

FilmArray® Instrument

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

Information Sheet



Visit www.filmarray.com
to see a video of how
simple the FilmArray really is.



The FilmArray: User-Friendly Multiplex PCR

The BioFire FilmArray is user-friendly multiplex PCR. This all in one system integrates sample preparation, amplification, detection, and analysis into one instrument that processes sample to results in about one hour.

- **Simple:** Two minutes hands-on time
- **Easy:** No precise pipetting
- **Fast:** Turnaround time of about one hour

**FREE
Demo!**

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.

The FilmArray – Sample in, Results out

Idaho Technology is now

BIO FIRE™
DIAGNOSTICS, INC.

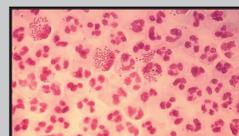
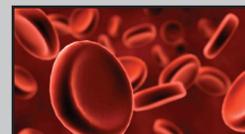
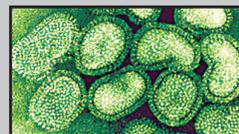
The FilmArray Panels

We currently offer the following panel:

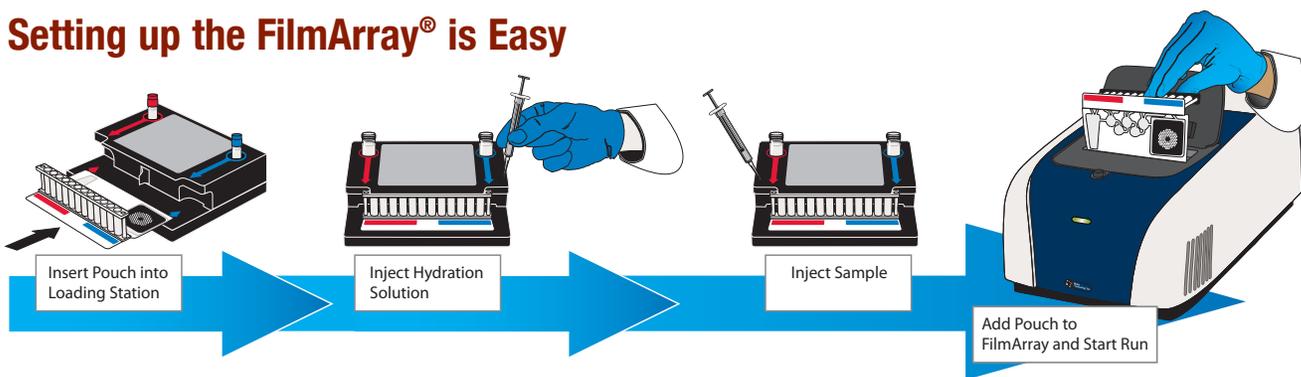
- Respiratory Panel

Applications currently under development:

- GI Panel
- Blood Culture ID Panel
- Meningitis Panel
- BioThreat Panel



Setting up the FilmArray® is Easy



Set-up a Run in 2 Minutes & Results in About 1 Hour

How Does the FilmArray Work?

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

First, the FilmArray extracts and purifies all nucleic acids from the unprocessed 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.

Intuitive Auto-Analysis Software

The FilmArray Software includes a step-by-step Wizard that walks the operator through loading the pouch and demonstrates how to perform a run. When the run is complete, the advanced software automatically analyzes and reports results in a simple and easy to read format.

FilmArray® Respiratory Panel IVD		FilmArray® Idaho Technology Inc. www.idahotech.com	
Run Summary			
Sample ID:	5805-3064-01	Run Date:	21 May 2012
Detected:	Adenovirus <i>Bordetella pertussis</i>		12:02 PM
Equivocal:	None	Controls:	Passed
Result Summary			
✓ Detected	Adenovirus		
Not Detected	Coronavirus 229E		
Not Detected	Coronavirus HKU1		
Not Detected	Coronavirus NL63		
Not Detected	Coronavirus OC43		
Not Detected	Human Metapneumovirus		
Not Detected	Human Rhinovirus/Enterovirus		
Not Detected	Influenza A		
Not Detected	Influenza B		
Not Detected	Parainfluenza Virus 1		
Not Detected	Parainfluenza Virus 2		
Not Detected	Parainfluenza Virus 3		
Not Detected	Parainfluenza Virus 4		
Not Detected	Respiratory Syncytial Virus		
✓ Detected	<i>Bordetella pertussis</i>		
Not Detected	<i>Chlamydomphila pneumoniae</i>		
Not Detected	<i>Mycoplasma pneumoniae</i>		
Run Details			
Pouch:	Respiratory Panel IVD v1.6	Protocol:	NPS v2.0
Run Status:	Completed	Operator:	Emily M (em)
Serial No.:	00117799	Instrument:	ITI FA "FA1171"
Lot No.:	102511		

System Specifications

Instrument Specifications

- Power Requirements: 90-264 VAC, 10 A
- Size: 25.4 x 39.3 x 16.5 cm (10 x 15.5 x 6.5 in.)
- Weight: 9 kg (20 lb.)

Performance Parameters

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

Environmental Specification

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

Desktop Software

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

CE IVD For in vitro diagnostic use. Products are region specific and may not be approved in some countries/regions. Please contact BioFire to obtain the appropriate information for your country of residence.

The purchase of this product includes a limited, nontransferable instrument license under specific claims of one or more U.S. patents as listed on BioFire Diagnostics, Inc. incomplete Web site (<http://www.biofire.com/LegalNotices/>) (the "Web Site") and owned by the University of Utah Research Foundation and/or BioFire Diagnostics, Inc. Any kits sold with this product and/or discussed herein (i) may be covered by one or more of the U.S. patents, as listed on the Web Site for the product and (ii) include a limited, nontransferable license to use the enclosed amount(s) in such kits according to the specified protocols.

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