bioMérieux receives Dual 510(k) clearance and CLIA-waiver approval for the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel

Marcy-l'Étoile (France), March 27th, 2024 – bioMérieux, a world leader in the field of *in vitro* diagnostics, has received U.S. Food and Drug Administration (FDA) 510(k) clearance and Clinical Laboratory Improvement Amendments (CLIA) waiver approval for the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel.

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. A fast and innovative syndromic testing range, BIOFIRE® SPOTFIRE® perfectly matches these new medical needs worldwide.

The BIOFIRE® SPOTFIRE® R/ST Panel is a unique multiplex PCR[1] test capable of detecting and identifying nucleic acids from up to 15 of the most common bacteria, viruses, and viral subtypes responsible for respiratory or sore throat infections[2] in about 15 minutes. Samples can be taken from a nasopharyngeal swab when a respiratory tract infection is suspected, or from a throat swab in case of a pharyngitis syndrome.

"To prescribe or not to prescribe antimicrobials is the age-old question for outpatient upper respiratory infections. The flexibility of this syndromic panel allows healthcare professionals to test for multiple pathogens with overlapping signs and symptoms, ultimately allowing the diagnostic to drive informed decision-making during the outpatient visit. These results further empower the advancement of antimicrobial stewardship and modernize patient care." declared Dr Charles K. Cooper, Executive Vice-President, Chief Medical Officer, bioMérieux

The BIOFIRE® SPOTFIRE® R/ST Panel is the third panel to receive FDA clearance for use on the BIOFIRE® SPOTFIRE® System. The two other panels available for use on this system are the BIOFIRE® SPOTFIRE® Respiratory (R) Panel and BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini, detecting 15 and 5 of the most common respiratory pathogens respectively.

A CLIA-waiver allows the BIOFIRE® SPOTFIRE® System and its so-authorized panels to be used by non-lab professionals and in any clinical setting where patients seek care including an urgent care, physician office, local pharmacy, student health clinic, or an emergency department.

"Receiving FDA clearance for the BIOFIRE® SPOTFIRE® R/ST Panel, just one year after the successful launch of the BIOFIRE® SPOTFIRE® solution, marks another milestone in our mission to move testing closer to the patient," said Jennifer Zinn, Executive Vice President, Clinical Operations, bioMérieux. *"With our innovative approach, we are committed to enhancing patient care by providing healthcare professionals with the tools they need to deliver expedited and effective diagnoses. Together, we are revolutionizing the landscape of healthcare, one diagnosis at a time."*

The BIOFIRE® SPOTFIRE® R/ST Panel is currently CE-marked under IVDD (In Vitro Diagnostic Directive) and has been submitted for CE-marking under IVDR (In Vitro Diagnostic Regulation).

PRESS RELEASE

bioMérieux will also submit the BIOFIRE® SPOTFIRE® Respiratory / Sore Throat (R/ST) Panel Mini to the FDA for review for a 510(k) clearance. This panel is intended to detect and identify nucleic acids from 5 of the most common viral and bacterial causes of respiratory tract infections from either a nasopharyngeal or throat swab[3] respectively. The BIOFIRE® SPOTFIRE® R/ST Panel Mini is not yet available for sale.

[1] Polymerase Chain Reaction

[2] Under its FDA-cleared and CLIA-waved version, the BIOFIRE® SPOTFIRE® R/ST Panel is capable of testing:
***Viruses**: Adenovirus, Coronavirus (seasonal),, Human metapneumovirus, Human rhinovirus/enterovirus, Influenza A, Influenza A subtype H3, Influenza A subtype H1-2009, Influenza B virus, Parainfluenza virus, Respiratory syncytial virus.*
[Respiratory only]: Coronavirus SARS-CoV-2.
***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)

*[3] **Viruses**: Human rhinovirus, Influenza A virus, Influenza B virus, Respiratory syncytial virus.*
[Respiratory only]: Coronavirus SARS-CoV-2.
***Bacteria**:*
[Sore Throat only]: Streptococcus pyogenes (group A Strep)

ABOUT BIOMÉRIEUX

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 2023, revenues reached €3.7 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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