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 viral bacteria nucleic acids, and viruses, select antimicrobial genes, in sputum-like specimens or bronchoalveolar lavage (BAL)-like specimens (BAL or mini-BALL) 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: 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 FILMARRAY Pneumonia Panel

The BIOFIRE® FILMARRAY® Pneumonia (PN) Panel is a multiplexed nucleic acid test intended for use with the BIOFIRE® FILMARRAY® 2.0 (BIOFIRE 2.0) or BIOFIRE® FILMARRAY® TORCH (BIOFIRE TORCH) systems for the simultaneous detection and identification of multiple respiratory viral and bacterial nucleic acids, as well as select antimicrobial resistance genes, in sputum-like specimens (included or expectorated sputum, or endotracheal aspirates) or bronchoalveolar lavage (BAL)-like specimens (BAL or mini-BAL) obtained from individuals suspected of lower respiratory tract infection.

The following bacteria are reported semi-quantitatively with bins representing approximately 10^4, 10^5, 10^6, or ≥10^7 genomic copies of bacterial nucleic acid per milliliter (copies/mL) of specimen, to aid in estimating relative abundance of nucleic acid from these common bacteria within a specimen:

Bacteria reported with bins of 10^4, 10^5, 10^6, or ≥10^7 copies/mL		
• *Acinetobacter calcoaceticus-baumannii complex*	• *Klebsiella oxytoca*	• *Serratia marcescens*
• *Enterobacter cloacae complex*	• *Klebsiella pneumoniae* group	• *Staphylococcus aureus*
• *Escherichia coli*	• *Moraxella catarrhalis*	• *Streptococcus agalactiae*
• *Haemophilus influenzae*	• *Proteus* spp.	• *Streptococcus pneumoniae*
• *Klebsiella aerogenes*	• *Pseudomonas aeruginosa*	• *Streptococcus pyogenes*

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

Atypical Bacteria	Antimicrobial Resistance Genes	Viruses
• *Chlamydia pneumoniae*	• CTX-M	• Adenovirus
• *Legionella pneumophila*	• IMP	• Coronavirus
• *Mycoplasma pneumoniae*	• KPC	• Human metapneumovirus
	• NDM	• Human rhinovirus/enterovirus
	• OXA-48-like	• Influenza A virus
	• VIM	• Influenza B virus
	• *mecA/C* and MREJ (MRSA)	• Parainfluenza virus
		• Respiratory syncytial virus

The BIOFIRE Pneumonia Panel is intended 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 viral and bacterial 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 10^4 copies/mL bin. Detection of analytes does not rule out co-infection with other organisms; the agent(s) detected by the BIOFIRE Pneumonia 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/.

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

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.

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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.