



Launch of BIOFIRE® MYCOPLASMA test for mycoplasma detection in biopharmaceutical products

Marcy l'Étoile (France) – July 16, 2020 – bioMérieux, a world leader in the field of *in vitro* diagnostics, has announced the launch of BIOFIRE® MYCOPLASMA, an innovative test for mycoplasma detection in pharmaceutical products used for biotherapeutics (antibodies, hormones, cell and gene therapies, etc.), the most vibrant sector in the pharmaceutical industry.

Mycoplasmas are bacteria found during biopharmaceutical manufacturing. Some species of mycoplasma cause respiratory and genital infections, thus representing a health hazard. They are difficult to detect creating a major risk during industrial production processes.

BIOFIRE® MYCOPLASMA is an innovative, rapid and very easy-to-use molecular biology test. This is because the DNA extraction, amplification and detection steps are fully automated and may be performed outside of the laboratory by nearly anyone after simple training.

The BIOFIRE® system used with this test includes all the reagents and controls necessary for the analysis in a single pouch, making it possible to perform the test close to where the samples are taken. Delivering results in less than one hour, BIOFIRE® MYCOPLASMA facilitates biopharmaceutical product controls and saves precious time during the production of therapies that are most often used by patients with serious disease, whose critical condition may require them to receive treatment as quickly as possible.

Mycoplasma detection has traditionally been based on tissue culture techniques, which take 28 days to deliver results, or on a PCR molecular biology method that provides results in just a few hours but must be performed in a specialized lab, requiring high-level expertise.

“Based on the BIOFIRE® technology used for several years in the field of clinical diagnostics, BIOFIRE® MYCOPLASMA allows our pharma sector customers to carefully monitor the risk of contamination at each step in their manufacturing processes. The simplicity and reliability of this pioneering microbiological control solution for biopharmaceutical products provides the perfect illustration of bioMérieux’s commitment to protect patients’ health while limiting the risk of a potential contamination in biopharmaceutical production facilities,” said Michael Reynier, VP Healthcare Business, Industrial Microbiology Unit at bioMérieux.

The new BIOFIRE® MYCOPLASMA test, which is available in the United States, will be launched in some countries in Europe and the Asia-Pacific region in the coming months.



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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