



**bioMérieux Receives IVDR Class D CE Marking for BIOFIRE®
Respiratory 2.1 *plus* Panel and BIOFIRE® FILMARRAY®
Pneumonia *plus* Panel, the first syndromic tests including
MERS-CoV to achieve this certification**

Marcy-l'Étoile (France), September 16th, 2026 – bioMérieux, a world leader in the field of *in vitro* diagnostics, announced that its BIOFIRE® Respiratory 2.1 *plus* (RP2.1*plus*) Panel and BIOFIRE® FILMARRAY® Pneumonia *plus* (PN*plus*) Panel have received CE marking under the IVDR* as Class D *in vitro* diagnostic devices, the highest risk classification under the regulation. The classification is driven by the inclusion of Middle East Respiratory Syndrome Coronavirus (MERS-CoV) on both test menus.

Although MERS-CoV infections remain relatively uncommon globally¹, the virus continues to be monitored by international health authorities and by laboratories due to its high mortality rate, and its capacity to trigger outbreaks in healthcare settings and through international travel. The continued inclusion of MERS-CoV in syndromic respiratory testing supports outbreak preparedness efforts by enabling clinicians to rapidly identify or rule out this high-consequence pathogen alongside a broad range of more commonly circulating respiratory agents from a single patient sample.

With the IVDR certification of BIOFIRE® RP2.1*plus* Panel and BIOFIRE® FILMARRAY® PN*plus* Panel, two multiplex tests that include MERS-CoV in their menus, bioMérieux marks an important regulatory milestone. This reinforces the company's long-standing commitment to providing healthcare professionals with access to comprehensive, high-quality diagnostic solutions for serious infectious diseases.

The BIOFIRE® RP2.1*plus* Panel provides broad syndromic testing for upper respiratory infections² in about 45 minutes while the BIOFIRE® FILMARRAY® PN*plus* Panel supports the diagnosis of lower respiratory tract infections by detecting a wide range of bacterial and viral pathogens as well as key antimicrobial resistance markers³ in about 1 hour. Both panels deliver actionable results that can help clinicians make informed decisions earlier in the patient's care pathway.

"Different respiratory infections often present with similar symptoms, making fast and comprehensive diagnostic information critical for patient management. By including MERS-CoV in a broad multiplex syndromic panel, healthcare providers can simultaneously test for the presence of multiple respiratory pathogens while also accounting for uncommon but clinically significant threats. This comprehensive approach can help support timely treatment decisions, appropriate infection control measures, and improved patient care." said Dr. Charles K. Cooper, Executive Vice President, Chief Medical Officer, bioMérieux.

The IVDR Class D classification in the European Union (EU) is subject to the most rigorous regulatory requirements. It is reserved for tests intended to detect pathogens that pose a high risk to public health, ensuring the highest level of confidence in test performance, quality, and reliability. Obtaining this certification represents a significant achievement for bioMérieux, and for the entire European diagnostic market.

"We are proud to be among the first companies to receive IVDR Class D certification for multiplex syndromic tests that include MERS-CoV. Achieving this milestone under the EU's strictest standards validates the quality of these two BIOFIRE® panels, empowering European healthcare systems and professionals to maintain preparedness for emerging and high-consequence respiratory threats. This certification is a testament to bioMérieux's scientific expertise and longstanding investment in innovation, regulatory excellence, and diagnostic stewardship — advancing our mission to improve public health worldwide." stated Jennifer Zinn, Executive Vice President, Clinical Operations, bioMérieux.

The newly IVDR certified panels will begin to be available on the European market early next year. In the meantime, laboratories will continue to receive BIOFIRE® RP2.1^{plus} and BIOFIRE® FILMARRAY® PN^{plus} panels without disruption, even as regulatory requirements evolve with consistent performance and reliability, since there have been no modifications to product design or intended purpose.

* In Vitro Diagnostic Regulation, in force in the European Union.

¹ <https://www.emro.who.int/health-topics/mers-cov/mers-outbreaks.html>

² **Viruses:** Adenovirus Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, MERS-CoV, SARS-CoV-2, Human metapneumovirus, Human rhinovirus/enterovirus, Influenza A virus, Influenza A virus A/H1, Influenza A virus A/H3, Influenza A virus A/H1-2009, Influenza B virus, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Respiratory syncytial virus

Bacteria: Bordetella parapertussis, Bordetella pertussis, Chlamydia pneumoniae, Mycoplasma pneumoniae

³ **Viruses:** Adenovirus, Coronavirus, Human metapneumovirus, Human rhinovirus/enterovirus, Influenza A virus, Influenza B virus, Middle East respiratory syndrome coronavirus (MERS-CoV), Parainfluenza virus, Respiratory syncytial virus

Bacteria: Acinetobacter calcoaceticus-baumannii complex, Enterobacter cloacae complex, Escherichia coli, Haemophilus influenzae, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae group, Moraxella catarrhalis, Proteus spp., Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus aureus, Streptococcus agalactiae, Streptococcus pneumoniae, Streptococcus pyogenes, Chlamydia pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae

Antimicrobial Resistance Genes: Carbapenemases, ESBL, Methicillin Resistance

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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