

# BIOFIRE® FILMARRAY® Panels

6 Tests. All in About an Hour.

Respiratory



Pneumonia



Gastrointestinal



Blood Culture Identification



Meningitis/Encephalitis



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 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 RP2.1 Panel Specifications**

<b>Sample Type:</b> nasopharyngeal swab in transport media or saline	<b>Hands-on Time:</b> approximately 2 minutes
<b>Sample Volume:</b> 0.3 mL	<b>Overall Performance:</b> 97.1% sensitivity and 99.3% specificity (prospective specimens) <sup>1</sup> <b>SARS-CoV-2:</b> 98.4% PPA and 100% 98.9% NPA <sup>2</sup>
<b>Storage Conditions:</b> all kit components stored at room temperature (15-25 °C)	

**Part Number**

**BIOFIRE RP2.1 Panel Reagent Kit (30 Pouches): 423742**

<sup>1</sup>Based on the prospective portion of the clinical study for the BIOFIRE® FILMARRAY® Respiratory 2 (RP2) Panel.

<sup>2</sup>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.



**VIRUSES**

Adenovirus  
Coronavirus 229E  
Coronavirus HKU1  
Coronavirus NL63  
Coronavirus OC43  
**Coronavirus 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  
Respiratory syncytial virus

**BACTERIA**

*Bordetella parapertussis*  
*Bordetella pertussis*  
*Chlamydia pneumoniae*  
*Mycoplasma pneumoniae*

\*Emergency Use Authorization

**BIOFIRE RP2.1-EZ Panel (EUA) Specifications**

<b>Sample Type:</b> nasopharyngeal swab in transport media or saline	<b>Hands-on Time:</b> approximately 2 minutes
<b>Sample Volume:</b> 0.3 mL	<b>Performance: Overall:</b> 97.1% sensitivity and 99.3% specificity (prospective specimens) <sup>1</sup> <b>SARS-CoV-2:</b> 98.0% sensitivity and 100% specificity (archived specimens) <sup>2</sup> <b>SARS-CoV-2:</b> 100% PPA and 100% NPA (contrived specimens) <sup>3</sup>
<b>Storage Conditions:</b> 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.

<sup>1</sup>Based on the prospective portion of the clinical study for the BIOFIRE® FILMARRAY® Respiratory 2 (RP2) Panel.

<sup>2</sup>Based on the archived specimen study in the BIOFIRE Respiratory 2.1 (RP2.1) Panel (EUA) submission.

<sup>3</sup>Based on the contrived specimen study in the BIOFIRE Respiratory 2.1 (RP2.1) Panel (EUA) submission.

\*This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;

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

\*The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics 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 declaration is terminated or authorization is 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 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)

**BIOFIRE PN Panel Specifications**

<b>Sample Type:</b> sputum (including ETA), bronchoalveolar lavage	<b>Hands-on Time:</b> approximately 2 minutes
<b>Performance:</b> bronchoalveolar lavage: 96.2% sensitivity and 98.3% specificity, sputum: 96.3% sensitivity and 97.2% specificity <sup>1</sup>	
<b>Storage Conditions:</b> all kit components stored at room temperature (15-25 °C) <sup>1</sup>	

**Part Number**

<b>BIOFIRE PN Panel Reagent Kit (30 Pouches):</b> RFIT-ASY-0144
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<sup>1</sup>Stated sensitivity and specificity are the aggregate performance from the prospective clinical study data.

**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)

**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**

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

**Part Numbers**

<b>BIOFIRE GI Panel Reagent Kit (30 Pouches):</b> RFIT-ASY-0116
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<sup>1</sup>Stated sensitivity and specificity are the aggregate performance from the prospective clinical study data.

**GRAM-NEGATIVE BACTERIA**

*Acinetobacter calcoaceticus-baumannii* complex  
*Bacteroides fragilis*  
*Enterobacteriales*  
*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 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**

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

**Part Number**

<b>BIOFIRE BCID2 Panel Reagent Kit (30 Pouches):</b> RFIT-ASY-0147
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<sup>1</sup>Stated sensitivity and specificity are the aggregate performance from the prospective clinical study data.

**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)*

**BIOFIRE ME Panel Specifications**

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

**Part Numbers**

<b>BIOFIRE ME Panel Reagent Kit (30 Pouches):</b> RFIT-ASY-0118	<b>BIOFIRE ME Panel Reagent Kit (6 Pouches):</b> RFIT-ASY-0119
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<sup>1</sup>Stated sensitivity and specificity are the aggregate performance from the prospective clinical study data.



**GRAM-POSITIVE BACTERIA**

- Anaerococcus prevotii/vaginalis*
- Clostridium perfringens*
- Cutibacterium avidum/granulosum*
- Enterococcus faecalis*
- Enterococcus faecium*
- Finexgoldia 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*

**BIOFIRE JI Panel Specifications**

<b>Sample Type:</b> synovial fluid	<b>Hands-on Time:</b> approximately 2 minutes
<b>Sample Volume:</b> 0.2 mL	<b>Performance:</b> 91.7% sensitivity, 99.8% specificity <sup>1</sup>
<b>Storage Conditions:</b> all kit components stored at room temperature (15-25 °C)	

**Part Number**

<b>BIOFIRE JI Panel Reagent Kit (30 Pouches):</b> RFIT-ASY-0138
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<sup>1</sup>Overall performance based on prospective clinical study for the BIOFIRE® Joint Infection Panel, data on file, BIOFIRE Diagnostics.



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