

# Proficiency Testing Materials for use with 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 FilmArray 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

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

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:

[http://www.cap.org/web/home/lab/catalogs-ordering-shipping?\\_afrLoop=642261054473530#!%40%40%3F\\_afrLoop%3D642261054473530%26\\_adf.ctrl-state%3D7xz7d7c3z\\_52](http://www.cap.org/web/home/lab/catalogs-ordering-shipping?_afrLoop=642261054473530#!%40%40%3F_afrLoop%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>

## Proficiency Testing Monitoring Guide 2018

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

Table 1. Proficiency Testing Materials for FilmArray Blood Culture Identification (BCID) Panel

FilmArray Blood Culture Identification (BCID) Panel						
Vendor	Survey Name	Part Number	FA Coverage	Format	Shipments/year	Notes
API	Blood Pathogen Panel for Molecular Multiplex Users	368	complete	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 FA BCID	3x 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 FA BCID	3x 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



## FilmArray® Gastrointestinal (GI) Panel

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Table 2. Proficiency Testing Materials for FilmArray Gastrointestinal (GI) Panel

FilmArray Gastrointestinal (GI) Panel						
Vendor	Survey Name	Part Number	FA Coverage	Format	Shipments/year	Notes
API	Gastrointestinal Panel for Molecular Multiplex Users	369	Complete	5 x 1.0 mL simulated stool specimens	3	Preferred panel for complete coverage
CAP	Gastrointestinal Panel for Molecular Multiplex Testing	GIP	Complete	3 x 1.0 mL simulated stool specimens	2	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	1 x 1.0 mL simulated stool specimens	2	



## FilmArray® Meningitis/Encephalitis (ME) Panel

Table 3. Proficiency Testing Materials for FilmArray Meningitis/Encephalitis (ME) Panel

FilmArray Meningitis/Encephalitis (ME) Panel						
Vendor	Survey Name	Part Number	FA Coverage	Format	Shipments/year	Notes
API	ME Panel for Molecular Multiplex Users	371	Complete	5 x 1.0 mL simulated CNS specimens	3	Preferred panel for complete coverage
CAP	ME Panel for Molecular Multiplex Users	IDME	Complete	3 x 1.0 mL simulated CNS specimens	2	Preferred panel for complete coverage
CAP	Nucleic Acid Amplification, Viruses	ID1	CMV, Enterovirus, EBV, HSV1, HSV2, HHV-6, Parvovirus B19, Varicella-zoster Virus	8 x 1.0 mL liquid specimens	2	



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

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 **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 FilmArray Respiratory Panel (RP) and Respiratory Panel (RP) EZ

FilmArray Respiratory Panel (RP) and Respiratory Panel (RP) EZ						
Vendor	Survey Name	Part Number	FA Coverage	Format	Shipments/year	Notes
API	Respiratory Panel for Molecular Multiplex Users	370	Complete	5 x 1.0 mL liquid specimens	3	Preferred panel for complete coverage
CAP	Infectious Disease Respiratory Panel for Molecular Multiplex Testing	IDR	Complete	6 x 1.0 mL liquid specimens	3	Preferred panel for complete coverage
CAP	Influenza A, B and RSV	ID3	Influenza A, B and RSV	5 x 1.0 mL liquid specimens	3	
CAP	Organism Nucleic Acid Amplification	IDO	Bacteria on FA RP	7 liquid or swab simulated clinical isolate specimens.	2	Not all sample types on IDO are appropriate for RP/RP2 panels- only test samples contained on respiratory panels.


 **Note:** Not all sample types on CAP IDO are appropriate for RP/RP2 panels- only test samples contained on respiratory panels. When sample is in liquid, add 300uL of the sample directly into the sample buffer. When the sample is a dry swab, add the swab to VTM, vortex, and then transfer 300uL to sample buffer.

Table 5. Proficiency Testing Materials for FilmArray® Respiratory Panel 2 (RP2)

FilmArray® Respiratory Panel 2 (RP2)						
Vendor	Product Name	Part Number	FA Coverage	Format	Shipments/year	Notes
API	Respiratory Panel for Molecular Multiplex users	370	Complete	5 x 1.0 mL liquid specimens	3	Preferred panel for complete coverage
CAP	Infectious Disease Respiratory Panel for Molecular Multiplex Testing	IDR	Complete	6 x 1.0 mL liquid specimens	3	Preferred panel for complete coverage
CAP	Influenza A, B and RSV	ID3	Influenza A, B and RSV	5 x 1.0 mL liquid specimens	3	
CAP	Organism Nucleic Acid Amplification	IDO	Bacteria on FA RP	7 liquid or swab simulated clinical isolate specimens.	2	Not all sample types on CAP IDO are appropriate for RP/RP2 panels- only test samples contained on respiratory panels.



**Note:** Not all sample types on CAP IDO are appropriate for RP/RP2 panels- only test samples contained on respiratory panels. When sample is in liquid, add 300uL of the sample directly into the sample buffer. When the sample is a dry swab, add the swab to VTM, vortex, and then transfer 300uL to sample buffer.

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## 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 FilmArray® 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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