

Proficiency Testing Materials for use with BioFire® FilmArray® Panels

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-tate=ni2atkwi7_25&_afrLoop=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#!



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/>

Proficiency Testing Monitoring Guide 2021



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	Bacterial Blood Culture, Molecular	BCM	Bacteria and resistance mechanisms on BioFire BCID	5 x 1.0 mL simulated positive blood culture fluid specimens	3	BCM and YBC will give complete coverage
CAP	Yeast Blood Culture, Molecular	YBC	Fungal organisms on BioFire BCID	5 x 1.0 mL simulated positive blood culture fluid specimens	3	BCM and YBC will give complete coverage
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® FilmArray® Blood Culture Identification 2 (BCID2) Panel

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	Complete coverage of all analytes on panel	5 x 1.0 mL simulated positive blood culture fluid specimens	3	Full coverage starting with 3rd Event 2020
CAP	Bacterial Blood Culture, Molecular	BCM	Bacteria and resistance mechanisms on BioFire BCID2	5 x 1.0 mL simulated positive blood culture fluid specimens	3	BCM and YBC will give complete coverage
CAP	Yeast Blood Culture, Molecular	YBC	Fungal organisms on BioFire BCID2	5 x 1.0 mL simulated positive blood culture fluid specimens	3	BCM and YBC will give complete coverage



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	

NOTE: The API Gastrointestinal Panel and the CAP GIP5 meet CMS requirements for bacteriology/virology identification. CAP GIP3 **does not** meet CMS requirements for bacteriology/virology identification.



BioFire® FilmArray® Meningitis/Encephalitis (ME) Panel

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	IDM5	Complete coverage of all analytes on panel	5 x 1.0 mL simulated CNS specimens	3	Preferred panel for complete coverage
WSLH	Meningitis Multiplex	PT05450	Bacterial molecular ID, Viral molecular ID, Fungal molecular ID	5 lyophilized specimens	3	

NOTE: The API ME Panel and the CAP IDM5 meet CMS requirements for bacteriology/virology identification. CAP IDME **does not** meet CMS requirements for bacteriology/virology.



BioFire® FilmArray® Pneumonia Panel

Table 5. 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



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



Note: For CAP IDR- the CAP Manufacturer Master List only provides codes for BioFire and BioFire waived (RP EZ). For CAP COV2- the CAP Manufacturer Master List now includes a listing for the BioFire (bioMerieux) RP2.1 (3697). There are no individual codes for BioFire RP or RP2. Please contact CAP for more information.

Table 6. Proficiency Testing Materials for non-SARS-CoV-2 analytes on BioFire RP, BioFire RP EZ, BioFire RP2, and BioFire RP2.1

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

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

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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