prepared with representative species/isolates at a known concentration in pooled synovial fluid matrix. 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% (≥19/20) of replicates tested. Confirmed LoD concentrations are listed in Table 51. Testing also confirmed that antimicrobial resistance genes can be detected at the LoD concentration of the applicable bacteria with which they are reported.

Table 51. Limit of Detection for Bacteria and Yeast Detected by the BioFire Joint Infection (JI) Panel

Analyte (Antimicrobial Resistance Gene)	Isolate ID[a]	LoD Concentration[b]
Gram Positive Bacteria		
Anaerococcus prevotii/vaginalis	ATCC 9321	4.8E+04 copies/mL
	ATCC 51170	
Clostridium perfringens	ATCC 13124[c]	1.3E+03 copies/mL
Cutibacterium avidum/granulosum	ATCC 25577	5.0E+04 copies/mL
	ATCC 25564	
***Enterococcus faecalis* (*vanA/B*)**	ATCC 51299	5.0E+03 copies/mL
***Enterococcus faecium* (*vanA/B*)**	ATCC 700221	1.2E+03 copies/mL
Finegoldia magna	ATCC 15794	3.1E+05 copies/mL
Parvimonas micra	ATCC 33270	4.8E+03 copies/mL
Peptoniphilus	ATCC 14963[d]	4.0E+04 copies/mL
Peptostreptococcus anaerobius	ATCC 27337	1.6E+04 copies/mL
***Staphylococcus aureus* (*mecA/C* and MREJ (MRSA))**	ATCC 43300[e]	4.2E+03 copies/mL
Staphylococcus lugdunensis	ATCC 43809	2.6E+03 copies/mL
***Streptococcus* spp.**	ATCC 25175[f]	2.5E+05 copies/mL
Streptococcus agalactiae	ATCC 13813	1.9E+04 copies/mL
Streptococcus pneumoniae	ATCC 6303	5.3E+02 copies/mL
Streptococcus pyogenes	ATCC 49399	8.9E+03 copies/mL
Gram Negative Bacteria		
Bacteroides fragilis	ATCC 25285	1.1E+03 copies/mL
Citrobacter	ATCC 8090[g]	4.7E+03 copies/mL
***Enterobacter cloacae* complex (VIM)**	AR Bank #0154[h]	1.3E+05 copies/mL
***Escherichia coli* (NDM)**	AR Bank #0150	6.0E+03 copies/mL
Haemophilus influenzae	ATCC 10211	6.9E+02 copies/mL
Kingella kingae	ATCC 23330	3.4E+03 copies/mL
***Klebsiella aerogenes* (OXA-48-like)**	AR Bank #0074	7.5E+03 copies/mL
***Klebsiella pneumoniae* group (KPC)**	AR Bank #0097[i]	1.6E+04 copies/mL
Morganella morganii	ATCC 25830[j]	2.2E+03 copies/mL
Neisseria gonorrhoeae	ATCC 19424	2.2E+03 copies/mL
***Proteus* spp.**	ATCC 35659[k]	5.2E+03 copies/mL
***Pseudomonas aeruginosa* (IMP)**	AR Bank #0092	1.3E+04 copies/mL
***Salmonella* spp. (CTX-M)**	AR Bank #0407[l]	1.6E+03 copies/mL
Serratia marcescens	ATCC 13880	1.1E+04 copies/mL
Yeast		
Candida	ATCC 6258[m]	1.0E+03 CFU/mL
Candida albicans	ATCC 90028	5.0E+02 CFU/mL

[a] AR Bank # refers to specific isolates obtained from the CDC & FDA Antibiotic Resistance Isolate Bank (Atlanta, GA).
[b] LoD concentration may vary from what is listed based on the accuracy and precision of the culture quantification method. Bacterial cultures were quantified in nucleic acid copies/mL by digital PCR and yeast cultures were quantified in CFU/mL by colony counting.
[c] LoD testing was also performed with another *C. perfringens* isolate (ATCC 8009).
[d] *Peptoniphilus assacharolyticus;* see Analytical Reactivity section for reactivity with other *Peptoniphilus* species near LoD.
[e] LoD testing was also performed with another methicillin-resistant *S. aureus* isolate (ATCC BAA-2313) carrying the *mecC* gene.
[f] *Streptococcus mutans;* see Analytical Reactivity section for reactivity with other *Streptococcus* species near LoD.
[g] *Citrobacter freundii;* see Analytical Reactivity section for reactivity with other *Citrobacter* species near LoD.
[h] *Enterobacter cloacae;* see Analytical Reactivity section for reactivity with other *Enterobacter cloacae* complex species near LoD.
[i] *Klebsiella pneumoniae*; see Analytical Reactivity section for reactivity with other *Klebsiella pneumoniae* group species near LoD.
[j] LoD testing was also performed with another *M. morganii* isolate (AR Bank# 0057).
[k] *Proteus mirabilis*; see Analytical Reactivity section for reactivity with other *Proteus* species near LoD.
[l] *Salmonella enterica* ssp. *enterica* serovar Concord. LoD testing was also performed with another *S. enterica* isolate (AR Bank #0127, *S. enterica* ssp. *enterica* serovar Senftenberg); see Analytical Reactivity section for reactivity with *Salmonella bongori* and other *Salmonella enterica* subspecies near LoD.
[m] *Candida krusei*; see Analytical Reactivity section for reactivity with other *Candida* species near LoD.

Analytical Reactivity (Inclusivity)

The analytical reactivity of BioFire JI Panel assays was assessed via a combination of *in silico* analysis of sequences available in public databases and testing of over 350 different isolates representing various species, subspecies, strains, serotypes, AMR gene types, and other characterized variants.

Isolates were initially tested at 1-3× LoD and results for each isolate tested and detected near LoD (within 10×) are shown in Table 53 – Table 91, as well as *in silico* reactivity predictions for species and/or AMR gene types that were not tested. Impaired reactivity (>10×) due to sequence variation or deletion under assay primers was identified or confirmed for some isolates in testing and for some sequences in the *in silico* analysis. Isolates/species are listed as Not Detected when detection was impaired by 100× or more relative to LoD, when an isolate was not detected at any concentration tested, and/or when *in silico* sequence analysis predicts impaired reactivity and detection for a large proportion of sequences evaluated for the specific species or AMR gene type .

A summary of known BioFire JI Panel reactivity limitations for specific isolates, species, or AMR gene types (impaired >10× or non-reactive) is provided in Table 52.

Table 52. Summary of JI Panel Reactivity Limitations Based on Testing and/or *In Silico* Sequence Analysis (also see Table 53 - Table 91)

Limitation	Analyte	Strain/Isolate/Variant
Unique isolates/variant sequences with known or predicted reactivity limitations		
Minor (detected at ≤30x LoD)	*Anaerococcus prevottii/vaginalis*[a]	clinical isolates (private collection) with variant sequences[a]
	Enterobacter cloacae complex[b]	Enterobacter hormaechei ATCC 49162[b]
	Pseudomonas aeruginosa	*Pseudomonas aeruginosa* ATCC 9027
	Candida albicans[c]	'petite' strains (altered or no mitochondrial DNA)[c]
Major (detected at ≥100x LoD) **or Not Detected**	*Cutibacterium granulosum*	clinical isolate (private collection) with variant sequence
	Enterobacter cloacae complex[b]	*Enterobacter asburiae* ATCC 35953, ATCC35954, and ATCC 35957[b]
	Haemophilus influenzae	clinical isolate (private collection; USA 2012) with gene target deletion
	Klebsiella aerogenes	*Klebsiella (Enterobacter) aerogenes* ATCC 29751
	Neisseria gonorrhoeae	*Neisseria gonorrhoeae* NCTC 13817 (strain WHO-U)
	Pseudomonas aeruginosa	*Pseudomonas aeruginosa* ATCC 25619
	Streptococcus pyogenes	clinical isolate (private collection; USA 2019) with gene target deletion or re-arrangement
	AMR gene types with known or predicted reactivity limitations	
	CTX-M	CTX-M types 74, 75, 113, 151
	IMP	IMP types 31, 35, 46
	mecA/C and MREJ[d,e]	MREJ type xv[d], xviii[e], xix[e], xx[e]
	OXA-48-like	see Table 89
	VIM	VIM types 7, 39, 45, 46, 61, 65, 67
	Rare or non-relevant species with known or predicted reactivity limitations	
	Candida spp.	several *Candida* species; see Table 82
	Citrobacter	*Citrobacter almonaticus*, *C. farmer*i, *C.gillenii*, *C. rodentium*, *C. sedlakii*
	Peptoniphilus	*Peptoniphilus coxii*, *P. duerdenii*, *P. ivorii*, *P. koenoeneniae*, *P. massiliensis*[f], *P. porci*, *P. olsenii*, *P. tyrelliae*
	Streptococcus spp.	*Streptococcus entericus*, *S.halitosis*, *S. hyovaginalis*, *S. pantholopis*

[a] Detection near LoD was impaired for four isolates of *A. vaginalis*. Sequencing revealed primer mismatches predicted to impair detection. Comparable sequence variants were observed in two *A. vaginalis* sequences retrieved from public databases. A limitation on reactivity is predicted for approximately 25% of *A. prevotii/vaginalis* sequences and isolates evaluated.

[b] Reactivity limitations observed or predicted for sequence variants identified for *E. hormaechei* ATCC 49162, *E. asburiae* ATCC 35953 (tested), ATCC 35954 (not tested), ATCC 35955 (not tested), and a small subset of database sequences for *E. cloacae*, *E. hormaechei*, *E. ludwigii* and *E. mori* with similar or less impactful variants under assay primers. Variant sequences with major or minor reactivity limitations represent less than 2% of sequences for ECC species.

[c] Petite strains of *Candida albicans* will not be detected by the Candida albicans-specific assay but will be amplified by the multi-species Candida assay and reported as *Candida* Detected.

[d] Sequence analysis predicts that approximately 40% of MREJ type xv-like sequences will not be detected due to a variant base at the 3' end of an assay primer.

[e] MREJ types xviii, xix and xx will not be detected. MREJ types xix and xx are described in association with methicillin-sensitive isolates, so the *mecA/C* and MREJ (MRSA) Not Detected result will be consistent with the methicillin-sensitive phenotype of isolates with these MREJ types.

[f] Not a validly published *Peptoniphilus* species.

Table 53. Results for *Anaerococcus prevotii/vaginalis* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Anaerococcus prevotii	ATCC 9321/DSM 20548	Type Strain	***Anaerococcus prevotii/vaginalis*** **Detected**[a]
	ATCC 14952/DSM 20473	M3	
	CCUG 72601	Sweden	
	VTK 400239	-	
Anaerococcus vaginalis	ATCC 51170/DSM 7457	Type Strain/Japan	
	DSM 25446	Ph9/France/2011	
	GRE 1654021	-	
	GRE 1653021	-	
	GRE 1554051[a]	-	
	GRE 1757298[a]	-	
	VTK 401665[a]	-	
	VTK 401672[a]	-	

[a] Variant sequence with mismatch to a primer that impairs detection near LoD (detected at 10-30× LoD). Similar variant sequences predicted to cause minor detection impairment represent ~25% of total *A. prevotii/vaginalis* sequences evaluated.

Table 54. Results for *Clostridium perfringens* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Clostridium perfringens	ATCC 13124	S 107 (Type Strain)/United States	***Clostridium perfringens*** **Detected**
	ATCC 27059	814 [Bp6x]	
	ATCC 3628	Strain 51	
	ATCC 8009	-	
	ATCC 9081	13942/United States	

Table 55. Results for *Cutibacterium avidum/granulosum* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Cutibacterium avidum	ATCC 25577	1689B, VPI 0179 (Type Strain)	***Cutibacterium avidum/granulosum*** **Detected**
	ATCC 49753	VPI 0575	
	ATCC 49754	VPI 0576	
	ATCC 49755	VPI 0589	
	ATCC 49769	VPI 0670	
Cutibacterium granulosum	ATCC 25564	VPI 0507 (Type Strain)	
	ATCC 11829	VPI 0210	
	ATCC 25746	D-34	
	CCUG 14831	Serovar 3 Czechoslovakia/1983	
	CCUG 43704	Sweden/2000	
	GRE 1554046	-	
	GRE 1760015[a]	United States	***Cutibacterium avidum/granulosum*** **Not Detected**[a]

[a] Isolate from private collection with variant sequence under assay primer(s) that impairs detection by 100× or more.

Table 56. Results for *Enterococcus faecalis* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Enterococcus faecalis	ATCC 51299	NJ-3/United States	***Enterococcus faecalis*** **Detected**
	ATCC 19433	Tissier/Type Strain	
	ATCC 49533	UWH 1936/United States	
	ATCC 700802	V583	
	ATCC BAA-2573	-	
	JMI 12536	-	

Table 57. Results for *Enterococcus faecium* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Enterococcus faecium	ATCC 700221	United States	***Enterococcus faecium*** **Detected**
	ATCC 19434	Grumbach (Type Strain)	
	ATCC 27270	X3 [F]	
	ATCC 51858	Vancomycin-dependent #4	
	ATCC BAA-2318	-	
	JMI 475	-	

Table 58. Results for *Finegoldia magna* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Finegoldia	ATCC 15794	2974	***Finegoldia***

Organism	Source ID	Strain/Location/Year	Result
magna	ATCC 14955	BU	***magna*** **Detected**
	ATCC 29328	WAL2508	
	ATCC 53516	312	
	DSM 20362	168	
	GRE 1556006	-	

Table 59. Results for *Parvimonas micra* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Parvimonas micra	ATCC 33270	3024A (Type Strain)	***Parvimonas micra*** **Detected**
	CCUG 56809	Sweden/2008	
	CCUG 57049	Sweden/2008	
	GRE 1651163	-	
	GRE 1757098	-	

Table 60. Results for *Peptoniphilus* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Peptoniphilus assacharolyticus	ATCC 14963	BAI, UW 228 (Type Strain)	***Peptoniphilus*** **Detected**
	ATCC 29743	WAL 3218	
Peptoniphilus allenii[a]	ATCC BAA-1643[a]	WAL 1768N	
Peptoniphilus gorbachii	ATCC BAA-1383	WAL 10418	
Peptoniphilus grossensis[a]	DSM 25475[a]	ph5 (Type Strain)/France	
Peptoniphilus harei	ATCC BAA-601	SBH 432 (Type Strain) United Kingdom	
	DSM 10021	SBH 064 United Kingdom	
	GRE 1554070	-	
Peptoniphilus indolicus	ATCC 29427	R13 (Type Strain)	
	GRE 1556024	-	
Peptoniphilus lacrimalis	ATCC 51171	GIFU 7667 (Type Strain)	
	CCUG 47146	United Kingdom/1998	
Peptoniphilus senegalensis	DSM 25694	JC140 (Type Strain) Senegal/2011	
Peptoniphilus coxii	ATCC BAA-2016	RMA 16757/United States/2007	***Peptoniphilus*** **Not Detected**[b]
Peptoniphilus duerdenii	ATCC BAA-1640	WAL 1998L/-/2007	
Peptoniphilus ivorii	ATCC BAA-602	SBH093/United Kingdom	
Peptoniphilus koenoeneniae[b]	ATCC BAA-1638[b]	WAL 20371/-/2007	
Peptoniphilus massiliensis[a]	ATCC BAA-1641	WAL 18041/-/2007	
Peptoniphilus porci	*In silico* prediction (not tested)		
Peptoniphilus olsenii	ATCC BAA-1384	WAL 12922/-/1995	
Peptoniphilus tyrelliae[b]	CCUG 59621[b]	RMA 19911/United States	
Other *Peptoniphilus* species	**Unknown Reactivity** (no sequences/not tested)		

[a] Isolates tested were characterized by the culture collection as *P. allenii, P. grossensis,* and *P. massiliensis*, though none are currently validly published *Peptoniphilus* species.
[b] *Peptoniphilus koenoeneniae* and *Peptoniphilus tyrelliae* were detected at a concentration >100× LoD.

Table 61. Results for *Peptostreptococcus anaerobius* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Peptostreptococcus anaerobius	ATCC 27337	A. Prevot 4372 (Type Strain)	***Peptostreptococcus anaerobius*** **Detected**
	ATCC 49031	MSHD	
	CCUG 37992	Sweden/1997	
	CCUG 38379	Japan	
	CCUG 46594	GIFU 7800/Sweden/1997	

Table 62. Results for *Staphylococcus aureus* Isolates Tested

Organism	Isolate ID[a]	Strain/Location/Year	PFGE Type/ PVL (+/-)	Result
Staphylococcus aureus	ATCC BAA-2313	M10/0148/Ireland/2010	CC130/-	***Staphylococcus aureus*** **Detected**
	ATCC BAA-1700	HFH-33798/ United States/2004	USA1000/+	
	ATCC BAA-1707	MW2 [HIP08270]	USA400/+	
	ATCC BAA-1749	96:308	USA900/-	
	ATCC BAA-1759	N7129	USA900/-	
	ATCC BAA-1764	7031	USA1100/+	
	ATCC BAA-1765	102-04	USA1200/-	
	ATCC BAA-2312	M10/0061/Ireland/2010	Unknown/-	

Organism		Isolate ID[a]	Strain/Location/Year	PFGE Type/ PVL (+/-)	Result
		NARSA NRS662	CO-34/United States/2005	USA300/+	
		NARSA NRS683	GA-298/United States/2005	USA300/+	
		NARSA NRS689	GA-442/United States/2006	USA700/-	
		NARSA NRS691	GA-62/United States/2005	USA500/-	
		NARSA NRS701	MN-082/United States/2006	USA200/-	
		NARSA NRS705	NY-12/United States/2005	USA100/-	
		NARSA NRS707	NY-155/United States/2005	USA300/+	
		NARSA NRS745	CA-629/United States/2006	USA1000/-	
		BEI NR-46081[a]	HIP12899/ United States/1996	USA1100/+	
		GRE 0860042	Paraguay	Unknown/-	
		NARSA NRS648	CA-347/United States/2005	USA600/-	
		SHSC Sun1	-	Unknown	
S. aureus	**ssp. *aureus***	ATCC 43300	F-182/United States	Unknown/-	
		ATCC 12600	Type Strain	Unknown	
		ATCC 14154	-	Unknown	
		ATCC 25923	Seattle 1945/United States	Unknown	
		ATCC BAA-39	Hungary/1993	Unknown/-	
		ATCC BAA-42	HDE288/Portugal.1996	USA800/-	
		ATCC BAA-44	HPV107	Iberian/-	
		ATCC BAA-1717	TCH1516/United States	USA300/+	
		ATCC BAA-1720	MRSA252	USA200/-	
	ssp. *anaerobius*	ATCC 35844	MVF-7/Spain	-	

[a] NARSA/NRS isolates were provided by the Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) for distribution by BEI Resources, NIAID, NIH.

Table 63. Results for *Staphylococcus lugdunensis* Isolates Tested

Organism	Source ID	Strain/Location/Year	Result
Staphylococcus lugdunensis	ATCC 43809	N860297 (Type Strain)/France	***Staphylococcus lugdunensis*** **Detected**
	ATCC 49576	LRA 260.05.79	
	ARCC 700582	7829/United States/1997	
	NCTC 7990	Kelly/England/1949	
	ATCC 700328	6733	

Table 64. Results for *Streptococcus* spp. Isolates Tested and Predicted Reactivity

Organism		Isolate ID	Strain/Location/Year	Result
Streptococcus acidominimus		*In silico* prediction (not tested)		***Streptococcus*** **spp. Detected**
Streptococcus agalactiae		See *S. agalactiae* table		
Streptococcus anginosus		ATCC 33397	Havill III. (R. Lancefield F68A) (Type Strain)	
Streptococcus australis		ATCC 700641	AI-1 (Type Strain)/Australia/1998	
Streptococcus azizii		*In silico* prediction (not tested)		
Streptococcus bovimastitidis		*In silico* prediction (not tested)		
Streptococcus bovis/equinus		ATCC 33317	Pearl 11, NCDO597 (Type strain)	
		ATCC 9812	H 12 B (type Strain)	
Streptococcus caballi		*In silico* prediction (not tested)		
Streptococcus canis		*In silico* prediction (not tested)		
Streptococcus castoreus		*In silico* prediction (not tested)		
Streptococcus constellatus		ATCC 27513	VPI 7712	
Streptococcus criceti		*In silico* prediction (not tested)		
Streptococcus cristatus/oligofermentans		ATCC 51100	CR311 (Type Strain)/United Kingdom	
Streptococcus cuniculi		*In silico* prediction (not tested)		
Streptococcus devriesei		*In silico* prediction (not tested)		
Streptococcus didelphis		*In silico* prediction (not tested)		
Streptococcus downei		*In silico* prediction (not tested)		
Streptococcus dysgalactiae	**ssp. *dysgalactiae***	ATCC 43078	NCDO 2023 (Type Strain) United Kingdom	
	ssp. *equisimilis*	ATCC 8543	LRA 06 11 76	
Streptococcus equi[a]	**ssp. *equi***	ATCC 33398	C 15	
	ssp. *zooepidemicus*	ATCC 43079	NCDO 1358 (Type Strain)/England	
Streptococcus ferus		*In silico* prediction (not tested)		
Streptococcus gallolyticus	**ssp. *gallolyticus***	DSM 16831	Type Strain/Australia	
	ssp. *pasteurianus*	ATCC 700338	RG	
Streptococcus gordonii		ATCC 10558	SK3 (Type Strain)	
Streptococcus halotolerans		*In silico* prediction (not tested)		
Streptococcus henryi		*In silico* prediction (not tested)		
Streptococcus himalayensis		*In silico* prediction (not tested)		

Organism		Isolate ID	Strain/Location/Year	Result
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	NCIMB 700599 (Type Strain)	
Streptococcus infantis		*In silico* prediction (not tested)		
Streptococcus iniae		*In silico* prediction (not tested)		
Streptococcus intermedius		ATCC 27335	VPI 3372A (Type Strain)	
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[b]		*In silico* prediction (not tested)		
Streptococcus mitis		ATCC 49456	NS 51; SK142 (Type Strain)	
Streptococcus mutans		ATCC 25175	IFO 13955 (Type Strain)	
Streptococcus oralis[c]	**-**	ATCC 35037	PB182; LVG/1 (Type Strain)	
	ssp. *tigurinis*	DSM 24864	AZ_3a (Type Strain)/Switzerland/2010	
Streptococcus orisasini		*In silico* prediction (not tested)		
Streptococcus orisratti		*In silico* prediction (not tested)		
Streptococcus ovis		*In silico* prediction (not tested)		
Streptococcus parasanguinis		ATCC 15912	SS 898 (Type Strain)	
Streptococcus parasuis		*In silico* prediction (not tested)		
Streptococcus parauberis		*In silico* prediction (not tested)		
Streptococcus penaeicida		*In silico* prediction (not tested)		
Streptococcus peroris		ATCC 700780	GTC 848, O-66 (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		See *S. pneumoniae* table		
Streptococcus porci		*In silico* prediction (not tested)		
Streptococcus porcinus		*In silico* prediction (not tested)		
Streptococcus pseudopneumoniae		ATCC BAA-960	CDC-SS-1757 (Type Strain) Canada/2002	
Streptococcus pseudoporcinus		*In silico* prediction (not tested)		
Streptococcus pyogenes		See *S. pyogenes* table		
Streptococcus ratti		*In silico* prediction (not tested)		
Streptococcus respiraculi		*In silico* prediction (not tested)		
Streptococcus ruminantium		*In silico* prediction (not tested)		
Streptococcus salivarius	**-**	ATCC 13419	C699 [S30D]	
	ssp. *thermophilus*	ATCC 19258	NCDO 573 (Type Strain)	
Streptococcus sanguinis		ATCC 10556	DSS-10 (Type Strain)	
Streptococcus sinensis		DSM 14990	HKU4 (Type Strain)/Hong Kong	
Streptococcus sobrinus[c]		ATCC 33478	SL1 (Type Strain)	
Streptococcus suis[c]		ATCC 43765	735 (Type Strain)	
Streptococcus thoraltensis		*In silico* prediction (not tested)		
Streptococcus troglodytae		*In silico* prediction (not tested)		
Streptococcus uberis[c]		*In silico* prediction (not tested)		
Streptococcus urinalis		*In silico* prediction (not tested)		
Streptococcus vestibularis		ATCC 49124	MM1 (Type Strain)/England	
Streptococcus entericus		*In silico* prediction (not tested)		***Streptococcus* spp. Not Detected**
Streptococcus halitosis		*In silico* prediction (not tested)		
Streptococcus hyovaginalis		*In silico* prediction (not tested)		
Streptococcus pantholopis		*In silico* prediction (not tested)		
Other *Streptococcus* species		**Unknown Reactivity** (no sequences/not tested)		

[a] Though the two isolates of *S. equi* tested were detected near LoD, *in silico* analysis predicts some impairment of detection for most (97%) *S. equi* sequences.
[b] *In silico* analysis identified 1/2 (50%) *S. minor* sequences with sequence variation that is predicted to impact reactivity.
[c] *In silico* analysis identified sequence variation that is predicted to impact reactivity in approximately 8% of *S. oralis* sequences evaluated and in approximately 2% (or less) of the *S. sobrinus, S. suis* and *S. uberis* sequences evaluated.

Table 65. Results for *Streptococcus agalactiae* Isolates Tested

Organism	Isolate ID	Serotype[a]	Strain/Location/Year	Result
Streptococcus agalactiae	ATCC 13813	II	G19 (Type Strain)	***Streptococcus***

Organism	Isolate ID	Serotype[a]	Strain/Location/Year	Result
	ATCC 12403	III	Typing strain D136C(3)	***agalactiae*** **Detected**
	ATCC BAA-2669	VIII	5030-08	
	CI 2460	-	-	
	ATCC BAA-611	V	2603 V/R	
	ATCC 12386	-	Grouping strain 090R	

[a] Assay is not serotype-dependent, the assay will react will all serotypes.

Table 66. Results for *Streptococcus pneumoniae* Isolates Tested

Organism	Isolate ID	Serotype [a]	Strain/Location/Year	Result
Streptococcus pneumoniae	ATCC 6303	3	CIP104225	***Streptococcus pneumoniae*** **Detected**
	ATCC 33400	1	SVI (Type Strain)	
	ATCC 700672	14	VH14/Spain	
	ATCC 700673	19A	19A-6/Hungary/1989	
	ATCC BAA-1409	-	62076/Canada/2005	
	ATCC BAA-341	5	SPN1439-106	

[a] Assay is not serotype-dependent, the assay will react will all serotypes.

Table 67. Results for *Streptococcus pyogenes* Isolates Tested

Organism	Isolate ID	Serotype[a]	Strain/Location/Year	Result
Streptococcus pyogenes	ATCC 12344	1	Typing strain T1	***Streptococcus pyogenes*** **Detected**
	ATCC 700294		SF370; M1 GAS	
	ATCC BAA-947		MGAS 5005/Canada/1996	
	ATCC 12384	3	C203	
	ATCC 12348	6	Typing strain S43	
	ATCC 19615	Unknown	Bruno	
	ATCC 49399		QC A62	
	P-03-0543 804 ISO[b]	Unknown	United States/2019	***Streptococcus pyogenes*** **Not Detected**[b]

[a] Assay is not serotype-dependent, the assay will react will all serotypes.
[b] Isolate was obtained from a clinical specimen; investigation suggests a gene target deletion or re-arrangement that prevents detection.

Table 68. Results for *Bacteroides fragilis* Isolates Tested

Organism	Isolate ID	Strain/Location/Year	Result
Bacteroides fragilis	ATCC 25285	VPI 2553 (Type)	***Bacteroides fragilis*** **Detected**
	ATCC BAA 2283	2-1-56 FAA	
	ATCC 29768	12256/P8	
	ATCC 29771	2044 [CDC 1261; M-488]	
	ATCC 43937	F1355 [WAL 78-189A]	

Table 69. Results for *Citrobacter* Isolates Tested

Organism	Isolate ID	Strain/Location/Year	Result
Citrobacter braakii	ATCC 51113	CDC 80-58 (Type Strain)/France	***Citrobacter*** **Detected**
Citrobacter europaeus	GRE 1953016	France	
Citrobacter freundii	ATCC 8090/ATCC 13316	Type Strain	
	ATCC 43864	LRA 117.03.76/France	
	AR Bank #0116	-	
	AR Bank #0157	-	
	GRE 1062177	-	
Citrobacter koseri	ATCC 27156	CDC 3613-63	
	ATCC 27028	14804 (Type Strain)/Denmark	
Citrobacter murliniae	ATCC 51118	CDC 2970-59 (Type Strain)	
Citrobacter pasteurii	*In silico* prediction (not tested)		
Citrobacter portucalensis	*In silico* prediction (not tested)		
Citrobacter werkmanii[a]	ATCC 51114	CDC 0876-58 [83I] (Type Strain)/Belgium	
Citrobacter youngae	ATCC 29935	460-61 (Type Strain)/United States	
Citrobacter amalonaticus	ATCC 25405	9823 (Type Strain)	***Citrobacter*** **Not Detected**
Citrobacter farmeri	ATCC 51112	CDC 2991-81 (Type Strain)/United States	
Citrobacter gillenii	ATCC 51117	CDC 4693-86	
Citrobacter rodentium	GRE 1654045	-	

Organism	Isolate ID	Strain/Location/Year	Result
Citrobacter sedlakii	ATCC 51494	-	
Citrobacter cronae	**Unknown Reactivity** (no sequence/not tested)		

[a] *In silico* analysis identified sequence variation that is predicted to impact reactivity in 3/6 (50%) *C. werkmanii* sequences.

Table 70. Results for *Enterobacter cloacae* complex Isolates Tested

Organism		Isolate ID	Strain	Result
Enterobacter asburiae[a]		GRE 1753006	**-**	***Enterobacter cloacae* complex Detected**
Enterobacter cloacae[a]	**-**	AR Bank #0154	**-**	
		NCTC 13464	-	
	ssp. *cloacae*	ATCC 13047	CDC 442-68 (Type Strain)	
		ATCC 222	CDC 435	
	ssp. *dissolvens*	ATCC 23373D-5 (gDNA)	ICPB ED105 (Type Strain)	
Enterobacter hormaechei[c]	**ssp. *hormaechei***	ATCC BAA-2082	-	
		ATCC 700323	-	
		ATCC 49162[b]	-	
	ssp. *oharea*	CCUG 53905T	Type Strain	
	ssp. *steigerwaltii*	CCUG 53904T	Type Strain	
	ssp. *xiangfangensis*	DSM 46348	-	
Enterobacter kobei		GRE 1753004	-	
Enterobacter ludwigii[a]		DSM 16688	EN-119	
		CCUG 23050	-	
Enterobacter mori[b]		DSM 26271	R18-2	
Enterobacter roggenkampii		DSM 16690	EN-117	
Enterobacter asburiae[a]		ATCC 35953[a]	CDC 1497-78 (Type Strain)	***Enterobacter cloacae* complex Not Detected**

[a] *Enterobacter asburiae* isolate ATCC 35953 has sequence variation under assay primers that impairs detection at 100×LoD and lower. A similar impact on reactivity is predicted for 6/76 (7.9%) *Enterobacter asburiae* sequences evaluated (including sequence from ATCC 35954 and ATCC 35955 (not tested)) and impaired amplification and detection is also predicted for a subset of *E. cloacae* (8/516, 1.6%) and *E. ludwigii* (2/25, 8.0%) sequences.
[b] *E. hormaechei* ssp. *hormaechei* isolate ATCC 49162 has sequence variation under assay primers that impairs detection at 10× LoD (~1.3E+06 copies/mL) and lower. A similar impact on reactivity is predicted for 10/685 (1.4%) *E. hormaechei* and 1/8 (12.5%) *E. mori* sequences evaluated.

Note: the designation of some *Enterobacter* species (e.g. *E. bugandensis*, *E. cancerogenus E. chengduensis*, etc.) as members of the *Enterobacter cloacae* complex is uncertain. *In silico* analysis predicts that the BioFire JI Panel will react efficiently with and detect *E. chengduensis* and a subset (~30%) of the *E. bugandensis* sequences evaluated. Reactivity with other *E. bugandensis* sequences is impaired ≥100-fold. Reactivity with *E. chengduensis* and *E. bugandensis* is also described as cross-reactivity in Table 93. *In silico* analysis and testing indicate that the BioFire JI Panel will not detect *E. cancerogenus*.

Table 71. Results for *Escherichia coli* Isolates Tested

Organism	Isolate ID	Strain/Location/Year	Result
Escherichia coli	CDC AR Bank 0150	-	***Escherichia coli* Detected**
	CDC AR Bank #0137	-	
	CDC AR Bank #0162	-	
	CDC AR Bank #0086	-	
	CDC AR Bank #0061	-	
	ATCC 11775	9001 U 5/41 (Type Strain)	
	GRE 1256018	-	
	Zeptometrix 0801905	Z136	

Table 72. Results for *Haemophilus influenzae* Isolates Tested

Organism	Serotype[a]	Isolate ID	Strain/Location/Year	Result
Haemophilus influenzae	a	ATCC 9006	AMC 36-A-3 [610, PCM 2436]	***Haemophilus influenzae* Detected**
	b	ATCC 10211	AMC 36-A-1 [572]	
	c	ATCC 49699	C 9007	
	d	ATCC 9008	AMC 36-A-6 [611]	
	e	ATCC 8142	595 Murray Biotype IV AMC 36-A-7 [595]	
	f	ATCC 700223	GA1264/United States	
	non-typeable	ATCC 33391	680 Biotype II (Type Strain)	
		ATCC 51997	INT 1 Biotype V/United States	

Organism	Serotype[a]	Isolate ID	Strain/Location/Year	Result
	Unknown	Clinical Isolate[b]	Utah/United States/2012	***Haemophilus influenzae*** **Not Detected**

[a] Assay reactivity is not serotype-dependent, the assay will react with all types and non-typeable isolates.
[b] Isolate was obtained from a clinical specimen; a deletion in the gene target was identified that prevents amplification/detection.

Table 73. Results for *Kingella kingae* Isolates Tested

Organism	Isolate ID	Strain/Location/Year	Result
Kingella kingae	ATCC 23330	4177/66 (Type Strain)	***Kingella kingae*** **Detected**
	ATCC 23331	2941	
	CCUG 63569	United Kingdom	
	CCUG 50167A	Sweden/2004	
	CCUG 44801	Sweden/2001	

Table 74. Results for *Klebsiella aerogenes* Isolates Tested

Organism	Isolate ID	Strain/Location/Year	Result
Klebsiella aerogenes	AR Bank #0074	-	***Klebsiella aerogenes*** **Detected**
	AR Bank #0062	-	
	AR Bank #0161	-	
	ATCC 13048	Type Strain/United States	
	GRE 1254066	-	
	ATCC 29751[a]	MULB-250	***Klebsiella aerogenes*** **Not Detected**

[a] *Klebsiella aerogenes* isolate ATCC 29751 has sequence variation under assay primers that impairs detection at 100×LoD and lower. A similar impact on reactivity is predicted for 9/193 (4.7%) *Klebsiella aerogenes* sequences evaluated.

Table 75. Results for *Klebsiella pneumoniae* group Isolates Tested

Organism		Isolate ID	Strain/Location/Year	Result
Klebsiella pneumoniae	-	AR Bank #0097	-	***Klebsiella pneumoniae*** **group Detected**
		AR Bank# 0079	-	
		AR Bank #0107	-	
		AR Bank #0075	-	
		JMI 766	-	
		AR Bank #0040	-	
		AR Bank# 0068	-	
		AR Bank# 0080	-	
	ssp. *ozaenae*	ATCC 11296	Type Strain/Sumatra/1931	
		AR Bank #0051	-	
	ssp. *pneumoniae*	ATCC 13883	Type strain /-/1955	
	ssp. *rhinosclermatis*	ATCC 13884	R-70 (Type Strain)/Sumatra	
Klebsiella quasipneumoniae	-	DSM 28211	Type Strain Austria/1997	
	ssp. *similipneumoniae*	DSM 28212	Type Strain Germany/1997	
Klebsiella variicola		ATCC BAA-830	F2R9 (Type Strain)	

Table 76. Results for *Morganella morganii* Isolates Tested

Organism		Isolate ID	Strain/Location/Year	Result
Morganella morganii	-	AR Bank# 0057	-	***Morganella morganii*** **Detected**
	ssp. *morganii*	ATCC 25830	M11 (Type Strain)	
		ATCC 33791	Potter	
	ssp. *sibonii*	ATCC 49948	CDC 9103-85	
		ATCC 51207	CDC 8246-91	

Table 77. Results for *Neisseria gonorrhoeae* Isolates Tested

Analyte	Isolate ID	Strain/Location/Year	Result
Neisseria gonorrhoeae	ATCC 19424	B 5025 (Type Strain)	***Neisseria gonorrhoeae*** **Detected**
	NCTC 6820	Gono 4/England/1944	
	ATCC 19088	CH-6/-/1983	
	ATCC 700825	FA1090	
	Zeptometrix 0801482	Z017	

Analyte	Isolate ID	Strain/Location/Year	Result
	NCTC 13817[a]	Sweden/2011	***Neisseria gonorrhoeae*** **Not Detected**

[a] Isolate (also described as WHO-U strain) carries an atypical variant of the gene target (suspected horizontal transfer with homologous gene in *N. meningitidis*) that is not detected by the assay.

Table 78. Results for *Proteus* spp.[a] Isolates Tested

Organism	Isolate ID	Strain/Location/Year	Result
Proteus alimentorum	*In silico* prediction (not tested)		***Proteus* spp. Detected**
Proteus columbae	*In silico* prediction (not tested)		
Proteus hauseri	ATCC 13315	Lehmann/Austria/1933	
	ATCC 700826	Type Strain/United States	
Proteus mirabilis	ATCC 35659	LRA 08 01 73/France	
	ATCC 29906	Type Strain	
	AR Bank #0156	United States	
	AR Bank #0159	-	
	GRE 1254053	-	
Proteus penneri	ATCC 33519	Type Strain/United States	
	ATCC 35197	United States	
Proteus terrae	DSM 29910	N5/687 (Type Strain)/Germany	
***Proteus terrae ssp. cibarius* (*Proteus cibarius*)**	DSM 100173	JS9 (Type Strain)/South Korea/2011	
Proteus vulgaris	ATCC 27973	CDC 1787-64-SC1/United States	
	ATCC 29905	Type Strain	

[a] The *Proteus* genus now also includes the species *P. cibi* and *P. faecis*. Reactivity with these species has not been evaluated.

Table 79. Results for *Pseudomonas aeruginosa* Isolates Tested

Analyte	Isolate ID	Strain/Location/Year	Result
Pseudomonas aeruginosa	AR Bank #0092	-	***Pseudomonas aeruginosa*** **Detected**
	ATCC 27853	Boston 41501	
	AR Bank #0064	-	
	AR Bank #0111	-	
	AR Bank #0103	-	
	AR Bank #0090	-	
	AR Bank #0100	-	
	AR Bank #0054	-	
	CUSM PS28	-	
	NCTC 13437	-	
	ATCC 9027[a]	-	***Pseudomonas aeruginosa*** **Not Detected**
	ATCC 25619[b]	-	

[a] *Pseudomonas aeruginosa* isolate ATCC 9027 has sequence variation under assay primers that impairs detection at 10× LoD and lower. Detection was observed in all replicates at 100× LoD (~1.3E+06 copies/mL). Similar impacts on reactivity are predicted for approximately 50/1524 (3.3%) *P. aeruginosa* sequences evaluated.
[b] *Pseudomonas aeruginosa* isolate ATCC 25619 has sequence variation under assay primers that prevents amplification and detection.

Table 80. Results for *Salmonella* spp. Isolates Tested

Organism (alternate ssp. designation)		Isolate ID	Serovar	Strain/Location/Year	Result
Salmonella bongori **(V)**		SGSC 3100 SARC11	-	RKS3041 CDC 750-72/-/1972	***Salmonella* spp. Detected**
		NCTC 10946	Brookfield	-	
		ATCC 43975	-	Type Strain	
Salmonella enterica	**ssp. *arizonae* (IIIa)**	ATCC 13314	-	Type Strain United States/1953	
	ssp. *diarizonae* (IIIb)	SGSC 3069 SARC8	-	RKS2979 CDC 678-94/California/1984	
	ssp. *enterica* (I)	AR Bank #0407	Concord	-	
		ATCC 700720	Typhimirium	LT2/-/1948	
		ATCC BAA-708	Enteritidis	-	
		SGSC 2210 SARA30	Heidelberg	Pennsylvania/1987	
		ATCC BAA-710	Montevideo	G4639/-/1993	
		AR Bank #0127	Senftenberg	-	
		ATCC 700931D-5 (gDNA)	Typhi	Ty2 Type Strain	

Organism (alternate ssp. designation)		Isolate ID	Serovar	Strain/Location/Year	Result
	ssp. *houtenae* (IV)	SGSC 3074 SARC9	-	RKS3015 CDC 2584-68/Panama/1968	
	ssp. *indica* (VI)	SGSC 3116 SARC13	-	RKS2995 CDC1363-65/India/1965	
	ssp. *salamae* (II)	SGSC 3047 SARC4	-	RKS2993 CDC3472-64/-/1964	

Table 81. Results for *Serratia marcescens* Isolates Tested

Organism		Isolate ID	Strain/Location/Year	Result
Serratia marcescens	-	API 1411137	-	***Serratia marcescens* Detected**
		API 1512393	-	
		AR Bank #0091	-	
		JMI 697	-	
	ssp. *marcescens*	ATCC 13880	BS 303 (Type Strain)/Czech Republic/1960	
	ssp. *sakuensis*	ATCC BAA-885	KRED (Type Strain)/Japan/1992	

Table 82. Results for *Candida* Isolates Tested (teleomorph name/taxonomic revisions are indicated in parentheses)

Analyte	Isolate ID	Strain	Result
Candida albicans	See *C. albicans* table		***Candida* Detected**
Candida dubliniensis	ATCC MYA-646	CBS 7987 (Type strain)	
	ATCC MYA-578	H12	
Candida glabrata (*Nakaseomyces glabrata*)	ATCC 15545	NRRl YB-4025	
	ATCC 2001	CBS 138 (Type strain)	
	CI-953	-	
Candida krusei (*Issatchenkia orientalis or Pichia kudriavzevii*)	ATCC 6258	Type Strain	
	ATCC 28870	CBS 2052 (Type strain)	
Candida metapsilosis	ATCC 96143	MCO429 [UTHSC 87-285]	
Candida orthopsilosis	ATCC 96139	MCO457 [R-430] (Type strain)	
Candida parapsilosis	ATCC 28475	CBS 2915 (Type strain)	
	ATCC 22019	CBS 604 (Type strain)	
Candida sojae	NRRL Y-17909	-	
Candida tropicalis	ATCC 750	Type Strain	
	ATCC 66029	AmMS 227	
Candida auris [a]	AR Bank #0381	-	***Candida* Not Detected**[a]
	AR Bank #0385	-	
	GRE 1756004[a]	-	
Candida ciferrii (*Trichomonascus ciferrii*)	ATCC 584433	CBS 5295	
Candida colliculosa (*Torulaspora delbrueckii*)	ATCC 10662	NRRL Y-866	
Candida duobushaemulonis	*In silico* prediction (not tested)		
Candida fabianii (*Cyberlindnera fabianii*)	*In silico* prediction (not tested)		
Candida famata (*Debaryomyces hansenii*)	ATCC 4144	D.R. 1658 No. 14	
Candida fermentati (*Pichia caribbica* or *Myerozyma carribica*)	*In silico* prediction (not tested)		
Candida guilliermondii (*Meyerozma guilliermondii*)	ATCC 38290	Tu 62304-2	
Candida haemolunii [a]	AR Bank #0393	-	
Candida holmii	DSM 70627	-	
Candida inconspicua [a] (*Pichia cactophila*)	ATCC 16783	CBS 180 (Type Strain)	
Candida intermedia [a]	ATCC 14439		
Candida jadinii	*In silico* prediction (not tested)		
Candida kefyr [a] (*Kluyveromyces marxianus*)	ATCC 42265	CBS 834	
	ATCC 204093	-	
Candida lipolytica (*Yarrowia lipolytica*)	ATCC 18944	NRRL YB-423-12	
Candida lusitaniae [a] (*Clavispora lusitaniae*)	ATCC 42720	45090	
	ATCC 34449	IFO 1019 (Type Strain)	

Analyte	Isolate ID	Strain	Result
Candida nivariensis [a] (*Nakaseomyces nivariensisa*)	CCUG 56432	-	
Candida norvegensis [a] (*Pichia norvegensis*)	GRE 0856055	-	
Candida pelliculosa (*Wickerhamomyces anomalus*)	*In silico* prediction (not tested)		
Candida rugosa (*Diutina rugosa*)	ATCC 10571	NRRL Y-1496	
Candida sphaerica [a] (*Kluyveromyces lactis*)	GRE 1951001		
Candida thermophila	ATCC 58401	-	
Candida utilis [a] (*Cyberlindnera jadinii*)	ATCC 22023	-	
Candida viswanathii [a]	ATCC 22981	-	

[a] Species may be detected at high concentration (>100×LoD).

Table 83. Results for *Candida albicans* Isolates Tested

Organism	Isolate ID	Strain	Result
Candida albicans	ATCC 90028	NCCLS 11	***Candida albicans*** **Detected**
	ATCC 10231	3147	
	ATCC 11006	Type Strain	
	ATCC 14053	NIH 3172	
	ATCC 22972	M 97	

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 84. Results for CTX-M Isolates Tested and Predicted Reactivity for CTX-M Types

CTX-M Type	Organism	Isolate ID	Result
CTX-M-2	*Klebsiella pneumoniae*	AR Bank #0107	**CTX-M Detected**
CTX-M-3	*Escherichia coli*	NCTC 13452	
	Shigella flexneri	AR Bank #0421	
CTX-M-8	*Escherichia coli*	NCTC 13463	
CTX-M-9	*Enterobacter cloacae*	NCTC 13464	
CTX-M-14	*Klebsiella pneumoniae*	AR Bank #0079	
CTX-M-15	*Citrobacter freundii*	GRE 1062177	
	Klebsiella pneumoniae	AR Bank #0075	
	Klebsiella pneumoniae	AR Bank #0040	
	Morganella morganii	AR Bank #0057	
	Salmonella enterica	AR Bank #0407	
CTX-M-22	*Proteus mirabilis*	GRE 1254053	
CTX-M-25	*Klebsiella pneumoniae*	NCTC 13465	
CTX-M-55	*Escherichia coli*	AR Bank #0346	
CTX-M-124	*Kluyvera ascorbata*[a]	AR Bank #0144	

In silico **Reactivity Predictions**[b]				
Detected		**Not Detected**	**Unknown Reactivity** (no sequences)	
CTX-M-1 – CTX-M-69	CTX-M-136 – CTX-M-139	CTX-M-74	CTX-M-70	CTX-M-140
CTX-M-71 – CTX-M-73	CTX-M-141 – CTX-M-142	CTX-M-75	CTX-M-119	CTX-M-143
CTX-M-76 – CTX-M-112	CTX-M-144	CTX-M-113	CTX-M-120	CTX-M-145
CTX-M-114 – CTX-M-117	CTX-M-146 – CTX-M-148	CTX-M-151	CTX-M-128	CTX-M-149
CTX-M-121 – CTX-M-127	CTX-M-150		CTX-M-133	CTX-M-153
CTX-M-129 – CTX-M-132	CTX-M-152		CTX-M-135	CTX-M-154
CTX-M-134	CTX-M-155 – CTX-M-229			

[a] Isolate was tested only to evaluate CTX-M assay reactivity, the species is not detected by the panel.
[b] A subset of CTX-M sequences (<1%) of various types have sequence variation under the assay primers that may impact detection.

Table 85. Results for IMP Isolates Tested and Predicted Reactivity for IMP Types

IMP Type	Organism	Isolate ID	Result
IMP-1	*Pseudomonas aeruginosa*	AR Bank #0103	**IMP Detected**
IMP-4	*Klebsiella aerogenes*	AR Bank #0161	
	Klebsiella pneumoniae	AR Bank #0080	
IMP-8	*Enterobacter cloacae*	AR Bank #0502	
	Klebsiella pneumoniae	GRE 1062084	
IMP-13	*Klebsiella pneumoniae*	Zeptometrix 0801904	
IMP-14	*Pseudomonas aeruginosa*	AR Bank #0092	

In silico Reactivity Predictions			
Detected[a]		**Not Detected**	**Unknown Reactivity** (no sequences)
IMP-1 – IMP-30 IMP-32 – IMP-34 IMP-37 – IMP-45 IMP-48 – IMP-49	IMP-51 – IMP-56 IMP-58 – IMP-64 IMP-66 – IMP-84	IMP-31 IMP-35 IMP-46	IMP-36 IMP-47 IMP-50 IMP-57 IMP-65

[a] Approximately 10% of IMP sequences of various types have mismatches to the assay primer(s) that may impact detection.

Table 86. Results for KPC Isolates Tested and Predicted Reactivity for KPC Types

KPC Type[a]	Organism	Isolate ID	Result
KPC-2	*Citrobacter freundii*	AR Bank #0116	**KPC Detected**
	Pseudomonas aeruginosa	CUSM PS28	
	Serratia marcescens	JMI 697	
KPC-3	*Klebsiella pneumoniae*	AR Bank #0097	
	Escherichia coli	AR Bank #0061	
KPC-4	*Klebsiella pneumoniae*	JMI 766	
KPC-5	*Pseudomonas aeruginosa*	AR Bank #0090	
KPC-6	*Proteus mirabilis*	AR Bank #0155	
KPC-11	*Klebsiella pneumoniae*	AR Bank #0525	
Unknown	*Enterobacter hormaechei*	BAA-2082	

[a] *In silico* analysis predicts reactivity with all KPC types (KPC-1 – KPC-46).

Table 87. Results for *mecA/C*[a] and MREJ (MRSA) and Predicted Reactivity for MREJ Types

Organism	Isolate ID[b]	Strain/Location/Year	SCCmec Type/ MREJ Type	Result
Methicillin-resistant *Staphylococcus aureus* (MRSA)	NARSA NRS705	NY-12	SCCmec Type II	***mecA/C* and MREJ (MRSA) Detected**
	NARSA NRS701	MN-082		
	ATCC BAA-1717	TCH1516	SCCmec Type IV	
	NARSA NRS683	GA-298		
	NARSA NRS662	CO-34		
	NARSA NRS707	NY-155		
	ATCC BAA-1707	MW2		
	NARSA NRS691	GA-62		
	NARSA NRS648	CA-347	SCCmec Type II or IV	
	NARSA NRS689	GA-442	SCCmec Type IV	
	ATCC BAA-1700	HFH-30137		
	BEI NR-46081[b]	HIP12899		
	ATCC 43300	F182 Kansas	SCCmec Type II	
	ATCC BAA-1720	-		
	NARSA NRS745	CA-629	SCCmec Type IV or V	
	ATCC BAA-2312	Ireland/2010	SCCmec Type XI (*mecC*)	
	ATCC BAA-2313	Ireland/2010		
	ATCC BAA-38	-	MREJ Type i	
	NARSA NRS686	-		
	ATCC BAA-44	-	MREJ Type ii	
	ATCC BAA-42	-		
	ATCC BAA-39	-	MREJ Type iii	
	ATCC BAA-40	-	MREJ Type iv	
	GRE1062264	-		
	ATCC BAA-2096	-	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	
	GRE 1062373	-	MREJ Type xv[c]	***mecA/C* and MREJ (MRSA) Not Detected**
	GRE 1062292	-	MREJ Type xviii	
Methicillin-sensitive *Staphylococcus aureus* (MSSA)	ATCC BAA-2421[d]	Mass/2010	SCCmec Type II (variant *mecA* gene[d])	***mecA/C* and MREJ (MRSA) Detected[d]**
	Rennes 1060728 DAC	-	Empty SCCmec cassette (no *mecA* or *mecC* gene)	***mecA/C* and MREJ (MRSA)**

Organism	Isolate ID[b]	Strain/Location/Year	SCCmec Type/ MREJ Type	Result
	GRE 1062519	-	MREJ Type xix[e]	**Not Detected**
***In silico* Reactivity Predictions for MREJ Types**				
Detected[f]			**Not Detected**	**Unknown Reactivity** (no sequences)
MREJ Type i	MREJ Type vii	MREJ Type xvi	MREJ xv[c]	MREJ Type viii
MREJ Type ii	MREJ Type ix	MREJ Type xvii	MREJ Type xviii	MREJ Type x
MREJ Type iii	MREJ Type xi	MREJ Type xxi	MREJ Type xix[e]	
MREJ Type iv	MREJ Type xii		MREJ Type xx[e]	
MREJ Type v	MREJ Type xiii			
MREJ Type vi	MREJ Type xiv			

[a] *In silico* analysis predicts that more than 99.9% of the *mecA* and *mecC* sequences evaluated will be detected.
[b] NARSA/NRS isolates were provided by the Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) for distribution by BEI Resources, NIAID, NIH.
[c] Approximately 40% of the MREJ type xv – like sequences evaluated have a sequence variation that is predicted to substantially impair or prevent detection by the MREJa assay. However, no limitations on detection are predicted for ~60% of MREJ type xv – like sequences evaluated. The prevalence of MREJ type xv, with or without the sequence variation, is currently unknown.
[d] Isolate carries a *mecA* gene variant that is amplified by the mecA/C assay but is non-functional. Reporting based on genotype will not match phenotype.
[e] Isolates with MREJ types xix and xx have been described as methicillin-sensitive; the BioFire JI Panel *mecA/C* and MREJ (MRSA) Not Detected result for isolates of these types is predicted to match their phenotypic methicillin-susceptibility profile.
[f] Approximately 1% of MREJ sequences of the various types have mismatches to the assay primer(s) that may impair detection.

Table 88. Results for NDM Isolates Tested and Predicted Reactivity for NDM Types

NDM Type	Organism	Isolate ID	Result
NDM-1	*Citrobacter freundii*	AR Bank #0157	**NDM Detected**
	Enterobacter cloacae	AR Bank #0038	
	Morganella morganii	AR Bank #0057	
	Proteus mirabilis	AR Bank #0159	
	Pseudomonas aeruginosa	AR Bank #0246	
	Salmonella enterica	AR Bank #0127	
NDM-2	*Acinetobacter baumannii*[a]	GRE 1153064	
NDM-5	*Escherichia coli*	AR Bank #0150	
NDM-6		AR Bank #0137	
NDM-7	*Klebsiella pneumoniae*	AR Bank #0138	
		AR Bank #0068	

***In silico* Reactivity Predictions**			
Detected[b]		**Unknown Reactivity (no sequences)**	
NDM-1 – NDM-13	NDM-32	NDM-14	NDM-33-39
NDM-15 – NDM-23	NDM-40	NDM-24 – NDM-26	
NDM-27 – NDM-29		NDM-30 – NDM-31	

[a] Isolate was tested only to evaluate NDM assay reactivity, the species is not detected by the panel.
[b] Less than 1% of NDM sequences of various types have mismatches to the assay primer(s) that may impact detection.

Table 89. Results for OXA-48-like Isolates Tested and Predicted Reactivity for OXA-*48*-like Types

OXA-48-like Type	Organism	Isolate ID	Result
OXA-48	*Klebsiella (Enterobacter) aerogenes*	AR Bank #0074	**OXA-48-like Detected**
OXA-48-like	*Serratia marcescens*	API 1411137	
OXA-162	*Klebsiella pneumoniae*	GRE 1355030	
OXA-181	*Klebsiella pneumoniae*	AR Bank #0051	
OXA-232	*Klebsiella pneumoniae*	AR Bank #0075	

***In silico* Reactivity Predictions**					
Detected			**Not Detected[a,b,c]**		
OXA-48	OXA-244	OXA-515	OXA-54[b]	OXA-439[c]	OXA-551[c]
OXA-48-like	OXA-245	OXA-519	OXA-163[c]	OXA-517[c]	OXA-552[c]
OXA-162	OXA-252	OXA-546	OXA-247[c]	OXA-535[c]	OXA-553[c]
OXA-181	OXA-370	OXA-547	OXA-405[c]	OXA-538[c]	OXA-567[c]
OXA-199	OXA-484	OXA-566	OXA-416[b]	OXA-548[c]	OXA-731[c]
OXA-204	OXA-505		OXA-436[c]	OXA-549[c]	
OXA-232	OXA-514		OXA-438[c]	OXA-550[c]	

[a] 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.
[b] OXA-54 and OXA-416 are progenitors of OXA-48-like found in *Shewanella* species and will not be detected.
[c] OXA-48-like types with altered carbapenem hydrolysis activity will not be detected.

Table 90. Results for *vanA/B* Isolates Tested

van Type	Organism	Isolate ID	Result
vanA	*Enterococcus faecium*	ATCC 700221	***vanA/B* Detected**
		JMI 475	
		ATCC BAA-2318	
	Enterococcus faecalis	JMI 12536	

van Type	Organism	Isolate ID	Result
		ATCC BAA-2573	
vanB	*Enterococcus faecium*	ATCC 51858	
	Enterococcus faecalis	ATCC 700802	
		ATCC 51575	
		ATCC BAA-2365	
		ATCC 51299	

Table 91. Results for VIM Isolates Tested and Predicted Reactivity for VIM Types

VIM Type	Organism	Isolate ID	Result
VIM-1	*Enterobacter cloacae*	AR Bank #0154	**VIM Detected**
VIM-2	*Pseudomonas aeruginosa*	AR Bank #0100	
VIM-4	*Pseudomonas aeruginosa*	AR Bank #0054	
VIM-7	*Escherichia coli*	GRE 1256018	
VIM-10	*Pseudomonas aeruginosa*	NCTC 13437	
VIM-11	*Pseudomonas aeruginosa*	AR Bank #0239	
VIM-27	*Klebsiella pneumoniae*	AR Bank #0040	

***In Silico* Reactivity Predictions**				
Detected[a]		**Not Detected**		**Unknown Reactivity** (no sequences)
VIM-1 – VIM-6 VIM-8 – VIM-20 VIM-23 – VIM-38 VIM-40 – VIM-44	VIM-47 – VIM-60 VIM-62 – VIM-64 VIM-66	VIM-7 VIM-39 VIM-45 VIM-46	VIM-61 VIM-65 VIM-67	VIM-21 VIM-22

[a] Approximately 3% of VIM sequences of various types have mismatches to assay primer(s) that may impact detection.

Analytical Specificity (Cross-Reactivity)

The potential for non-specific amplification and detection (cross-reactivity) by the BioFire JI Panel assays was evaluated by *in silico* analysis of available sequences and by testing high concentrations of on-panel and off-panel organisms (and antimicrobial resistance genes). Each organism was tested in triplicate with most bacteria tested at a concentration >1.0E+08 CFU/mL and most yeast tested at a concentration >1.0E+06 CFU/mL. Off-panel fungi, viruses, and parasites were tested at the highest cultured concentration possible.

The on-panel and off-panel organisms tested are listed in Table 93. Testing included species and AMR genes that are genetically related to the species or AMR genes detected by the panel (same genus or otherwise related) as well as unrelated organisms that may be found in synovial fluid as pathogens or contaminants (e.g. skin microorganisms, viruses, etc.). All observed or predicted cross-reactivities (summarized in Table 92 and indicated with shading in Table 93) are associated with very closely-related species (same genus) or AMR genes derived from similar lineages.

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 92. Summary of BioFire JI Panel Cross-Reactivity with Closely-Related Off-Panel Species and/or AMR Genes

BioFire JI Panel Result	Cross-Reactive Organism/AMR Gene
Closely-Related Species (same genus)	
Anaerococcus prevottii/vaginalis	*Anaerococcus degeneri*
	Anaerococcus hydrogenalis
	Anaerococcus lactolyticus
	Anaerococcus murdochii
	Anaerococcus nagyae
	Anaerococcus octavius
	Anaerococcus senegalensis
	Anaerococcus tetradius
Bacteroides fragilis	*Bacteroides xylanisolvens*
Clostridium perfringens	*Clostridium cadaveris*
	Clostridium fallax
Enterobacter cloacae complex	*Enterobacter bugandensis*[b]
	Enterobacter chengduensis[b]
Escherichia coli	*Escherichia albertii*
	Escherichia fergusonii
	Shigella boydii

BioFire JI Panel Result	Cross-Reactive Organism/AMR Gene
	Shigella dysenteriae
	Shigella flexneri
	Shigella sonnei
Haemophilus influenzae	*Haemophilus aegyptius*
Kingella kingae	*Kingella negevensis*
Proteus spp.	*Cosenzaea* (*Proteus*) *myxofaciens*
Staphylococcus aureus[b] (and *mecA/C* and MREJ (MRSA))	*Staphylococcus argenteus*[b]
	Staphylococcus schweitzeri[b]
AMR Genes Derived from Similar Lineages	
CTX-M[c]	*ampC*, bla_{KLU}, bla_{OXY}, bla_{RAHN}
vanA/B	*vanM*

[a] *Enterobacter bugandensis* and *E. chengduensis* are recently identified species that are very closely-related to ECC species. Both are indicated as cross-reactive with the *Enterobacter cloacae* complex assay because their designation as ECC members is currently uncertain.

[b] *Staphylococcus aureus*, *S. argenteus* and *S. schweitzeri* are closely-related members of the *Staphylococcus aureus* complex.

[c] CTX-M cross-reactivity with ancestral bla_{KLU} genes and other related beta-lactamases is predicted to be inefficient and will only occur at high concentrations. The cross-reactive product will only be reported as CTX-M Detected if an applicable gram-negative bacterial species is also detected in the sample.

Table 93. On-Panel and Off-Panel Organisms and AMR Genes Evaluated for Analytical Specificity of the BioFire JI Panel
Species and AMR genes in **bold** font were detected or are predicted to be detected by the panel at high concentration.
Grey shading indicates cross-reactivity.

Species/AMR Genes Tested for Evaluation of Analytical Specificity			
Gram-Positive Bacteria			
Acidipropionibacterium acidipropionici	*Corynebacterium striatum*	*Mycobacterium marinum*	***Streptococcus intermedius***
Acidipropionibacterium jensenii	*Corynebacterium urealyticum*	*Mycobacterium tuberculosis*	***Streptococcus mitis***
Actinomyces israelii	*Cutibacterium (Propionibacterium) acidifaciens*	*Nocardia brasiliensis*	***Streptococcus mutans***
Actinomyces naeslundii	*Cutibacterium (Propionibacterium) acnes*	***Parvimonas micra***	***Streptococcus oligofermentans***
Actinomyces (Schaalia) odontolyticus	***Cutibacterium avidum***	*Peptococcus niger*	***Streptococcus oralis***
Aerococcus urinae	***Cutibacterium granulosum***	***Peptoniphilus allenii***	***Streptococcus parasanguinis***
Aerococcus sanguinicola	*Cutibacterium (Propionibacterium) namnetense*	***Peptoniphilus asaccharolyticus***	***Streptococcus peroris***
Anaerococcus degeneri[a]	*Enterococcus avium*	*Peptoniphilus coxii*[c]	***Streptococcus pneumoniae***
Anaerococcus hydrogenalis[a]	*Enterococcus casseliflavus*	*Peptoniphilus duerdenii*[c]	***Streptococcus pseudopneumoniae***
Anaerococcus lactolyticus[a]	*Enterococcus cecorum*	***Peptoniphilus gorbachii***	***Streptococcus pyogenes***
Anaerococcus murdochii[a]	*Enterococcus durans*	***Peptoniphilus grossensis***	***Streptococcus salivarius (ssp. salivarius & thermophilus)***
Anaerococcus nagyae[a]	***Enterococcus faecalis***	***Peptoniphilus harei***	***Streptococcus sanguinis***
Anaerococcus octavius[a]	***Enterococcus faecium***	***Peptoniphilus indolicus***	***Streptococcus sinensis***
Anaerococcus pacaensis	*Enterococcus gallinarum*	*Peptoniphilus ivorii*[c]	***Streptococcus suis***
Anaerococcus prevotii	*Enterococcus hirae*	***Peptoniphilus koenoeneniae***	***Streptococcus vestibularis***
Anaerococcus senegalensis[a]	*Enterococcus mundtii*	***Peptoniphilus lacrimalis***	***Staphylococcus argenteus***[d]
Anaerococcus tetradius[a]	*Enterococcus pseudoavium*	*Peptoniphilus massiliensis*[c]	***Staphylococcus aureus***
Anaerococcus vaginalis	*Enterococcus raffinosus*	*Peptoniphilus olsenii*[c]	*Staphylococcus capitis*
Atopobium parvulum	*Enterococcus saccharolyticus*	***Peptoniphilus senegalensis***	*Staphylococcus caprae*
Bifidobacterium bifidum	*Filifactor alocis*	***Peptoniphilus tyrelliae***	*Staphylococcus carnosus*
Bifidobacterium dentium	***Finegoldia magna***	***Peptostreptococcus anaerobius***	*Staphylococcus cohnii*
Blautia producta	*Gallicola barnesae*	*Peptostreptococcus stomatis*	*Staphylococcus epidermidis*
Brevibacterium linens	*Gemella haemolysans*	*Propionibacterium freudenreichii*	*Staphylococcus equorum*
Clostridium botulinum	*Gemella morbllorum*	*Rhodococcus equi*	*Staphylococcus haemolyticus*
Clostridium butyricum	*Gemella sanguinis*	*Sarcina (Clostridium) ventriculii*	*Staphylococcus hominis*
Clostridium cadaveris[b]	*Gordonia bronchialis*	*Slackia heliotrinitrireducens*	*Staphylococcus intermedius*
Clostridium clostridioforme	*Granulicatella adiacens*	***Streptococcus agalactiae***	***Staphylococcus lugdunensis***
Clostridioides (Clostridium) difficile	*Helcococcus kunzii*	***Streptococcus alactolyticus***	*Staphylococcus lutrae*
Clostridium fallax[b]	*Lactobacillus casei*	***Streptococcus anginosus***	*Staphylococcus pasteuri*
Clostridium perfringens	*Lactobacillus rhamnosus*	***Streptococcus australis***	*Staphylococcus pseudointermedius*
Clostridium ramosum	*Lactobacillus salivarius*	***Streptococcus bovis***	*Staphylococcus saprophyticus*
Clostridium septicum	*Lactococcus garvieae*	***Streptococcus constellatus***	*Staphylococcus schleiferi*
Clostridium sordellii	*Lactococcus lactis*	***Streptococcus cristatus***	***Staphylococcus schweitzeri***[d]
Clostridium sphenoides	*Listeria monocytogenes*	***Streptococcus downei***	*Staphylococcus warneri*
Clostridium sporogenes	*Lysinibacillus sphaericus*	***Streptococcus dysgalactiae (ssp dysgalactiae & equisimilis)***	*Staphylococcus xylosus*
Clostridium tertium	*Macrococcus caseolyticus*	***Streptococcus equi***	*Vagococcus fluvialis*
Clostridium tetani	*Micrococcus luteus*	***Streptococcus equinus***	
Corynebacterium diphtheriae	*Murdochiella asaccharolytica*	***Streptococcus gallolyticus (ssp. gallolyticus & pasteurianus)***	
Corynebacterium pseudodiphtheriticum	*Mycobacterium abscessus*	***Streptococcus gordonii***	
Corynebacterium jeikeium	*Mycobacterium kansasii*	***Streptococcus infantarius***	
Gram-Negative Bacteria			
Actinobacillus arthritidis	*Cronobacter malonaticus*	***Klebsiella pneumoniae***	*Pseudomonas alcaligenes*
Acidaminococcus fermentans	*Cronobacter muytjensii*	***Klebsiella quasipneumoniae***	*Pseudomonas chlororaphis*

Species/AMR Genes Tested for Evaluation of Analytical Specificity			
Acinetobacter nosocomialis	*Cronobacter sakazakii*	***Klebsiella variicola***	*Pseudomonas fluorescens*
Acinetobacter schindleri	*Cronobacter turicensis*	*Kluyvera intermedia*	*Pseudomonas luteola*
Aeromonas hydrophila	*Cronobacter zurichensis (Siccibacter turicensis)*	*Kosakonia* (*Enterobacter*) *sacchari*	*Pseudomonas mendocina*
Aggregatibacter actinomycetemcomitans	*Edwardsiella tarda*	*Lelliotia* (*Enterobacter*) *amnigena*	*Pseudomonas nitroreducens*
Bacteroides dorei	*Eikenella corrodens*	*Lelliotia* (*Enterobacter*) *nimipressuralis*	*Pseudomonas oryzihabitans*
Bacteroides caccae	***Enterobacter asburiae***	*Leclercia adecarboxylata*	*Pseudomonas otitidis*
Bacteroides eggerthii	***Enterobacter bugandensis***[h]	*Massilia timonae*	*Pseudomonas pertucinogena*
Bacteroides forsytus	*Enterobacter cancerogenus*	*Megasphaera elsdenii*	*Pseudomonas protegens*
Bacteroides fragilis	***Enterobacter chengduensis***[h]	*Megasphaera indica*	*Pseudomonas putida*
Bacteroides helcogenes	***Enterobacter cloacae***	*Megasphaera massiliensis*	*Pseudomonas stutzeri*
Bacteroides stercoris	***Enterobacter hormaechei***	*Moraxella catarrhalis*	*Ralstonia pickettii*
Bacteroides thetaiotaomicron	***Enterobacter kobei***	*Moraxella lacunata*	*Raoultella ornithinolytica*
Bacteroides uniformis	***Enterobacter ludwigii***	***Morganella morganii***	*Raoultella planticola*
Bacteroides vulgatus	***Enterobacter mori***	*Neisseria cinerea*	***Salmonella bongori***
Bacteroides xylanisolvens[e]	***Escherichia albertii***[i]	***Neisseria gonorrhoeae***	***Salmonella enterica***
Bacteroides ovatus	***Escherichia coli***	*Neisseria flava*	*Serratia ficaria*
Bordetella flabilis	***Escherichia fergusonii***[i]	*Neisseria flavescens*	*Serratia fonticola*
Borrelia burgdorferi	*Escherichia hermannii*	*Neisseria lactamica*	*Serratia liquefaciens*
Brucella abortus	*Escherichia vulneris*	*Neisseria meningitidis*	***Serratia marcescens***
Brucella melitensis	*Fusobacterium nucleatum*	*Neisseria mucosa*	*Serratia odorifera*
Brucella suis	***Haemophilus aegyptius***[j]	*Neisseria perflava*	*Serratia plymuthica*
Burkholderia mallei	*Haemophilus ducreyi*	*Neisseria sicca*	*Serratia proteamaculens*
Burkholderia multivorans	*Haemophilus haemolyticus*	*Neisseria subflava*	*Serratia rubidaea*
Burkholderia pseudomallei	***Haemophilus influenzae***	*Pantoea agglomerans*	*Shewanella algae*
Campylobacter jejuni	*Haemophilus parahaemolyticus*	*Parabacteroides distasonis*	*Shewanella denitrificans*
Cedecea davisae	*Haemophilus parainfluenzae*	*Parabacteroides merdae*	*Shewanella putrefaciens*
Citrobacter amalonaticus[f]	*Haemophilus parasuis*	*Pasteurella multocida*	***Shigella boydii***[i]
Citrobacter braakii	*Haemophilus quentini*	*Photorhabdus asymbiotica*	***Shigella dysenteriae***[i]
Citrobacter europaeus	*Haemophilus sputorum*	*Pluralibacter* (*Enterobacter*) *gergoviae*	***Shigella flexneri***[i]
Citrobacter farmeri[f]	*Hafnia alvei*	*Porphyromonas gingivalis*	***Shigella sonnei***[i]
Citrobacter freundii	*Hafnia paralvei*	*Prevotella intermedia*	*Shimwellia blattae*
Citrobacter gillenii[f]	*Kingella denitrificans*	*Prevotella melaninogenica*	*Stenotrophomonas maltophilia*
Citrobacter koseri	***Kingella kingae***	*Prevotella nigrescens*	*Stenotrophomonas rhizophila*
Citrobacter murlinae	***Kingella negevensis***[k]	***Proteus hauseri***	*Trabulsiella guamensis*
Citrobacter rodentium[f]	*Kingella oralis*	***Proteus mirabilis***	*Veillonella atypica*
Citrobacter sedlakii[f]	***Klebsiella aerogenes***	***Proteus penneri***	*Veillonella dispar*
Citrobacter werkmanii	*Klebsiella grimontii*	***Proteus vulgaris***	*Veillonella parvula*
Citrobacter youngae	*Klebsiella michiganensis*	*Providencia rettgeri*	*Veillonella rogosae*
Cosenzaea* (*Proteus*) *myxofaciens[g]	*Klebsiella oxytoca*	*Providencia stuartii*	*Vibrio vulnificus*
		Pseudomonas aeruginosa	*Yersinia enterocolitica*
Mycoplasma and Intracellular Bacteria			
Chlamydia trachomatis	*Mycoplasma fermentans*	*Mycoplasma hominis*	*Mycoplasma penetrans*
Mycoplasma arthritidis	*Mycoplasma genitalium*	*Mycoplasma orale*	*Ureaplasma urealyticum*
Antimicrobial Resistance Genes			
Genes/sequences linked to methicillin or vancomycin resistance	**Extended-spectrum beta-lactamases (ESBLs), beta-lactamases, porins and carbapenemases**		
***mecA/C* and MREJ (MRSA)**	***AmpC***[m]	***bla*$_{\text{OXA-48-like}}$**	OmpC
vanA/B	***bla*$_{\text{CTX-M}}$**	***bla*$_{\text{OXY}}$**[m]	OmpK
vanM[l]	***bla*$_{\text{IMP}}$**	***bla*$_{\text{RAHN}}$**[m]	SHV

Species/AMR Genes Tested for Evaluation of Analytical Specificity			
	***bla*$_{KPC}$**	***bla*$_{VIM}$**	SME
	***bla*$_{KLU}$** [m]	CMY(II)	SPM
	***bla*$_{NDM}$**		TEM
Yeast and Fungi			
Aspergillus candidus	***Candida dubliniensis***	***Candida nivariensis*** (*Nakaseomyces nivariensisa*)[n]	*Exophiala dermatitidis*
Aspergillus clavatus	*Candida famata* (*Debaryomyces hansenii*)[n]	***Candida (Pichia) norvegensis***[n]	*Exophiala xenobiotica*
Aspergillus fumigatus	***Candida glabrata (Nakaseomyces glabrataa)***	***Candida orthopsilosis***	*Histoplasma capsulatum*
Aspergillus terreus	*Candida* (*Meyerozma*) *guilliermondii*[n,o]	***Candida parapsilosis***	*Malassezia fufur*
Blastomyces dermatitidis	***Candida haemolunii***[n]	*Candida* (*Diutina*) *rugosa*[n]	*Malassezia globosa*
Coccidioides immitis	*Candida holmii*[n]	***Candida sojae***	*Neosartorya fischeri*
Cryptococcus gattii	***Candida intermedia***[n]	***Candida sphaerica*** (*Kluyveromyces lactis*)[n]	*Penicillium chrysogenum*
Cryptococcus neoformans	***Candida kefyr*** (*Kluyveromyces marxianus*)[n]	*Candida thermophila*[n,p]	*Talaromyces* (*Penecillium*) *marneffei*
Candida albicans	***Candida krusei* (*Issatchenkia orientalis*)**	***Candida tropicalis***	*Saccharomyces cerevisiae*
Candida auris[n]	*Candida* (*Yarrowia*) *lipolytica*[n]	***Candida utilis*** (*Cyberlindnera jadinii*)[n]	*Schizosaccharomyces pombe*
Candida (*Trichomonascus*) *ciferrii*[n]	***Candida (clavispora) lusitaniae***[n]	***Candida viswanathii***[n]	*Sporothrix schenckii*
Candida colliculosa (*Torulaspora delbrueckii*)[n]	***Candida metapsilosis***		
Parasites			
Cryptosporidium parvum		*Entamoeba histolytica*	
Viruses			
Chikungunya Virus	Hepatitis C Virus (HCV)	Human T-cell Lymphotropic Virus (HTLV)	Rubella Virus
Dengue Virus	Herpes Simplex Virus 1 (HSV-1)	Parvovirus B19	Varicella Zoster Virus (VZV)
Epstein Barr Virus (EBV)	Herpes Simplex Virus 2 (HSV-2)	Measles Virus	West Nile Virus (WNV)
Hepatitis A Virus (HAV)	Human Immunodeficiency Virus (HIV)	Mumps Virus	Zika Virus
Hepatitis B Virus (HBV)			

[a] Various *Anaerococcus* species are detected as *Anaerococcus prevotii/vaginalis* due to cross-reactivity. The efficiency of the cross-reactivity varies by species.
[b] *Clostridium cadaveris* and *Clostridium fallax* are detected as *Clostridium perfringens* due to cross-reactivity. Sequence analysis predicts a similar risk of cross-reactivity at high concentrations for *C. baratii*, *C. disporicum* and *C. grantii*.
[c] The Peptoniphilus assay may not react with several *Peptoniphilus* species; see Analytical Reactivity.
[d] *Staphylococcus argenteus* and *Staphylococcus schweitzeri* are detected as *Staphylococcus aureus* (all three species are part of the *S. aureus* complex) due to cross-reactivity. *mecA/C* and MREJ (MRSA) was also detected in the *S. argenteus* isolate.
[e] *Bacteroides xylanisolvens* is detected as *Bacteroides fragilis* due to cross-reactivity.
[f] The Citrobacter assay may not react with several *Citrobacter* species; see Analytical Reactivity.
[g] *Cosenzaea myxofaciens* (formerly *Proteus myxofaciens*) is detected as *Proteus spp*. due to cross-reactivity.
[h] *Enterobacter bugandensis* (tested) and *Enterobacter chengduensis* (not tested, *in silico* prediction only) are detected as *Enterobacter cloacae* complex due to cross-reactivity.
[i] *Escherichia albertii*, *Escherichia fergusonii* and *Shigella* species are detected as *Escherichia coli* due to cross-reactivity.
[j] *Haemophilus aegyptius* (formerly described as *H. influenzae* biogroup *aegyptius*) is detected as *Haemophilus influenzae* due to cross-reactivity.
[k] *Kingella negevensis* is detected as *Kingella kingae* due to cross-reactivity.
[l] *vanM* is detected as *vanA/B* (not tested, *in silico* prediction only) due to cross-reactivity.
[m] The CTX-M assay cross-reacts weakly with the *bla*$_{OXY}$ gene carried in an isolate of *Klebsiella michiganensis* (reported as N/A because and applicable bacterium is not detected by the panel). Based on sequence analysis, the CTX-M assay is predicted to cross-react weakly with the *bla*$_{OXY}$ gene, *bla*$_{RAHN}$ gene (found primarily in *Rahnella* and *Leminorella* species), *bla*$_{KLU}$ genes (isolated primarily from *Kluyvera* species), and some variants of *ampC* (not observed when tested at high concentration in this study).
[n] Several of the *Candida* species detected at the high concentrations tested in this study may not be detected at lower concentrations; see Analytical Reactivity.
[o] *C. guilliermondii* is also classified as *Candida fermentatis*.
[p] *C. thermophila* is also classified as *Candida (Hansenula) parapolymorpha.*

Reproducibility

A multi-variable study was performed to evaluate the precision (reproducibility) of analyte detection on the BioFire FilmArray 2.0 and BioFire FilmArray Torch systems. Reproducibility represents the run-to-run variability of results under actual use conditions over time and is measured as agreement with the expected result. The study evaluated contrived samples containing a subset of representative organisms and AMR genes at two concentrations (and negative). The study incorporated potential variation introduced by site (three), day (five), operator (at least two per site), instrument module/system, and reagent kit lot (three). 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 480 valid runs overall. A summary of the reproducibility results (percent (%) agreement with the expected Detected, Not Detected or N/A result) for each analyte (by site and system) is provided in Table 94.

Table 94. Reproducibility of the BioFire Joint Infection (JI) Panel Results on BioFire FilmArray 2.0 and BioFire FilmArray Torch systems

Analyte (Isolate Source ID)	Concentration	Expected Result	Agreement with Expected Result								
			BioFire FilmArray 2.0				BioFire FilmArray Torch				All Sites/Systems [95% Confidence Interval]
			Site A	Site B	Site C	System Total	Site A	Site B	Site C	System Total	
Gram Positive Bacteria											
Anaerococcus prevotii/vaginalis	**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%]**
Clostridium perfringens	**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%]**
Cutibacterium avidum/granulosum	**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%]**
Enterococcus faecalis	**Negative (no analyte)**	**Not Detected**	80/80 (100%)	80/80 (100%)	80/80 (100%)	**240/240 (100%)**	79/80 (98.8%)	80/80 (100%)	79/80 (98.8%)	**238/240 (99.2%)**	**478/480 99.6% [98.5%-99.9%]**
***Enterococcus faecium* (ATCC 700221)**	**Moderate Positive (3× LoD) 3.6E+03 copies/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% [97.0-100.0%]**
	Low Positive (1× LoD) 1.2E+03 copies/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% [97.0-100.0%]**
	Negative (no analyte)	**Not 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% [98.5-100.0%]**

Analyte (Isolate Source ID)	Concentration	Expected Result	Agreement with Expected Result								
			BioFire FilmArray 2.0				BioFire FilmArray Torch				All Sites/Systems [95% Confidence Interval]
			Site A	Site B	Site C	System Total	Site A	Site B	Site C	System Total	
Finegoldia magna	**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%]**
Parvimonas micra	**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%]**
Peptoniphilus	**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%]**
***Peptostreptococcus anaerobius* (ATCC 27337)**	**Moderate Positive (3× LoD) 4.8E+04 copies/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% [97.0-100.0%]**
	Low Positive (1× LoD) 1.6E+04 copies/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% [97.0-100.0%]**
	Negative (no analyte)	**Not 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% [98.5-100.0%]**
***Staphylococcus aureus* (ATCC 43300)**	**Moderate Positive (3× LoD) 1.3E+04 copies/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% [97.0-100.0%]**
	Low Positive (1× LoD) 4.2E+03 copies/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% [97.0-100.0%]**
	Negative (no analyte)	**Not Detected**	40/40 (100%)	40/40 (100%)	40/40 (100%)	**120/120 (100%)**	40/40 (100%)	40/40 (100%)	39/40 (97.5%)	**119/120 (99.2%)**	**239/240 99.6% [97.7-99.9%]**
Staphylococcus lugdunensis	**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%]**
***Streptococcus* spp. (*Streptococcus pneumoniae;* ATCC 6303)**	**Moderate Positive** (see *Streptococcus pneumoniae*)	**Detected**	18/20 (90%)	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%]**
	Low Positive (see *Streptococcus pneumoniae*)	**Detected**	19/20 (95%)	19/20 (100%)	20/20 (100%)	**58/60 (96.7%)**	19/20 (95%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**118/120 98.3% [94.1-99.8%]**

Analyte (Isolate Source ID)	Concentration	Expected Result	Agreement with Expected Result								
			BioFire FilmArray 2.0				BioFire 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**	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% [98.5-100.0%]**
Streptococcus agalactiae	**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%]**
***Streptococcus pneumoniae* (ATCC 6303)**	**Moderate Positive (3× LoD) 1.6E+03 copies/mL**	**Detected**	18/20 (90%)	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%]**
	Low Positive (1× LoD) 5.3E+02 copies/mL	**Detected**	19/20 (95%)	19/20 (100%)	20/20 (100%)	**58/60 (96.7%)**	19/20 (95%)	20/20 (100%)	20/20 (100%)	**60/60 (100%)**	**118/120 98.3% [94.1-99.8%]**
	Negative (no analyte)	**Not 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% [98.5-100.0%]**
Streptococcus pyogenes	**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%]**
Gram Negative Bacteria											
***Bacteroides fragilis* (ATCC 25285)**	**Moderate Positive (3× LoD) 3.3E+03 copies/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% [97.0-100.0%]**
	Low Positive (1× LoD) 1.1E+03 copies/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% [97.0-100.0%]**
	Negative (no analyte)	**Not 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% [98.5-100.0%]**
***Citrobacter* (*Citrobacter freundii*; ATCC 8090)**	**Moderate Positive (3× LoD) 1.4E+04 copies/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% [97.0-100.0%]**
	Low Positive (1× LoD) 4.7E+03 copies/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% [97.0-100.0%]**
	Negative (no analyte)	**Not 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% [98.5-100.0%]**

Analyte (Isolate Source ID)	Concentration	Expected Result	Agreement with Expected Result								
			BioFire FilmArray 2.0				BioFire FilmArray Torch				All Sites/Systems [95% Confidence Interval]
			Site A	Site B	Site C	System Total	Site A	Site B	Site C	System Total	
***Enterobacter cloacae* complex**	**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%]**
***Escherichia coli* AR-Bank#0150**	**High Positive (30× LoD) 1.8E+05 copies/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% [97.0-100.0%]**
	Moderate Positive (10× LoD) 6.0E+04 copies/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% [97.0-100.0%]**
	Negative (no analyte)	**Not 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% [98.5-100.0%]**
***Haemophilus influenzae* ATCC 10211**	**Moderate Positive (3× LoD) 2.1E+03 copies/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% [97.0-100.0%]**
	Low Positive (1× LoD) 6.9E+02 copies/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% [97.0-100.0%]**
	Negative (no analyte)	**Not 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% [98.5-100.0%]**
Kingella kingae	**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%]**
Klebsiella aerogenes	**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%]**
***Klebsiella pneumoniae* group (*Klebsiella pneumoniae*; AR-Bank#0097)**	**Moderate Positive (3× LoD) 4.8E+04 copies/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% [97.0-100.0%]**
	Low Positive (1× LoD) 1.6E+04 copies/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% [97.0-100.0%]**
	Negative (no analyte)	**Not 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% [98.5-100.0%]**

Analyte (Isolate Source ID)	Concentration	Expected Result	Agreement with Expected Result								
			BioFire FilmArray 2.0				BioFire FilmArray Torch				All Sites/Systems [95% Confidence Interval]
			Site A	Site B	Site C	System Total	Site A	Site B	Site C	System Total	
Morganella morganii	**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%]**
***Neisseria gonorrhoeae* ATCC 19424**	**Moderate Positive (3× LoD) 6.6E+03 copies/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% [97.0-100.0%]**
	Low Positive (1× LoD) 2.2E+03 copies/mL	**Detected**	19/20 (95%)	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**	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% [98.5-100.0%]**
***Proteus* spp.**	**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%]**
Pseudomonas aeruginosa	**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%]**
***Salmonella* spp.**	**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%]**
Serratia marcescens	**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%]**
Antimicrobial Resistance Genes											
CTX-M	**Negative (no analyte)**	**Not Detected or N/A**	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%]**
IMP	**Negative (no analyte)**	**Not Detected or N/A**	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%]**
KPC (*Klebsiella pneumoniae*; AR-Bank#0097)	**Moderate Positive** (see *Klebsiella pneumoniae*)	**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% [97.0-100.0%]**
	Low Positive (see *Klebsiella pneumoniae*)	**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% [97.0-100.0%]**

Analyte (Isolate Source ID)	Concentration	Expected Result	Agreement with Expected Result								
			BioFire FilmArray 2.0				BioFire 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 or N/A**	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% [98.5-100.0%]**
***mecA/C* and MREJ (MRSA) (*Staphylococcus aureus*; ATCC 43300)**	**Moderate Positive** (see *Staphylococcus aureus*)	**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% [97.0-100.0%]**
	Low Positive (see *Staphylococcus aureus*)	**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% [97.0-100.0%]**
	Negative (no analyte)	**Not Detected or N/A**	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% [98.5-100.0%]**
NDM (*Escherichia coli*; AR-Bank#0150)	**High Positive** (see *Escherichia coli*)	**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% [97.0-100.0%]**
	Moderate Positive (see *Escherichia coli*)	**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% [97.0-100.0%]**
	Negative (no analyte)	**Not Detected or N/A**	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% [98.5-100.0%]**
OXA-48-like	**Negative (no analyte)**	**Not Detected or N/A**	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%]**
***vanA/B* (*Enterococcus faecium*; *vanB* ATCC 700221)**	**Moderate Positive** (see *Enterococcus faecium*)	**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% [97.0-100.0%]**
	Low Positive (see *Enterococcus faecium*)	**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% [97.0-100.0%]**
	Negative (no analyte)	**Not Detected or N/A**	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% [98.5-100.0%]**
VIM	**Negative (no analyte)**	**Not Detected or N/A**	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%]**
Yeast											

Analyte (Isolate Source ID)	Concentration	Expected Result	Agreement with Expected Result								
			BioFire FilmArray 2.0				BioFire FilmArray Torch				All Sites/Systems [95% Confidence Interval]
			Site A	Site B	Site C	System Total	Site A	Site B	Site C	System Total	
***Candida* (*Candida krusei*; ATCC 6258)**	**Moderate Positive (3× LoD) 3.0E+03 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% [97.0-100.0%]**
	Low Positive (1× LoD) 1.0E+03 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% [97.0-100.0%]**
	Negative[a] (no analyte)	**Not Detected**	**N/A[a]**								
***Candida albicans* (ATCC 90028)**	**Moderate Positive (3× LoD) 1.5E+03 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% [97.0-100.0%]**
	Low Positive (1× LoD) 5.0E+02 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% [97.0-100.0%]**
	Negative (no analyte)	**Not 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% [98.5-100.0%]**
Overall Agreement with the Expected Results [95% Confidence Interval]			**18,468/18,480 99.9% [99.89%-99.97%]**								

[a] Negative data were not collected for the *Candida* result since each of the four samples tested in the study contained a *Candida* species (*C. albicans* or *C. krusei*).

Interference

Potentially interfering substances that could be present in synovial fluid specimens were evaluated for their effect on BioFire JI Panel performance. The substances tested included endogenous components of synovial fluid (e.g. blood, collagen, human genomic DNA, rheumatoid factor, etc.), exogenous substances (e.g. prescribed or over-the-counter medications, antibiotics, imaging contrast agents, components of joint prostheses, etc.), technique-specific substances (disinfecting agents, specimen collection materials, etc.) and potentially competing commensal or infectious microorganisms.

Each substance was added to multi-analyte contrived samples prepared in pooled synovial fluid matrix. Samples contained multiple organisms (and AMR genes) at a low concentration (near LoD). Substances were tested at concentrations equal to or greater than the levels expected in clinical synovial fluid specimens, and potentially competing microorganisms were added at the highest possible concentration to evaluate the 'worst case' scenario for interference.

Valid and accurate results were obtained for each sample containing substances and microorganisms at the concentrations listed in Table 95 (no interference observed).

Table 95. Evaluation of Potentially Interfering Substances for the BioFire JI Panel – No Interference Observed

Substance Tested	Reference Range[a] (Synovial Fluid or Whole Blood)	Test Concentration
Endogenous Substances		
Blood[b]	0 – 10%[c]	30% v/v
Cholesterol	<2 mg/mL	4 mg/mL
C-reactive protein	0.59 – 55.5 µg/mL[d]	0.17 mg/mL
Fibronectin	0.1 – 1.0 mg/mL[e]	3 mg/mL
Lactate	0.1 – 1.89 mg/mL[f]	5.7 mg/mL
Monosodium urate/ Uric Acid	0.035-0.072 mg/mL[g]	0.235 mg/mL
Calcium phosphate	25 – 45 µg/mL	120 µg/mL
Calcium oxalate	1 – 2.4 µg/mL	7.9 µg/mL
Bilirubin	up to 0.02 mg/mL	0.4 mg/mL
White Blood Cells	1E+06-1E+07 cells/mL[h]	3.0E+07 cells/mL
Rheumatoid Factor	up to 600 IU/mL[i,j]	1,800 International Units/mL[j]
Type II collagen	0.07 – 3.37 µg/mL[k]	10.1 µg/mL
Exogenous Substances		
Over-the-Counter Treatments and Pain Relievers (Oral and Topical)		
Acetaminophen	0.052 mg/mL	156 µg/mL
Salicylic Acid	9.52 µg/mL	28.6 µg/mL
Ibuprofen	0.073 mg/mL	219 µg/mL
Capsaicin Cream (0.1% capsaicin)	Not Determined	0.5% (m/v)
Salicylate Cream (30% methyl salicylate)	Not Determined	0.5% (m/v)
Camphor Balm (11% camphor)	Not Determined	0.5% (m/v)
Arnica Gel (7% *Arnica montana*)	Not Determined	0.5% (m/v)
Antifungals/Antibiotics		
Nystatin	Not Determined	5,000 Units/mL
Fluconazole	8.5 µg/mL	25.5 µg/mL
Mupirocin	0.05 µg/mL	1.5 µg/mL
Ceftriaxone	280 µg/mL	840 µg/mL
Vancomycin	40 µg/mL	120 µg/mL
Clindamycin	17 µg/mL	51 µg/mL
Triple Antibiotic Ointment (10000 U polymyxin B, 3.5 mg neomycin, 500 U bacitracin)	Not Determined	0.5% (m/v)
Physician-Administered Pain Relievers/Anesthetics		
Hydrocortisone	25 mg dose[l]	8.3 mg/mL

Substance Tested	Reference Range[a] (Synovial Fluid or Whole Blood)	Test Concentration
Hyaluronic acid	48 mg dose[m]	16 mg/mL
Lidocaine	up to 300 mg dose (10 mL of 2% lidocaine)[n]	23 mg/mL
Substances Associated with Joint Prostheses		
Cobalt Ions	up to ~20 µg/mL[o]	20 µg/mL
Chromium Ions	up to ~50 µg/mL[p]	50 µg/mL
Ultra-High Molecular Weight Polyethylene	40.9 mg/2 M cycles[q,r]	1 mg/mL
Polymethyl methacrylate Bone Cement	Not Determined	1% m/v
Imaging Contrast Agents		
Iohexol	302 – 755 mg dose[s]	250 mg/mL

Substance Tested	Test Concentration
Technique-Specific Substances	
Disinfectants/Cleaning Substances	
Ethanol	1.0% v/v
Bleach	1.0% v/v (600 ppm)
Povidone-iodine	1.0% v/v
Specimen Collection Materials	
K_2-EDTA (anticoagulant)	0.99 µg/mL
Competitive Microorganisms	
Streptococcus pyogenes	7.56E+08 CFU/mL
Escherichia coli	8.10E+08 CFU/mL
Finegoldia magna	8.77E+07 CFU/mL
Candida albicans	7.89E+07 CFU/mL
Cutibacterium acnes	1.12E+07 cells/mL
Staphylococcus epidermidis	8.78E+08 CFU/mL
Corynebacterium striatum	7.80E+08 CFU/mL
Cryptococcus neoformans	1.00E+07 CFU/mL
Parvovirus B19	7.00E+04 International Units/mL
Chikungunya virus	2.16E+07 genomic equivalents/mL

[a] EP37: Supplemental Table for Interference Testing in Clinical Chemistry – First Edition (2018), unless otherwise noted.
[b] Includes evaluation of interference from red blood cells, glucose, haemoglobin, triglycerides and other components of whole blood.
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[q] Affatato, S, et al. Wear Behaviours and Oxidation Effects on Different UHMWPE Acetabular Cups Using a Hip Joint Simulator. *Materials (Basel)*, 11 (3): 433 (2018).
[r] Wear rate represents average wear for standard UHMWPE acetabular hip prothesis after 2 million cycles (approx. one year).
[s] Ominpaque 350 Prescribing Information.

NOTE: Avoid contact between samples and bleach prior to testing (bleach can damage nucleic acids and prevent amplification and detection by the panel).

NOTE: The BioFire JI Panel is not intended for use with synovial fluid in media. Media/broths may contain contaminating nucleic acids (bioburden) that can generate false positive results.

APPENDIX A

Symbols Glossary

ISO 15223-1 Medical devices - Symbols to be used with medical devices labels, labeling and information to be supplied					
5.1.1 	Manufacturer	5.1.2 	Authorized representative in the European Community	5.1.4 	Use-By date (YYYY-MM-DD)
5.1.5 	Batch Code (Lot Number)	5.1.6 	Catalog Number	5.1.7 	Serial Number
5.2.8 	Do Not Use if Package Is Damaged	5.3.2 	Keep Away from Sunlight	5.3.7 	Temperature Limit
5.4.2 	Do Not Reuse	5.4.3 	Consult Instructions for Use	5.5.1 	In vitro Diagnostic Medical Device
5.5.5 	Contains Sufficient For <n> Tests			5.7.10 	Unique Device Identifier (UDI)
Use of Symbols in Labeling – 81 FR 38911, Docket No. (FDA-2013-N-0125)					
Rx Only	Prescription Use Only				
United Nations Globally Harmonized System of Classification and Labeling of chemicals (GHS) (ST/SG/AC.10/30)					
	Serious eye damage, Category 1		Acute toxicity, oral, Category 4 & Skin corrosion, irritation, Category 2		Acute aquatic hazard, Category 1 & Long-term aquatic hazard, Category 1
European Union In Vitro Diagnostic Directive (IVDD 98/79/EC) and European In Vitro Diagnostic Regulation (IVDR 2017/746)			**Medical Device Regulation 2002 (UK MDR 2002)**		
	European Union Conformity				UK Conformity Assessed
Manufacturer Symbols (BioFire Diagnostics, LLC)					
	The NOTE symbol explains how to perform the BioFire JI test more efficiently.				
	A BioFire Joint Infection kit				European Union Product Importer

APPENDIX B

Contact and Legal Information

Customer and Technical Support	
Reach Us on the Web http://www.BioFireDX.com **Reach Us by Email** support@BioFireDX.com **Reach Us by Mail** 515 Colorow Drive Salt Lake City, UT 84108 USA	**Reach Us by Phone** 1-800-735-6544 – Toll Free (801) 736-6354 – Utah **Reach Us by Fax** (801) 588-0507
Customer and Technical Support outside of the U.S.	
Contact the local bioMérieux sales representative or an authorized distributor for technical support.	

BioFire Diagnostics, LLC
515 Colorow Drive
Salt Lake City, UT 84108
USA

Qarad EC-REP BV
Pas 257
B-2440 Geel, Belgium

bioMérieux SA
376, Chemin de l'Orme
69280 Marcy l'Etoile-
France

bioMérieux UK Ltd
Chineham Gate
Crockford Lane
Basingstoke RG24 8NA
UK

NOTE FOR CUSTOMERS WITHIN THE EUROPEAN UNION (EU): Any serious incident that has occurred in relation to the device must be reported to BioFire Diagnostics, LLC or local bioMérieux sales representative and the competent authority of the Member State in which the user and/or the patient is established.

Warranty Information

Product warranty information is available online at:

http://www.biofiredx.com/support/documents/

For warranty information for customers outside the United States, contact the local bioMérieux sales representative or an authorized distributor.

APPENDIX C

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202. User Protocol for Evaluation of Qualitative Test Performance; NCCLS Approved Guideline. Published online 2008.

REVISION HISTORY

Version	Revision Date	Description of Revision(s)
01	June 2022	Initial release

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BIOFIRE® PANELS

6 Panels. 170+ Targets. ~1 Hour.

BIOFIRE®
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23 Targets. ~45 Minutes.

BIOFIRE®
BLOOD CULTURE IDENTIFICATION 2 PANEL
43 Targets. ~1 Hour.

BIOFIRE® FILMARRAY®
GASTROINTESTINAL PANEL
22 Targets. ~1 Hour.

BIOFIRE® FILMARRAY®
MENINGITIS/ ENCEPHALITIS PANEL
14 Targets. ~1 Hour.

BIOFIRE® FILMARRAY®
PNEUMONIA *PLUS* PANEL
34 Targets. ~1 Hour.

BIOFIRE®
JOINT INFECTION PANEL
39 Targets. ~1 Hour.

PIONEERING DIAGNOSTICS

BIOFIRE®
RESPIRATORY 2.1 *PLUS* (RP2.1*plus*) PANEL

23 Targets. ~45 Minutes.

VIRUSES

Adenovirus
Coronavirus 229E
Coronavirus HKU1
Coronavirus NL63
Coronavirus OC43
Middle East respiratory syndrome coronavirus (MERS-CoV)
Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
Human metapneumovirus
Human rhinovirus/enterovirus
Influenza A virus
Influenza A virus A/H1
Influenza A virus A/H3
Influenza A virus A/H1-2009
Influenza B virus
Parainfluenza virus 1
Parainfluenza virus 2
Parainfluenza virus 3
Parainfluenza virus 4
Respiratory syncytial virus

BACTERIA

Bordetella parapertussis
Bordetella pertussis
Chlamydia pneumoniae
Mycoplasma pneumoniae

CE 2797

BIOFIRE RP2.1*plus* Panel Specifications

Sample Type: nasopharyngeal swab in transport media or saline

Sample Volume: 0.3 mL

Storage Conditions: all kit components stored at room temperature (15-25 ˚C)

Hands-On Time: approximately 2 minutes

Overall Performance: 97.1% sensitivity, 99.3% specificity[1]
SARS-CoV-2 Performance: 98.4% PPA, 98.9% NPA[2]

Part Number

BIOFIRE RP2.1*plus* Panel Reagent Kit (30 Pouches): 423740

1. Overall performance based on prospective clinical study for the BIOFIRE® FILMARRAY® Respiratory 2 *plus* Panel, data on file, BioFire Diagnostics.
2. Overall performance based on prospective SARS-CoV-2 clinical study for the BIOFIRE® Respiratory 2.1 *plus* Panel in comparison to 3 EUA tests, data on file, BioFire Diagnostics.

BIOFIRE®
BLOOD CULTURE IDENTIFICATION 2 (BCID2) PANEL

43 Targets. ~1 Hour.

GRAM-NEGATIVE BACTERIA

Acinetobacter calcoaceticus-baumannii complex
Bacteroides fragilis
Enterobacterales
- *Enterobacter cloacae* complex
- *Escherichia coli*
- *Klebsiella aerogenes*
- *Klebsiella oxytoca*
- *Klebsiella pneumoniae* group
- *Proteus* spp.
- *Salmonella* spp.
- *Serratia marcescens*

Haemophilus influenzae
Neisseria meningitidis
Pseudomonas aeruginosa
Stenotrophomonas maltophilia

GRAM-POSITIVE BACTERIA

Enterococcus faecalis
Enterococcus faecium
Listeria monocytogenes
Staphylococcus spp.
- *Staphylococcus aureus*
- *Staphylococcus epidermidis*
- *Staphylococcus lugdunensis*

Streptococcus spp.
- *Streptococcus agalactiae*
- *Streptococcus pneumoniae*
- *Streptococcus pyogenes*

YEAST

Candida albicans
Candida auris
Candida glabrata
Candida krusei
Candida parapsilosis
Candida tropicalis
Cryptococcus (C. neoformans/C. gattii)

ANTIMICROBIAL RESISTANCE GENES

Carbapenemases
IMP
KPC
OXA-48-like
NDM
VIM

Colistin Resistance
mcr-1

ESBL
CTX-M

Methicillin Resistance
mecA/C
mecA/C and MREJ (MRSA)

Vancomycin Resistance
vanA/B

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BIOFIRE BCID2 Panel Specifications

Sample Type: positive blood culture

Sample Volume: 0.2 mL

Storage Conditions: all kit components stored at room temperature (15-25 ˚C)

Hands-On Time: approximately 2 minutes

Performance: 99.0% sensitivity, 99.8% specificity[3]

Part Number

BIOFIRE BCID2 Panel Reagent Kit (30 Pouches): RFIT-ASY-0147

3. Overall performance is the aggregate of the prospective, archived, and seeded data from the clinical studies. Data on file, BioFire Diagnostics.

BIOFIRE® FILMARRAY®
GASTROINTESTINAL (GI) PANEL

22 Targets. ~1 Hour.

BACTERIA
Campylobacter (C. jejuni/C. coli/C. upsaliensis)
Clostridioides (Clostridium) difficile (toxin A/B)
Plesiomonas shigelloides
Salmonella
Vibrio (V. parahaemolyticus/V. vulnificus/V. cholerae)
  Vibrio cholerae
Yersinia enterocolitica
Diarrheagenic *Escherichia coli/Shigella*
  Enteroaggregative *E. coli* (EAEC)
  Enteropathogenic *E. coli* (EPEC)
  Enterotoxigenic *E. coli* (ETEC) *lt/st*
  Shiga-like toxin-producing *E. coli* (STEC) *stx1/stx2*
    E. coli O157
  Shigella/Enteroinvasive *E. coli* (EIEC)

VIRUSES
Adenovirus F40/41
Astrovirus
Norovirus GI/GII
Rotavirus A
Sapovirus (I, II, IV, and V)

PARASITES
Cryptosporidium
Cyclospora cayetanensis
Entamoeba histolytica
Giardia lamblia

US FDA-cleared | CE

BIOFIRE GI Panel Specifications

Sample Type: stool sample in Cary Blair
Sample Volume: 0.2 mL
Storage Conditions: all kit components stored at room temperature (15-25 ˚C)
Hands-On Time: approximately 2 minutes
Performance: 98.5% sensitivity, 99.2% specificity[4]

Part Number

BIOFIRE GI Panel Reagent Kit (30 Pouches): RFIT-ASY-0116
BIOFIRE GI Panel Reagent Kit (6 Pouches): RFIT-ASY-0104

4. Overall performance based on prospective clinical study for the BIOFIRE® FILMARRAY® Gastrointestinal Panel, data on file, BioFire Diagnostics.

BIOFIRE® FILMARRAY®
MENINGITIS/ENCEPHALITIS (ME) PANEL

14 Targets. ~1 Hour.

Atitiktis_3

BACTERIA
Escherichia coli K1
Haemophilus influenzae
Listeria monocytogenes
Neisseria meningitidis
Streptococcus agalactiae
Streptococcus pneumoniae

VIRUSES
Cytomegalovirus (CMV)
Enterovirus (EV)
Herpes simplex virus 1 (HSV-1)
Herpes simplex virus 2 (HSV-2)
Human herpesvirus 6 (HHV-6)
Human parechovirus (HPeV)
Varicella zoster virus (VZV)

YEAST
Cryptococcus (C. neoformans/C. gattii)

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BIOFIRE ME Panel Specifications

Sample Type: cerebrospinal fluid (CSF)

Sample Volume: 0.2 mL

Storage Conditions: all kit components stored at room temperature (15-25 ˚C)

Hands-On Time: approximately 2 minutes

Performance: 94.2% sensitivity, 99.8% specificity[5]

Part Number

BIOFIRE ME Panel Reagent Kit (30 Pouches): RFIT-ASY-0118

BIOFIRE ME Panel Reagent Kit (6 Pouches): RFIT-ASY-0119

5. Overall performance based on prospective clinical study for the BIOFIRE® FILMARRAY® Meningitis/Encephalitis Panel, data on file, BioFire Diagnostics.

BIOFIRE® FILMARRAY®
PNEUMONIA *PLUS* (PN*plus*) PANEL

34 Targets. ~1 Hour.

BACTERIA (Semi-Quantitative)
Acinetobacter calcoaceticus-baumannii complex
Enterobacter cloacae complex
Escherichia coli
Haemophilus influenzae
Klebsiella aerogenes
Klebsiella oxytoca
Klebsiella pneumoniae group
Moraxella catarrhalis
Proteus spp.
Pseudomonas aeruginosa
Serratia marcescens
Staphylococcus aureus
Streptococcus agalactiae
Streptococcus pneumoniae
Streptococcus pyogenes

ATYPICAL BACTERIA (Qualitative)
Chlamydia pneumoniae
Legionella pneumophila
Mycoplasma pneumoniae

VIRUSES
Adenovirus
Coronavirus
Human metapneumovirus
Human rhinovirus/enterovirus
Influenza A virus
Influenza B virus
Middle East respiratory syndrome coronavirus (MERS-CoV)
Parainfluenza virus
Respiratory syncytial virus

ANTIMICROBIAL RESISTANCE GENES
Carbapenemases
IMP
KPC
NDM
OXA-48-like
VIM

ESBL
CTX-M

Methicillin Resistance
mecA/C and MREJ (MRSA)

US FDA-cleared | CE 2797

BIOFIRE PN*plus* Panel Specifications

Sample Type: BAL-like (including mini-BAL), Sputum-like (including ETA)

Hands-On Time: approximately 2 minutes

Performance: BAL-like (including mini-BAL): 96.2% sensitivity, 98.4% specificity; Sputum-like (including ETA): 96.3% sensitivity, 97.3% specificity[6]

Storage Conditions: all kit components stored at room temperature (15-25 ˚C)

Part Number

BIOFIRE PN*plus* Panel Reagent Kit (30 Pouches): RFIT-ASY-0143

6. Overall performance based on prospective clinical study for the BIOFIRE® FILMARRAY® Pneumonia *plus* Panel, data on file, BioFire Diagnostics.

BIOFIRE®
JOINT INFECTION (JI) PANEL

39 Targets. ~1 Hour.

GRAM-POSITIVE BACTERIA
Anaerococcus prevotii/vaginalis
Clostridium perfringens
Cutibacterium avidum/granulosum
Enterococcus faecalis
Enterococcus faecium
Finegoldia magna
Parvimonas micra
Peptoniphilus
Peptostreptococcus anaerobius
Staphylococcus aureus
Staphylococcus lugdunensis
Streptococcus spp.
- *Streptococcus agalactiae*
- *Streptococcus pneumoniae*
- *Streptococcus pyogenes*

GRAM-NEGATIVE BACTERIA
Bacteroides fragilis
Citrobacter
Enterobacter cloacae complex
Escherichia coli
Haemophilus influenzae
Kingella kingae
Klebsiella aerogenes
Klebsiella pneumoniae group
Morganella morganii
Neisseria gonorrhoeae
Proteus spp.
Pseudomonas aeruginosa
Salmonella spp.
Serratia marcescens

YEAST
Candida spp.
- *Candida albicans*

ANTIMICROBIAL RESISTANCE GENES
Carbapenemases
IMP
KPC
NDM
OXA-48-like
VIM

ESBL
CTX-M

Methicillin Resistance
*mec*A/C and MREJ (MRSA)

Vancomycin Resistance
*van*A/B

US FDA-cleared | CE 2797

BIOFIRE JI Panel Specifications

Sample Type: synovial fluid

Sample Volume: 0.2 mL

Storage Conditions: all kit components stored at room temperature (15-25 ˚C)

Hands-On Time: approximately 2 minutes

Performance: 91.7% sensitivity, 99.8% specificity[7]

Part Number

BIOFIRE JI Panel Reagent Kit (30 Pouches): RFIT-ASY-0138

7. Overall performance based on prospective clinical study for the BIOFIRE® Joint Infection Panel, data on file, BioFire Diagnostics.

Scan the QR code
for more information.

Learn more about the BIOFIRE range of commercially-available panels for syndromic infectious disease diagnostics.

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Product availability varies by country. Consult your bioMérieux representative.