

# 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 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-state=ni2atkwi7\\_25&\\_afLoop=231986540573538#!](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](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	378	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 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 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

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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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