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

Marcy l'Étoile (France) - March 18, 2021 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announced that BioFire Diagnostics, its subsidiary specialized in molecular syndromic infectious disease testing, has received U.S. Food and Drug Administration (FDA) De Novo authorization for the BIOFIRE® RP2.1 Panel. This panel allows for the detection of 22 viral and bacterial pathogens responsible for respiratory infections, including SARS-CoV-2 (the cause of COVID-19 disease). The panel is the first SARS-CoV-2 diagnostic test of any kind that has been granted De Novo status by U.S. FDA, having gone through the normal U.S. FDA review pathway outside of the Emergency Use Authorization (EUA) track.

This De Novo authorization will be concurrent with the revocation of the U.S. FDA EUA that was obtained on May 1st, 2020 for this panel. The BIOFIRE® RP2.1 Panel EUA and De Novo kits are identical with the exception of changes to the labeling.

The De Novo application was supported by a multicenter prospective clinical study in which the performance of the BIOFIRE® RP2.1 Panel SARS-CoV-2 assay was evaluated in over 500 specimens against a combined reference of three independent molecular SARS-CoV-2 assays, each with U.S. FDA EUA designation. The BIOFIRE® RP2.1 Panel SARS-CoV-2 assay demonstrated positive percent agreement (PPA) of 98.4% and negative percent agreement (NPA) of 98.9%.

Pierre Boulud, Chief Operating Officer, Clinical Operations of bioMérieux said: ***"The De Novo authorization of the BIOFIRE® RP2.1 Panel demonstrates how BioFire is dedicated to responding to a rapidly-evolving global pandemic with urgency and accuracy. This is the first U.S. FDA De Novo authorized Covid-19 test."***

The BIOFIRE® RP2.1 Panel allows healthcare providers to quickly identify common respiratory pathogens found in patients presenting with acute respiratory tract infection, using one simple test. The BIOFIRE® RP2.1 Panel yields results in approximately 45 minutes using nasopharyngeal swab (NPS) samples in transport media or saline. It runs on the fully automated BIOFIRE® FILMARRAY® 2.0 and BIOFIRE® Torch Systems with only 2 minutes of sample preparation time.

ABOUT BIOMÉRIEUX'S GLOBAL RESPONSE TO COVID-19

bioMérieux provides several SARS-CoV-2 diagnostic solutions:

- **ARGENE® SARS-CoV-2 R-GENE®** and **SARS-CoV-2 RESPI R-GENE®**: these tests are available in certain international markets outside of the US and rely on real-time PCR technology and can be used with most commercially available amplification PCR-platforms. The SARS-CoV-2 RESPI R-GENE® allows the simultaneous (multiplex) detection of SARS-CoV-2, influenza viruses A and B and two other respiratory pathogens (RSV and hMPV).

PRESS RELEASE

- **BIOFIRE® COVID-19 test**: this fully automated SARS-CoV-2 test provides results from a patient sample in 45 minutes. It is suitable for use in emergency situations for critically ill patients. The BIOFIRE® COVID-19 test was developed with funding from the U.S. Department of Defense (DoD) and is produced in Utah (USA).
- **BIOFIRE® Respiratory 2.1 *plus* Panel***:* this test is available in certain international markets outside of the US and includes the detection of MERS-Coronavirus in addition to the other pathogens of the BIOFIRE® RP2.1 Panel in approximately 45 minutes.
- **BIOFIRE® Respiratory 2.1-EZ Panel**: this panel identifies 19 pathogens associated with respiratory infections, including SARS-CoV-2 in approximately 45 minutes, and is used in point of care and near patient (e.g. CLIA-waived) settings. Available in the US only.
- **EMAG®** and **easyMAG®**: equipment and associated reagents are pivotal for the extraction of nucleic acids prior to the amplification and detection of specific gene sequences. These systems are in high demand as a means of preparing nucleic acids from clinical specimens.
- **VIDAS® anti-SARS-CoV-2 IgM and anti-SARS-CoV-2 IgG:** these two serology tests detect antibodies as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

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 2020, revenues reached €3.1 billion, with over 93% 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.

CONTACTS

Investor Relations
bioMérieux
Franck Admant
Tel.: + 33 4 78 87 20 00
investor.relations@biomerieux.com

Media Relations
bioMérieux
Olivier Rescanière
Tel.: + 33 4 78 87 20 00
media@biomerieux.com

Image Sept
Laurence Heilbronn
Tel.: + 33 1 53 70 74 64
lheilbronn@image7.fr

Claire Doligez
Tel.: + 33 1 53 70 74 48
cdoligez@image7.fr