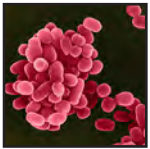
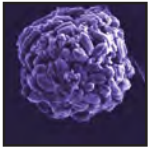
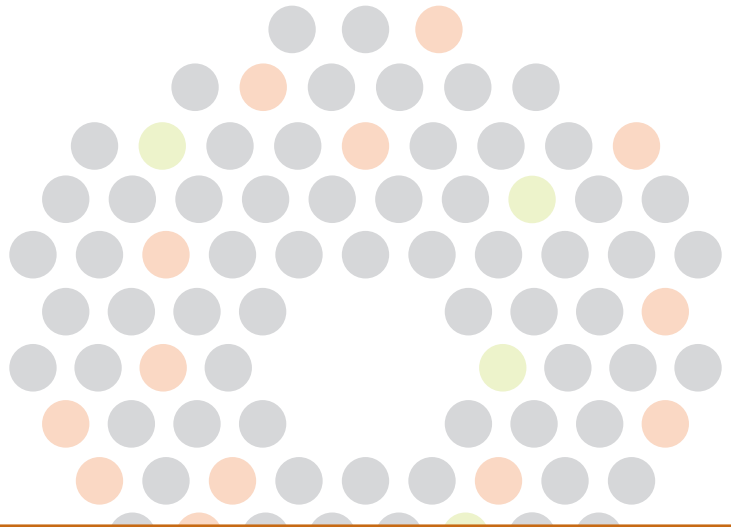




1 Test. 16 BioThreat Pathogens/26 Targets. All in about an hour.



- *Bacillus anthracis*, 3 Targets
- *Brucella* species, 2 Targets
- *Burkholderia mallei / pseudomallei*
- Botulinum toxin gene
- *Coxiella burnetii*, 2 Targets
- Ebola virus
- EEE virus
- *Francisella tularensis*, 2 Targets
- Marburg virus, 2 Targets
- Ricin toxin gene
- *Rickettsia*, 2 Targets
- Variola virus
- VEE virus, 2 Targets
- WEE virus
- *Yersinia pestis*, 2 Targets
- Orthopox genus viruses, 2 Targets



26
Targets

Comprehensive BioThreat Detection

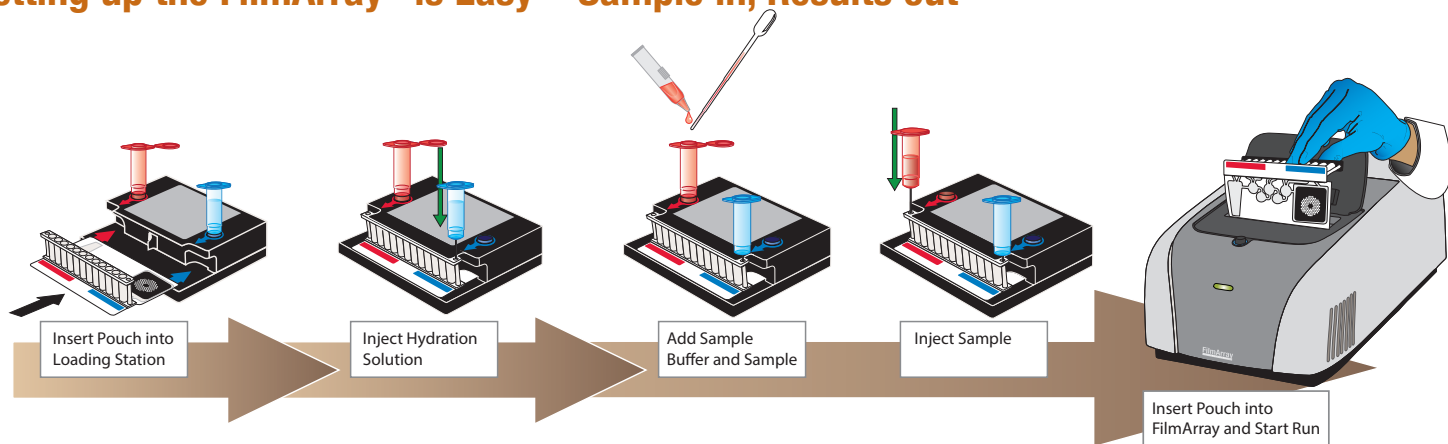
- **Multi-Use:** Used for BioThreat Detection and Pandemic BioSurveillance.
- **Easy-to-Use:** 2 minutes of hands-on time.
- **Fully Automated:** Sample prep, amplification, identification, and reporting.
- **Single Instrument Integration:** Minimal equipment and consumables.
- **Freeze-dried Reagents:** Room temperature stable.
- **More Sample Types:** Integrated sample prep removes PCR inhibitors and allows BioThreat detection in challenging environmental sample types.



If you are interested in a free, no obligation demonstration of the FilmArray in your lab visit www.BioFireDefense.com or call 1-801-266-3592

**FREE
Demo!**

Setting up the FilmArray® is Easy – Sample in, Results out



Fully Automated Operation

The FilmArray pouch contains all the required reagents for sample preparation, reverse transcription-PCR, PCR, and detection in a freeze-dried, room temperature stable format. Prior to a run, the operator injects hydration solution and the unknown sample into the pouch. The FilmArray instrument does the rest.

First, the FilmArray extracts and purifies all nucleic acids from the unknown sample. Next, the FilmArray performs a nested multiplex PCR. During the first-stage PCR, the FilmArray performs a single, large volume, massively multiplexed reaction. Last, individual singleplex second-stage PCR reactions detect the products from the first stage PCR.

Using endpoint melting curve data, the FilmArray software automatically generates a result for each target.

FilmArray® BioThreat Panel		BIO FIRE	
www.BioFireDx.com			
Run Summary			
Sample ID: BT Ver DFL/PBS test concentration	Run Date: 11 Dec 2012 2:28 PM		
Detected: <i>Bacillus anthracis</i> <i>Brucella melitensis</i>	Controls: Passed		
Equivocal: None			
Result Summary			
✓ Detected	<i>Bacillus anthracis</i>		
✓ Detected	<i>Brucella melitensis</i>		
Not Detected	<i>Burkholderia mallei/pseudomallei</i>		
Not Detected	<i>Clostridium botulinum</i>		
Not Detected	<i>Coxiella burnetii</i>		
Not Detected	<i>Francisella tularensis</i>		
Not Detected	<i>Ricinus communis</i>		
Not Detected	<i>Rickettsia prowazekii</i>		
Not Detected	<i>Yersinia pestis</i>		
Not Detected	Ebola Zaire		
Not Detected	Marburg virus		
Not Detected	Orthopox genus virus		
Not Detected	Variola virus		
Not Detected	EEE virus		
Not Detected	VEE virus		
Not Detected	WEE virus		
Run Details			
Pouch: BioThreat Panel v2.4	Protocol: BT PBS v2.0		
Run Status: Completed	Operator: Garrison Alger (garrison)		
Serial No.: 00257302	Instrument: ITI FA "FA1113"		
Lot No.: 120730B			

Ordering Information

Catalog No.	Description
FLM1-ASY-0108	FilmArray BioSurveillance System – US Config.
FLM1-ASY-0109	FilmArray BioSurveillance System – EURO Config.
FLM1-ASY-0110	FilmArray BioSurveillance System – UK Config.
FLM1-ASY-0111	FilmArray BioSurveillance System – AUS Config.
RFIT-ASY-0094	BioThreat Pouch Kit

*Contact us about our FDA cleared panels

System Specifications

Sample Handling

- Sample Types: Swab, liquid, culture, powder
- Sample Volume: 250 µL

Reagents

- Freeze-dried in durable plastic pouches
- Room temperature storage

Instrument Specifications

- Weight: 9 kg (20 lbs)
- Size: 25.4 x 39.3 x 16.5 cm (10 x 15.5 x 6.5 in.)

Power Requirements

- 90-264 VAC, 10 A

Performance Parameters

- Hands on time: Approx. 2 minutes
- Run turn-around time: Approx. 1 hour

Environmental Specification

- Operating: 15 °C to 30 °C at 20 to 80% humidity
- Storage: -30 °C to 65 °C

Desktop Software (Pre-loaded on supplied laptop)

- Windows-based instrument control and data analysis software
- Barcode reader for data input
- Automated qualitative analysis and reporting
- Separate advanced analysis software

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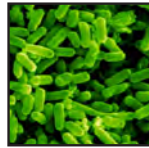
FilmArray Blood Culture Identification Panel

1 Test. 27 Targets. All in about an hour.



Gram-Positive Bacteria

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



Gram-Negative Bacteria

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



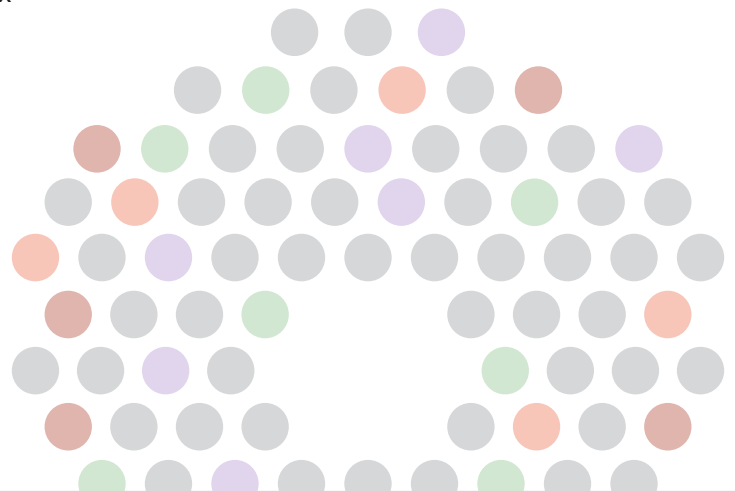
Yeast

Candida albicans
Candida glabrata
Candida krusei
Candida parapsilosis
Candida tropicalis



Antibiotic Resistance Genes

mecA - methicillin resistant
vanA/B - vancomycin resistant
KPC - carbapenem resistant



1
Hour

Identify Pathogens from Positive Blood Cultures in About 1 Hour

For In-vitro Diagnostic Use
FDA Cleared | CE IVD Marked

The FilmArray Blood Culture Identification Panel (BCID) tests for a comprehensive list of 24 pathogens and 3 antibiotic resistance genes associated with bloodstream infections. With just one test you can identify pathogens in 9 out of 10 positive blood cultures in about an hour with only 2 minutes of hands-on time.

- **Simple:** 2 minutes of hands-on time
- **Easy:** No precise measuring or pipetting required
- **Fast:** Turnaround time of about 1 hour
- **Comprehensive:** 27 target BCID panel



If you are interested in a free, no obligation demonstration of the FilmArray in your laboratory visit www.biofiredx.com or call 1-800-735-6544.

FREE Demo!



Panel Specifications

Sample Handling	Performance Parameters
<ul style="list-style-type: none"> Sample Type: Positive Blood Culture Sample Volume: 200 µL 	<ul style="list-style-type: none"> Hands-on time: 2 minutes Run turnaround time: about 1 hour

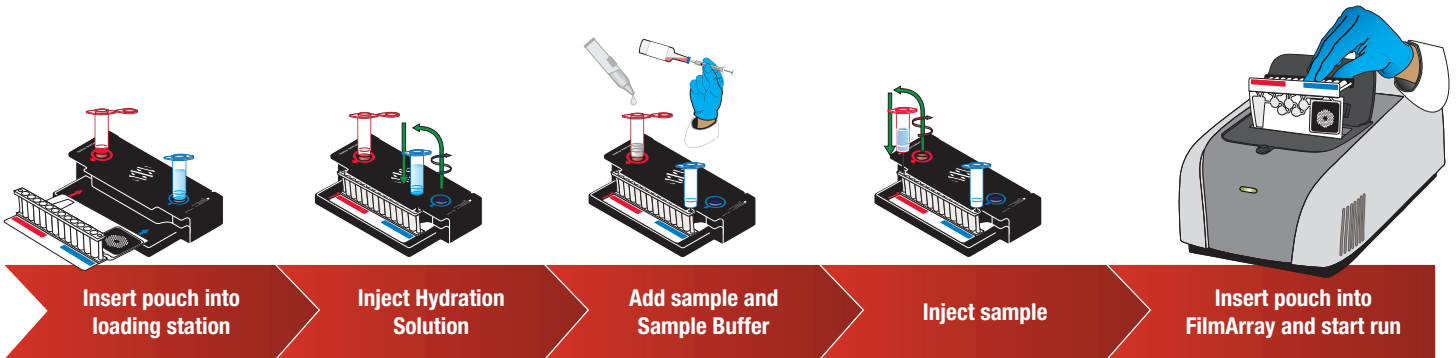
How Does the FilmArray Work?

The FilmArray reagent pouch stores all the necessary reagents for sample preparation, PCR and detection in a freeze-dried format. Prior to a run, the user injects Hydration Solution and positive blood culture sample combined with Sample Buffer into the pouch. The FilmArray instrument does the rest.

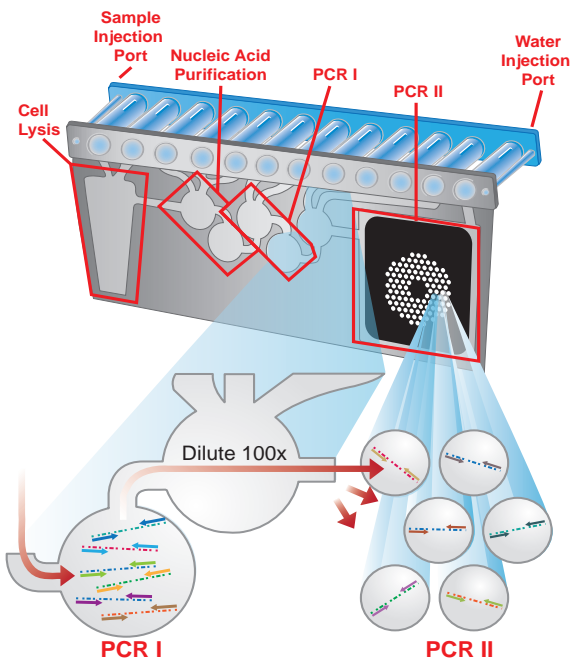
First, the FilmArray extracts and purifies all nucleic acids from the sample. Next, the FilmArray performs a nested multiplex PCR. During the first-stage PCR, the FilmArray performs a single, large volume, massively multiplexed reaction. Last, individual singleplex second-stage PCR reactions detect the products from the first stage PCR.

Using endpoint melting curve data, the FilmArray software automatically generates a result for each target in a single report.

Setting up the FilmArray is Easy – Sample in, Results out



The FilmArray Pouch and Analysis Report



FilmArray® BCID Panel		BIOFIRE www.BioFireDx.com	
Run Summary			
Sample ID:	SDY_9621_LED_50_6	Run Date:	29 May 2013 3:41 PM
Organisms Detected:	<i>Enterobacteriaceae</i> <i>Klebsiella pneumoniae</i>	Controls:	Passed
Applicable Antimicrobial Resistance Genes:	KPC - Detected		
Result Summary - Interpretations			
Antimicrobial Resistance Genes			
✓ Detected	KPC (carbapenem-resistance gene)		
⊘ N/A	<i>mecA</i> (methicillin-resistance gene)		
⊘ N/A	<i>vanA/B</i> (vancomycin-resistance genes)		
⚠ NOTE: Antimicrobial resistance can occur via multiple mechanisms. A Not Detected result for the FilmArray antimicrobial resistance gene assays does not indicate antimicrobial susceptibility. Subculturing is required for species identification and susceptibility testing of isolates.			
Gram Positive Bacteria			
Not Detected	<i>Enterococcus</i>		
Not Detected	<i>Listeria monocytogenes</i>		
Not Detected	<i>Staphylococcus</i>		
Not Detected	<i>Staphylococcus aureus</i>		
Not Detected	<i>Streptococcus</i>		
Not Detected	<i>Streptococcus agalactiae</i> (Group B)		
Not Detected	<i>Streptococcus pneumoniae</i>		
Not Detected	<i>Streptococcus pyogenes</i> (Group A)		
Gram Negative Bacteria			
Not Detected	<i>Acinetobacter baumannii</i>		
✓ Detected	<i>Enterobacteriaceae</i>		
Not Detected	<i>Enterobacter cloacae</i> complex		
Not Detected	<i>Escherichia coli</i>		
Not Detected	<i>Klebsiella oxytoca</i>		
✓ Detected	<i>Klebsiella pneumoniae</i>		
Not Detected	<i>Proteus</i>		
Not Detected	<i>Serratia marcescens</i>		
Not Detected	<i>Haemophilus influenzae</i>		
Not Detected	<i>Neisseria meningitidis</i>		
Not Detected	<i>Pseudomonas aeruginosa</i>		
Yeast			
Not Detected	<i>Candida albicans</i>		
Not Detected	<i>Candida glabrata</i>		
Not Detected	<i>Candida krusei</i>		
Not Detected	<i>Candida parapsilosis</i>		
Not Detected	<i>Candida tropicalis</i>		
Run Details			
Pouch:	BCID Panel	Protocol:	BCID
Run Status:	Completed	Operator:	RJones
Serial No.:	00631374	Instrument:	FA2075
Lot No.:	125313		

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FilmArray™ Gastrointestinal Panel

1 Test. 22 Targets. All in about an hour.



Bacteria

Campylobacter (jejuni, coli and upsaliensis)

Clostridium difficile (toxin A/B)

Plesiomonas shigelloides

Salmonella

Yersinia enterocolitica

Vibrio (parahaemolyticus, vulnificus and cholerae)

Vibrio cholerae

Diarrheagenic *E. coli*/Shigella

Enteroaggregative *E. coli* (EAEC)

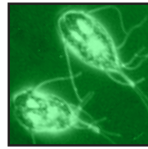
Enteropathogenic *E. coli* (EPEC)

Enterotoxigenic *E. coli* (ETEC) *lt/st*

Shiga-like toxin-producing *E. coli* (STEC) *stx1/stx2*

E. coli O157

Shigella/Enteroinvasive *E. coli* (EIEC)



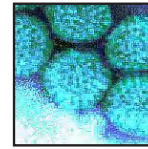
Parasites

Cryptosporidium

Cyclospora cayetanensis

Entamoeba histolytica

Giardia lamblia



Viruses

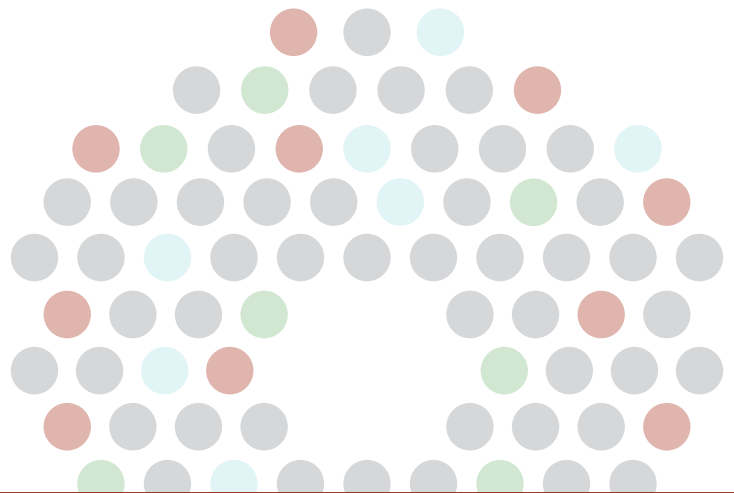
Adenovirus F 40/41

Astrovirus

Norovirus GI/GII

Rotavirus A

Sapovirus (I, II, IV and V)



22
Targets

Comprehensive Panel of 22 Targets

The FilmArray Gastrointestinal (GI) Panel tests for common gastrointestinal pathogens including viruses, bacteria and parasites that cause infectious diarrhea. The integrated FilmArray system brings sample to results in about an hour, with only 2 minutes of hands-on time.

- **Simple:** 2 minutes of hands-on time
- **Easy:** No precise measuring or pipetting required
- **Fast:** Turnaround time of about 1 hour
- **Comprehensive:** 22 target GI panel

For In-vitro Diagnostic Use
FDA-cleared



If you are interested in a free, no obligation demonstration of the FilmArray in your laboratory visit www.filmarray.com or call 1-800-735-6544.

**FREE
Demo!**

FilmArray™

The fastest way to better results.

Panel Specifications

Sample Handling

- Sample Type: Stool in Cary Blair
- Sample Volume: 200 µL

Performance Parameters

- Hands-on time: Approx. 2 minutes
- Run turnaround time: About 1 hour

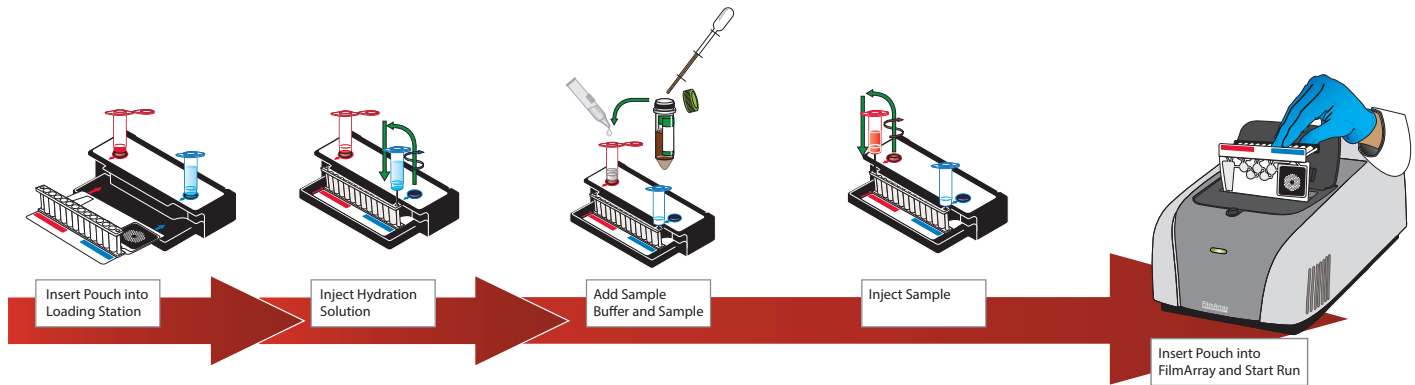
How Does the FilmArray Work?

The FilmArray reagent pouch stores all the necessary reagents for sample preparation, reverse transcription, PCR and detection in a freeze-dried format. Sample is collected in Cary Blair transport media. Prior to a run, the user injects hydration solution and sample combined with sample buffer mix into the pouch. The FilmArray instrument does the rest.

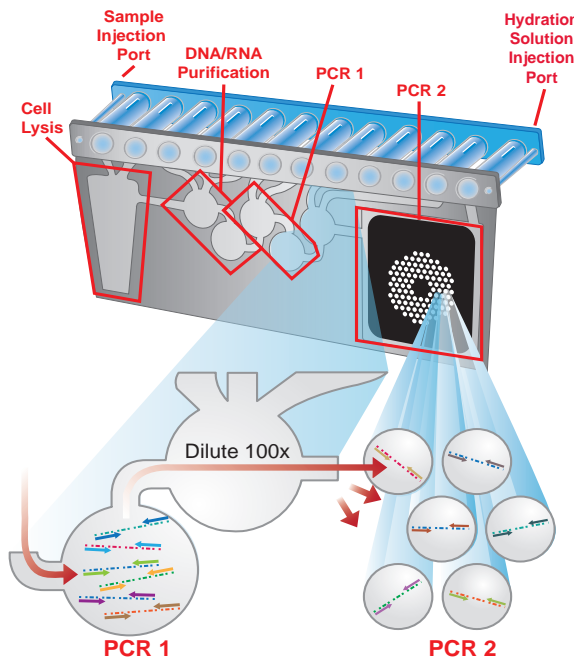
First, the FilmArray extracts and purifies all nucleic acids from the sample. Next, the FilmArray performs a nested multiplex PCR. During the first-stage PCR, the FilmArray performs a single, large volume, massively multiplexed reaction. Last, individual singleplex second-stage PCR reactions detect the products from the first stage PCR.

Using endpoint melting curve data, the FilmArray software automatically generates a result for each target in a single report.

Setting up the FilmArray is Easy – Sample in, Results out



The FilmArray Pouch and Analysis Report



FilmArray™ GI Panel		BIO FIRE	
		www.BioFireDx.com	
Run Summary			
Sample ID:	009196-03-0790	Run Date:	27 Sep 2013
Detected:	<i>Clostridium difficile</i> toxin A/B	Controls:	Passed
Result Summary			
Bacteria			
Not Detected	<i>Campylobacter</i>		
✓ Detected	<i>Clostridium difficile</i> toxin A/B		
Not Detected	<i>Plesiomonas shigelloides</i>		
Not Detected	<i>Salmonella</i>		
Not Detected	<i>Vibrio</i>		
Not Detected	<i>Vibrio cholerae</i>		
Not Detected	<i>Yersinia enterocolitica</i>		
Diarrheagenic E. coli/Shigella			
Not Detected	Enteropathogenic <i>E. coli</i> (EPEC)		
Not Detected	Enterotoxigenic <i>E. coli</i> (ETEC) <i>lt/st</i>		
Not Detected	Shiga-like toxin-producing <i>E. coli</i> (STEC) <i>stx1/stx2</i>		
⊕ N/A	<i>E. coli</i> O157		
Not Detected	<i>Shigella</i> /Enteroinvasive <i>E. coli</i> (EIEC)		
Parasites			
Not Detected	<i>Cryptosporidium</i>		
Not Detected	<i>Cyclospora cayentanensis</i>		
Not Detected	<i>Entamoeba histolytica</i>		
Not Detected	<i>Giardia lamblia</i>		
Viruses			
Not Detected	Adenovirus F 40/41		
Not Detected	Astrovirus		
Not Detected	Norovirus GI/GII		
Not Detected	Rotavirus A		
Not Detected	Sapovirus		
Run Details			
Pouch:	GI Panel v2.1	Protocol:	Stool FA v2.3
Run Status:	Completed	Operator:	John Madison (jrm)
Serial No.:	00788640	Instrument:	ITI FA "FA1315"
Lot No.:	133813		

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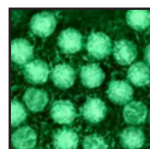
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FilmArray® Meningitis/Encephalitis Panel

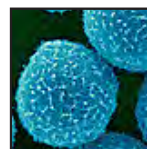
1 Test. 14 Targets. All in about an hour.



Bacteria



Viruses

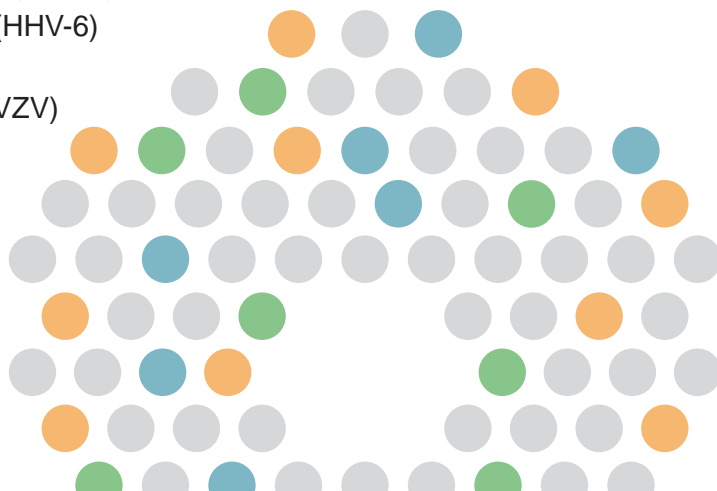


Fungi

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

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)

Cryptococcus neoformans/gattii



14

Targets

Comprehensive Panel of 14 Targets

The FilmArray Meningitis/Encephalitis (ME) Panel tests cerebrospinal fluid (CSF) for a variety of pathogens including bacteria, viruses, and fungi. The integrated FilmArray system yields sample to results in about an hour, with only 2 minutes of hands-on time.

- **Simple:** 2 minutes of hands-on time
- **Easy:** No precise measuring or pipetting required
- **Fast:** Turnaround time of about 1 hour
- **Comprehensive:** 14 bacterial, viral, and fungal targets

For In Vitro Diagnostic Use
FDA cleared and CE marked



If you are interested in a free, no obligation demonstration of the FilmArray in your laboratory visit www.BioFireDX.com or call 1-800-735-6544.

**FREE
Demo!**



FilmArray®

Panel Specifications

Sample Requirements

- Sample Type: Cerebrospinal Fluid (CSF)
- Sample Volume: 200 µL

Performance Parameters

- Hands-on time: Approx. 2 minutes
- Run turnaround time: About 1 hour

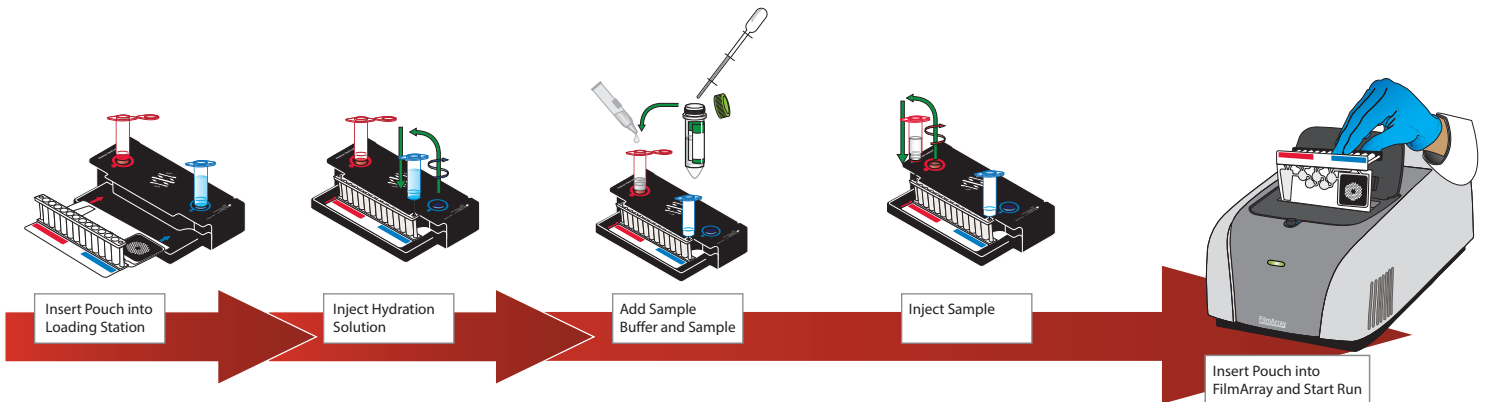
How Does the FilmArray Work?

The FilmArray reagent pouch stores all the necessary reagents for sample preparation, reverse transcription, PCR and detection in a freeze-dried format. Prior to a run, the user injects hydration solution and sample combined with sample buffer into the pouch. The FilmArray instrument does the rest.

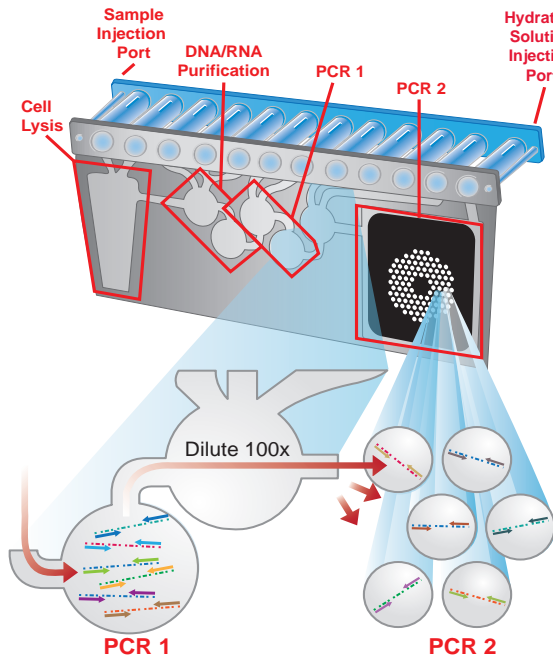
First, the FilmArray extracts and purifies all nucleic acids from the sample. Next, the FilmArray performs a nested multiplex PCR. During the first-stage PCR, the FilmArray performs a single, large volume, massively multiplexed reaction. Last, individual singleplex second-stage PCR reactions detect the products from the first stage PCR.

Using endpoint melting curve data, the FilmArray software automatically generates a result for each target in a single report.

Setting up the FilmArray is Easy – Sample in, Results out



The FilmArray Pouch and Analysis Report



FilmArray [®] Meningitis / Encephalitis (ME) Panel - IVD		BIO FIRE	
<small>www.BioFireDx.com</small>			
Run Summary			
Sample ID:	14067-0295	Run Date:	21 Jun 2015 1:47 PM
Detected:	Human herpesvirus 6	Controls:	Passed
<p>WARNING: The FilmArray ME panel does not distinguish between latent and active CMV and HHV-6 infections. Detection of these viruses may indicate primary infection, secondary reactivation, or the presence of latent virus. Results should always be interpreted in conjunction with other clinical, laboratory and epidemiological data.</p>			
Result Summary			
		Bacteria	
Not Detected	<i>Escherichia coli</i> K1		
Not Detected	<i>Haemophilus influenzae</i>		
Not Detected	<i>Listeria monocytogenes</i>		
Not Detected	<i>Neisseria meningitidis</i>		
Not Detected	<i>Streptococcus agalactiae</i>		
Not Detected	<i>Streptococcus pneumoniae</i>		
		Viruses	
Not Detected	Cytomegalovirus		
Not Detected	Enterovirus		
Not Detected	Herpes simplex virus 1		
Not Detected	Herpes simplex virus 2		
Not Detected	Human herpesvirus 6		
Not Detected	Human parechovirus		
✓ Detected	Varicella zoster virus		
		Yeast	
Not Detected	<i>Cryptococcus neoformans/gattii</i>		
Run Details			
Pouch:	ME Panel v1.4	Protocol:	CSF v2.0
Run Status:	Completed	Operator:	Ashley Hunter (ah)
Serial No.:	01422247	Instrument:	ITI FA "FA2430"
Lot No.:	140411A		

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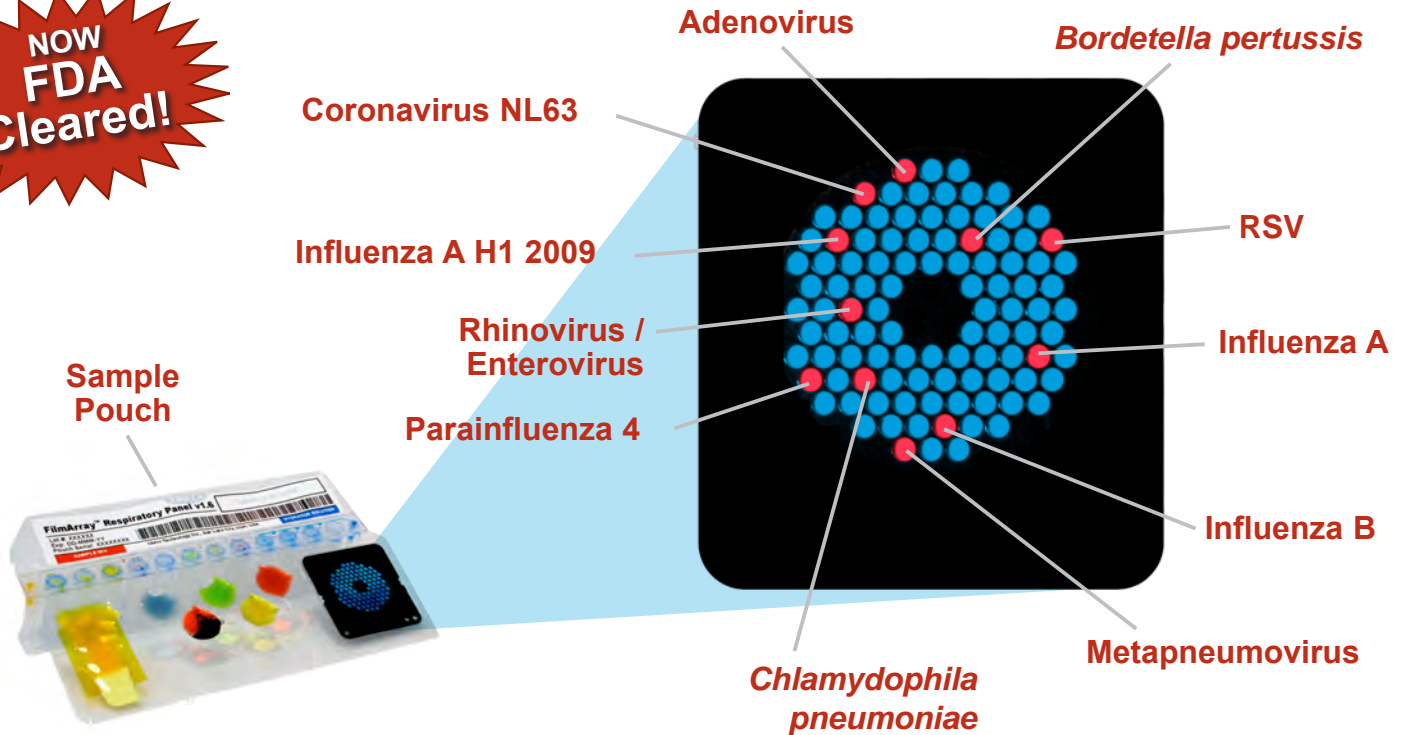
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FilmArray[®] Respiratory Panel

For In-vitro Diagnostic Use

Information Sheet



20
Targets

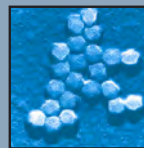
Respiratory Pathogen Detection Made Simple

The FilmArray Respiratory Panel tests for a comprehensive panel of 20 respiratory viruses and bacteria which cause URTIs. The FilmArray instrument integrates sample preparation, amplification, detection, and analysis into one simple system that requires 2 minutes of hands on time and has a total run time of about 1 hour.

- **Simple:** Two minutes of hands on time
- **Easy:** No precise measuring or pipetting required
- **Fast:** Turnaround time of about 1 hour
- **Comprehensive:** 20 target respiratory panel

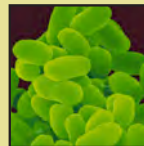
The FilmArray Respiratory Panel

Simultaneous detection of 20 targets:



Viruses

- Adenovirus
- Coronavirus HKU1
- Coronavirus NL63
- Coronavirus 229E
- Coronavirus OC43
- Influenza A
- Influenza A H1
- Influenza A H1 2009
- Influenza A H3
- Influenza B
- Metapneumovirus
- Parainfluenza 1
- Parainfluenza 2
- Parainfluenza 3
- Parainfluenza 4
- Respiratory Syncytial Virus
- Rhinovirus /Enterovirus



Bacteria

- *Bordetella pertussis*
- *Chlamydomphila pneumoniae*
- *Mycoplasma pneumoniae*

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BIO FIRE[™]
DIAGNOSTICS, INC.

If you are interested in a free, no obligation demonstration of the FilmArray in your laboratory visit www.filmarray.com or call 1-800-735-6544.

**FREE
Demo!**

Upper Respiratory Tract Infections (URTI)

It is estimated that adults get 2-4 upper respiratory tract infections each year while children average 6-12 upper respiratory tract infections a year. The estimated economic impact of non-influenza related upper respiratory tract infections is \$40 billion annually in the US. ¹

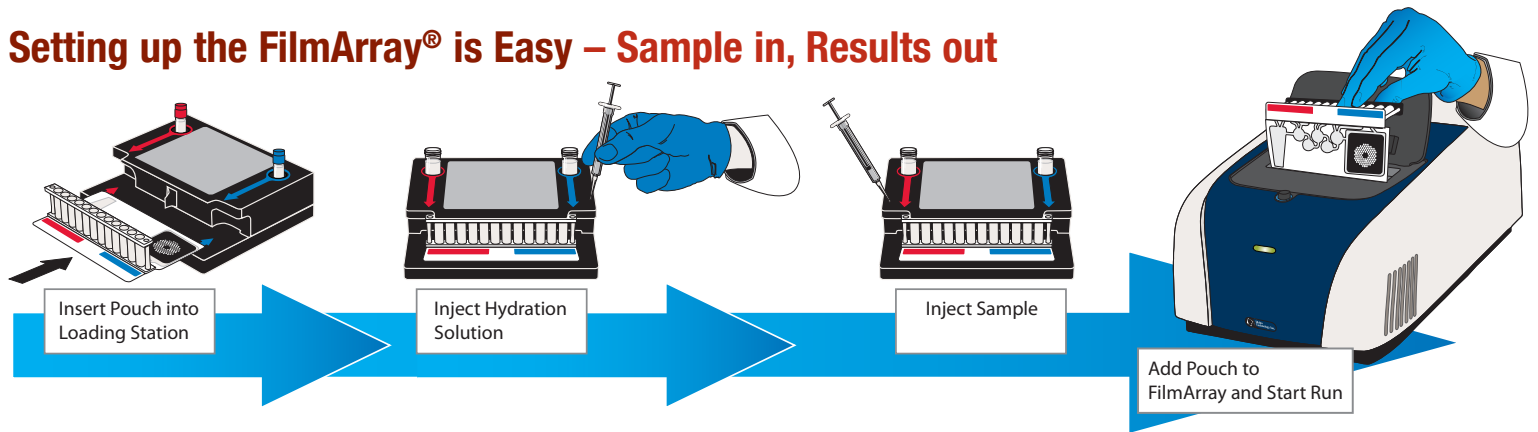
A respiratory tract infection can be the result of one of dozens of viral or bacterial pathogens. The symptoms caused by these different pathogens are nearly indistinguishable, but how a healthcare provider chooses to treat a respiratory infection may depend greatly on a rapid and accurate diagnosis of the responsible pathogen.

Unfortunately, rapidly delivering accurate results has been a challenge for traditional diagnostic methods. This potentially increases the chance that patients remain undiagnosed or misdiagnosed and may end up not receiving critical medications, or receive unnecessary antibiotics.

Rapid and accurate diagnostic testing for respiratory pathogens may aid healthcare providers in diagnosing patients, which may improve patient management, help limit the spread of disease, and reduce overall healthcare costs.



Setting up the FilmArray® is Easy – Sample in, Results out



Clinical Sensitivity and Specificity of the FilmArray Respiratory Pouch

Virus	Sensitivity		Specificity
	Prospective	Retrospective	Prospective
Adenovirus	88.9%	100%	98.3%
Coronavirus HKU1	95.8%	n/a	99.8%
Coronavirus NL63	95.8%	n/a	100%
Coronavirus 229E	100%	100%	99.80%
Coronavirus OC43	100%	100%	99.60%
Human Metapneumovirus	94.6%	n/a	99.2%
Human Rhinovirus/Enterovirus	92.7%	95.7%	94.6%
Influenza A	90.0%	n/a	99.8%
Influenza A/H1	n/a	100%	100%
Influenza A/H3	n/a	100%	100%
Influenza A/H1-2009	88.9%*	100%	99.6%
Influenza B	n/a	100%	100%
Parainfluenza Virus 1	100%*	97.1%	99.9%
Parainfluenza Virus 2	87.4%*	100%	99.8%
Parainfluenza Virus 3	95.8%	100%	98.8%
Parainfluenza Virus 4	100%*	100%	99.9%
Respiratory Syncytial Virus	100%	n/a	89.1%
<i>Bordetella pertussis</i>	100%*	94.6%	99.90%
<i>Chlamydomphila pneumoniae</i>	100%*	100% [†]	100%
<i>Mycoplasma pneumoniae</i>	100%*	84.4%	100%

[†]Spiked *Chlamydomphila pneumoniae* samples were used to test retrospective sensitivity.

*Due to low prevalence in the prospective study, clinical sensitivity for these pathogens was based on less than 10 positive samples.

1. Cooper RJ, Hoffman JR, Bartlett JG, et al: Principles of appropriate antibiotic use for acute pharyngitis in adults: Background. *Ann Intern Med.* 2001, 134: 509-517.

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