bioMérieux receives *De Novo* FDA Authorization for its BIOFIRE® Joint Infection (JI) Panel

Marcy l'Étoile, France - May 4, 2022 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announces that its BIOFIRE® Joint Infection (JI) Panel has received *De Novo* authorization from the US Food and Drug Administration (FDA). This panel tests for 31 pathogens implicated in most acute joint infections, and also includes 8 antimicrobial resistance (AMR) genes to optimize antibiotic therapy and stewardship.

Joint infections ("septic arthritis") are serious infections involving either native or prosthetic joints. They are medical emergencies which can occur at all ages, and can lead to functional joint impairment, long-lasting disability, and may even be life-threatening. The number of prosthetic joint infections is rising globally as the number of joint replacements increases.

Optimal treatment of joint infections depends on a rapid and accurate diagnosis. However, the diagnosis of joint infections remains challenging as the available diagnostic methods have variable accuracy, may have long turnaround times, and are often negatively impacted by prior antimicrobial therapy.

The BIOFIRE® Joint Infection Panel is the newest syndromic panel intended to aid in the diagnosis of the specific agents causing joint infections.

The BIOFIRE® JI Panel allows healthcare providers to quickly identify pathogens commonly found in patients presenting with suspected joint infections, along with AMR genes to optimally guide antibiotic therapy, all in one simple rapid test.

With a rapid turnaround time of about 1 hour and a broad panel menu of 39 targets, the BIOFIRE® JI Panel addresses unmet needs in joint infection diagnostics. Through fast and accurate results, the BIOFIRE® JI Panel may provide more informed decision-making for pathogen-guided management of patients with joint infections. It may also help guide surgical and antibiotic decision-making, thus aiding in Antimicrobial Stewardship (AMS).

The BIOFIRE® JI Panel provides results using synovial fluid samples obtained directly from the affected joint. It runs on the fully automated BIOFIRE® FILMARRAY® 2.0 and BIOFIRE® Torch Systems with only 2 minutes of sample preparation time.

bioMérieux is targeting a commercial launch in the US within the next two months, and then the BIOFIRE® JI Panel will be gradually registered and deployed in other countries, including those that recognize FDA authorization. It will be submitted for CE-marking under the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) in the coming weeks.

Pierre Boulud, Chief Operating Officer, Clinical Operations, said: "*The BIOFIRE® Joint Infection Panel expands bioMerieux's syndromic offering to a new disease state in addition to the 5 other syndromes covered by the BIOFIRE® menu, making it the broadest menu of highly multiplex syndromic panels in existence and available to the labs today.*

PRESS RELEASE

Thanks to this panel, we address an important diagnostic need to help Emergency Department and Infectious Disease physicians, pediatricians, and also orthopedic surgeons faced with these important joint infections. This De Novo *authorization demonstrates bioMerieux's continued innovative leadership in molecular syndromic testing and our commitment to addressing vital needs in infectious disease diagnostics."*

Mark Miller, Chief Medical Officer, stated: *"The BIOFIRE® Joint Infection Panel should provide clinicians with a faster and more accurate diagnosis, thus potentially reducing the delay to initiate appropriate antimicrobial therapy, speeding up surgical decision-making, and improving overall management to benefit patients and improve outcomes."*

ABOUT BIOFIRE® FILMARRAY®

The BIOFIRE® solution is a U.S. FDA-cleared and CE-marked closed multiplex PCR and fully-automated system that integrates sample preparation, amplification, and detection. A BIOFIRE® test requires only two minutes of hands-on time and has a total run time in as little as 45 minutes, depending on the panel.
The BIOFIRE® range has the largest infectious disease pathogen menu commercially available. It is composed panels covering 6 syndromes, whose availability varies by country:

- BIOFIRE® Respiratory Panels (RP, RP2, RP2*plus*, RP2.1, and RP2.1*plus*), identifying between 20 and 23 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*) Panels, identifying 33 to 34 targets (18 bacteria, 8 to 9 viruses, 7 resistance 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 organisms in a given sample.
- BIOFIRE® Blood Culture Identification 2 (BCID2), identifying 43 of the most common causes of bloodstream infections and associated antimicrobial resistance 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.
- BIOFIRE® Joint Infection (JI) Panel, identifying 31 common causes of joint infections and 8 antimicrobial resistance genes directly from synovial fluid.

As of March 31st, 2022, the number of BIOFIRE® FILMARRAY® Systems installed globally reached more than 22,500 units.

ABOUT BIOMÉRIEUX

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics since 1963, bioMérieux is present in 44 countries and serves more than 160 countries with the support of a large network of distributors. In 2021, revenues reached €3.4 billion, with over 90% of sales outside of France.

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.
www.biomerieux.com.

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

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