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

** · 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 Panels.

Technical Note
BioFire Diagnostics, LLC
www.biofiredx.com
FLM1-PRT-0251-19

QS-339J-01

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® FILMARRAY® Blood Culture Identification (BCID) Panel

BIOFIRE BCID Panel		
Vendor	**Product Name**	**Part Number**
Maine Molecular Quality Controls, Inc.	FilmArray® BCID Control Panel	M235

Table 2. QC Materials for BIOFIRE® Blood Culture Identification 2 (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]
Streck LLC	MDx-Chex® for BCID2	250065[2,3]

[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® FILMARRAY® Gastrointestinal (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® Joint Infection (JI) Panel

BIOFIRE JI Panel		
Vendor	**Product Name**	**Part Number**
Maine Molecular Quality Controls, Inc.	BioFire® JI Control Panel	M420[1,2]

[1]CE-IVD marked
[2] For in vitro Diagnostic Use; an FDA cleared class II Assayed Control

Table 5. QC Materials for BIOFIRE® FILMARRAY® Meningitis/Encephalitis (ME) Panel

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

Table 6. QC Materials for BIOFIRE® FILMARRAY® Pneumonia Panel and Pneumonia *plus* Panels

BIOFIRE Pneumonia and Pneumonia*plus* Panels		
Vendor	**Product Name**	**Part Number**
Maine Molecular Quality Controls, Inc.	FilmArray® Pneumonia/ Pneumonia*plus* Control	M340[2,3,4]

[2] For in vitro Diagnostic Use; an FDA cleared class II Assayed Control
[3]Control contains MERS-CoV2 recombinant material
[4]CE-IVD marked

Technical Note
BioFire Diagnostics, LLC
www.biofiredx.com
FLM1-PRT-0251-19

QS-339J-01

Table 7. QC Materials for BIOFIRE® Respiratory Panel 2.1 (RP2.1), RP2.1*plus*, and RP2.1-EZ (EUA)*

BIOFIRE RP2.1, RP2.1*plus*, RP2.1-EZ (EUA)		
Vendor	**Product Name**	**Part Number**
Bio-Rad/Exact Diagnostics	EDX 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*plus* 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

* · *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.

Table 8. QC Materials for BIOFIRE® SPOTFIRE® Respiratory (R) Panel and BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini

SPOTFIRE R Panel and SPOTFIRE R Panel Mini		
Vendor	**Product Name**	**Part Number**
For use with the QC workflow in CLIA-Waived or CLIA-Moderate setting¥		
Maine Molecular Quality Controls, Inc.	SPOTFIRE® RSP Positive Control	M42638[2]
	SPOTFIRE® RSP Negative Control	M42738[2]
For use with the patient workflow in CLIA-Moderate settings		
Bio-Rad/ Exact Diagnostics	EDX RP Positive Run Control/ RP Negative Run Control	RPPOS[1,3,4]/ RPNEG[1,3]
Microbiologics	Respiratory Control Panel (22 Targets)	8247[1]
ZeptoMetrix, LLC	NATtrol™ Respiratory Panel (RSP) Controls	NATRSPC-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

¥ 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 9. QC Materials for BIOFIRE® SPOTFIRE® Respiratory/ Sore Throat (R/ST) Panel (OUS only)*

SPOTFIRE R/ST Panel		
Vendor	**Product Name**	**Part Number**
For use with the QC workflow in CLIA-Waived or CLIA-Moderate setting¥		
Maine Molecular Quality Controls, Inc.	SPOTFIRE® RSP Positive Control	M42638[1]
	SPOTFIRE® RSP Negative Control	M42738[1]

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

[1] For in vitro Diagnostic Use; an FDA cleared class II Assayed Control

* *This product is not available for sale in the United States.*

Technical Note
BioFire Diagnostics, LLC
www.biofiredx.com
FLM1-PRT-0251-19

QS-339J-01

Technical Support Contact Information

bioMérieux 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: biofiresupport@biomerieux.com
Phone: +1-801-736-6354, select Option 5