



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 the BIOFIRE® FILMARRAY Tropical Fever (TF) Panel assay on the BIOFIRE FILMARRAY Systems. The BIOFIRE FILMARRAY TF Panel assay qualitatively detects the following target 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*). The FilmArray TF Positive control is composed of synthetic DNA and RNA in stabilizing solutions, buffers, and preservatives. The FilmArray TF Negative control contains buffers and preservatives. The FilmArray TF Control Panel M527 is designed for and intended to be used solely with the BIOFIRE FILMARRAY TF Panel. 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 contains surrogate control material composed of synthetic DNA and RNA corresponding to genome segments of the pathogens listed as detected in Table 1. FilmArray TF Negative does not contain nucleic acid and serves as a true negative control to monitor contamination.

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 contamination. Early investigation can prevent failed assay runs.

COMPOSITION:

FilmArray TF Control Panel M527 is comprised of 12 single-use tubes, 200µL each, 6 tubes of FilmArray TF Positive, and 6 tubes of FilmArray TF Negative. The FilmArray TF Positive control is composed of synthetic DNA and RNA suspended in a non-infectious solution of buffers, preservatives, and stabilizers. Tables 1 and 2 list the pathogens that are detected in the FilmArray TF Control Panel M527 when tested by the BIOFIRE FILMARRAY TF Panel assay on the BIOFIRE FILMARRAY Systems. FilmArray TF Negative control contains only buffers and preservatives.

STORAGE and STABILITY:

FilmArray TF Control Panel M527 can be shipped on dry ice or cold packs, depending on destination, 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 2°C – 8°C. FilmArray TF Positive and FilmArray TF Negative are for single use. Discard after use according to your local and federal regulations.

PRECAUTIONS, WARNINGS and LIMITATIONS:

- Use the control as provided. Do not dilute.
- This product is intended for *in vitro* diagnostic use only.
- This product is for use solely with BIOFIRE FILMARRAY TF Panel on BIOFIRE FILMARRAY Systems. It does not contain the entire genome of the pathogens listed in Tables 1 and 2.
- Appearance: Positive control is slightly cloudy; Negative control is clear.
- Quality control materials should be used in accordance with local, state, 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.

ORDERING INFORMATION:

FilmArray TF Control Panel M527

Part Number: M527

Kit Contains: 12 tubes x 200µL

6 each of Positive & Negative

INSTRUCTIONS FOR USE:

1. Allow the control to be tested to come completely to room temperature (18° – 25°C) before use, 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 first 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 TF Panel pouch, as you would a patient whole blood specimen, according to BIOFIRE FILMARRAY TF 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 TF Panel instructions, refer to the appropriate Quick Guide or Instructions for Use provided by BioFire Diagnostics, LLC.

EXPECTED VALUES:

The expected results when FilmArray TF Control Panel M527 is tested with the BIOFIRE FILMARRAY TF Panel are listed in Tables 1 and 2.

Table 1. FilmArray TF Positive Control

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.

Table 2. FilmArray TF Negative Control

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

REPRESENTATIVE PERFORMANCE DATA:

Three (3) lots of FilmArray TF Positive and 3 lots of FilmArray TF Negative were tested with the BIOFIRE FILMARRAY TF Panel on BIOFIRE FILMARRAY systems at 3 sites. A total of 255 control samples were tested, incorporating 9 unique pouch lots, multiple operators, and instruments. Of the 255 samples tested, 3 results were invalid and the remaining 252 valid results were correct calls, for a rate of 100% correct results.

Summary of Performance Data for FilmArray TF Control Panel M527									
Site	Total Tests	Invalid*	Correct Pos Control Results	Incorrect Pos Control Results	Percent Correct Pos	Correct Neg Control Results	Incorrect Neg Control Results	Percent Correct Neg	Total Percent Correct
1	120	0	60	0	100%	60	0	100%	100%
2	73	1	36	0	100%	36	0	100%	100%
3	62	2	30	0	100%	30	0	100%	100%
Total	255	3	126	0	100%	126	0	100%	100%

*Invalid results are not included in percent correct.

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