



bioMérieux receives U.S. 510(k) clearance and CLIA-waiver for Anterior Nasal Swab specimens, an additional sample type for use with the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini

Marcy-l'Étoile (France), August 18, 2025 – 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) 510(k) clearance and Clinical Laboratory Improvement Amendments (CLIA) waiver for the addition of Anterior Nasal Swab (ANS) as a validated specimen type for this panel, specifically for use with the respiratory test menu. By swabbing only the anterior part of the nasal cavity, ANS provides significantly more comfort for the patient.

Since the COVID-19 pandemic, the need for decentralized diagnostic testing, also known as Point-of-Care testing, has become increasingly important in many countries, particularly in the United States. Bringing diagnostic solutions closer to the patient may speed-up the time-to-result to rapidly identify the origin of infectious diseases and determine the appropriate treatment. With these advancements, sampling methods have also diversified, especially with the adoption of ANS, which has gained widespread recognition for the ease of collection, superior patient comfort, and comparable reliability to nasopharyngeal swabs¹.

Launched in the United States in 2024, the BIOFIRE® SPOTFIRE® R/ST Panel Mini is a single multiplex PCR* test that detects 5 of the most common viral and bacterial causes of respiratory or sore throat infections² in about 15 minutes. Already offering two sampling methods, nasopharyngeal swab and throat swab, the BIOFIRE® SPOTFIRE® R/ST Panel Mini now includes a third sample type with ANS specifically for use with the respiratory menu. Offering sample type flexibility enables healthcare professionals to adapt their approach to enhance patient well-being.

"Today, beyond the accuracy of diagnostic results, patients seek greater comfort in testing. The COVID-19 pandemic has especially underscored the importance of patient well-being in healthcare settings. The opportunity to provide the same quality and performance with a less invasive sample with our BIOFIRE® SPOTFIRE® R/ST Panel Mini truly illustrates our mission to make an impact on patients' health." declared Dr Charles K. Cooper, Executive Vice-President, Chief Medical Officer, bioMérieux.

"Anterior Nasal Swab specimen collection clearance on the BIOFIRE® SPOTFIRE® R/ST Panel Mini marks another milestone in bioMérieux's comprehensive Point-of-Care (POC) offer and strengthens our presence in this market segment. As our technology and the market advance, we will continue to keep the patient top-of-mind – innovating best-in-class POC diagnostic solutions for a better healthcare experience and improved clinical outcomes," noted Jennifer Zinn, Executive Vice President, Clinical Operations, bioMérieux.

The additional ANS specimen type for the BIOFIRE® SPOTFIRE® R/ST Panel Mini will be available for use in the United States before the respiratory season, specifically in the third quarter of 2025.

PRESS RELEASE

* Polymerase Chain Reaction

¹ Lee RA, Herigon JC, Benedetti A, Pollock NR, Denking CM. 2021. Performance of Saliva, Oropharyngeal Swabs, and Nasal Swabs for SARS-CoV-2 Molecular Detection: a Systematic Review and Meta-analysis. *J Clin Microbiol* 59:10.1128/jcm.02881-20. <https://doi.org/10.1128/jcm.02881-20>.

² **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 2024, revenues reached €4 billion, with over 93% 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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