bioMérieux receives US FDA CLIA-waiver for the BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini

Marcy-l'Étoile (France), May 9th, 2023 – bioMérieux, a world leader in the field of *in vitro* diagnostics, has received U.S. Food and Drug Administration (FDA) Clinical Laboratory Improvement Amendments (CLIA) waiver for the fast and accurate multiplex PCR*-based BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini. This waiver comes in addition to the 510(k) clearance obtained last April.

The COVID-19 pandemic has demonstrated the need for healthcare professionals to have diagnostic tests available as close as possible to the patient, providing actionable results quickly. The BIOFIRE® SPOTFIRE® R Panel Mini is the second multiplex PCR-based test cleared for use on the BIOFIRE® SPOTFIRE® System. Both this system and its 15-target BIOFIRE® SPOTFIRE® Respiratory Panel received FDA-clearance and CLIA-waiver in February 2023.

The new BIOFIRE® SPOTFIRE® R Panel Mini detects five of the most common viral causes of upper respiratory tract infections: SARS-CoV-2 (virus associated with COVID-19), Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), and Rhinovirus, in about 15 minutes.

"We know that in the post-pandemic world patients justifiably demand diagnostic results which are important to them and their families. The inclusion of Rhinovirus into this syndromic panel increases clinicians' ability to provide their patients with a definitive result compared to the other respiratory tests available in the United States which contain only the other 1-4 viruses" declared Mark Miller, Executive Vice-President, Chief Medical Officer, bioMérieux.

The BIOFIRE® SPOTFIRE® System is a small, scalable, multiplex PCR platform designed to bring central laboratory diagnostic results to the decentralized point-of-care (POC) clinical setting. It is the first FDA-cleared PCR system to provide results in under 20 minutes and can run both a large multiplex respiratory test in the 12-25 pathogen target range, and a small multiplex respiratory test in the 3-5 pathogen target range.

CLIA-waiver allows the BIOFIRE® SPOTFIRE® System and its two existing respiratory panels to be used by non-lab professionals at the point-of-care.

"CLIA-waiver for BIOFIRE® SPOTFIRE® facilitates use in any clinical setting where patients seek care; be it an urgent care, physician office, local pharmacy, student health clinic, or emergency department" said Jennifer Zinn, General Manager and Head of Clinical Operations, North America, bioMérieux. "Providing results in just 15 minutes, BIOFIRE® SPOTFIRE® has the potential to improve clinical decisions, optimize clinical operations, and most importantly, support antimicrobial stewardship at the individual provider level.

The BIOFIRE® SPOTFIRE® system with panels will further expand bioMérieux's presence in the United States CLIA-waived market.

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PRESS RELEASE

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A world leader in the field of *in vitro* diagnostics since 1963, bioMérieux is present in 45 countries and serves more than 160 countries with the support of a large network of distributors. In 2022, revenues reached €3.6 billion, with over 90% of sales outside of France.

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 food, pharmaceutical and cosmetic products.
www.biomerieux.com.

bioMérieux is listed on the Euronext Paris stock market.
Symbol: BIM – ISIN Code: FR0013280286
Reuters: BIOX.PA/Bloomberg: BIM.FP

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