Evaluation of the BioFire® Pneumonia Panel *plus* on low respiratory paired samples shows ETA as equally useful as BAL

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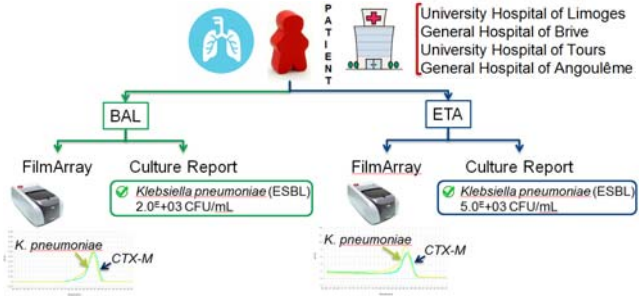
ECCMID 2018 • Madrid APRIL 21 - 24

BACKGROUND

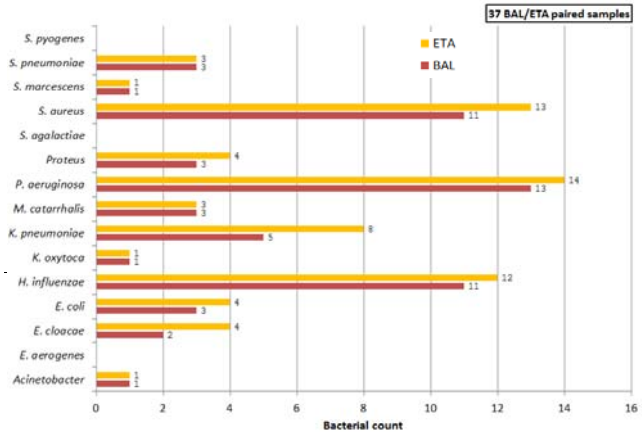
Lower Respiratory Tract Infections (LRTIs) such as pneumonia are a major global health burden. Rapid pathogen identification is critical for determining appropriate therapy. Culture of respiratory tract specimens, including broncho-alveolar lavage (BAL), sputum and endotracheal aspirates (ETA) is a time-consuming technique often associated with poor sensitivity. The BioFire® Pneumonia Panel *plus* allows rapid identification of the main bacterial and viral agents with determination of approximate DNA amount for common bacteria, as well as detection of several antibiotic resistance markers (ARM) from BAL, ETA and sputum. In this study we evaluated the diagnostic value of ETA specimens by using the BioFire® Pneumonia Panel *plus* detection profile in paired ETA - BAL samples.

MATERIAL/METHODS

An IUO version of the BioFire® Pneumonia Panel *plus* was tested using 37 paired BAL and ETA samples collected from patients suspected of ventilator-associated pneumonia at four different French hospitals. Samples were residual and stored at -80°C before testing. FilmArray results (organisms and bacteria quantity) were individually compared to standard microbiologic reports.

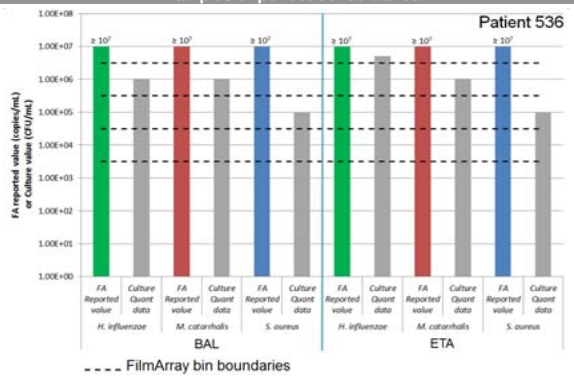


TOTAL FILMARRAY DETECTION OF BACTERIAL PATHOGENS IN 37 BAL/ETA SAMPLES
Highlighting similarity between BAL and ETA profile

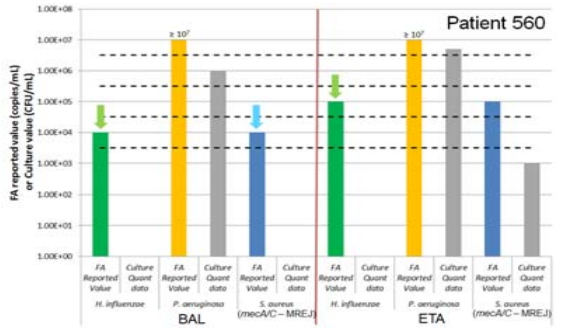


COMPARISON OF BAL AND ETA PROFILES

Examples of perfect concordance

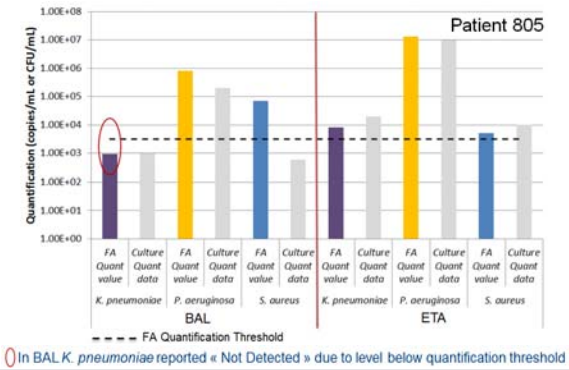


Plural Detections by FilmArray



H. influenzae detected by an independent molecular assay at 9.2E+02 CFU/mL in BAL and at 6.1E+04 CFU/mL in ETA; *S. aureus* detected at 7.0E+02 CFU/mL in BAL.

Additional Detection by Culture



In BAL *K. pneumoniae* reported « Not Detected » due to level below quantification threshold

CONCORDANCE ANALYSIS BETWEEN BAL AND ETA DETECTION PROFILES (Culture versus FilmArray)

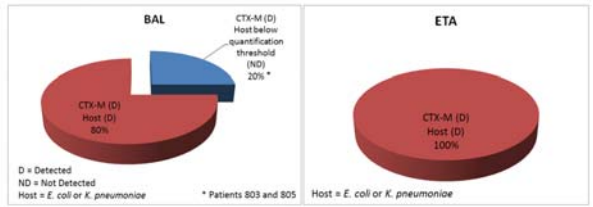
Culture		ETA ND	ETA D	Overall % agreement
BAL	ND	4	5	89
	D	2	53	

FilmArray		ETA ND	ETA D	Overall % agreement
BAL	ND	4	10	84
	D	2	57	

D=Detected; ND=Not Detected

DETECTION OF ESBL RESISTANCE

Detection of ESBL resistance linked to the presence of the CTX-M β-lactamase gene: 100% detection by FilmArray (8 CTX-M FA detections out of 8 ESBL positive specimens)



EXAMPLE OF MRSA DETECTION

Patient	Sample type	FA report: *mecA/C* - MREJ	FA report: *S. aureus* (copies/mL)	Clinical report (Culture): *S. aureus* D/ND (CFU/mL)	Clinical report (Culture): Phenotypic Abx Resistance Profile
560	BAL	D [a]	D (1.24E+04)[b]	ND	N/A
	ETA	D [a]	D (1.14E+05)	D (1.0E+03)	Sensitive to Penicillin
805	BAL	D	D (7.16E+04)	D (6.0E+02)	Resistant to Penicillin
	ETA	D	D (5.12E+03)	D (1.0E+04)	Resistant to Penicillin

D=Detected; ND=Not Detected; N/A=Not Applicable; Abx=Antibiotics
[a] MecA/C confirmed by an independent molecular assay (although with late Cp)
[b] Confirmed by an independent molecular assay (*S. aureus* detected at 7.0E+02 CFU/mL)

POSITIVE PREDICTED VALUE

	FA versus Culture		After investigation [a]	
	BAL	ETA	BAL	ETA
PPV	>80%	>79%	100%	>92%
Combined PPV	>80%		96%	

[a] After comparison with an independent molecular method

CONCLUSION

Our results showed good correlation with current standard diagnostic methods and highlight the ability of the BioFire® Pneumonia Panel *plus* to accurately identify bacterial pathogens from LRT specimens. ETA appears equally useful as BAL for the diagnosis of pneumonia.

The BioFire® Pneumonia Panel plus has not been evaluated by FDA or other regulatory agencies for In Vitro *Diagnostic use.*