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

bioMérieux developed the following Health Program & Insurance guide for healthcare providers who administer the BIOFIRE® Respiratory 2.1-EZ (RP2.1-EZ) Panel (EUA)* for the detection and differentiation of nucleic acids from multiple viral and bacterial respiratory organisms, including nucleic acid from Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory infection consistent with COVID-19 by their healthcare provider. We describe below our current understanding of the coverage, coding, and payment for administering the BIOFIRE RP2.1-EZ Panel (EUA) as of January 1, 2023.

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-EZ Panel (EUA)

The BIOFIRE® Respiratory Panel 2.1-EZ (RP2.1-EZ) (EUA), for use only on the BIOFIRE® FILMARRAY® 2.0 EZ Configuration System, is a multiplexed polymerase chain reaction (PCR) test intended for the simultaneous qualitative detection and differentiation of nucleic acids from multiple viral and bacterial respiratory organisms, including nucleic acid from SARS-CoV-2, in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory infection consistent with COVID-19 by their healthcare provider.

The BIOFIRE Respiratory Panel 2.1 EZ (RP2.1-EZ) (EUA) is intended for the detection and differentiation of nucleic acid from the SARS-CoV-2 and 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 • Coronavirus SARS-CoV-2	• Human Metopneumovirus • Human Rhinovirus/Enterovirus • Influenza A, including subtypes H1, H3 and H1-2009 • Influenza B • Parainfluenza virus* • Respiratory Syncytial Virus

*Four types of parainfluenza virus (PIV1, PIV2, PIV3, and PIV4) can be detected and will be reported as Parainfluenza Virus Detected (type information is not reported).

The BIOFIRE RP2.1-EZ Panel (EUA) is only for use under Emergency Use Authorization (EUA) pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360bbb-3).

The BIOFIRE RP2.1-EZ Panel (EUA) 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 RP2.1-EZ Panel (EUA) is authorized for use in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation.

SARS-CoV-2 RNA and nucleic acids from the other respiratory viral and bacterial organisms identified by the BIOFIRE RP2.1-EZ Panel (EUA) are generally detectable in nasopharyngeal (NPS) swabs during the acute phase of infection. Positive results from individuals exhibiting signs and/or symptoms of respiratory infection are indicative of the presence of the identified microorganism(s). Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results are indicative of the presence of the identified organism and do not rule out co-infection with other organisms. The agent detected may not be the definite cause of disease. The results of the BIOFIRE RP2.1-EZ Panel (EUA) should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results are indicative of the presence of the identified organism and do not rule out co-infection with other viruses. The agent detected by the BIOFIRE RP2.1-EZ may not be the definite cause of the disease.

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 generated by the BIOFIRE RP2.1-EZ Panel (EUA) 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. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions.

Negative SARS-CoV-2 results must be combined with clinical observations, patient history, and epidemiological information. Negative results for other organisms identified by the BIOFIRE RP2.1-EZ Panel (EUA) may require additional laboratory testing (e.g., bacterial, and viral culture, immunofluorescence, and radiography) when evaluating a patient with possible respiratory tract infection.

For more information on Medicare and select state Medicaid programs' coverage of the BIOFIRE® RP2.1-EZ Panel (EUA), please consult CodeMap http://www.codemap.com/biofire.

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-EZ Panel (EUA), 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 RP2.1-EZ Panel (EUA) may be described by the following CPT code:

> **CPT code 87633 QW*** – respiratory virus (eg, 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 RP2.1-EZ Panel (EUA), 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 RP2.1-EZ Panel (EUA). 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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*This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories; This product has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2 from multiple respiratory viral and bacterial organisms; and, The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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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 RP2.1-EZ Panel (EUA), please visit our website: www.biomerieux-diagnostics.com