

DON'T MISS A DIAGNOSIS.



**BIOFIRE
DEFENSE**
A bioMérieux Company

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



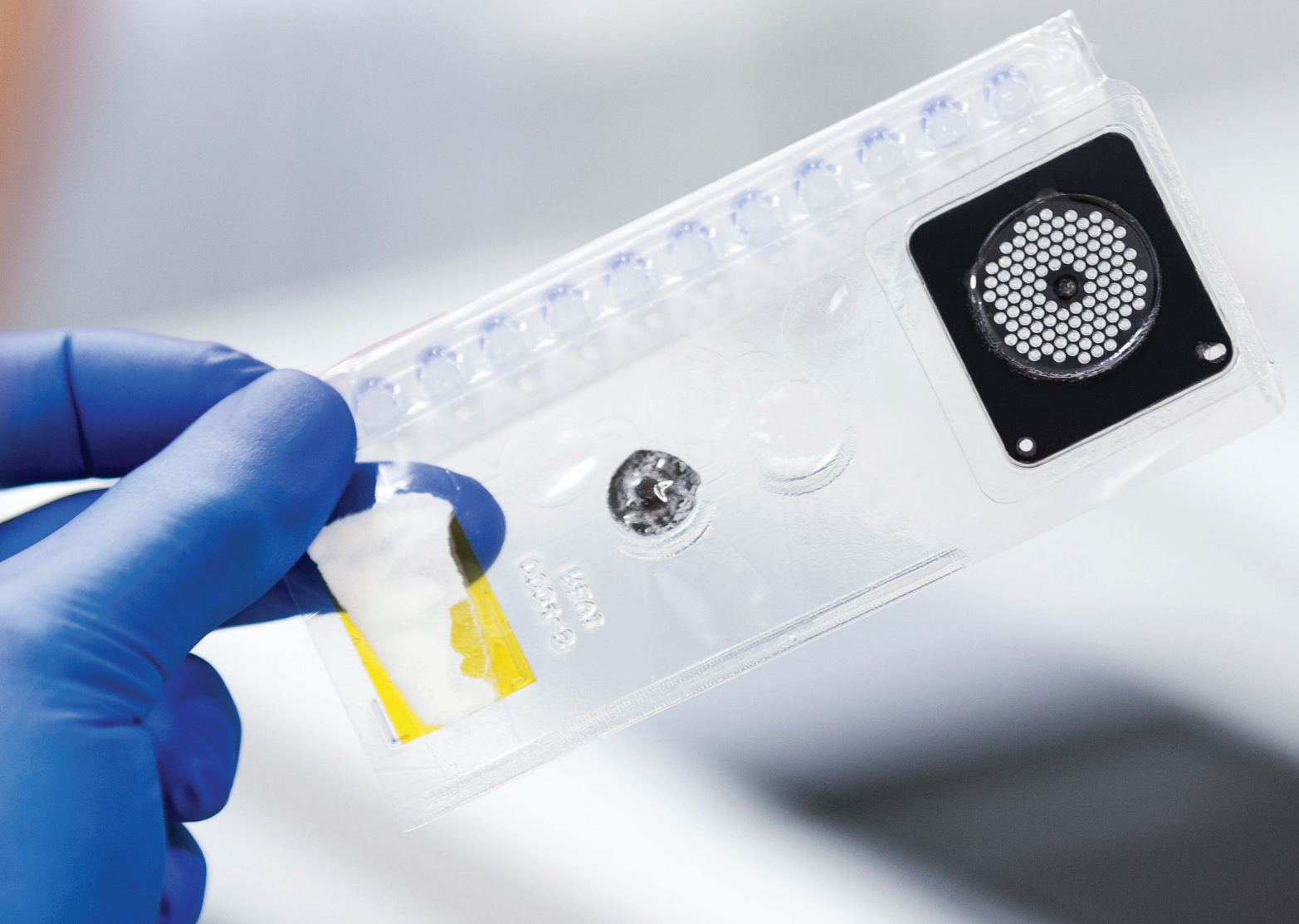
BIOFIRE®
GLOBAL FEVER
PANEL

BioFire Defense, LLC is the sole authorized supplier of bioMérieux's BIOFIRE product line to Defense Health Agency (DHA) care sites.

TRADITIONAL VS. SYNDROMIC TESTING

The BIOFIRE® line of products from BioFire Defense 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 BioFire Defense can better detect and identify the target with just one easy diagnostic test.

As the industry leader, BioFire Defense 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 for the most common syndromes and additional panels for high consequence testing. These panels are US FDA-cleared and 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.

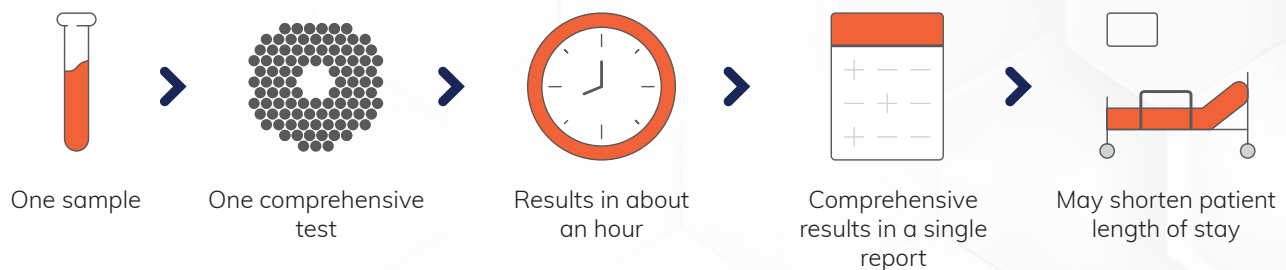
TRADITIONAL TESTING

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.

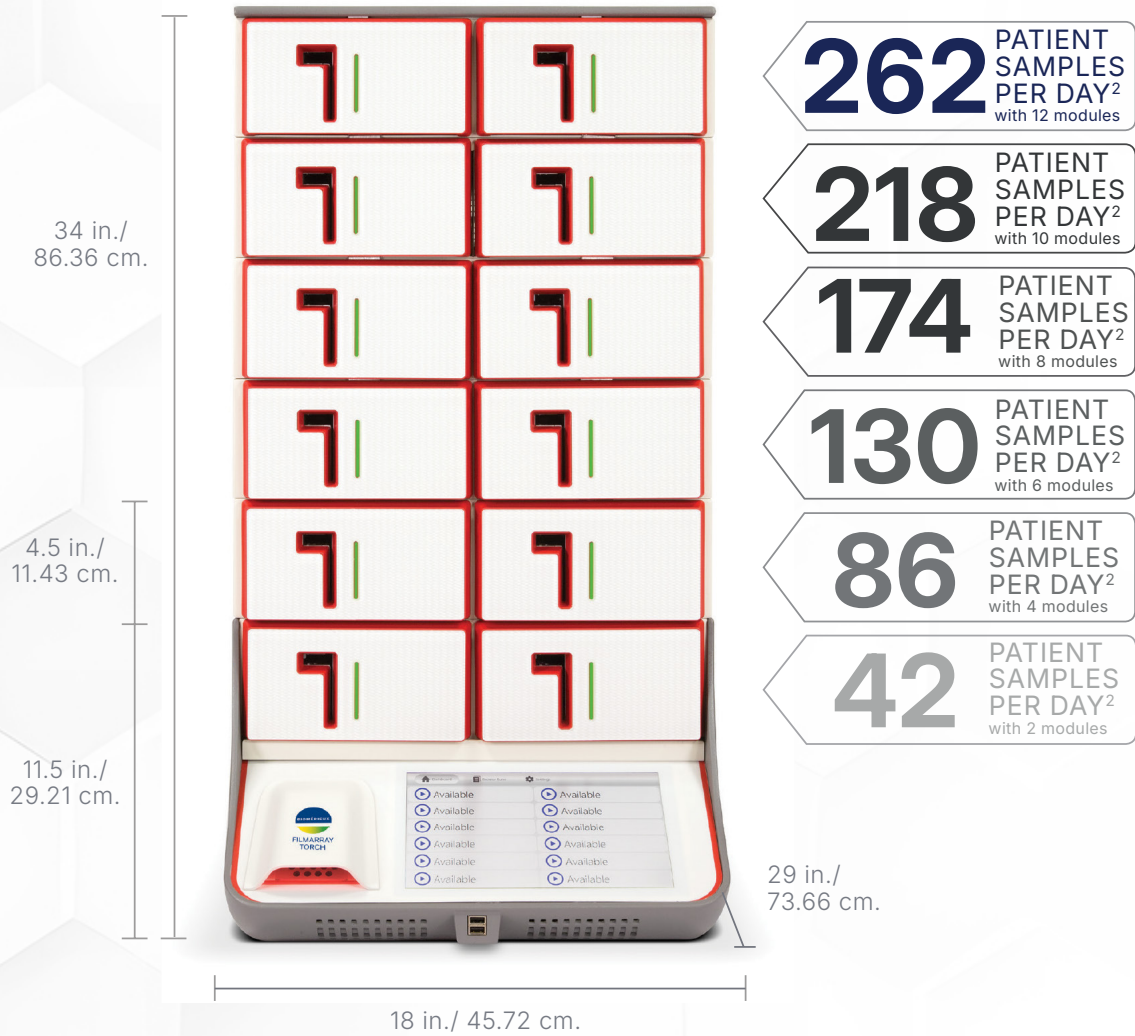


1. Cybulski RJ, et al. Clin Infect Dis. 2018;67(11):1688-96.

BIOFIRE® SYNDROMIC TESTING PANELS

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.



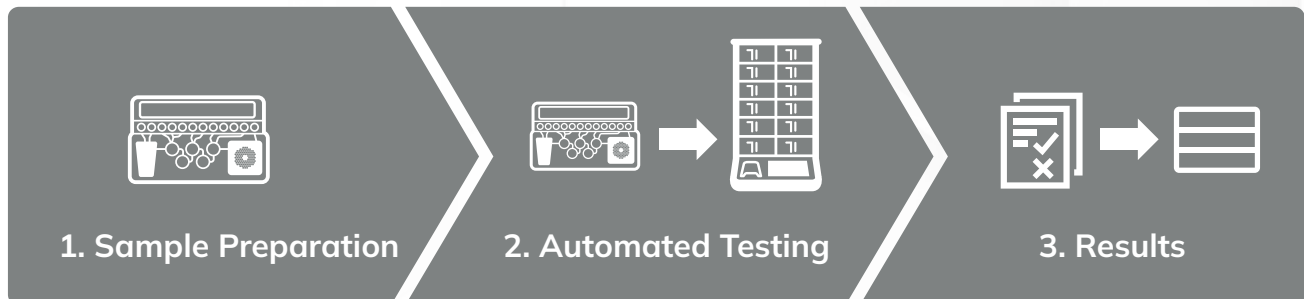
All-in-one technology

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

BIOFIRE® SYNDROMIC TESTING PANELS



“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 PANELPANEL



BIOFIRE® FILMARRAY® MENINGITIS/ENCEPHALITIS PANEL



BIOFIRE® FILMARRAY® PNEUMONIA PANEL



BIOFIRE® JOINT INFECTION PANEL



BIOFIRE® GLOBAL FEVER PANEL

Product availability varies by country. Consult your BioFire Defense 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 BioFire Defense 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 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 BioFire Defense 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 0157
– *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 | 

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 BioFire Defense 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 BioFire Defense 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

BACTERIA (SEMI-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
– OXA-48-like
– NDM
– 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 | CE₂₇₉₇

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 BioFire Defense 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 cloacaecomplex
Escherichia coli
Haemophilus influenzae
Kingella kingae
Klebsiella aerogenes
Klebsiella pneumoniae group
Morganella morganii
Neisseria gonorrhoeae
Proteusspp.
Pseudomonas aeruginosa
Salmonella spp.
Serratia marcescens

YEAST

Candida spp.
– *Candida albicans*

ANTIMICROBIAL RESISTANCE GENES

Carbapenemases

– IMP
– KPC
– OXA-48-like
– NDM
– 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 BioFire Defense Representative.



BIOFIRE® GLOBAL FEVER (GF) PANEL

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

1 TEST. 6 TARGETS. ~50 MINUTES.

The BIOFIRE GF Panel tests for a syndromic grouping of bacteria, viruses and parasites most often associated with tropical fever infections. Using multiplex PCR technology, the BIOFIRE GF 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 BioFire Defense)

Product availability varies by country. Consult your BioFire Defense Representative.

PEACE OF MIND **ALL THE TIME**

First in diagnostics. First in customer care.

BioFire Defense has a skilled team dedicated to customer success. Our Customer Technical Support team provides global product support, solution training courses, assistance, Authority to Operate (ATO) compliance and instrument troubleshooting. We are committed to the speedy resolution of all technical issues.



Support

For Customer Technical Support, please call +1-801-262-3592.



Help at Your Fingertips

Our website **BioFireDefense.com** provides support documents to assist with verification, software downloads, Instructions for Use, quick guides, technical notes, and other product resources.

Born from a pioneering legacy, BioFire Defense stands at the forefront of molecular diagnostics and biothreat detection. Backed by bioMérieux, we're a trusted partner for the U.S. government, military, and public health agencies. Our core strength is innovative PCR technology, delivering fast, comprehensive results for critical decisions.

As we look to the future, BioFire Defense remains dedicated to advancing testing capabilities, expanding our reach, and pioneering solutions that address evolving challenges. We continue to be guided by our mission drivers, our commitment to public health, and our vision of a healthier, safer world.

To learn more, speak with your BioFire Defense representative or visit www.BioFireDefense.com.



BIOFIRE
DEFENSE
A bioMérieux Company

79 West 4500 South, Suite 14
Salt Lake City, Utah 84107, USA
+1-801-262-3592
www.BioFireDefense.com

Learn more at



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