



BIOFIRE® Respiratory Panel 2.1 *plus* with SARS-CoV-2 is CE marked

Marcy l'Étoile (France) - July 15, 2020 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announced that the BIOFIRE® Respiratory Panel 2.1 *plus* (RP2.1*plus*) is CE marked. The BIOFIRE® Respiratory Panel 2.1 *plus* (RP2.1*plus*) tests for 23 pathogens (19 viruses, including SARS-CoV-2, and 4 bacteria) responsible for the most frequent respiratory tract infections. It will be commercially available in all countries that recognize CE marking from now on or shortly thereafter .

The BIOFIRE® RP2.1*plus* advances the existing BIOFIRE® Respiratory Panel 2 *plus* (RP2*plus*) by adding SARS-CoV-2 to the panel menu while maintaining an assay runtime of about 45 minutes. The BIOFIRE® RP2.1*plus* panel also includes an assay for the Middle East Respiratory Syndrome Coronavirus (MERS-CoV). This new panel allows healthcare providers to quickly identify patients with common respiratory pathogens and differentiate those with COVID-19, using one single test. The BIOFIRE® RP2.1*plus* runs on the fully automated BIOFIRE® FILMARRAY® 2.0 and BIOFIRE® FILMARRAY® TORCH systems and is extremely easy to use.

“The availability of BIOFIRE® RP2.1*plus* in all countries recognizing CE marking represents a global syndromic response to this unprecedented COVID-19 pandemic,” said Pierre Boulud, Chief Operating Officer, Executive Vice President, Clinical Operations at bioMérieux. “With increasing reagent production capacity and an installed base of more than 14 000 BIOFIRE® units throughout the world, BIOFIRE® RP2.1*plus* will play a key role now and in the upcoming respiratory season as healthcare providers face the regular group of respiratory pathogens as well as SARS-CoV-2”, he added.

The BIOFIRE® RP2.1*plus* Panel is part of a suite of products in response to the COVID - 19 pandemic. The ARGENE® SARS-CoV-2 R-GENE® was launched in March 2020, followed by the U.S. FDA EUA cleared BIOFIRE® RP2.1 panel and the VIDAS® anti-SARS- CoV-2 IgM and anti-SARS-CoV-2 IgG tests. These complementary tests help meet the varying needs of bioMérieux’s diverse customers and patients throughout the world.

About the BIOFIRE® solution

The BIOFIRE® solution is a U.S. FDA-cleared and CE-marked multiplex PCR closed and fully-automated system that integrates sample preparation, amplification, and detection. A BIOFIRE® test requires only two minutes of hands-on time and has a total run time of about 45 to 75 minutes, depending on the panel.

The BIOFIRE® range has the largest infectious disease pathogen menu commercially available composed of:

- BIOFIRE® Respiratory Panels (RP, RP2, RP2*plus*, RP2.1 and RP2.1*plus*), identifying between 20 and 23 respiratory viruses and bacteria performed directly on nasopharyngeal swabs in transport media.
- BIOFIRE® COVID-19 test detects SARS-CoV-2 in approximately 45 minutes from a nasopharyngeal swab in transport media.



- BIOFIRE® RP EZ, identifying 11 viral and 3 bacterial pathogens associated with respiratory infections. FDA-cleared and CLIA-waived for use in the US only.
- BIOFIRE® Pneumonia (PN) and Pneumonia *plus* (PN*plus*) Panels, identifying 33 to 34 targets (18 bacteria, 8 to 9 viruses, 7 resistance genes to antibiotics) in sputum (including endotracheal aspirate) and bronchoalveolar lavage (including mini-BAL). 15 of the bacterial targets are reported with semi-quantitative information about the abundance of organisms in a given sample.
- BIOFIRE® Blood Culture Identification 2 (BCID2), identifying 43 of the most common causes of bloodstream infections and associated antimicrobial resistances directly from positive blood culture.
- BIOFIRE® Gastrointestinal (GI) Panel, identifying 22 of the most common viral, bacterial, and parasitic causes of infectious diarrhea directly from stool in Cary Blair transport media.
- BIOFIRE® Meningitis/Encephalitis (ME) Panel, identifying 14 bacterial, viral, and fungal causes of meningitis and encephalitis directly from cerebrospinal fluid.

ABOUT BIOMÉRIEUX

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics for over 55 years, bioMérieux is present in 44 countries and serves more than 160 countries with the support of a large network of distributors. In 2019, revenues reached €2.7 billion, with over 90% of international sales.

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.



bioMérieux is listed on the Euronext Paris stock market.

Symbol: BIM – ISIN Code: FR0013280286

Reuters: BIOX.PA/Bloomberg: BIM.FP

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