



bioMérieux submits Dual 510(k) and CLIA-waiver application to FDA for the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel

Marcy-l'Étoile (France), September 22nd, 2023 – bioMérieux, a world leader in the field of *in vitro* diagnostics, has submitted the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel to U.S. Food and Drug Administration (FDA) for a dual 510(k) clearance and CLIA¹-waiver. This panel is already CE-marked (IVDD²).

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/ST Panel is a unique multiplex PCR³ test capable of detecting 15 of the most common bacteria, viruses, and viral subtypes responsible for respiratory or sore throat infections⁴ in about 15 minutes. Samples can be taken using either a nasopharyngeal or throat swab, depending on whether a respiratory tract infection or pharyngitis is suspected, based on signs and symptoms experienced by the patient.

“This new panel enhances the clinicians’ ability to focus patient care by choosing one of these two important tests to identify the most relevant pathogens using a single pouch” declared Mark Miller, Executive Vice-President, Chief Medical Officer, bioMérieux.

“There is a great need for rapid and reliable diagnostic solutions for common infections, particularly in this era of increasing antimicrobial resistance when we need to use antibiotics only when appropriate. Patients and families expect clear direction from physicians when managing respiratory and sore throat infections. Performing rapid syndromic testing closer to the patient has important medical value, giving clarity on treatment options, and providing peace of mind for patients and their loved ones.”

The BIOFIRE® SPOTFIRE® R/ST Panel is the third panel submitted for FDA review to be used on the BIOFIRE® SPOTFIRE® System. Two other FDA-cleared and CLIA-waived panels are available for use on this system. The [BIOFIRE® SPOTFIRE® Respiratory Panel](#) and [BIOFIRE® SPOTFIRE® Respiratory Panel Mini](#) detect 15 and 5 of the most common respiratory pathogens respectively.

“We’re thrilled to submit the BIOFIRE® SPOTFIRE® R/ST Panel to the US FDA, and to demonstrate once again, our leadership in the field of syndromic diagnostics, and our intention to reach as many patients as possible where they are first seen!” said Jennifer Zinn, Executive Vice President, Clinical Operations, bioMérieux. *“In fact, throat infections are one of the most common causes of patient visits to medical centers. By offering practitioners a unique and innovative way of testing for the agents that cause most respiratory tract infections, including sore throat, using a single multiplex panel of 15 targets, we’ll be helping them to save time and improve patient management.”*

The BIOFIRE® SPOTFIRE® solution allows bioMérieux to further expand its syndromic testing technology outside of the traditional clinical laboratories to Point-of-Care testing locations, offering healthcare professionals the ability to deliver results to patients during their visit.

PRESS RELEASE



The BIOFIRE® SPOTFIRE® R/ST Panel is already CE-marked (IVDD) to address the European market.

- (1) *Clinical Laboratory Improvement Amendments*
- (2) *In Vitro Diagnostic Directive*
- (3) *Polymerase Chain Reaction*
- (4) **Viruses:** Adenovirus, Coronavirus (seasonal), Coronavirus SARS-CoV-2, Human metapneumovirus, Human rhinovirus/enterovirus, Influenza A, Influenza A subtype H3, Influenza A subtype H1-2009, Influenza B virus, Parainfluenza virus, Respiratory syncytial virus.
Bacteria: *Chlamydia pneumoniae*, *Mycoplasma pneumoniae*,
[Respiratory only]: *Bordetella pertussis*, *Bordetella parapertussis*,
[Sore Throat only]: *Streptococcus dysgalactiae* (group C/G Strep), *Streptococcus pyogenes* (group A Strep)

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Pioneering Diagnostics

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.

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