bioMérieux announces the expansion of the CE marking of its molecular biology ARGENE® SARS-CoV-2 diagnostic test to include saliva specimens.

Marcy l'Etoile, France – November 16, 2020 – bioMérieux, a world leader in the field of *in vitro* diagnostics, has announced the expansion of its ARGENE® range for the detection of SARS-CoV-2. As a complement to nasopharyngeal swab specimens, the singleplex SARS-CoV-2 R-GENE® real-time PCR test may now be used on saliva and oropharyngeal (throat) swab specimens for the detection of the virus that causes COVID-19. This development helps optimize laboratory workflows.

The CE-marked SARS-CoV-2 R-GENE® test covers the above three sample types. This allows bioMérieux to address the recommendation issued by the French National Authority for Health (HAS) on September 18, 2020, which encourages the preferential use of saliva swabs to test symptomatic individuals for whom it is difficult or impossible to use nasopharyngeal swabs.

"True to its commitment to combat the COVID-19 pandemic, bioMérieux has taken into account the needs of laboratories. Expanding the use of the ARGENE® molecular test to include saliva swab specimens will make the test more acceptable to many patients, and will make it easier to perform," said François Lacoste, Executive Vice President, R&D.

The expansion of the CE marking to include saliva and oropharyngeal swab specimens has been declared to the French National Agency of Medicines and Health Products Safety (ANSM).This new type of specimen is now mentioned in the list of tests authorized by the French Directorate General of Health.

Moreover, the Company will soon release a high-throughput test for the simultaneous (multiplex) detection of influenza viruses A and B and SARS-CoV-2, including a cellular control to check the quality of the sample. It will be available in Europe and in countries that recognize CE marking. This new test will be part of the same test kit for the detection of two other disease agents that often circulate during the winter months, RSV (human respiratory syncytial virus) and HMPV (human metapneumovirus).

About the ARGENE® SARS-COV-2 R-GENE® test:
As for all tests in the ARGENE® range, the SARS-COV-2 R-GENE® test is an open assay, meaning that it may be performed by any laboratory using PCR technology on most commercially-available nucleic acid extraction and amplification platforms. Results are delivered in 4 to 5 hours, and a large number of patient samples may be processed simultaneously. The entire ARGENE® range for the detection of SARS-CoV-2 is produced in France at the bioMérieux site in Verniolle (Ariège).

PRESS RELEASE

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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