

BioFire® ME Control Panel M262

English

INTENDED USE:

BioFire® ME Control Panel M262 is intended for use as an external positive and negative quality control to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of *Escherichia coli* K1, *Haemophilus influenzae*, *Listeria monocytogenes*, *Neisseria meningitidis*, *Streptococcus agalactiae*, *Streptococcus pneumoniae*, Cytomegalovirus, Enterovirus, Herpes simplex virus 1, Herpes simplex virus 2, Human herpesvirus 6, Human parechovirus, Varicella zoster virus and *Cryptococcus neoformans/gattii* with the BioFire FilmArray® Meningitis/Encephalitis (ME) Panel assay performed on BioFire FilmArray systems. Meningitis (infection of meninges surrounding the brain and spinal cord) and encephalitis (infection of the brain) may be fatal depending on the infectious agent. Clinical symptoms caused by a wide variety of pathogens are often indistinguishable. Therefore, rapid laboratory diagnosis is critical to initiate and guide treatment.

PRODUCT SUMMARY and PRINCIPLE:

BioFire ME Control Panel M262 is composed of 2 controls, BioFire ME Positive M263 and BioFire ME Negative M264. BioFire ME Positive M263 contains synthetic RNA corresponding to genome segments of pathogens listed in Table 1. BioFire ME Negative M264 contains non-target RNA. The synthetic RNA is specifically designed for and intended to be used solely with the BioFire FilmArray ME Panel on the BioFire FilmArray System.

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.

COMPOSITION:

The BioFire ME Control Panel M262 is comprised of 12 single use tubes, 6 tubes of BioFire ME Positive M263 and 6 tubes of BioFire ME Negative M264, 200µL each. BioFire ME Positive M263 control contains synthetic RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. BioFire ME Negative M264 control contains buffers and preservatives. Table 1 lists the pathogens that are detected in the BioFire ME Positive M263 when tested with the BioFire FilmArray ME Panel.

INSTRUCTIONS FOR USE:

1. Allow the control to be tested to come to room temperature (18° – 25°C), **approximately 30 minutes**.
2. Use the control as provided. **DO NOT DILUTE**.
3. Immediately before use, **mix the control thoroughly by first inverting several times followed by vortexing the tube for 3-5 seconds**. Tap the tube several times on the bench to remove any control caught in the cap before opening the tube.
4. Prepare Sample Mix according to BioFire instructions, being sure to invert the control and sample buffer mixture **at least 3 times**. Load and run a BioFire FilmArray ME Pouch, using the control as you would use a patient specimen, according to BioFire FilmArray ME Quick Guide or Instructions for Use.
5. Discard after use according to your local and federal regulations.

PRECAUTIONS and WARNINGS:

- Do not dilute. Use the control as provided.
- This product is intended for *in vitro* diagnostic use only.
- This product is only for use with BioFire FilmArray ME Panel on the BioFire FilmArray systems. It does not contain the entire genome of the pathogens listed in Tables 1 and 2.
- Appearance: cloudy
- 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.
- BioFire ME Control Panel M262 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

STORAGE and STABILITY:

BioFire ME Control Panel M262 should be stored frozen (-25°C to -15°C). Unopened BioFire ME Control Panel M262 is stable through the expiration date printed on the kit label when consistently stored frozen. BioFire ME Positive M263 and BioFire ME Negative M264 are for single use. Discard after use according to your local and federal regulations.

EXPECTED VALUES:

The expected results when the controls are analyzed are listed in Table 1 & 2.

Table 1: BioFire ME Positive M263 FilmArray Result Summary

Result Summary	
Bacteria	
✓Detected	<i>Escherichia coli</i> K1
✓Detected	<i>Haemophilus influenzae</i>
✓Detected	<i>Listeria monocytogenes</i>
✓Detected	<i>Neisseria meningitidis</i>
✓Detected	<i>Streptococcus agalactiae</i>
✓Detected	<i>Streptococcus pneumoniae</i>
Viruses	
✓Detected	Cytomegalovirus
✓Detected	Enterovirus
✓Detected	Herpes simplex virus 1
✓Detected	Herpes simplex virus 2
✓Detected	Human herpesvirus 6
✓Detected	Human parechovirus
✓Detected	Varicella zoster virus
Yeast	
✓Detected	<i>Cryptococcus neoformans/gattii</i>

Table 2: BioFire ME Negative M264 FilmArray Result Summary

Result Summary	
Bacteria	
Not Detected	<i>Escherichia coli</i> K1
Not Detected	<i>Haemophilus influenzae</i>
Not Detected	<i>Listeria monocytogenes</i>
Not Detected	<i>Neisseria meningitidis</i>
Not Detected	<i>Streptococcus agalactiae</i>
Not Detected	<i>Streptococcus pneumoniae</i>
Viruses	
Not Detected	Cytomegalovirus
Not Detected	Enterovirus
Not Detected	Herpes simplex virus 1
Not Detected	Herpes simplex virus 2
Not Detected	Human herpesvirus 6
Not Detected	Human parechovirus
Not Detected	Varicella zoster virus
Yeast	
Not Detected	<i>Cryptococcus neoformans/gattii</i>

ORDERING INFORMATION:

BioFire® ME Control Panel M262

Part Number: M262

CONT Kit Contains: 12 tubes x 200µL

6 Positive (+) controls and 6 Negative (-) controls

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