

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 Diagnostics and are compatible with the BIOFIRE Panels indicated. All proficiency testing programs listed are monitored at BioFire Diagnostics. 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. The 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 the 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)
<https://www.cap.org/laboratory-improvement/proficiency-testing>
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.ctrltate=ni2atkwi7_25&_afLoop=231986540573538#!

Wisconsin State Lab of Hygiene (WSLH)

Phone: 800-462-5261 (M-F 8:00 AM to 4:30 PM (CT))
<https://wslhpt.org/>



Proficiency Testing Monitoring Guide 2023

Proficiency Testing (PT) specimens should be handled like a patient specimen and tested using routine methods. Laboratories should follow instructions provided by the PT provider for specific handling instructions, such as rehydration. Media should not be added unless directed by the PT provider. Liquid samples should be mixed prior to testing.



BIOFIRE® FILMARRAY® Blood Culture Identification Panels

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 provide 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 provide complete coverage
WSLH	Blood Pathogen Multiplex (BPM)	PT05480	Bacterial, fungal and resistance genes on BCID	5 specimens	3	New for 2023



Table 2. Proficiency Testing Materials for BIOFIRE BCID2 Panel

BIOFIRE BCID2 Panel						
Vendor	Survey Name	Part Number	BIOFIRE BCID2 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 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
WSLH	Blood Pathogen Multiplex (BPM)	PT05480	Bacterial, fungal and resistance genes on BCID	5 specimens	3	New for 2023



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 (EP)	PT05380	Complete coverage of all analytes on panel	5 stool specimens	3	Complete coverage

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



BIOFIRE® Joint Infection (JI) Panel

Table 4. Proficiency Testing Materials for BIOFIRE Joint Infection Panel

BIOFIRE Joint Infection Panel						
Vendor	Survey Name	Part Number	BIOFIRE JI coverage	Format	Shipments/year	Notes
API	Joint Infection Panel	390	Complete coverage of all analytes on panel	5 x 1.0 mL liquid specimens	3	Preferred panel for complete coverage
CAP	Molecular testing for Joint infections	JIP	Complete coverage of all analytes on panel	5 x 1.0 mL liquid specimens	3	Preferred panel for complete coverage



BIOFIRE® FILMARRAY® Meningitis/Encephalitis (ME) Panel

Table 5. 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 (MEP)	PT05450	Bacterial molecular ID, Viral molecular ID, Fungal molecular ID	5 specimens	3	Complete coverage

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



BIOFIRE® FILMARRAY® Pneumonia Panel

Table 6. 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
WSLH	Pneumonia Multiplex (PNM)	PT05490	Complete coverage of all analytes on panel	5 specimens	3	New for 2023



BIOFIRE® FILMARRAY® Respiratory Panels- Including Respiratory Panel (RP), Respiratory Panel 2.1 (RP2.1), and RP2.1- EZ (EUA)*



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

Table 7. Proficiency Testing Materials for all analytes on BIOFIRE RP, BIOFIRE RP2.1, and BIOFIRE RP2.1-EZ (EUA)*

BIOFIRE RP, RP2.1, and RP2.1-EZ (EUA)*						
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 (RP)	PT06240	Complete coverage of all analytes on panel	5 specimens	3	Complete coverage

Table 8. Proficiency Testing Materials for SARS-CoV-2 on BIOFIRE RP2.1 and BIOFIRE RP2.1-EZ (EUA)*

SARS-CoV-2 Coverage for RP2.1 and RP2.1-EZ (EUA)**						
Vendor	Survey Name	Part Number	BIOFIRE Coverage	Format	Shipments/year	Notes
API	SARS-CoV-2 liquid (molecular)	385	Whole genome SARS-CoV-2, including variants of concern	2 liquid specimens	3	
CAP	SARS-CoV-2 Molecular	COV2	Whole genome SARS-CoV-2	3 x 1.5 mL liquid specimens	2	

* · This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;

· This product has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2 from multiple respiratory viral and bacterial organisms; and,

· The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Technical Support Contact Information

bioMérieux 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: biofiresupport@biomerieux.com
Phone: +1-801-736-6354, select Option 5

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