



## bioMérieux launches the BIOFIRE® FILMARRAY® Pneumonia Panels with FDA clearance and CE Marking

**Marcy l'Étoile, France – November 13, 2018** – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announced the Food and Drug Administration (FDA) 510(k) clearance of the BIOFIRE® FILMARRAY® Pneumonia Panel and the CE-Mark of the BIOFIRE® FILMARRAY® Pneumonia Panel *plus*. The BIOFIRE® FILMARRAY® Pneumonia Panels aid in the diagnosis of lower respiratory tract infections.

bioMérieux's molecular biology affiliate, BioFire Diagnostics, builds upon its 25 years of molecular diagnostics expertise with the development of its most advanced panels to date, the BIOFIRE® FILMARRAY® Pneumonia Panels. The BIOFIRE® FILMARRAY® Pneumonia Panel identifies 33 targets in sputum (including endotracheal aspirate) and bronchoalveolar lavage (including mini-BAL) sample types. The target list includes: 18 bacteria, 8 viruses and 7 antimicrobial resistance genes. The BIOFIRE® FILMARRAY® Pneumonia Panel *plus* includes the same targets with the addition of the MERS-CoV emergent virus.

These two innovative panels report results in semi-quantitative levels for 15 bacteria which may help clinicians to differentiate colonization from true invasive infection. It is the first time the BIOFIRE® FILMARRAY® System has utilized its real-time PCR quantification capabilities, and the first time the FDA has cleared a semi-quantitative multiplex panel.

BIOFIRE® tests enable a molecular syndromic approach – simultaneously testing for the most likely organisms that cause a similar set of signs and symptoms. The BIOFIRE® Pneumonia Panels bring fast, accurate, and comprehensive syndromic testing to lower respiratory tract infections and complement the existing portfolio of BIOFIRE® FILMARRAY® Respiratory Panels to offer a comprehensive diagnostic solution for respiratory infections. Results for the Pneumonia Panels are available in approximately 1 hour in the totally automated BIOFIRE® FILMARRAY® system, with only a few minutes of hands-on time.

Blake Buchan, PhD, Associate Director Clinical Microbiology at the Medical College of Wisconsin, was a principal investigator on the BIOFIRE® Pneumonia Panel clinical study. Dr. Buchan said: *“Pneumonia patients are often treated empirically with broad spectrum antibiotic therapy. Syndromic molecular panels can identify pathogens in lower respiratory tract infections quickly and reliably. These tools will empower stewardship efforts and help patients avoid unnecessary antibiotics. In our research with the syndromic panel, we found that up to ~60%<sup>1</sup> of patients could have had their empiric therapy altered by the result.”*

Randy Rasmussen, CEO of BioFire Diagnostics and Executive VP Molecular Biology of bioMérieux, said: *“Pneumonia is one of the most common reasons patients go to the hospital, yet the underlying cause of the infection is frequently not identified. This leads to over-treatment of the patient and overuse of antibiotics. This new panel illustrates our commitment to serve public health allowing targeted, effective treatment of a patient's pneumonia.”*

The BIOFIRE® Pneumonia Panels are compatible with all existing BIOFIRE® FILMARRAY® Instruments including the BIOFIRE® FILMARRAY®, BIOFIRE® FILMARRAY® 2.0, and BIOFIRE® FILMARRAY® Torch Systems. bioMérieux plans to make its BIOFIRE® Pneumonia Panel commercially available in the U.S. and E.U. next month.



## ABOUT THE BIOFIRE® FILMARRAY® RANGE

The BIOFIRE® FILMARRAY® System is an FDA-cleared and CE-marked multiplex PCR system that integrates sample preparation, amplification, and detection into one closed system. The BIOFIRE® FILMARRAY® System requires only two minutes of hands-on time and has a total run time of about 45 to 75 minutes, depending on the panel. The BIOFIRE® FILMARRAY® System has the largest infectious disease pathogen menu commercially available composed of:

- BIOFIRE® FILMARRAY® **Pneumonia Panel**, a comprehensive panel of 33 respiratory viruses, bacteria, and antimicrobial resistance genes performed directly on sputum, endotracheal aspirate, or bronchoalveolar lavage (including mini-BAL).
- BIOFIRE® FILMARRAY® **Pneumonia Panel plus**, a comprehensive panel of 34 respiratory viruses, bacteria, and antimicrobial resistance genes performed directly on sputum, endotracheal aspirate, or bronchoalveolar lavage (including mini-BAL).
- BIOFIRE® FILMARRAY® **Respiratory Panel**, a comprehensive panel of 20 respiratory viruses and bacteria performed directly on nasopharyngeal swabs in viral transport media.
- BIOFIRE® FILMARRAY® **Respiratory Panel 2** (RP2), a comprehensive panel of 21 respiratory viruses and bacteria performed directly on nasopharyngeal swabs in transport media.
- BIOFIRE® FILMARRAY® **Respiratory Panel 2 plus** (RP2plus), a comprehensive panel of 22 respiratory viruses and bacteria performed directly on nasopharyngeal swabs in transport media.
- BIOFIRE® FILMARRAY® **RP EZ** for the detection of 11 viral and 3 bacterial pathogens associated with respiratory infections. FDA cleared and CLIA-waived for use in the US only.
- BIOFIRE® FILMARRAY® **Blood Culture Identification** (BCID) Panel, capable of identifying 27 of the most common causes of bloodstream infections and associated antimicrobial resistances directly from positive blood culture.
- BIOFIRE® FILMARRAY® **Gastrointestinal** (GI) Panel, for identification of 22 of the most common viral, bacterial, and parasitic causes of infectious diarrhea directly from stool in Cary Blair transport media.
- BIOFIRE® FILMARRAY® **Meningitis/Encephalitis** (ME) Panel, identifying 14 bacterial, viral, and fungal causes of meningitis and encephalitis directly from cerebrospinal fluid.

As of September 30, 2018, the number of BIOFIRE® FILMARRAY® Systems installed globally reached about 7,600 units.

## ABOUT BIOMÉRIEUX

### *Pioneering Diagnostics*

A world leader in the field of *in vitro* diagnostics for more than 50 years, bioMérieux is present in more than 150 countries through 43 subsidiaries and a large network of distributors. In 2017, revenues reached €2.3 billion, with over 90% of international sales.

bioMérieux provides diagnostic solutions (systems, reagents, software) which determine the source of disease and contamination to improve patient health and ensure consumer safety. Its products are mainly used for diagnosing infectious diseases. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products.

 bioMérieux is listed on the Euronext Paris stock market  
Symbol: BIM - ISIN Code: FR0013280286  
Reuters: BIOX.PA/Bloomberg: BIM.FP

Corporate website: [www.biomerieux.com](http://www.biomerieux.com). Investor website: [www.biomerieux-finance.com](http://www.biomerieux-finance.com).

## CONTACTS

### **Investor Relations**

#### **bioMérieux**

Sylvain Morgeau

Tel.: + 33 4 78 87 22 37

[investor.relations@biomerieux.com](mailto:investor.relations@biomerieux.com)

### **Media Relations**

#### **bioMérieux**

Aurore Sergeant

Tel.: + 33 4 78 87 20 53

[media@biomerieux.com](mailto:media@biomerieux.com)

#### **Image Sept**

Laurence Heilbronn

Tel.: + 33 1 53 70 74 64

[lheilbronn@image7.fr](mailto:lheilbronn@image7.fr)

Claire Doligez

Tel.: + 33 1 53 70 74 48

[cdoligez@image7.fr](mailto:cdoligez@image7.fr)

### **BioFire Diagnostics, LLC**

Wade Stevenson

Tel.: +1 801-736-6354 x1463

[wade.stevenson@biofiredx.com](mailto:wade.stevenson@biofiredx.com)

<sup>i</sup> 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 Thoracic Society Conference, May 20<sup>th</sup> 2018 San Diego CA