



Health Program & Insurance Guide for the BIOFIRE® FILMARRAY® Pneumonia (PN) Panel

bioMérieux developed the following health program & insurance guide for laboratories that administer the BIOFIRE® FILMARRAY® Pneumonia (PN) Panel, which is FDA-cleared for the simultaneous qualitative detection and identification of nucleic acids from multiple respiratory bacteria and viruses, as well as antimicrobial genes, in sputum-like specimens or bronchoalveolar lavage (BAL)-like specimens (BAL or mini-BAL) obtained from individuals suspected of lower respiratory tract infections in the United States. We describe below our current understanding of the coverage, coding and payment for administering the BIOFIRE PN 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 FILMARRAY Pneumonia Panel

The BIOFIRE PN Panel, for use with the BIOFIRE® FILMARRAY® 2.0 or BIOFIRE® FILMARRAY® TORCH systems, is a qualitative multiplexed nucleic acid-based *in vitro* diagnostic test capable of the simultaneous detection and identification of nucleic acids from multiple respiratory bacteria and viruses, as well as select antimicrobial resistance genes obtained from sputum-like or bronchoalveolar lavage (BAL)-like specimens (BAL or mini-BAL) obtained from individuals suspected of lower respiratory tract infection.

The BIOFIRE PN Panel is intended for the detection and identification of the following organism types and subtypes:

Bacteria reported with bins of 10 ⁴ , 10 ⁵ , 10 ⁶ , or ≥10 ⁷ copies/mL		
<ul style="list-style-type: none"> Acinetobacter calcoaceticus-baumannii complex Enterobacter cloacae complex Escherichia coli Haemophilus influenzae Klebsiella aerogenes 	<ul style="list-style-type: none"> Klebsiella oxytoca Klebsiella pneumoniae group Moraxella catarrhalis Proteus spp. Pseudomonas aeruginosa 	<ul style="list-style-type: none"> Serratia marcescens Staphylococcus aureus Streptococcus agalactiae Streptococcus pneumoniae Streptococcus pyogenes

The following atypical bacteria, antimicrobial resistance genes and viruses are reported qualitatively:

Atypical Bacteria	Antimicrobial Resistance Genes	Viruses
<ul style="list-style-type: none"> Chlamydia pneumoniae Legionella pneumophila Mycoplasma pneumoniae 	<ul style="list-style-type: none"> CTX-M IMP KPC NDM OXA-48-like VIM mecA/C and MREJ 	<ul style="list-style-type: none"> Adenovirus Coronavirus Human Metapneumovirus Human Rhinovirus/Enterovirus Influenza A Influenza B Parainfluenza Virus Respiratory Syncytial Virus

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

The detection and identification of specific bacterial and viral nucleic acids, as well as the estimation of relative abundance of nucleic acid from common bacterial analytes, within specimens collected from individuals exhibiting signs and/or symptoms of a respiratory infection, aids in the diagnosis of lower 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, pathogens below the limit of detection, or in the case of bacterial analytes, present at levels below the lowest reported 10⁴ copies/mL bin. Detection of analytes does not rule out co-infection with other organisms; the agent(s) detected by the BIOFIRE PN 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 lower respiratory tract infection.

For more information on the BIOFIRE PN 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® PN 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 PN 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), multiplex reverse transcription and amplified probe technique and 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 PN 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 PN 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 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 PN Panel, please visit our website: www.biomerieux-diagnostics.com.