



# BioFire® Bone and Joint Infection Panel

For Investigational Use Only

## The BioFire BJI Panel Evaluation Program Guidelines

Dear Participant,

Thank you for evaluating the BioFire® Bone and Joint Infection (BJI) Panel. This panel tests an anticipated 39 targets, including 8 antimicrobial resistance genes, from synovial fluid. Please take a moment to read through the Evaluation Program Guidelines before you begin running pouches.

### Evaluation Program Objective

The goal of this program is for you to evaluate the BioFire BJI Panel in your laboratory and assess how the workflow and results of this panel compare with your current testing procedures. It is important to get input from a broad range of stakeholders at your institution on how this panel will change practices and workflow. We suggest forming an evaluation team that includes relevant clinician groups (Orthopedic Surgeons, Infections Disease, and Pharmacy) as well as Laboratory Directors, Managers, and Technologists. You will be asked to complete a short online survey about your experience with the panel. You will also be asked to report de-identified sample level data to evaluate how the panel compares to the standard of care.

### Investigational Use Only

The BioFire BJI Panel is for Investigational Use Only (IUO). Do not use results from this panel to make patient care decisions.

### Material

The BioFire BJI Panel IUO kits contain 60 reagent pouches ([PLACEHOLDER TEXT]) to be run on your existing BioFire® FilmArray® System instrument. If you are new to BioFire, you will be receiving an instrument on loan in addition to reagent kits. Verification material will not be supplied.

### Panel Overview

The BioFire BJI Panel uses nested multiplex PCR, followed by melting-curve analysis, to detect select organisms and antimicrobial resistance (AMR) genes in synovial fluid samples of patients with suspected bone and joint infections. The panel identifies specific gram-positive, gram-negative, yeast, and AMR genes as shown in Figure 1. The intended use of the BioFire BJI Panel is to aid in timely diagnosis of bone and joint infections via simultaneous detection and identification of etiologically relevant bacteria and fungi in synovial fluid derived from individuals suspected of septic arthritis or prosthetic joint infections.

### Sample Recommendations

The sample requirement for the BioFire BJI Panel is 0.2 mL of synovial fluid.



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**Figure 1. The BioFire BJI Panel proposed menu**

## 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

*mecA/C* and MREJ

### Vancomycin Resistance

*vanA/B*

## Software Requirements

In order to run the BioFire BJI Panel IUO reagent pouches on the BioFire® System, the BioFire BJI Panel IUO software module will need to be installed on your existing BioFire® FilmArray® 2.0 or BioFire® FilmArray® Torch System instrument. Your local Field Application Specialist will be in touch with you to install the module. The software update and/or addition of the BioFire BJI Panel IUO software will not affect the other BioFire® FilmArray® Panels you may be running. Therefore, BioFire is not recommending any additional verification. If you are new to BioFire, your Field Application Specialist will be responsible for installing your loaner BioFire instrument in addition to the IUO software.

## Reporting

When the BioFire BJI Panel run is completed, the system outputs a detection summary showing which organisms were “Detected” or “Not Detected”. Additionally, applicable AMR genes will be displayed for the “Detected” organisms with an indication if these genes were “Detected” or “Not Detected”. If the report displays “N/A”, the AMR gene was not reported because an organism associated with the gene was not detected. Figure 2 details the conditional reporting structure of the AMR genes.



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## Discrepancy Analysis and Support

If you obtain a discrepant result with your stand of care when running the BioFire BJI panel, you have the option to retain the sample and report the discrepancy to BioFire technical support. A representative may ask for more information or for the sample to be sent back to BioFire. BioFire is dedicated to providing the best customer service available. If you have questions, concerns, or additional feedback on the panel, please do not hesitate to reach out to us.

## BioFire Customer Technical Support

Email: [support@biofiredx.com](mailto:support@biofiredx.com)

Phone: 1-800-735-6544, Option 5

## Program Completion

If you used a loaner instrument, the program duration shall be limited to less than 90 days, and your Field Application Specialist will be in touch to facilitate the instruments return to BioFire. BioFire will notify all program participants when the BioFire BJI Panel is cleared by the Food and Drug Administration (FDA) for In Vitro Diagnostic (IVD) use. The program will end when you receive this notice or June 2021, whichever is sooner. Upon completion of the program, your Field Application Specialist will be in touch with you again to remove the BioFire BJI Panel IUO software from your system or to upgrade your system to the IVD version of the software if you choose. Please schedule a time to remove or upgrade the software within 90 days of program completion.

Thank you for your participation in this program and for the valuable feedback you are providing!



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**Figure 2. Conditional reporting of AMR genes.**

Antimicrobial Resistance Gene(s)	<i>mecA/C</i> MREJ(MRSA)	<i>Staphylococcus aureus</i>
	<i>vanA/B</i>	<i>Enterococcus faecalis</i>
	OXA-48-like	<i>Citrobacter</i> <i>Enterobacter cloacae complex</i> <i>Escherichia coli</i> <i>Klebsiella aerogenes</i> <i>Klebsiella pneumoniae group</i>
	CTX-M IMP KPC NDM VIM	<i>Citrobacter</i> <i>Enterobacter cloacae complex</i> <i>Escherichia coli</i> <i>Klebsiella aerogenes</i> <i>Klebsiella pneumoniae group</i>



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