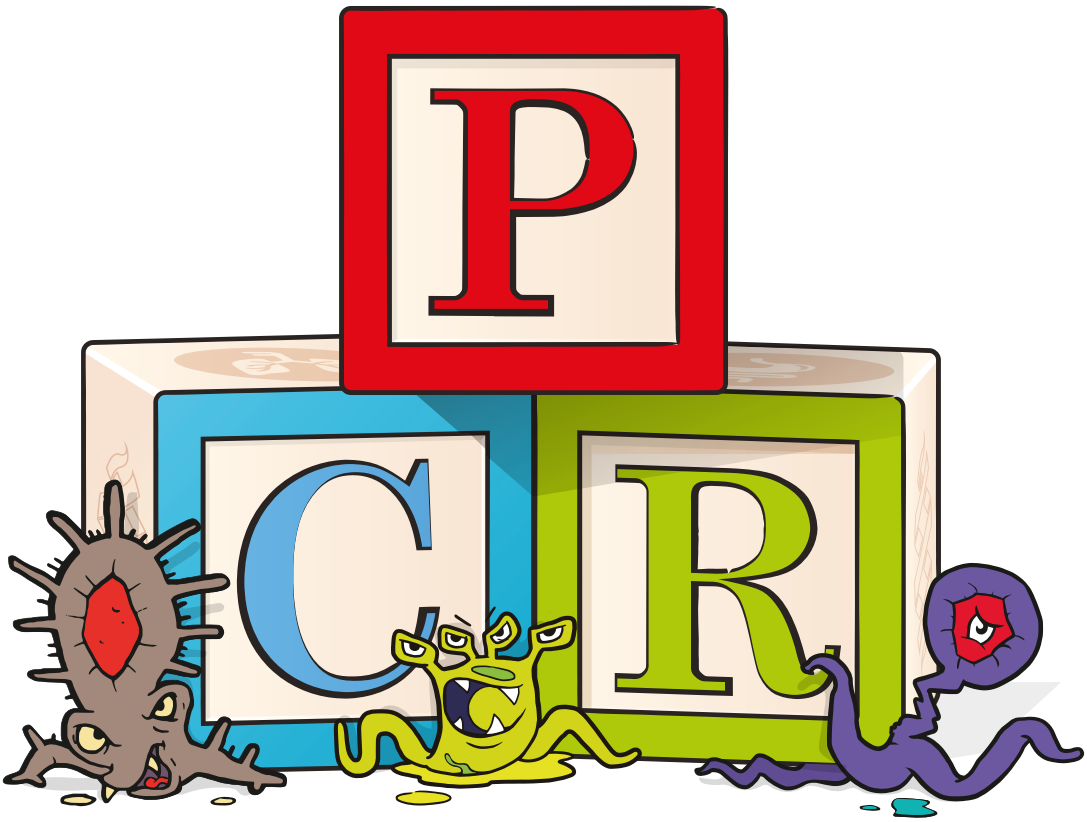
Faster Answers. Relieved Parents.

The results pediatricians need now with syndromic infectious disease testing from BioFire.



BIOMÉRIEUX

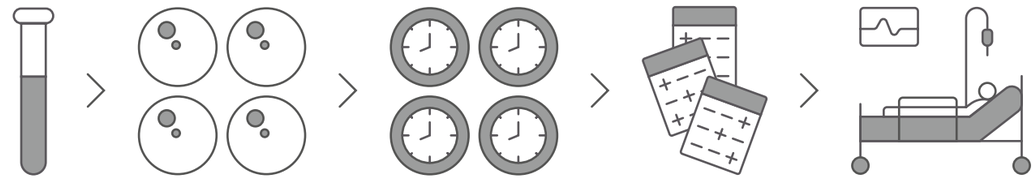
BIOFIRE®

Diagnosing Pediatric Infections Can Be A Challenge.

It is often tricky to decipher the cause of varied symptoms while communicating with kids and anxious parents.

The BioFire® FilmArray® System uses a syndromic approach—simultaneously testing for multiple pathogens that can cause similar symptoms—to deliver actionable results in about an hour.

Traditional Testing



One sample

Multiple tests ordered

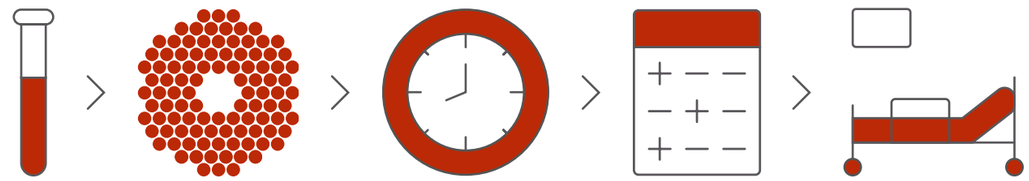
Results take hours to days

Individual results in separate reports

Longer patient length of stay[1]

VS

Syndromic Testing



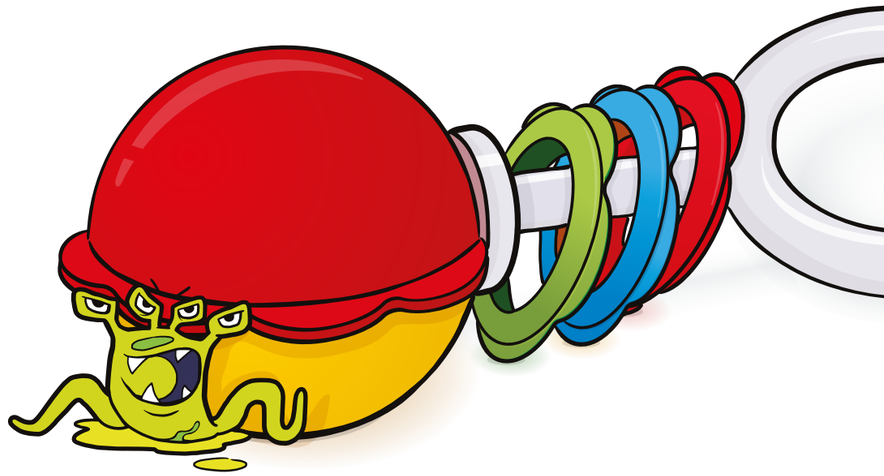
One sample

One comprehensive test

Takes about an hour for results

Multiple results in one report

Improves patient management[1]



Create Confidence in Treatment Plans for Children and Relieve Anxious Parents with Faster Answers from the BioFire® FilmArray® Panels.

BioFire® FilmArray®
Meningitis/Encephalitis Panel
1 Test. 14 Targets. ~1 Hour.

BioFire® Respiratory 2.1 *plus* Panel
1 Test. 23 Targets. ~45 Minutes.

BioFire® FilmArray®
Gastrointestinal Panel
1 Test. 22 Targets. ~1 Hour.

BioFire® Blood Culture Identification 2 Panel
1 Test. 43 Targets. ~1 Hour.

BioFire® FilmArray®
Pneumonia *plus* Panel
1 Test. 34 Targets. ~1 Hour.

Product availability varies by country. Please contact your local bioMérieux representative for details.

1. Brendish 2017.

Avoid Unnecessary Antimicrobials for Pediatric Meningitis Patients.

In a retrospective observational study, 7 infants (mean age = 2.4 months) had a clinical diagnosis of sepsis of unknown etiology. A cerebrospinal fluid (CSF) analysis was completely normal in all the infants. Similarly, blood tests showed normal total white blood cell and neutrophil counts in all infants and a CRP less than 10 in 90% of the infants. CSF and blood cultures showed no growth in all infants. All infants received intravenous antibiotics and 45% of infants received intravenous antiviral treatment at presentation.

The BioFire ME Panel identified human parechovirus (HPeV) in the CSF of all 7 infants. The study concluded that infants who present with clinical features of meningitis but do not demonstrate CSF pleocytosis or elevated CRP could still have HPeV meningitis. Therefore, using the BioFire ME Panel can help avoid unnecessary antibiotics, antivirals, and prolonged hospital stays.[1]

A CASE STUDY

BioFire® FilmArray®
Meningitis/Encephalitis Panel

1 Test. 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

Sample Type: Cerebrospinal fluid
Sample Volume: 0.2 mL

US FDA-cleared | CE-marked

Overall 94.2% Sensitivity | 99.8% Specificity[2]

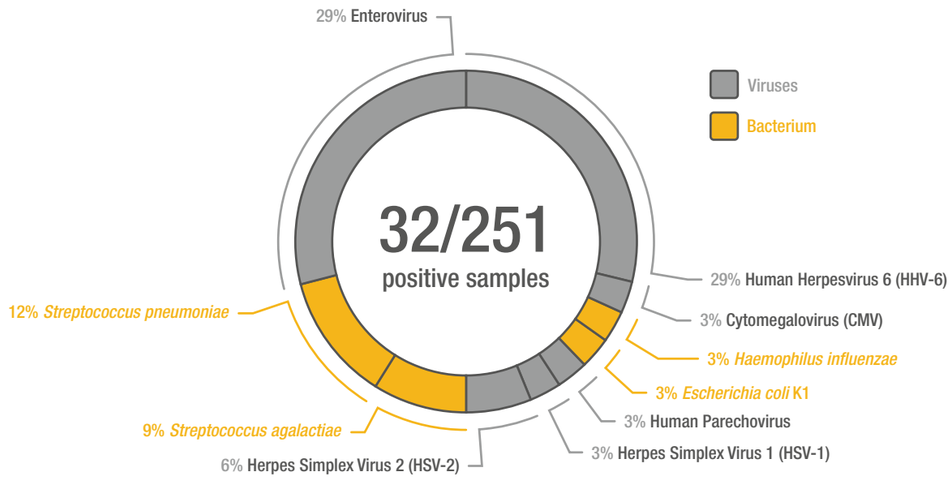
BioFire® FilmArray®
Meningitis/Encephalitis Panel

1 Test. 14 Targets. ~1 Hour.

The BioFire ME Panel tests for a comprehensive set of 14 of the most common bacterial, viral, and fungal pathogens associated with central nervous system (CNS) infections in about one hour using only 0.2 mL of cerebrospinal fluid (CSF).[3]

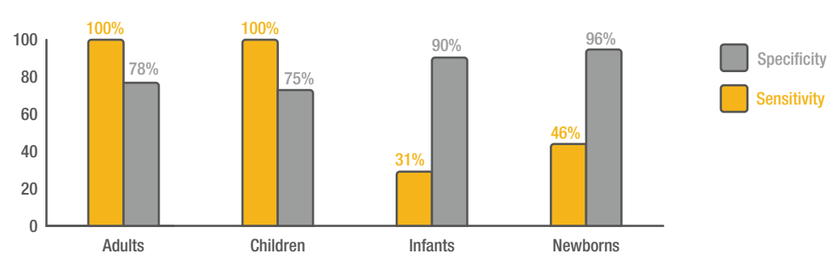
The Comprehensive BioFire ME Panel Simplifies Test Ordering and Increases Diagnostic Yield.[4,5]

Distribution of BioFire ME Panel Positive Results in Pediatric Patients[4]



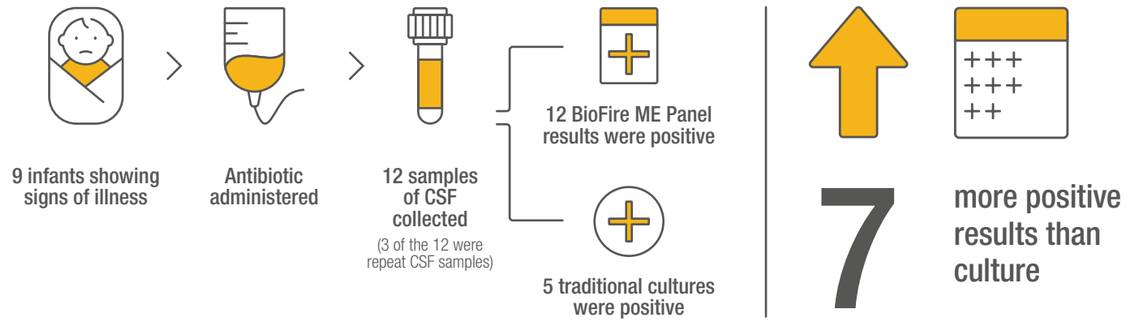
CSF Cell Count Sensitivity is Limited in Infants and Neonates When Compared to BioFire ME Panel Results.

Correlation of Cell Count to a Positive BioFire ME Panel Result[5]

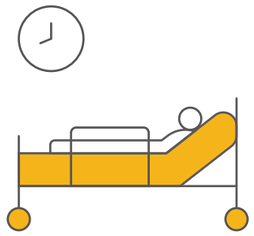


BioFire® FilmArray® Meningitis/Encephalitis (ME) Panel

The BioFire ME Panel Improves Sensitivity of Pathogen Detection Compared to Culture.[6]



The BioFire ME Panel Reduces Length of Stay for Children with Aseptic Meningitis.[7]



8 days
Traditional testing

VS

5 days
Viral detection
BioFire ME Panel

3-day reduction

The BioFire ME Panel Reduces the Duration of Therapy for Children with Aseptic Meningitis.[7]

7 days
Traditional testing

VS

4 days
BioFire ME Panel

3-day reduction

1. Kanagaratnam 2019, 2. Data on file, BioFire Diagnostics, 3. BioFire ME Panel Instructions for Use, 4. Naccache 2018, 5. Lumley 2018, 6. Arora 2017, 7. Posnakoglou 2019.

Know What to Do When it's Not the Flu.

A two-month-old infant presented with fever and respiratory failure. An influenza A/B and respiratory syncytial virus (RSV) antigen test was negative. The infant was started on an antibiotic (cefotaxime) and began a treatment regimen of high-flow oxygen therapy, followed by non-invasive ventilation, then mechanical ventilation. The BioFire® FilmArray® Respiratory (RP) Panel returned a positive identification of rhinovirus and RSV. Based on that result, along with a negative culture result, the antibiotic was discontinued after 48 hours.[1]

A CASE STUDY

BioFire®
Respiratory 2.1 *plus* Panel

1 Test. 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
- 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*

Sample Type: Nasopharyngeal swab in transport media
Sample Volume: 0.3 mL

CE-marked

Overall 97.1% Sensitivity | 99.3% Specificity (prospective specimens)*

SARS-CoV-2: 98.0% Sensitivity | 100% Specificity (archived specimens)**

SARS-CoV-2: 100% PPA | 100% NPA (contrived specimens)***

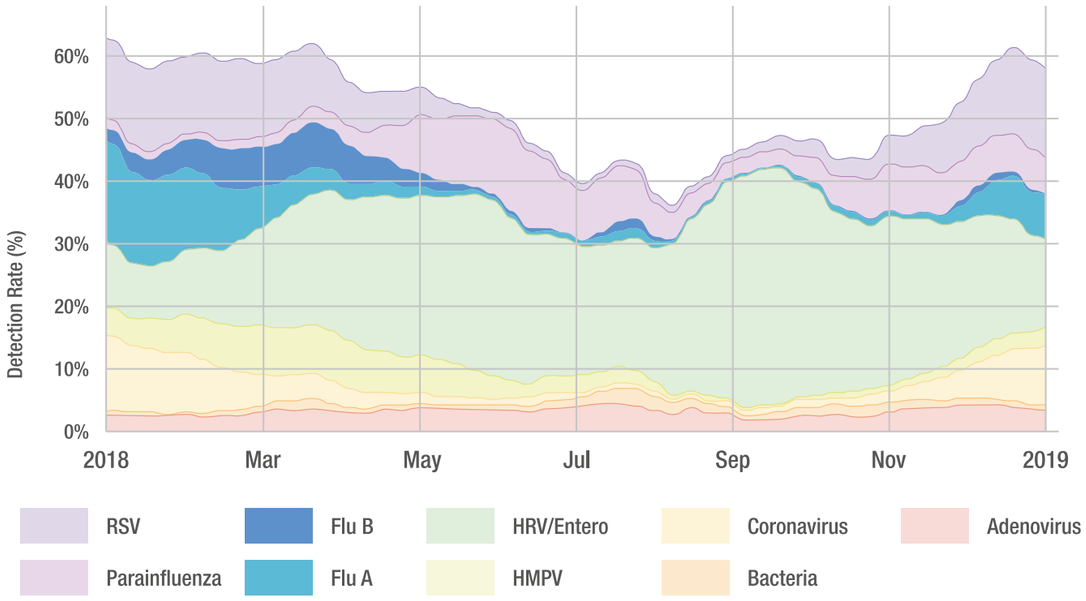
*Based on the prospective portion of the clinical study for the BioFire® FilmArray® Respiratory 2 (RP2) Panel
**Based on the archived specimen study in the BioFire® Respiratory 2.1 (RP2.1) Panel EUA submission
***Based on the contrived specimen study in the BioFire RP2.1 Panel EUA submission

BioFire® Respiratory 2.1 *plus* Panel

1 Test. 23 Targets. ~45 Minutes.

The BioFire RP2.1*plus* Panel can detect 23 different pathogens in about 45 minutes, enabling clinicians to make timely treatment decisions.

U.S. Respiratory Season[2]



Impact of Rapid Molecular Syndromic Testing on Pediatric Patients.

The BioFire® RP Panel helps reduce length of stay and improve the use of antimicrobials for patients with a positive result versus a negative result.

Length of Stay Decreased by

1.35 days[8]

Improved the Use of Antibiotics, Antivirals, and Infection Control[1,3,4,5]

BioFire® Respiratory 2.1 *plus* (RP2.1*plus*) Panel

Speed to Results.

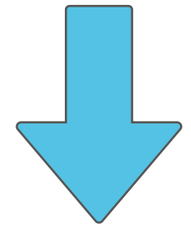
The BioFire® RP Panel dramatically reduces time to diagnosis compared to traditional testing methods.[7]

26.8 hrs

Before BioFire RP Panel Adoption

3.1 hrs

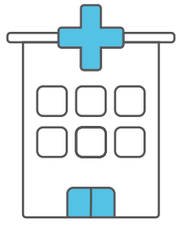
After BioFire RP Panel Adoption



85%

drop in turnaround time

Overall Costs for Patients With a Positive Test Result.[7]



$231 Saved

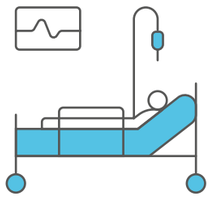
Reduction of hospital costs per patient.

+

$17 Saved

Reduction of antibiotic cost per patient.

=



$248 Saved

Per patient with a positive result when compared pre/post BioFire implementation.

1. Jordan Garcia 2018, 2. BioFire® Syndromic Trends, 3. McFall 2017, 4. Subramony 2016, 5. Xu 2013, 6. Data on file, BioFire Diagnostics, 7. Rogers 2015, 8. Kitano, et. al. 2019.

Reduce the Risk of a Missed Diagnosis for Gastrointestinal Illnesses.

A 5-year-old child presented at the emergency department with abdominal pain, vomiting, a moderate fever, and diarrhea that had lasted three days. A stool culture was ordered and the patient was started on ceftriaxone IV. On day 1, he was transferred to a pediatric intensive care unit, where his symptoms worsened and Hemolytic Uremic Syndrome (HUS) was confirmed. The traditional tests (stool culture, ova and parasite microscopy, and virus immunoassay) were negative, whereas the BioFire GI Panel detected *E.coli* 0157 and norovirus. The ceftriaxone was stopped and the child was started on Zithromax.[1]

A CASE STUDY

BioFire® FilmArray®
Gastrointestinal Panel

1 Test. 22 Targets. ~1 Hour.

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*
  - 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 F40/41
- Astrovirus
- Norovirus GI/GII
- Rotavirus A
- Sapovirus (I, II, IV, and V)

PARASITES
- *Cryptosporidium*
- *Cyclospora cayetanensis*
- *Entamoeba histolytica*
- *Giardia lamblia*

Sample Type: Stool in Cary Blair medium
Sample Volume: 0.2 mL

US FDA-cleared | CE-marked

Overall 98.5% Sensitivity | 99.2% Specificity[2]

BioFire® FilmArray®
Gastrointestinal Panel

1 Test. 122 Targets. ~1 Hour.

The BioFire GI Panel tests for a comprehensive set of 22 gastrointestinal pathogens associated with gastroenteritis, with results in about one hour, from 200µL of stool collected in Cary Blair transport medium.

The Burden of Diarrheal Disease.

525,000
children under five die from diarrhea each year[3]

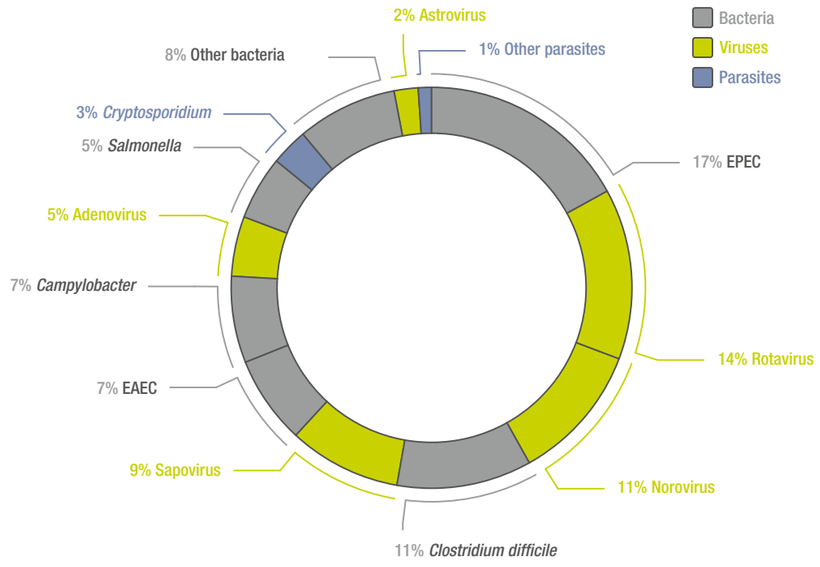
2nd
highest rate of fatalities in children under five[3]

HUS
(Hemolytic Uremic Syndrome)
A major cause of pediatric acute kidney damage[4]

The BioFire GI Panel Provides a Comprehensive Picture of the Etiology of the Disease in Children,[5] Reducing the Risk of a Missed Diagnosis.[5,6,7]

Two-year hospital-based surveillance activity (January 2016–Jaunary 2018) for the pathogens detected by the BioFire GI Panel in children with a clinical suspicion of bacterial and/or viral infectious acute gastroenteritis in Italy.[5]

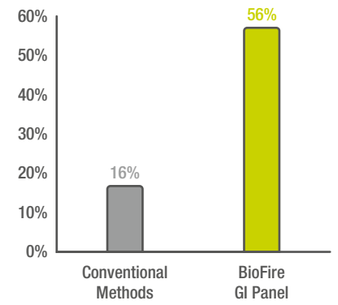
Distribution of the BioFire GI Panel Positive Results in Pediatric Patients[5]



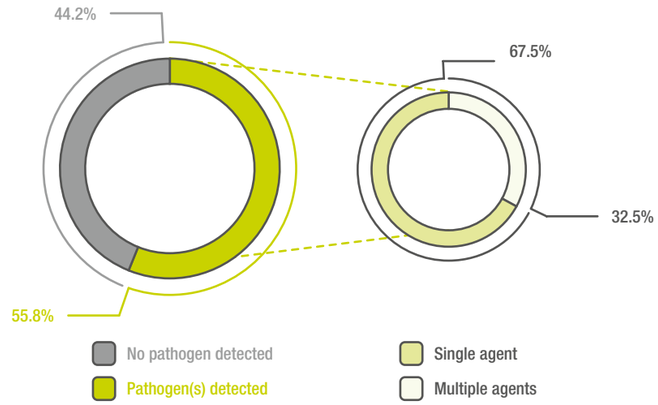
BioFire® FilmArray® Gastrointestinal (GI) Panel

The BioFire GI Panel Increases Diagnostic Yield Compared to Conventional Methods.[5,8]

Pathogen Positivity for Pediatric Patients Compared to Conventional Methods[8]



Diagnostic Yield of the BioFire GI Panel in Pediatric Patients[5]



The BioFire GI Panel Can Help to:

Determine
Determine the right treatment for pediatric patients[5,6,7,8]

Optimize
Optimize the number of children who could benefit from an appropriate antibiotic treatment in case of traveler's diarrhea[9]

Decrease
Decrease inappropriate antibiotic prescriptions when coupled with an antimicrobial stewardship program[10]

Reduce
Reduce the number of additional stool tests[6] of pediatric patients

1. Data on file, bioMérieux, 2. Data on file, BioFire Diagnostics, 3. WHO fact sheet, 4. Boyce 1995, 5. Calderaro 2018, 6. Stockmann 2015, 7. Bourzac 2016, 8. Beal 2017, 9. Pouletty 2019, 10. Keske 2018.

Shorten the Time to Effective Antimicrobial Treatment for Bloodstream Infections.

A 3-month-old infant presented at the emergency department with erythematous plaques on the neck and shoulder area, along with 2 days of fever. Leucocyte count and blood gas analysis were normal, but the infant had abnormally low hemoglobin levels and a thrombocytosis. The patient tested negative for both respiratory syncytial virus (RSV) and influenza A/B. A *Streptococcus* group A infection was suspected, so amoxicillin and clavulanic acid were administered for 3 days.

The clinical situation did not improve, and the child was transferred to the ICU at day 3 with very high CRP and PCT values. The antibiotic therapy was changed to cefotaxime and clindamycin. Two days later, the BioFire BCID Panel detected *Staphylococcus aureus* as the unexpected causative agent. This led to the initiation of an effective antibiotic treatment after 6 days in the hospital, and the infant was able to leave the ICU after 8 additional days.[1]

A CASE STUDY

BioFire®
Blood Culture Identification 2 Panel

1 Test. 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

Sample Type: Positive blood culture
Sample Volume: 0.2 mL

US FDA-cleared | CE-marked

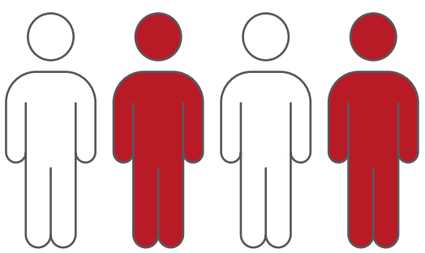
Overall 99% Sensitivity | 99.8% Specificity[2]

BioFire® Blood Culture Identification 2 Panel

1 Test. 43 Targets. ~1 Hour.

The BioFire BCID2 Panel identifies the most common causes of bloodstream infections in pediatric patients. The panel identifies 33 potential pathogens, including gram-positive bacteria, gram-negative bacteria, and yeast, as well as 10 antimicrobial resistance genes from 0.2 mL of positive blood culture media in about 1 hour.[3]

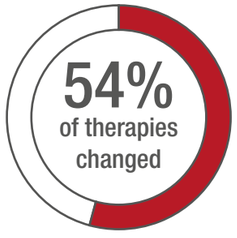
Who Should Get Tested?



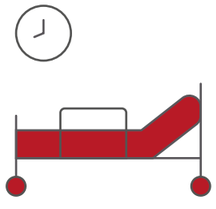
Initial empiric antimicrobial therapy is recommended for patients with suspicion of a bloodstream infection or sepsis until organism identification and antimicrobial susceptibility data become available.[4]

The BioFire BCID Panel reliably identifies bacteria and *Candida* spp. in positive blood cultures from adult and pediatric patients with monomicrobial or polymicrobial bloodstream infections.

BioFire BCID Panel Results Directly Impact the Clinical Management of Pediatric Patients with Bloodstream Infections.



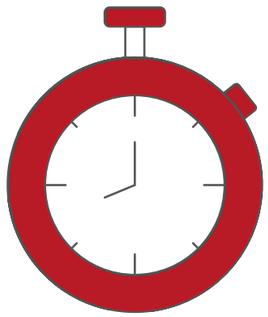
In a study in the United Kingdom, use of the BioFire BCID Panel in the framework of an antibiotic stewardship program altered clinical management in 63 of 117 (54%) episodes of bloodstream infections in a cohort of 100 pediatric patients. In this study, 10 children could be discharged earlier compared to routine care, saving a total of 12 bed days.[5]



12 bed days saved

BioFire® Blood Culture Identification (BCID & BCID2) Panels

Rapid Pathogen Identification with the BioFire BCID Panel Can Help Shorten the Time to Optimal Antimicrobial Therapy.



Shorten Time to Optimal Therapy

Combined with appropriate antimicrobial stewardship, the BioFire BCID Panel can shorten the time to optimal antibiotic therapy in pediatric patients with bloodstream infections. The median time to optimal therapy could be reduced from 60 hours to 27 hours in a study at the Children's Hospital of Colorado (USA).[6]

33-hour reduction

The BioFire BCID Panel Improves Antimicrobial Stewardship and Significantly Decreases Unnecessary Antibiotic Use.

Decrease Unnecessary Antibiotic Use

The rapid identification of microorganisms by means of the BioFire BCID Panel improves antimicrobial stewardship in children with bloodstream infections. Unnecessary antibiotic initiation for children with a culture that contained organisms considered to be contaminants significantly decreased from 76% to 26%, and initiation of vancomycin was reduced significantly, from 56% to 14%.[6]

Unnecessary antibiotic use reduced from 76% to 26%

1. Jordan 2018, 2. Data on file, BioFire Diagnostics, 3. BioFire BCID Panel Instructions for Use, 4. Rhodes 2016, 5. Ray 2016, 6. Messacar 2017.

Detect More Pneumonia Targets than Standard of Care.

Pneumonia patients need appropriate therapy quickly, but it can take days to identify pathogens with traditional culture methods, leaving physicians without microbiology results to inform their therapy choices. In about an hour, the BioFire® PN*plus* Panel provides results for 18 bacteria, 9 viruses, and 7 antimicrobial resistance genes, providing timely information to assist in therapy decisions.

BioFire® FilmArray®
Pneumonia *plus* Panel

1 Test. 34 Targets. ~1 Hour.

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
- 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)

Sample Type: BAL (including mini-BAL), Sputum (including endotracheal aspirate)
Sample Volume: 0.2 mL

US FDA-cleared | CE-marked

BAL: Overall 96.2% Sensitivity | 98.4% Specificity[1]

Sputum: Overall 96.3% Sensitivity | 97.3% Specificity[1]

BioFire® FilmArray®

Pneumonia *plus* Panel

1 Test. 34 Targets. ~1 Hour.

The BioFire PN*plus* Panel reliably identifies 27 clinically relevant pathogens and 7 antimicrobial resistance genes directly from lower respiratory tract specimens.[2] For bacteria, the test provides semi-quantitative concentrations to help facilitate distinguishing colonizing organisms from true pathogens.

The Challenges with Pneumonia.

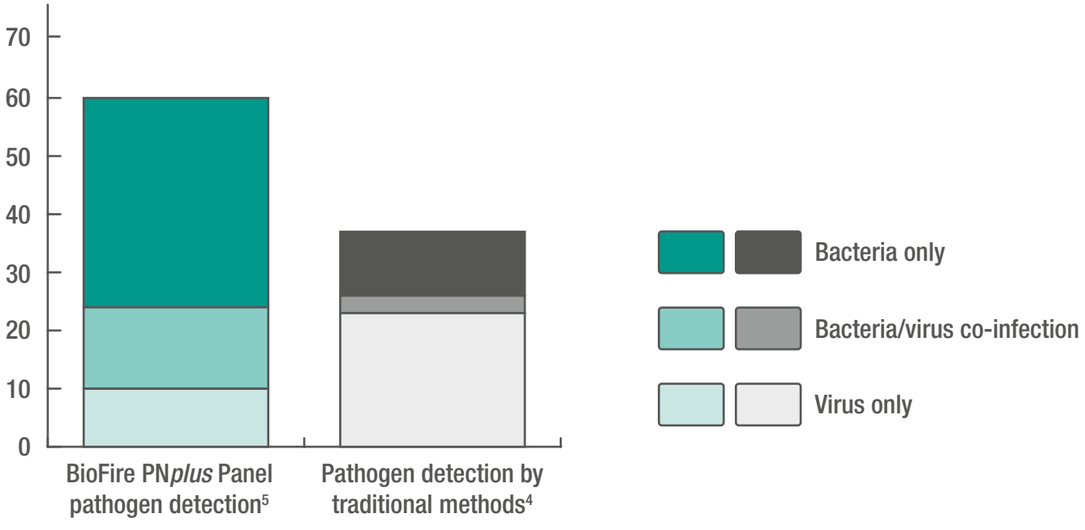
#1

Pneumonia is the leading cause of death for children under 5[3]

Pneumonia patients require appropriate therapy quickly. Traditional culture methods are insensitive and time consuming, identifying causative agents in 24–48 hours or, all too often, failing to identify anything at all.[4] The BioFire PN*plus* Panel is a PCR-based assay that detects bacteria, viruses, and antimicrobial resistence genes from sputum, endotracheal aspirates and bronchoalveolar lavage (including mini-BAL) specimens with a sensitivity and a specificity of >96% in about 1 hour.[1]

Traditional Pneumonia Testing is Often Inconclusive.

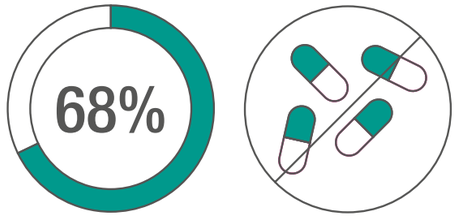
A multicenter study of community-acquired pneumonia requiring hospitalization only identifed a bacterial agent in 14% of samples.[4] The BioFire PN*plus* Panel identifies a bacteria in up to 50% of patient specimens.[5]



The BioFire® FilmArray® Pneumonia *plus* (PN*plus*) Panel

The BioFire PN*plus* Panel Effectively Guides the Adjustment of Empiric Antibiotic Therapy.

In a recent clinical evaluation, the BioFire PN*plus* Panel was run on 259 adult patient samples.[6] Chart reviews revealed that up to 68% of empiric antibiotic courses could have been altered to more appropriate therapy, saving more than 18,000 hours of antibiotic exposure in this cohort.

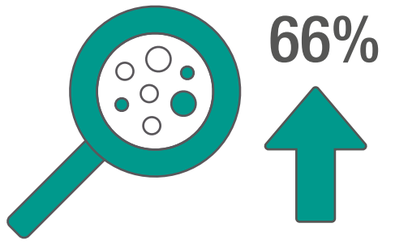


Antibiotic adjustments could have been made

>18,000 hours

of antibiotic exposure saved in this cohort

The BioFire PN*plus* Panel Impacts Appropriate Antimicrobial Therapy in Pediatric Patients.



more bacterial targets detected

In a study of 100 sputum and sputum-like samples from pediatric patients (median age=6 years), the BioFire PN*plus* Panel detected 66% more bacterial and 5% more viral targets than the culture-based standard of care.[7]

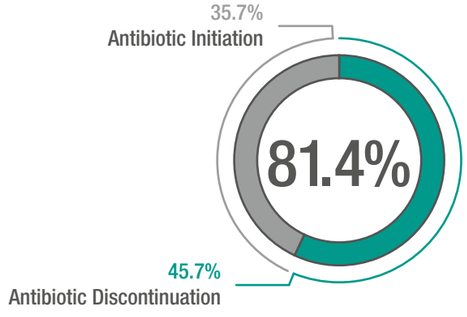


Chart abstraction for pathogen detection and antibiotic utilization indicated that the BioFire PN*plus* Panel may lead to appropriate antimicrobial initiation and discontinuation in 35.7% and 45.7% of patients, respectively.[7]

1. Data on file, BioFire Diagnostics, 2. BioFire PNplus Panel Instructions for Use, 3. WHO fact sheet, 4. Jain 2015, 5. BioFire PN Panel clinical study, 6. Buchan, ATS 2018, 7. Pandey, ECCMID 2019.

Syndromic Testing

1. Brendish NJ, *et al.* Routine molecular point-of-care testing for respiratory viruses in adults presenting to hospital with acute respiratory illness (ResPOC): a pragmatic, open-label, randomised controlled trial. Lancet Respir Med. 2017 May;5(5):401-41.

BioFire® ME Panel

1. Kanagaratnam M, Jyothish D. G115(P) Parechovirus meningitis in infants – time for routine CSF viral screening? *Archives of Disease in Childhood* 2019;104:A47
2. Data on file, BioFire Diagnostics. The stated performance is the overall aggregate performance of the prospective clinical study data presented in the IFU.
3. BioFire FilmArray Meningitis/Encephalitis (ME) CE-IVD Instruction for Use.
4. Naccache SN, *et al.* 2018. One year in the life of a rapid syndromic panel for meningitis/encephalitis: a pediatric tertiary care facility's experience. J Clin Microbiol 56:e01940-17. https://doi.org/10.1128/JCM.01940-17.
5. Lumley S, *et al.* Letters to the Editor: Multiplex PCR reveals high prevalence of enterovirus and HHV6 in acellular paediatric cerebrospinal fluid samples. Journal of Infection Volume 77, Issue 3, September 2018, Pages 249-257.
6. Arora H, *et al.* Enhanced Identification of Group B Streptococcus and Escherichia Coli in Young Infants with Meningitis Using the Biofire Filmarray Meningitis/Encephalitis Panel. The Pediatric Infectious Disease Journal, Volume 36, Number 7, July 2017.
7. Posnakoglou L, *et al.* Eur J Clin Microbiol Infect Dis. 2020 Jul 18.

BioFire® RP2.1*plus* Panel

1. Jordan Garcia I. Clinical case from "Urgent Microbiology testing in the critically ill patient" H. Sant Joan de Déu, Barcelona, 2018.
2. BioFire Syndromic Trends - www.syndromictrends.com.
3. McFall, *et al.*, Impact of Early Multiplex FilmArray Respiratory Pathogen Panel (RPP) Assay on Hospital Length of Stay in Pediatric Patients Younger Than 3 Months Admitted for Fever or Sepsis Workup; Clinical Pediatrics. 2017 Feb.
4. Subramony A, *et al.* J Pediatr. 2016; doi:10.1016/j.jpeds.2016.02.050. Graphs adapted from data in original publication.
5. Xu M. *et al.*, Implementation of filmarray respiratory viral panel in a core laboratory improves testing turnaround time and patient care. Am J Clin Pathol 2013; 139:118–23.
6. Based on a meta-analysis of the following studies:
   Xu M, Qin X, Astion M, Rutledge J, Simpson J, Jerome K, Englund J, Zerr D, Migita R, Rich S, Childs J, Cent A, Del Beccaro M. Implementation of FilmArray Respirator Viral Panel in a Core Laboratory Improves Testing Turnaround Time and Patient Care. Am. J Clin Pathol 2013;139:118-123. Poelman R, van der Meer J, van Leer-Buter C, Riezebos-Brilman A, Friedrich A, Niesters B. Point-of-Impact Testing in the Emergency Department: Diagnostic for Respiratory Viral Infections. European Society for Clinical Virology 2015, Poster #1126. Pettit N, Matushek S, Charnot-Katsikas A, Tesic V, Boonlayangoor S, Brielmaier B, Pisano J. Comparison of Turnaround Time (TAT) and Time to Oseltamivir Discontinuation between Two Respiratory Viral Panel Testing (RVP) Methodologies. J. Med Microbiol., March 2015; 64:312-313. Gelfer G, Leggett J, Myers J, Wang L, Gilbert D. The Clinical Impact of the Detection of Potential Etilologic Pathogens of Community-acquired Pneumonia. Diag Micro Infect Dis. 2015; 83:400-406. Rappo U, Schuetz A, Jenkins S, Calfee D, Walsh T, Wells M, Hollenberg J, Glesby M. Impact of Early Detection of Respiratory Viruses by Multiplex PCR on Clinical Outcomes in Adult Patients. J. Clin. Microbiol. 2016; JCM.00549-16. Brendish N, Malachira A, Armstrong L, Houghton R, Aitken S, Nyimbili E, Ewings S, Lillie P, Clark T. Routine molecular point-of-care testing for respiratory viruses in adults presenting to hospital with acute respiratory illness (ResPOC): a pragmatic, open-label, randomized controlled trial. Lancet Respir Med. 2017 May; 5(5):401-411. Rogers B, Shankar P, Jerris R, Kotzbauer D, Anderson E, Watson R, O'Brien L, Uwindatwa F, McNamara K, Bost J. Impact of a Rapid Respiratory Panel Test on Patient Outcomes. Arch. Path. & Lab. Med. 2015;139(5): 636-41. Martinez R, Kay HE, Scicchitano LM, Wolk DM. Implementation of Non-Batched Respiratory Virus Assay Significantly Impacts Patient Outcomes in the ICU. Clinical Virology Symposium, Poster #C-368, May 2016.
7. Rogers BB *et al.*, Impact of a rapid respiratory panel test on patient outcomes. Arch Pathol Lab Med 2015, 139:636–641.
8. Kitano T., *et. al.* The impact analysis of a multiplex PCR respiratory panel for hospitalized pediatric respiratory infections in Japan. Journal of Infection and Chemotherapy, Volume 26, Issue 1, 82-85.

References

BioFire® GI Panel

1. Cas cliniques et recommendations pour l'approche syndromique, bioMérieux, 11-18.
2. Data on file, BioFire Diagnostics. The stated performance is the overall aggregate performance of the prospective clinical study data presented in the IFU.
3. WHO fact sheet May 2017.
4. Boyce TG, *et al. Escherichia coli* O157:H7 and the Hemolytic–Uremic Syndrome. N Engl J Med 1995; 333:364-368.
5. Calderaro A, *et al.* Contribution of the FilmArray® Gastrointestinal Panel in the laboratory diagnosis of gastroenteritis in a cohort of children: a two-year prospective study. Int J Med Microbiol. 2018 Jul;308(5):514-521.
6. Stockmann C, *et al.* How well does physician selection of microbiologic tests identify *Clostridium difficile* and other pathogens in paediatric diarrhoea? Insights using multiplex PCR-based detection. Clin Microbiol Infect. 2015 Feb;21(2):179.
7. Bourzac KM, *et al.* Missed Opportunities for Treatment: Implementation of a Molecular Diagnostic for Pediatric Acute Gastroenteritis (GE): The FilmArray® GI Panel IMPACT Study. ECCMID 2016 poster.
8. Beal SG, *et al.* A Gastrointestinal PCR Panel Improves Clinical Management and Lowers Health Care Costs. J Clin Microbiol. 2017 Dec 26;56(1).
9. Pouletty M, *et al.* Multiplex PCR reveals a high prevalence of multiple pathogens in traveller's diarrhoea in children. Arch Dis Child. 2019 Feb;104(2):141-146.
10. Keske Ş, *et al.* Rapid Molecular Detection of Gastrointestinal Pathogens and Its Role in Antimicrobial Stewardship. J Clin Microbiol. 2018 Apr 25;56(5).

BioFire® BCID2 Panel

1. Jordan Garcia I. Clinical case from "Urgent Microbiology testing in the critically ill patient" H. Sant Joan de Déu, Barcelona, 2018.
2. Data on file, BioFire Diagnostics. The stated performance is the overall aggregate performance of the prospective clinical study data presented in the IFU.
3. BioFire FilmArray BCID Instruction Booklet, available at https://www.online-ifu.com/ITI0045.
4. Rhodes A, *et al.* Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock: 2016. Intensive Care Med (2017) 43(3):304–377.
5. Ray ST, *et al.* Rapid Identification of Microorganisms by FilmArray Blood Culture Identification Panel Improves Clinical Management in Children. Pediatr Infect Dis J. 2016; 35(5):e134-8.
6. Messacar K, *et al.* Clinical Impact and Provider Acceptability of Real-Time Antimicrobial Stewardship Decision Support for Rapid Diagnostics in Children With Positive Blood Culture Results. J Ped Infect Dis Soc 2017;6(3):267-274.

BioFire® PN*plus* Panel

1. Data on file, BioFire Diagnostics. The stated performance is the overall aggregate performance of the prospective clinical study data presented in the IFU. Performance data is for pathogen detection only.
2. BioFire Pneumonia Panel plus Instructions for use, available at https://www.online-ifu.com/ITI0038.
3. WHO fact sheet, November 2016.
4. Jain S, *et al.* Community-Acquired Pneumonia Requiring Hospitalization among U.S. Adults. N Engl J Med. 2015; 373(5):415-427.
5. Data on file, BioFire Diagnostics, LLC. Number of detections taken from the prospection portion of the BioFire PN Panel clinical study.
6. Buchan BW, *et al.* Clinical Evaluation and Potential Impact of a Semi-Quantitative Multiplex Molecular Assay for the Identification of Pathogenic Bacteria and Viruses in Lower Respiratory Specimens. Poster A107, presented at the ATS Conference 2018.
7. Pandey U, *et al.* Performance evaluation and potential clinical utility of the BioFire® FilmArray® Pneumonia Panel in a tertiary care paediatric hospital. Poster P1555, presented at the ECCMID Conference 2019.

Notes

Syndromic Testing: The Right Test, The First Time.

bioMérieux S.A.
69280 Marcy l"Etoile
France
Tel.:+33 (0) 4 78 87 20 00
Fax: +33 (0) 4 78 87 20 90
www.biomerieux.com

Manufactured by:
BioFire Diagnostics, LLC
515 Colorow Drive
Salt Lake City, UT 84108
USA
www.biofiredx.com

BFR0000-4502-02