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FilmArray® GI Control Panel M238

INTENDED USE:

The FilmArray® GI Control Panel M238 is intended for use as an external positive and negative assayed quality control to monitor performance of the BIOFIRE® FILMARRAY Gastrointestinal (GI) Panel and the BIOFIRE FILMARRAY Gastrointestinal (GI) Panel Mid assays on the BIOFIRE FILMARRAY systems. BIOFIRE FILMARRAY Gastrointestinal (GI) Panel and the BIOFIRE FILMARRAY Gastrointestinal (GI) Panel Mid assays qualitatively detect the following targets: *Campylobacter* (*C. jejuni*/*C. coli*/*C. upsaliensis*), *Clostridium* (*Clostridioides*) *difficile* toxin A/B, *Plesiomonas shigelloides*, *Salmonella*, *Vibrio* (*V. parahaemolyticus*/*V. vulnificus*/*V. cholerae*), *Yersinia enterocolitica*, Enterotoxigenic *E. coli* (EPEC), 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. The FilmArray GI Control Panel M238 contains synthetic RNA transcripts in stabilizing solution, buffers, and preservatives. The FilmArray GI Control Panel M238 is designed for and intended to be used solely with the BIOFIRE FILMARRAY GI Panel and the BIOFIRE FILMARRAY GI Panel Mid assays. This product is not intended to replace manufacturer internal controls provided with these devices.

PRODUCT SUMMARY and PRINCIPLE:

FilmArray GI Control Panel M238 is composed of 2 controls, FilmArray GI Control M239 and FilmArray GI Control M240, both of which contain surrogate control material composed of synthetic RNA corresponding to genome segments of pathogens, as listed in Tables 1 and 2. FilmArray GI Control M239 serves as a negative control for those pathogens found in FilmArray GI Control M240, and FilmArray GI Control M240 serves as a negative control for those pathogens found in FilmArray GI Control M239.

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. The FilmArray GI Control Panel M238 does not contain the entire genome of the pathogens listed in Tables 1 and 2.

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, WARNINGS and LIMITATIONS:

- Do not dilute. Use the control as provided.
- This product is intended for *in vitro* diagnostic use only.
- This product is for use solely with BIOFIRE FILMARRAY GI Panel or BIOFIRE FILMARRAY 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.
- Quality control materials should be used in accordance with local, state, and federal regulations and accreditation requirements.
- Appearance: cloudy
- This product does not contain any biological material of human or animal origin. Universal Precautions are NOT required when handling this product.
- FilmArray GI Control Panel M238 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

INSTRUCTIONS FOR USE:

- Allow the control to be tested to come completely to room temperature (18° to 25°C), **approximately 30 minutes**.
- Use the control as provided. **DO NOT DILUTE**.
- 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.
- 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 GI Panel Pouch or BIOFIRE FILMARRAY GI Panel Mid Pouch, using the control as you would use a patient specimen, according to BIOFIRE FILMARRAY GI Panel or BIOFIRE FILMARRAY GI Panel Mid Quick Guide or Instructions for Use.
- Discard after use according to your local and federal regulations.

ORDERING INFORMATION:

FilmArray GI Control Panel M238

Part Number: M238

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

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EXPECTED VALUES:

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

Table 1: BIOFIRE FILMARRAY 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		
Enterotoxigenic <i>E. coli</i> (EPEC)	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

* EPEC will be reported as N/A (Not Applicable) regardless of the EPEC assay result when STEC is detected.

** *E. coli* O157 will be reported as N/A (Not Applicable) when STEC is not detected.

Table 2: BIOFIRE FILMARRAY GI Panel Mid Result Summary

Assay	M239 Call	M240 Call
Bacteria		
<i>Campylobacter</i> (<i>C. jejuni</i> / <i>C. coli</i> / <i>C. upsaliensis</i>)	Not Detected	Detected
<i>Clostridioides</i> (<i>Clostridium</i>) <i>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</i> (<i>V. parahaemolyticus</i> / <i>V. vulnificus</i> / <i>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

REPRESENTATIVE PERFORMANCE DATA:

Six (6) lots of FilmArray GI Control M239 and 6 lots of FilmArray GI Control M240 were tested with the BIOFIRE FILMARRAY GI Panel or the BIOFIRE FILMARRAY GI Panel Mid assays on the BIOFIRE FILMARRAY systems at two sites. A total of 165 control samples were tested, incorporating 20 pouch lots and multiple operators and instruments. Of the 165 samples tested, there were 0 Invalid test results and 165 correct results, for a rate of 100% correct results.

Summary of Performance Data for FilmArray GI Control Panel M238									
Site	Total Tests	Invalid	Correct M239 Results	Incorrect M239 Results	Percent Correct M239	Correct M240 Results	Incorrect M240 Results	Percent Correct M240	Total Percent Correct
1	40	0	20	0	100%	20	0	100%	100%
2	125	0	59	0	100%	66	0	100%	100%
Total	165	0	79	0	100%	86	0	100%	100%



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