Health Program & Insurance Guide for the BIOFIRE® SPOTFIRE® Respiratory (R) Panel

bioMérieux developed the following Health Program & Insurance guide for healthcare providers who administer the BIOFIRE® SPOTFIRE® Respiratory (R) Panel (SPOTFIRE R Panel), which is FDA-cleared for the simultaneous, qualitative detection and differentiation of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections. We describe below our current understanding of the coverage, coding and payment for administering the BIOFIRE® SPOTFIRE® Respiratory (R) 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 SPOTFIRE Respiratory Panel

The BIOFIRE® SPOTFIRE® Respiratory (R) Panel (SPOTFIRE R Panel) is a multiplexed polymerase chain reaction (PCR) test intended for use with the BIOFIRE® SPOTFIRE® System for the simultaneous, qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections.

The following organism types and subtypes are identified and differentiated using the SPOTFIRE R Panel:

Bacteria	Viruses	

• *Bordetella parapertussis*
• *Bordetella pertussis*
• *Chlamydia pneumoniae*
• *Mycoplasma pneumoniae*
	• Adenovirus
	• Coronavirus (seasonal)
	• Coronavirus SARS-CoV-2
	• Human metapneumovirus
	• Human rhinovirus/enterovirus
		• Influenza A virus
		  ○ Influenza A virus A/H1-2009
		  ○ Influenza A virus A/H3
		• Influenza B virus
		• Parainfluenza virus
		• Respiratory syncytial virus

Nucleic acids from the viral and bacterial organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. The detection and identification are indicative of the presence of the identified microorganism and aids in diagnosis if used in conjunction with other clinical and epidemiological information. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

The BIOFIRE SPOTFIRE Respiratory Panel is for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high, moderate or waived complexity tests. The BIOFIRE SPOTFIRE Respiratory Panel is authorized for use in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation.

Laboratories and patient care settings within the United States and its territories may be required to report all SARS-CoV-2 results to the appropriate public health authorities.

Negative results in the setting of a respiratory illness may be due to infection with pathogens that are not detected by this test, or lower respiratory tract infection that may not be detected by an NPS specimen. Positive results do not rule out coinfection with other organisms. The agent(s) detected by the SPOTFIRE R Panel may not be the definite cause of disease.

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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® SPOTFIRE® Respiratory R Panel please consult CodeMap http://www.codemap.com/biofire.

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® SPOTFIRE® Respiratory Panel may be described by the following CPT code:

> ***CPT code 87633*** *– Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (e.g., adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets*

If the practice/lab running the test is CLIA Waived, a QW modifier is required (see below:)

> ***CPT code 87633 QW**** *– Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (e.g., adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets*
> *Use modifier 'QW' to indicate a CLIA waived laboratory test

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® SPOTFIRE® Respiratory (R) Panel, please consult CodeMap http://www.codemap.com/biofire. 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® SPOTFIRE® Respiratory (R) 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 appeal. 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 SPOTFIRE Respiratory R Panel, please visit our website: www.biomerieux-diagnostics.com

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