

BIOFIRE® PANELS

7 Panels. 175+ Targets. ~1 Hour.



**BIOFIRE®
RESPIRATORY 2.1 *PLUS*
PANEL**

22 Targets. ~45 Minutes.



**BIOFIRE®
BLOOD CULTURE
IDENTIFICATION 2 PANEL**

43 Targets. ~1 Hour.



**BIOFIRE® FILMARRAY®
GASTROINTESTINAL
PANEL**

22 Targets. ~1 Hour.



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

14 Targets. ~1 Hour.



**BIOFIRE® FILMARRAY®
PNEUMONIA *PLUS* PANEL**

33 Targets. ~1 Hour.



**BIOFIRE®
JOINT INFECTION
PANEL**

39 Targets. ~1 Hour.



**BIOFIRE® FILMARRAY®
TROPICAL FEVER
PANEL**

6 Targets. ~50 Minutes.



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

23 Targets. ~45 Minutes.

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



BIOFIRE FILMARRAY RP2.1*plus* Panel Specifications

Sample Type: nasopharyngeal swab in transport media or saline

Hands-On Time: approximately 2 minutes

Sample Volume: 0.3 mL

Overall Performance: 97.1% sensitivity, 99.3% specificity¹
SARS-CoV-2 Performance: 98.4% PPA, 98.9% NPA²

Storage Conditions: all kit components stored at room temperature (15-25 °C)

Part Number

BIOFIRE FILMARRAY RP2.1*plus* Panel Reagent Kit (30 Pouches): 423740

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

2. 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

43 Targets. ~1 Hour.

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

FDA cleared |  2797

BIOFIRE FILMARRAY BCID2 Panel Specifications

Sample Type: positive blood culture

Hands-On Time: approximately 2 minutes

Sample Volume: 0.2 mL

Performance: 99.0% sensitivity, 99.7% specificity³

Storage Conditions: all kit components stored at room temperature (15-25 °C)

Part Number

BIOFIRE FILMARRAY BCID2 Panel Reagent Kit (30 Pouches): RFIT-ASY-0147

³. 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

22 Targets. ~1 Hour.

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

FDA cleared | CE₂₇₉₇

BIOFIRE FILMARRAY GI Panel Specifications

Sample Type: stool sample in Cary Blair

Hands-On Time: approximately 2 minutes

Sample Volume: 0.2 mL

Performance: 98.7% sensitivity, 99.2% specificity⁴

Storage Conditions: all kit components stored at room temperature (15-25 °C)

Part Number

BIOFIRE FILMARRAY GI Panel Reagent Kit (30 Pouches): RFIT-ASY-0116

BIOFIRE FILMARRAY GI Panel Reagent Kit (6 Pouches): RFIT-ASY-0104

⁴ Data on file, BioFire Diagnostics. The stated performance is the overall aggregate performance of the prospective clinical study data presented in the IFU.

Product availability varies by country. Consult your bioMérieux representative.



BIOFIRE® FILMARRAY® MENINGITIS/ENCEPHALITIS (ME) PANEL

14 Targets. ~1 Hour.

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)

FDA cleared |  2797

BIOFIRE FILMARRAY ME Panel Specifications

Sample Type: cerebrospinal fluid (CSF)

Hands-On Time: approximately 2 minutes

Sample Volume: 0.2 mL

Performance: 94.2% sensitivity, 99.8% specificity⁵

Storage Conditions: all kit components stored at room temperature (15-25 °C)

Part Number

BIOFIRE FILMARRAY ME Panel Reagent Kit (30 Pouches): RFIT-ASY-0118 **BIOFIRE FILMARRAY ME Panel Reagent Kit (6 Pouches):** RFIT-ASY-0119

⁵ 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

34 Targets. ~1 Hour.

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)



BIOFIRE FILMARRAY PN*plus* Panel Specifications

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

Hands-On Time: approximately 2 minutes

Performance: BAL-like (including mini-BAL): 96.2% sensitivity, 98.4% specificity; Sputum-like (including ETA): 96.3% sensitivity, 97.4% specificity⁶

Storage Conditions: all kit components stored at room temperature (15-25 °C)

Part Number

BIOFIRE FILMARRAY PN*plus* Panel Reagent Kit (30 Pouches): RFIT-ASY-0143

6. 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

39 Targets. ~1 Hour.

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

FDA cleared |  2797

BIOFIRE FILMARRAY JI Panel Specifications

Sample Type: synovial fluid

Hands-On Time: approximately 2 minutes

Sample Volume: 0.2 mL

Performance: 91.7% sensitivity, 99.8% specificity⁷

Storage Conditions: all kit components stored at room temperature (15-25 °C)

Part Number

BIOFIRE FILMARRAY JI Panel Reagent Kit (30 Pouches): RFIT-ASY-0138

⁷ 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

6 Targets. ~50 Minutes.

VIRUSES

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

BACTERIA

Leptospira spp.

PARASITES

Plasmodium spp.
Plasmodium falciparum
Plasmodium vivax/ovale

FDA cleared | CE₂₇₉₇

BIOFIRE FILMARRAY TF Panel Specifications

Sample Type: Human whole blood collected in EDTA tubes

Hands-On Time: approximately 2 minutes

Sample Type: 0.2 mL

Performance: 95.1% Sensitivity⁸ and 99.8% Specificity⁸

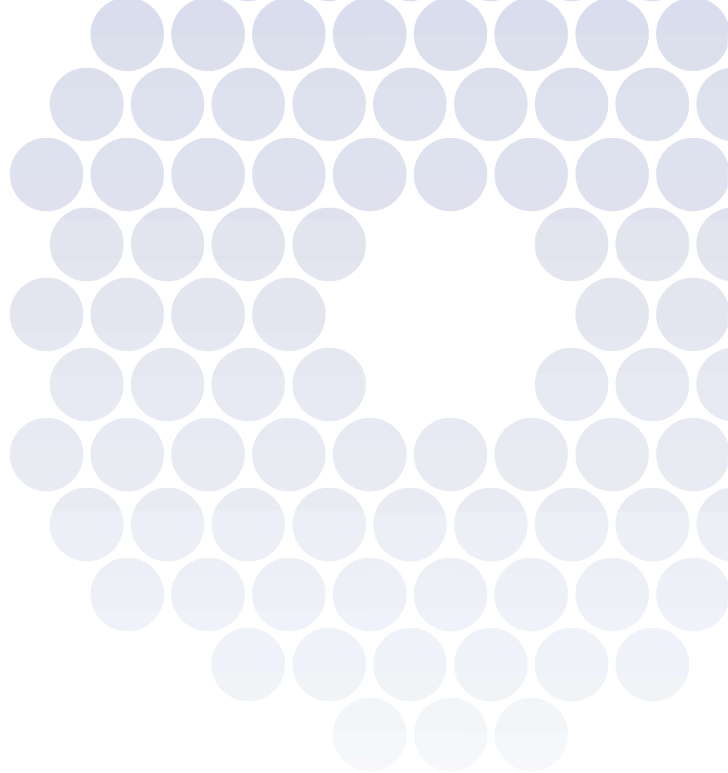
Storage Conditions: all kit components stored at room temperature (18-30 °C)

Part Number

BIOFIRE FILMARRAY TF Panel Reagent Kit (6 Pouches): 424803

⁸ 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.



Scan the QR code
for more information.

Learn more about the BIOFIRE range of commercially-available
panels for syndromic infectious disease 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

Manufactured by:
BioFire Diagnostics, LLC
515 Colorow Drive
Salt Lake City, UT 84108 USA
Tel: +1-801-736-6354

Product availability varies by country. Consult your bioMérieux representative.