

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 Proficiency Testing and PT Referral October 2024.

<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 9:00 AM – 12:00 PM and 1:00 PM-4:00 PM Eastern Time)

API Catalog: <https://ppt.api-pt.com/catalog.aspx>

Aurevia (formerly LabQuality)

Website: <https://www.aurevia.com/labquality-eqas>

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

Catalog: https://26293608.fs1.hubspotusercontent-eu1.net/hubfs/26293608/Publications/EQA%20product%20catalogues/Aurevia_Product_Catalogue_2026_210x280_web_v4.pdf?hsCtaAttrib=248000824533



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 Central Time)

CAP Proficiency Testing Catalog: <https://www.cap.org/laboratory-improvement/catalogs-ordering-and-shipping>

CAP Proficiency Testing Manual: <https://www.cap.org/gated-assets/uploads/private/2025-Proficiency-Testing-Manual-FINAL.pdf>

INSTAND e.V.

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

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

Catalog: <https://www.instand-ev.de/en/instand-eqas/eqas-program-2025/#c830>

Association for Medical Quality Control (MQZH)

Website: <https://mqzh.ch/cm/en/home-en.html>

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://ukneqas.org.uk/>

Phone: + 44 (0)114 261 1689

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 (Central Time))

Catalog: https://wslhpt.org/wp-content/uploads/2025/08/2026_WSLHPT_Clinical_Catalog.pdf WSLH is available only in the US.

Proficiency Testing/ External Quality Assessment Monitoring Guide 2026

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® 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)	PT 05480	Complete coverage of all analytes on panel	5 x 1.0 mL simulated positive blood culture specimens	3	Provides complete coverage

NOTE: The API Blood Pathogen Panel, the CAP Blood Culture Panel and the WSLH Blood Pathogen Multiplex meet CMS requirements for bacteriology and fungal identification.



BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel and BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel Mid

Table 2. Proficiency Testing/ EQA Materials for BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel and BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel Mid

BIOFIRE FILMARRAY GI Panel and GI Panel Mid						
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

TECHNICAL ::: NOTE

Aurevia (LabQuality)	Gastrointestinal viral multiplex	5304	Covers on-panel Viruses only	3 x 1.0 mL simulated samples	2	5304 + 5472 +5191 provides complete coverage
Aurevia (LabQuality)	Faecal parasites multiplex	5472	Covers on-panel parasites only	3 lyophilized samples	4	
Aurevia (LabQuality)	Faecal bacterial pathogens multiplex	5191	Covers on-panel bacteria only	3 lyophilized samples (simulated or bacterial)	4	
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
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
QCMD	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
QCMD	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
QCMD	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	PT0538 0	Complete coverage of all analytes on panel	5 x 1.0 mL simulated stool specimens	3	Provides complete coverage

NOTE: The API Gastrointestinal Panel, the CAP Gastrointestinal Panel 5, and the WSLH GI Multiplex Panel meet CMS requirements for bacteriology, parasitology, and virology identification.



BIOFIRE® Joint Infection Panel

Table 3. Proficiency Testing/EQA Materials for BIOFIRE® Joint Infection 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	5 x 1.0 mL liquid specimens	3	Preferred panel for complete coverage
CAP	Joint Infection Panel	JIP	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>
QCMD	Joint Infection Panel	QAM24 4227	<i>Candida albicans</i> , <i>Enterococcus faecalis</i> , <i>Escherichia coli</i> , <i>Staphylococcus aureus</i> (MSSA, MRSA), <i>Pseudomonas aeruginosa</i> , <i>Streptococcus agalactiae</i> , <i>S. pyogenes</i>	10 x 1.0 mL cultured and/or clinical material	1	Partial coverage

NOTE: The API Joint/Wound Infection Panel and the CAP Joint Infection Panel meet CMS requirements for bacteriology and fungal identification.



BIOFIRE® FILMARRAY® Meningitis/Encephalitis (ME) Panel

Table 4. Proficiency Testing/ EQA Materials for BIOFIRE® FILMARRAY® Meningitis/Encephalitis (ME) Panel

BIOFIRE FILMARRAY ME Panel						
Vendor	Survey Name	Part Number	BIOFIRE® Coverage	Format	Shipments / year	Notes
API	Meningitis 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

Aurevia (LabQuality)	Meningitis-encephalitis multiplex	5303	Complete coverage of all analytes on panel	3 x 1.0 mL simulated samples	4	Preferred panel for complete coverage
CAP	Meningitis 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
MQZH	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)	QAV174 195	Incomplete coverage of on-panel viruses	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
QCMD	Central Nervous System II (Non-Viral Meningitis and Encephalitis)	QAM17 4196	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	PT0545 1	Complete coverage of all analytes on panel	2 lyophilized specimens	3	Provides complete coverage. Educational survey.

NOTE: The API Meningitis Panel and the CAP IDM5 meet CMS requirements for bacteriology, virology and fungal identification.



BIOFIRE® FILMARRAY® Pneumonia (PN) Panel and BIOFIRE® FILMARRAY® Pneumonia Panel *plus*

Table 5. Proficiency Testing/ EQA Materials for BIOFIRE® FILMARRAY® Pneumonia (PN) and Pneumonia *plus* Panels

BIOFIRE Pneumonia and Pneumoniaplus Panels						
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>
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* API and CAP surveys do not include MERS-CoV challenges.

NOTE: The API Pneumonia Panel and the CAP Infectious Disease, Pneumonia meet CMS requirements for bacteriology and virology identification.



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

Table 6. Proficiency Testing/ EQA Materials for BIOFIRE® RP2.1 and RP2.1*plus*

BIOFIRE RP2.1 and RP2.1 <i>plus</i>						
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	5 x 1.0 mL liquid specimens	3	Provides coverage for all targets except MERS-CoV on RP2.1 <i>plus</i>
Aurevia (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>
CAP	Infectious Disease Respiratory Panel for Molecular Multiplex Testing	IDR	Complete coverage of all analytes on RP2.1	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
INSTAND	Respiratory virus panel 2 for multiplex tests	432	Incomplete coverage of on-panel viruses	4 lyophilized samples (cell culture lysates)	2	Partial coverage



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
QCMD	Respiratory I plus	QAM20 4216	Incomplete coverage of on-panel viruses	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
QCMD	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
QCMD	Respiratory III	QAM17 4193	Incomplete coverage of on-panel bacteria	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
QCMD	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	PT0624 0	Complete coverage of all analytes on RP2.1	5 x 1.0 mL liquid specimens	3	Provides coverage for all targets except MERS-CoV on RP2.1 <i>plus</i>

* MERS Coronavirus is only available through the QCMD MERS25 survey.

NOTE: The API Respiratory Panel, the CAP Infectious Disease, Respiratory and the WSLH Respiratory Panel meet CMS requirements for bacteriology and virology identification.

Table 7. Proficiency Testing/EQA Materials for BIOFIRE® SPOTFIRE® Respiratory (R) Panel and Respiratory (R) Panel Mini

SPOTFIRE R Panel and R Panel Mini						
Vendor	Survey Name	Part Number	SPOTFIRE® 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
Aurevia (LabQuality)	Respiratory infections multiplex	5300	Complete coverage of all analytes on panel	4 x 1.0 mL simulated samples	4	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
MQZH	Respiratory Panel	B19	Complete coverage of all analytes on panel	1 liquid sample	4	Provides complete coverage
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
QCMD	Respiratory I plus	QAM20 4216	Incomplete coverage of on-panel viruses	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
QCMD	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
QCMD	Respiratory III	QAM17 4193	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	PT0624 0	Complete coverage of all analytes on panel	5 x 1.0 mL liquid specimens	3	Provides complete coverage

NOTE: The API Respiratory Panel, the CAP Infectious Disease, Respiratory and the WSLH Respiratory Panel meet CMS requirements for bacteriology and virology identification.

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

SPOTFIRE R/ST Panel, R/ST <i>plus</i> Panel, R/ST Mini, and R/ST <i>plus</i> Panel Mini						
Vendor	Survey Name	Part Number	SPOTFIRE® 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



TECHNICAL ::: NOTE

Aurevia (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
Aurevia (LabQuality)	<i>Streptococcus pyogenes</i>	5595	<i>Streptococcus pyogenes</i> (Group A), detection in pharyngeal sample	3 simulated pharyngeal samples	4	<i>S. pyogenes</i> for Sore Throat Panel only
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
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	QAV164 188	Incomplete coverage of on-panel viruses	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
QCMD	Respiratory I plus	QAM20 4216	Incomplete coverage of on-panel viruses	10 x 1.0 mL cultured and/or clinical material	1 or 2	Partial coverage
QCMD	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
QCMD	Respiratory III	QAM17 4193	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	PT0624 0	Complete coverage of all analytes on Respiratory panel	5 x 1.0 mL liquid specimens	3	Complete coverage for Respiratory Panel only

NOTE: The API Respiratory Panel, the CAP Infectious Disease, Respiratory and the WSLH Respiratory Panel meet CMS requirements for bacteriology and virology identification.



BIOFIRE® FILMARRAY® Tropical Fever (TF) Panel

Table 9. Proficiency Testing/ EQA Materials for BIOFIRE® FILMARRAY® Tropical Fever (TF) Panel

BIOFIRE FILMARRAY TF Panel						
Vendor	Survey Name	Part Number	BIOFIRE® Coverage	Format	Shipments / year	Notes
API	Global Fever Panel	395	Complete coverage of all analytes on panel	2 x 0.5 mL simulated specimens	3	Preferred panel for complete coverage
Aurevia (LabQuality)	Malaria, antigen and nucleic acid detection	5430	Plasmodium	3 whole blood samples	4	Partial coverage
INSTAND	Virus genome detection- Dengue	369	Dengue virus	4 x 1.5 mL samples (lyophilized plasma or cell culture lysates)	3	Partial coverage/ unable to monitor at bioMérieux
	Virus genome detection- Chikungunya	392	Chikungunya virus	4 x 1.5 mL samples (lyophilized plasma or cell culture lysates)	3	Partial coverage
UK NEQAS	Malaria (Molecular)	-	Plasmodium	4 lyophilized blood samples	4	Partial coverage
QCMD	CHIKV25	QAV154 175	Chikungunya virus	10 lyophilized samples	1	Partial coverage
	DENVRNA25	QAV114 148	Dengue virus	10 lyophilized samples	1	
	MALARIA25	QAP214 218	Malaria	10 lyophilized samples	1	

NOTE: The API Global Fever Panel meets CMS requirements for bacteriology, parasite and virology identification.

Technical Support Contact Information

bioMérieux is dedicated to providing the best customer support available. If you have questions or concerns about this process, please contact your local bioMérieux representative or your authorized distributor.

*All product names, trademarks and registered trademarks are property of their respective owners.