





# **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.

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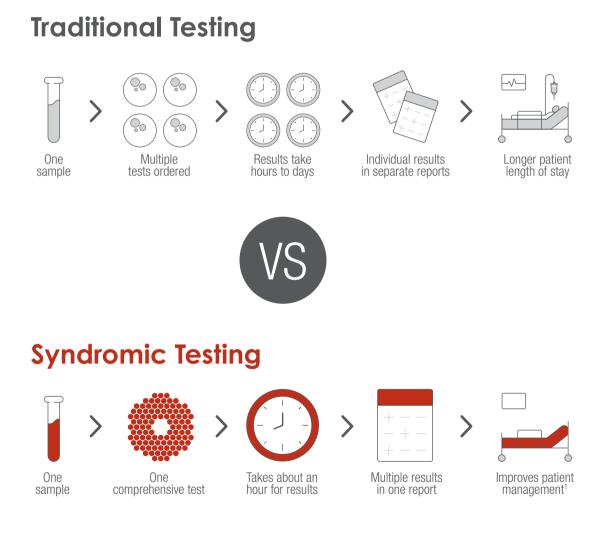
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# Don't Guess. Know.

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.



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



# 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<sup>®</sup> FilmArray<sup>®</sup> 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<sup>®</sup> 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.



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.

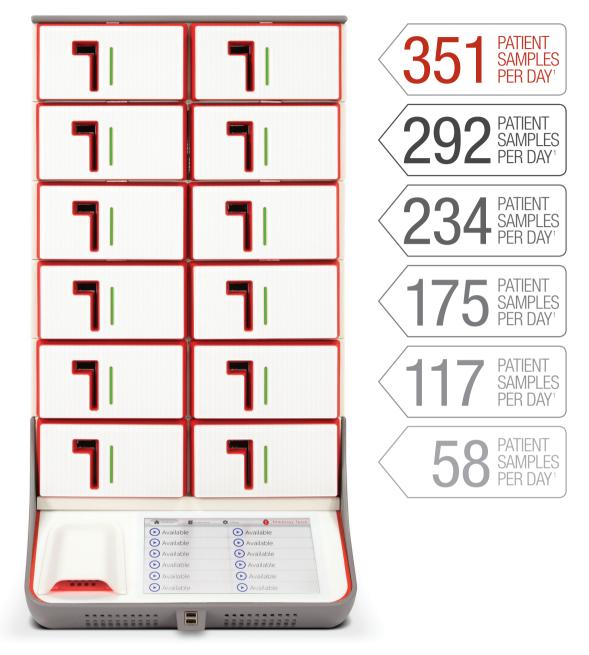


### Comprehensive

Syndromic testing eliminates serial testing that can be frustrating and timeconsuming 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.



# Scalable configuration for customized throughput from 1 to 12 modules.

<sup>1</sup>Calculations based on running the BioFire® Respiratory 2.1 *plus* 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.



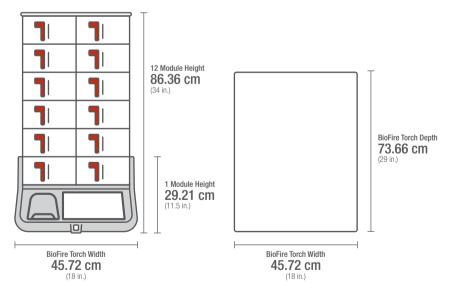
## Connectivity

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.<sup>2</sup>



<sup>2</sup>In 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

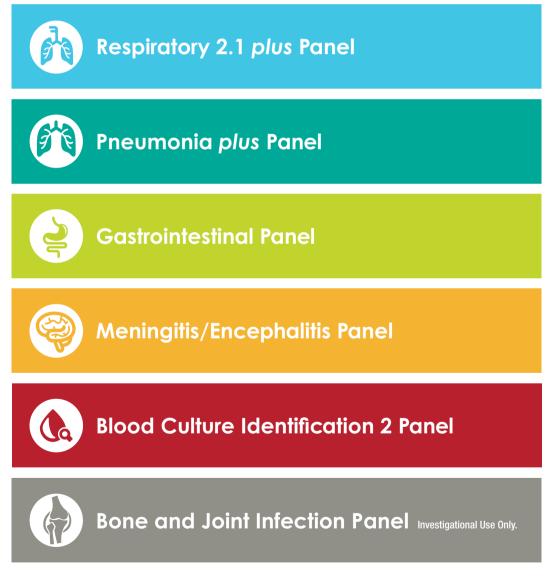
3. Machiels J., et al. Impact of the BioFire FilmArray gastrointestinal panel on patient care and infection control. PLoS One. 2020;15(2):e0228596. Published 2020 Feb 6. doi:10.1371/journal.pone.0228596.

# 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.



Product availability varies by country. Consult your bioMérieux representative.



Sample Type: 0.3 mL of nasopharyngeal swab CE-marked

# 23 Targets in One Test

The BioFire<sup>®</sup> 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<sup>®</sup> 2.0 and the BioFire<sup>®</sup> 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 Bhinovirus/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





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 calcoaceticusbaumannii 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

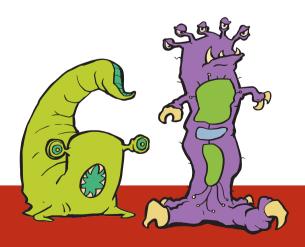
Adenovirus Coronavirus Human Metapneumovirus Human Rhinovirus/Enterovirus Influenza A Middle East Respiratory Syndrome Coronavirus (MERS-CoV) Influenza B Parainfluenza Virus Respiratory Syncytial Virus

#### ANTIMICROBIAL RESISTANCE GENES Carbapenemases

IMP KPC NDM OXA-48-like VIM

ESBL CTX-M

Methicillin Resistance mecA/C and MREJ (MRSA)





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<sup>®</sup> FilmArray<sup>®</sup> 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

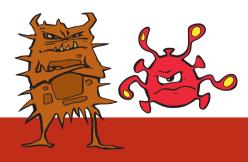
Campylobacter (jejuni, coli, and upsaliensis) Clostridioides (Clostridium) difficile (toxin A/B) Plesiomonas shigelloides Salmonella Vibrio (parahaemolyticus, vulnificus, and cholerae) Vibrio cholerae Yersinia enterocolitica Diarrheagenic E.coli/Shigella Enteroaggregative E.coli (EAEC) Enteropathogenic E.coli (EPEC) Enterotoxigenic E.coli (ETEC) It/st Shiga-like toxin-producing E.coli (STEC) stx1/stx2 E.coli 0157 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: 0.2 mL of uncentrifuged cerebrospinal fluid (CSF) CE-marked and US FDA-cleared

# 14 Targets in One Test

The BioFire<sup>®</sup> FilmArray<sup>®</sup> 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.

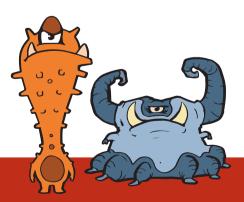
# Panel Menu

#### 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





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

# 43 Targets in One Test

The BioFire<sup>®</sup> 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 calcoaceticusbaumannii 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

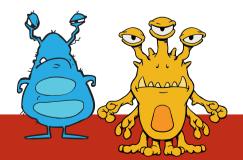
VIM

Colistin Resistance mcr-1

ESBL CTX-M

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

Vancomycin Resistance vanA/B





\*Investigational use only. Not for use in diagnostic procedures.

# **39 Targets in One Test**

The BioFire<sup>®</sup> Bone and Joint Infection (BJI) Panel tests for common causes of prosthetic joint infections, septic arthritis, and other musculoskeletal infections. The BioFire BJI Panel includes assays for 39 targets, including gram-positive bacteria, gram-negative bacteria, yeast, and antibiotic resistance genes. Fast results on a comprehensive menu of targets may help guide quick surgical and therapeutic decision making.

# 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 spp. 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* 

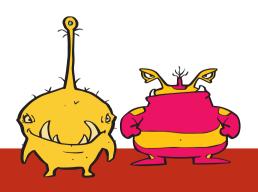
## ANTIMICROBIAL RESISTANCE GENES

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.

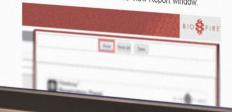
Visit **biofiredx.com** to find Advisory Notices, Information Sheets, Product Support Documents, and other resources.

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Quick Search		Date	Sample ID	Pouch Type	Protocol	Lot Number	Serial Number	Pouch Result	Operator	Instrument	States
Contraction of the second second	80000	12/2/2013 8:22:09 PM	BCID FA1.5	BCID Panel v2.0	8Cv21	136813	00830988	Pass	Daniel Goldga	FA2426	Completed +
Reyword Saach		12/2/2013 8:21:46 PM		8CID Panel v2.0	8C-v21	136813	00831041	Pass	Daniel Goldoa	FA2414	
		12/2/2013 8:21:45 PM	BCID FA1.5	8CID Panel v2.0	BC v2.1	136813	00831052	Pass	Damel Goldga	FA2408	Completed
Starth Separational Clear		12/2/2013 8:21:35 PM	BCID FA1.5	BCID Panel v2.0	8Cv21	136813	00831001	Pass	Daniel Goldga	FA2411	Completed
		12/2/2013 7:40:45 PM	RP FA15	Respiratory Pa.	NPS v20	142013	00948375	Pass			Completed
Advanced Stands		12/2/2013 7:40:32 PM	RP FALS	Respiratory Pa	NP5 v20	142013	00948415	Pass	Daniel Goldga	FLM1007	Completed
Wara Deta is Toley		12/2/2013 7:40:13 PM	89 FA15	Respiratory Pa.	NPS v2.0	142013	00948383	Pass Pass	Daniel Goldga	FA1176	Completed
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Teday		12/2/2013 5:53:33 PM	89 FA15	Respiratory Pa		142013	00948403	Pass	Daniel Goldga	FA1177	Completed
1at 201204	-	12/2/2013 5:53:19 PM	RP FA15	Respiratory Pa.		142013		Pass	Daniel Goldga	FA1248	Completed
Ref 133/27/4	5	12/2/2013 5:52:56 PM	89 FA15	Respiratory Pa.		142013	00948402	Pass	Daniel Goldga	FA1236	Completed
Sargia bis	-	12/2/2013 3:59:29 PM	RP FALS	Respiratory Pa.		142013	00948437	Pass	Daniel Goldga	FA1109	Completed
	b i i	12/2/2013 3:59:18 PM	RP FALS	Respiratory Pa_			00948395	Pass	Daniel Goldga	FA1176	Completed
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Potosi	Þ	12/2/2013 3:58:44 PM	RP FALS		NPS v2.0	142013	00948438	Pass	Daniel Goldga	FA1141	Completed
Pout field		11/20/2013 1:41:38 PM	56894	Smoke v1.0	NoData	142013	00948387	Pass	Daniel Goldoa	FA1236	Completed
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lear		11/19/2013 5:01:50 PM	BCID FA15	BCID Panel v20 BCID Panel v20		136313	00825073	Pass	Daniel Goldga	FA1141	Completed
lag .		11/19/2013 4:58:47 PM	BCID FALS			136313	00825063	Pass		FUM1007	Completed
	1000	11/19/2013 10:56:33 AM	RP FA1.5	BCID Panel v2.0		136313	00825060	Pass	Enk Huynh (eh)		Completed
			BCID FALS	Respiratory Pa.		138713	00864697	Pass		FA1173	Completed
		Constant and and	1	BCID Panel v2.0	8C v2.1	136313	00825071	Pass	Erik Hujinh (eh)	FA1173	Completed

4. Click on the red View Report tab to open the View Report window.

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www.biomerieux.com

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