Changi General Hospital
SingHealth

Tel: (65) 6788 8833
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Changi General Hospital
2 Simei Street 3
Singapore 529889
www.cgh.com.sg
Reg No 198904226R

Test Name	Pneumonia Multiplex PCR (Viral/ Bacterial/ Resistance Gene)
Specimen Type	1. Bronchoalveolar lavage (BAL) 2. Endotracheal aspirate (ETTA) 3. Sputum
Special Instructions For Laboratory	
Specimen Storage And Transport	Transport to laboratory for testing as quickly as possible. If delay in specimen transport or testing is anticipated, samples should be refrigerated for up to 1 day.
Specimen Minimum Volume	Minimum sample volume required: 1 ml
Test Method	PCR (Biofire FilmArray Multiplex PCR) (FDA approved)
Expected Result	Detected, Not Detected, Inhibitory
Reference Ranges	NA
Turn Around Time	1 day
Days Of Testing	Daily
Hospital	CGH
Laboratory	Microbiology Lab
Discipline	Microbiology
Contact Details	68504935 / 36

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Clinical Information

SUMMARY OF TEST

The Pneumonia Multiplex PCR (Viral/ Bacterial/ Resistance Gene) (abbreviated as Pneumonia panel (PN)) is a commercial PCR FDA-approved test for detection of nucleic acids of multiple bacteria, atypical bacteria and viruses which may be associated with lower respiratory tract infections.

A separate sample should ALWAYS be sent for routine microbiological culture (as a minimum, aerobic culture, and the following tests if clinically appropriate: anaerobic culture, fungal culture or mycobacterial culture).

Organism targets which are NOT present in the Pneumonia Panel will not be detected by the PCR assay. In particular, the following potential respiratory pathogens will need separate test orders: *Mycobacterium tuberculosis*, *Legionella* species (non-*pneumophila*), *Burkholderia pseudomallei*, *Pneumocystis jirovecii* (*carinii*), MERS-Coronavirus, SARS-Coronavirus-2 and avian strains of Influenza A (H5 and H7).

The following organisms are detected by Pneumonia panel:

Bacteria
Haemophilus influenzae
Klebsiella oxytoca
Klebsiella pneumoniae group
Moraxella catarrhalis
Pseudomonas aeruginosa
Staphylococcus aureus
Streptococcus pneumoniae
Streptococcus pyogenes
#Acinetobacter calcoaceticus-baumannii complex
#Serratia marcescens
#Enterobacter cloacae complex
#Escherichia coli
#Streptococcus agalactiae
#Proteus spp.
#Klebsiella (Enterobacter) aerogenes
Resistance genes
mecA/C & MREJ (applicable only to *S. aureus*)
CTX-M (applicable only to Enterobacterales)
Atypical bacteria
Chlamydia pneumoniae
Legionella pneumophila
Mycoplasma pneumoniae
Atypical bacteria
Chlamydia pneumoniae
Legionella pneumophila
Mycoplasma pneumoniae
Viruses
Adenovirus
Human Coronavirus (229E, OC43, HKU1, NL63)
Human Metapneumovirus
Human Rhinovirus/Enterovirus
Influenza A
Influenza B
Parainfluenza Virus (1-4)
Respiratory Syncytial Virus

#organisms listed with this symbol will only be reported on request; please specify on order that all organisms should be reported

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	APPROPRIATE CLINICAL USAGE 1. Patients with severe community-acquired pneumonia (CAP) (admitted to ICU, HDU, or with significant respiratory failure) 2. Immuno-compromised patients with CAP (e.g. active malignancy, immunosuppressant therapies, etc) 3. CAP patients on empiric expanded-spectrum antibiotics (vancomycin or a carbapenem) 4. Patients not responding to typical therapy 5. Patients with suspected infection with atypical organisms 6. Patients with severe hospital-acquired pneumonia (HAP) #all organisms tested should be reported, please request on test order
Link Out For Additional Information	

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Remarks

The performance of the Pneumonia (PN) panel was evaluated in several trials. The largest multi-centre trial concluded that the PN panel showed a sensitivity of 100% for 15/22 etiologic targets using BAL specimens and for 10/24 targets using sputum specimens, when compared to reference culture. All other targets had sensitivities of ≥75% or were unable to be calculated due to low prevalence in the study population. Specificity for all targets was ≥87%, with many false-positive results compared to culture. A quarter (25%) of false-positive results were resolved by detecting the reported organism in the reference culture but below standard reporting thresholds. A further 73% were resolved in favour of the Pneumonia panel, using alternative molecular methods. The final determination of false-positive results was concordant with with Pneumonia panel in 99.7% of cases.

Full analytical performance data for the PN assay based on manufacturer's submitted data is available from this document on the intranet (CLICK HERE).

LIMITATIONS OF ASSAY

The PN Panel test may detect non-viable organisms, or organisms which may represent sample colonisation or contamination. Results should always be interpreted in the context of clinical history and other diagnostics tests.
The performance of the test may be affected by inappropriate sample collection, handling and transportation.
The effect of antibiotic treatment on test performance including semi-quantitative bin results has not been specifically evaluated.
Viral and bacterial nucleic acids may persist in vivo independent of organism viability. Detection of organism target(s) does not imply that the corresponding organisms are infectious.
The performance of the FilmArray Pneumonia Panel has not been established for monitoring treatment of infection.
Positive results for the following microbes are subject to known limitations for potential cross-reactivity, listed in Table 1.

Table 1: Assay cross-reactivity

Pneumonia Panel Reports as **Detected**	**Potential cross-reactivity**	**Comment**
Klebsiella oxytoca	Klebsiella michiganensis	
Staphylococcus aureus	Staphylococcus argenteus	Detected at high concentrations.
	Staphylococcus schweitzeri	Detected at high concentrations.
Pseudomonas aeruginosa	Pseudomonas putida	
Human rhino/enterovirus	Bordetella species	Cross-reactivity with B. pertussis confirmed at high concentrations, and in-silico cross-reactivity predicted with other Bordetella species.
Parainfluenza virus	Aspergillus niger	Detected at high concentrations.