



FilmArray® GI Control Panel M238

INTENDED USE:

The FilmArray® GI Control Panel M238 is intended for use (as applicable) as an external positive and negative quality control for nucleic acid testing procedures to monitor the qualitative detection and identification of *Campylobacter*, *Campylobacter (C. jejuni/C. coli/C. upsaliensis)*, *Clostridium difficile* toxin A/B, *Clostridioides (Clostridium) difficile* (toxin A/B), *Plesiomonas shigelloides*, *Salmonella*, *Vibrio cholerae*, *Vibrio (V. parahaemolyticus/V. vulnificus/V. cholerae)*, *Yersinia enterocolitica*, Enteroaggregative *E. coli* (EAEC), Enteropathogenic *E. coli* (EPEC), Enterotoxigenic *E. coli* (ETEC) *lt/st*, Shiga-like toxin-producing *E. coli* (STEC) *stx1/stx2*, *E. coli* O157, *Shigella*/Enteroinvasive *E. coli* (EIEC), *Cryptosporidium*, *Cyclospora cayetanensis*, *Entamoeba histolytica*, *Giardia lamblia*, Adenovirus F 40/41, Astrovirus, Norovirus GI/GII, Rotavirus A, and Sapovirus with the BIOFIRE® FILMARRAY Gastrointestinal (GI) Panel and the BIOFIRE FILMARRAY Gastrointestinal (GI) Panel Mid assays on the BIOFIRE FILMARRAY systems. Detection of the viruses, bacteria and protozoa listed in Tables 1 and 2 are an important aid to the diagnosis of gastrointestinal illness.

PRODUCT SUMMARY and PRINCIPLE:

FilmArray GI Control Panel M238 is composed of 2 controls, FilmArray GI Control M239 and FilmArray GI Control M240, both containing synthetic RNA corresponding to genome segments of pathogens listed in Tables 1 and 2. The synthetic RNA is specifically designed for and intended to be used solely with the BIOFIRE GI Panel and BIOFIRE GI Panel Mid on the BIOFIRE FILMARRAY System.

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 or malfunctioning equipment. Early investigation can prevent failed assay runs.

COMPOSITION:

The FilmArray GI Control Panel M238 is comprised of 12 single use tubes, 6 tubes of FilmArray GI Control M239 and 6 tubes of FilmArray GI Control M240, 200µL each. The controls contain synthetic 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 GI Control Panel M238 when tested by the BIOFIRE GI Panel and BIOFIRE GI Panel Mid assays.

STORAGE and STABILITY:

FilmArray GI Control Panel M238 should be stored frozen (-25°C to -15°C). Unopened FilmArray GI Control Panel M238 is stable through the expiration date printed on the kit label when consistently stored frozen. FilmArray GI Control M239 and FilmArray GI Control M240 are for single use. 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* analytical testing and is provided for Research Use Only, not for diagnostic procedures.
- This product is only for use with BIOFIRE GI Panel or BIOFIRE GI Panel Mid assay 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.
- FilmArray GI Control Panel M238 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), **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 GI Panel Pouch or BIOFIRE GI Panel Mid Pouch, using the control as you would use a patient specimen, according to BIOFIRE GI Panel or BIOFIRE GI Panel Mid Quick Guide or Instructions for Use.
5. Discard after use according to your local and federal regulations.

EXPECTED VALUES:

The expected results when the controls are analyzed with BIOFIRE assays are listed in Tables 1 and 2.

Table 1: BIOFIRE GI Panel Result Summary

Assay	M239 Call	M240 Call
Bacteria		
<i>Campylobacter</i>	Not Detected	Detected
<i>Clostridium difficile</i> toxin A/B	Detected	Not Detected
<i>Plesiomonas shigelloides</i>	Detected	Not Detected
<i>Salmonella</i>	Not Detected	Detected
<i>Vibrio</i>	Detected	Not Detected
<i>Vibrio cholerae</i>	Detected	Not Detected
<i>Yersinia enterocolitica</i>	Detected	Not Detected
Diarrheagenic E. coli/Shigella		
Enteroaggregative <i>E. coli</i> (EAEC)	Detected	Not Detected
Enteropathogenic <i>E. coli</i> (EPEC)	Ø N/A	Detected
Enterotoxigenic <i>E. coli</i> (ETEC) <i>lt/st</i>	Not Detected	Detected
Shiga-like toxin-producing <i>E. coli</i> (STEC) <i>stx1/stx2</i>	Detected	Not Detected
<i>E. coli</i> O157	Detected	Ø N/A
<i>Shigella</i> /Enteroinvasive <i>E. coli</i> (EIEC)	Detected	Not Detected
Parasites		
<i>Cryptosporidium</i>	Detected	Not Detected
<i>Cyclospora cayetanensis</i>	Not Detected	Detected
<i>Entamoeba histolytica</i>	Not Detected	Detected
<i>Giardia lamblia</i>	Not Detected	Detected
Viruses		
Adenovirus F 40/41	Detected	Not Detected
Astrovirus	Not Detected	Detected
Norovirus GI/GII	Not Detected	Detected
Rotavirus A	Not Detected	Detected
Sapovirus	Detected	Not Detected

Table 2: BIOFIRE GI Panel Mid Result Summary

Assay	M239 Call	M240 Call
Bacteria		
<i>Campylobacter (C. jejuni/C. coli/C. upsaliensis)</i>	Not Detected	Detected
<i>Clostridioides (Clostridium) difficile</i> (toxin A/B)	Detected	Not Detected
<i>Salmonella</i>	Not Detected	Detected
Shiga-like toxin-producing <i>E. coli</i> (STEC) <i>stx1/stx2</i>	Detected	Not Detected
<i>Shigella</i> /Enteroinvasive <i>E. coli</i> (EIEC)	Detected	Not Detected
<i>Vibrio (V. parahaemolyticus/V. vulnificus/V. cholerae)</i>	Detected	Not Detected
<i>Yersinia enterocolitica</i>	Detected	Not Detected
Parasites		
<i>Cryptosporidium</i>	Detected	Not Detected
<i>Cyclospora cayetanensis</i>	Not Detected	Detected
<i>Giardia lamblia</i>	Not Detected	Detected
Viruses		
Norovirus GI/GII	Not Detected	Detected

ORDERING INFORMATION:

FilmArray® GI Control Panel M238
Part Number: M238

CONT Kit Contains: 12 tubes x 200µL
 6 each of M239 & M240