

# Quality Control Materials for use with BioFire® FilmArray® Panels

## Introduction

The Clinical Laboratory Improvement Amendments (CLIA), passed in 1988, establishes quality standards for all laboratory testing to ensure the accuracy and reliability of patient test results, regardless of where the test is performed. CLIA regulations require a laboratory to have quality control (QC) procedures to monitor the accuracy and precision of the complete testing process.

This document provides a listing of QC materials that have been tested at BioFire and are compatible with the BioFire Panels indicated. The information in this document is meant to be a guideline and may not be inclusive.

For guidelines to assist your laboratory in developing an individualized quality control plan for BioFire® FilmArray® Systems, please refer to the Example Individualized Quality Control Plan (IQCP) Risk Analysis for the following panels:

- BioFire® FilmArray® Blood Culture Identification (BCID) Panel-FLM1-PRT-0217
- BioFire® Blood Culture Identification 2 (BCID2) Panel –BFR0000-6645
- BioFire® FilmArray® Gastrointestinal (GI) Panel-FLM1-PRT-0218
- BioFire® FilmArray® Meningitis/Encephalitis (ME) Panel-FLM1-PRT-0219
- BioFire® FilmArray® Pneumonia Panel-FLM2-PRT-0313
- BioFire® FilmArray® Respiratory Panel (RP)-BFR0000-8660
- BioFire® FilmArray® Respiratory Panel EZ (RP EZ)- BFR0000-8660
- BioFire® FilmArray® Respiratory Panel 2 (RP2)- BFR0000-8660
- BioFire® FilmArray® Respiratory Panel 2 *plus* (RP2*plus*) -BFR0000-8660
- BioFire® Respiratory Panel 2.1 (RP2.1)-BFR0000-8660
- BioFire® Respiratory Panel 2.1 *plus* (RP2.1*plus*)- BFR000-8660
- BioFire® Respiratory Panel 2.1-EZ (RP2.1-EZ)-BFR000-8660



**Note:** The QC materials listed are appropriate for use with the panel described and may not be compatible with other BioFire Panels.

## Quality Control Resources

Table 1. QC Materials for BioFire BCID Panel

BioFire BCID Panel		
Vendor	Product Name	Part Number
Maine Molecular Quality Controls, Inc.	FilmArray® BCID Control Panel	M235
Microbiologics	Blood Culture Identification (BCID) Control Panel (Inactivated)	8215*

\* For in vitro Diagnostic Use; an FDA Cleared Class I Unassayed Control

**Table 2. QC Materials for BioFire BCID2 Panel**

BioFire BCID2 Panel		
Vendor	Product Name	Part Number
Maine Molecular Quality Controls, Inc.	FilmArray® BCID2 Control Panel	M416*

\*For in vitro Diagnostic Use; an FDA cleared class II Assayed control

**Table 3. QC Materials for BioFire GI Panel**

BioFire GI Panel		
Vendor	Product Name	Part Number
Maine Molecular Quality Controls, Inc.	FilmArray® GI Control Panel	M238
ZeptoMetrix, LLC	NATtrol™ GI Controls	NATGIC-BIO

**Table 4. QC Materials for BioFire ME Panel**

BioFire ME Panel		
Vendor	Product Name	Part Number
Maine Molecular Quality Controls, Inc	INTROL® ME Control Panel	M262
ZeptoMetrix, LLC	NATtrol™ Meningitis/Encephalitis (ME) Controls	NATMEC-BIO

**Table 5. QC Materials for BioFire Pneumonia Panel and Pneumonia *plus* Panel**

BioFire Pneumonia Panel and Pneumonia <i>plus</i> Panel		
Vendor	Product Name	Part Number
Maine Molecular Quality Controls, Inc.	FilmArray® Pneumonia/ Pneumonia <i>plus</i> Control	M340*§
Microbiologics	Pneumonia (33 Targets) Control Panel	8244‡

\*For in vitro Diagnostic Use; an FDA cleared class II Assayed control

‡ For in vitro Diagnostic Use; an FDA Cleared Class I Unassayed Control

§ Control contains MERS-CoV2 recombinant material

**Table 6. QC Materials for BioFire RP**

<b>BioFire RP</b>		
<b>Vendor</b>	<b>Product Name</b>	<b>Part Number</b>
Exact Diagnostics	RP Positive Run Control/ RP Negative Run Control	RPPOS/ RPNEG
Maine Molecular Quality Controls, Inc.	FilmArray® RP Control Panel	M210
Microbiologics	Respiratory (21 Targets) Control Panel	8217 <sup>‡</sup>
ZeptoMetrix, LLC	NATtrol™ RP Multimarker Controls	MDZ001 <sup>‡</sup>

<sup>‡</sup> For in vitro Diagnostic Use; an FDA Cleared Class I Unassayed Control

**Table 7. QC Materials for BioFire RP EZ**

<b>BioFire RP EZ</b>		
<b>Vendor</b>	<b>Product Name</b>	<b>Part Number</b>
Exact Diagnostics	RP Positive Run Control/ RP Negative Run Control	RPPOS/ RPNEG
Maine Molecular Quality Controls, Inc.	FilmArray® RP EZ Control Panel	M265 <sup>*</sup>
Microbiologics	Respiratory (21 Targets) Control Panel	8217 <sup>‡</sup>
ZeptoMetrix, LLC	NATtrol™ RP Multimarker Controls	MDZ001 <sup>‡</sup>

<sup>\*</sup> For in vitro Diagnostic Use; an FDA cleared class II Assayed control

<sup>‡</sup> For in vitro Diagnostic Use; an FDA Cleared class I Unassayed Control

**Table 8. QC Materials for BioFire RP2 and RP2plus**

<b>BioFire RP1 and RP2plus</b>		
<b>Vendor</b>	<b>Product Name</b>	<b>Part Number</b>
Exact Diagnostics	RP Positive Run Control/ RP Negative Run Control	RPPOS <sup>§</sup> / RPNEG
Maine Molecular Quality Controls, Inc	FilmArray® RP2/RP2plus Control Panel	M315 <sup>*§</sup>
Microbiologics	Respiratory (21 Targets) Control Panel	8217 <sup>‡</sup>
ZeptoMetrix, LLC	NATtrol™ Respiratory Panel 2.1 (RP2.1) Controls	NATRPC2.1-BIO

<sup>\*</sup> For in vitro Diagnostic Use; an FDA cleared class II Assayed control

<sup>‡</sup> For in vitro Diagnostic Use; an FDA Cleared class I Unassayed Control

<sup>§</sup> Control contains MERS-CoV2 recombinant material

**Table 9. QC Materials for BioFire RP2.1, RP2.1 *plus*, and RP2.1-EZ**

BioFire RP2.1, RP2.1 <i>plus</i> , and RP2.1-EZ		
Vendor	Product Name	Part Number
Maine Molecular Quality Controls, Inc.	BioFire RP2.1/RP2.1 <i>plus</i> Control Panel	M441*§
Microbiologics	Respiratory Control Panel (22 Targets)	8247*
ZeptoMetrix, LLC	NATtrol™ Respiratory Panel 2.1 (RP2.1) Controls	NATRPC2.1-BIO

§ Control contains MERS-CoV2 recombinant material

\* For in vitro Diagnostic Use; an FDA cleared class II Assayed control

‡ For in vitro Diagnostic Use; an FDA Cleared class I Unassayed Control



**Note:** Quality control options are discussed more thoroughly in *External Control Material Options for BioFire® Respiratory Panel 2.1 (RP2.1)* BFR000-8900.

## Technical Support Contact Information

BioFire is dedicated to providing the best customer support available. If you have any questions or concerns about this process, please contact the BioFire Technical Support team for assistance.

BioFire Technical Support  
 Email: [support@biofiredx.com](mailto:support@biofiredx.com)  
 Phone: +1-801-736-6354, select Option 5

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