

Quality Control Materials for use with 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 FilmArray 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 FilmArray® Systems, please refer to the Example Individualized Quality Control Plan (IQCP) Risk Analysis for the following panels:

FilmArray Respiratory Panel (RP)-FLM1-PRT-0216
FilmArray Blood Culture Identification (BCID) Panel- FLM1-PRT-0217
FilmArray Gastrointestinal (GI) Panel-FLM1-PRT-0218
FilmArray Meningitis/Encephalitis (ME) Panel-FLM1-PRT-0219
FilmArray Respiratory Panel (RP) EZ- FLM1-PRT-0234
FilmArray Respiratory Panel 2 (RP2)-FLM2-PRT-0281
FilmArray Respiratory Panel 2 *plus* (RP2*plus*)-FLM2-PRT-0282



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

Quality Control Resources

Table 1. QC Materials for FilmArray® Blood Culture Identification (BCID) Panel

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 FilmArray® Gastrointestinal (GI) Panel

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

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

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

Table 4. QC Materials for FilmArray® Respiratory Panel (RP)

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

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

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

Table 6. QC Materials for FilmArray® Respiratory Panel 2 (RP2) and Respiratory Panel 2 plus (RP2plus)

FilmArray® Respiratory Panel 2 (RP2) and Respiratory Panel 2 plus (RP2plus)		
Vendor	Product Name	Part Number
Maine Molecular Quality Controls, Inc	FilmArray RP2/RP2plus Control Panel	M315
Zeptomatrix	NATtrol™ Respiratory Panel 2 (RP2) Controls	NATRPC2-BIO

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



A BIOMÉRIEUX COMPANY