bioMérieux serology tests for SARS-CoV-2 on VIDAS® undergo validation preceding imminent launch

Marcy l'Étoile, France – May 06, 2020 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announced performance validation and the upcoming launch of VIDAS® anti-SARS-CoV-2 serology tests to detect antibodies in people who have been exposed to the SARS-CoV-2 that causes the COVID-19 disease.

Building on years of experience in developing immunoassays, bioMérieux worked closely with several hospitals to develop and validate the performances of two tests. VIDAS® anti-SARS-CoV-2 IgM and anti-SARS-CoV-2 IgG will identify in less than 30 minutes the presence of antibodies in people who have been infected with SARS-CoV-2. In this context, clinical specificity is particularly important to ensure that testing of uninfected individuals consistently shows a negative result. Both VIDAS® anti-SARS-CoV-2 IgM and anti-SARS-CoV-2 IgG demonstrated excellent clinical specificity data.

François Lacoste, Executive VP R&D at bioMérieux stated: "*Thanks to the engagement and the experience of our research and development teams, bioMérieux is now going to launch two new serology assays to assess the immune response following SARS-CoV-2 infection. These tests will complement our three already launched molecular tests for the direct detection of the virus. Offering complementary testing solutions to laboratories is crucial to help overcome this pandemic. True to its commitment to serve public health, bioMérieux is one of the few players to propose a complete diagnostic solution for COVID-19 disease*".

Hospitals and private laboratories can run the tests on bioMérieux's VIDAS® analyzers (MINI VIDAS®, VIDAS® and VIDAS® 3) which are widely available with more than 30 000 systems installed around the world.

bioMérieux aims to have the VIDAS® anti-SARS-CoV-2 serology tests available by mid-May as RUO (Research Use Only). They will be CE marked rapidly thereafter and bioMérieux will file a request for Emergency Use Authorization (EUA) to the US Food and Drug Administration.

Thanks to the expertise and a close collaboration between R&D, industrialization and manufacturing on the same site in France, bioMérieux is planning on an accelerated ramp-up to produce several million serology tests per month in the coming weeks.

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** (CE-marked on April 10th, under EUA assessment by the FDA): 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 23rd, 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).

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- **BIOFIRE® Respiratory Panel 2.1** (RP2.1) (EUA granted on May 1st, 2020): this new panel includes SARS-CoV-2 in addition to 21 other common respiratory pathogens and delivers results in approximately 45 minutes. A **BIOFIRE® Respiratory Panel 2.1 *plus*** will also be available in international markets and will include the detection of MERS-Coronavirus in addition to the SARS-CoV-2 virus. Both panels can be run on the FILMARRAY® 2.0 and FILMARRAY® TORCH platforms. Tests were developed and are produced in Utah (USA).
- **EMAG®** and **easyMAG®** equipments 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.

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

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