



## Health Program & Insurance Guide for the BIOFIRE® Joint Infection (JI) Panel

bioMérieux developed the following health program & insurance guide for laboratories that administer the BIOFIRE® Joint Infection (JI) Panel, which is FDA-cleared for the simultaneous qualitative detection and identification of multiple bacterial and yeast nucleic acids and potentially associated markers of antimicrobial resistance from synovial fluid obtained from individuals suspected to have a joint infection such as septic arthritis and prosthetic joint infections in the United States. We describe below our current understanding of the coverage, coding and payment for administering the BIOFIRE JI Panel as of: January 1, 2024.

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### About the BIOFIRE Joint Infection Panel

The BIOFIRE® Joint Infection (JI) Panel is a multiplexed nucleic-acid-based, *in vitro* diagnostic test intended for use with the BIOFIRE® FILMARRAY® 2.0 and BIOFIRE® FILMARRAY® TORCH systems for the simultaneous detection and identification of multiple bacterial and yeast nucleic acids 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		Gram Negative Bacteria	
<ul style="list-style-type: none"> <li>Anaerococcus prevotii/vaginalis</li> <li>Clostridium perfringens</li> <li>Cutibacterium avidum/granulosum</li> <li>Enterococcus faecalis</li> <li>Enterococcus faecium</li> <li>Fingoldia magna</li> <li>Parvimonas micra</li> <li>Peptoniphilus</li> </ul>	<ul style="list-style-type: none"> <li>Peptostreptococcus anaerobius</li> <li>Staphylococcus aureus</li> <li>Staphylococcus lugdunensis</li> <li>Streptococcus spp.               <ul style="list-style-type: none"> <li>Streptococcus agalactiae</li> <li>Streptococcus pneumoniae</li> <li>Streptococcus pyogenes</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Bacteroides fragilis</li> <li>Citrobacter</li> <li>Enterobacter cloacae complex</li> <li>Escherichia coli</li> <li>Haemophilus influenzae</li> <li>Kingella kingae</li> <li>Klebsiella aerogenes</li> </ul>	<ul style="list-style-type: none"> <li>Klebsiella pneumoniae group</li> <li>Morganella morganii</li> <li>Neisseria gonorrhoeae</li> <li>Proteus spp.</li> <li>Pseudomonas aeruginosa</li> <li>Salmonella spp.</li> <li>Serratia marcescens</li> </ul>
Antimicrobial Resistance Genes		Yeast	
<ul style="list-style-type: none"> <li>CTX-M</li> <li>KPC</li> <li>NDM</li> <li>vanA/B</li> </ul>	<ul style="list-style-type: none"> <li>IMP</li> <li>mecA/C and MREJ (MRSA)</li> <li>OXA-48-like</li> <li>VIM</li> </ul>	<ul style="list-style-type: none"> <li>Candida               <ul style="list-style-type: none"> <li>Candida albicans</li> </ul> </li> </ul>	

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.

The BIOFIRE JI Panel is indicated as an aid in the diagnosis of specific agents of joint infections 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 organisms. The BIOFIRE JI Panel is not intended to monitor treatment for joint infection.

For more information on the BIOFIRE JI Panel, please consult the Instructions for Use located at: <https://www.biofiredx.com/support/documents/>.



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### Coverage

Coverage is a payer's determination that items and services are medically necessary for a patient and may be included under the patient's health insurance benefits. Coverage varies by payer. Healthcare providers should consult with individual payers regarding their coverage policies, including any applicable coverage criteria or documentation requirements.

For more information on Medicare and select state Medicaid programs coverage of the BIOFIRE® JI Panel, please consult CodeMap <http://www.codemap.com/biofiredx>.

### Coding

Coding enables healthcare providers to communicate to payers the items and services furnished to a patient in order to obtain payment for those items and services. It is the sole responsibility of the healthcare provider to determine the most appropriate codes to report on a claim, upon consultation of specific payer policies.

Based on currently available information, the BIOFIRE JI Panel may be described by the following CPT code:

**CPT code 87999** – Unlisted microbiology procedure.\*

*\*Tests billed using CPT® code 87999 to Medicare Administrative Contractors utilizing MolDx Local Coverage Articles require additional test identification information. For more information, please email: [biofiredx@codemap.com](mailto:biofiredx@codemap.com)*

### Payment

Payment is the amount that a payer renders to a healthcare provider for furnishing items and services to a patient. Patients may also have cost-sharing obligations, including deductibles, coinsurance or copayments, depending on their health insurance benefits. Payment amounts vary by payer and by geographic location, and are frequently updated, but are generally an allowable amount minus any patient cost-sharing amount. Healthcare providers should consult with individual payers regarding applicable current allowable amounts.

For more information on Medicare and select state Medicaid programs' allowable rates for the BIOFIRE JI Panel, please consult CodeMap <http://www.codemap.com/biofiredx>. Medicare rate limits can also be found on the CMS website within the Clinical Laboratory Fee Schedule (CLFS) section; the CLFS is updated quarterly.

It is recommended that healthcare providers consult with individual payers regarding allowable amounts for the BIOFIRE JI Panel. Allowable information can be found in your participating provider agreements with your payers or you can access your payers' online provider resources. For customers that are employees or part of health systems and or Hospitals, please contact your Revenue Cycles Management or Managed Care departments.

### Additional Information

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