

# 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® 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

-  **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 may not be appropriate for verification of test method performance (College of American Pathology All Common Checklist: 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>• For in vitro Diagnostic Use; an FDA cleared class II Assayed Control</li> <li>• RUO</li> <li>• CE-IVD</li> </ul> |
| ZeptoMetrix, LLC                       | NATtrol™ GI Controls        | NATGIC-BIO     | • RUO   |
|  |                             | NATGIC-BIO-IVD | • For in vitro Diagnostic Use; a Class I Unassayed Control  |

**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     | • RUO  |
|                                       |  | NATMEC-BIO-IVD | • For in vitro Diagnostic Use; an FDA cleared Class I Unassayed Control          |

**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) and RP2.1*plus*

| <b>BIOFIRE RP2.1 and RP2.1 <i>plus</i></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/RP2.1 <i>plus</i> 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> <li>• CE marked (transition to IVDR in progress)</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 and the BIOFIRE® SPOTFIRE® 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<sup>y</sup></b> |   |                    |  |
| 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>                            |
| <b>For use in the patient workflow in CLIA-Moderate settings</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>                                     |
| 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> <li>• CE marked (transition to IVDR in progress)</li> </ul> |



|                  |   |             |       |
|------------------|---|-------------|-------|
| ZeptoMetrix, LLC | NATtrol™ Respiratory/Sore Throat (R/ST) Control | NATRSTC-BIO | • RUO |
|------------------|---|-------------|-------|

\*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, the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat *plus* Panel, the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini and the BIOFIRE® SPOTFIRE® Respiratory/Sore Throat *plus* (R/ST*plus*) Panel Mini

| SPOTFIRE R/ST Panel, R/ST <i>plus</i> Panel, R/ST Panel Mini, and R/ST <i>plus</i> 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> |
| ZeptoMetrix, LLC  | NATtrol™ Respiratory/Sore Throat (R/ST) Control Kit   | NATRSTK-BIO-IVD | <ul style="list-style-type: none"> <li>• For in vitro Diagnostic Use; a Class I Unassayed Control</li> </ul>                            |
| For use in the patient workflow in CLIA-Moderate settings                                     |   |                 |   |
| ZeptoMetrix, LLC  | NATtrol™ Respiratory/Sore Throat (R/ST) Control   | NATRSTC-BIO     | • RUO   |

\* QC material is compatible with the QC workflow on the SPOTFIRE R/ST Panel, the SPOTFIRE R/ST*plus* Panel, the SPOTFIRE R/ST Panel Mini, and the SPOTFIRE R/ST*plus* 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        | • RUO             |

## Technical Support Contact Information

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.