



## Health Program & Insurance Guide for the BIOFIRE® FILMARRAY®

### Meningitis/Encephalitis (ME) Panel

bioMérieux developed the following health program & insurance guide for laboratories that administer the BIOFIRE® FILMARRAY® Meningitis/Encephalitis (ME) Panel, which is FDA-cleared for the simultaneous qualitative detection and identification of nucleic acids from multiple bacteria, viral, and yeast directly from cerebrospinal fluid (CSF) specimens obtained via lumbar puncture from individuals with signs and/or symptoms of meningitis and/or encephalitis, in the United States. We describe below our current understanding of the coverage, coding and payment for administering the BIOFIRE ME Panel as of: January 1, 2024.

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#### About the BIOFIRE FILMARRAY Meningitis/Encephalitis Panel

The BIOFIRE® FILMARRAY® Meningitis/Encephalitis (ME) Panel is a qualitative multiplexed nucleic acid-based *in vitro* diagnostic tested intended for use with BIOFIRE® FILMARRAY® Systems. The BIOFIRE ME Panel is capable of simultaneous detection of multiple bacterial, viral, and yeast nucleic acids directly from cerebrospinal fluid (CSF) specimens obtained via lumbar puncture from individuals with signs and/or symptoms of meningitis and/or encephalitis.

The following organisms are identified using the BIOFIRE ME Panel:

Bacteria	Viruses
<ul style="list-style-type: none"> <li>• <i>Escherichia coli</i> K1</li> <li>• <i>Haemophilus influenzae</i></li> <li>• <i>Listeria monocytogenes</i></li> <li>• <i>Neisseria meningitidis</i> (encapsulated)</li> <li>• <i>Streptococcus agalactiae</i></li> <li>• <i>Streptococcus pneumoniae</i></li> </ul>	<ul style="list-style-type: none"> <li>• Cytomegalovirus</li> <li>• Enterovirus</li> <li>• Herpes simplex virus 1</li> <li>• Herpes simplex virus 2</li> <li>• Human herpesvirus 6</li> <li>• Human parechovirus</li> <li>• Varicella zoster virus</li> </ul>
Yeast	
<ul style="list-style-type: none"> <li>• <i>Cryptococcus neoformans/gattii</i></li> </ul>	

The BIOFIRE ME 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 ME Panel is indicated as an aid in the diagnosis of specific agents of meningitis and/or encephalitis and results are meant to be used in conjunction with other clinical, epidemiological, and laboratory data. Results from the BIOFIRE ME Panel are not intended to be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results do not rule out co-infection with organisms not included in the BIOFIRE ME Panel. The agent detected may not be the definite cause of the disease. Negative results do not preclude central nervous system (CNS) infection. Not all agents of CNS infection are detected by this test and sensitivity in clinical use may differ from that described in the package insert.

The BIOFIRE ME Panel is not intended for testing of specimens collected from indwelling CNS medical devices.

The BIOFIRE ME Panel is intended to be used in conjunction with standard of care culture for organism recovery, serotyping, and antimicrobial susceptibility testing.

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

**CPT code 87483** – *Infectious agent detection by nucleic acid (DNA or RNA); central nervous system pathogen (eg, Neisseria meningitidis, Streptococcus pneumoniae, Listeria, Haemophilus influenzae, E. coli, Streptococcus agalactiae, enterovirus, human parechovirus, herpes simplex virus type 1 and 2, human herpesvirus 6, cytomegalovirus, varicella zoster virus, Cryptococcus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 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 ME 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 ME 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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