Health Program & Insurance Guide for the BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel

bioMérieux developed the following health program & insurance guide for laboratories that administer the BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel, which is FDA-cleared for the simultaneous qualitative detection and identification of nucleic acids from multiple bacteria, viruses and parasites in stool samples obtained from individuals with signs and/or symptoms of gastrointestinal infection, in the United States. We describe below our current understanding of the coverage, coding and payment for administering the BIOFIRE GI 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 Gastrointestinal Panel

The BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel is a qualitative multiplexed nucleic acid-based *in vitro* diagnostic test intended for use with BIOFIRE® FILMARRAY® Systems. The BIOFIRE GI Panel is capable of the simultaneous detection and identification of nucleic acids from multiple bacteria, viruses, and parasites directly from stool samples obtained from individuals with signs and/or symptoms of gastrointestinal infection.

The following bacteria (including several diarrheagenic E. coli/Shigella pathotypes), parasites, and viruses are identified using the BIOFIRE GI Panel:

Bacteria	Viruses
• *Campylobacter (C. jejuni/C. coli/C. upsaliensis)* • *Clostridiodes (Clostridium) difficile (C.difficile)* toxin A/B • *Plesiomonas shigelloides* • *Salmonella* • *Vibrio (V. parahaemolyticus/V. vulnificus/V. cholerae/) V. cholerae* • *Yersinia enterocolitica*	• Adenovirus F 40/41 • Astrovirus • Norovirus GI/GII • Rotavirus A • Sapovirus (Genogroups I, II, IV, and V)
Diarrheagenic *E. coli/Shigella*	**Parasites**
• Enteroaggregative *Escherichia coli* (EAEC) • Enteropathogenic *Escherichia coli* (EPEC) • Enterotoxigenic *Escherichia coli* (ETEC) *lt/st* • Shiga-like toxin-producing *Escherichia coli* (STEC) *stx1/stx2 E. coli* O157 • *Shigella*/Enteroinvasive *Escherichia coli* (EIEC)	• *Cryptosporidium* • *Cyclospora cayetanensis* • *Entamoeba histolytica* • *Giardia lamblia*

The BIOFIRE GI 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 GI Panel is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness and results are meant to be used in conjunction with other clinical, laboratory, and epidemiological data. Positive results do not rule out co-infection with organisms not included in the BIOFIRE GI Panel. The agent detected may not be the definite cause of the disease. Concomitant culture is necessary for organism recovery and further typing of bacterial agents. The BIOFIRE GI Panel is not intended to monitor or guide treatment for *C. difficile* infection.

Negative results generated by the BIOFIRE GI Panel in the setting of clinical illness compatible with gastroenteritis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome or Crohn's disease.

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

> ***CPT code 87507*** *– Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), 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 GI 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 GI 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 Cycle Management or Managed Care departments.

Additional Information

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