BIOFIRE® Respiratory Panel 2.1 (RP2.1) with SARS-CoV-2 obtains FDA Emergency Use Authorization

Marcy l'Étoile (France) - May 4, 2020 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announced that BioFire Diagnostics, its subsidiary specialized in syndromic infectious disease testing, has received Emergency Use Authorization by the U.S. Food and Drug Administration for the BIOFIRE® RP2.1 panel, which includes 22 pathogens that cause respiratory infections, including SARS-CoV-2 (the cause of COVID-19 disease).

The inclusion of SARS-CoV-2 in the BIOFIRE® RP2.1 panel allows healthcare providers to quickly identify patients with common respiratory pathogens, as well as those with COVID-19, using one simple test. The BIOFIRE® RP2.1 panel takes approximately 45 minutes and tests nasopharyngeal swab samples in transport media. It runs on the fully automated FILMARRAY® 2.0 and FILMARRAY® TORCH systems and is extremely easy to use.

bioMérieux is currently making every effort to scale up supply of the BIOFIRE® RP2.1 panel at its production facilities in Salt Lake City (Utah, USA). Test kits will be available for commercial distribution in the USA under EUA as well as internationally where regulatory approval allows. In a context of high demand for COVID-19 testing, bioMérieux expects to steadily build inventory levels to address the needs of the thousands of labs and healthcare professionals using one of the nearly 12,000 FILMARRAY® systems worldwide.

Andrea Kendell, *ad interim* CEO at BioFire Diagnostics said: "*The BIOFIRE® RP2.1 panel represents our syndromic solution to this unprecedented COVID-19 pandemic. BioFire is dedicated to responding to a rapidly-evolving global epidemiological landscape with urgency and accuracy and this illustrates our contribution to bioMérieux's public health mission. We believe the syndromic BIOFIRE® RP2.1 panel will play a key role now and in the upcoming respiratory season as healthcare providers and patients will likely face the regular group of respiratory pathogens as well as SARS-CoV-2*". Kendell further highlighted the need for BioFire's syndromic approach by pointing out that emerging data suggest patients with COVID-19 may frequently be co-infected with other viruses and/or bacteria.

bioMérieux plans to submit the BIOFIRE® RP2.1 panel for FDA *de novo* clearance. Outside of the USA, bioMérieux is simultaneously pursuing CE Mark certification for the BIOFIRE® Respiratory 2.1*plus* (RP2.1*plus*) panel, which also includes detection of MERS-CoV, on an accelerated timeline.

The BIOFIRE® RP2.1 test is the third molecular test from bioMérieux in response to the COVID-19 pandemic. The ARGENE® SARS-CoV-2 R-GENE® test and the BIOFIRE® COVID-19 test were launched in March. These three complementary tests help meet the varying needs of bioMérieux diverse customers and patients throughout the world.

PRESS RELEASE

About Emergency Use Authorization

The BIOFIRE® RP2.1 test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories only for the detection and differentiation of nucleic acid of SARS-CoV-2 from multiple respiratory viral and bacterial organisms.

This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

About the BIOFIRE® FILMARRAY® solution

The BIOFIRE® FILMARRAY® is an FDA-cleared and CE-marked multiplex PCR closed and fully-automated system that integrates sample preparation, amplification, and detection. 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*) Panels, 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 organisms in a given sample.
- BIOFIRE® Blood Culture Identification 2 (BCID2), identifying 43 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.

ABOUT BIOMÉRIEUX

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics for over 55 years, bioMérieux is present in 44 countries and serves more than 160 countries with the support of a large network of distributors. In 2019, revenues reached €2.7 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.

BIM LISTED EURONEXT

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

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