



bioMérieux Receives IVDR CE-Marking for Two BIOFIRE® SPOTFIRE® Panels to Strengthen Near-Patient Respiratory and Sore Throat Diagnostics Across Europe

Marcy-l'Étoile (France), March 19, 2026 – bioMérieux, a world leader in the field of *in vitro* diagnostics, announces that its BIOFIRE® SPOTFIRE® Respiratory/Sore Throat *plus* (R/ST*plus*) Panel and BIOFIRE® SPOTFIRE® Respiratory/Sore Throat *plus* (R/ST*plus*) Panel Mini have been CE-marked under the IVDR*. The certification includes conformity assessment for near-patient testing, enabling its use outside traditional laboratories, directly at the point of care. These multiplex PCR** tests can simultaneously detect the most common pathogens responsible for respiratory and sore throat infections, within a timeframe aligned with a typical patient visit.

Respiratory infections are among the most prevalent illnesses worldwide and represent a major global health burden, with millions of severe cases each year worldwide¹. In the context of multiple respiratory pathogens circulating at the same time, and causing similar non-specific symptoms, rapid and accurate identification of the causative agent is essential—not only to guide timely and appropriate treatment, but also to prevent the inappropriate use of antibiotics and help address the escalating challenge of antimicrobial resistance.

Compatible with the compact innovative BIOFIRE® SPOTFIRE® System, the BIOFIRE® SPOTFIRE® R/ST*plus* Panel and the BIOFIRE® SPOTFIRE® R/ST*plus* Panel Mini are unique multiplex PCR tests capable of identifying nucleic acids for the most common bacteria, viruses, and viral subtypes responsible for respiratory or sore throat infections, in about 15 minutes.

The BIOFIRE® SPOTFIRE® R/ST*plus* Panel detects 15 pathogens² and the BIOFIRE® SPOTFIRE® R/ST*plus* Panel Mini detects up to 6 pathogens³, including human Rhinovirus/Enterovirus, Strep A, Flu A/B, RSV and SARS-CoV-2. Together, these assays deliver a flexible and tailored solution that empowers clinicians to choose the right test the first time, to the right patient, all on a single streamlined platform that combines clinical flexibility with operational simplicity.

“By expanding respiratory testing to include human rhinovirus/enterovirus alongside influenza, RSV, and SARS-CoV-2 in a targeted panel, we significantly increase the likelihood of obtaining a clinically relevant answer close to the patient. Positive findings can help avoid unnecessary procedures and inappropriate antibiotic treatments while accelerating high-confidence clinical decisions. Importantly, because rhinovirus/enterovirus circulates year-round, this expanded testing approach provides consistent value well beyond the winter season,” declared Dr Charles K. Cooper, Executive Vice President, Chief Medical Officer, bioMérieux.

Delivering adaptable, cost-effective point-of-care testing solutions

The BIOFIRE® SPOTFIRE® R/ST*plus* Panel is intended to replace the previously commercialized BIOFIRE® SPOTFIRE® R/ST Panel, which was CE-marked under IVDD***, as the product transitions to its new registration under IVDR. In addition,

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bioMérieux is introducing the BIOFIRE® SPOTFIRE® R/STplus Panel Mini, further strengthening its dynamic and contextual respiratory testing approach in Europe.

Samples may be collected using either a nasopharyngeal or a throat swab, depending on the suspected infection. The BIOFIRE® SPOTFIRE® R/STplus Panel Mini also offers a third sampling method with anterior nasal swab specifically for use with the respiratory menu. Flexibility in sample types facilitates testing in non-traditional locations.

“The IVDR CE-marking certification of these two R/ST panels is an important milestone for bioMérieux — strengthening our ability to support healthcare professionals with flexible, cost-effective point-of-care testing solutions across Europe. With proven commercial performance and a rapidly expanding menu, BIOFIRE® SPOTFIRE® is a testament of bioMérieux’s leadership and commitment to diagnostic innovation for improved patient outcomes,” commented Jennifer Zinn, Executive Vice President, Clinical Operations, bioMérieux.

The BIOFIRE® SPOTFIRE® R/STplus Panel and the BIOFIRE® SPOTFIRE® R/STplus Panel Mini will be available in the second quarter of 2026 in countries recognizing CE-marking. Availability in other countries—excluding the United States—will follow based on local regulatory processes.

* *In Vitro Diagnostic Regulation*

** *Polymerase Chain Reaction*

*** *In Vitro Diagnostic Directive*

¹ Zimmerman RK, Balasubramani GK, D’Agostino HEA, Clarke L, Yassin M, Middleton DB, Silveira FP, Wheeler ND, Landis J, Peterson A, Suyama J, Weissman A, Nowalk MP. Population-based hospitalization burden estimates for respiratory viruses, 2015-2019. *Influenza Other Respir Viruses*. 2022 Nov;16(6):1133-1140. doi: 10.1111/irv.13040. Epub 2022 Aug 22. Erratum in: *Influenza Other Respir Viruses*. 2025 Oct;19(10):e70168. doi: 10.1111/irv.70168. PMID: 35996836; PMCID: PMC9530548.

² **Viruses:** Adenovirus, Coronavirus SARS-CoV-2, 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.

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:** Coronavirus SARS-CoV-2, Human rhinovirus/enterovirus, Influenza A virus, Influenza B virus, Respiratory syncytial virus.

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 46 countries and serves more than 160 countries with the support of a large network of distributors. In 2025, revenues reached €4.1 billion, with over 94% 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 agri-food, pharmaceutical and cosmetic products.

www.biomerieux.com.



bioMérieux is listed on the Euronext Paris stock market.

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