510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K251526

B Applicant

Maine Molecular Quality Controls, Inc.

C Proprietary and Established Names

FilmArray GI Control Panel M238

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PMN	Class II	21 CFR 866.3920 - Assayed Quality Control Material For Clinical Microbiology Assays	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain a substantial equivalence determination for the FilmArray GI Control Panel M238.

B Measurand:

Multi-analyte quality control materials

C Type of Test:

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*, 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. 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.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for 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*, 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. 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

For use on the BIOFIRE FILMARRAY Torch and BIOFIRE FILMARRAY 2.0 instrument systems

IV Device/System Characteristics:

A Device Description:

FilmArray GI Control Panel M238, is a quality control panel consisting of 2 single use, ready-to-use, liquid controls, FilmArray GI Control M239 and FilmArray GI Control M240. Each kit of FilmArray GI Control Panel M238 is comprised of 6 tubes of M239 and 6 tubes of M240. Together the 2 controls contain synthetic RNA corresponding to genome segments of all the pathogens detected by the BIOFIRE FILMARRAY Gastrointestinal (GI) Panel and BIOFIRE FILMARRAY GI Panel Mid assays, suspended in a non-infectious solution of buffers, preservatives and stabilizers.

Each liquid control provided with the FilmArray GI Control Panel M238 is processed separately according to the manufacturer's Instructions for Use for testing patient samples on both the BIOFIRE FILMARRAY GI Panel and BIOFIRE FILMARRAY GI Panel Mid assays.

The FilmArray GI Control Panel M238 is intended for use as external positive and negative quality controls to monitor the detection and identification of the GI pathogens detected by BIOFIRE FILMARRAY Gastrointestinal (GI) Panel (Table 1), and BIOFIRE FILMARRAY GI Panel Mid (Table 2).

Table 1. Bacteria, Viruses, and Parasites Detected by the BIOFIRE FILMARRAY GI Panel

Bacteria	Viruses
Campylobacter (C. jejuni/C. coli/ C. upsaliensis)	Adenovirus F 40/41
Clostridium difficile (toxin A/B)	Astrovirus
Plesiomonas shigelloides	Norovirus GI/GII
Salmonella	Rotavirus A
Vibrio (V. parahaemolyticus/V. vulnificus/ V. cholerae)	Sapovirus (Genogroups I, II, IV, and V)
V. cholerae	
Yersinia enterocolitica	
Diarrheagenic *E. coli/Shigella*	**Parasites**
Enteroaggregative *E. coli* (EAEC)	*Cryptosporidium*
Enteropathogenic *E. coli* (EPEC)	*Cyclospora cayetanensis*
Enterotoxigenic E. coli (ETEC) lt/st	*Entamoeba histolytica*
Shiga-like toxin-producing *E. coli* (STEC) *stx1/stx2*	*Giardia lamblia*
E. coli O157	
Shigella/Enteroinvasive *E. coli* (EIEC)	

Table 2. Bacteria, Viruses, and Parasites Detected by the BIOFIRE FILMARRAY GI Panel Mid

Bacteria	Viruses
Campylobacter (C. jejuni/C. coli/ C. upsaliensis)	Norovirus GI/GII
Clostridioides (Clostridium) difficile (toxin A/B)	
Salmonella	

Shiga-like toxin-producing *E. coli* (STEC) *stx1/stx2*	**Parasites**
*Shigella/*Enteroinvasive *E. coli* (EIEC)	*Cryptosporidium*
Vibrio (V. parahaemolyticus/V. vulnificus/ V. cholerae)	*Cyclospora cayetanensis*
Yersinia enterocolitica	*Giardia lamblia*

When used together, both tubes detect all the organisms detected by BIOFIRE GI Panel and the BIOFIRE GI Panel Mid assays. Since there is no overlap of organisms between M239 and M240, each tube may serve as negative control for the organisms contained in the other tube.

The synthetic RNA contained in controls M239 and M240 is specifically designed for and intended to be used solely with the BIOFIRE GI Panel and the BIOFIRE GI Panel Mid on the BIOFIRE FILMARRAY Torch and the BIOFIRE FILMARRAY Systems.

Table 3. FilmArray GI Control Panel M238 Contents

FilmArray GI Control M239	FilmArray GI Control M240
E.coli 0157	Astrovirus
Enteroaggregative *E. coli* (EAEC)	*Campylobacter* 1
Shiga-like toxin-producing *E. coli* (STEC) *stx1/stx 2*	*Enteropathogenic E. coli* (EPEC)
Sapovirus (Genogroups I, II, IV, and V)	Enterotoxigenic E. coli (ETEC) l*t/st* 2
Shigella/Enteroinvasive *E. coli* (EIEC)	*Giardia lamblia*
Cryptosporidium 1	*Salmonella*
Clostridium difficile (toxin A/B)	*Campylobacter* 2
Vibrio cholerae	Enterotoxigenic E. coli (ETEC) *lt/st* 1
Adenovirus F 40/41	*Cyclospora cayetanensis*
Vibrio	Enterotoxigenic E. coli (ETEC) l*t/st* 3
Plesiomonas shigelloides	*Entamoeba histolytica*
Cryptosporidium 1	Enterotoxigenic E. coli (ETEC) l*t/st* 3
Yersinia enterocolitica	Rotavirus A 1
	Rotavirus A 2
	Norovirus GI/GII 1
	Norovirus GI/GII 2

B Principle of Operation:

Each liquid control provided with the FilmArray GI Control Panel M238 is processed separately according to the manufacturer's Instructions for Use for testing patient samples on both the BIOFIRE FILMARRAY GI Panel and BIOFIRE FILMARRAY GI Panel Mid assays. Results are reported automatically by the FilmArray GI Control Panel M238 Software as either "Detected", "Undetected" or "INVALID [failure reason]".

V Substantial Equivalence Information:

A Predicate Device Name(s):

BioFire RP2.1/RP2.1plus Control Panel M441

B Predicate 510(k) Number(s):
K202196

C Comparison with Predicate(s):

Device & Predicate Device(s):	K251526	K202196
Device Trade Name	FilmArray GI Control Panel M238	BioFire RP2.1/RP2.1plus Control Panel M441
General Device Characteristic Similarities		
Intended Use/Indications For 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)*,	BioFire RP2.1/RP2.1plus Control Panel M441 is intended for use as an external positive and negative assayed quality control to monitor the performance of in vitro laboratory nucleic acid testing procedures for the qualitative detection of Adenovirus, Coronavirus, Human Metapneumovirus, Human Rhinovirus/ Enterovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H1-2009, Influenza A subtype H3, Influenza B, Middle East Respiratory Syndrome Coronavirus, Parainfluenza Virus, Respiratory Syncytial Virus, Severe Acute Respiratory Syndrome Coronavirus 2, *Bordetella parapertussis, Bordetella pertussis, Chlamydia pneumoniae,* and *Mycoplasma pneumoniae* on the BIOFIRE Respiratory

Device & Predicate Device(s):	K251526	K202196
	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. 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.	Panel 2.1 (RP2.1), BIOFIRE Respiratory Panel 2.1 plus (RP2.1plus) and BIOFIRE Respiratory Panel 2.1-EZ (RP2.1-EZ) assay performed on the BIOFIRE FILMARRAY systems. BIOFIRE RP2.1/RP2.1plus Positive control is composed of synthetic RNA transcripts specifically designed for and intended to be used solely with the BIOFIRE RP2.1, BIOFIRE RP2.1plus and BIOFIRE RP2.1-EZ assay. This product is not intended to replace manufacturer controls provided with the device.
Physical format	Ready-to-Use Liquid	Same
Directions for Use	Process like patient sample	Same

Device & Predicate Device(s):	K251526	K202196
Composition	Synthetic RNA transcripts suspended in a non-infectious solution of buffers, preservatives and stabilizers.	Same
Assay steps monitored	Reverse transcription, amplification, detection, identification	Same
Test System	BIOFIRE FILMARRAY 2.0 and BIOFIRE FILMARRAY Torch	Same
General Device Characteristic Differences		
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*, 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	Adenovirus, Coronavirus, Human Metapneumovirus, Human Rhinovirus/ Enterovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H1-2009, Influenza A subtype H3, Influenza B, Middle East Respiratory Syndrome Coronavirus, Parainfluenza Virus, Respiratory Syncytial Virus, Severe Acute Respiratory Syndrome Coronavirus 2, *Bordetella parapertussis, Bordetella pertussis, Chlamydia pneumoniae*, and *Mycoplasma pneumoniae*

Device & Predicate Device(s):	K251526	K202196
	GI/GII, Rotavirus A, and Sapovirus	
Number of pathogen targets monitored simultaneously in one assay	22	23

VI Standards/Guidance Documents Referenced:

None referenced

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Reproducibility

A reproducibility study was conducted at two sites with the BIOFIRE FILMARRAY GI Panel on BIOFIRE FILMARRAY 2.0 and BIOFIRE FILMARRAY Torch systems. Testing included evaluation of seventy-nine (79) samples of FilmArray GI Control M239 and eighty-six (86) samples of FilmArray GI Control M240 with six lots each on different days across two sites using 20 unique BIOFIRE FILMARRAY GI Panel pouch lots and incorporating 9 operators and multiple instruments, for a total of 165 tests.

Of the 165 samples tested, the correct analytes were detected (for positive controls) or not detected (for negative controls) resulting in a correct call rate of 100% (Table 4).

Table 4: Summary of Performance Data for FilmArray GI Control Panel M238

Site	Total Tests	Invalid	Correct M239 Control Results	Incorrect M239 Control Results	Percent Correct M239 (95% CI)	Correct M240 Results	Incorrect M240 Results	Percent Correct M240 (95% CI)	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% (95.3% - 100%)	86	0	100% (95.7% -100%)	100%

Within-run precision (Repeatability)

Two lot each of FilmArray GI Control M239 and FilmArray GI Control M240 were tested six times on two pouch lot, by the same operator and on the same day to demonstrate within-run precision on the BIOFIRE FILMARRAY 2.0 or BIOFIRE FILMARRAY Torch Systems.

Table 5. Summary of Within-run Precision for FilmArray GI Control Panel M238

Control	Control Lot #	Number of Tests	Correct Results
FilmArray GI Control M239	C08JAN21B	6	6/6
FilmArray GI Control M239	H11NOV21C	6	6/6
FilmArray GI Control M240	F12JAN21B	6	6/6
FilmArray GI Control M240	A16NOV21B	6	6/6

Lot-to-Lot precision

A subset of the reproducibility data generated from the 125 samples of FilmArray GI Control Panel M238 tested at MMQCI was analyzed to demonstrate lot-to-lot variability. Data for 7 samples each of FilmArray GI Control M239 and FilmArray GI Control M240 were analyzed for reproducibility with one pouch lot on 1 BIOFIRE FILMARRAY 2.0 or BIOFIRE FILMARRAY Torch instrument at a single site (MMQCI) with 2 operators.

Table 6. Summary of FilmArray GI Control M239 and FilmArray GI Control M240 Lot-to-Lot Testing

Control	Control Lot #	Number of Tests	Correct Results
FILMARRAY GI M239	E14AUG23B	7	7/7
FILMARRAY GI M239	B01FEB24D	7	7/7
FILMARRAY GI M240	A15AUG23F	7	7/7
FILMARRAY GI M240	C02FEB24C	7	7/7

A Cp data analysis was also conducted for the precision study results and no significant difference in the mean Cp values was observed based on testing of FilmArray GI Control Panel M238 lots on different days by multiple operators at external and internal sites. The reproducibility and precision studies evaluating the FilmArray GI Control Panel M238 are acceptable.

2. Linearity:

   Not applicable.

3. Analytical Specificity/Interference:

   Not applicable

4. Assay Reportable Range:

   Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Open Vial Stability

Not applicable because the FilmArray GI Control Panel M238 is packaged for single use.

Closed Vial Real-time Stability

A closed vial real-time stability study was conducted for the FilmArray GI Control Panel M238 which tested three lots each of FilmArray GI Control M239 and FilmArray GI Control M240 stored at -25 to -15 °C up to 112 months. The real-time stability study for the FilmArray GI Control Panel M238 supports a shelf-life of 36 months under the chosen storage conditions (-25 to -15 °C).

Shipping Stability

A shipping study conducted for the FilmArray GI Control Panel M238 evaluated performance for shipping conditions at frozen -25° to -15°C. One lot each of FilmArray GI Control M239 and FilmArray GI Control M240 were packed for shipping according to dry ice shipping instructions for a simulated 5-day delivery followed by simulating shipping/receiving condition. Testing was performed in duplicate with BIOFIRE FILMARRAY GI Panel on the BIOFIRE FILMARRAY 2.0 or BIOFIRE FILMARRAY Torch systems. Simulated shipping studies for the FilmArray GI Control Panel M238 support shipping under dry ice conditions.

6. Detection Limit:

   Not applicable.

7. Assay Cut-Off:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not applicable.

2. Matrix Comparison:

   The matrix of the FilmArray GI Control Panel M238 is synthetic. To investigate the potential effects of the synthetic matrix on the BIOFIRE FILMARRAY GI Panel assay, equal volumes of the same concentration of Inactivated Salmonella enterica pathogen (acquired from a commercial vendor) were spiked into 270µL of FilmArray GI Control M239 and 270µL of stool in Cary Blair transport media, followed by testing with the BIOFIRE GI Panel assay on the BIOFIRE FILMARRAY 2.0 and BIOFIRE FILMARRAY Torch systems in triplicates. The acceptance criteria were correct results for all spiked stool and spiked synthetic matrix samples.

   Positive expected calls were obtained for the spiked simulated clinical sample and spiked FilmArray GI Control M239 (Detected for *Salmonella enterica*). No inhibition was observed

for the inactivated *Salmonella enterica* spiked into either the synthetic matrix or in the Cary Blair transport media.

The results indicated that the FilmArray GI Control Panel M238 matrix has no effect on the assay.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

FilmArray GI Panel M238 is a qualitative control and the expected results in the results for BIOFIRE FILMARRAY GI panel and the BIOFIRE FILMARRAY GI Panel Mid are listed in the tables below.

Table 7: BIOFIRE FILMARRAY GI Panel Result Summary

Target	M239 Call	M240 Call
Bacteria		
Campylobacter	Not Detected	Detected
Clostridium difficile toxin A/B	Detected	Not Detected
Plesiomonas shigelloides	Detected	Not Detected
Salmonella	Not Detected	Detected
Vibrio	Detected	Not Detected
Vibrio cholerae	Detected	Not Detected
Yersinia enterocolitica	Detected	Not Detected
Diarrheagenic *E. coli/Shigella*		
Enteroaggregative *E. coli* (EAEC)	Detected	Not Detected
Enteropathogenic *E. coli* (EPEC)	NA*	Detected
Enterotoxigenic *E. coli* (ETEC) *lt/st*	Not Detected	Detected

Target	M239 Call	M240 Call
Shiga-like toxin-producing *E. coli* (STEC) *stx1/stx2*	Detected	Not Detected
E. coli O157	Detected	NA**
Shigella/Enteroinvasive *E. coli* (EIEC)	Detected	Not Detected
Parasites		
Cryptosporidium	Detected	Not Detected
Cyclospora cayetanensis	Not Detected	Detected
Entamoeba histolytica	Not Detected	Detected
Giardia lamblia	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 8: BIOFIRE FILMARRAY GI Panel Mid Result Summary

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

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.