The BioFire® Diagnostics FilmArray® Pneumonia Panel

ICD-10 Coordination and Maintenance Committee Meeting

March 17th, 2020

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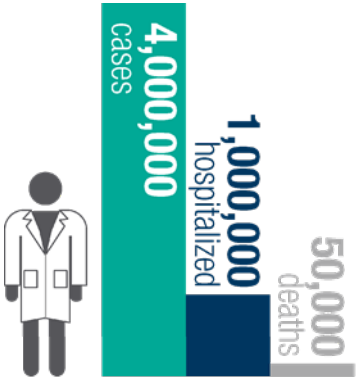
BFDX-MKT-0291-02

Clinical and Economic Burden of Pneumonia



Clinical Burden[1,2]

Economic Burden[3,4]

Rapid and empiric therapy is recommended

- In the ED — CAP guidelines[5]
- In the ICU — VAP guidelines[6]
- Pneumonia is a leading cause of sepsis, where guidelines require antibiotics within one hour[7,8]

Delayed antibiotics has been shown to cause poor outcomes in cases of systemic infections[9]

1. Cleveland Clinic: Center for Continuing Education [internet]. Lundhurst, OH: Cleveland Clinic c2000-2017. Community-Acquired pneumonia; 2010 August [cited 2017 Aug 8]; [about 12 screens] Available from: http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/infectious-disease/communityacquired-pneumonia/#bib2
2. CDC 24/7: Saving Lives, Protecting People [internet]. Atlanta: Centers For Disease Control and Prevention; National Center for Health Statistics, Pneumonia; 2017 January 20 [cited 2017 Aug 8]; [about 3 screens] Available from: https://www.cdc.gov/nchs/fastats/pneumonia.htm
3. Pfuntner A, Wier LM, Steiner C. Costs for Hospital Stays in the United States, 2010. HCUP Statistical Brief #146. January 2013. Agency for Healthcare Research and Quality, Rockville, MD.
4. Broulette J, Yu H, Pyenson B, Iwasaki K, Sato R. The Incidence Rate and Economic Burden of Community-Acquired Pneumonia in a Working-Age Population. American Health & Drug Benefits. 2013;6(8):494-503
5. Metlay JP. Diagnosis and Treatment of Adults with Community-acquired Pneumonia. An Official Clinical Practice Guideline of the American Thoracic Society and Infectious Diseases Society of America. Am J Respir Crit Care Med Vol 200, Iss 7, pp e45–e67, Oct 1, 2019
6. Kalil, AC et al. Management of Adults With Hospital-acquired and Ventilator-associated Pneumonia: 2016 Clinical Practice Guidelines by the Infectious Diseases Society of America and the American Thoracic Society. Clin Infect Dis. 2016 Sep 1;63(5):e61-e111
7. Mayr FB, Yende S, Angus DC. Epidemiology of severe sepsis. Virulence. 2013;5(1):4-11.
8. Rhodes, A et al. Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2016 Intensive Care Med. 2017 Mar;43(3):304-377. doi: 10.1007/s00134-017-4683-6.
9. Kumar et al. Duration of hypotension before initiation of effective antimicrobial therapy is the critical determinant of survival in human septic shock. Critical Care Med, 34: 1589-1596, 2006.

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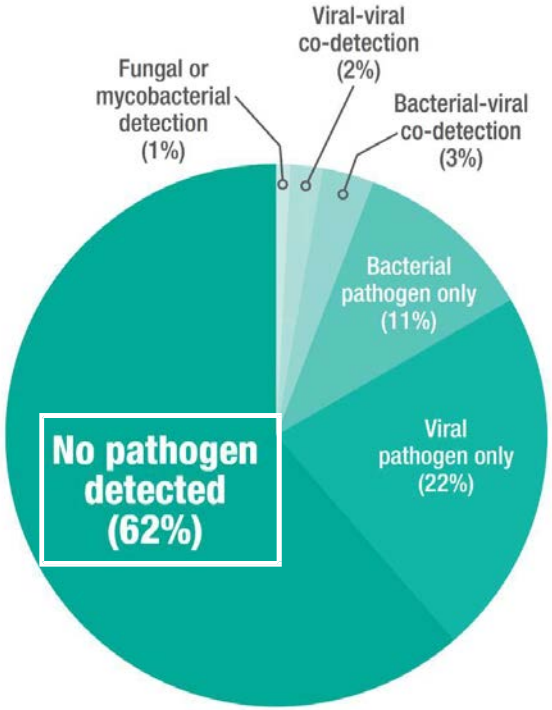
No Specific Diagnosis for the Majority of CAP Patients

Jain S, et al. Community-Acquired Pneumonia Requiring Hospitalization among U.S. Adults. New England Journal of Medicine.

- CDC-funded study on the etiology of pneumonia, using culture for bacterial ID
- 2,488 pneumonia patients enrolled
- Identified a pathogen in only 38% of patients
- Only 14% had bacteria identified



Quote from the authors:

"The low pathogen-detection yield among adults who were hospitalized for pneumonia highlights the need for more sensitive diagnostic methods and innovative discovery of pathogens."

1) Jain S, Self WH, Wunderink RG, et al. Community-Acquired Pneumonia Requiring Hospitalization among U.S. Adults. The New England journal of Medicine. 2015;373(5):415-427. doi:10.1056/NEJMoa1500245

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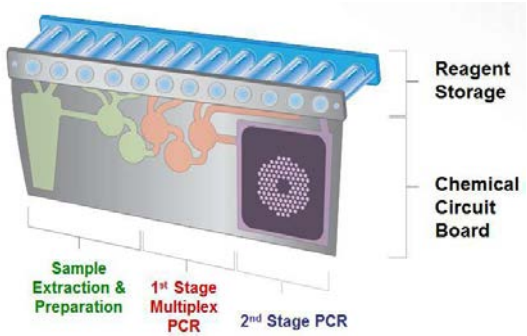
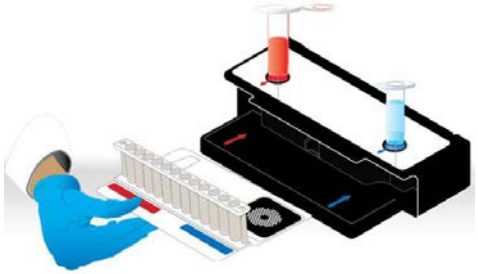
The BioFire® FilmArray® Systems

Highly multiplex nested PCR reaction

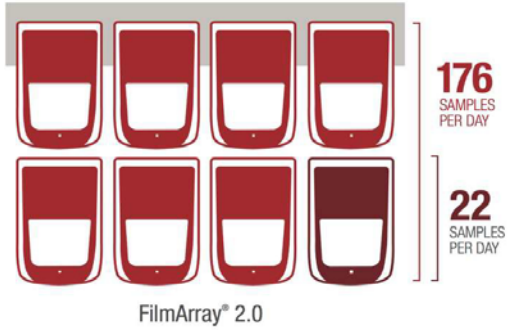


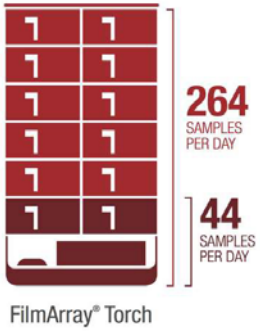
Self contained pouch



Set up: 2 mins hands on time

Random access: Results in ~ 1 hr





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Unique Features* of the Pneumonia Panel

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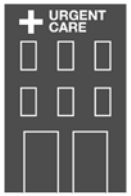
Approved for All Ages

Approved across multiple settings

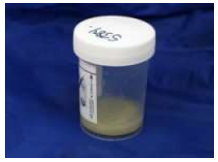


Outpatients

Emergency Departments

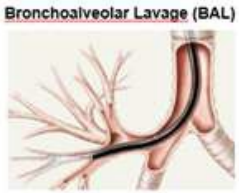
Hospitalized Patients

Multiple sample types



Sputum-like

BAL-like



Refer to Instructions for Use: RFIT-PRT-0575-01 November 2018

* Only FDA cleared assay with these features

Broad Scope of Pathogen Classes and Resistance Markers

Bacteria

Semi-Quantitative

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 pyogenes

Atypical Bacteria

Chlamydia pneumoniae
Legionella pneumophila Mycoplasma pneumoniae

Viruses

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

Antimicrobial Resistance Gene

METHICILLIN RESISTANCE
mec A/C and MREJ

CARBAPENEMASES
KPC NDM
Oxa-48-like VIM
IMP

ESBL

CTX-M

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Overall Assay Performance

Composite Results	PPA (Sensitivity)	NPA (Specificity)
BAL Overall	96.2%	98.3%
Sputum Overall	96.3%	97.2%

Results compared to culture and independent PCR assays direct from clinical specimen

Results	PPA (Sensitivity)	Range	NPA (Specificity)	Range
Resistance Markers	96.2%	80.0-100%	98.3%	87.5%-100%
Viral Detections	96.3%	76.4%-100%	97.2%	98.2%-100%

Results compared to independent PCR assays direct from clinical specimen

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The BioFire® Pneumonia Panel Clinical Improvement

BIOMÉRIEUX

FilmArray®

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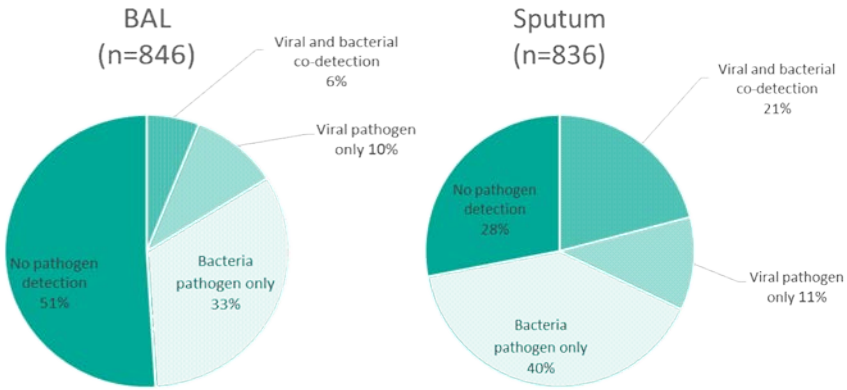
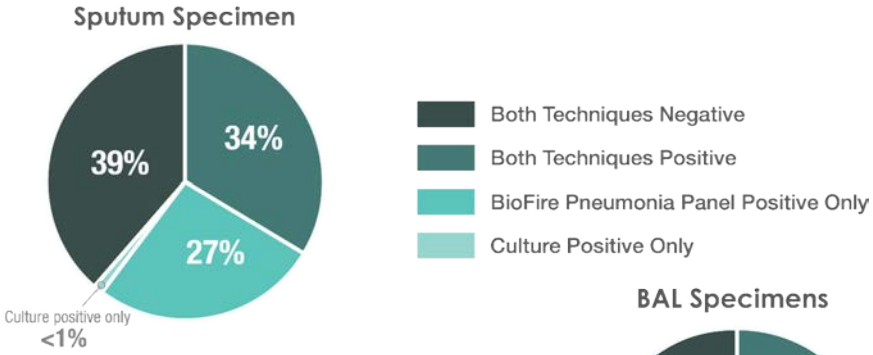
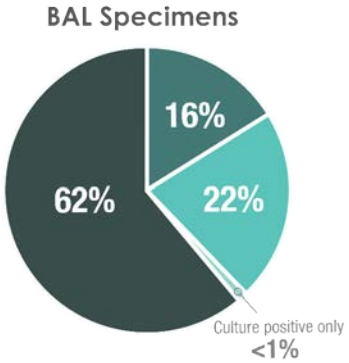
More Potential Pathogens Identified

- 8 Center US clinical study for FDA clearance: compared to SOC, quantitative culture, NGS, sequencing
- The BioFire® Pneumonia Panel identified a potential pathogen in 48.8% of BAL samples and 72% of sputum samples <u>and significantly more than culture</u>





Of the 875 "PCR-positive culture-negative" specimens in the clinical study, 871 were resolved upon further investigation with independent molecular comparator methods[1]



Very high positive and negative predictive value

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More Potential Pathogens Identified: Impact on Clinical Care

- A study of 120 patients compared routine methods to molecular methods.[1]
- BioFire Pneumonia Panel detected pathogens in 66.7% of patients compared to 41.7% by routine methods
- 27% of patients had negative outcomes (unresolved by 21 days or pneumonia was considered cause of death)
  - 15.6% of these patients had organism resistant to initial therapy based on routine method results.
  - This increased to 41.9% when considering BioFire Results (p=0.029)
  - BioFire Pneumonia panel attributed significantly more patients to active therapy group than routine methods (p=0.005)

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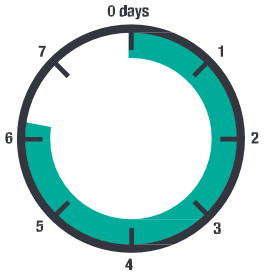
1. Enne, V.I et al. INHALE WP2: Appropriateness of Antimicrobial Prescribing for Hospital-acquired and Ventilator-associated Pneumonia (HAP/VAP) in UK ICUs assessed against PCR-based Molecular

The Potential for De-escalation

A study of 259 BAL specimens run on the BioFire® Pneumonia Panel assessed hypothetical changes to antimicrobial therapy.[1]

- Up to 50% of patients could have been de-escalated.
- The BioFire Pneumonia Panel could have saved over 18,000 hours of antibiotic use.
- Antibiotics could have been removed 3-4 days earlier, including 62 courses of vancomycin

Appropriate Antimicrobial Stewardship.



Antibiotic use could have been reduced by an average of **6.2** days per patient.

Data from IUO panel. The performance characteristics of this product have not been established.

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1. Buchan B.W. et al. Clinical Evaluation and Potential Impact of a Semi-Quantitative Multiplex Molecular Assay for the Identification of Pathogenic Bacteria and Viruses in Lower Respiratory Specimens. American

Summary of BioFire® Pneumonia Panel

- BioFire Pneumonia Panel Solution:
  - FDA cleared molecular method for testing both sputum and bronchoalveolar lavage (BAL) samples from CAP, HCAP and VAP patients allowing directed treatment decisions to be made in hours rather than days.
  - FDA approved for use across all ages and all healthcare settings
  - FDA approved for the semi-quantitative detection of 15 bacterial pathogens
  - FDA cleared panel that detects bacteria, atypical bacteria, viruses and resistance markers

- BioFire Pneumonia Pivotal Trial Data:
  - High sensitivity and specificity of semi-quantitative and qualitative test results

- BioFire Pneumonia Panel Clinical Improvement:
  - Faster time to organism ID and preliminary resistance profile
  - Increased diagnostic yield
  - Faster time to optimal therapy
  - Improved antibiotic stewardship

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Common Coding Questions for BioFire Pneumonia Panel

- Where in the medical record should coders look to find evidence of the use of BioFire Pneumonia Panel
  - The medical record will show use of the BioFire Pneumonia Panel under laboratory tests.
  - Other locations in the medical record might include: 1) Progress notes; 2)Admission notes; or 3) Pneumonia care bundle
- Common terms used to describe the use of the BioFire Pneumonia Panel
  - BioFire Pneumonia Panel, BioFire PN, BioFire PP
  - NOT: BioFire RP panel, BioFire Viral panel

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A Unique Code for the BioFire Pneumonia Panel should be included in the ICD-10-PCS

- BioFire Pneumonia Panel provides comprehensive results in a clinical relevant time frame allowing for improved therapeutic decision making.
- BioFire Diagnostics received 510(k) clearance for the BioFire Pneumonia Panel on November 9th, 2019
- Current codes do not describe the collection and testing of lower respiratory specimens for bacterial, viral, and Abx susceptibility targets
- Unique codes accurately identifying the BioFire Pneumonia panel in the ICD-10-PCS will facilitate capturing information in patient record.

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Thank You

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