



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 (serotypes 1, 2, 3, and 4), *Leptospira* spp., *Plasmodium* spp. (including species differentiation of *Plasmodium falciparum* and *Plasmodium vivax/ovale*) on the BIOFIRE® FILMARRAY Tropical Fever Panel performed on the BIOFIRE FILMARRAY Systems. This product is not intended to replace manufacturer internal controls provided with this device.

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 routine monitoring of test systems, validation, verification, proficiency assessment, and training procedures. Quality controls that are consistent from lot to lot assist the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents, malfunctioning equipment, or environmental contamination. Early investigation can prevent failed assay runs and incorrect patient test results.

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 Systems.

STORAGE and STABILITY:

FilmArray TF Control Panel M527 can be shipped on dry ice or cold packs, depending on destination, and should be stored refrigerated (2°C to 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, not for diagnostic procedures.
- This product is only for use solely with BIOFIRE FILMARRAY Tropical Fever Panel on the BIOFIRE FILMARRAY Systems. It does not contain the entire genome of the pathogens listed in Table 1.
- Appearance: Positive control is slightly cloudy; Negative control is clear.
- Quality control materials should be used in accordance with local, state, and federal regulations and accreditation requirements.
- This product does not contain any biological material of human or animal origin. Universal Precautions are NOT required when handling this product.
- 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°C to 25°C) before use, for approximately 30 minutes if frozen due to dry ice shipping.
2. Use the control as provided. **Do Not Dilute.**
3. Immediately before use, mix the control **thoroughly** by flicking the tubes 3 times followed by inverting at least 3 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 FilmArray TF Control Panel M527 is tested with the 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</i> spp.
✓	Detected	<i>Plasmodium falciparum</i>
✓	Detected	<i>Plasmodium vivax/ovale</i>
Bacteria		
✓	Detected	<i>Leptospira</i> spp.
FilmArray TF Negative Result Summary		
Result Summary		
Viruses		
	Not Detected	Chikungunya virus
	Not Detected	Dengue virus
Parasites		
	Not Detected	<i>Plasmodium</i> spp.
	Not Detected	<i>Plasmodium falciparum</i>
	Not Detected	<i>Plasmodium vivax/ovale</i>
Bacteria		
	Not Detected	<i>Leptospira</i> spp.

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ORDERING INFORMATION:

FilmArray TF Control Panel M527

Part Number: M527-R

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