



BIOFIRE® FILMARRAY® Tropical Fever Panel, a syndromic PCR test targeting causes of tropical fever infections, receives U.S. FDA Special 510(k) clearance

Marcy-l'Étoile (France), December 9th, 2024 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announces that its BIOFIRE® FILMARRAY® Tropical Fever (TF) Panel has received U.S. Food and Drug Administration (FDA) Special 510(k) clearance. This innovative polymerase-chain reaction (PCR) testing solution offers fast and accurate pathogen identification in patients with unexplained fever, helping to optimize treatment overall.

Tropical fevers are defined as infections that are prevalent in, or are unique to, tropical and subtropical regions. As the pathogens are increasingly spreading to parts of the world previously unaffected and can also be imported by travelers, these infections, including malaria, chikungunya, dengue, and leptospirosis, affect over 100 countries worldwide, causing more than 316 million infections and over 500,000-600,000 deaths annually¹.

Presentation of tropical fever infections are often non-specific and overlapping, complicating efforts to distinguish mild self-limiting illness from more severe diseases that require prompt and targeted treatment. The BIOFIRE® FILMARRAY® Tropical Fever (TF) Panel allows healthcare providers to quickly identify pathogens commonly found in patients presenting with suspected tropical fever infections in one fast easy-to-use test.

“Thanks to this BIOFIRE® FILMARRAY® Tropical Fever Panel, we address an important diagnostic need to help laboratories, physicians, pediatricians, and traveler clinics faced with these unexplained fevers in endemic and non-endemic regions. This syndromic test is expected to provide faster and more accurate diagnoses, potentially reducing delays in starting appropriate antimicrobial therapy, preventing complications, and improving patient management and outcomes. The U.S. FDA Special 510(k) clearance demonstrates bioMérieux’s continued innovative leadership in syndromic testing and our commitment to addressing vital needs in infectious disease diagnostics.” declared Charles K. Cooper, Executive Vice President, Chief Medical Officer at bioMérieux.

The BIOFIRE® FILMARRAY® TF Panel, that has 6 targets* and a run time of about 50 minutes, addresses unmet needs in tropical fever diagnostics. This innovative panel speciates between *Plasmodium falciparum* and *Plasmodium vivax/ovale* which may help healthcare providers target appropriate malaria treatment faster. The BIOFIRE® FILMARRAY® TF Panel provides results using whole blood in Ethylenediaminetetraacetic acid (EDTA) tubes. It runs on the fully automated BIOFIRE® FILMARRAY® 2.0 and BIOFIRE® TORCH Systems with only 2 minutes of sample preparation time.

“Tropical fever infections are often complicated to diagnose in a clinically actionable timeframe — resulting in preventable deaths or unnecessary antibiotic use. Our BIOFIRE® FILMARRAY® Tropical Fever Panel augments bioMérieux’s innovative molecular diagnostics portfolio, providing highly accurate results in less than an hour to aid clinicians in the timely diagnosis of tropical fever infections for optimized therapy decisions. It’s a true game changer for healthcare professionals and their patients, supporting bioMérieux’s global mission to improve public health and preserve antibiotic

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efficacy,” proclaimed Jennifer Zinn, Executive Vice President, Clinical Operations at bioMérieux.

bioMérieux is aiming for a commercial launch in targeted countries, including the United States, in the first quarter of 2025. It will be submitted for CE-marking under the *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) prior to the global launch. The BIOFIRE® FILMARRAY® TF Panel will then be gradually registered and deployed in additional countries.

Development of the BIOFIRE® FILMARRAY® TF Panel was a joint effort by the U.S. Department of Defense (DoD), National Institutes of Health (NIH), and BioFire Defense, a bioMérieux-owned U.S. subsidiary. Launch of the BIOFIRE® FILMARRAY® TF Panel showcases bioMérieux’s unique ability to work with the public sector to apply its expertise in molecular biology and *in vitro* diagnostics (IVD) to enhance national security and routine clinical care.

¹ <https://www.who.int/news-room/fact-sheets/detail/vector-borne-diseases>

* *The BIOFIRE® FILMARRAY® Tropical Fever (TF) Panel is capable of testing: Chikungunya, Dengue (serotypes 1, 2, 3, & 4), Leptospira, Plasmodium species, Plasmodium falciparum, Plasmodium vivax/ovale.*

ABOUT BIOFIRE® FILMARRAY®

The BIOFIRE®FILMARRAY® Solution is a U.S. FDA-cleared and/or CE-marked closed multiplex PCR 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 in as little as ~45 minutes to ~1 hour, depending on the panel. The BIOFIRE® FILMARRAY® Panel portfolio includes 7 syndromic panels or panel ranges:

- BIOFIRE® Respiratory Panels (RP2.1 and RP2.1*plus*)
- BIOFIRE® Pneumonia (PN) and Pneumonia *plus* (PN*plus*) Panels
- BIOFIRE® Blood Culture Identification 2 (BCID2) Panel
- BIOFIRE® Gastrointestinal (GI) Panel
- BIOFIRE® Meningitis/Encephalitis (ME) Panel
- BIOFIRE® Joint Infection (JI) Panel
- BIOFIRE® Tropical Fever (TF) Panel

As of September 30th, 2024, the number of BIOFIRE® FILMARRAY® Systems installed globally reached 26,250 units.

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.

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bioMérieux is listed on the Euronext Paris stock market.
Symbol: BIM – ISIN Code: FR0013280286
Reuters: BIOX.PA/Bloomberg: BIM.FP

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