GENETIC ASSAYS
A Molecular Diagnostics Laboratory

Pneu Pneumonia Panel

GA Test Code **7638**

Method ***FDA-cleared*** BioFire® FilmArray® Pneumonia Panel by nested multiplex PCR

Bacteria (reported semi-quantitatively with copies/mL bin results)

Acinetobacter calcoaceticus-baumannii complex
Enterobacter cloacae complex
Escherichia coli
Haemophilus influenzae
Klebsiella aerogenes
Klebsiella oxytoca
Klebsiella pneumoniae group
Moraxella catarrhalis
Proteus spp.
Pseudomonas aeruginosa
Serratia marcescens
Staphylococcus aureus
Streptococcus agalactiae
Streptococcus pneumoniae
Streptococcus piogene

Antimicrobial Resistance Genes

CTX-M
IMP
KPC
mecA/C and MREJ
NDM
OXA-48-like
VIM

Atypical Bacteria (qualitative)

Chlamydia pneumoniae
Legionella pneumophila
Mycoplasma pneumoniae

Viruses (qualitative)

Adenovirus
Coronavirus
Human Metapneumovirus
Human Rhinovirus/Enterovirus
Influenza A
Influenza B
Parainfluenza Virus
Respiratory Syncytial Virus

Specimens

Bronchial Washings: 0.5 (min 0.2) mL, refrigerated for up to 96 hours, in sterile plastic leak-proof container. Ship with cold pack.
Performance: 96.2% Sensitivity and 98.3% Specificity

Sputum: 0.5 (min 0.2) mL, ambient (24 hrs) or refrigerated (96 hrs) in sterile plastic leak-proof container. Ship with cold pack.
Performance: 96.3% Sensitivity and 97.2% Specificity

Causes for Rejection

Time and/or temperature instructions not followed; QNS for analysis.
NOTE: Specimens should not be centrifuged, pre-processed, treated with any mucolytic or decontaminating agents, nor placed into transport media.

Reference Range Not Detected

Turnaround Time 1-6 hours from receipt of sample

CPT Codes 87150, 87486, 87541, 87581, 87632, 87640, 87798
PLA Code 0151U* (for Medicare patients)

*This PLA Code is subject to a Medicare Limited Coverage Policy (MLCP) and may require a signed Advanced Beneficiary Notice (ABN) when ordering. Tests subject to an MLCP must meet medical necessity criteria in order to be covered by Medicare. MLCP tests ordered without a supportive ICD-10 code will not satisfy medical necessity and therefore will not be covered by Medicare. Physicians (or others authorized by law to order tests) should only order tests that are medically necessary for the diagnosis or treatment of a patient. These orders may require an ABN signed by the patient, which confirms they are responsible for payment.

Description

The ***FDA-cleared*** BioFire FilmArray Pneumonia Panel is a multiplexed nucleic acid test intended for the simultaneous detection and identification of multiple respiratory viral and bacterial nucleic acids, as well as select antimicrobial resistance genes, in sputum or bronchoalveolar lavage (BAL)-like specimens obtained from individuals suspected of lower respiratory tract infection.

Pathogens infecting the lower respiratory tract cause acute local and systemic disease, with the most severe cases occurring in children, elderly, and immunocompromised individuals. Due to the similarity of diseases caused by many viruses and bacteria, diagnosis based on clinical symptoms alone is difficult. Identification of potential causative agents, as well as the relative abundance of common bacterial agents, provides data to aid the physician in determining appropriate patient treatment and public health response for disease containment.