EC Declaration of Conformity

Manufacturer/Supplier Information	**BioFire Diagnostics, LLC** 515 Colorow Drive Salt Lake City, Utah 84108, USA SRN: US-MF-000003311
EU Authorized Representative	**QbD RepS BV** Groenenborgerlaan 16, 2610 Wilrijk, Belgium SRN: BE-AR-000000040
Notified Body	**BSI** Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands Notified Body Identification No: 2797

We BioFire Diagnostics, LLC, declare under our sole responsibility that the product:

Product Reference	Product Name	Basic UDI-DI
424803	BIOFIRE® FILMARRAY® Tropical Fever (TF) Panel	357302BUDI002231TD

Meets the provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

According to Annex VIII, Rule 3(c), this product is classified as Class C and has been certified to the requirements of Annex IX (reference CE Certificate #IVDR 735494). BioFire Diagnostics' quality system is registered to EN ISO 13485:2016. There are no common specifications (CS) applicable to this product.

Salt Lake City, Utah, USA
Place of issue

March 28, 2025
Date of issue

Karli Plenert
Digitally signed by Karli Plenert
Date: 2025.03.28 20:05:00 -04'00'

Karli Plenert
Sr Director, Regulatory Affairs

Intended Purpose

Intended Use

The BIOFIRE® FILMARRAY® Tropical Fever (TF) Panel is an automated, qualitative, multiplexed polymerase chain reaction (PCR) test intended for use with BIOFIRE® FILMARRAY® 2.0 and BIOFIRE® FILMARRAY® TORCH Systems. The BIOFIRE FILMARRAY TF Panel detects and identifies selected bacterial, viral, and parasitic nucleic acids directly from EDTA whole blood collected from individuals with signs and/or symptoms of acute febrile illness or recent acute febrile illness and known or suspected exposure to the following target pathogens: chikungunya virus, dengue virus (serotypes 1, 2, 3 and 4), Leptospira spp., and Plasmodium spp. (including species differentiation of Plasmodium falciparum and Plasmodium vivax/ovale).

Evaluation for more common causes of acute febrile illness (e.g., infections of the upper and lower respiratory tract or gastroenteritis, as well as non-infectious causes) should be considered prior to evaluation with this panel. Results are meant to be used in conjunction with other clinical, epidemiologic, and laboratory data, in accordance with the guidelines provided by the relevant public health authorities.

The BIOFIRE FILMARRAY TF Panel is not intended to be used as the sole basis for diagnosis, treatment, or other management decisions. Positive results do not rule out co-infection with other organisms not included on the BIOFIRE FILMARRAY TF Panel, nor do negative results rule out infection. Negative results from the BIOFIRE FILMARRAY TF Panel may require additional testing if clinically indicated. Not all pathogens that cause acute febrile illness are detected by this test, and negative results do not rule out the presence of other infections.

In the United States, patient travel history, exposure risk, and consultation of the CDC Yellow Book should be considered prior to use of the BIOFIRE FILMARRAY TF Panel as some pathogens are more common in certain geographical locations.

Intended User and Use Environment

The BIOFIRE FILMARRAY TF Panel is intended for use by trained medical and laboratory professionals in a laboratory setting or under the supervision of a trained laboratory professional.