

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® Joint Infection (JI) Panel: BFR0000-9504
 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*): BFR0000-8660
 BioFire® Respiratory Panel 2.1-EZ (RP2.1-EZ): BFR0000-8660



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



Note: The use of routine quality control materials is not appropriate for verification of test method performance (COM.40300). Please refer to BioFire Laboratory Verification Tech Notes for further instruction on verification protocols.

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 ¹

¹ 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 ^{2,3}
Microbiologics	Blood Culture Identification Control Panel (43 Targets)	8254 ^{1,3}

¹ For in vitro Diagnostic Use; an FDA cleared Class I Unassayed Control

² For in vitro Diagnostic Use; an FDA cleared Class II Assayed control

³ CE-IVD marked

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 ¹
ZeptoMetrix, LLC	NATtrol™ GI Controls	NATGIC-BIO

¹ CE-IVD marked

Table 4. QC Materials for BioFire Joint Infection (JI) Panel

BioFire GI Panel		
Vendor	Product Name	Part Number
Maine Molecular Quality Controls, Inc.	BioFire JI Control Panel	M420 ¹

¹ CE-IVD marked

Table 5. QC Materials for BioFire ME Panel

BioFire ME Panel		
Vendor	Product Name	Part Number
Maine Molecular Quality Controls, Inc	INTROL® ME Control Panel	M262 ¹
ZeptoMetrix, LLC	NATtrol™ Meningitis/Encephalitis (ME) Controls	NATMEC-BIO

¹ CE-IVD marked

Table 6. 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 ^{2,3,4}
Microbiologics	Pneumonia (33 Targets) Control Panel	8244 ¹

¹ For in vitro Diagnostic Use; an FDA cleared Class I Unassayed Control

² For in vitro Diagnostic Use; an FDA cleared Class II Assayed control

³ Control contains MERS-CoV2 recombinant material

⁴ CE-IVD marked

Table 7. QC Materials for BioFire RP

BioFire RP		
Vendor	Product Name	Part Number
Exact Diagnostics	RP Positive Run Control/ RP Negative Run Control	RPPOS ^{1,2,3} / RPNEG ^{1,2}
Maine Molecular Quality Controls, Inc.	FilmArray® RP Control Panel	M210
Microbiologics	Respiratory Control Panel (22 Targets)	8247 ¹
ZeptoMetrix, LLC	NATtrol™ RP Multimarker Controls	MDZ001 ¹

¹ For in vitro Diagnostic Use; an FDA cleared Class I Unassayed Control

² CE-IVD marked

³ Control contains MERS-CoV2 recombinant material

Table 8. QC Materials for BioFire RP EZ

BioFire RP EZ		
Vendor	Product Name	Part Number
Exact Diagnostics	RP Positive Run Control/ RP Negative Run Control	RPPOS ^{1,3,4} / RPNEG ^{1,3}
Maine Molecular Quality Controls, Inc.	FilmArray® RP EZ Control Panel	M265 ²
ZeptoMetrix, LLC	NATtrol™ RP Multimarker Controls	MDZ001 ¹

¹ For in vitro Diagnostic Use; an FDA cleared Class I Unassayed Control

² For in vitro Diagnostic Use; an FDA cleared Class II Assayed control

³ CE-IVD marked

⁴ Control contains MERS-CoV2 recombinant material

Table 9. QC Materials for BioFire RP2 and RP2*plus*

BioFire RP1 and RP2 <i>plus</i>		
Vendor	Product Name	Part Number
Exact Diagnostics	RP Positive Run Control/ RP Negative Run Control	RPPOS ^{1,3,4} / RPNEG ^{1,3}
Maine Molecular Quality Controls, Inc	FilmArray® RP2/RP2 <i>plus</i> Control Panel	M315 ^{2,3,4}
Microbiologics	Respiratory (22 Targets) Control Panel	8247 ¹
ZeptoMetrix, LLC	NATtrol™ Respiratory Panel 2.1 (RP2.1) Controls	NATRPC2.1-BIO

¹ For in vitro Diagnostic Use; an FDA cleared class I Unassayed Control

² For in vitro Diagnostic Use; an FDA cleared class II Assayed control

³ CE-IVD marked

⁴ Control contains MERS-CoV2 recombinant material

Table 10. 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
Exact Diagnostics	RP Positive Run Control/ RP Negative Run Control	RPPOS ^{1,3, 4} / RPNEG ^{1,3}
Maine Molecular Quality Controls, Inc.	BioFire RP2.1/RP2.1 <i>plus</i> Control Panel	M441 ^{2,3,4}
Microbiologics	Respiratory Control Panel (22 Targets)	8247 ¹
ZeptoMetrix, LLC	NATtrol™ Respiratory Panel 2.1 (RP2.1) Controls	NATRPC2.1-BIO

¹ For in vitro Diagnostic Use; an FDA cleared Class I Unassayed Control

² For in vitro Diagnostic Use; an FDA cleared Class II Assayed control

³ CE-IVD marked

⁴ Control contains MERS-CoV2 recombinant material



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
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