



bioMérieux submits enhanced BIOFIRE® BCID2 Panel for FDA clearance

Marcy l'Étoile, France - January 14, 2020 – bioMérieux, a world leader in the field of *in vitro* diagnostics, announces that BioFire Diagnostics, its molecular biology affiliate, has submitted to the Food and Drug Administration for 510(k) clearance of the BIOFIRE® Blood Culture Identification 2 (BCID2) Panel. The BIOFIRE® BCID2 Panel includes several additional pathogens, an expanded list of antimicrobial resistance genes, and many revised targets compared to the existing BIOFIRE® BCID Panel.

Randy Rasmussen, CEO of BioFire Diagnostics and Executive VP Molecular Biology of bioMérieux said: *“Rapid identification of bloodstream infections and detection of antimicrobial resistance genes are more important than ever for hospitals and their patients. Our expanded panel and syndromic approach means that a single, comprehensive test will allow for the detection of the most common clinically relevant pathogens and their resistance profile, enabling more targeted, effective treatment.”*

The existing BIOFIRE® BCID Panel, available since 2013, along with BIOFIRE®'s portfolio of syndromic tests, have changed lab workflow and patient management across multiple disease states. The new generation of the BIOFIRE® BCID Panel includes 26 bacteria, 7 yeasts, and 10 antimicrobial resistance genes. These comprise emerging pathogens, such as *Candida auris*, as well as new targets to more accurately identify methicillin-resistant *Staphylococcus aureus* (MRSA) and other resistant organisms. The improved breadth and performance of BCID2 panel aims at reinforcing BIOFIRE®'s leadership in the diagnosis of bloodstream infections.

The BIOFIRE® BCID2 Panel is compatible with the FILMARRAY® 2.0 and FILMARRAY® TORCH systems. bioMérieux plans on pursuing BIOFIRE® BCID2 Panel registration in other parts of the world as well.

About the BIOFIRE® FILMARRAY® PLATFORM:

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. A BIOFIRE® FILMARRAY® test 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® range has the largest infectious disease pathogen menu commercially available, composed of:

- BIOFIRE® Respiratory Panel (RP, RP2 and RP2*plus*), identifying between 20 and 22 respiratory viruses and bacteria performed directly on nasopharyngeal swabs in transport media.
- BIOFIRE® RP EZ, identifying 11 viral and 3 bacterial pathogens associated with respiratory infections. FDA-cleared and CLIA-waived for use in the US only.
- BIOFIRE® Pneumonia (PN) and Pneumonia *plus* (PN*plus*) Panel, identifying 33 to 34 targets (18 bacteria, 8 to 9 viruses, 7 resistant genes to antibiotics) in sputum (including endotracheal aspirate) and bronchoalveolar lavage (including mini-BAL). 15 of the bacterial targets are reported with semi-quantitative information about the abundance of organism in a given sample.



- BIOFIRE® Blood Culture Identification (BCID) Panel, identifying 27 of the most common causes of bloodstream infections and associated antimicrobial resistances directly from positive blood culture.
- BIOFIRE® Gastrointestinal (GI) Panel, identifying 22 of the most common viral, bacterial, and parasitic causes of infectious diarrhea directly from stool in Cary Blair transport media.
- BIOFIRE® Meningitis/Encephalitis (ME) Panel, identifying 14 bacterial, viral, and fungal causes of meningitis and encephalitis directly from cerebrospinal fluid.

As of September 30, 2019, the number of BIOFIRE® FILMARRAY® systems installed globally reached about 9,800.

ABOUT BIOMÉRIEUX

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics for over 55 years, bioMérieux is present in 43 countries and serves more than 160 countries with the support of a large network of distributors. In 2018, revenues reached €2.4 billion, with over 90% of international sales.

bioMérieux provides diagnostic solutions (systems, reagents, software and services) 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. Investor website: www.biomerieux-finance.com

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