

The BioFire® FilmArray® Panels

5 Tests. All in About an Hour.

Respiratory



Pneumonia



Gastrointestinal



Blood Culture Identification



Meningitis/Encephalitis



Under FDA Review

Joint Infection*



**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

Influenza A/H1

Influenza A/H3

Influenza A/H1-2009

Influenza B

Parainfluenza Virus 1

Parainfluenza Virus 2

Parainfluenza Virus 3

Parainfluenza Virus 4

Respiratory Syncytial Virus

BACTERIA*Bordetella pertussis**Bordetella parapertussis**Chlamydia pneumoniae**Mycoplasma pneumoniae***BioFire RP2.1 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 and 99.3% specificity (prospective specimens) ¹ SARS-CoV-2: 98.4% PPA and 100% 98.9% NPA ²
Storage Conditions: all kit components stored at room temperature (15-25 °C)	

Part Number**BioFire RP2.1 Panel Reagent Kit (30 Pouches): 423742**¹Based on the prospective portion of the clinical study for the BioFire® FilmArray® Respiratory 2 (RP2) Panel.²Overall 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.

**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
Influenza A/H1
Influenza A/H3
Influenza A/H1-2009
Influenza B
Parainfluenza Virus
Respiratory Syncytial Virus

BACTERIA

Bordetella pertussis
Bordetella parapertussis
Chlamydia pneumoniae
Mycoplasma pneumoniae

*Emergency Use Authorization

BioFire RP2.1-EZ Panel (EUA) Specifications

Sample Type: nasopharyngeal swab in transport media or saline	Hands-on Time: approximately 2 minutes
Sample Volume: 0.3 mL	Performance: Overall: 97.1% sensitivity and 99.3% specificity (prospective specimens) ¹ SARS-CoV-2: 98.0% sensitivity and 100% specificity (archived specimens) ² SARS-CoV-2: 100% PPA and 100% NPA (contrived specimens) ³
Storage Conditions: all kit components stored at room temperature (15-25 °C)	

Part Number**BioFire RP2.1-EZ Panel (EUA) Reagent Kit (30 Pouches): 423883**

Authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Only for sale in the USA.

¹Based on the prospective portion of the clinical study for the BioFire® FilmArray® Respiratory 2 (RP2) Panel.

²Based on the archived specimen study in the BioFire Respiratory 2.1 (RP2.1) Panel (EUA) submission.

³Based on the contrived specimen study in the BioFire Respiratory 2.1 (RP2.1) Panel (EUA) submission.

*This test has not been FDA cleared or approved;

*This test has been authorized by FDA under an EUA for use by authorized laboratories;

*This test has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2 from multiple respiratory viral and bacterial organisms; and

*This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

**BACTERIA****Semi-Quantitative Bacteria**

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 Bacteria**

Chlamydia pneumoniae
Legionella pneumophila
Mycoplasma pneumoniae

VIRUSES

Adenovirus
Coronavirus
Human Metapneumovirus
Human Rhinovirus/Enterovirus
Influenza A
Influenza B
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 PN Panel Specifications

Sample Type: sputum (including ETA), bronchoalveolar lavage

Hands-on Time: approximately 2 minutes

Performance: bronchoalveolar lavage: 96.2% sensitivity and 98.3% specificity, sputum: 96.3% sensitivity and 97.2% specificity

Storage Conditions: all kit components stored at room temperature (15-25 °C)¹

Part Number

BioFire PN Panel Reagent Kit (30 Pouches): RFIT-ASY-0144

**BACTERIA**

Campylobacter (jejuni, coli, and upsaliensis)
Clostridioides (Clostridium) difficile (toxin A/B)
Plesiomonas shigelloides
Salmonella
Vibrio (parahaemolyticus, vulnificus, and cholerae)
Vibrio cholerae
Yersinia enterocolitica
Diarrheagenic *E.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)

VIRUSES

Adenovirus F 40/41
Astrovirus
Norovirus GI/GII
Rotavirus A
Sapovirus (I, II, IV, and V)

PARASITES

Cryptosporidium
Cyclospora cayetanensis
Entamoeba histolytica
Giardia lamblia

BioFire GI Panel Specifications

Sample Type: stool sample in Cary Blair	Hands-on Time: approximately 2 minutes
Sample Volume: 0.2 mL	Performance: 98.5% sensitivity and 99.2% specificity ¹
Storage Conditions: all kit components stored at room temperature (15-25 °C)	

Part Numbers

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

GRAM-NEGATIVE BACTERIA

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

GRAM-POSITIVE BACTERIA

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

YEAST

Candida albicans
Candida auris
Candida glabrata
Candida krusei
Candida parapsilosis
Candida tropicalis
Cryptococcus neoformans/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

BioFire BCID2 Panel Specifications

Sample Type: positive blood culture	Hands-on Time: approximately 2 minutes
Sample Volume: 0.2 mL	Performance: 99% sensitivity and 99.8% specificity ¹
Storage Conditions: all kit components stored at room temperature (15-25 °C)	

Part Number

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

**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 neoformans/gattii

BioFire ME Panel Specifications

Sample Type: cerebrospinal fluid (CSF)	Hands-on Time: approximately 2 minutes
Sample Volume: 0.2 mL	Performance: 94.2% sensitivity and 99.8% specificity ¹
Storage Conditions: all kit components stored at room temperature (15-25 °C)	

Part Numbers

BioFire ME Panel Reagent Kit (30 Pouches): RFIT-ASY-0118	BioFire ME Panel Reagent Kit (6 Pouches): RFIT-ASY-0119
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BioFire® Joint Infection (JI) Panel*

39 Targets/~1 Hour

*Investigational use only. Currently under FDA review; panel menu subject to change. Not available for sale.

GRAM-POSITIVE BACTERIA

Anaerococcus prevotii/vaginalis
Clostridium perfringens
Cutibacterium avidum/
granulosum
Enterococcus faecalis
Enterococcus faecium
Finegoldia 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

Vancomycin Resistance

vanA/B

Proposed BioFire JI Panel Specifications

Sample Type: synovial fluid	Hands-on Time: approximately 2 minutes
Sample Volume: 0.2 mL	Storage Conditions: all kit components stored at room temperature (15-25 °C)



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