

BFR0000-2897-03

Faster answers. Relieved parents.

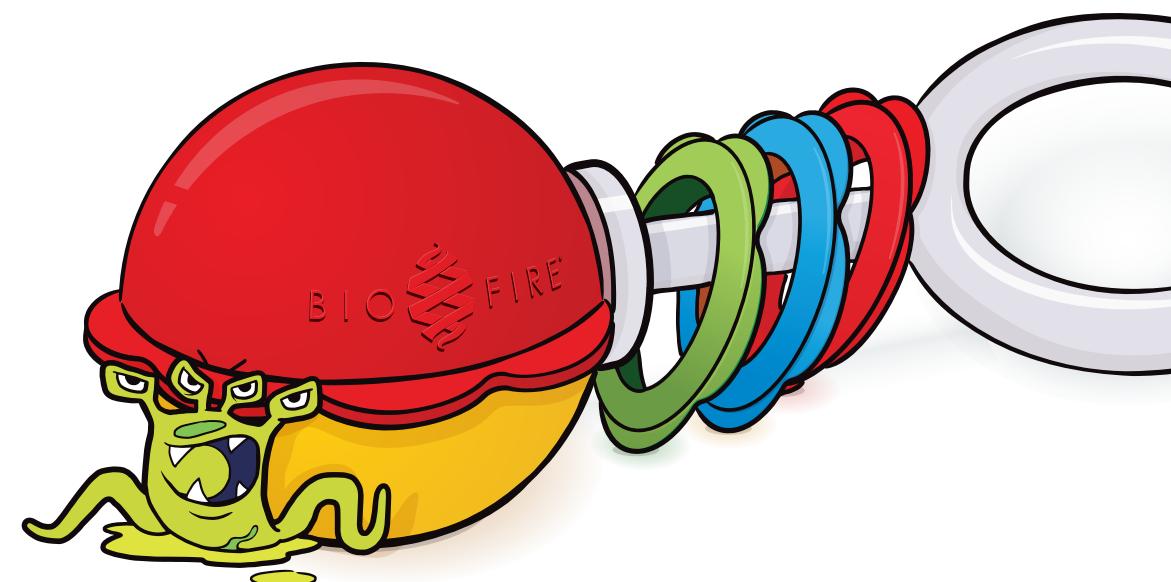
The results you need fast
with syndromic infectious
disease testing from BioFire.

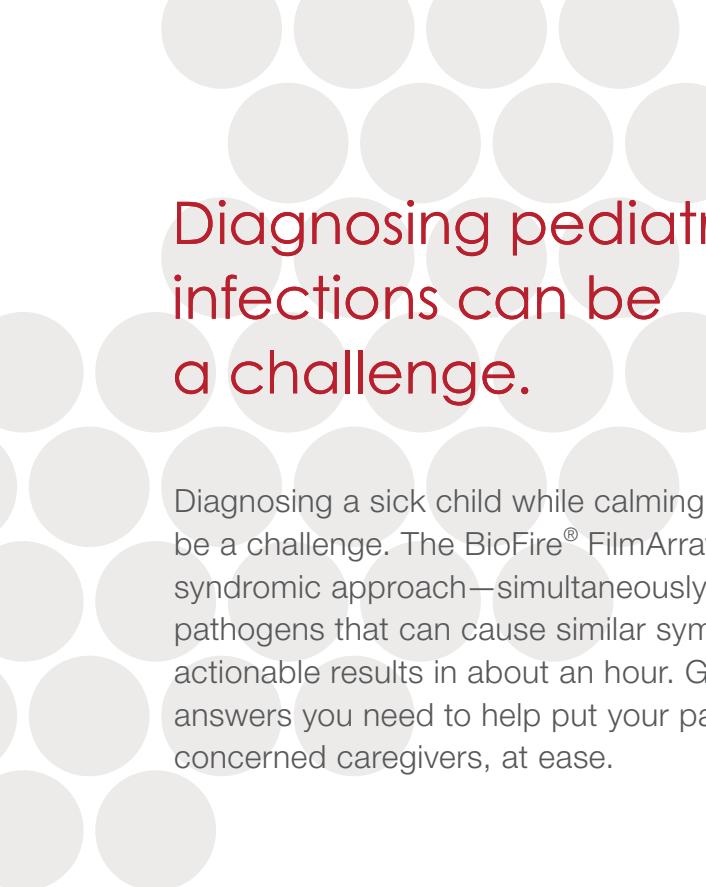
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Syndromic Testing: The Right Test, The First Time.

Respiratory • Blood Culture Identification • Gastrointestinal • Meningitis/Encephalitis • Pneumonia





Diagnosing pediatric infections can be a challenge.

Diagnosing a sick child while calming anxious parents can be a challenge. The BioFire® FilmArray® Panels utilize a syndromic approach—simultaneously testing for different pathogens that can cause similar symptoms—to deliver actionable results in about an hour. Get the fast, reliable answers you need to help put your patients, and their concerned caregivers, at ease.



Fast. Rapid turnaround time facilitates efficient diagnosis and treatment decisions.



Accurate. Superior sensitivity and specificity for results you can trust.



Comprehensive. Check for a broad spectrum of pathogens to help determine the best course of action in the shortest amount of time.



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Syndromic Testing:

A symptom-driven broad grouping of probable pathogens in one, rapid test.

Improve hospital and patient outcomes.

There are more than 250 published papers that describe the performance and utility of the BioFire® FilmArray® Panels. Learn how the five FDA-cleared panels can improve outcomes when timing is critical.

BioFire FilmArray Panels



Respiratory

1 Test / 21 Targets / ~45 Minutes



Blood Culture Identification

1 Test / 27 Targets / ~1 Hour



Gastrointestinal

1 Test / 22 Targets / ~1 Hour



Meningitis/Encephalitis

1 Test / 14 Targets / ~1 Hour



Pneumonia

1 Test / 33 Targets / ~1 Hour



Improve Treatment Decisions

BioFire® FilmArray® Respiratory Panel

Avoidance of antibiotics in 30% of pediatric patients tested⁵

BioFire® FilmArray® Meningitis/Encephalitis Panel

Potential avoidance of unnecessary acyclovir use in HSV-negative pediatric patients²

BioFire® FilmArray® Gastrointestinal Panel

17% increase in targeted, rather than empiric, therapy⁶

BioFire® FilmArray® Blood Culture Identification Panel

33.5-hour reduction in median time to optimal therapy in a children's hospital⁷



Reduce Turnaround Time

BioFire® FilmArray® Respiratory Panel

38% increase in pediatric patients receiving a result while in the emergency department¹

BioFire® FilmArray® Meningitis/Encephalitis Panel

10.3-hour reduction in time-to-result compared to batch method²

BioFire® FilmArray® Gastrointestinal Panel

84% reduction in time-to-result compared to stool culture methods³

BioFire® FilmArray® Blood Culture Identification Panel

70% reduction in time-to-organism identification compared to conventional organism ID alone⁴



Shorten Patient Stays

BioFire® FilmArray® Respiratory Panel

5-day reduction in hospital stay for febrile infants with a positive result (compared to a negative result)⁹

BioFire® FilmArray® Meningitis/Encephalitis Panel

30% avoidance of unnecessary hospital admissions¹⁰

BioFire® FilmArray® Gastrointestinal Panel

12-hour average reduction in the mean length of stay per patient³

BioFire® FilmArray® Blood Culture Identification Panel

14.4-hour reduction in the mean length of stay for patients with contaminated blood cultures due to coagulase-negative staphylococci¹²



Identify Pathogens More Often

BioFire® FilmArray® Respiratory Panel

42% positive identification rate in a pediatric population⁸

BioFire® FilmArray® Meningitis/Encephalitis Panel

More than double the positivity rate of targeted send-out testing¹⁰

BioFire® FilmArray® Gastrointestinal Panel

3 to 7-fold increase in positive results compared to stool culture^{3,6,13,14}



Reduce Unnecessary Testing

BioFire® FilmArray® Respiratory Panel

19% reduction in use of chest radiographs in children⁸

BioFire® FilmArray® Gastrointestinal Panel

Reduction in use of X-rays, ultrasounds, and CT scans in pediatric and adult patients³

References

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2. Messacar, Diagn Microbiol Infect Dis. 2016 Sep;86(1):118-20.
3. Beal et al. JCM. Jan 2018, 56 (1): JCM.01457-17.
4. MacVane S, et al. J Clin Microbiol. October 2016 vol. 54
5. Sutton C, Walton P, Williams M, Bastian T, Wright M, Spires S. Impact of Multiplex Polymerase Chain Reaction Testing for Respiratory Pathogen Detection in Pediatric Patients, ID Week 2017, poster 1607.
6. Cybulski et al. CID. 2018.
7. Messacar K, et al. J Pediatric Infect Dis Soc. 2017 Sep 1;6(3):267-274
8. Subramony A, Zachariah P, Krones A, Whittier S, Saiman L. J Pediatr. 2016; doi: 10.1016/j.jpeds.2016.02.050016.02.050.
9. McFall, et al., Pediatrics. 2017 Feb;:000992281774066.
10. McNabb, et al. 2017. Presented at Carolinas Health Quality Summit.
11. Rand et al. Diagnostic Microbiology and Infectious Disease. 2015. Volume 82, Issue 2, 154-157.
12. Pardo J, et al. Diagn Microbiol Infect Dis. 2016; 84(2):159-164
13. Spina A, Kerr KG, Cormican M, Barbut F, Eigenthaler A, Zerva L, Tassios P, Popescu GA, Rafila A, Eerola E, Batista J, Maass M, Aschbacher R, Olsen KE, Allerberger F. 2015. Spectrum of enteropathogens detected by the FilmArray GI Panel in a multicentre study of community-acquired gastroenteritis. Clin Microbiol Infect. 21(8):719-28.
14. Axelrad, J. E., et al. (2019). "Impact of Gastrointestinal Panel Implementation on Health Care Utilization and Outcomes." J Clin Microbiol 57(3): e01775-01718.



The BioFire® FilmArray® Respiratory Panel 2 (RP2)

1 Test. 21 Targets. ~45 Minutes.

BioFire RP2 Targets

VIRUSES

Adenovirus
Coronavirus 229E
Coronavirus HKU1
Coronavirus NL63
Coronavirus OC43
Human Metapneumovirus
Human Rhinovirus/Enterovirus
Influenza A
Influenza A/H1
Influenza A/H1-2009
Influenza A/H3
Influenza B
Parainfluenza Virus 1
Parainfluenza Virus 2
Parainfluenza Virus 3
Parainfluenza Virus 4
Respiratory Syncytial Virus

BACTERIA

Bordetella parapertussis
Bordetella pertussis
Chlamydia (Chlamydophila) pneumoniae
Mycoplasma pneumoniae

Panel Specifications

Sample Type:	nasopharyngeal swab in transport media	Hands-On Time:	approximately 2 minutes
Sample Volume:	0.3 mL	Performance:	97.1% sensitivity and 99.3% specificity*
Storage Conditions:			all kit components stored at room temperature (15–25 °C)

Part Numbers

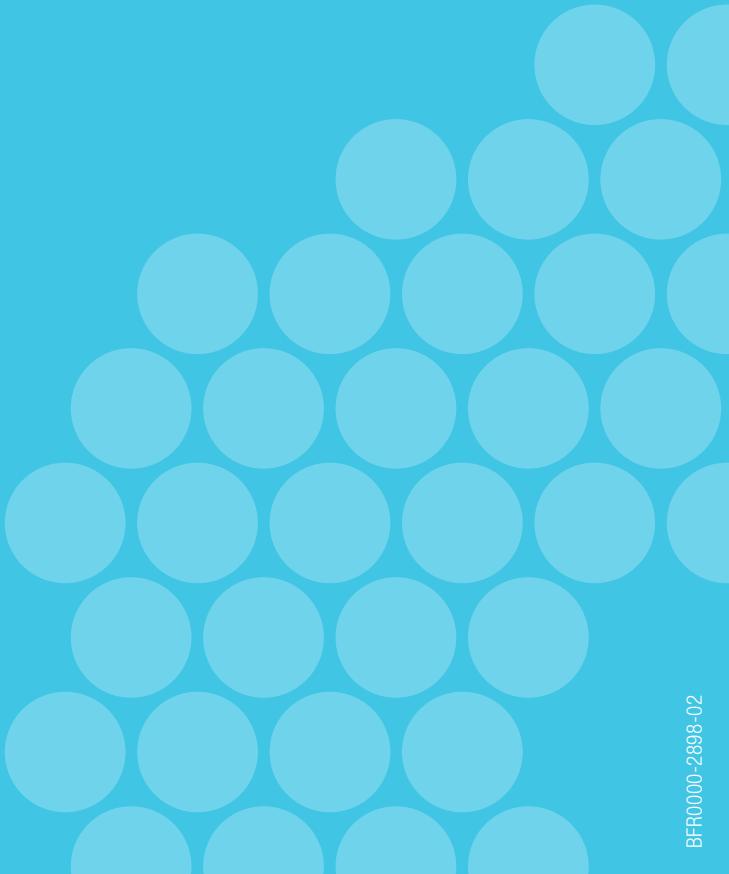
BioFire RP2 Reagent Kit (30 Pouches): RFIT-ASY-0129 | BioFire RP2 Reagent Kit (6 Pouches): RFIT-ASY-0130

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The BioFire® FilmArray® Respiratory Panel 2 (RP2)

1 Test. 21 Targets. ~45 Minutes.





The BioFire® FilmArray® Blood Culture Identification (BCID) Panel

1 Test. 27 Targets. ~1 Hour.

BioFire BCID Panel Targets

GRAM-NEGATIVE BACTERIA

Acinetobacter baumannii
Enterobacteriaceae
Enterobacter cloacae complex
Escherichia coli
Klebsiella oxytoca
Klebsiella pneumoniae
Proteus
Serratia marcescens
Haemophilus influenzae
Nelsseria meningitidis
Pseudomonas aeruginosa

ANTIMICROBIAL RESISTANCE GENES

KPC – carbapenem resistance
mecA – methicillin resistance
vanA/B – vancomycin resistance

GRAM-POSITIVE BACTERIA

Enterococcus
Listeria monocytogenes
Staphylococcus
Staphylococcus aureus
Streptococcus
Streptococcus agalactiae
Streptococcus pneumoniae
Streptococcus pyogenes

YEAST

Candida albicans
Candida glabrata
Candida krusei
Candida parapsilosis
Candida tropicalis

Panel Specifications

Sample Type: positive blood culture

Hands-On Time: approximately 2 minutes

Sample Volume: 0.2 mL

Performance: 98% sensitivity and 99.9% specificity*

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

Part Numbers

BioFire BCID Panel Reagent Kit (30 Pouches): RFIT-ASY-0126

BioFire BCID Panel Reagent Kit (6 Pouches): RFIT-ASY-0127

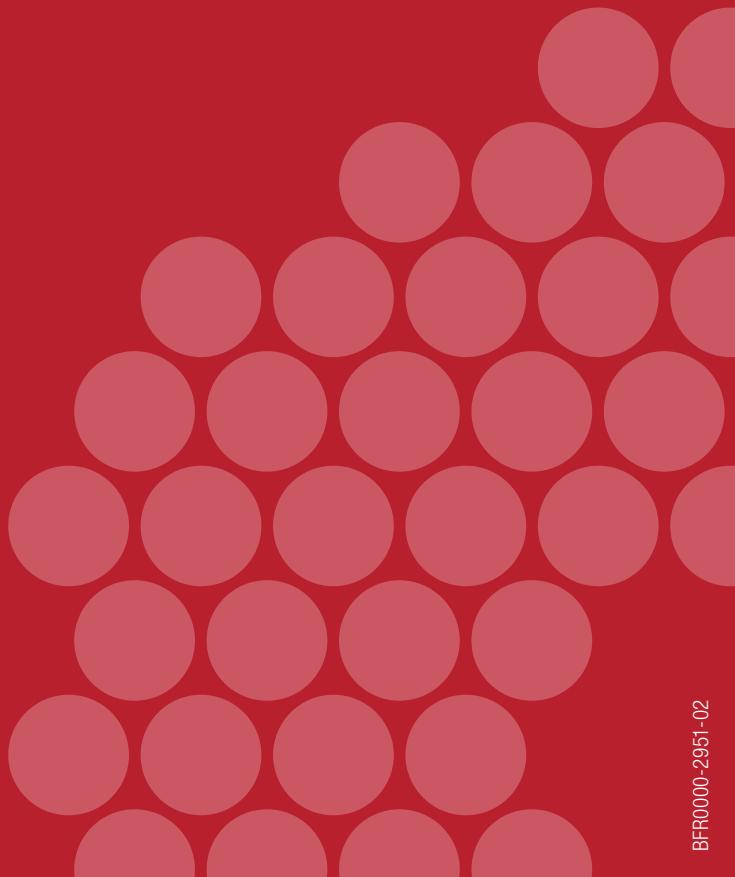
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*The stated performance is the aggregate of the prospective data from the clinical study



The BioFire® FilmArray® Blood Culture Identification (BCID) Panel

1 Test. 27 Targets. ~1 Hour.





The BioFire® FilmArray® Meningitis/Encephalitis (ME) Panel

1 Test. 14 Targets. ~1 Hour.

BioFire ME Panel Targets

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

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

Part Numbers

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

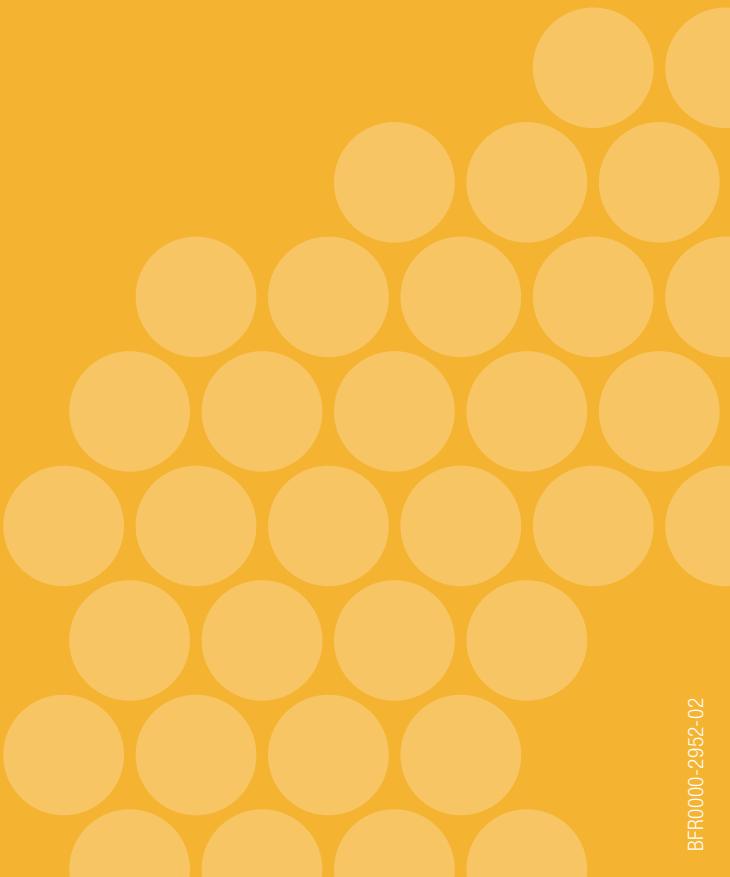
BioFire ME Panel Reagent Kit (6 Pouches): RFIT-ASY-0119

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The BioFire® FilmArray® Meningitis/Encephalitis (ME) Panel

1 Test. 14 Targets. ~1 Hour.





The BioFire® FilmArray® Gastrointestinal (GI) Panel

1 Test. 22 Targets. ~1 Hour.

BioFire GI Panel Targets

BACTERIA

Campylobacter (jejuni, coli, and upsaliensis)
Clostridium difficile (toxin A/B)
Plesiomonas shigelloides
Salmonella
Vibrio (parahaemolyticus, vulnificus, and cholerae)
Vibrio cholerae
Yersinia enterocolitica
 Diarrheagenic *E.coli*/*Shigella*
 Enteroinvasive *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 (genogroups I, II, IV, and V)

PARASITES

Cryptosporidium
Cyclospora cayetanensis
Entamoeba histolytica
Giardia lamblia

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

Part Numbers

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

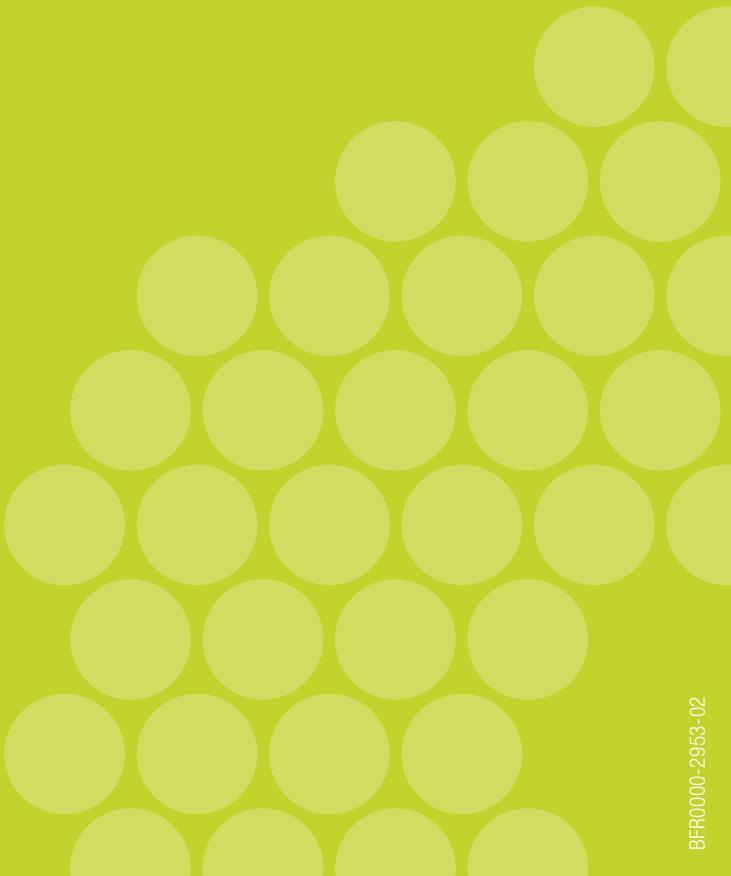
BioFire GI Panel Reagent Kit (6 Pouches): RFIT-ASY-0104

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The BioFire® FilmArray® Gastrointestinal (GI) Panel

1 Test. 22 Targets. ~1 Hour.





The BioFire® FilmArray® Pneumonia Panel

1 Test. 33 Targets. ~1 Hour.

BioFire Pneumonia Panel Targets

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)

Panel Specifications

Sample Types: sputum (including ETA), bronchoalveolar lavage

Hands-On Time: approximately 2 minutes

Performance: bronchoalveolar lavage—96.2% sensitivity and 98.3% specificity, sputum-like—96.3% sensitivity and 97.2% specificity*

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

Part Numbers

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

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The BioFire® FilmArray® Pneumonia Panel

1 Test. 33 Targets. ~1 Hour.

