BioFire FilmArray® Pneumonia Panel® Educational Handout

What is the BioFire FilmArray® Pneumonia Panel®?

A multiplex PCR test that detects certain organisms and resistance genes from respiratory samples. Results are available an hour after test initiated. This technology allows moving from empiric to targeted antimicrobial therapy earlier in treatment.

What does it identify?

Bacteria (semi-quantitative)	Viruses & Atypical Pathogens	Resistance Genes
Acinetobacter calcoaceticus-	Legionella pneumophila	Methicillin-resistance
baumannii complex	Mycoplasma pneumoniae	(mecA/mecC and MREJ)
Enterobacter cloacae	Chlamydia pneumonia	
Escherichia coli		<u>ESBL</u>
Haemophilus influenzae	Influenza A	(CTX-M)
Klebsiella aerogenes	Influenza B	
Klebsiella oxytoca	Adenovirus	<u>Carbapenemases</u>
Klebsiella pneumoniae group	Coronavirus	(KPC, NDM, Oxa48-like,
Moraxella catarrhalis	Parainfluenza virus	VIM, IMP)
Proteus spp.	Respiratory Syncytial virus	
Pseudomonas aeruginosa	Human Rhinovirus/Enterovirus	
Serratia marcescens	Human Metapneumovirus	
Staphylococcus aureus		
Streptococcus agalactiae		
Streptococcus pneumoniae		
Streptococcus pyogenes		

<u>Note</u>: The pneumonia panel is only capable of detecting organisms and resistance genes included in the list above. Almost all common HAP pathogens are present, but it won't detect <u>all</u> gram-negative pathogens (eg, *Stenotrophomonas, Morganella*, or *Citrobacter*).

How is it ordered/run?

The test is not ordered. It is run <u>automatically</u> on respiratory samples meeting the following criteria:

- Adult patients in an ICU at Atrium Health Wake Forest Baptist
- Culture obtained by BAL or TA

<u>Note</u>: The pneumonia panel will be performed on the first TA or BAL sample meeting testing criteria and will not be repeated on samples collected in the subsequent 72 hours. <u>All samples will receive standard culture and susceptibility testing as well.</u>

How will results be reported?

Results will appear as part of the respiratory culture report similar to how BCID2 PCR test results appear for blood cultures. The results for each target on the panel will appear a day or two prior to the standard culture results (see attached screen shot). When the organism identification and susceptibilities from the standard culturing processes are available, the culture report will be updated with this new information.

<u>Note</u>: When compared to cultures, the panel is very sensitive; it typically detects the organisms that grow on standard culture. However, because it can identify targets at low levels (including targets from dead organisms), it sometimes will detect organisms that do not grow on standard culture. Possible scenarios that explain positive and negative results:

- Panel reports that no organisms are detected can mean:
 - No organism is present (within detection limit of the test)
 - o An organism not included in the panel is present (eg, S. maltophilia)
- Panel reports an organism (\pm a resistance gene). This can mean:
 - o The organism detected will eventually grow on the culture

- o The organism detected will not grow on culture; possible reasons include:
 - The panel identified target from dead organisms
 - The organism identified is difficult to grow on culture (eg., atypical bacteria)
 - The concentration of organism detected is too low to be significant
 - The patient is receiving current ABX therapy inhibiting cx growth

What decisions can be made based on the panel results?

As with all diagnostic tests, results from the respiratory panel need to be evaluated <u>in view of the patient's unique scenario and clinical condition</u>. Here are possible antimicrobial changes based on panel results that would be reasonable in most situations (assuming patient has pneumonia):

- If only gram-negative organism(s) identified: discontinue anti-MRSA agents
- If *S. aureus* susceptible to oxacillin (no *mecA/C* & MREJ) identified: change to targeted β-lactam therapy
- If only gram-positive organism(s) identified: de-escalate antipseudomonal agents
 - o Consider discontinuing all gram-negative agents
- If both gram-positive and gram-negative organisms identified: tailor coverage as appropriate
- If organism identified is not covered by current therapy: modify therapy to treat pathogen(s)
- If no organisms identified, approach depends on clinical situation. Considerations:
 - Stop all antibiotics (if infection unlikely)
 - o D/C anti-MRSA antibiotics (recommended for almost all situations)
 - Continue current antibiotics (if patient is severely ill and infection is suspected, but source of infection unclear)
 - o Evaluate for another infectious source (if clinical condition indicates infection)

Examples of possible scenarios and <u>potential</u> therapy changes (these examples assume patient has VAP & was started on empiric therapy of vancomycin/cefepime at time of culture; times after culture collection are hypothetical)

	Time after		
Case	culture obtained	Test result	Therapy change
1	8 hours	Panel: Klebsiella oxytoca	D/C vanc; continue cefepime
		detected	
	24 h	GNRs growing from resp cxs	No change
	48 h	Final resp cx: <i>Klebsiella oxytoca</i> ; susceptible to cefazolin	Change cefepime to cefazolin
2	8 h	Panel: S. aureus and MecA/C	Cont vanc; consider D/Cing cefepime
		detected	or de-escalating to ceftriaxone
			(depending on pt condition)
	24 h	Only gram-positive cocci	D/C gram-negative antibiotics if not
		growing on resp cx	done previously
	48 h	Final resp cx: MRSA	Cont vanc or change to PO linezolid
3	8 h	Panel: E. coli & CTX-M detected	D/C vanc; change cefepime to
			meropenem to cover ESBL
	24 h	GNRs growing from resp cxs	No change
	48 h	Final resp cx: ESBL-E. coli	Change meropenem to cipro as
		susceptible to cipro	appropriate
4	8 h	Panel: MRSA & Pseudomonas	No change
		detected	
	24 h	GPC growing on cx	No change
	48 h	Final resp cx: MRSA only	D/C cefepime (PsA likely non-
			significant as no growth on culture)

Whom do I contact for questions about the pneumonia panel?

Microbiology lab (6-2658) or CAUSE secure chat (WFMC CAUSE Antimicrobial Stewardship Approval)

Screen shot of pneumonia panel results

Pneumonia Panel, Qualitative PCR		
tus: Final result Visible to patient: Yes (not seen)		
Result Notes		
Component	Ref Range & Units	
Acinetobacter calcoaceticus -baumannii complex PCR	Not Detected	Not Detected
Adenovirus PCR	Not Detected, Invalid	Not Detected
Chlamydophila pneumoniae PCR	Not Detected	Not Detected
Coronavirus PCR	Not Detected, Invalid	Not Detected
CTX-M Cephalosporin Resistance Gene PCR	Not Detected	Not Detected
Enterobacter cloacae complex PCR	Not Detected	Not Detected
Escherichia coli PCR	Not Detected	Not Detected
Haemophilus influenzae PCR	Not Detected	Detected >=1e7 copies/mL
Human Metapneumovirus PCR	Not Detected, Invalid	Not Detected
Human Rhinovirus/Enterovirus PCR	Not Detected, Invalid	Not Detected
IMP Carbapenem Reistant Gene PCR	Not Detected	Not Detected
Influenza A PCR	Not Detected, Invalid	Not Detected
Influenza B PCR	Not Detected	Not Detected
Klebsiella aerogenes PCR	Not Detected	Detected 1e4 copies/mL !
Klebsiella oxytoca PCR	Not Detected	Not Detected
Klebsiella pneumoniae Group PCR	Not Detected	Not Detected
KPC Carbapenem Resistant Gene PCR	Not Detected	Not Detected
Legionella Pneumophila PCR	Not Detected	Not Detected
Moraxella Catarrhalis PCR	Not Detected	Not Detected
Mycoplasma pneumoniae PCR	Not Detected	Not Detected
NDM Carbapenem Resistant Gene PCR	Not Detected	Not Detected
OXA-48-Like Carbapenem Resistant Gene PCR	Not Detected	Not Detected
Parainfluenza Virus PCR	Not Detected	Not Detected
Proteus species PCR	Not Detected	Not Detected
Pseudomonas aeruginosa PCR	Not Detected	Not Detected
Respiratory Syncytial Virus PCR	Not Detected, Invalid, Negative	Not Detected
Serratia marcescens PCR	Not Detected	Not Detected
Staphylococcus aureus PCR	Not Detected	Not Detected
Streptococcus agalactiae PCR	Not Detected	Not Detected

(Results for the remaining organisms and resistance genes on the panel would be similarly listed, followed by the narrative comment below. Results for "typical" bacteria include a semi-quantitative result when detected; atypical bacteria, viruses, and resistance genes only report if the target was detected or not.)

Narrative

CLINICAL INTERPRETATION: Detection of bacterial nucleic acid may be indicative of colonization or presence of normal respiratory flora and may not indicate the causative agent of pneumonia. Similarly detection of viral INA may be indicative of persistence of DNA from a previous viral infection and may not indicate the causative agent of pneumonia. Clinical correlation is recommended. Semi-quantitative (copies/mL) results generated by the FilmArray Pneumonia Famel are not equivalent to CFU/mL and may not consistently correlate with the quantity of bacteria reported by the respiratory culture. Clinical correlation is advised to determine significance of semi-quantitative results (copies/mL) for clinical management.

METHODOLOGY: The FilmArray® Pneumonia Panel is a multiplexed nucleic acid test for the simultaneous detection and identification of multiple viral and bacterial pathogens, as well as select antimicrobial resistance genes.

COMMENT: The Pneumonia Panel test is performed by the laboratory on quantitative respiratory cultures obtained by BAL or tracheal aspiration from adult ICU patients at Atrium Health Wake Forest Baptist. Repeat testing will not be performed within 3 days of previous panel results.

The coronavirus detected by this assay will not detect Sars-CoV-2 (Covid-19).

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This test has been approved by the U.S. Food and Drug Administration for bronchoalveolar lavage and tracheal aspirate specimens