



BIO  FIRE®



BIO  FIRE®

The purchase of this product includes a limited, non-transferable license under specific claims of one or more US patents listed on the BioFire Diagnostics website (<http://www.biofiredx.com/legal-notices/>) owned by BioFire and/or the Research Foundation of The University of Utah. The blue logo, BioFire and FilmArray logos, and BIOMÉRIEUX, BIOFIRE, and FILMARRAY are used, pending, and/or registered trademarks belonging to bioMérieux or BioFire or one of their subsidiaries or companies. Document and/or picture not legally binding. Modifications can be made without prior notice. No part of this document may be reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose, without the express written permission of bioMérieux/BioFire Diagnostics.

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
BioFire is wholly owned by bioMérieux.

www.biofiredx.com

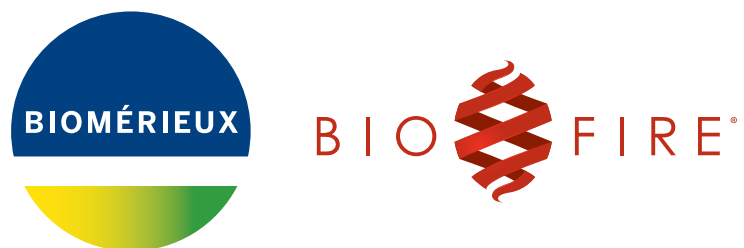
BF00001-3800-01 9321052 008/GB/A





BIO  FIRE®



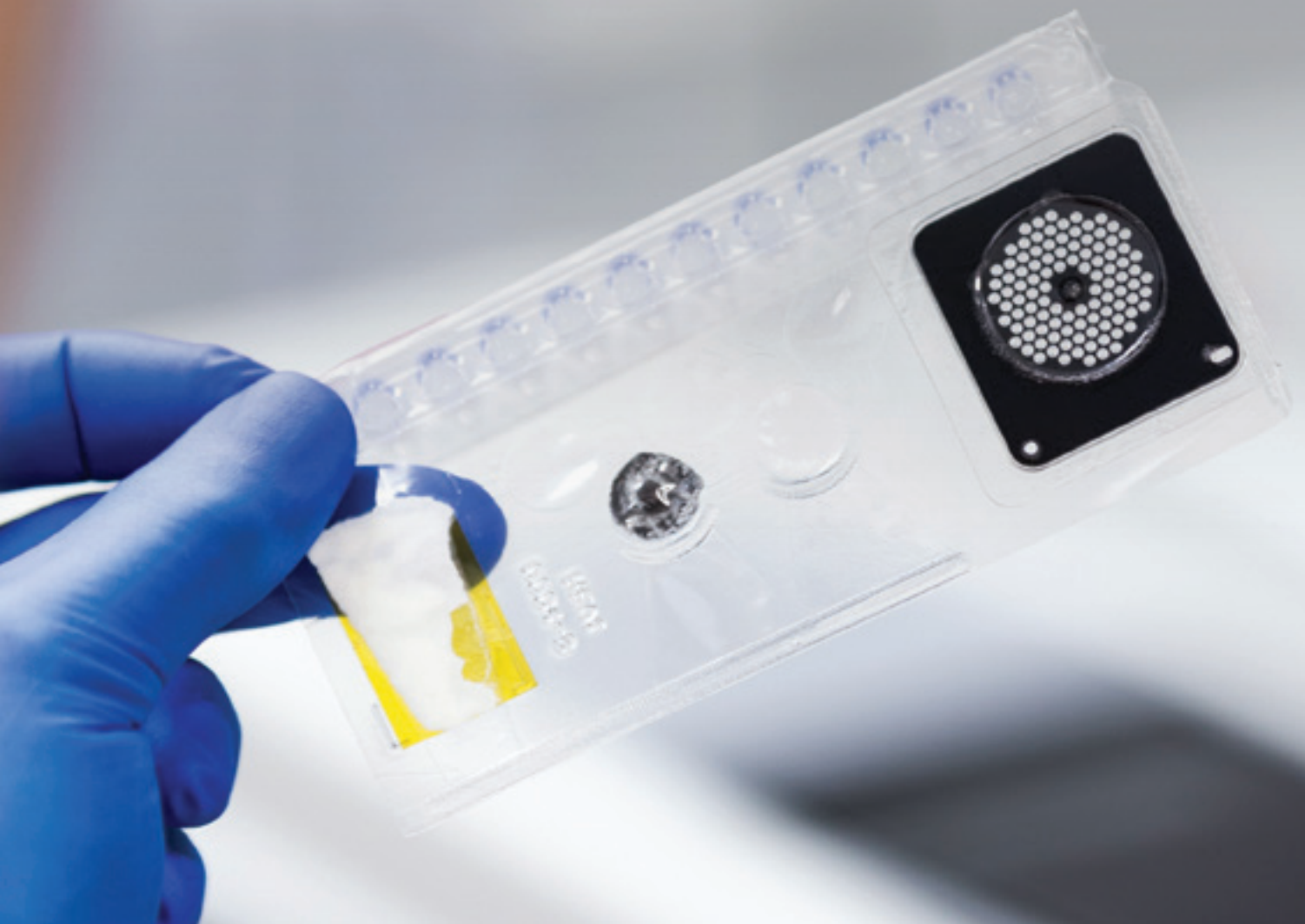


Syndromic Testing: The Right Test, The First Time.

bioMérieux's line of BioFire products is evolving
infectious disease diagnostics.



The BioFire syndromic approach
empowers clinicians to choose
the right test, the first time.



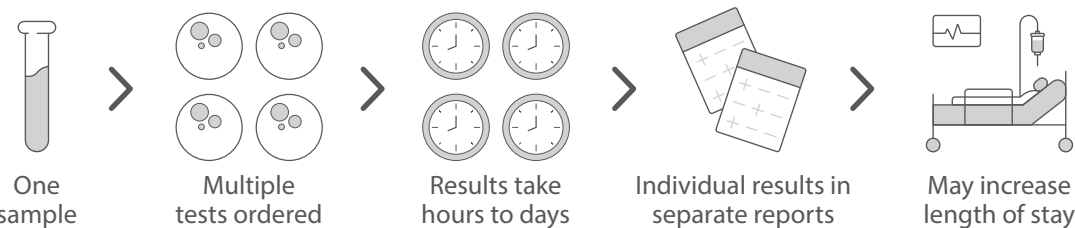
Don't Guess. Know.

Many infectious diseases present with similar signs and symptoms. Traditional targeted diagnostics limit testing to only the pathogens most commonly associated with a clinical syndrome. Because this testing method is so narrowly defined, it can leave many infections undiagnosed and may lead to additional downstream testing, patient dissatisfaction, and compromised patient care.

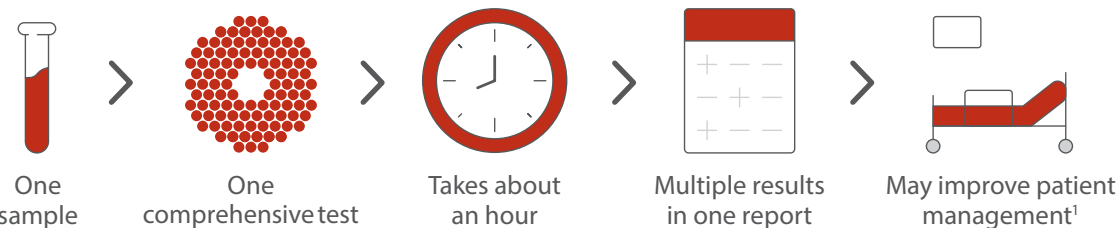
BioFire's syndromic approach to infectious disease diagnostics helps quickly identify pathogens, greatly reduces the guesswork in diagnostics, may increase patient satisfaction, can help improve patient care, and helps make the world a healthier place.

Choose the right test, the first time. Choose syndromic testing from BioFire.

Traditional Testing



Syndromic Testing



¹Brendish NJ, et al. Lancet Respir Med. 2017 May;5(5):401-411.



Sample ID	Amount (μl)	Date	Batch
01-01-2023-001	100	01-01-2023	001
01-01-2023-002	100	01-01-2023	002
01-01-2023-003	100	01-01-2023	003
01-01-2023-004	100	01-01-2023	004
01-01-2023-005	100	01-01-2023	005
01-01-2023-006	100	01-01-2023	006
01-01-2023-007	100	01-01-2023	007
01-01-2023-008	100	01-01-2023	008
01-01-2023-009	100	01-01-2023	009
01-01-2023-010	100	01-01-2023	010

The Fastest Way to Better Results.



Faster Results

With about an hour turnaround time, BioFire's syndromic testing helps clinicians make vital decisions regarding admission, isolation, cohorting, antiviral or antibiotic therapy, and additional diagnostic testing.



Better Results

By harnessing the power of syndromic testing, labs can increase the probability of identifying a pathogen in patients with symptoms of an infectious disease. Each BioFire® FilmArray® Panel increases the capability of detecting co-infections and may result in shorter length of stay and improved downstream savings.

*“FilmArray from BioFire has massively influenced the way we now manage our patients and infection control situations. For example, rapid diagnosis of whooping cough [*B. pertussis* on BioFire® Respiratory 2.1 plus Panel] has enabled us to initiate effective treatment and infection control measures within hours of patient's arrival to the hospital. Previously, a result from reference lab would typically take three to four days.”*

Dr. Mitul Patel

Consultant Microbiologist

Birmingham Children's Hospital, UK



Syndromic Testing Streamlines Laboratory Processes.

BioFire products can be used by any technician, on any shift, at any time. This helps hospitals provide the same standard of care 24/7 and removes the need to delay or send out samples for additional testing.



Fast

With a run time of about an hour, syndromic testing enables laboratories to provide answers to physicians in a clinically actionable time frame.



Easy

BioFire's syndromic approach is easy, and test preparation requires only two minutes of hands-on time. Results are given in a positive or negative report for each pathogen from a broad test menu.



Comprehensive

Syndromic testing eliminates serial testing that can be frustrating and time-consuming for laboratories. It consolidates quality control and proficiency testing as well as minimizes the time required to keep and maintain multiple instruments.

The BioFire® FilmArray® Torch:

The most advanced syndromic testing.



351 PATIENT
SAMPLES
PER DAY¹
with 12 modules

292 PATIENT
SAMPLES
PER DAY¹
with 10 modules

234 PATIENT
SAMPLES
PER DAY¹
with 8 modules

175 PATIENT
SAMPLES
PER DAY¹
with 6 modules

117 PATIENT
SAMPLES
PER DAY¹
with 4 modules

58 PATIENT
SAMPLES
PER DAY¹
with 2 modules

Scalable configuration for customized
throughput from 1 to 12 modules.

¹Calculations based on running the BioFire® Respiratory 2.1 Panel over a 24-hour day.



Intuitive

Provides faster input and navigation through an optimized user experience with a touchscreen interface, integrated barcode scanner, and intuitive instrument control.



Access

Improved testing and laboratory productivity with random and continuous access sample loading.



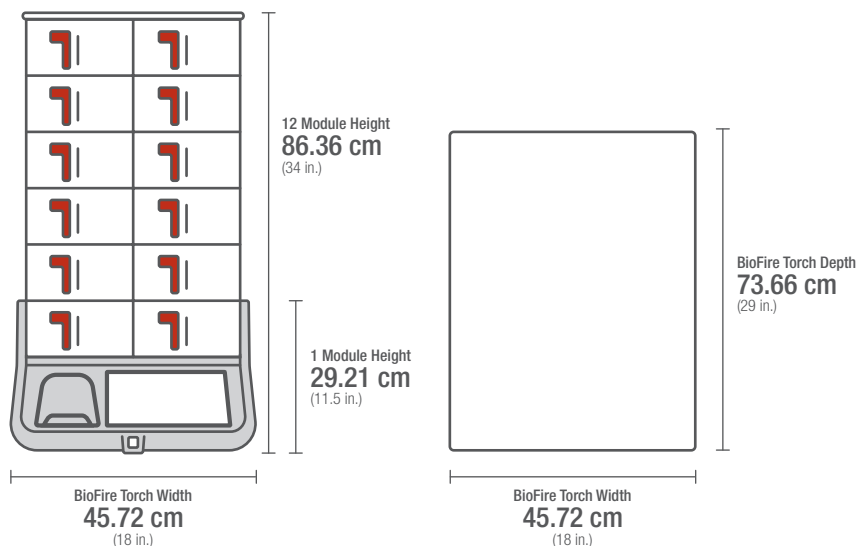
Connectivity

Makes data management automated and efficient through the BioFire® FilmArray® Link Technology that can seamlessly integrate into Laboratory Information System (LIS).



Radically Reduced Footprint

The BioFire® Torch offers the most scalable system with the same footprint.²



²In comparison to existing BioFire® FilmArray® Systems.



“In conclusion, the BioFire® FilmArray® Gastrointestinal Panel is a broad, multiplex gastrointestinal panel with a rapid turnaround time, resulting in a significant reduction of unnecessary isolation days, antibiotic therapy and prevention of additional diagnostic procedures in patients with clinical suspicion of infectious gastroenteritis.”³

Julian Machiels, MD

Consultant Microbiologist

3. Machiels J., et al. Impact of the BioFire FilmArray gastrointestinal panel on patient care and infection control. PLoS One. 2020;15(2):e0226596. Published 2020 Feb 6. doi:10.1371/journal.pone.0226596.

Fast Answers With BioFire Syndromic Panels.

Comprehensive Panels Offer Better Diagnostics

Comprehensive panels take out the guesswork. Each BioFire® Panel targets an infectious disease syndrome by combining a broad grouping of probable pathogenic causes into a single test.

The CE-marked BioFire Panels test for viruses, bacteria, parasites, yeast, and antimicrobial resistance genes.



Respiratory 2.1 *plus* Panel



Pneumonia *plus* Panel



Gastrointestinal Panel



Meningitis/Encephalitis Panel



Blood Culture Identification 2 Panel

Product availability varies by country. Consult your bioMérieux representative.

Pending US FDA Review



Joint Infection Panel*

*Investigational use only. Not for use in diagnostic procedures. Currently under FDA Review, panel menu subject to change. Not available for sale.



BioFire® Respiratory 2.1 *plus* Panel

Sample Type: 0.3 mL of nasopharyngeal swab in transport media or saline
CE-marked

23 Targets in One Test

The BioFire® Respiratory 2.1 **plus** (RP2.1**plus**) Panel identifies the most common viral and bacterial pathogens—including SARS-CoV-2—that cause respiratory tract infections, which can present with nearly indistinguishable symptoms. An unprecedented run time of about 45 minutes enables higher efficiency and throughput on the BioFire® FilmArray® 2.0 and the BioFire® Torch Systems, and offers faster results to clinicians, potentially enabling better-informed diagnosis and treatment of patients. Higher overall sensitivity across a broader spectrum of pathogens means the BioFire RP2.1**plus** Panel offers the world the fastest way to better results in the detection of respiratory pathogens.

Panel Menu

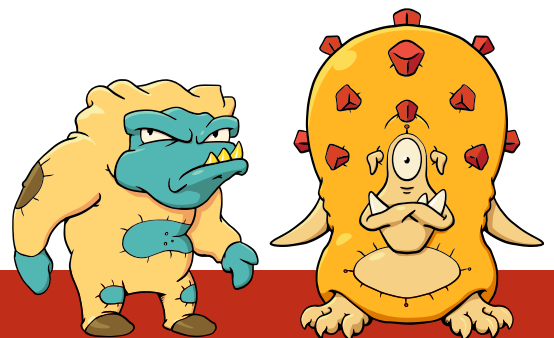
VIRUSES

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/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 pneumoniae
Mycoplasma pneumoniae





BioFire® FilmArray®

Pneumonia *plus* Panel

Sample Type: Sputum (including ETA) and BAL (including mini-BAL)
CE-marked and US FDA-cleared

34 Targets in One Test

The BioFire Pneumonia *plus* Panel tests for 27 of the the most common bacterial and viral pathogens associated with various types of community/hospital-acquired pneumonia, along with 7 antimicrobial resistance genes. Quickly identifying the probable causative agent can help a healthcare provider determine how best to treat a lower respiratory tract infection.

Panel Menu

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

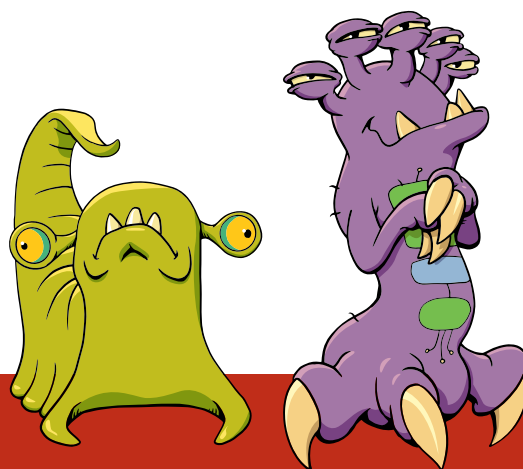
VIRUSES

Adenovirus
Coronavirus
Human Metapneumovirus
Human Rhinovirus/Enterovirus
Influenza A
Middle East Respiratory
Syndrome Coronavirus (MERS-
CoV)
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® FilmArray®

Gastrointestinal Panel

Sample Type: 0.2 mL stool collected in Cary Blair transport medium
CE-marked and US FDA-cleared

22 Targets in One Test

The BioFire® FilmArray® Gastrointestinal (GI) Panel tests stool in Cary Blair for the bacteria, viruses, and parasites commonly associated with gastroenteritis. Quickly identifying the probable pathogen can ensure appropriate treatment and patient management and help decrease infectious gastroenteritis, which can lead to severe illness or death.

Panel Menu

BACTERIA

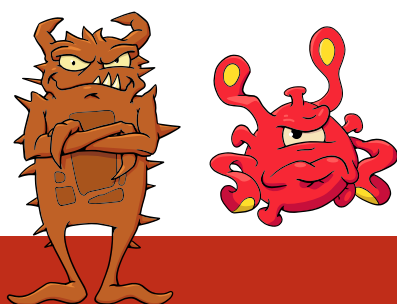
Campylobacter (jejuni, coli, and upsaliensis)
Clostridioides (Clostridium) difficile (toxin A/B)
Plesiomonas shigelloides
Salmonella
Vibrio (parahaemolyticus, vulnificus, and cholerae)
 Vibrio cholerae
Yersinia enterocolitica
Diarrheagenic E. coli/Shigella
 Enteraggregative E. coli (EAEC)
 Enteropathogenic 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 cayentanensis
Entamoeba histolytica
Giardia lamblia





BioFire® FilmArray®

Meningitis/Encephalitis Panel

Sample Type: 0.2 mL of uncentrifuged cerebrospinal fluid (CSF)
CE-marked and US FDA-cleared

14 Targets in One Test

The BioFire® FilmArray® Meningitis/Encephalitis (ME) Panel identifies the most common viral, bacteria, and yeast pathogens that cause infections in the central nervous system which, in some cases, can be life-threatening. Rapidly identifying the probable cause of these potentially severe conditions can allow faster decisions on appropriate therapy.

Panel Menu

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® Blood Culture Identification 2 Panel

Sample Type: 0.2 mL positive blood culture media
CE-marked and US FDA-cleared

43 Targets in One Test

The BioFire® Blood Culture Identification 2 (BCID2) Panel tests for the most common causes of bloodstream infections, including gram-positive, gram-negative, and yeast pathogens, and 10 antibiotic resistance genes. Quickly identifying the probable cause of bloodstream infections may help clinicians reduce the time to appropriate antimicrobial therapy and positively impact patient survival.

Panel Menu

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

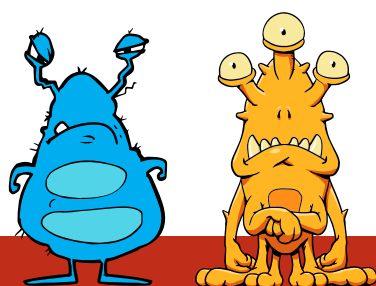
Carbapenemases
IMP
KPC
OXA-48-like
NDM
VIM

Colistin Resistance
mcr-1

ESBL
CTX-M

Methicillin Resistance
mecA/C
mecA/C and MREJ (MRSA)

Vancomycin Resistance
vanA/B





BioFire® Joint Infection Panel*

Sample Type: 0.2 mL of synovial fluid

*Investigational use only. Not for use in diagnostic procedures. Currently under FDA Review, panel menu subject to change. Not available for sale.

39 Targets in One Test

The proposed BioFire® Joint Infection (JI) Panel tests for common causes of prosthetic joint infections and septic arthritis. The BioFire JI Panel includes assays for 39 targets, including gram-positive bacteria, gram-negative bacteria, yeast, and antibiotic resistance genes.

Panel Menu

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

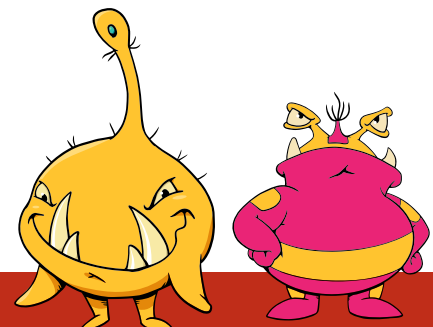
ANTIMICROBIAL RESISTANCE GENES

Carbapenemases
IMP
KPC
NDM
OXA-48-like
VIM

ESBL
CTX-M

Methicillin Resistance
mecA/C and MREJ

Vancomycin Resistance
vanA/B



Peace of Mind All the Time.

First in Diagnostics. First in Customer Care.

bioMérieux has a skilled team dedicated to client success. Our customer support team provides global product support, solution training courses, LIS connectivity assistance, and instrument or chemistry related troubleshooting. We are committed to the speedy resolution of all technical issues.



International Support

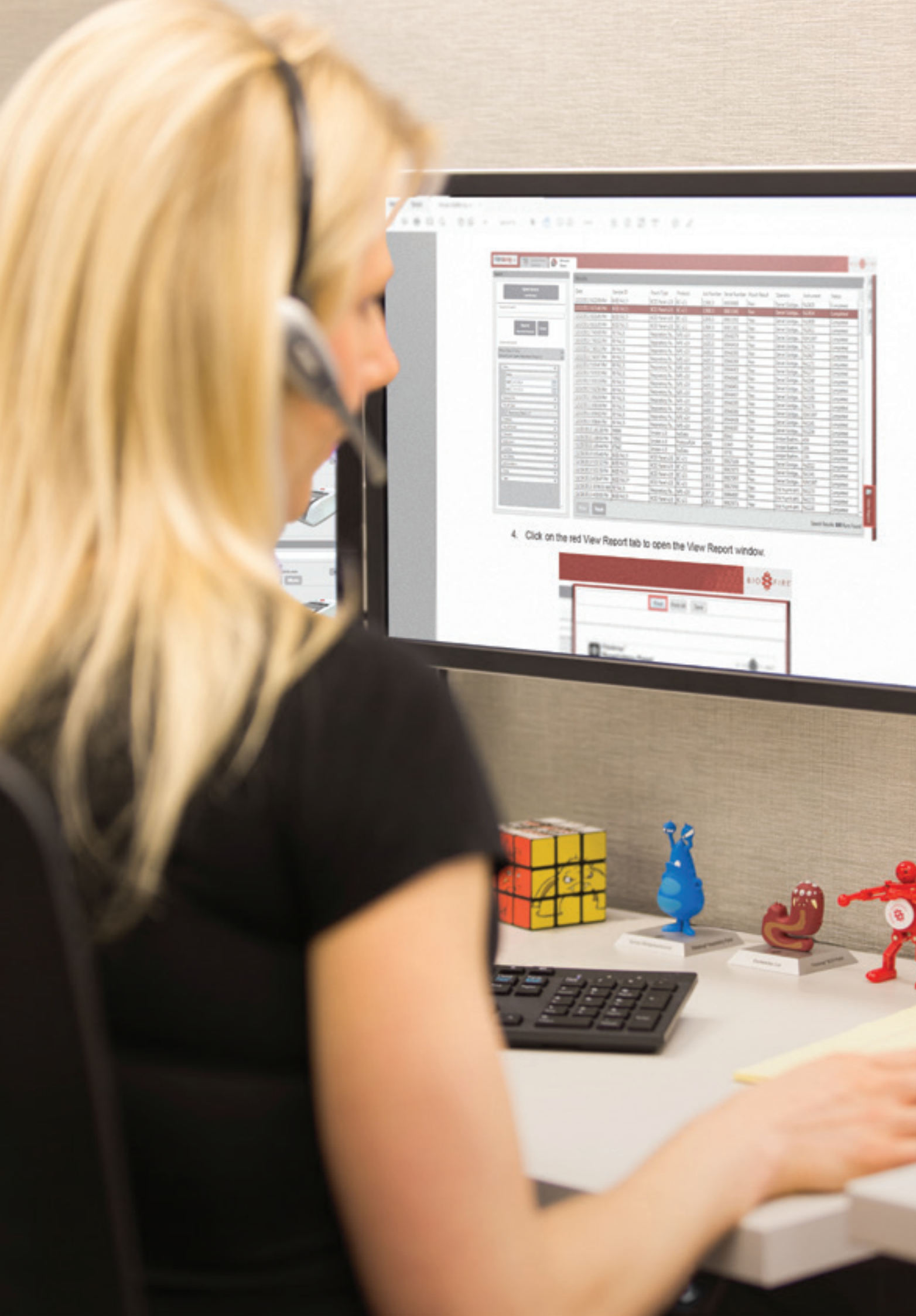
For international BioFire technical assistance and support, please contact your local bioMérieux representative or distributor.



Help at Your Fingertips

With a complete suite of resources, our customers have access to everything they need for set-up, verification, and integration of the BioFire® FilmArray® System. Our website provides documents to assist with verification, EC Declarations of Conformity, and continuing education for all customers.

Visit biofiredx.com to find Advisory Notices, Information Sheets, Product Support Documents, and other resources.





The purchase of this product includes a limited, non-transferable license under specific claims of one or more US patents listed on the BioFire Diagnostics website (<http://www.biofiredx.com/legal-notices/>) owned by BioFire and/or the Research Foundation of The University of Utah. The blue logo, BioFire and FilmArray logos, and BIOMÉRIEUX, BIOFIRE, and FILMARRAY are used, pending, and/or registered trademarks belonging to bioMérieux or BioFire or one of their subsidiaries or companies. Document and/or picture not legally binding. Modifications can be made without prior notice. No part of this document may be reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose, without the express written permission of bioMérieux / BioFire Diagnostics.

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
BioFire is wholly owned by bioMérieux.

www.biofiredx.com