PRESS RELEASE

bioMérieux Receives Emergency Use Authorization for Its VIDAS® SARS-COV-2 Antibody Serology Tests

Durham, N.C. – August 7, 2020 — bioMérieux, a world leader in the field of *in vitro* diagnostics, is announcing today that it has received Emergency Use Authorization by the U.S. Food and Drug Administration of its VIDAS® SARS-COV-2 IgM and VIDAS® SARS-COV-2 IgG serology tests. These tests are intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

Building on decades of experience in developing immunoassays, bioMérieux worked closely with several academic medical centers to develop and validate the performance of the two tests. In less than 30 minutes, the VIDAS® SARS-COV-2 IgM and VIDAS® SARS-COV-2 IgG tests can detect the presence of antibodies to the SARS-CoV-2 spike glycoprotein in people who have been infected with SARS-CoV-2 virus. In this context of the COVID-19 pandemic, clinical specificity is particularly important to ensure that testing of uninfected individuals consistently shows a negative result. Both tests have demonstrated excellent clinical performance, with 100% sensitivity, and 99.4% or greater specificity[1].

"*Slowing the spread of COVID-19 has been challenging for everyone and the pandemic has further proved just how critical the role of diagnostics is in the fight against infectious diseases*," Brian Armstrong Head of North America Clinical Operations of bioMérieux. "*We are proud to launch the VIDAS® SARS-COV-2 antibody tests, further expanding our COVID-19 comprehensive solutions to support faster diagnosis and treatment decisions and prevention of transmission*."

The bioMérieux VIDAS® SARS-COV-2 tests are commercially available and laboratories can run them on all VIDAS® systems, which includes the MINI VIDAS®, VIDAS®, and VIDAS® 3.

About bioMérieux global response to COVID-19

bioMérieux already provides several solutions for the molecular detection of SARS-CoV-2:

- **ARGENE® SARS-COV-2 R-GENE® test** (EUA granted on May 6, 2020): this test relies on the real-time PCR technology and can be used with most commercially available amplification PCR-platforms. The SARS-COV-2 R-GENE® test allows many patients to be tested simultaneously and provide results in 4 to 5 hours. It has been developed and is produced in France.

- **BIOFIRE® COVID-19 test** (EUA granted on March 23, 2020): this test is a fully automated test that 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 (RP2.1) Panel** (EUA granted on May 1, 2020): this new panel includes SARS-CoV-2 in addition to 21 other common respiratory pathogens and delivers results in approximately 45 minutes. This test can be run on the FILMARRAY® 2.0 and FILMARRAY® TORCH platforms. This test was developed and is produced in Utah (USA).

- **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 for many SARS-CoV-2 RT-PCR tests available on the market. Reagents are produced in France, instruments in Italy.

- **BIOMÉRIEUX AGILIST**: software-as-a-service provides speed and agility that is essential to COVID-19 reporting. Our dynamic dashboards provide meaningful insights that help hospitals and clinicians monitor, analyze, and visualize their COVID-19 data.

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
U.S. website: www.biomerieux-usa.com

[1] ≥15 days post-symptoms onset

CONTACTS

Investor Relations
bioMérieux
Sylvain Morgeau
Tel.: + 33 4 78 87 51 36
investor.relations@biomerieux.com

Media Relations
SEEZ
Liza Deckelbaum
Tel.: (919) 645-0782
lizad@thestoneagency.com

- BIOFIRE® RESPIRATORY PANEL 2.1, BIOFIRE® COVID-19, SARS-COV-2 R-GENE®, and VIDAS® SARS-COV-2 tests have not been FDA cleared or approved;
- BIOFIRE® RESPIRATORY PANEL 2.1, BIOFIRE® COVID-19, SARS-COV-2 R-GENE®, and VIDAS® SARS-COV-2 tests have been authorized by FDA under an EUA for use by authorized laboratories;
- BIOFIRE® RESPIRATORY PANEL 2.1, BIOFIRE® COVID-19, SARS-COV-2 R-GENE® tests have been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens;
- VIDAS® SARS-COV-2 tests have been authorized only for the detection of IgG and IgM antibodies against SARS-CoV-2, not for any other viruses or pathogens;
- BIOFIRE® RESPIRATORY PANEL 2.1, BIOFIRE® COVID-19, SARS-COV-2 R-GENE®, and VIDAS® SARS-COV-2 tests have only been authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for the 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.