

# Proficiency Testing Materials for use with BioFire® FilmArray® Panels

## Introduction

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This document provides a listing of proficiency testing materials that have been tested at BioFire and are compatible with the BioFire Panels indicated. All proficiency testing programs listed are monitored at BioFire. The information in this document is meant to be a guideline and may not be inclusive.

## Resources

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The laboratory director is responsible for determining the appropriate proficiency tests for each laboratory. Proficiency testing (PT) requirements can be complicated and are based upon the analytes tested, methods utilized and specialty/subspecialty categories pertaining to the CLIA certification of the individual laboratory. Therefore, the College of American Pathologists (CAP) has delegated advisors to assist with defining the appropriate PT programs required for Clinical Laboratory Implementation Act (CLIA) compliance if using BioFire Panels. CAP recommends that the each laboratory contact them directly to ensure they are compliant with current CLIA and CAP regulations. The best way to ensure compliance is to develop your proficiency testing plan in coordination with CLIA or CAP or the regulatory body governing your laboratory.

CLIA Brochure #8 PROFICIENCY TESTING  
CLIA Facts #26 PROFICIENCY TESTING INFORMATION

### American Proficiency Institute (API)

Website: [www.api-pt.com](http://www.api-pt.com)  
Phone: 800-333-0958 (M-F 8:00 AM – 5:00 PM ET)  
API Catalog: [www.api-pt.com/catalog.aspx](http://www.api-pt.com/catalog.aspx)

### College of American Pathologists (CAP)

Phone: 800-323-4040 (M-F 7:00 AM - 5:30 PM CT)  
[http://www.cap.org/web/home/lab/proficiency-testing?\\_adf.ctrl-tate=ni2atkwi7\\_25&\\_afrLoop=231986540573538#!](http://www.cap.org/web/home/lab/proficiency-testing?_adf.ctrl-tate=ni2atkwi7_25&_afrLoop=231986540573538#!)

CAP Proficiency Testing Catalog:  
<https://www.cap.org/laboratory-improvement/catalogs-ordering-and-shipping>

CAP Proficiency Testing Manual:  
[https://www.cap.org/laboratory-improvement/proficiency-testing?\\_adf.ctrl-tate=ni2atkwi7\\_25&\\_afrLoop=231986540573538#!](https://www.cap.org/laboratory-improvement/proficiency-testing?_adf.ctrl-tate=ni2atkwi7_25&_afrLoop=231986540573538#!)



**Wisconsin State Lab of Hygiene (WSLH)**  
 Phone: 800-462-5261 (M-F 8:00 AM to 4:30 PM (CT))  
<http://www.slh.wisc.edu/proficiency/>

## Proficiency Testing Monitoring Guide 2021



### BioFire® FilmArray® Blood Culture Identification (BCID) Panel

Table 1. Proficiency Testing Materials for BioFire BCID Panel

| BioFire BCID Panel |  |             |   |   |                  |   |
|--------------------|--|-------------|---|---|------------------|---|
| Vendor             | Survey Name  | Part Number | BioFire BCID Coverage                                 | Format  | Shipments / year | Notes                                   |
| API                | Blood Pathogen Panel for Molecular Multiplex Users | 368         | Complete coverage of all analytes on panel            | 5 x 1.0 mL simulated positive blood culture fluid specimens | 3                | Preferred panel for complete coverage   |
| CAP                | Bacterial Blood Culture, Molecular                 | BCM         | Bacteria and resistance mechanisms on BioFire BCID    | 5 x 1.0 mL simulated positive blood culture fluid specimens | 3                | BCM and YBC will give complete coverage |
| CAP                | Yeast Blood Culture, Molecular                     | YBC         | Fungal organisms on BioFire BCID                      | 5 x 1.0 mL simulated positive blood culture fluid specimens | 3                | BCM and YBC will give complete coverage |
| WSLH               | Blood Culture Multiplex                            | PT05360     | Identification of bacteria and yeast in Blood Culture | 5 x 1.0 mL simulated positive blood culture fluid specimens | 3                | Challenges growth in blood culture      |

## BioFire® FilmArray® Blood Culture Identification 2 (BCID2) Panel

Table 2. Proficiency Testing Materials for BioFire BCID2 Panel

| BioFire BCID2 Panel |  |             |   |   |                |  |
|---------------------|--|-------------|---|---|----------------|--|
| Vendor              | Survey Name  | Part Number | BioFire BCID Coverage                               | Format  | Shipments/year | Notes                                      |
| API                 | Blood Pathogen Panel for Molecular Multiplex Users | 368         | Complete coverage of all analytes on panel          | 5 x 1.0 mL simulated positive blood culture fluid specimens | 3              | Full coverage starting with 3rd Event 2020 |
| CAP                 | Bacterial Blood Culture, Molecular                 | BCM         | Bacteria and resistance mechanisms on BioFire BCID2 | 5 x 1.0 mL simulated positive blood culture fluid specimens | 3              | BCM and YBC will give complete coverage    |
| CAP                 | Yeast Blood Culture, Molecular                     | YBC         | Fungal organisms on BioFire BCID2                   | 5 x 1.0 mL simulated positive blood culture fluid specimens | 3              | BCM and YBC will give complete coverage    |



## BioFire® FilmArray® Gastrointestinal (GI) Panel

Table 3. Proficiency Testing Materials for BioFire GI Panel

| BioFire GI Panel |  |             |  |                                      |                |                                       |
|------------------|--|-------------|--|--------------------------------------|----------------|---------------------------------------|
| Vendor           | Survey Name  | Part Number | BioFire GI Coverage                        | Format                               | Shipments/year | Notes                                 |
| API              | Gastrointestinal Panel for Molecular Multiplex Users   | 369         | Complete coverage of all analytes on panel | 5 x 1.0 mL simulated stool specimens | 3              | Preferred panel for complete coverage |
| CAP              | Gastrointestinal Panel for Molecular Multiplex Testing | GIP5        | Complete coverage of all analytes on panel | 5 x 1.0 mL simulated stool specimens | 3              | Preferred panel for complete coverage |
| WSLH             | GI Multiplex   | PT05380     | Complete coverage of all analytes on panel | 5 x 1.0 mL simulated stool specimens | 3              |                                       |

NOTE: The API Gastrointestinal Panel and the CAP GIP5 meet CMS requirements for bacteriology/virology identification. CAP GIP3 **does not** meet CMS requirements for bacteriology/virology identification.



## BioFire® FilmArray® Meningitis/Encephalitis (ME) Panel

Table 4. Proficiency Testing Materials for BioFire ME Panel

| BioFire ME Panel |  |             |   |                                    |                |                                       |
|------------------|--|-------------|---|------------------------------------|----------------|---------------------------------------|
| Vendor           | Survey Name                            | Part Number | BioFire ME Coverage   | Format                             | Shipments/year | Notes                                 |
| API              | ME Panel for Molecular Multiplex Users | 371         | Complete coverage of all analytes on panel                      | 5 x 1.0 mL simulated CNS specimens | 3              | Preferred panel for complete coverage |
| CAP              | ME Panel for Molecular Multiplex Users | IDM5        | Complete coverage of all analytes on panel                      | 5 x 1.0 mL simulated CNS specimens | 3              | Preferred panel for complete coverage |
| WSLH             | Meningitis Multiplex                   | PT05450     | Bacterial molecular ID, Viral molecular ID, Fungal molecular ID | 5 lyophilized specimens            | 3              |                                       |

NOTE: The API ME Panel and the CAP IDM5 meet CMS requirements for bacteriology/virology identification. CAP IDME **does not** meet CMS requirements for bacteriology/virology.



## BioFire® FilmArray® Pneumonia Panel

Table 5. Proficiency Testing Materials for BioFire Pneumonia Panel

| BioFire Pneumonia Panel |  |             |  |                             |                |                                       |
|-------------------------|--|-------------|--|-----------------------------|----------------|---------------------------------------|
| Vendor                  | Survey Name  | Part Number | BioFire Pneumonia Coverage                 | Format                      | Shipments/year | Notes                                 |
| API                     | Pneumonia Panel for Molecular Multiplex users                      | 378         | Complete coverage of all analytes on panel | 5 x 1.0 mL liquid specimens | 3              | Preferred panel for complete coverage |
| CAP                     | Infectious Disease Pneumonia Panel for Molecular Multiplex Testing | IDPN        | Complete coverage of all analytes on panel | 5 x 1.0 mL liquid specimens | 3              | Preferred panel for complete coverage |



## BioFire® FilmArray® Respiratory Panels- Including Respiratory Panel (RP), Respiratory Panel (RP) EZ, Respiratory Panel 2 (RP2), Respiratory Panel 2.1 (RP2.1), and RP2.1-EZ



Note: For CAP IDR- the CAP Manufacturer Master List only provides codes for BioFire and BioFire waived (RP EZ). There are no individual codes for BioFire RP or RP2. For CAP COV2- the CAP Manufacturer Master List now includes a listing for the BioFire (bioMerieux) RP2.1 (3697). Please contact CAP for more information.

Table 6. Proficiency Testing Materials for non-SARS-CoV-2 analytes on BioFire RP, BioFire RP EZ, BioFire RP2, BioFire RP2.1, and BioFire RP2.1-EZ

| BioFire RP, RP EZ, RP2, RP2.1*, and RP2.1-EZ* |  |             |   |                             |                 |                                       |
|---|--|-------------|---|-----------------------------|-----------------|---------------------------------------|
| Vendor  | Survey Name  | Part Number | BioFire Coverage                            | Format                      | Shipments/ year | Notes*                                |
| API   | Respiratory Panel for Molecular Multiplex Users                      | 370         | Complete coverage of all analytes on panel* | 5 x 1.0 mL liquid specimens | 3               | Preferred panel for complete coverage |
| CAP   | Infectious Disease Respiratory Panel for Molecular Multiplex Testing | IDR         | Complete coverage of all analytes on panel* | 5 x 1.0 mL liquid specimens | 3               | Preferred panel for complete coverage |
| WSLH  | Respiratory Multiplex  | PT06240     | Complete coverage of all analytes on panel* | 5 x 1.0 mL liquid specimens | 3               |                                       |

\* These panels cover all non-SARS-CoV-2 Detections

Table 7. Proficiency Testing Materials for SARS-CoV-2 on BioFire RP2.1, and BioFire RP2.1-EZ

| SARS-CoV-2 Coverage for RP2.1 and RP2.1-EZ |                        |             |                                  |                             |                 |       |
|--|------------------------|-------------|----------------------------------|-----------------------------|-----------------|-------|
| Vendor                                     | Survey Name            | Part Number | BioFire Coverage                 | Format                      | Shipments/ year | Notes |
| API  | SARS-CoV-2 (molecular) | 385         | Complete Coverage for SARS-CoV-2 | 2 x 1.5 mL liquid specimens | 3               |       |
| CAP  | SARS-CoV-2 Molecular   | COV2        | Complete Coverage for SARS-CoV-2 | 3 x 1.5 mL liquid specimens | 2               |       |
| WSLH                                       | SARS-CoV-2             | PT-06260    | Complete Coverage for SARS-CoV-2 | 3 liquid specimens          | 2               |       |

## Technical Support Contact Information

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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

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