

Quality Control Materials for use with BioFire® FilmArray® Panels

TECHNICAL ::: NOTE

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® Respiratory Panel (RP)-FLM1-PRT-0216

BioFire® FilmArray® Blood Culture Identification (BCID) Panel- FLM1-PRT-0217

BioFire® FilmArray® Gastrointestinal (GI) Panel-FLM1-PRT-0218

BioFire® FilmArray® Meningitis/Encephalitis (ME) Panel-FLM1-PRT-0219

BioFire® FilmArray® Respiratory Panel (RP) EZ- FLM1-PRT-0234

BioFire® FilmArray® Respiratory Panel 2 (RP2)-FLM2-PRT-0281

BioFire® FilmArray® Respiratory Panel 2 *plus* (RP2*plus*)-FLM2-PRT-0282

BioFire® FilmArray® Pneumonia Panel-FLM2-PRT-0313



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 Blood Culture Identification (BCID) Panel

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

Table 2. QC Materials for BioFire® FilmArray® Gastrointestinal (GI) Panel

BioFire® FilmArray® Gastrointestinal (GI) Panel		
Vendor	Product Name	Part Number
Maine Molecular Quality Controls, Inc	FilmArray GI Control Panel	M238
ZeptoMetrix Corporation	NATtrol GI Controls	NATGIC-BIO

Table 3. QC Materials for BioFire® FilmArray® Meningitis/Encephalitis (ME) Panel

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

Table 4. QC Materials for BioFire® FilmArray® Pneumonia Panel

BioFire® FilmArray® Pneumonia Panel		
Vendor	Product Name	Part Number
Maine Molecular Quality Controls, Inc	FilmArray® Pneumonia/ Pneumonia <i>plus</i> Control	M340

Table 5. QC Materials for BioFire® FilmArray® Respiratory Panel (RP)

BioFire® FilmArray® Respiratory Panel (RP)		
Vendor	Product Name	Part Number
Maine Molecular Quality Controls, Inc	FilmArray RP Control Panel	M210
ZeptoMetrix Corporation	NATtrol™ RP Multimarker Controls	MDZ001

Table 6. QC Materials for BioFire® FilmArray® Respiratory Panel (RP) EZ

BioFire® FilmArray® Respiratory Panel (RP) EZ		
Vendor	Product Name	Part Number
Maine Molecular Quality Controls, Inc	FilmArray RP EZ Control Panel*	M265
ZeptoMetrix Corporation	NATtrol™ RP Multimarker Controls	MDZ001

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

Table 7. QC Materials for BioFire® FilmArray® Respiratory Panel 2 (RP2) and Respiratory Panel 2 *plus* (RP2*plus*)

BioFire® FilmArray® Respiratory Panel 2 (RP2) and Respiratory Panel 2 <i>plus</i> (RP2<i>plus</i>)		
Vendor	Product Name	Part Number
Maine Molecular Quality Controls, Inc	FilmArray RP2/RP2 <i>plus</i> Control Panel*	M315
ZeptoMetrix Corporation	NATtrol™ Respiratory Panel 2 (RP2) Controls	NATRPC2-BIO

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

TECHNICAL ::: NOTE

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 FilmArray Technical Support team for assistance.

BioFire Technical Support

Email: support@biofiredx.com

Phone: +1-801-736-6354, select Option 5

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