



BIOMÉRIEUX

DON'T MISS A **DIAGNOSIS.**

BIOFIRE® fast syndromic PCR testing for infectious diseases



BIOFIRE®
RESPIRATORY 2.1
PANEL



BIOFIRE®
BLOOD CULTURE
IDENTIFICATION 2 PANEL



BIOFIRE® FILMARRAY®
GASTROINTESTINAL
PANEL



BIOFIRE® FILMARRAY®
MENINGITIS/
ENCEPHALITIS PANEL



BIOFIRE® FILMARRAY®
PNEUMONIA PANEL



BIOFIRE®
JOINT INFECTION
PANEL



BIOFIRE® FILMARRAY®
TROPICAL FEVER
PANEL



BIOFIRE®
FIREWORKS™

PIONEERING DIAGNOSTICS





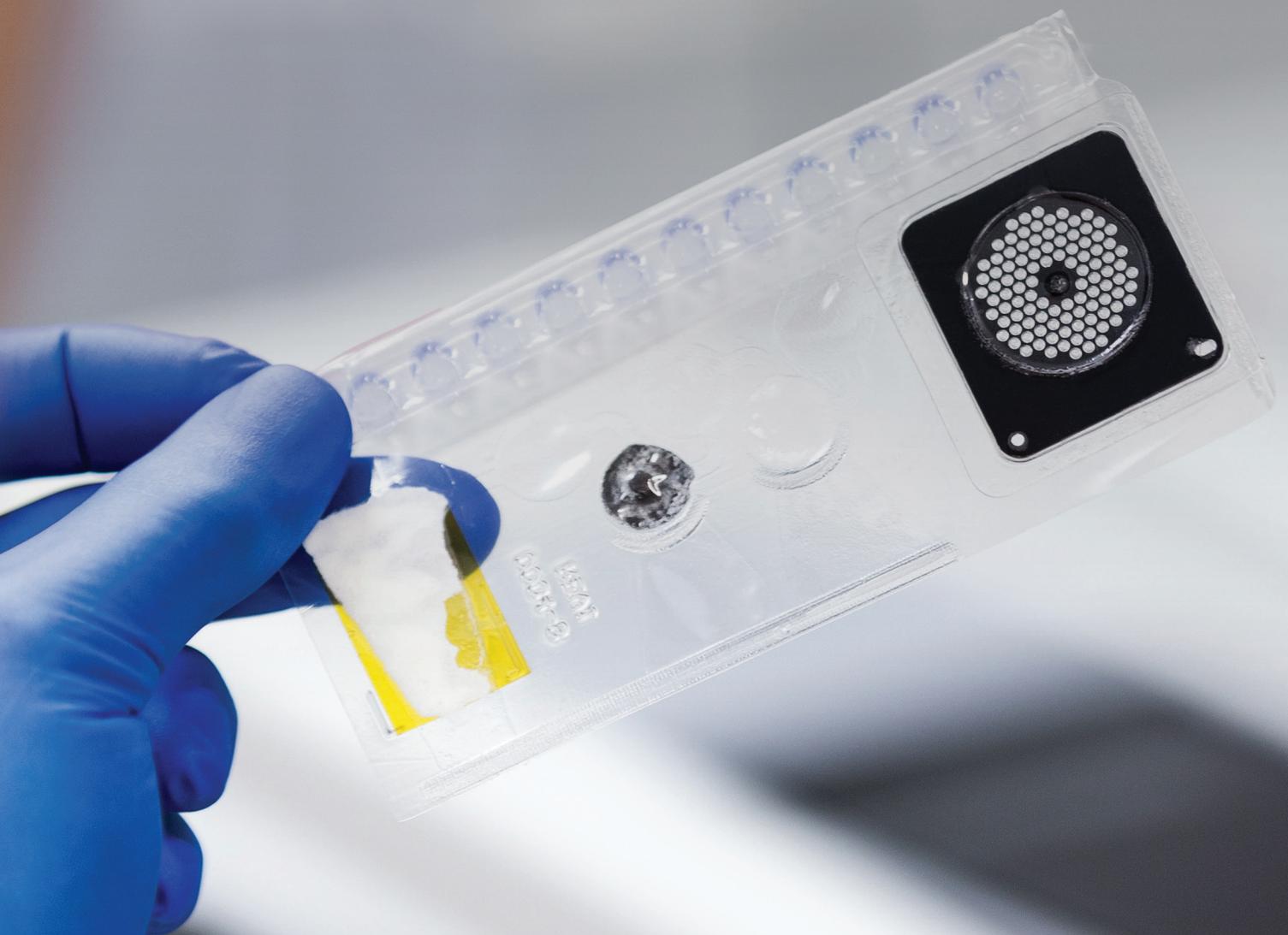
BIOFIRE® Syndromic Testing

Don't miss the right test
the first time.

TRADITIONAL VS. SYNDROMIC TESTING	3
BIOFIRE® FILMARRAY® TORCH	4
BIOFIRE® SYNDROMIC TESTING PANELS	7
RESPIRATORY	8
BLOODSTREAM INFECTION	9
GASTROINTESTINAL	10
MENINGITIS/ENCEPHALITIS	11
PNEUMONIA	12
JOINT INFECTION	13
TROPICAL FEVER	14
BIOFIRE® FIREWORKS™	15
CUSTOMER SUPPORT	16

**The BIOFIRE® line of products
from bioMérieux is evolving
infectious disease diagnostics.**

**The BIOFIRE syndromic approach
empowers clinicians and lab
personnel to choose the right test
the first time.**



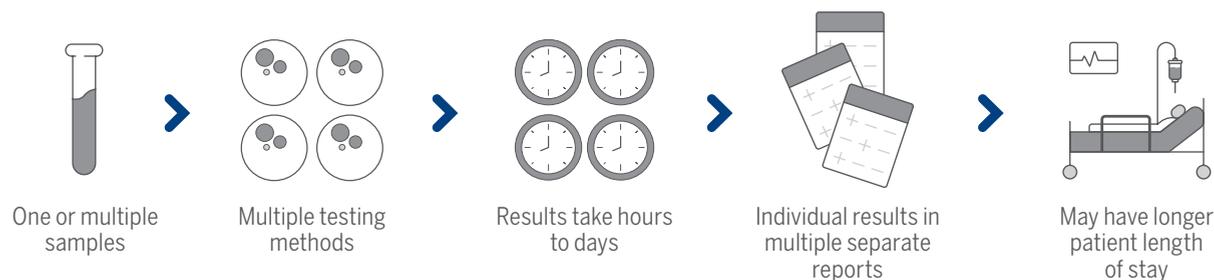
The BIOFIRE® syndromic approach is a symptom-driven broad grouping of probable pathogens into one fast test. Using multiplex PCR technology, a BIOFIRE syndromic test targets a comprehensive menu of microorganisms that may present with similar signs and symptoms. The syndromic approach **maximizes the chance of getting the right answer in a clinically relevant time frame.**

Targeted infectious disease diagnostics limit testing to only a few pathogens associated with a clinical syndrome. By using a molecular syndromic approach and a broad test menu, syndromic testing from bioMérieux can better detect and identify the target with just one easy diagnostic test.

As the industry leader, bioMérieux sets the standard for syndromic infectious disease diagnostics. While the BIOFIRE technology is highly sophisticated, simplicity is a trademark characteristic of the BIOFIRE System. BIOFIRE offers 7 comprehensive panels that are US FDA-cleared and/or CE-marked, designed to detect the most common pathogens and antimicrobial resistance genes. Our innovative, easy-to-use solutions help health care providers better detect and identify infectious targets, enabling quicker, more effective patient care.

Traditional Testing

Traditional methods of pathogen identification can be time consuming and lack sensitivity.¹



Syndromic Testing

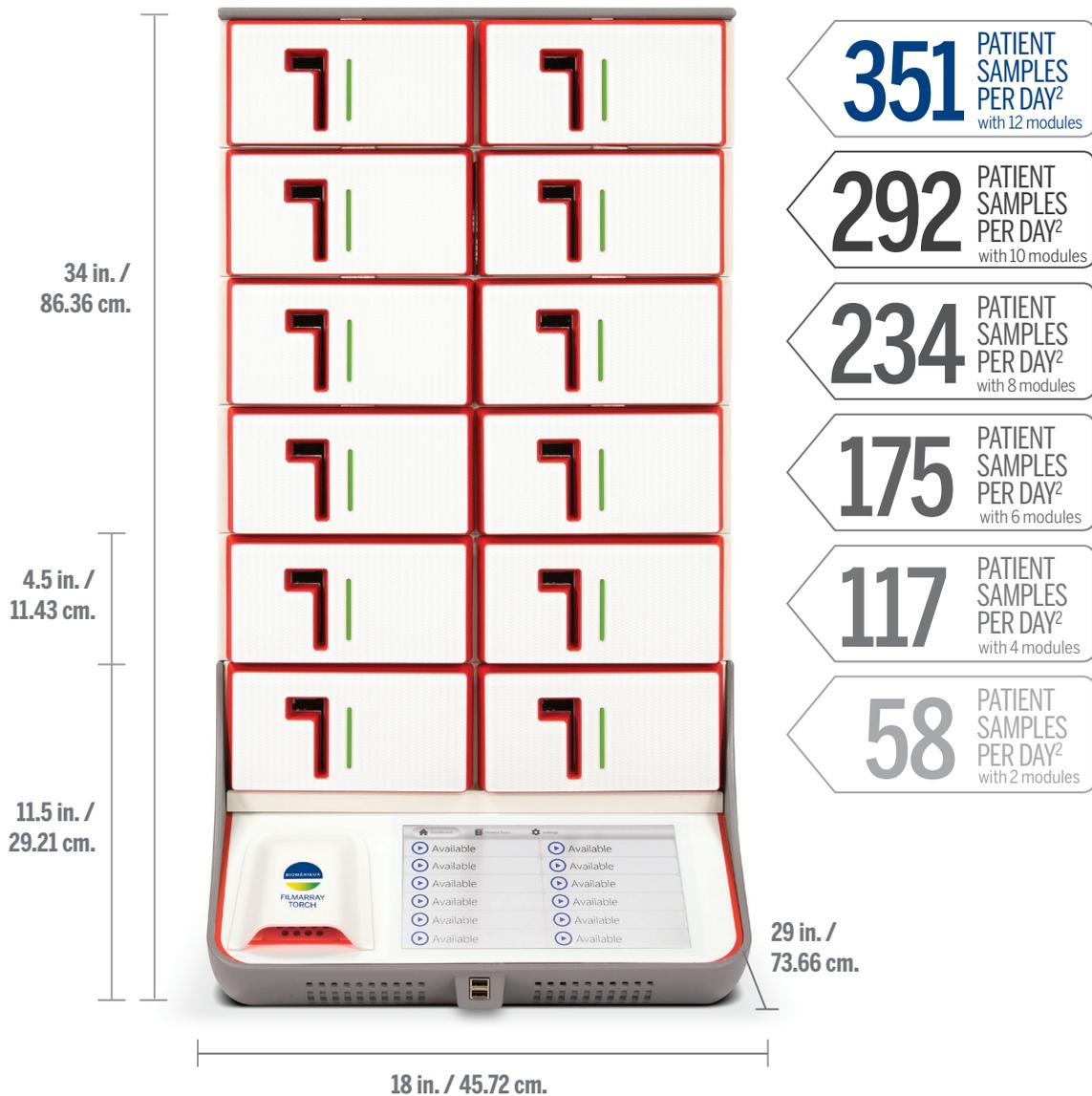
Syndromic testing provides a streamlined workflow and fast, comprehensive results.



1. Cybulski RJ, et al. Clin Infect Dis. 2018;67(11):1688-96.

The BIOFIRE® FILMARRAY® TORCH

The most advanced syndromic testing



Scalable configuration with a modular design from 1 to 12 modules



High throughput for running up to 351 tests per day



Optimized footprint with just 18 in. (46 cm.) of bench space needed

2. Calculations based on running the BIOFIRE® Respiratory 2.1 plus Panel over a 24-hour day.

Easier Testing, Faster Results



2 minutes of hands-on time

Sample preparation and test loading are quick and easy, taking just two minutes of hands-on time to complete.



Results in about an hour

The BIOFIRE FILMARRAY TORCH's automated syndromic molecular test can be completed in about an hour.



Bidirectional connection to LIS

The BIOFIRE FILMARRAY TORCH can be interfaced with the Laboratory Information System (LIS) in either unidirectional or bidirectional HL7 configurations—saving time and reducing the likelihood of error without sacrificing data security. The BIOFIRE FILMARRAY TORCH is capable of interfacing with most major LIS.



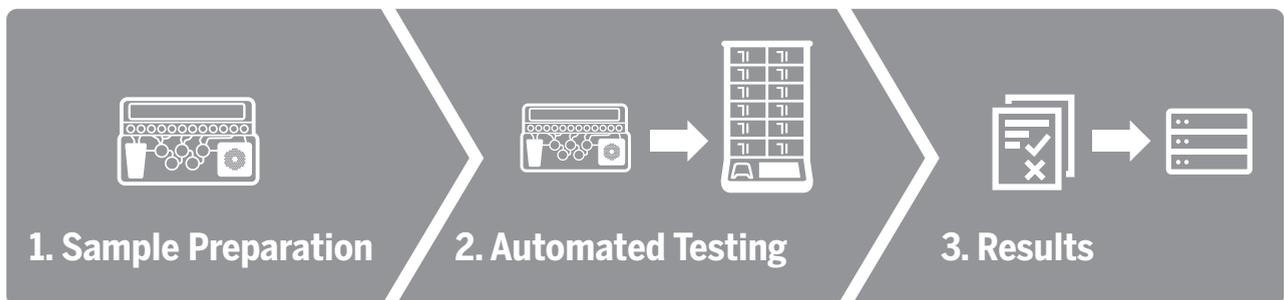
All-in-one technology

The user-friendly, multiplex, nested PCR system incorporates sample preparation, amplification, detection, and analysis in one pouch.

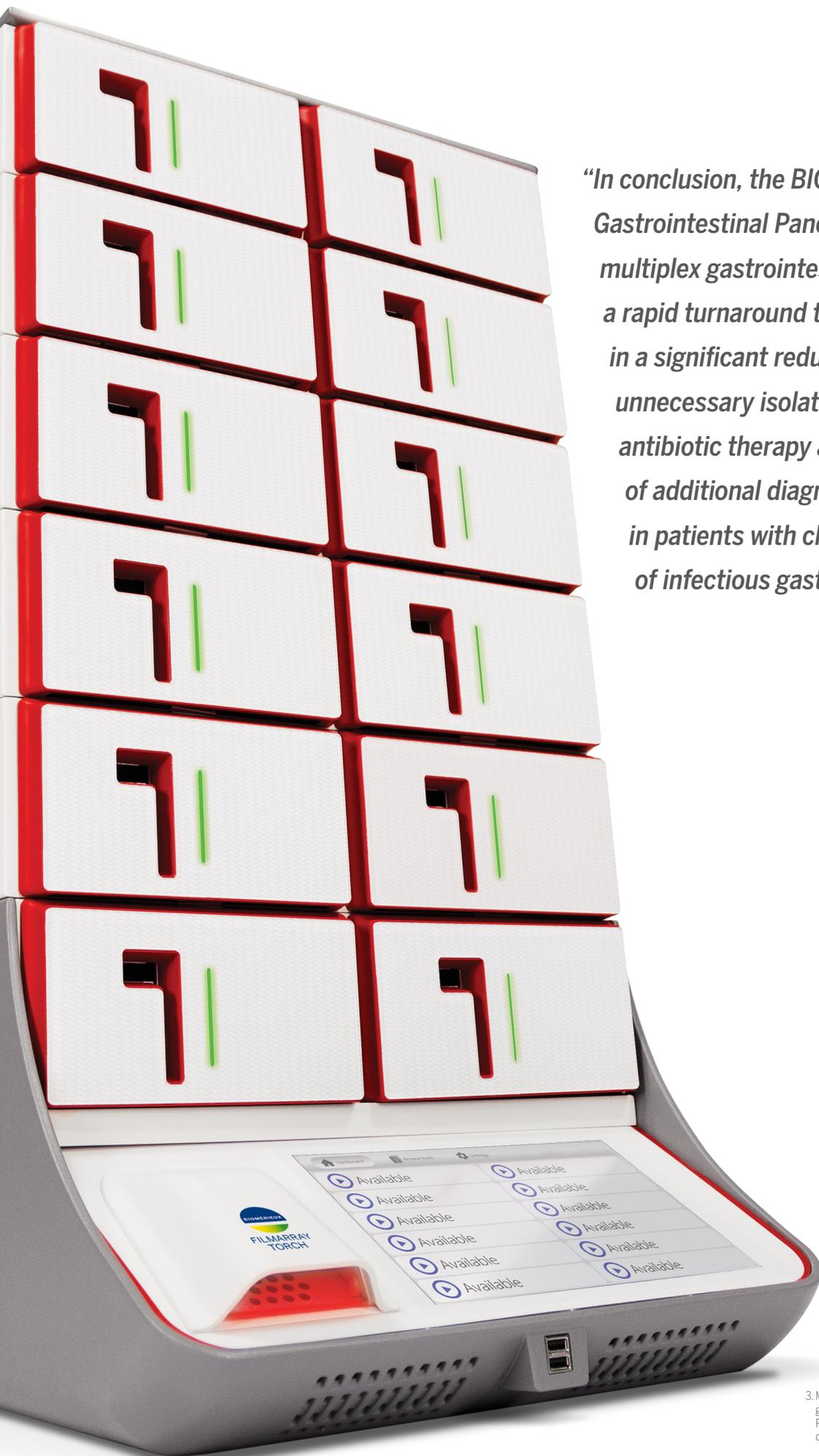


Any tech, any shift

With no precise pipetting required, the BIOFIRE FILMARRAY TORCH can be easily used by any tech on any shift at any size institution.*



*Can be run by any technician with proper laboratory training



“In conclusion, the BIOFIRE® FILMARRAY® Gastrointestinal Panel is a broad, multiplex gastrointestinal panel with a rapid turnaround time, resulting in a significant reduction of unnecessary isolation days, antibiotic therapy and prevention of additional diagnostic procedures in patients with clinical suspicion of infectious gastroenteritis.”³

3. Machiels J, et al. Impact of the BioFire FilmArray gastrointestinal panel on patient care and infection control. PLoS One. 2020;15(2):e0228596. Published 2020 Feb 6. doi:10.1371/journal.pone.0228596.

Fast Answers with BIOFIRE® Syndromic Panels

Comprehensive panels offer better diagnostics

Comprehensive panels remove the guesswork. Each BIOFIRE Panel targets an infectious disease syndrome by combining a broad grouping of probable pathogenic causes into a single test.

The CE-marked and/or FDA cleared BIOFIRE Panels test for viruses, bacteria, parasites, yeast, and antimicrobial resistance genes.

175+
TARGETS
~1hr



BIOFIRE® RESPIRATORY 2.1 PANEL



BIOFIRE® BLOOD CULTURE IDENTIFICATION 2 PANEL



BIOFIRE® FILMARRAY® GASTROINTESTINAL PANEL



BIOFIRE® FILMARRAY® MENINGITIS/ENCEPHALITIS PANEL



BIOFIRE® FILMARRAY® PNEUMONIA PANEL



BIOFIRE® JOINT INFECTION PANEL



BIOFIRE® FILMARRAY® TROPICAL FEVER PANEL

Product availability varies by country. Consult your bioMérieux representative.



BIOFIRE® RESPIRATORY 2.1 (RP2.1) PANEL

Sample Type: 0.3 mL of nasopharyngeal swab in transport media or saline

1 Test. 22 Targets. ~45 Minutes.

The BIOFIRE FILMARRAY RP2.1 Panel identifies the most common viral and bacterial pathogens—including SARS-CoV-2—that cause respiratory tract infections, which can present with nearly indistinguishable symptoms. An unprecedented run time of about 45 minutes enables higher efficiency and throughput on the BIOFIRE® FILMARRAY® 2.0 and the BIOFIRE® FILMARRAY® TORCH Systems. Fast and accurate respiratory PCR test results may enable better-informed diagnosis and treatment of patients. Quick turnaround on a broad menu of pathogens may also help clinicians make vital decisions regarding admission, isolation, cohorting, and additional diagnostic testing.

Panel Menu

VIRUSES

Adenovirus
Coronavirus 229E
Coronavirus HKU1
Coronavirus NL63
Coronavirus OC43
Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
Human metapneumovirus
Human rhinovirus/enterovirus

Influenza A virus
Influenza A virus A/H1
Influenza A virus A/H3
Influenza A virus A/H1-2009
Influenza B virus
Parainfluenza virus 1
Parainfluenza virus 2
Parainfluenza virus 3
Parainfluenza virus 4
Respiratory syncytial virus

BACTERIA

Bordetella parapertussis
Bordetella pertussis
Chlamydia pneumoniae
Mycoplasma pneumoniae

Overall Performance: 97.1% sensitivity, 99.3% specificity⁴

SARS-CoV-2 Performance: 98.4% PPA, 98.9% NPA⁵

FDA cleared

4. Overall performance based on prospective clinical study for the BIOFIRE® FILMARRAY® Respiratory 2 *plus* Panel, data on file, BioFire Diagnostics.

5. Overall performance based on prospective SARS-CoV-2 clinical study for the BIOFIRE® Respiratory 2.1 *plus* Panel in comparison to 3 EUA tests, data on file, BioFire Diagnostics.

Product availability varies by country. Consult your bioMérieux representative.



BIOFIRE® BLOOD CULTURE IDENTIFICATION 2 (BCID2) PANEL

Sample Type: 0.2 mL positive blood culture media

1 Test. 43 Targets. ~1 Hour.

The BIOFIRE FILMARRAY BCID2 Panel tests a single positive blood culture sample to simultaneously provide results for multiple organisms and organism groups that cause bloodstream infections, as well as genetic markers associated with antimicrobial resistance. Fast identification of the organism(s) in the blood culture, along with information about antimicrobial resistance gene presence for select microorganisms, may aid in making appropriate treatment decisions.⁶

Panel Menu

GRAM-NEGATIVE BACTERIA

*Acinetobacter calcoaceticus-
baumannii* complex
Bacteroides fragilis
Enterobacterales
Enterobacter cloacae complex
Escherichia coli
Klebsiella aerogenes
Klebsiella oxytoca
Klebsiella pneumoniae group
Proteus spp.
Salmonella spp.
Serratia marcescens
Haemophilus influenzae
Neisseria meningitidis
Pseudomonas aeruginosa
Stenotrophomonas maltophilia

GRAM-POSITIVE BACTERIA

Enterococcus faecalis
Enterococcus faecium
Listeria monocytogenes
Staphylococcus spp.
Staphylococcus aureus
Staphylococcus epidermidis
Staphylococcus lugdunensis
Streptococcus spp.
Streptococcus agalactiae
Streptococcus pneumoniae
Streptococcus pyogenes

YEAST

Candida albicans
Candida auris
Candida glabrata
Candida krusei
Candida parapsilosis
Candida tropicalis
Cryptococcus (C. neoformans/C. gattii)

ANTIMICROBIAL RESISTANCE GENES

Carbapenemases

IMP
KPC
OXA-48-like
NDM
VIM

Colistin Resistance

mcr-1

ESBL

CTX-M

Methicillin Resistance

mecA/C
mecA/C and MREJ (MRSA)

Vancomycin Resistance

vanA/B

Performance: 99.0% sensitivity, 99.7% specificity⁷

FDA cleared | CE₂₇₉₇

6. Sparks R, et al. Pathology, 2021. 53(7):889-895

7. Overall performance is the aggregate of the prospective, archived, and seeded data from the clinical studies. Data on file, BioFire Diagnostics.

Product availability varies by country. Consult your bioMérieux representative.



BIOFIRE® FILMARRAY® GASTROINTESTINAL (GI) PANEL

Sample Type: 0.2 mL stool collected in Cary Blair transport medium

1 Test. 22 Targets. ~1 Hour.

The BIOFIRE FILMARRAY GI Panel tests stool in Cary Blair for the bacteria, viruses, and parasites most commonly associated with gastroenteritis. Quickly identifying the probable pathogen can ensure appropriate targeted treatment and patient management and help decrease infectious gastroenteritis, which can lead to prolonged or severe illness.

Panel Menu

BACTERIA

Campylobacter (*C. jejuni*/*C. coli*/*C. upsaliensis*)
Clostridioides (*Clostridium*) *difficile* (toxin A/B)*
Plesiomonas shigelloides
Salmonella
Vibrio (*V. parahaemolyticus*/*V. vulnificus*/*V. cholerae*)
Vibrio cholerae
Yersinia enterocolitica
Diarrheagenic *Escherichia coli*/*Shigella*
Enteroaggregative *E. coli* (EAEC)
Enteropathogenic *E. coli* (EPEC)
Enterotoxigenic *E. coli* (ETEC) *lt/st*
Shiga-like toxin-producing *E. coli* (STEC) *stx1/stx2*
E. coli O157
Shigella/Enteroinvasive *E. coli* (EIEC)

*Selective reporting available for *C. Diff*

VIRUSES

Adenovirus F40/41
Astrovirus
Norovirus GI/GII
Rotavirus A
Sapovirus (I, II, IV, and V)

PARASITES

Cryptosporidium
Cyclospora cayetanensis
Entamoeba histolytica
Giardia lamblia

Performance: 98.7% sensitivity, 99.2% specificity⁸

FDA cleared | CE₂₇₉₇

⁸ Overall performance based on prospective clinical study for the BIOFIRE® FILMARRAY® Gastrointestinal Panel, data on file, BioFire Diagnostics.

Product availability varies by country. Consult your bioMérieux representative.



BIOFIRE® FILMARRAY® MENINGITIS/ENCEPHALITIS (ME) PANEL

Sample Type: 0.2 mL of cerebrospinal fluid (CSF)

1 Test. 14 Targets. ~1 Hour.

Every minute counts and time to diagnosis is critical when it comes to meningitis and encephalitis. The right treatment depends on fast identification of the pathogen as bacterial, viral, or yeast. The BIOFIRE FILMARRAY ME Panel utilizes a syndromic approach—simultaneously testing for a comprehensive set of 14 of the most common pathogens associated with central nervous system (CNS) infections—to deliver actionable results in about an hour, allowing clinicians to make timely and optimal treatment decisions.

Panel Menu

BACTERIA

Escherichia coli K1
Haemophilus influenzae
Listeria monocytogenes
Neisseria meningitidis
Streptococcus agalactiae
Streptococcus pneumoniae

VIRUSES

Cytomegalovirus (CMV)
Enterovirus (EV)
Herpes simplex virus 1 (HSV-1)
Herpes simplex virus 2 (HSV-2)
Human herpesvirus 6 (HHV-6)
Human parechovirus (HPeV)
Varicella zoster virus (VZV)

YEAST

Cryptococcus (C. neoformans/C. gattii)

Performance: 94.2% sensitivity, 99.8% specificity⁹

FDA cleared | CE₂₇₉₇

⁹ Overall performance based on prospective clinical study for the BIOFIRE® FILMARRAY® Meningitis/Encephalitis Panel, data on file, BioFire Diagnostics.

Product availability varies by country. Consult your bioMérieux representative.



BIOFIRE® FILMARRAY® PNEUMONIA (PN) PANEL

Sample Type: Sputum-like (including ETA) and BAL-like (including BAL and mini BAL)

1 Test. 33 Targets. ~1 Hour.

Fast identification of probable causative pathogens and antimicrobial resistance genes can help healthcare providers quickly determine how best to treat a lower respiratory tract infection. The BIOFIRE FILMARRAY PN Panel tests for 26 of the most common bacterial and viral pathogens associated with pneumonia, along with 7 antimicrobial resistance genes.

Panel Menu

BACTERIA (SEMI-QUANTITATIVE)

*Acinetobacter calcoaceticus-
baumannii* complex
Enterobacter cloacae complex
Escherichia coli
Haemophilus influenzae
Klebsiella aerogenes
Klebsiella oxytoca
Klebsiella pneumoniae group
Moraxella catarrhalis
Proteus spp.
Pseudomonas aeruginosa
Serratia marcescens
Staphylococcus aureus
Streptococcus agalactiae
Streptococcus pneumoniae
Streptococcus pyogenes

ATYPICAL BACTERIA (QUALITATIVE)

Chlamydia pneumoniae
Legionella pneumophila
Mycoplasma pneumoniae

VIRUSES

Adenovirus
Coronavirus
Human metapneumovirus
Human rhinovirus/enterovirus
Influenza A virus
Influenza B virus
Parainfluenza virus
Respiratory syncytial virus

ANTIMICROBIAL RESISTANCE GENES

Carbapenemases

IMP
KPC
NDM
OXA-48-like
VIM

ESBL

CTX-M

Methicillin Resistance

mecA/C and MREJ (MRSA)

Performance: BAL-like (including BAL and mini-BAL): 96.2% sensitivity, 98.3% specificity;
Sputum-like (including ETA): 96.3% sensitivity, 97.3% specificity¹⁰

FDA cleared |  2797

¹⁰. Overall performance based on prospective clinical study for the BIOFIRE® FILMARRAY® Pneumonia Panel, data on file, BioFire Diagnostics.

Product availability varies by country. Consult your bioMérieux representative.



BIOFIRE® JOINT INFECTION (JI) PANEL

Sample Type: 0.2 mL of synovial fluid

1 Test. 39 Targets. ~1 Hour.

The BIOFIRE FILMARRAY JI Panel tests for common causes of prosthetic joint infections and septic arthritis. The BIOFIRE FILMARRAY JI Panel includes assays for 39 targets, including gram-positive bacteria, gram-negative bacteria, yeast, and antibiotic resistance genes. Through fast pathogen identification, the BIOFIRE FILMARRAY JI Panel may aid in pathogen guided patient management.

Panel Menu

GRAM-POSITIVE BACTERIA

Anaerococcus prevotii/vaginalis
Clostridium perfringens
Cutibacterium avidum/granulosum
Enterococcus faecalis
Enterococcus faecium
Fingoldia magna
Parvimonas micra
Peptoniphilus
Peptostreptococcus anaerobius
Staphylococcus aureus
Staphylococcus lugdunensis
Streptococcus spp.
Streptococcus agalactiae
Streptococcus pneumoniae
Streptococcus pyogenes

GRAM-NEGATIVE BACTERIA

Bacteroides fragilis
Citrobacter
Enterobacter cloacae complex
Escherichia coli
Haemophilus influenzae
Kingella kingae
Klebsiella aerogenes
Klebsiella pneumoniae group
Morganella morganii
Neisseria gonorrhoeae
Proteus spp.
Pseudomonas aeruginosa
Salmonella spp.
Serratia marcescens

YEAST

Candida spp.
Candida albicans

ANTIMICROBIAL RESISTANCE GENES

Carbapenemases

IMP
KPC
NDM
OXA-48-like
VIM

ESBL

CTX-M

Methicillin Resistance

mecA/C and MREJ (MRSA)

Vancomycin Resistance

vanA/B

Performance: 91.7% sensitivity, 99.8% specificity¹¹

FDA cleared | CE₂₇₉₇

¹¹ Overall performance based on prospective clinical study for the BIOFIRE® Joint Infection Panel, data on file, BioFire Diagnostics.

Product availability varies by country. Consult your bioMérieux representative.



BIOFIRE® FILMARRAY® TROPICAL FEVER (TF) PANEL

Sample Type: 0.2 mL of human whole blood collected in EDTA tubes

1 Test. 6 Targets. ~50 Minutes.

The BIOFIRE FILMARRAY TF Panel tests for a syndromic grouping of bacteria, viruses and parasites most often associated with tropical fever infections. Using multiplex PCR technology, the BIOFIRE FILMARRAY TF Panel enables fast, accurate results on 6 targets in ~ 50 minutes.

Panel Menu

VIRUSES

Chikungunya
Dengue (serotypes 1,2,3 and 4)

BACTERIA

Leptospira spp.

PARASITES

Plasmodium spp.
Plasmodium falciparum
Plasmodium vivax/ovale

Performance: 95.1% sensitivity, 99.8% specificity¹²

FDA cleared | CE₂₇₉₇

¹² Performance claims are based on DEN200043 (De Novo) Global Fever Panel Clinical Studies (on file at bioMérieux)

Product availability varies by country. Consult your bioMérieux representative.

Data-driven Decision Making

Take your BIOFIRE® Systems even further with BIOFIRE® FIREWORKS™.



BIOFIRE® FIREWORKS™

Boost efficiency, improve productivity with data-powered insights for BIOFIRE systems.

Take BIOFIRE systems further with data-driven decisions. FIREWORKS™ offers a centralized data management web portal that delivers comprehensive insights and analytics on BIOFIRE System performance, test results, utilization, pathogen surveillance, workflow management, and more.

Safe, Secure, and Private.

At bioMérieux, we understand that keeping customer and patient data safe is critical which is why we place cybersecurity at the heart of our business. FIREWORKS™ is designed, developed, and implemented following industry standards and regulations utilizing the Secure Development Lifecycle to ensure safety, security, and privacy.



BIOMÉRIEUX VISION SUITE

BIOMÉRIEUX VISION SUITE turns laboratory and hospital data into insightful, actionable information to support diagnostic and clinical decisions at all stages.

By providing a comprehensive suite of software solutions that collect, analyze, and merge various sources of data, BIOMÉRIEUX VISION SUITE empowers you to make the right decisions at the right time.

Peace of Mind All the Time

First in diagnostics. First in customer care.

bioMérieux has a skilled team dedicated to client success. Our customer support team provides global product support, solution training courses, LIS connectivity assistance, and instrument or chemistry related troubleshooting. We are committed to the speedy resolution of all technical issues, maximized when using VILINK® for remote support and troubleshooting through a secure connection. Moreover VILINK® enables automatic software, firmware and security updates—including FIREWORKS installation and updates.



International Support

For international BIOFIRE technical assistance and support, please contact your local bioMérieux representative or distributor.

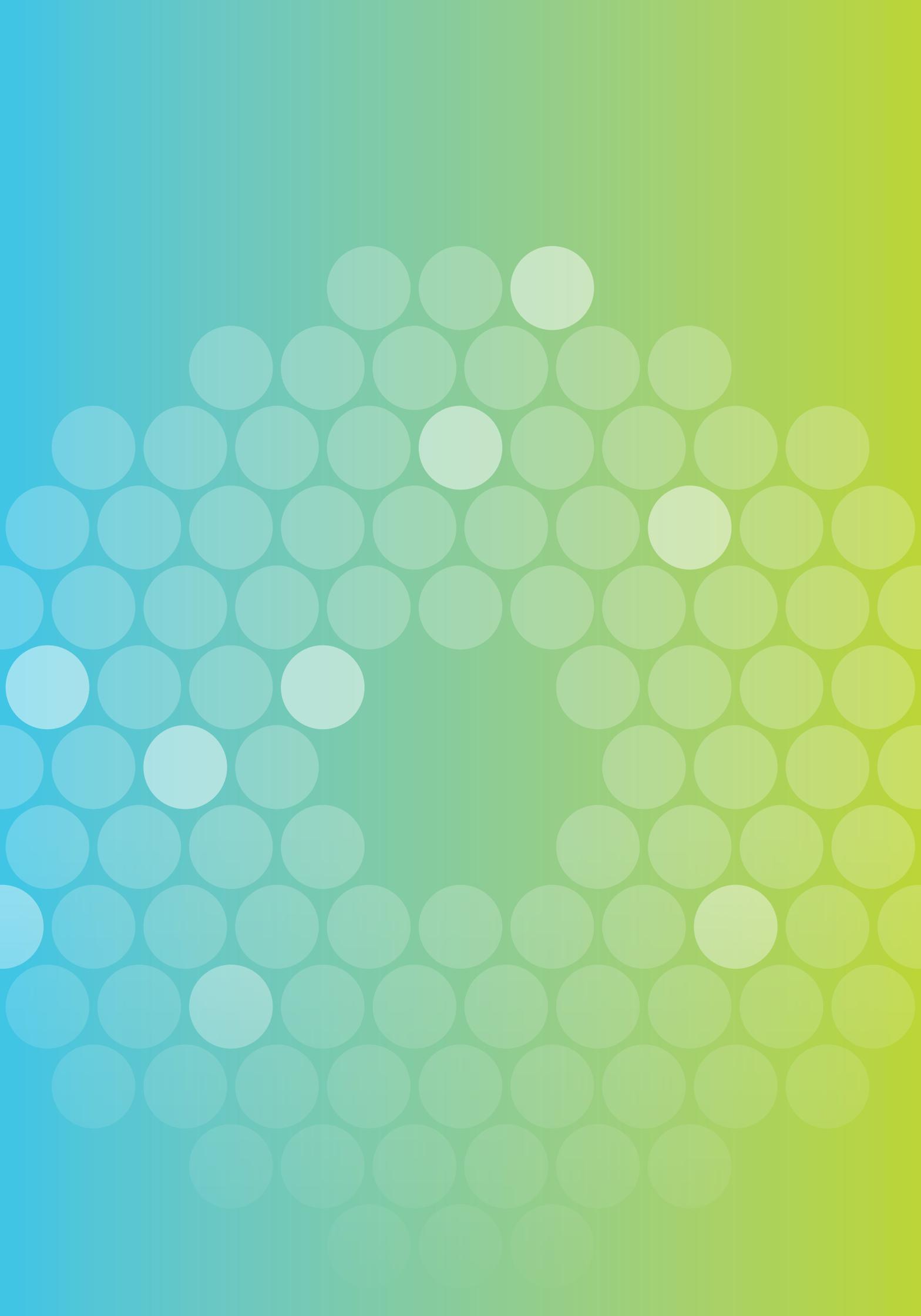


Help at Your Fingertips

With a complete suite of resources, our customers have access to everything they need for set-up, verification, and integration of BIOFIRE® FILMARRAY® Systems.

Our website provides documents to assist with verification, EC Declarations of Conformity, and continuing education for all customers.

Our website [biomerieux.com](https://www.biomerieux.com) provides documents to assist with verification, EC Declarations of Conformity, Advisory Notices, Information Sheets, Product Support Documents, and other resources.





The purchase of this product includes a limited, non-transferable license under specific claims of one or more US patents listed on the bioMérieux website (<http://www.biomerieux-usa.com/patents>) owned by bioMérieux, BioFire Diagnostics, and/or the Research Foundation of The University of Utah.

The blue logo, BIOFIRE and FILMARRAY logos, and BIOMÉRIEUX, BIOFIRE, and FILMARRAY are used, pending, and/or registered trademarks belonging to bioMérieux or BioFire or one of their subsidiaries or companies. Document and/or picture not legally binding. Modifications can be made without prior notice. No part of this document may be reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose, without the express written permission of bioMérieux / BioFire Diagnostics.

Contact Us

bioMérieux S.A.
69280 Marcy l'Etoile
France
Tel: +33 (0) 4 78 87 20 00
Fax: +33 (0) 4 78 87 20 90
biomerieux.com

Product availability varies by country. Consult your bioMérieux representative.

9329108 007/GB/D/ BMX.1.164300.2