

BIO  FIRE® FilmArray®





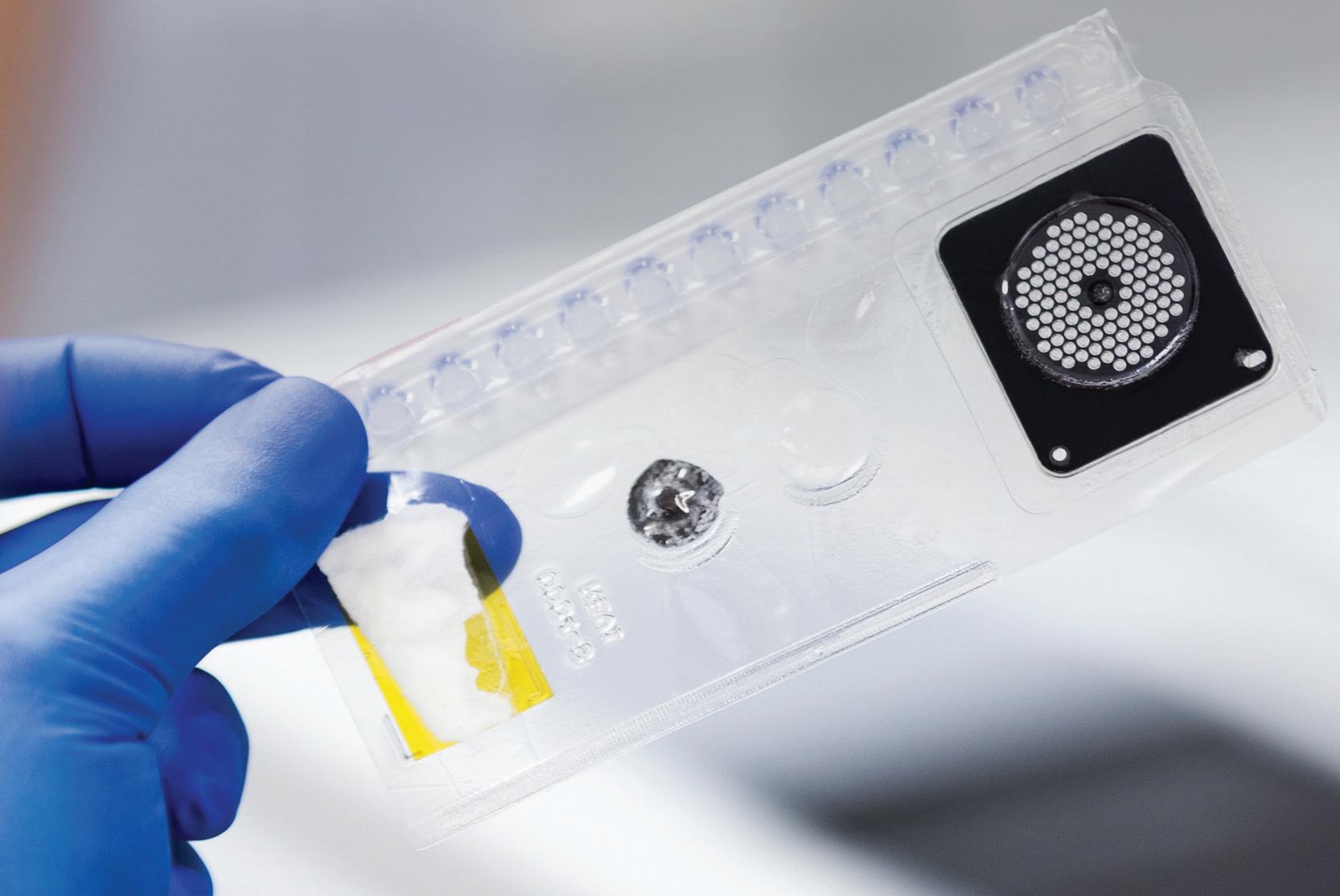


**Syndromic Testing: The Right Test, The First Time.**

Infectious disease diagnostics  
has evolved. BioFire's syndromic  
approach is making the world  
a healthier place.



The industry-leading  
BioFire® FilmArray® System harnesses  
the power of syndromic testing  
and empowers clinicians to choose  
the right test, the first time.



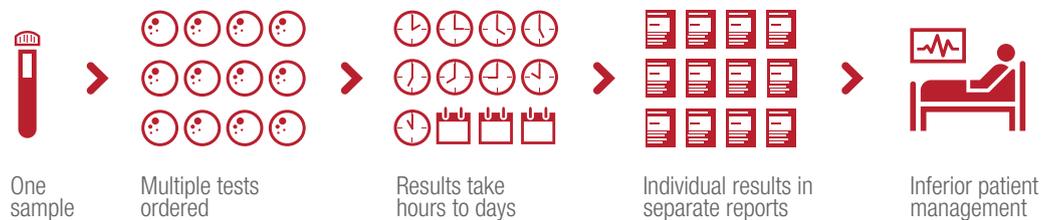
# Don't Guess. Know.

Many infectious diseases present with similar signs and symptoms. Traditional targeted diagnostics limit testing to only the most common pathogens 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, improves patient care, and helps make the world a healthier place.

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

## Traditional Testing



## Syndromic Testing





# The Fastest Way to Better Results.



## Faster Results

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

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## Better Results

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

*"I have extensive experience with the [FilmArray]. I truly believe that [it is] absolutely essential in my clinical practice. The information can assist in antibiotic stewardship and, equally important, in proper isolation of patients in our facilities. It is rapid and accurate."*

### **Ricardo Flores, MD**

Medical Director

PICU Department of Pediatrics at Dignity Health

San Francisco, CA USA

# BioFire's Syndromic Testing Streamlines Laboratory Processes.

BioFire's syndromic infectious disease testing simplifies laboratory processes across the world. It can be used by any technician, on any shift, at any time, providing the same standard of care 24/7 and removing the need to delay or send out samples for additional testing.



## Fast

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

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## Easy

BioFire's syndromic approach is so easy anyone can do it, 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.

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## Comprehensive

Syndromic infectious disease 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 Global Standard for Syndromic Testing: The BioFire® FilmArray® 2.0.

## One Streamlined System With Many Applications

The BioFire 2.0 has set the standard for molecular infectious disease diagnostic testing on a global level. It provides a single database management of up to eight instruments per computer with high throughput and BioFire® FilmArray® Laboratory Information System (LIS) interfacing capability. This enables quicker turnaround times and increased accuracy by minimizing manual data entry.





## High Throughput

The BioFire® FilmArray® 2.0 can test up to 176 samples a day.

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## BioFire® FilmArray® Link Technology

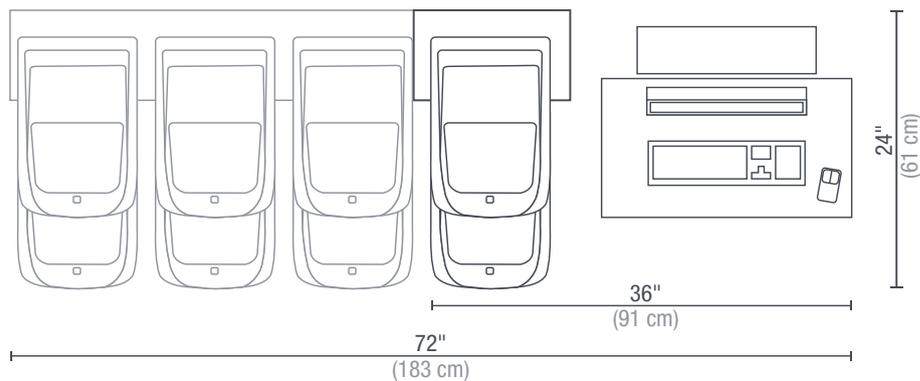
LIS-interfacing capabilities enable quicker turnaround times and increased accuracy by minimizing manual data entry.

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## Scalable Configuration and Random Access

Single database management of up to eight instruments with random access allows you to simultaneously run multiple FDA-cleared and CE-marked panels.



# The Most Advanced Syndromic Testing Platform: The BioFire® FilmArray® Torch.

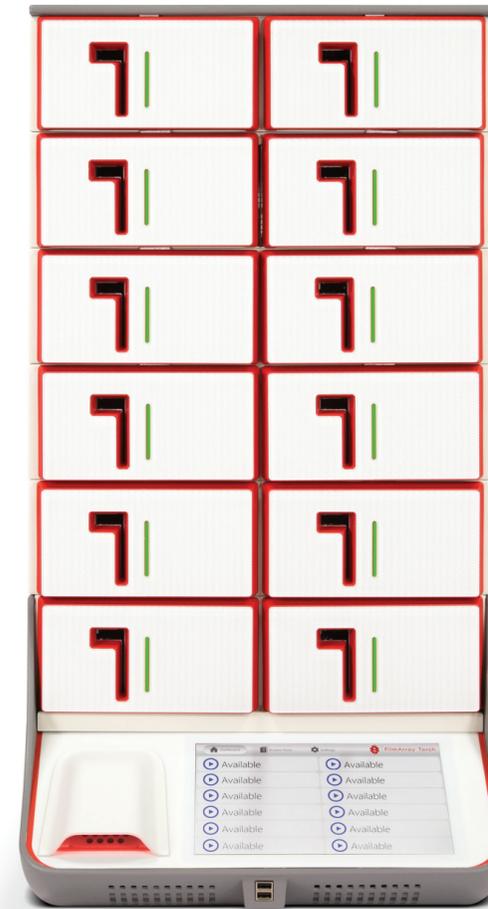
## The Most Advanced Testing Solution Yet

BioFire Torch is the latest advancement in molecular infectious disease diagnostics.

The high-throughput BioFire Torch is a fully integrated, random access system designed to meet every laboratory's infectious disease testing needs. The BioFire Torch is compatible with all CLIA-moderate BioFire® FilmArray® Panels, providing the quick, comprehensive, and accurate results expected from the most advanced testing solution.

*"The FilmArray is fast. Very fast. And that is what physicians want in a children's hospital."*

**Christy Stamper**  
Technician  
Dayton Children's Hospital  
Dayton, OH USA



### Scalable Configuration for Customized Throughput



#### 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.



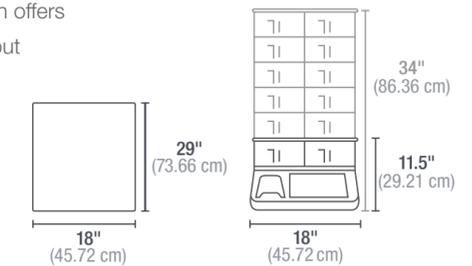
#### Connectivity

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® FilmArray® Torch offers up to **six times** the throughput per square foot of laboratory bench space.<sup>2</sup>



<sup>1</sup>Based on a 24-hour day.  
<sup>2</sup>In comparison to existing BioFire® FilmArray® Systems.



## Fast Answers With the BioFire® FilmArray® 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 five FDA-cleared and CE-marked BioFire Panels test for viruses, bacteria, parasites, yeast, and antimicrobial resistance genes.

-  **Respiratory Panels**
-  **Blood Culture Identification Panel**
-  **Gastrointestinal Panel**
-  **Meningitis/Encephalitis Panel**
-  **Pneumonia Panel**



**BioFire® FilmArray® Respiratory Panels**  
 Sample Type: Nasopharyngeal Swab FDA-cleared and CE-marked

### The BioFire® FilmArray® Respiratory Panel (RP) 20 Targets in One Test

The BioFire RP tests for a comprehensive set of 20 respiratory viral and bacterial pathogens in about an hour. The BioFire RP identifies the most common viral and bacterial pathogens that cause respiratory tract infections that present with nearly indistinguishable symptoms. The rapid and accurate identification of the probable causative agents helps inform how a healthcare provider chooses to treat a respiratory tract infection.

### The BioFire® FilmArray® Respiratory Panel 2 (RP2) 21 Targets in One Test

The BioFire RP2 is faster, more accurate, and more comprehensive than ever. An unprecedented run time of about 45 minutes enables higher efficiency and throughput on the BioFire® FilmArray® 2.0 and the BioFire® FilmArray® 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 that the BioFire RP2 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  
 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*

\*Available only on the BioFire RP2





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# Blood Culture Identification Panel

Sample Type: Positive Blood Culture    FDA-cleared and CE-marked

## 27 Targets in One Test

The BioFire BCID Panel tests for a comprehensive set of 24 gram-positive, gram-negative, and yeast pathogens, and three antibiotic resistance genes associated with bloodstream infections. The BioFire BCID Panel detects and identifies the most common causes of bloodstream infections. Quickly identifying the probable cause of sepsis may help clinicians reduce the time to appropriate antimicrobial therapy and positively impact patient survival.

## Panel Menu

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### GRAM-POSITIVE BACTERIA

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

### GRAM-NEGATIVE BACTERIA

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

### YEAST

*Candida albicans*  
*Candida glabrata*  
*Candida krusei*  
*Candida parapsilosis*  
*Candida tropicalis*

### ANTIMICROBIAL RESISTANCE GENES

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





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# Gastrointestinal Panel

Sample Type: Stool in Cary Blair FDA-cleared and CE-marked

## 22 Targets in One Test

The BioFire GI Panel tests for a comprehensive set of 22 gastrointestinal pathogens. The BioFire GI Panel tests stool in Cary Blair for common pathogens 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

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### BACTERIA

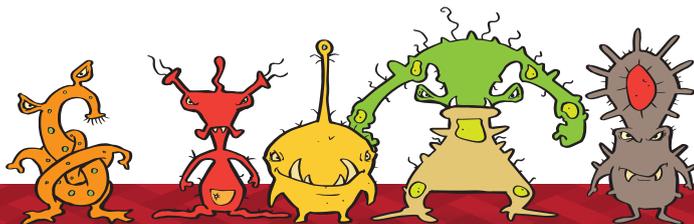
*Campylobacter (jejuni, coli, and upsaliensis)*  
*Clostridium difficile* (toxin A/B)  
*Plesiomonas shigelloides*  
*Salmonella*  
*Vibrio (parahaemolyticus, vulnificus, and cholerae)*  
*Vibrio cholerae*  
*Yersinia enterocolitica*  
**Diarrheagenic E.coli/Shigella:**  
Enteraggregative *E.coli* (EAEC)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





BioFire® FilmArray®

# Meningitis/Encephalitis Panel

Sample Type: Cerebrospinal Fluid (CSF) FDA-cleared and CE-marked

## 14 Targets in One Test

The BioFire ME Panel tests for a comprehensive set of 14 bacteria, viruses, and yeast. The BioFire 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

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### BACTERIA

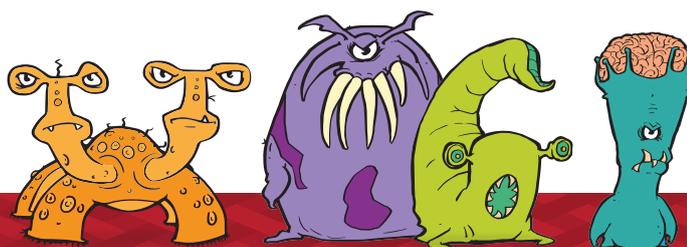
*Escherichia coli* K1  
*Haemophilus influenzae*  
*Listeria monocytogenes*  
*Neisseria meningitidis*  
*Streptococcus agalactiae*  
*Streptococcus pneumoniae*

### VIRUSES

Cytomegalovirus (CMV)  
Enterovirus  
Herpes Simplex Virus 1 (HSV-1)  
Herpes Simplex Virus 2 (HSV-2)  
Human Herpesvirus 6 (HHV-6)  
Human Parechovirus  
Varicella Zoster Virus (VZV)

### YEAST

*Cryptococcus neoformans/gattii*





**BioFire® FilmArray®  
Pneumonia Panel**

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

### 33 Targets in One Test

The BioFire Pneumonia Panel tests for a comprehensive set of 26 pathogens and 7 antibiotic resistance markers. The BioFire Pneumonia Panel identifies the most common bacterial and viral pathogens associated with various types of community/hospital-acquired pneumonia. Quickly identifying the probable causative agent enables the healthcare provider to make more effective and informed treatment decisions.

### 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
- Influenza B
- Parainfluenza Virus
- Respiratory Syncytial Virus

#### ANTIMICROBIAL RESISTANCE GENES

##### Methicillin Resistance

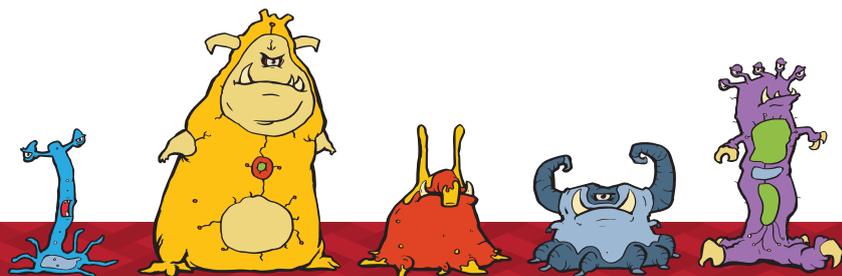
- mecA/C* and MREJ

##### Carbapenemases

- IMP
- KPC
- NDM
- OXA-48-like
- VIM

##### ESBL

- CTX-M



# First in Diagnostics. First in Customer Care.

BioFire Diagnostics 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.



## Customer Technical Support

For BioFire technical assistance and support:

**+1 801-736-6354**

**Toll Free: +1 800-735-6544**

**[biofiredx.com/support](https://biofiredx.com/support)**

**[support@biofiredx.com](mailto:support@biofiredx.com)**

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## International Support

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

**[biomerieux.com/en/customer-service](https://biomerieux.com/en/customer-service)**

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## Help at Your Fingertips

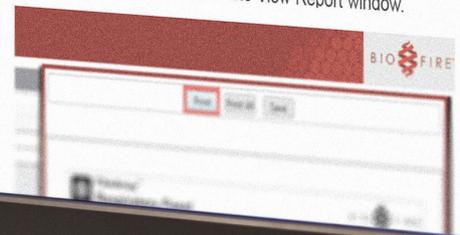
With a complete suite of resources, our customers have access to everything they need for set-up, verification, and integration of the BioFire® FilmArray® System. Our website provides documents to assist with verification, EC Declarations of Conformity, and continuing education for all customers.

Visit **[biofiredx.com](https://biofiredx.com)** to find Advisory Notices, Information Sheets, Product Support Documents, and other resources.



Date	Sample ID	Pouch Type	Protocol	Lot Number	Serial Number	Pouch Result	Operator	Instrument	Status
12/2/2013 8:22:09 PM	BC1D FALLS	BC1D Panel v2.0	BC v2.1	136313	00870565	Pass	Daniel Golog...	FA2426	Completed
12/2/2013 8:21:46 PM	BC1D FALLS	BC1D Panel v2.0	BC v2.1	136313	00870564	Pass	Daniel Golog...	FA2424	Completed
12/2/2013 8:21:45 PM	BC1D FALLS	BC1D Panel v2.0	BC v2.1	136313	00871262	Pass	Daniel Golog...	FA2408	Completed
12/2/2013 8:21:35 PM	BC1D FALLS	BC1D Panel v2.0	BC v2.1	136313	00871261	Pass	Daniel Golog...	FA2411	Completed
12/2/2013 7:40:45 PM	RP FALLS	Respiratory Pa...	NPS v2.0	142013	00948379	Pass	Daniel Golog...	FLM7007	Completed
12/2/2013 7:40:32 PM	RP FALLS	Respiratory Pa...	NPS v2.0	142013	00948416	Pass	Daniel Golog...	FA1176	Completed
12/2/2013 7:40:07 PM	RP FALLS	Respiratory Pa...	NPS v2.0	142013	00948382	Pass	Daniel Golog...	FA2427	Completed
12/2/2013 5:53:47 PM	RP FALLS	Respiratory Pa...	NPS v2.0	142013	00948368	Pass	Daniel Golog...	FA1171	Completed
12/2/2013 5:53:33 PM	RP FALLS	Respiratory Pa...	NPS v2.0	142013	00948403	Pass	Daniel Golog...	FA1177	Completed
12/2/2013 5:53:19 PM	RP FALLS	Respiratory Pa...	NPS v2.0	142013	00948402	Pass	Daniel Golog...	FA1248	Completed
12/2/2013 5:52:56 PM	RP FALLS	Respiratory Pa...	NPS v2.0	142013	00948437	Pass	Daniel Golog...	FA1236	Completed
12/2/2013 3:59:29 PM	RP FALLS	Respiratory Pa...	NPS v2.0	142013	00948395	Pass	Daniel Golog...	FA1109	Completed
12/2/2013 3:59:18 PM	RP FALLS	Respiratory Pa...	NPS v2.0	142013	00948389	Pass	Daniel Golog...	FA1176	Completed
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12/2/2013 3:58:44 PM	RP FALLS	Respiratory Pa...	NPS v2.0	142013	00948387	Pass	Daniel Golog...	FA1241	Completed
11/20/2013 1:41:38 PM	SMOKE	Smoke v1.0	NoData	13564	85643	Fail	Jamber Boehm...	FA1236	Completed
11/20/2013 1:38:53 PM	SMOKE	Smoke v1.0	ProtocolFLM	46952	11645	Fail	Jamber Boehm...	45N	Completed
11/20/2013 1:38:46 PM	SMOKE	Smoke v1.0	NoData	12345	35791	Fail	Jamber Boehm...	35N	Completed
11/19/2013 5:03:46 PM	BC1D FALLS	BC1D Panel v2.0	BC v2.1	136313	00872029	Pass	Daniel Golog...	FA2022	Completed
11/19/2013 5:02:32 PM	BC1D FALLS	BC1D Panel v2.0	BC v2.1	136313	00872073	Pass	Daniel Golog...	FA1141	Completed
11/19/2013 5:02:50 PM	BC1D FALLS	BC1D Panel v2.0	BC v2.1	136313	00872063	Pass	Daniel Golog...	FLM7007	Completed
11/19/2013 4:58:47 PM	BC1D FALLS	BC1D Panel v2.0	BC v2.1	136313	00872000	Pass	Eric Haysht (eh)	FA1173	Completed
11/19/2013 4:56:53 AM	RP FALLS	Respiratory Pa...	NPS v2.0	138713	00864697	Pass	Eric Haysht (eh)	FA1173	Completed
11/18/2013 4:00:05 PM	BC1D FALLS	BC1D Panel v2.0	BC v2.1	136313	00872071	Pass	Eric Haysht (eh)	FA1130	Completed

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





## About BioFire Diagnostics

BioFire Diagnostics impacts the way molecular diagnostics are performed all over the world. We simplify our customers' lives with innovative, easy-to-use solutions that provide fast and accurate results. With our easy tests, laboratories across the globe detect and identify infectious agents, making the world a healthier place.







A BIOMÉRIEUX COMPANY

**[biofiredx.com](http://biofiredx.com)**

**BioFire Diagnostics, LLC**

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