

Proficiency Testing and External Quality Assessment Materials for use with BIOFIRE® FILMARRAY® and BIOFIRE® SPOTFIRE® Panels

Introduction

This document provides a listing of proficiency testing and external quality assessment materials that have been tested at bioMérieux and are compatible with the BIOFIRE® Panels indicated. All proficiency testing and external quality assessment programs listed are monitored at bioMérieux. 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 or external quality assessment programs for each laboratory. Proficiency testing (PT) and external quality assessment (EQA) requirements can be complicated and are based upon the analytes tested, methods utilized, and specialty/subspecialty categories and requirements will vary by region.

For laboratories operating in accordance with CLIA guidelines; the best way to ensure compliance is to develop your proficiency testing plan in coordination with CLIA or the College of American Pathologists (CAP) or the regulatory body governing your laboratory. Laboratories in other regions should refer to guidelines set by the regulatory body governing your laboratory for more information.

Contact the PT/EQA Provider for more information on program availability in your laboratory's region.

Department of Health and Human Services, Centers for Medicare & Medicaid Services

CLIA Brochure #8. Proficiency Testing and PT Referral, Dos and Don'ts. September 2017.
<https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/cliabrochure8.pdf>

American Proficiency Institute (API)

Website: www.api-pt.com
Phone: 800-333-0958 (M-F 8:00 AM – 4:00 PM EST)
API Catalog: <https://api-pt.com/catalog-ordering-information>

College of American Pathologists (CAP)

Website: <https://www.cap.org/laboratory-improvement/proficiency-testing>
Phone: 800-323-4040 (M-F 7:00 AM - 5:30 PM CST)
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&_afrLoop=231986540573538#!



INSTAND e.V.

Website: <https://www.instand-ev.de/en/>

Phone: +49 (0) 211 1592 13-0

Catalog: https://www.instand-ev.de/fileadmin/user_upload/INSTAND-Katalog_2025_EN.pdf

LabQuality

Website: <https://www.labquality.com/>

Phone: +358 9 8566 8200 (weekdays from 8:30–16:00 (EET))

Catalog: <https://www.labquality.com/external-quality-assessment/eqa-program>

Association for Medical Quality control (MQZH)

Website: <https://www.mqzh.ch/cm/en/>

Phone: +41 44 255 34 11

Catalog: <https://www.mqzh.ch/cm/fr/katalog-fr.html>

Quality Control for Molecular Diagnostics (QCMD)

Website: <https://www.qcmd.org/en/>

Phone: +44 (0)141 945 6474 (Monday – Friday 9:00 AM – 5:00 PM (UK Time))

Catalog: https://www.qcmd.org/en/qcmd_eqa_schemes/

UK NEQAS

Website: <https://ukneqasmicro.org.uk/>

Phone: + 44 (0)208 905 9890

Catalog: <https://ukneqasmicro.org.uk/schemes/uk-neqas-microbiology-eqa-schemes/>

Wisconsin State Laboratory of Hygiene (WSLH)

Website: <https://wslhpt.org/>

Phone: 800-462-5261 (M-F 8:00 AM to 4:30 PM (CST))

Catalog: <https://wslhpt.org/proficiency-testing-programs-for-clinical-laboratories/>

WSLH is available only in the US.

Proficiency Testing/ External Quality Assessment Monitoring Guide 2025

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

NOTE: PT/EQA requirements vary by region. Refer to guidelines set by the regulatory body governing your laboratory for more information. Contact the PT/EQA Provider for more information on program availability in your laboratory's region.



BIOFIRE® FILMARRAY® Blood Culture Identification 2 (BCID2) Panel

Table 1. Proficiency Testing/EQA Materials for BIOFIRE BCID2 Panel

BIOFIRE® BCID2 Panel						
Vendor	Survey Name	Part Number	BIOFIRE® 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 provide 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	
WSLH	Blood Pathogen Multiplex (BPM)	PT05481	Complete coverage of all analytes on panel	2 x 1.0 mL simulated stool specimens	3	Provides complete coverage



BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel

Table 2. Proficiency Testing/ EQA Materials for BIOFIRE GI Panel

BIOFIRE® GI Panel						
Vendor	Survey Name	Part Number	BIOFIRE® 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; available in the US only
CAP	Gastrointestinal Panel, Global	GIPN	Covers most targets on BIOFIRE GI Panel	5 x 1.0 mL simulated stool specimens	3	Partial coverage; available outside US only
INSTAND	Gastrointestinal Virus Panel for Multiplex Tests	430	Covers on-panel Viruses only	3 lyophilized samples (faecal or cell culture lysates)	2	Partial coverage



Lab Quality	Gastrointestinal viral multiplex	5304	Covers on-panel Viruses only	3 x 1.0 mL simulated samples	2	5304 + 5472 +5191 provides complete coverage
	Faecal parasites multiplex	5472	Covers on-panel parasites only	3 lyophilized samples	4	
	Faecal bacterial pathogens multiplex	5191	Covers on-panel bacteria only	3 lyophilized samples (simulated or bacterial)	4	
MQZH	BIOFIRE/ Filmarray Gastrointestinal Panel	B18	Complete coverage of all analytes on panel	1 liquid sample	4	Preferred panel for complete coverage
QCMD	Diarrheagenic <i>Escherichia coli</i>	QAB154 179	Covers all the Diarrheagenic <i>E. coli</i> / <i>Shigella</i>	8 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
	Bacterial Gastroenteritis	QAB124 153	Incomplete coverage of on-panel bacteria	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
	Parasitic Gastroenteritis	QAP124 154	Incomplete coverage of on-panel parasites	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
	Viral Gastroenteritis	QAV124 152	Complete coverage of on-panel viruses	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
UK NEQAS	Viral gastroenteritis	-	Incomplete coverage of on-panel viruses	4 x freeze dried human faeces	2	Partial coverage
WSLH	GI Multiplex	PT05380	Complete coverage of all analytes on panel	5 x 1.0 mL simulated stool specimens	3	Provides complete coverage; available in the US only

NOTE: The API Gastrointestinal Panel, the CAP GIP5, and the WSLH GI Multiplex Panel meet CMS requirements for bacteriology/virology identification.



BIOFIRE® Joint Infection (JI) Panel

Table 3. Proficiency Testing/ EQA Materials for BIOFIRE JI Panel

BIOFIRE® Joint Infection Panel						
Vendor	Survey Name	Part Number	BIOFIRE® coverage	Format	Shipments/year	Notes
API	Joint/ Wound Infection Panel	390	Complete coverage of all analytes on panel (except <i>Clostridium perfringens</i>)	5 x 1.0 mL liquid specimens	3	Provides coverage for all targets except <i>C. perfringens</i>
CAP	Joint infection Panel	JIP	Complete coverage of all analytes on panel (except	5 x 1.0 mL liquid specimens	3	Provides coverage for all targets

			<i>Clostridium perfringens</i>)			except <i>C. perfringens</i>
QCMD	Joint Infection Panel	QAM244227	Unknown	10 x 1.0 mL cultured and/or clinical material	1	EQA Pilot



BIOFIRE® FILMARRAY® Meningitis/Encephalitis (ME) Panel

Table 4. Proficiency Testing/ EQA Materials for BIOFIRE ME Panel

BIOFIRE® ME Panel						
Vendor	Survey Name	Part Number	BIOFIRE® 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
Lab Quality	Meningitis-encephalitis multiplex	5303	Complete coverage of all analytes on panel	3 x 1.0 mL simulated samples	4	Preferred panel for complete coverage
MQZH	BIOFIRE/ Filmarray Meningitis Panel	B23	Complete coverage of all analytes on panel	1 liquid sample	4	Preferred panel for complete coverage
INSTAND	Viral Meningitis / Encephalitis for Multiplex Tests	433	Complete coverage of on-panel viruses	4 lyophilized samples (cell culture lysates)	2	Covers on-panel Viruses only
QCMD	Central Nervous System I (Viral Meningitis and Encephalitis)	QAV1741 95	Incomplete coverage of on-panel viruses	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
	Central Nervous System II (Non-Viral Meningitis and Encephalitis)	QAM174 196	Complete coverage of on-panel bacteria/fungi	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
WSLH	Meningitis Multiplex	PT05451	Complete coverage of all analytes on panel	2 lyophilized specimens	3	Provides complete coverage

NOTE: The API ME Panel, the CAP IDM5, and the WSLH Meningitis Multiplex meet CMS requirements for bacteriology/virology identification.



BIOFIRE® FILMARRAY® Pneumonia Panel and BIOFIRE® FILMARRAY® Pneumonia Panel*plus*

Table 5. Proficiency Testing Materials for BIOFIRE PN and PN*plus* Panels

BIOFIRE® Pneumonia Panel and Pneumonia Panel <i>plus</i>						
Vendor	Survey Name	Part Number	BIOFIRE® coverage	Format	Shipments/ year	Notes
API	Pneumonia Panel for Molecular Multiplex users	378	Complete coverage of all analytes on Pneumonia panel*	5 x 1.0 mL liquid specimens	3	Provides coverage for all targets except MERS-CoV on Pneumonia Panel <i>plus</i>
CAP	Infectious Disease Pneumonia Panel for Molecular Multiplex Testing	IDPN	Complete coverage of all analytes on Pneumonia panel*	5 x 1.0 mL liquid specimens	3	Provides coverage for all targets except MERS-CoV on Pneumonia Panel <i>plus</i>

* API and CAP surveys do not include MERS-CoV challenges.



BIOFIRE® FILMARRAY® Respiratory Panels- Including Respiratory Panel 2.1 (RP2.1), Respiratory Panel 2.1 *plus* (RP2.1*plus*), and Respiratory Panel 2.1-EZ (RP2.1-EZ) (EUA)* and BIOFIRE® SPOTFIRE® Panels including the BIOFIRE® SPOTFIRE® Respiratory (R) Panel, Respiratory (R) Panel Mini, Respiratory/Sore Throat (R/ST) Panel, and Respiratory/Sore Throat (R/ST) Panel Mini

Table 6. Proficiency Testing/ EQA Materials for all analytes on BIOFIRE RP2.1, RP2.1*plus*, and RP2.1-EZ (EUA)*

BIOFIRE® RP2.1, RP2.1 <i>plus</i> , 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 RP2.1/RP2.1-EZ panel	5 x 1.0 mL liquid specimens	3	Provides coverage for all targets except MERS-CoV on RP2.1 <i>plus</i>
CAP	Infectious Disease Respiratory Panel for Molecular Multiplex Testing	IDR	Complete coverage of all analytes on RP2.1/RP2.1-EZ panel	5 x 1.0 mL liquid specimens	3	Provides coverage for all targets except MERS-CoV on RP2.1 <i>plus</i>
INSTAND	Respiratory virus panel 1 for multiplex tests	431	Complete coverage of on-panel viruses on RP2.1	4 lyophilized samples (cell culture lysates)	2	Partial coverage

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INSTAND	Respiratory virus panel 2 for multiplex tests	432	Incomplete coverage of on-panel viruses	4 lyophilized samples (cell culture lysates)	2	Partial coverage
LabQuality	Respiratory infections multiplex	5300	Complete coverage of all analytes on RP2.1	4 x 1.0 mL simulated samples	4	Provides coverage for all targets except MERS-CoV on RP2.1 <i>plus</i>
MQZH	Respiratory Panel	B19	Complete coverage of all analytes on RP2.1	1 liquid sample	4	Provides coverage for all targets except MERS-CoV on RP2.1 <i>plus</i>
QCMD	Respiratory I	QAV164 188	Incomplete coverage of on-panel viruses	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
	Respiratory I plus	QAM204 216	Incomplete coverage of on-panel viruses	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
	Respiratory II	QAV164 189	Incomplete coverage of on-panel viruses	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
	Respiratory III	QAM174 193	Incomplete coverage of on-panel bacteria	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
	MERS Coronavirus	QAV154 181	MERS-CoV only	8 x 1.0 mL cultured and/or clinical material	1	MERS-CoV only
UK NEQAS	Molecular Detection of Respiratory Viruses	-	Complete coverage of on-panel viruses	4 x freeze dried simulated nasopharyngeal aspirates or throat swab samples	3	Partial coverage
WSLH	Respiratory Multiplex	PT06240	Complete coverage of all analytes on RP2.1/RP2.1-EZ panel	5 x 1.0 mL liquid specimens	3	Provides coverage for all targets except MERS-CoV on RP2.1 <i>plus</i>

NOTE: MERS Coronavirus is only available through the QCMD MERS25 survey.

* · 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.

Table 7. Proficiency Testing/EQA Materials for all analytes on BIOFIRE SPOTFIRE Respiratory Panel and BIOFIRE SPOTFIRE Respiratory Panel Mini

SPOTFIRE® Respiratory Panel and SPOTFIRE® Respiratory Panel Mini						
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
Lab Quality	Respiratory infections multiplex	5300	Complete coverage of all analytes on panel	4 x 1.0 mL simulated samples	4	Preferred panel for complete coverage
MQZH	Respiratory Panel	B19	Complete coverage of all analytes on panel	1 liquid sample	4	Provides complete coverage
QCMD	Respiratory I	QAV164188	Incomplete coverage of on-panel viruses	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
	Respiratory I plus	QAM204216	Incomplete coverage of on-panel viruses	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
	Respiratory II	QAV164189	Incomplete coverage of on-panel viruses	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
	Respiratory III	QAM174193	Incomplete coverage of on-panel bacteria	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
UK NEQAS	Molecular Detection of Respiratory Viruses	-	Covers on-panel Viruses only	4 x freeze dried simulated nasopharyngeal aspirates or throat swab samples	3	Partial coverage
WSLH	Respiratory Multiplex	PT06240	Complete coverage of all analytes on panel	5 x 1.0 mL liquid specimens	3	Provides complete coverage

Table 8. Proficiency Testing/ EQA Materials for analytes on BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel and BIOFIRE® SPOTFIRE® Respiratory/Sore Throat (R/ST) Panel Mini

SPOTFIRE® R/ST Panel and SPOTFIRE® R/ST Panel Mini						
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 of Respiratory and Sore Throat Panels
CAP	Infectious Disease Respiratory Panel for Molecular Multiplex Testing	IDR	Complete coverage of all analytes on Respiratory panel	5 x 1.0 mL liquid specimens	3	Complete coverage for Respiratory Panel only
LabQuality	Respiratory infections multiplex	5300	Complete coverage of all analytes on Respiratory panel	4 x 1.0 mL simulated samples	4	Complete coverage for Respiratory Panel only
	<i>Streptococcus pyogenes</i>	5593	<i>Streptococcus pyogenes</i> on Sore Throat Panel	3 simulated pharyngeal samples	4	<i>S. pyogenes</i> for Sore Throat Panel only
MQZH	Respiratory Panel	B19	Complete coverage of all analytes on Respiratory panel	1 liquid sample	4	Complete coverage for Respiratory Panel only
QCMD	Respiratory I	QAV164188	Incomplete coverage of on-panel viruses	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
	Respiratory I plus	QAM204216	Incomplete coverage of on-panel viruses	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
	Respiratory II	QAV164189	Incomplete coverage of on-panel viruses	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
	Respiratory III	QAM174193	Incomplete coverage of on-panel bacteria	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
UK NEQAS	Molecular Detection of Respiratory Viruses	-	Covers on-panel Viruses only	4 x freeze dried simulated nasopharyngeal aspirates or	3	Partial coverage

				throat swab samples		
WSLH	Respiratory Multiplex	PT06240	Complete coverage of all analytes on Respiratory panel	5 x 1.0 mL liquid specimens	3	Complete coverage for Respiratory Panel only

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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