Health Program & Insurance Guide for the BIOFIRE® Respiratory 2.1 (RP2.1) Panel

bioMérieux developed the following Health Program & Insurance guide for laboratories that administer the BIOFIRE® Respiratory 2.1 (RP2.1) Panel, which is FDA-cleared for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs obtained from individuals suspected of respiratory tract infections, including COVID-19, in the United States. We describe below our current understanding of the coverage, coding, and payment for administering the BIOFIRE RP2.1 Panel as of: September 1, 2022.

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 Respiratory 2.1 Panel

The BIOFIRE RP2.1 Panel, for use with the BIOFIRE® FILMARRAY® 2.0 or BIOFIRE® FILMARRAY® TORCH Systems, is a polymerase chain reaction (PCR)-based test intended for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs obtained from individuals suspected of respiratory tract infections, including COVID-19.

The BIOFIRE RP2.1 Panel is intended for the detection and identification of nucleic acid from the following organism types and subtypes:

Bacteria	Viruses	
• *Bordetella parapertussis* • *Bordetella pertussis* • *Chlamydia pneumoniae* • *Mycoplasma pneumoniae*	• Adenovirus • Coronavirus 229E • Coronavirus HKU1 • Coronavirus NL63 • Coronavirus OC43 • Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) • Human Metopneumovirus • Human Rhinovirus/Enterovirus	• Influenza A, including subtypes H1, H3 and H1-2009 • Influenza B • Parainfluenza Virus 1 • Parainfluenza Virus 2 • Parainfluenza Virus 3 • Parainfluenza Virus 4 Respiratory Syncytial Virus

The BIOFIRE RP2.1 Panel is for use by trained medical and laboratory professionals in a laboratory setting or under the supervision of a trained laboratory professional.

Nucleic acids from the respiratory viral and bacterial organisms identified by the BIOFIRE RP2.1 Panel are generally detectable in nasopharyngeal specimens during the acute phase of infection. The detection and identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and/or symptoms of respiratory infection is indicative of the presence of the identified microorganism and aids in the diagnosis of respiratory infection if used in conjunction with other clinical and epidemiological information. The results of the BIOFIRE RP2.1 Panel should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

Negative results generated by the BIOFIRE RP2.1 Panel in the setting of a respiratory illness may be due to infection with pathogens not detected by this test, or lower respiratory tract infection that may not be detected by a nasopharyngeal specimen. Positive results do not rule out co-infection with other organisms. The agent(s) detected by the BIOFIRE RP2.1 Panel may not be the definite cause of disease. Additional laboratory testing (e.g., bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.

For more information on the BIOFIRE RP2.1 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® RP2.1 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 RP2.1 Panel may be described by the following Proprietary Laboratory Analysis (PLA) code:

> ***PLA code 0202U*** *– Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected*

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 RP2.1 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 RP2.1 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

In providing this Health Program & Insurance guide, bioMérieux makes no warranties, express, implied or statutory, including, but not limited to, warranties of merchantability, fitness for a particular purpose and/or non-infringement. bioMérieux assumes no responsibility for omissions or errors contained in this guide. This guide presents no promise, commitment, statement or guarantee by bioMérieux concerning proper billing or coding practices or levels of payment or charges. This information does not constitute reimbursement or legal advice. The existence of codes does not guarantee coverage or payment for any procedure by any payer. The healthcare provider is solely responsible for determining the appropriate coverage, coding and payment policies for individual patients.

Applicable FARS/DFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT®, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

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 RP2.1 Panel, please visit our website: www.biomerieux-diagnostics.com

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