

Proficiency Testing Materials for use with BioFire® FilmArray® Panels

TECHNICAL
::: NOTE

Introduction

This document provides a listing of proficiency testing materials that have been tested at BioFire and are compatible with the BioFire 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

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&_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

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/>

TECHNICAL ::: NOTE

Proficiency Testing Monitoring Guide 2019



BioFire® FilmArray® Blood Culture Identification (BCID) Panel

Table 1. Proficiency Testing Materials for BioFire FilmArray Blood Culture Identification (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

TECHNICAL ::: NOTE

Table 2. Proficiency Testing Materials for BioFire FilmArray Gastrointestinal (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 FilmArray Meningitis/Encephalitis (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))

TECHNICAL ::: NOTE



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 FilmArray Respiratory Panel (RP), BioFire Respiratory Panel 2 (RP2) and Respiratory Panel (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
CAP	Organism Nucleic Acid Amplification	IDO	<i>B. paraptussis</i> , <i>B. pertussis</i> , <i>C. pneumoniae</i>	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.
WSLH	Respiratory Multiplex	PT06240	Complete coverage of all analytes on panel	5 x 1.0 mL liquid specimens	3	



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.

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 FilmArray Technical Support team for assistance.

BioFire Technical Support

Email: support@biofiredx.com

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

**TECHNICAL
::: NOTE**

