

# Quality Control Materials for use with BIOFIRE® FILMARRAY® and BIOFIRE® SPOTFIRE® Panels

## Introduction

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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 bioMérieux 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® and BIOFIRE® SPOTFIRE® Systems, please refer to the Example Individualized Quality Control Plan (IQCP) Risk Analysis for the following panels:




BIOFIRE® Blood Culture Identification 2 (BCID2) Panel: BFR0000-6645  
 BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel: FLM1-PRT-0218  
 BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel Mid: 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® 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) (EUA)\*: BFR000-8660  
 BIOFIRE® SPOTFIRE® Respiratory (R) Panel: BFR0001-2499  
 BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini: BFR0001-2499  
 BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel: BFR0001-2499  
 BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini: BFR0001-2499  
 BIOFIRE® FILMARRAY® Tropical Fever Panel: BFR0001-0958

*\* · This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.*

*· This product has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2 from multiple respiratory viral and bacterial organisms; and,*

*· The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.*



-  **Note:** The QC materials listed are appropriate for use with the Panel described and may not be compatible with other BIOFIRE or SPOTFIRE 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.
-  **Note:** Adding commercial QC samples to transport media will dilute samples below the intended pathogen concentration and may lead to missed detections. In addition, QC samples should never be pooled prior to testing.

## Quality Control Resources

**Table 1.** QC Materials for BIOFIRE® Blood Culture Identification 2 (BCID2) Panel

BIOFIRE BCID2 Panel			
Vendor	Product Name	Part Number	Regulatory Status
Maine Molecular Quality Controls, Inc.	FilmArray® BCID2 Control Panel	M416	<ul style="list-style-type: none"> <li>• For in vitro Diagnostic Use; an FDA cleared class II Assayed Control</li> <li>• RUO</li> <li>• CE-IVD</li> </ul>
Microbiologics	Blood Culture Identification Control Panel (43 Targets)	8254	<ul style="list-style-type: none"> <li>• For in vitro Diagnostic Use; a Class I Unassayed Control</li> <li>• CE-IVD</li> </ul>
Streck LLC	MDx-CheX® for BCID2	250065	<ul style="list-style-type: none"> <li>• For in vitro Diagnostic Use; an FDA cleared class II Assayed Control</li> <li>• CE-IVD</li> </ul>

**Table 2.** QC Materials for BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel and BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel Mid

BIOFIRE FILMARRAY GI and GI Panel Mid			
Vendor	Product Name	Part Number	Regulatory Status
Maine Molecular Quality Controls, Inc.	FilmArray® GI Control Panel	M238	<ul style="list-style-type: none"> <li>• RUO</li> <li>• CE-IVD</li> </ul>
ZeptoMetrix, LLC	NATtrol™ GI Controls	NATGIC-BIO	<ul style="list-style-type: none"> <li>• RUO</li> </ul>

**Table 3. QC Materials for BIOFIRE® Joint Infection Panel**

BIOFIRE Joint Infection Panel			
Vendor	Product Name	Part Number	Regulatory Status
Maine Molecular Quality Controls, Inc.	BIOFIRE JI Control Panel	M420	<ul style="list-style-type: none"> <li>• For in vitro Diagnostic Use; an FDA cleared class II Assayed Control</li> <li>• RUO</li> <li>• CE-IVD</li> </ul>

**Table 4. QC Materials for BIOFIRE® FILMARRAY® Meningitis/Encephalitis (ME) Panel**

BIOFIRE FILMARRAY ME Panel			
Vendor	Product Name	Part Number	Regulatory Status
Maine Molecular Quality Controls, Inc	BIOFIRE® ME Control Panel	M262	<ul style="list-style-type: none"> <li>• RUO</li> <li>• CE-IVD marked</li> </ul>
ZeptoMetrix, LLC	NATtrol™ Meningitis/Encephalitis (ME) Controls	NATMEC-BIO	<ul style="list-style-type: none"> <li>• RUO</li> </ul>

**Table 5. QC Materials for BIOFIRE® FILMARRAY® Pneumonia (PN) and Pneumoniaplus Panels**

BIOFIRE FILMARRAY PN and Pneumoniaplus Panels			
Vendor	Product Name	Part Number	Regulatory Status
Maine Molecular Quality Controls, Inc.	FilmArray® Pneumonia/Pneumoniaplus Control	M340*	<ul style="list-style-type: none"> <li>• For in vitro Diagnostic Use; an FDA cleared class II Assayed Control</li> <li>• RUO</li> <li>• CE-IVD</li> </ul>

\*Control contains MERS-CoV2 recombinant material

**Table 6.** QC Materials for BIOFIRE® Respiratory Panel 2.1 (RP2.1), RP2.1plus, and RP2.1-EZ (EUA)\*

<b>BIOFIRE RP2.1, RP2.1 plus, and RP2.1-EZ (EUA)</b>			
<b>Vendor</b>	<b>Product Name</b>	<b>Part Number</b>	<b>Regulatory Status</b>
Bio-Rad/ Exact Diagnostics	EDX RP Positive Run Control/ RP Negative Run Control	RPPOS*/ RPNEG	<ul style="list-style-type: none"> <li>• For in vitro Diagnostic Use; a Class I Unassayed Control</li> <li>• CE-IVD</li> </ul>
Maine Molecular Quality Controls, Inc.	BIOFIRE® RP2.1/RP2.1plus Control Panel	M441*	<ul style="list-style-type: none"> <li>• For in vitro Diagnostic Use; an FDA cleared class II Assayed Control</li> <li>• RUO</li> <li>• CE-IVD</li> </ul>
Microbiologics	Respiratory Control Panel (22 Targets)	8247	<ul style="list-style-type: none"> <li>• For in vitro Diagnostic Use; a Class I Unassayed Control</li> </ul>
ZeptoMetrix, LLC	NATtrol™ Respiratory Panel 2.1 (RP2.1) Controls	NATRPC2.1-BIO	<ul style="list-style-type: none"> <li>• RUO</li> </ul>

\*Control contains MERS-CoV recombinant material

**Table 7.** QC Materials for BIOFIRE® SPOTFIRE® Respiratory (R) Panel Respiratory (R) Panel Mini

<b>SPOTFIRE R Panel and R Panel Mini</b>			
<b>Vendor</b>	<b>Product Name</b>	<b>Part Number</b>	<b>Regulatory Status</b>
<b>For use with the QC workflow in CLIA-Waived or CLIA-Moderate setting*</b>			
Maine Molecular Quality Controls, Inc.	SPOTFIRE® RSP Positive Control	M42638	<ul style="list-style-type: none"> <li>• For in vitro Diagnostic Use; an FDA cleared class II Assayed Control</li> <li>• RUO</li> </ul>
	SPOTFIRE® RSP Negative Control	M42738	<ul style="list-style-type: none"> <li>• For in vitro Diagnostic Use; an FDA cleared class II Assayed Control</li> <li>• RUO</li> </ul>
	SPOTFIRE® RSP Pos & Neg Controls (contains M42638 Positive Control and M42738 Negative Control)	M425	<ul style="list-style-type: none"> <li>• For in vitro Diagnostic Use; an FDA cleared class II Assayed Control</li> <li>• RUO</li> </ul>



For use in the patient workflow in CLIA-Moderate settings			
Bio-Rad/ Exact Diagnostics	EDX RP Positive Run Control/ RP Negative Run Control	RPPOS*/ RPNEG	<ul style="list-style-type: none"> <li>• For in vitro Diagnostic Use; a Class I Unassayed Control</li> <li>• CE-IVD</li> </ul>
Microbiologics	Respiratory Control Panel (22 Targets)	8247	<ul style="list-style-type: none"> <li>• For in vitro Diagnostic Use; a Class I Unassayed Control</li> </ul>
ZeptoMetrix, LLC	NATtrol™ Respiratory/Sore Throat (R/ST) Control	NATRSTC-BIO	<ul style="list-style-type: none"> <li>• RUO</li> </ul>

\*Control contains MERS-CoV recombinant material

‡ QC material is compatible with the QC workflow on the SPOTFIRE R Panel and the SPOTFIRE R Panel Mini and will produce a PASS or FAIL result.

**Table 8.** QC Materials for BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel and R/ST Panel Mini

SPOTFIRE R/ST Panel and R/ST Panel Mini			
Vendor	Product Name	Part Number	Regulatory Status
For use with the QC workflow in CLIA-Waived or CLIA-Moderate setting‡			
Maine Molecular Quality Controls, Inc.	SPOTFIRE® RSP Pos & Neg Controls (Contains M42638 Positive Control and M42738 Negative Control)	M425	<ul style="list-style-type: none"> <li>• For in vitro Diagnostic Use; an FDA cleared class II Assayed Control</li> <li>• RUO</li> </ul>
For use in the patient workflow in CLIA-Moderate settings			
ZeptoMetrix, LLC	NATtrol™ Respiratory/Sore Throat (R/ST) Control	NATRSTC-BIO	<ul style="list-style-type: none"> <li>• RUO</li> </ul>

‡ QC material is compatible with the QC workflow on the SPOTFIRE R/ST Panel and the R/ST Panel Mini and will produce a PASS or FAIL result.

**Table 9.** QC Materials for BIOFIRE® FILMARRAY® Tropical Fever (TF) Panel

BIOFIRE FILMARRAY TF Panel			
Vendor	Product Name	Part Number	Regulatory Status
Maine Molecular Quality Controls, Inc	FilmArray TF Control Panel	M527	<ul style="list-style-type: none"> <li>• RUO</li> </ul>

## Technical Support Contact Information

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bioMérieux is dedicated to providing the best customer support available. If you have questions or concerns about this process, please contact your local bioMérieux representative or your authorized distributor.

\*All product names, trademarks and registered trademarks are property of their respective owners.

