



# BioFire® Bone & Joint Infection (BJI) Panel Quick Guide

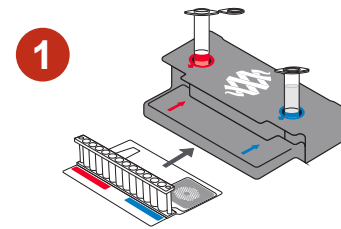
For use with BioFire® FilmArray® 2.0 and BioFire® FilmArray® Torch Systems

For investigational use only

**⚠ To avoid contamination, always wear gloves and work behind a protective shield.**

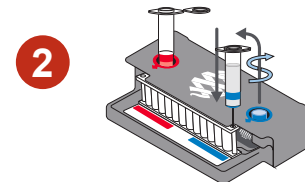
## Step 1: Prepare Pouch

- Insert pouch into BioFire® FilmArray® Pouch Loading Station.
- Place BioFire® FilmArray® Sample Injection Vial into red well.
- Place BioFire® FilmArray® Hydration Injection Vial into blue well.



## Step 2: Hydrate Pouch

- Unscrew Hydration Injection Vial, leaving cap in Pouch Loading Station, and insert into pouch hydration port.
- Forcefully push down to puncture seal.
- Wait as Hydration Solution is drawn into pouch.

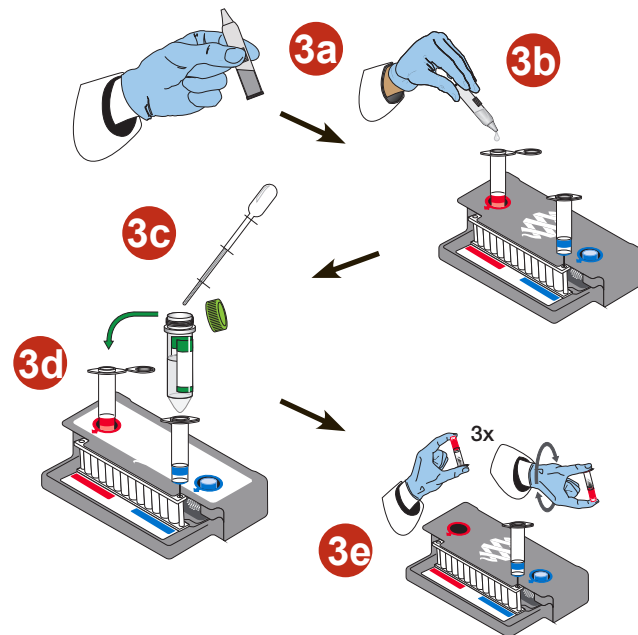


## Step 3: Prepare Sample Mix

- Add BioFire® FilmArray® Sample Buffer to Sample Injection Vial.
  - Invert Sample Buffer Ampoule so that tip is facing up (see figure 3a).

**Note:** Do not touch the tip of the ampoule.

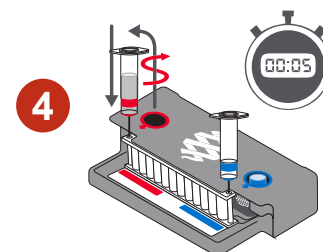
- Firmly pinch textured plastic tab on side of ampoule until seal snaps.
- With the tip facing down, dispense Sample Buffer into Sample Injection Vial using a slow, forceful squeeze, followed by a second squeeze. Avoid generating excessive bubbles.
- Using Transfer Pipette, draw up specimen to **second line** (see figure 3c).
- Add sample to Sample Injection Vial (see figure 3d).
- Discard the Transfer Pipette in an appropriate biohazard waste container.
- Tightly close lid of Sample Injection Vial.
- Mix sample by gently inverting Sample Injection Vial **3 times** (see figure 3e).
- Return Sample Injection Vial to red well of Pouch Loading Station.



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

## Step 4: Load Sample Mix

- Unscrew Sample Injection Vial from cap.
- Pause for 5 seconds, then remove Sample Injection Vial, leaving cap in Pouch Loading Station.
- Insert Sample Injection Vial into pouch sample port.
- Forcefully push down to puncture seal.
- Wait as Sample Mix is drawn into pouch.
- Remove the Sample Injection Vial and the Hydration Injection Vial from the pouch and discard in the appropriate biohazard container.



## Step 5: Run Pouch

- Follow instructions on BioFire System for initiating a test.





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The two-page BioFire BJI Panel report is displayed upon the completion of a run and contains the following 3 sections:

**Run Summary Section**—Displays information about the sample and a summary of the control and test results.

## 1. Organisms Detected:

- Names of any detected organisms
- If 'None', no organisms were detected
- If '▲ Invalid', RETEST SAMPLE

## 2. Applicable Antimicrobial Resistance Genes Detected:

Displays results for antimicrobial resistance gene(s) associated with detected organism(s).

## 3. Controls:

- If 'Passed', results are valid.
- If '▲ Failed', RETEST SAMPLE.
- If '▲ Invalid', RETEST SAMPLE.

**Result Summary Section**—Lists the test results for each pathogen targeted by the BioFire BJI Panel.

- If 'N/A', antimicrobial resistance gene was not reported because an organism associated with the gene was not detected.
- If 'Not Detected', organism or antimicrobial resistance gene was not detected.
- If 'Detected', organism or antimicrobial resistance gene was detected.

If '▲ Invalid', RETEST SAMPLE.

**NOTE:** If repeated 'Invalid' results are obtained, contact BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor.

**Run Details Section**—Displays information about the pouch, instrument, run status, and operator.

## 7. Run Status:

- If 'Completed', run is complete.
- If Incomplete, Aborted, Instrument Error, or Software Error, RETEST SAMPLE.

**NOTE:** If repeated 'Error' messages are obtained, contact BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor.

BioFire® Bone and Joint Infection (BJI) Panel - IUO		BIO FIRE	
		www.BioFireDx.com	
<b>Run Summary</b>			
1	Sample ID: Demo Report	3	Run Date: 01 Jan 2020 12:00 AM
2	Organisms Detected: <i>Staphylococcus aureus</i>		Controls: Passed
	Applicable Antimicrobial Resistance Genes Detected: <i>mecA/C</i> and <i>MREJ</i> (MRSA)		
<p>⚠ 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 Bone and Joint Infection Panel results should be used in conjunction with culture results for the determination of susceptibility or resistance.</p>			
<b>Result Summary</b>			
<b>Antimicrobial Resistance Genes</b>			
4	N/A	CTX-M	
	N/A	IMP	
	N/A	KPC	
	Detected	<i>mecA/C</i> and <i>MREJ</i> (MRSA)	
	N/A	NDM	
	N/A	OXA-48-like	
	N/A	<i>vanA/B</i>	
	N/A	VIM	
<b>Gram Positive Bacteria</b>			
5	Not Detected	<i>Anaerococcus prevotii/vaginalis</i>	
	Not Detected	<i>Clostridium perfringens</i>	
	Not Detected	<i>Cutibacterium avidum/granulosum</i>	
	Not Detected	<i>Enterococcus faecalis</i>	
	Not Detected	<i>Enterococcus faecium</i>	
	Not Detected	<i>Finexigdia magna</i>	
	Not Detected	<i>Parvimonas micra</i>	
	Not Detected	<i>Peptoniphilus</i>	
6	Not Detected	<i>Peptostreptococcus anaerobius</i>	
	Detected	<i>Staphylococcus aureus</i>	
	Not Detected	<i>Staphylococcus lugdunensis</i>	
	Not Detected	<i>Streptococcus</i> spp.	
	Not Detected	<i>Streptococcus agalactiae</i>	
	Not Detected	<i>Streptococcus pneumoniae</i>	
	Not Detected	<i>Streptococcus pyogenes</i>	
<b>Gram Negative Bacteria</b>			
	Not Detected	<i>Bacteroides fragilis</i>	
	Not Detected	<i>Citrobacter</i>	
	Not Detected	<i>Enterobacter cloacae</i> complex	
	Not Detected	<i>Escherichia coli</i>	
	Not Detected	<i>Haemophilus influenzae</i>	
	Not Detected	<i>Kingella kingae</i>	
	Not Detected	<i>Klebsiella aerogenes</i>	
	Not Detected	<i>Klebsiella pneumoniae</i> group	
	Not Detected	<i>Morganella morganii</i>	
	Not Detected	<i>Neisseria gonorrhoeae</i>	
	Not Detected	<i>Proteus</i> spp.	
	Not Detected	<i>Pseudomonas aeruginosa</i>	
	Not Detected	<i>Salmonella</i> spp.	
	Not Detected	<i>Serratia marcescens</i>	
<b>Yeast</b>			
	Not Detected	<i>Candida</i>	
	Not Detected	<i>Candida albicans</i>	
<b>Run Details</b>			
7	Pouch: BJI Panel v1.1	Protocol: SF v3.0	
	Run Status: Completed	Operator: Jane Doe	
	Serial No.: 01010001	Instrument: FA0000	
	Lot No.: 111111		



BY BIOMÉRIEUX