

Proficiency Testing Materials for use with BioFire® FilmArray® Panels

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Introduction

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

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
Phone: 800-333-0958 (M-F 8:00 AM – 5:00 PM ET)
API Catalog: 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-state=ni2atkwi7_25&_afLoop=231986540573538#!

CAP Proficiency Testing Catalog:

http://www.cap.org/web/home/lab/catalogs-ordering-shipping?_afLoop=642261054473530#!%40%40%3F_afLoop%3D642261054473530%26_adf.ctrl-state%3D7xz7d7c3z_52

CAP Proficiency Testing Manual:

<http://www.cap.org/ShowProperty?nodePath=/UCMCon/Contribution/Folders/WebContent/pdf/pt-manual.pdf>

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/>

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Proficiency Testing Monitoring Guide 2019



BioFire® FilmArray® Blood Culture Identification (BCID) Panel

Table 1. Proficiency Testing Materials for BioFire BCID Panel

| BioFire® FilmArray® Blood Culture Identification (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 | Gram Positive Blood Culture Panel for Molecular Multiplex Testing | GPBC | Gram positive organisms on BioFire BCID | 3 x 1.0 mL simulated positive blood culture fluid specimens | 2 | No coverage of yeasts on panel |
| CAP | Gram Negative Blood Culture Panel for Molecular Multiplex Testing | GNBC | Gram negative organisms on BioFire BCID | 3 x 1.0 mL simulated positive blood culture fluid specimens | 2 | No coverage of yeasts on panel |
| CAP | Blood Culture | BCS | N/A- Graded by blood culture method | 2 specimens for inoculation of blood culture bottles | 2 | Challenges growth in blood culture; graded by blood culture method |
| CAP | Blood Culture, <i>Staphylococcus aureus</i> | BCS1 | <i>S. aureus</i> only | 3 specimens for inoculation of blood culture bottles | 2 | Challenges growth in blood culture |
| 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 | |



BioFire® FilmArray® Gastrointestinal (GI) Panel

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Table 2. Proficiency Testing Materials for BioFire GI Panel

| BioFire® FilmArray® Gastrointestinal (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 |
| CAP | Stool Pathogen | SP | Adenovirus 40/41, <i>C. difficile</i> , Rotavirus, Shiga toxin | 2 x 1.0 mL simulated stool specimens | 2 | |
| CAP | Stool Pathogen-1 | SP-1 | Norovirus only | 1 x 1.0 mL simulated stool specimens | 2 | |
| WSLH | GI Multiplex | PT05380 | Complete coverage of all analytes on panel | 5 x 1.0 mL simulated stool specimens | 3 | |



BioFire® FilmArray® Meningitis/Encephalitis (ME) Panel

Table 3. Proficiency Testing Materials for BioFire ME Panel

| BioFire® FilmArray® Meningitis/Encephalitis (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 | IDME | Complete coverage of all analytes on panel | 3 x 1.0 mL simulated CNS specimens | 2 | Preferred panel for complete coverage |
| CAP | Nucleic Acid Amplification, Viruses | ID1 | CMV, Enterovirus, HSV1, HSV2, HHV-6, Varicella-zoster Virus | 8 x 1.0 mL liquid specimens | 2 | |



BioFire® FilmArray® Respiratory Panels (Including Respiratory Panel (RP), Respiratory Panel (RP) EZ, and Respiratory Panel 2 (RP2))



Note: The CAP Manufacturer Master List only provides codes for BioFire (RP and RP2) and BioFire waived (RP EZ) methods. There is no visibility with CAP on whether RP or RP2 panels were used.

Table 4. Proficiency Testing Materials for BioFire RP, BioFire RP2 and BioFire RP EZ

| BioFire® FilmArray® Respiratory Panel (RP), Respiratory Panel 2 (RP2) and Respiratory Panel (RP) EZ | | | | | | |
|---|--|-------------|--|-----------------------------|----------------|---------------------------------------|
| Vendor | Survey Name | Part Number | BioFire RP and RP EZ 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 | |

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BioFire® FilmArray® Pneumonia Panel

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Table 5. Proficiency Testing Materials for BioFire Pneumonia Panel

| BioFire® FilmArray® Pneumonia Panel | | | | | | |
|-------------------------------------|--|-------------|---|---|----------------|---------------------------------------|
| Vendor | Survey Name | Part Number | BioFire Pneumonia Coverage | Format | Shipments/year | Notes |
| API | Pneumonia Panel for Molecular Multiplex users | TBD | Complete coverage of all analytes on panel | 2 x 1.0 mL liquid specimens | 2* | Preferred panel for complete coverage |
| API | Respiratory Panel for Molecular Multiplex users | 370 | Covers viruses and atypical bacteria bacteria on Pneumonia Panel | 5 x 1.0 mL liquid specimens | 3 | |
| API | Blood Pathogen Panel for Molecular Multiplex Users | 368 | <i>A. baumannii</i> , <i>Enterobacter</i> sp, <i>E. cloacea</i> complex, <i>E. coli</i> , <i>H. influenzae</i> , <i>Klebsiella oxytoca</i> , <i>K. pneumoniae</i> , <i>Proteus</i> sp, <i>P. aeruginosa</i> , <i>S. marscens</i> , <i>S. aureus</i> , <i>S. pneumoniae</i> , <i>S. pyogenes</i> , <i>mecA</i> , <i>KPC</i> , <i>CTX-M</i> , <i>IMP</i> , <i>NDM</i> , <i>OXA</i> , <i>VIM</i> | 5 x 1.0 mL simulated positive blood culture fluid specimens | 3 | |
| CAP | Infectious Disease Respiratory Panel for Molecular Multiplex Testing | IDR | Covers viruses and atypical bacteria bacteria on Pneumonia Panel | 5 x 1.0 mL liquid specimens | 3 | |
| CAP | Gram Positive Blood Culture Panel for Molecular Multiplex Testing | GPBC | <i>S. aureus</i> , <i>S. pneumoniae</i> , <i>S. pyogenes</i> | 3 x 1.0 mL simulated positive blood culture fluid specimens | 2 | |
| CAP | Gram Negative Blood Culture Panel for Molecular Multiplex Testing | GNBC | <i>A. baumannii</i> , <i>E. cloacea</i> complex, <i>E. coli</i> , <i>H. influenzae</i> , <i>Klebsiella oxytoca</i> , <i>K. pneumoniae</i> , <i>Proteus</i> sp, <i>P. aeruginosa</i> , <i>S. marscens</i> | 3 x 1.0 mL simulated positive blood culture fluid specimens | 2 | |



Note: The API Pneumonia Panel will be available for 2 shipments in 2019, starting with the 2nd Microbiology Testing event. Three shipments per year will occur in subsequent years.

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

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

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