



Health Program & Insurance Guide for the BIOFIRE® Blood Culture Identification 2 (BCID2) Panel

bioMérieux developed the following health program & insurance guide for laboratories that administer the BIOFIRE® Blood Culture Identification 2 (BCID2) Panel, which is FDA-cleared for the simultaneous qualitative detection and identification of multiple bacterial and yeast nucleic acids and select genetic determinants associated with antimicrobial resistance, performed directly on blood culture specimens identified as positive by a continuous blood culture system from individuals suspected of bloodstream infections (BSIs) in the United States. We describe below our current understanding of the coverage, coding and payment for administering the BIOFIRE BCID2 Panel as of: January 1, 2024.

The information contained in this guide is not legal or coding advice; it is general information for reference purposes only. It is not intended to suggest any manner in which healthcare providers can increase or maximize compensation from any payer. It is not intended to guarantee coverage, coding or payment. This information is gathered from third-party sources and is subject to change without notice, including as a result of changes in laws, regulations, rules and policies. This information may not be all-inclusive and changes may have occurred subsequent to publication of this document. Before filing claims, healthcare providers should always check applicable laws and regulations, and consult individual payers regarding billing and compensation matters, including for specific coverage, coding and payment information. Healthcare providers are solely responsible for determining appropriate charging and billing practices, and for ensuring compliance with Medicare, Medicaid and all other third-party payer requirements, as well as accurate coding, documentation and medical necessity for the services provided. bioMérieux specifically disclaims liability or responsibility for the results or consequences of any actions taken in reliance on information in this general reference document.

About the BIOFIRE FILMARRAY Blood Culture Identification 2 Panel

The BIOFIRE BCID2 Panel, for use with the BIOFIRE® FILMARRAY® 2.0 or BIOFIRE® FILMARRAY® TORCH systems, is a qualitative multiplexed nucleic acid-based *in vitro* diagnostic test capable of the simultaneous detection and identification of nucleic acids from multiple bacterial and yeast nucleic acids and select genetic determinants associated with antimicrobial resistance, performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system. Results are intended to be interpreted in conjunction with Gram stain results. We describe below our current understanding of coverage, coding, and payment for administering the BIOFIRE BCID2 Panel.

The following organism types and subtypes are identified using the BIOFIRE BCID2 Panel:

Gram Positive Bacteria	Gram Negative Bacteria
<ul style="list-style-type: none"> • <i>Enterococcus faecalis</i> • <i>Enterococcus faecium</i> • <i>Listeria monocytogenes</i> • <i>Staphylococcus</i> spp. <ul style="list-style-type: none"> ○ <i>Staphylococcus aureus</i> ○ <i>Staphylococcus epidermidis</i> ○ <i>Staphylococcus lugdunensis</i> • <i>Streptococcus</i> spp. <ul style="list-style-type: none"> ○ <i>Streptococcus agalactiae</i> (Group B) ○ <i>Streptococcus pneumoniae</i> ○ <i>Streptococcus pyogenes</i> (Group A) 	<ul style="list-style-type: none"> • <i>Acinetobacter calcoaceticus-baumannii</i> complex • <i>Bacteroides fragilis</i> • <i>Haemophilus influenzae</i> • <i>Neisseria meningitidis</i> (encapsulated) • <i>Pseudomonas aeruginosa</i> • <i>Stenotrophomonas maltophilia</i>
Yeast	Antimicrobial Resistance Genes
<ul style="list-style-type: none"> • <i>Candida albicans</i> • <i>Candida auris</i> • <i>Candida glabrata</i> • <i>Candida krusei</i> • <i>Candida parapsilosis</i> • <i>Candida tropicalis</i> • <i>Cryptococcus neoformans/gattii</i> 	<ul style="list-style-type: none"> • <i>Enterobacterales</i> <ul style="list-style-type: none"> ○ <i>Enterobacter cloacae</i> complex ○ <i>Escherichia coli</i> ○ <i>Klebsiella aerogenes</i> ○ <i>Klebsiella oxytoca</i> ○ <i>Klebsiella pneumoniae</i> group ○ <i>Proteus</i> spp. ○ <i>Salmonella</i> spp. ○ <i>Serratia marcescens</i> • <i>mecA/C</i> and MREJ (MRSA) • NDM • OXA-48-like • <i>vanA/B</i> • VIM

The BIOFIRE BCID2 Panel is for use by trained medical and laboratory professionals in a laboratory setting or under the supervision of a trained laboratory professional.

The BIOFIRE BCID2 Panel is indicated as an aid in the diagnosis of specific agents of bloodstream infection and results are meant to be used in conjunction with other clinical and laboratory findings. Positive results do not rule out co-infection with organisms not included in the BIOFIRE BCID2 Panel. The BIOFIRE BCID2 Panel is not intended to monitor treatment for bloodstream infection.

For more information on the BIOFIRE BCID2 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® BCID2 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 BCID2 Panel may be described by the following CPT code:

CPT code 87154 – Culture, typing; identification of blood pathogen and resistance typing, when performed, by nucleic acid (DNA or RNA) probe, multiplexed amplified probe technique including multiplex reverse transcription, when performed, per culture or isolate, 6 or more targets

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 BCID2 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 BCID2 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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To ensure compliance with Federal and State laws and regulations, including HIPAA, bioMérieux is unable to provide specific billing guidance, and/or support with patient appeals. bioMérieux does not recommend codes for specific cases. bioMérieux does not promote the off-label use of its diagnostic tests.

For more information regarding bioMérieux or the BIOFIRE BCID2 Panel, please visit our website: www.biomerieux-diagnostics.com.