bioMérieux receives U.S. FDA Special 510(k) clearance and CLIA-waiver for its BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini

Marcy-l'Étoile (France), June 26th, 2024 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announces that its BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini has received U.S. Food and Drug Administration (FDA) Special 510(k) clearance and CLIA-waiver (Clinical Laboratory Improvement Amendments).

The COVID-19 pandemic demonstrated the need for healthcare professionals to have diagnostic tests as close as possible to the patient and provide actionable results quickly. More and more tests are carried out outside hospital labs directly in Emergency Departments (ED) or at the Point of Care (POC). This market is particularly active in the United States. A fast and innovative syndromic testing solution, the BIOFIRE® SPOTFIRE® range perfectly matches these new medical needs.

For use on the BIOFIRE® SPOTFIRE® system, the BIOFIRE® SPOTFIRE® R/ST Panel Mini is a unique multiplex PCR* test that detects 5 of the most common viral and bacterial causes of respiratory or sore throat infections[1] in about 15 minutes. Samples can be taken from a nasopharyngeal swab when a respiratory tract infection is suspected or from a throat swab when pharyngitis is suspected.

The BIOFIRE® SPOTFIRE® system is a unique POC platform providing fast results and offering flexibility with the capability of running either a large multiplex respiratory test with up to 15 pathogens with the BIOFIRE® SPOTFIRE® R/ST Panel, already FDA-cleared and CLIA-waived, or a small multiplex respiratory test with 5 pathogens with the BIOFIRE® SPOTFIRE® R/ST Panel Mini. This flexibility allows clinicians to choose the right test for their patients.

"The medical community continues to bring enhanced technology closer to patients, allowing clinicians to have more information to make real-time decisions. Regarding strep throat, Group A Streptococcus accounts for approximately 20% of sore throat cases and has historically been diagnosed via antigen tests. Including it on this PCR panel with common viral causes of strep throat, including rhinovirus, represents a step forward in healthcare, ultimately increasing diagnostic yield and removing the need to reflex to culture in most patients." declared Dr Charles K. Cooper, Executive Vice-President, Chief Medical Officer.

The BIOFIRE® SPOTFIRE® R/ST Panel Mini is now the fourth** panel of the BIOFIRE® SPOTFIRE® range to be FDA-cleared and CLIA-waived. When implementing decentralized testing, CLIA-waiver is key because it allows for this system and panels to be used by non-lab professionals in POC settings where patients may seek care such as urgent cares, physician offices, local pharmacies, student health clinics, or emergency departments.

"With our BIOFIRE® SPOTFIRE® R/ST Panel Mini, we bring a fast, highly sensitive and targeted panel to test for 4 of the most common respiratory viruses (including influenzas) and Streptococcus A, from one throat swab, all at the same time. Our offer meets the current needs of the growing decentralized, POC market bringing syndromic testing to the frontline of patient care. With this innovation, clinicians now can confidently tell their

PRESS RELEASE

patients quickly what is making them sick and get them on the right treatment pathway, limiting the overuse of antibiotics." commented Jennifer Zinn, Executive Vice President, Clinical Operations.

The new BIOFIRE® SPOTFIRE® R/ST Panel Mini will be available in the third quarter of 2024 in the United States. It is intended to be commercialized together with the larger multiplex BIOFIRE® SPOTFIRE® R/ST Panel to further expand bioMérieux's presence in the North American outpatient market.

** Polymerase Chain Reaction*
*** Three other tests have received 510(k) clearance and CLIA-waiver from the U.S. FDA: BIOFIRE® SPOTFIRE® Respiratory (R) Panel, BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini and BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel.*

*[1] **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

CONTACTS

INVESTORS RELATIONS

Aymeric Fichet
Tel.: +33 (0)4 78 87 20 00
investor.relations@biomerieux.com

MEDIA RELATIONS

CORPORATE
Romain Duchez
Tel.: +33 (0)4 78 87 20 00
media@biomerieux.com

UNITED STATES
Liza Deckelbaum (SEEZ)
Tel. : (919) 521-0507
lizad@seeztoday.com

FRANCE
Laurence Heilbronn (Image 7)
Tel.: +33 (0)1 53 70 74 48
lheilbronn@image7.fr

PRESS RELEASE