

BIO  FIRE® | FilmArray®





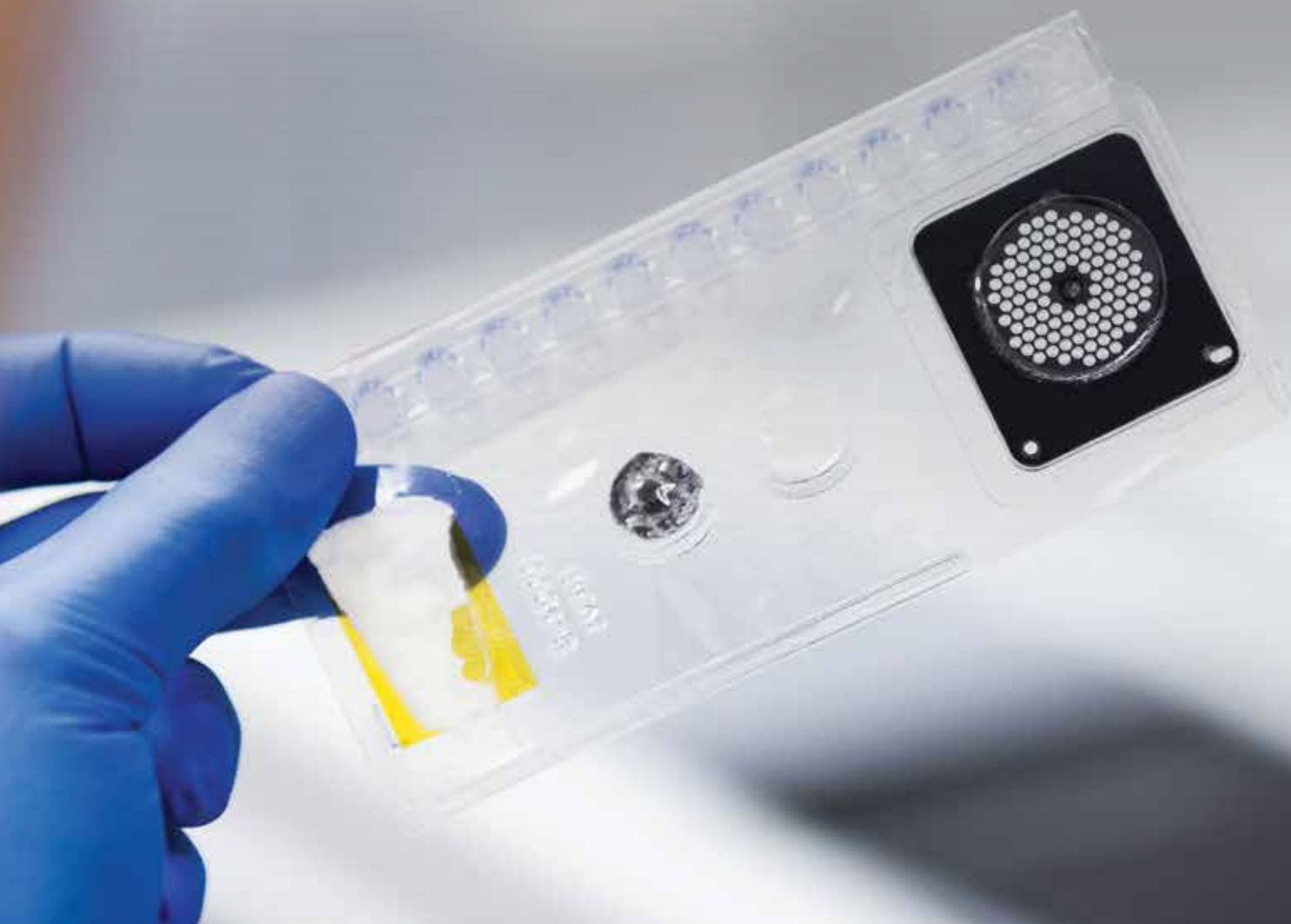
A BIOMÉRIEUX COMPANY

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



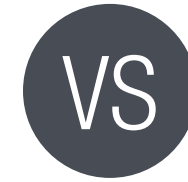
Don't guess. Know.

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 lead to additional downstream testing, patient dissatisfaction and compromised patient care.

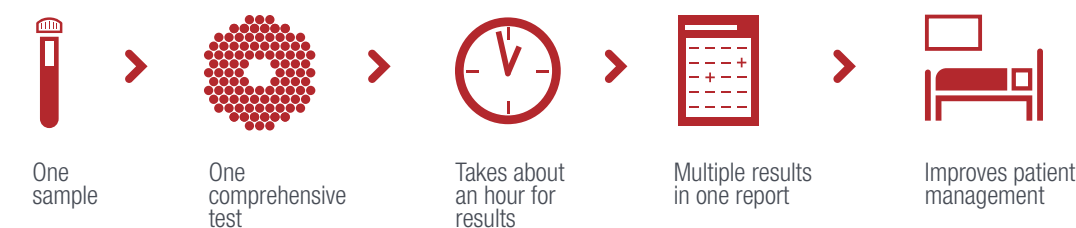
BioFire's syndromic approach to infectious disease diagnostics helps quickly identify actual causative agents, greatly reduces the guesswork in diagnostics, increases patient satisfaction, improves patient care and helps make the world a healthier place.

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 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 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 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 testing enables laboratories to provide answers to physicians in a clinically actionable time frame.



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.



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 global standard for syndromic testing, the FilmArray® 2.0.

One streamlined system with many applications

FilmArray 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 Laboratory Information System (LIS) interfacing capability which enables quicker turnaround times and increased accuracy by minimizing manual data entry.



High Throughput

FilmArray® 2.0 can test up to 175 samples a day.



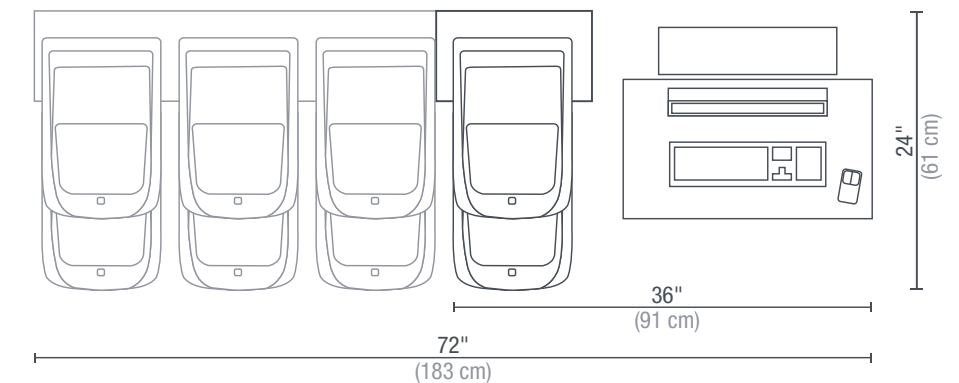
FilmArray Link Technology

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



Scalable Configuration and Random Access

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



The most advanced syndromic testing platform, the FilmArray® Torch.

The most advanced testing solution yet

FilmArray Torch is the latest advancement in molecular infectious disease diagnostics. The high throughput FilmArray Torch is a fully integrated, random access system designed to meet every laboratory's infectious disease testing needs. The FilmArray Torch is compatible with all existing 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

"It's hard to imagine any other system that can do 20 results in an hour with just a few minutes of hands-on time."

Ray Widen, PhD
Scientific Director
Tampa General Hospital
Tampa, FL USA



Scalable configuration for customized throughput

264 PATIENT SAMPLES PER DAY*

220 PATIENT SAMPLES PER DAY*

176 PATIENT SAMPLES PER DAY*

132 PATIENT SAMPLES PER DAY*

88 PATIENT SAMPLES PER DAY*

44 PATIENT SAMPLES PER 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.



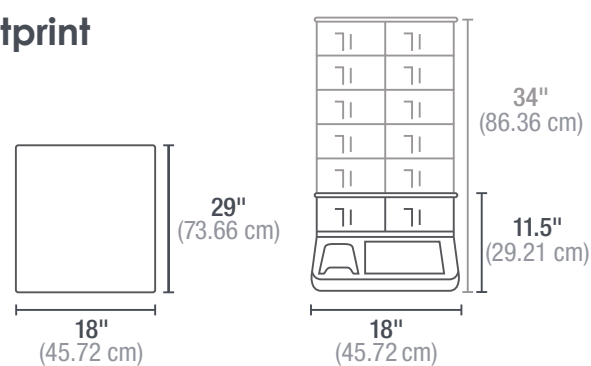
Connectivity

Makes data management automated and efficient through FilmArray link technology that can seamlessly integrate into Laboratory Information System (LIS).



Radically Reduced Footprint

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



¹ Based on a 24-hour day.

² In comparison to existing FilmArray® Systems.



Appropriate therapy and fast answers with the FilmArray® Panels.

Comprehensive panels offer better diagnostics

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

The four FDA-cleared and CE-IVD marked FilmArray Panels test for viruses, bacteria, parasites, yeast and antimicrobial resistance genes.



Respiratory Panel



Blood Culture Identification Panel



Gastrointestinal Panel



Meningitis/Encephalitis Panel



Lower Respiratory Tract Infection Panel
Currently In Development



Respiratory Panel

Sample Type: Nasopharyngeal Swab FDA-cleared and CE-IVD Marked

20 targets in one test

The FilmArray® Respiratory Panel (RP) tests for a comprehensive set of 20 respiratory viral and bacterial pathogens in about an hour. The FilmArray 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 determine how a healthcare provider chooses to treat a respiratory tract infection.

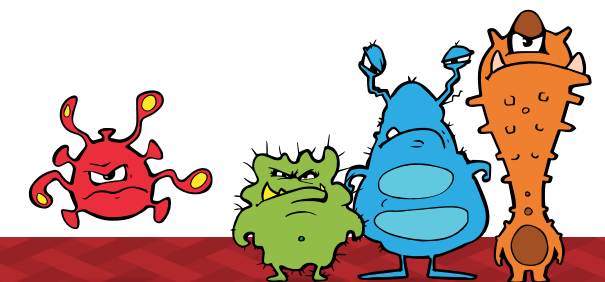
Respiratory Panel Menu

Viruses:

- Adenovirus
- Coronavirus HKU1
- Coronavirus NL63
- Coronavirus 229E
- Coronavirus OC43
- 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*
- Chlamydomphila pneumoniae*
- Mycoplasma pneumoniae*





Blood Culture Identification Panel

Sample Type: Positive Blood Culture

FDA-cleared and CE-IVD Marked

27 targets in one test

The FilmArray® Blood Culture Identification (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 FilmArray 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.

BCID Panel Menu

Gram-Negative Bacteria:

- Acinetobacter baumannii*
- Haemophilus influenzae*
- Neisseria meningitidis*
- Pseudomonas aeruginosa*

Enterobacteriaceae

- Enterobacter cloacae* complex
- Escherichia coli*
- Klebsiella oxytoca*
- Klebsiella pneumoniae*
- Proteus*
- Serratia marcescens*

Antimicrobial Resistance Genes:

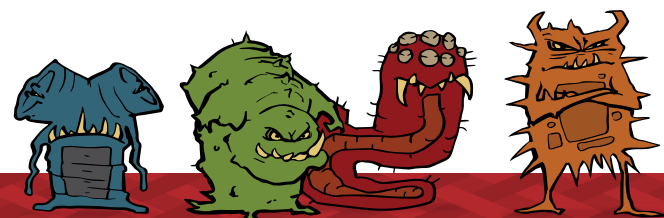
- mecA* – methicillin resistance
- vanA/B* – vancomycin resistance
- KPC – carbapenem resistance

Gram-Positive Bacteria:

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

Yeast:

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



Gastrointestinal Panel

Sample Type: Stool in Cary Blair

FDA-cleared and CE-IVD Marked

22 targets in one test

The FilmArray® Gastrointestinal (GI) Panel tests for a comprehensive set of 22 gastrointestinal pathogens. The FilmArray 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.

GI Panel Menu

Bacteria:

- Campylobacter (jejuni, coli and upsaliensis)*
- Clostridium difficile* (toxin A/B)
- Plesiomonas shigelloides*
- Salmonella*
- Yersinia enterocolitica*
- Vibrio (parahaemolyticus, vulnificus and cholerae)*
- Vibrio cholerae*

Viruses:

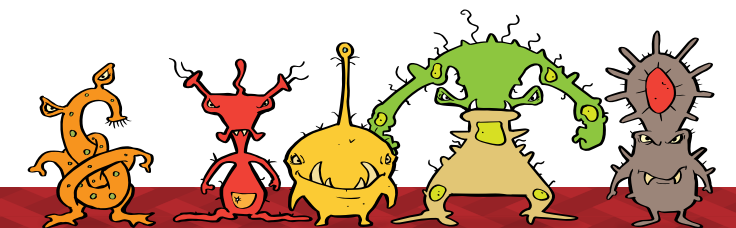
- Adenovirus F40/41
- Astrovirus
- Norovirus GI/GII
- Rotavirus A
- Sapovirus (I, II, IV and V)

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)

Parasites:

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





Meningitis/Encephalitis Panel

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

14 targets in one test

The FilmArray® Meningitis/Encephalitis (ME) Panel tests for a comprehensive set of 14 bacteria, viruses and yeast. The FilmArray ME Panel identifies the most common viral, bacterial 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.

ME Panel Menu

Bacteria:

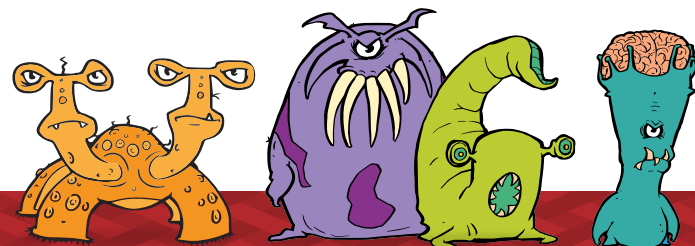
- Escherichia coli K1*
- Haemophilus influenzae*
- Listeria monocytogenes*
- Neisseria meningitidis*
- Streptococcus agalactiae*
- Streptococcus pneumoniae*

Yeast:

- Cryptococcus neoformans/gattii*

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)



Lower Respiratory Tract Infection Panel

Sample Type: TBD

Currently In Development

37 targets in one test

The FilmArray® Lower Respiratory Tract Infection (LRTI) Panel will test for a comprehensive set of 30 pathogens and 7 antibiotic resistance markers. The FilmArray LRTI Panel will identify the most common bacterial, viral and fungal pathogens associated with various types of community/hospital-acquired pneumonia. Quickly identifying the probable causative agent helps determine how a healthcare provider chooses to treat a lower respiratory tract infection.

LRTI Panel Menu

Quantitative Bacteria:

- Acinetobacter calcoaceticus-baumannii complex*
- Enterobacter aerogenes/cloacae complex*
- Escherichia coli*
- Haemophilus influenzae*
- Klebsiella oxytoca*
- Klebsiella pneumoniae group*
- Moraxella catarrhalis*
- Proteus spp.*
- Pseudomonas aeruginosa*
- Serratia marcescens*
- Staphylococcus aureus*
- Streptococcus agalactiae*
- Streptococcus pneumoniae*
- Streptococcus pyogenes*

Fungi:

- Cryptococcus neoformans/gattii*
- Pneumocystis jirovecii*

Viruses:

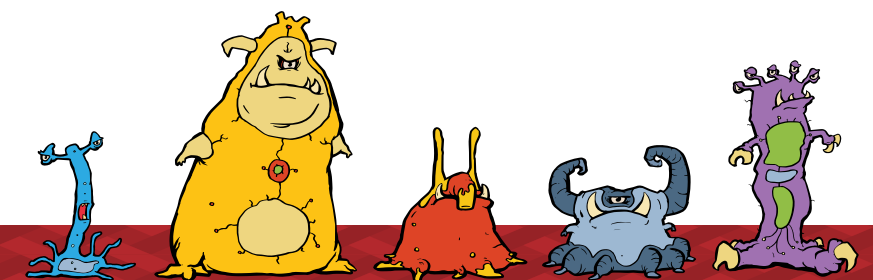
- Adenovirus
- Coronavirus
- Human Metapneumovirus
- Human Rhinovirus/Enterovirus
- Influenza A
- Influenza B
- MERS Coronavirus
- Parainfluenza Virus
- Respiratory Syncytial Virus

Qualitative Bacteria:

- Chlamydia pneumoniae*
- Cryptococcus pneumophila*
- Mycoplasma pneumoniae*

Antibiotic Resistance Markers:

- bla_{CTX-M}*
- bla_{IMP}*
- bla_{KPC}*
- bla_{NDM}*
- bla_{OXA-48-like}*
- bla_{VIM}*
- mecA/mecC* and MREJ



First in Diagnostics. First in Customer Care.

BioFire Diagnostics has a skilled team dedicated to your 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.



U.S. Support

For FilmArray technical assistance and support:

+1-801-736-6354

Toll Free: 1-800-735-6544

BioFireDX.com/support

support@BioFireDX.com



International Support

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

biomerieux.com/en/customer-service

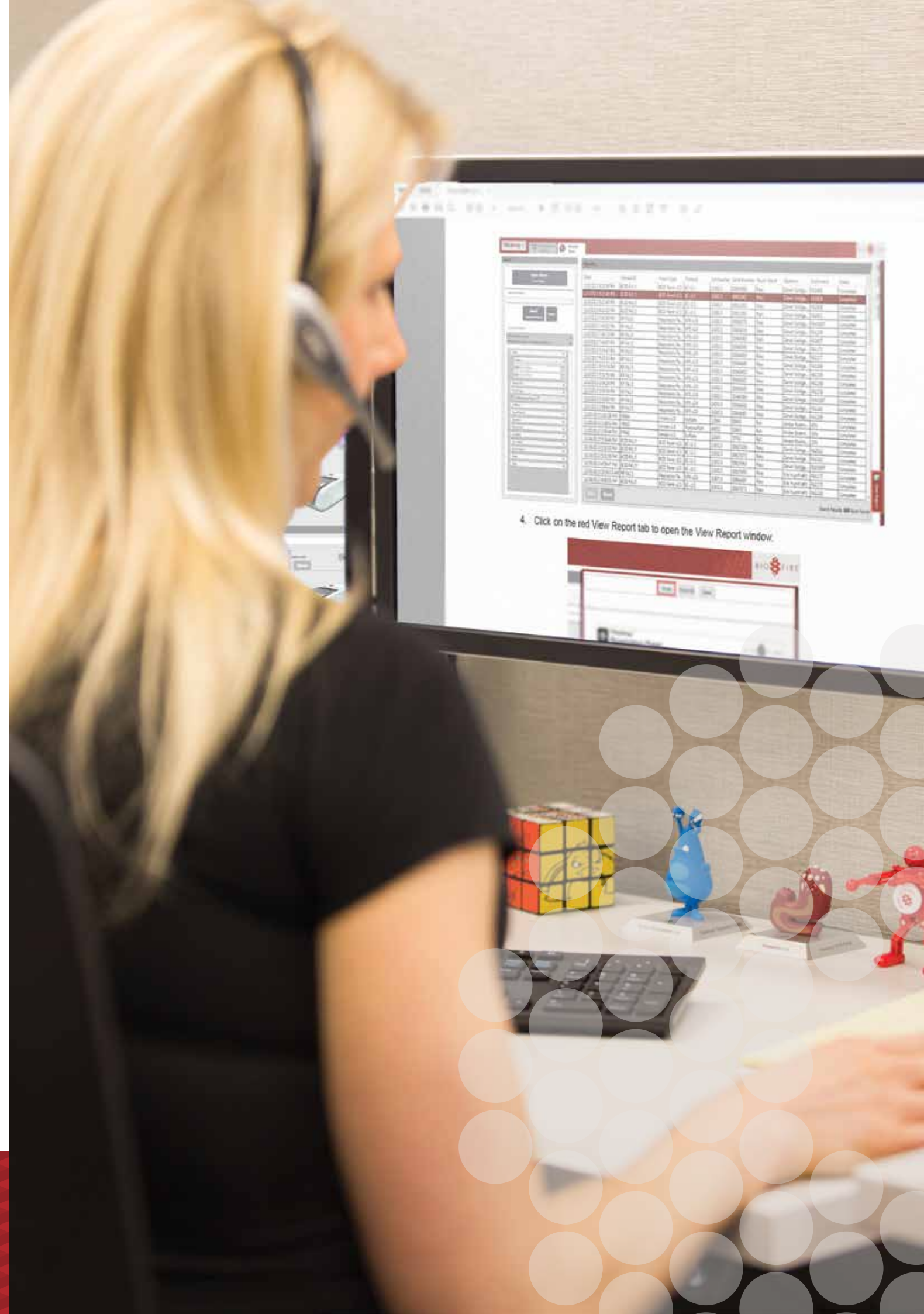


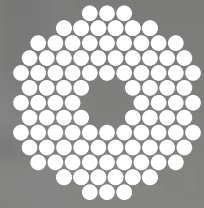
Help at Your Fingertips

With a complete suite of resources, our customers have access to everything they need for set-up, verification and integration of the 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:

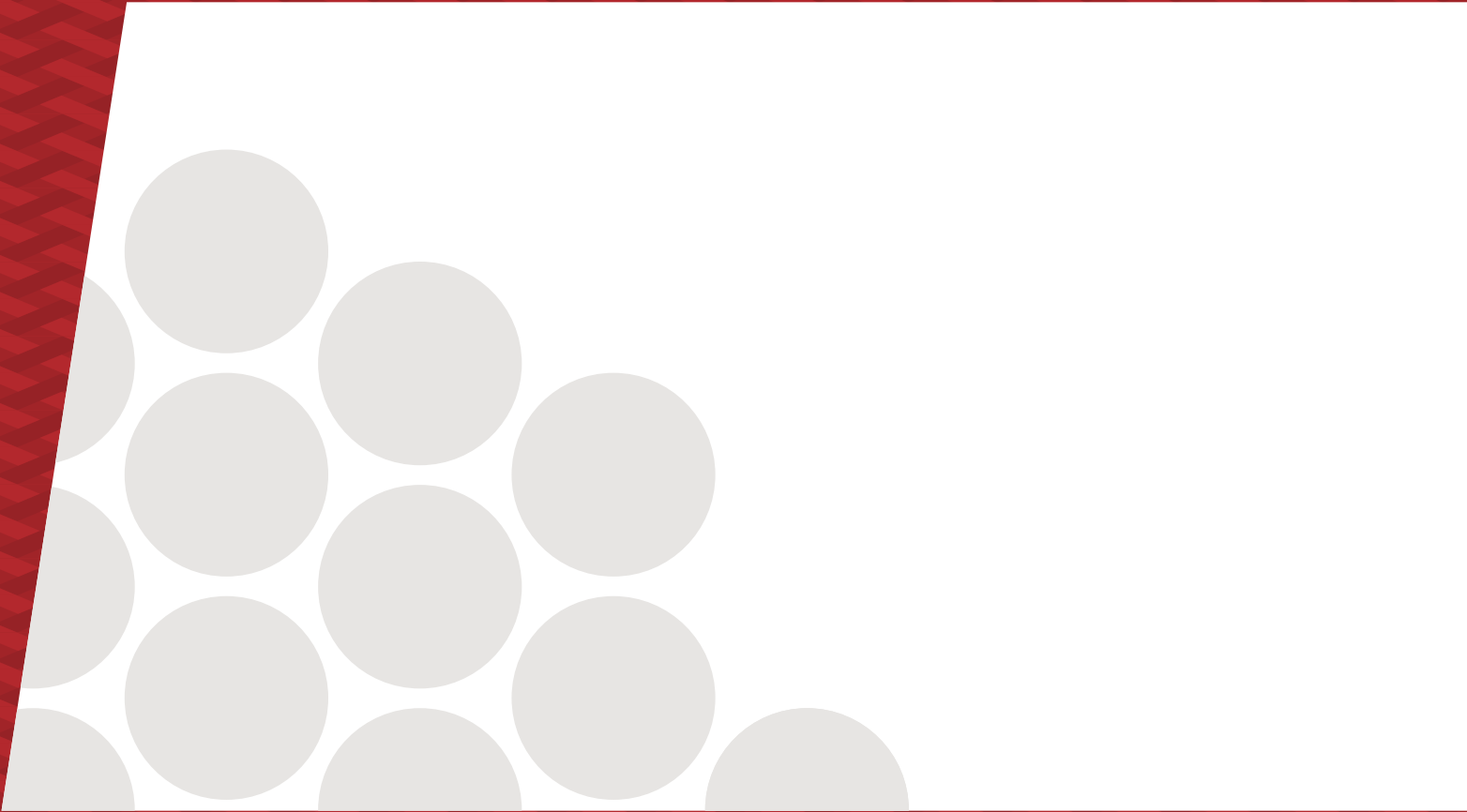
- Advisory Notices
- Information Sheets
- Product Support Documents
- And more





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.





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BioFireDX.com

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