

## FilmArray® GI Control Panel M238

### INTENDED USE:

The FilmArray® GI Control Panel M238 is intended for *in vitro* use as a quality control to monitor the detection and identification of multiple gastrointestinal pathogens as performed by the FilmArray® Gastrointestinal (GI) Panel assay on the FilmArray® instrument. Detection of the viruses, bacteria and protozoa listed in Table 1 is an important aid to the diagnosis of gastrointestinal illness.

FilmArray® GI Control Panel M238 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

### PRODUCT SUMMARY and PRINCIPLE:

FilmArray® GI Control Panel M238 is comprised of synthetic RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers.

Best practice is to establish a quality control program for every assay performed by the laboratory.<sup>1, 2</sup> 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 FilmArray® GI Control Panel M238 is comprised of 12 tubes, 200µL each, containing synthetic RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. Table 1 lists the pathogens that are monitored by the FilmArray® GI Control Panel M238 when tested by the FilmArray® Gastrointestinal Panel on the FilmArray® instrument.

### 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 continuously 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.

### INSTRUCTIONS FOR USE:

1. Allow the control to be tested to come to room temperature (18° – 25°C).
2. Use the control as provided. **DO NOT DILUTE.**
3. Prepare and hydrate a pouch according to FilmArray® Instructions.
4. Immediately before use, mix the control by briefly vortexing the tube for 3 – 5 seconds and then shake the tube down firmly to remove any droplets caught in the cap.
5. Using the FilmArray® transfer pipette, draw up the control to 2<sup>nd</sup> line.
6. Analyze the control as you would a patient sample by adding the control to the FilmArray® Sample Buffer.
7. Discard after use according to your local and federal regulations.

### PRECAUTIONS and WARNINGS:

- Do not dilute.
- This product is intended for *in vitro* analytical testing and is provided for Research Use Only, not for use in diagnostic procedures.
- This product does not contain any biological material of human or animal origin.

### EXPECTED VALUES:

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for FilmArray® GI Control Panel M238 in demonstrating adequate system performance. Recoveries may vary depending on instrumentation, reagents and systematic or random errors. The expected results when the controls are analyzed are listed in Table 1.

**Table 1: FilmArray® Result Summary Interpretation**

| Assay   | M2393718<br>Call | M2402818<br>Call |
|---|------------------|------------------|
| <b>Bacteria</b>   |                  |                  |
| <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     |
| <b>Diarrheagenic <i>E.coli</i>/Shigella</b>                       |                  |                  |
| Enteropathogenic <i>E. coli</i> (EPEC)                            | Detected         | Not Detected     |
| Enterotoxigenic <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     |
| <b>Parasites</b>  |                  |                  |
| <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         |
| <b>Viruses</b>  |                  |                  |
| 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     |

### ORDERING INFORMATION:

FilmArray® GI Control Panel M238  
**Part Number: M238**  
 Kit Contains: 12 tubes x 200 µL  
 6 each of M2393718 & M2402818

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1. ISO 15189: Medical laboratories – Particular requirements for quality and competence.
2. CAP Molecular Pathology Checklist; Commission on Laboratory Accreditation, Laboratory Accreditation Program, Mol.20000