



FilmArray® TF Control Panel M527

INTENDED USE:

The FilmArray® TF Control Panel M527 is intended for use as an external positive and negative assayed quality control to monitor the performance of in vitro laboratory nucleic acid testing procedures for the qualitative detection of viral, bacterial, and parasitic pathogens: Chikungunya virus, Dengue virus, *Plasmodium spp.*, *Plasmodium falciparum*, *Plasmodium vivax/ovale*, and *Leptospira spp.* on the BIOFIRE® FILMARRAY Tropical Fever Panel performed on the BIOFIRE FILMARRAY 2.0 or Torch systems.

PRODUCT SUMMARY and PRINCIPLE:

FilmArray TF Control Panel M527 is composed of 2 controls, FilmArray TF Positive and FilmArray TF Negative. FilmArray TF Positive is composed of synthetic DNA and RNA corresponding to genome segments of pathogens listed as detected in Table 1. FilmArray TF Negative does not contain nucleic acid.

Quality controls can be used for validation, verification, proficiency assessment, and training procedures. Routine use of quality controls that are consistent lot to lot assists the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents. Early investigation can prevent failed assay runs. At a minimum, controls should be run at the frequency recommended by the BIOFIRE FILMARRAY Tropical Fever Panel assay manufacturer's recommendations for external quality control testing.

COMPOSITION:

FilmArray TF Control Panel M527 is comprised of 12 tubes, 200µL each, 6 tubes of FilmArray TF Positive, and 6 tubes of FilmArray TF Negative. The controls are composed of synthetic DNA and RNA suspended in a non-infectious solution of buffers, preservatives, and stabilizers. Table 1 lists the pathogens that are detected in the FilmArray TF Control Panel M527 when tested by the BIOFIRE FILMARRAY Tropical Fever Panel assay on the BIOFIRE FILMARRAY 2.0 or Torch systems.

STORAGE and STABILITY:

FilmArray TF Control Panel M527 can be shipped on dry ice or cold packs, and should be stored at 2°C – 8°C upon receipt. Unopened FilmArray TF Control Panel M527 is stable through the expiration date printed on the kit label when consistently stored refrigerated. FilmArray TF Positive and FilmArray TF Negative are for single use. Discard after use according to your local and federal regulations.

PRECAUTIONS and WARNINGS:

- Use the control as provided. Do not dilute.
- This product is intended for *In Vitro* analytical testing and is provided for Research Use only.
- This product is only for use with BIOFIRE FILMARRAY Tropical Fever Panel on the BIOFIRE FILMARRAY Torch or 2.0 systems. It does not contain the entire genome of the pathogens listed in Table 1.
- This product is not intended for use as a substitute for the internal controls provided in the BIOFIRE FILMARRAY Tropical Fever Panel.
- This product does not contain any biological material of human or animal origin. Universal Precautions are NOT required when handling this product.
- Quality control materials should be used in accordance with local, state, federal regulations and accreditation requirements.
- FilmArray TF Control Panel M527 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

INSTRUCTIONS FOR USE:

1. Allow the control to be tested to come to room temperature (18° – 25°C) for approximately 15 minutes.
2. Use the control as provided. **DO NOT DILUTE.**
3. Immediately before use, mix the control **thoroughly** by inverting 3-5 times. Gently tap the tube 3 times on the bench to remove any control caught in the cap before opening the tube.
4. Prepare, hydrate and load the BIOFIRE FILMARRAY Tropical Fever Panel pouch, as you would a patient whole blood specimen, according to BIOFIRE FILMARRAY Tropical Fever Panel Instructions for Use or Quick Guide.
*Note: It is important to **thoroughly** mix the QC sample with the Sample Buffer by inverting the Sample Injection Vial 3 times, as described in the Quick Guide.*
5. Discard after use according to your local and federal regulations.

For complete BIOFIRE FILMARRAY Tropical Fever Panel instructions, refer to the appropriate Quick Guide or Instruction Booklet provided by BioFire Diagnostics, LLC.

EXPECTED VALUES:

The expected results when controls are analyzed with BIOFIRE FILMARRAY Tropical Fever Panel are listed in Table 1.

Table 1: FilmArray TF Positive & Negative Control Result Summary:

FilmArray TF Positive Result Summary		
Result Summary		
Viruses		
✓	Detected	Chikungunya virus
✓	Detected	Dengue virus
Parasites		
✓	Detected	<i>Plasmodium spp.</i>
✓	Detected	<i>Plasmodium falciparum</i>
✓	Detected	<i>Plasmodium vivax/ovale</i>
Bacteria		
✓	Detected	<i>Leptospira spp.</i>
FilmArray TF Negative Result Summary		
Result Summary		
Viruses		
Not Detected	Not Detected	Chikungunya virus
Not Detected	Not Detected	Dengue virus
Parasites		
Not Detected	Not Detected	<i>Plasmodium spp.</i>
Not Detected	Not Detected	<i>Plasmodium falciparum</i>
Not Detected	Not Detected	<i>Plasmodium vivax/ovale</i>
Bacteria		
Not Detected	Not Detected	<i>Leptospira spp.</i>

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ORDERING INFORMATION:

FilmArray TF Control Panel M527

Part Number: M527

Kit Contains: 12 tubes x 200µL
6 each of Positive & Negative