

# 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® 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® FilmArray® Meningitis/Encephalitis (ME) Panel-FLM1-PRT-0219  
BioFire® FilmArray® Pneumonia Panel-FLM2-PRT-0313  
BioFire® FilmArray® Respiratory Panel (RP)-FLM1-PRT-0216  
BioFire® FilmArray® Respiratory Panel EZ (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® Respiratory Panel 2.1 (RP2.1)-BFR0000-8600



**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 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        |

**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        |

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

**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        |
| ZeptoMetrix Corporation                | NATtrol™ GI Controls        | NATGIC-BIO  |

**Table 4. QC Materials for BioFire ME Panel**

| BioFire 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 5. QC Materials for BioFire Pneumonia 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        |

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

§ Control contains MERS-CoV2 recombinant material

**Table 6. QC Materials for BioFire RP**

| BioFire RP                            |  |              |
|---------------------------------------|--|--------------|
| Vendor                                | Product Name                                     | Part Number  |
| Exact Diagnostics                     | RP Positive Run Control/ RP Negative Run Control | RPPOS/ RPNEG |
| Maine Molecular Quality Controls, Inc | FilmArray® RP Control Panel                      | M210         |
| Microbiologics                        | Respiratory (21 Targets) Control Panel           | 8217         |
| ZeptoMetrix Corporation               | NATtrol™ RP Multimarker Controls                 | MDZ001       |

**Table 7. 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/ RPNEG |
| Maine Molecular Quality Controls, Inc | FilmArray® RP EZ Control Panel*                  | M265         |
| Microbiologics                        | Respiratory (21 Targets) Control Panel           | 8217         |
| ZeptoMetrix Corporation               | NATtrol™ RP Multimarker Controls                 | MDZ001       |

**Table 8. QC Materials for BioFire RP2 and RP2plus**

| BioFire RP2 and RP2plus               |  |              |
|---------------------------------------|--|--------------|
| Vendor                                | Product Name   | Part Number  |
| Exact Diagnostics                     | RP Positive Run Control <sup>§</sup> / RP Negative Run Control | RPPOS/ RPNEG |
| Maine Molecular Quality Controls, Inc | FilmArray® RP2/RP2plus Control Panel <sup>§</sup>              | M315         |
| Microbiologics                        | Respiratory (21 Targets) Control Panel                         | 8217         |
| ZeptoMetrix Corporation               | NATtrol™ Respiratory Panel 2 (RP2) Controls                    | NATRPC2-BIO  |

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

§ Control contains MERS-CoV2 recombinant material

**Table 9. QC Materials for BioFire RP2.1**

| BioFire RP2.1*                        |  |             |
|---------------------------------------|--|-------------|
| Vendor                                | Product Name                           | Part Number |
| Maine Molecular Quality Controls, Inc | BioFire® RP2.1/RP2.1plus Control Panel | M441        |

\* Other 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](mailto:support@biofiredx.com)

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



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

**TECHNICAL  
::: NOTE**