bioMérieux receives Emergency Use Authorization for BIOFIRE® COVID-19 test

Marcy l'Étoile, France - March 24, 2020 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announced that its subsidiary, BioFire Defense, has received Emergency Use Authorization by the U.S. Food and Drug Administration of its BIOFIRE® COVID-19 test for use in CLIA moderate and high complexity clinical laboratories to detect SARS-CoV-2.

The BIOFIRE® COVID-19 test detects SARS-CoV-2 in approximately 45 minutes from a nasopharyngeal swab in transport media. This test runs on the fully automated FILMARRAY® 2.0 and FILMARRAY® TORCH platforms and is extremely easy to use, therefore requiring minimal training and skills in molecular biology.

BIOFIRE® COVID-19 was developed with funding from the U.S. Department of Defense (DoD) by leveraging an existing contract agreement with BioFire Defense. This is the second of three tests being developed for diagnostic use as part of bioMérieux's strategic response to the COVID-19 pandemic.

"The rapid development of this test is a combined result of the extensive effort and dedication of our employees, the assistance of our partner Midwest Research Institute Global, and the confidence entrusted to us by the U.S. Department of Defense", said Bob Lollini, CEO of BioFire Defense.

bioMérieux is currently making every effort to scale up supply of the BIOFIRE® COVID-19 test at multiple production facilities in Salt Lake City (Utah, USA). The initial test kits are committed to the DoD for redistribution. Test kits will be available for commercial distribution in the United States under the EUA as well as internationally where regulatory approval allows. bioMérieux expects to have maximum production capability within a few weeks to address the needs of the thousands of labs and healthcare professionals using one of the nearly 11 000 BIOFIRE® systems worldwide.

"In the face of this unprecedented global sanitary crisis, bioMérieux is now launching a second diagnostic test for the detection of SARS-CoV2. True to our commitment to public health we are making every effort to provide a comprehensive diagnostic approach that meets the highest performance and quality standards to help physicians mount an effective response to the ongoing COVID-19 pandemic", said Dr. Mark Miller, Executive Vice President and Chief Medical Officer of bioMérieux.

bioMérieux has also received authorization to sell the BIOFIRE® COVID-19 test External Control Kit. This positive control material may be used for quality control and laboratory verification of the test.

PRESS RELEASE

About bioMérieux's commitment to fight COVID-19 pandemic

bioMérieux already launched the SARS-COV-2 R-GENE® test. This real-time PCR test running on open platforms has been validated by the French Reference Center for respiratory infectious diseases, highlighting its excellent performance. It is produced and available in France and is expected to be rapidly CE-marked and submitted to the FDA for an EUA (Emergency Use Authorization) as well.

bioMérieux is also developing an expanded version of its BIOFIRE® FILMARRAY® Respiratory Panel 2, which will be called the BIOFIRE® Respiratory Panel 2.1 (RP2.1). This new panel will include SARS-CoV-2 in addition to the 21 other common respiratory pathogens and will deliver results in approximately 45 minutes. It will also be available on the FILMARRAY® 2.0 and FILMARRAY® TORCH platforms.

About Emergency Use Authorization

The BIOFIRE® COVID-19 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 of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

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*) 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.

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.

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.
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