

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

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## 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&\\_afLoop=231986540573538#!](http://www.cap.org/web/home/lab/proficiency-testing?_adf.ctrl-tate=ni2atkwi7_25&_afLoop=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/>

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## Proficiency Testing Monitoring Guide 2020



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

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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	Partial coverage of analytes on BioFire BCID2	5 x 1.0 mL simulated positive blood culture fluid specimens	3	Expanded coverage for BCID2 available for 3rd testing event of 2020
CAP	Gram Positive Blood Culture Panel for Molecular Multiplex Testing	GPBC	Partial coverage of Gram positive organisms on BioFire BCID2	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	Partial coverage of Gram negative organisms on BioFire BCID2	3 x 1.0 mL simulated positive blood culture fluid specimens	2	No coverage of yeasts on panel



## 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	



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

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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	IDME	Complete coverage of all analytes on panel	3 x 1.0 mL simulated CNS specimens	2	Preferred panel for complete coverage
WSLH	Meningitis Multiplex	PT05450	Bacterial molecular ID, Viral molecular ID, Fungal molecular ID	5 lyophilized specimens	3	



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



**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.

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**Table 5. Proficiency Testing Materials for non-SARS-CoV-2 analytes on BioFire RP, BioFire RP2, BioFire RP2.1 and BioFire RP EZ**

BioFire RP, RP2, RP2.1* and RP 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 6. Proficiency Testing Materials for SARS-CoV-2 on BioFire RP2.1**

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



## BioFire® FilmArray® Pneumonia Panel

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Table 7. 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

## 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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