



**BIOMÉRIEUX**

# DON'T MISS A **DIAGNOSIS.**

BIOFIRE® fast syndromic PCR testing for infectious diseases



BIOFIRE®  
**RESPIRATORY 2.1 PLUS  
PANEL**



BIOFIRE®  
**BLOOD CULTURE  
IDENTIFICATION 2 PANEL**



BIOFIRE® FILMARRAY®  
**GASTROINTESTINAL  
PANEL**



BIOFIRE® FILMARRAY®  
**MENINGITIS/  
ENCEPHALITIS PANEL**



BIOFIRE® FILMARRAY®  
**PNEUMONIA PLUS PANEL**



BIOFIRE®  
**JOINT INFECTION  
PANEL**



BIOFIRE® FILMARRAY®  
**TROPICAL FEVER  
PANEL**



BIOFIRE®  
**FIREWORKS™**

**PIONEERING DIAGNOSTICS**





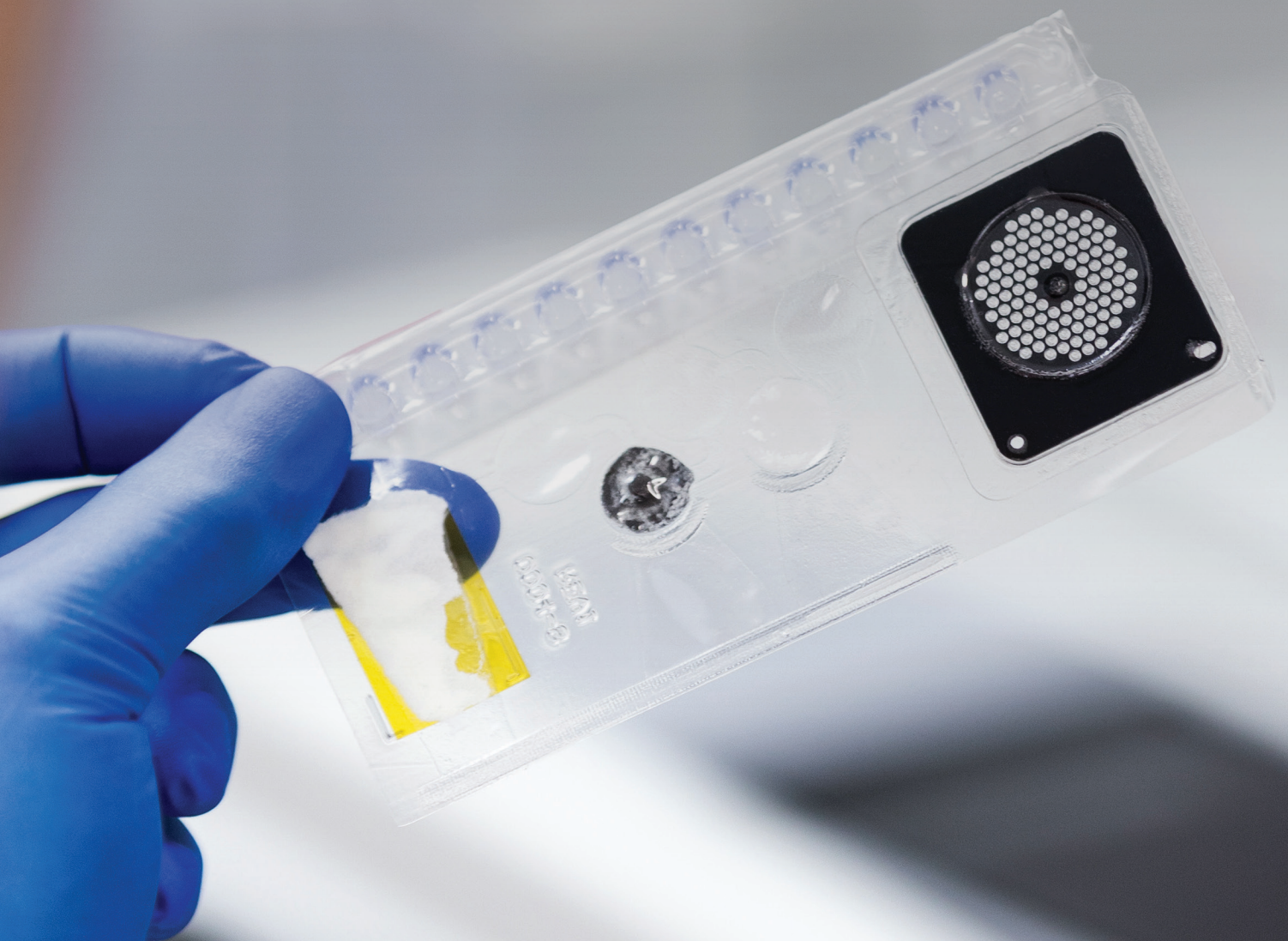
# BIOFIRE® Syndromic Testing

Don't miss the right test  
the first time.

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**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.**



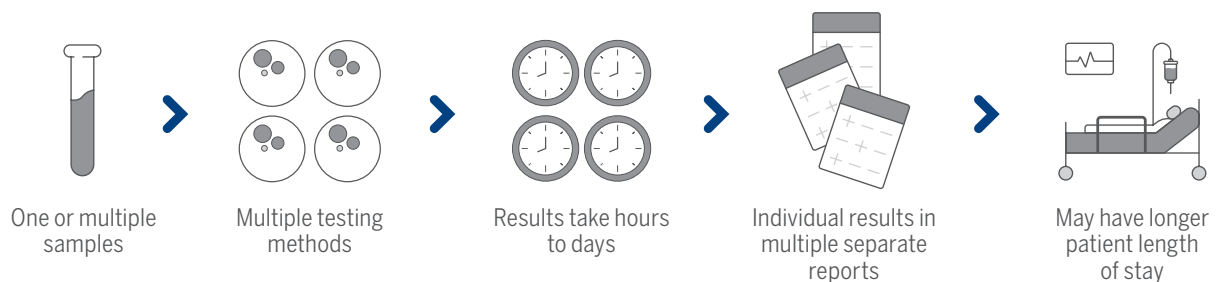
The BIOFIRE® syndromic approach is a symptom-driven broad grouping of probable pathogens into one fast test. Using multiplex PCR technology, a BIOFIRE syndromic test targets a comprehensive menu of microorganisms that may present with similar signs and symptoms. The syndromic approach **maximizes the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

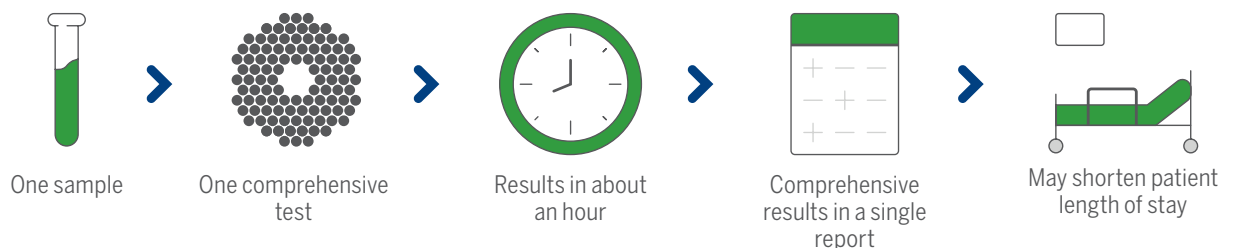
## Traditional Testing

Traditional methods of pathogen identification can be time consuming and lack sensitivity.<sup>1</sup>



## Syndromic Testing

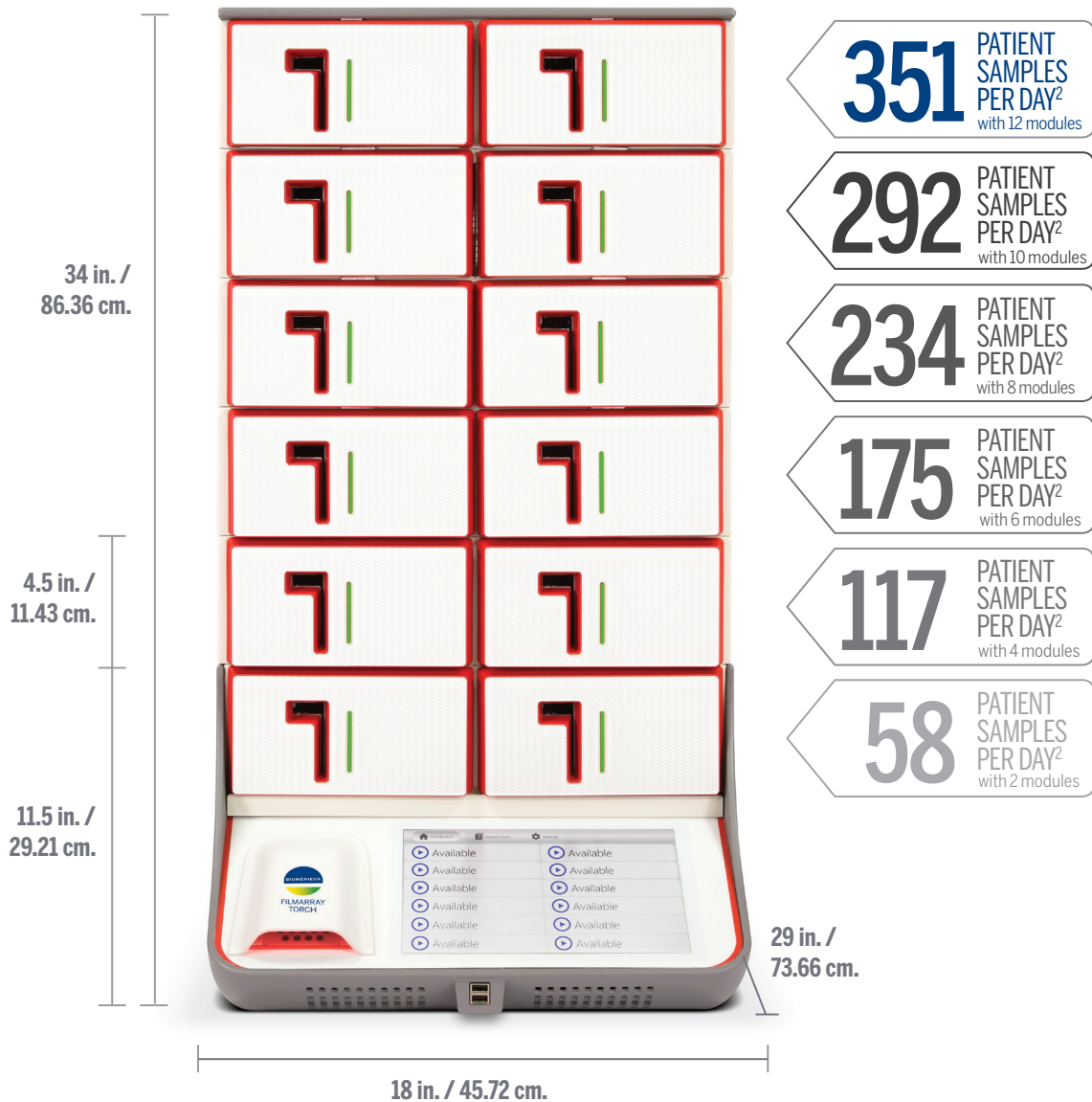
Syndromic testing provides a streamlined workflow and fast, comprehensive results.



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.



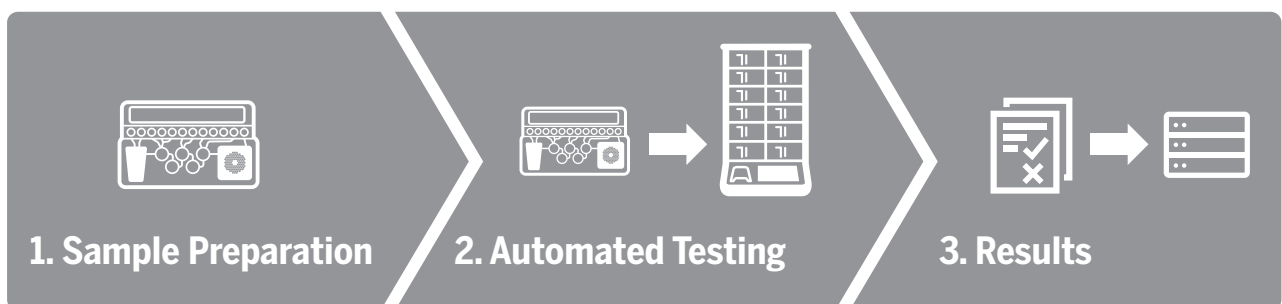
## All-in-one technology

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.”<sup>3</sup>*

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 *plus* PANEL**



**BIOFIRE® BLOOD CULTURE IDENTIFICATION 2 PANEL**



**BIOFIRE® FILMARRAY® GASTROINTESTINAL PANEL**



**BIOFIRE® FILMARRAY® MENINGITIS/ENCEPHALITIS PANEL**



**BIOFIRE® FILMARRAY® PNEUMONIA *plus* PANEL**



**BIOFIRE® JOINT INFECTION PANEL**



**BIOFIRE® FILMARRAY® TROPICAL FEVER PANEL**

Product availability varies by country. Consult your bioMérieux representative.



# BIOFIRE® RESPIRATORY 2.1 PLUS (RP2.1plus) PANEL

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

## 1 Test. 23 Targets. ~45 Minutes.

The BIOFIRE RP2.1plus 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  
Middle East respiratory syndrome coronavirus (MERS-CoV)  
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% specificity<sup>4</sup>

**SARS-CoV-2 Performance:** 98.4% PPA, 98.9% NPA<sup>5</sup>



4. Overall performance based on prospective clinical study for the BIOFIRE® 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 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.<sup>6</sup>

## 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% specificity<sup>7</sup>

FDA cleared | CE<sub>2797</sub>

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% specificity<sup>8</sup>

FDA cleared | CE<sub>2797</sub>

<sup>8</sup> 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% specificity<sup>9</sup>

FDA cleared | CE<sub>2797</sub>

<sup>9</sup> 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 *PLUS* (PN*plus*) PANEL

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

## 1 Test. 34 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*plus* Panel tests for 27 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  
Middle East respiratory syndrome  
coronavirus (MERS-CoV)  
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, 98.4% specificity;  
Sputum-like (including ETA): 96.3% sensitivity, 97.4% specificity<sup>10</sup>



<sup>10</sup>. Overall performance based on prospective clinical study for the BIOFIRE® FILMARRAY® Pneumonia *plus* 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 JI Panel tests for common causes of prosthetic joint infections and septic arthritis. The BIOFIRE 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 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% specificity<sup>11</sup>

FDA cleared | CE<sub>2797</sub>

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% specificity<sup>12</sup>

FDA cleared |  2797

<sup>12</sup> 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.

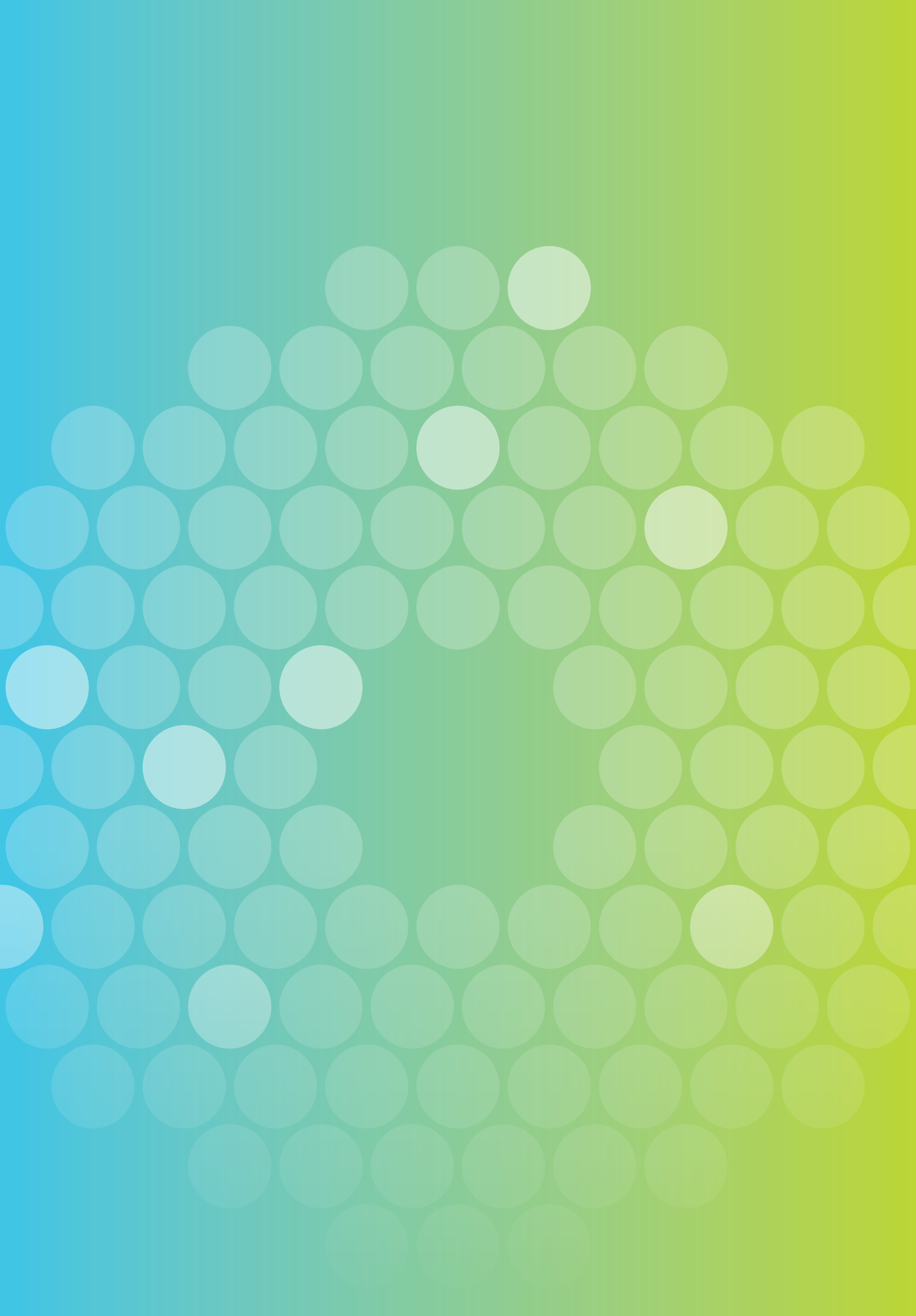


### Help at Your Fingertips

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.

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Product availability varies by country. Consult your bioMérieux representative.

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