



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 (NPS) 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: January 1, 2023.

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About the BIOFIRE Respiratory 2.1 Panel

The BIOFIRE® Respiratory 2.1 (RP2.1) Panel is a PCR-based multiplexed nucleic acid test intended for the use with the BIOFIRE® FILMARRAY® 2.0 or BIOFIRE® FILMARRAY® TORCH Systems 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, including COVID-19.

The following organism types and subtypes are identified using the BIOFIRE RP2.1:

Bacteria	Viruses
<ul style="list-style-type: none"> • <i>Bordetella parapertussis</i> • <i>Bordetella pertussis</i> • <i>Chlamydia pneumoniae</i> • <i>Mycoplasma pneumoniae</i> 	<ul style="list-style-type: none"> • 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 virus • Influenza A virus A/H1 • Influenza A virus A/H3 • Influenza A virus A/H1-2009 • Influenza B virus • Parainfluenza Virus 1 • Parainfluenza Virus 2 • Parainfluenza Virus 3 • Parainfluenza Virus 4 • Respiratory syncytial virus

The BIOFIRE RP2.1 Panel is intended 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 this test are generally detectable in NPS 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 this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. 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 BioFire RP2.1 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.

Laboratories 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 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

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

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