

# The BioFire® FilmArray® Panels

6 Tests. All in About an Hour.

Respiratory



Pneumonia



Gastrointestinal



Bone and Joint Infection\*



Blood Culture Identification



Meningitis/Encephalitis





\*Emergency Use Authorization

**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 (Chlamydophila) pneumoniae*
- Mycoplasma pneumoniae*

**BioFire RP2.1 Panel Specifications**

<b>Sample Type:</b> nasopharyngeal swab in transport media	<b>Hands-on Time:</b> approximately 2 minutes
<b>Sample Volume:</b> 0.3 mL	<b>Performance:</b> 97.1% sensitivity and 99.3% specificity <sup>1</sup>
<b>Storage Conditions:</b> all kit components stored at room temperature (15-25 °C)	

**Part Number**

**BioFire RP2.1 Panel EUA Reagent Kit (30 Pouches): 423738**

\*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 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**

<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	
<b>Storage Conditions:</b> all kit components stored at room temperature (15-25 °C) <sup>1</sup>	

**Part Number**

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

**BACTERIA**

*Campylobacter (jejuni, coli, and upsaliensis)*  
*Clostridium (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**

<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	<b>BioFire GI Panel Reagent Kit (6 Pouches):</b> RFIT-ASY-0104
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\*Investigational use only. Not for use in diagnostic procedures.

**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

**Vancomycin Resistance**

*vanA/B*

**Proposed BioFire BJI Panel Specifications**

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

**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*  
   *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**

<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**

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

BioFire ME Panel Reagent Kit (30 Pouches): RFIT-ASY-0118	BioFire ME Panel Reagent Kit (6 Pouches): RFIT-ASY-0119
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