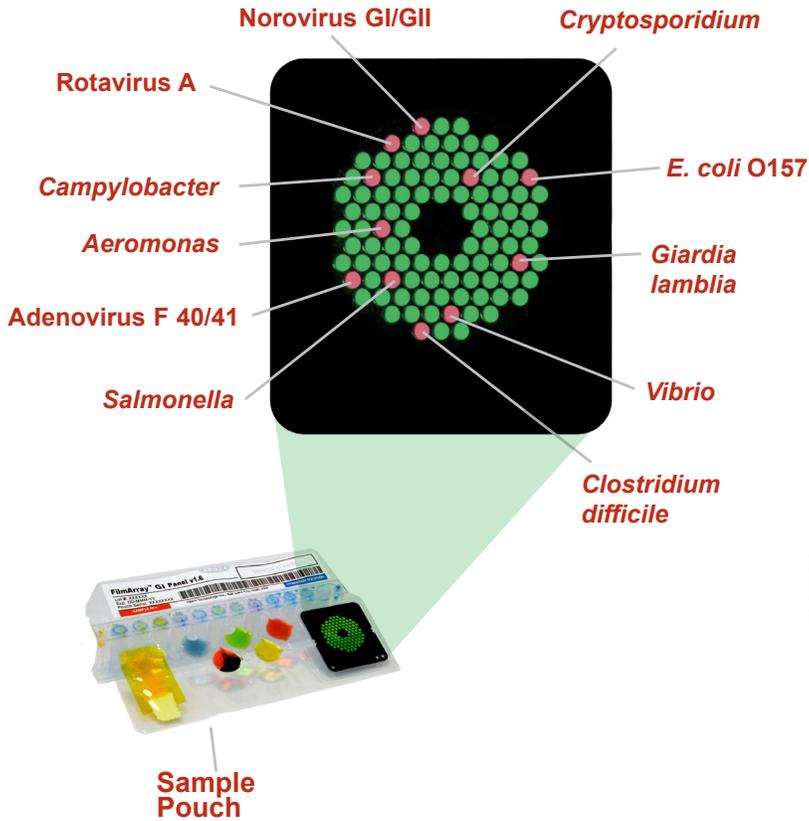


FilmArray® GI Panel

For Research Use Only
Not for Use in Diagnostic Procedures

Information Sheet



The FilmArray: User-Friendly Multiplex PCR

The FilmArray GI Panel tests for a comprehensive panel of common gastrointestinal (GI) pathogens that cause infectious diarrhea. The FilmArray integrates sample preparation, amplification, detection, and analysis into one simple system that requires approximately 5 minutes of hands-on time and has a total run time of 1 hour.

- **Simple:** ~5 minutes of hands-on time
- **Easy:** No precise measuring or pipetting required
- **Fast:** Turnaround time of one hour
- **Comprehensive:** 23 target GI panel

The FilmArray GI Panel

Simultaneous detection of 23 targets:



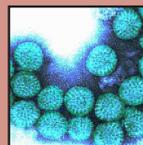
Bacteria

- *Aeromonas*
- *Campylobacter*
- *Clostridium difficile*
- *Plesiomonas shigelloides*
- *Salmonella*
- *Vibrio*
- *Vibrio cholerae*
- *Yersinia enterocolitica*



Diarrheagenic *E. coli*/Shigella

- Enterotoxigenic *E. coli* (ETEC) *lt/st*
- Enteropathogenic *E. coli* (EPEC)
- Shiga toxin producing *E. coli* (STEC) *stx1/stx2*
- *Shigella*/Enteroinvasive *E. coli* (EIEC)
- Enteroaggregative *E. coli* (EAEC)
- *E. coli* O157



Viruses

- Adenovirus F40/41
- Human Astrovirus
- Norovirus GI/GII
- Rotavirus A
- Sapovirus



Protozoa

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

Idaho Technology is now



Panel Specifications

Sample Handling	Performance Parameters
<ul style="list-style-type: none"> Sample Type: Stool diluted 1:10 in Cary-Blair Sample Volume: 25 µL of Stool 	<ul style="list-style-type: none"> Hands on time: Approx. 5 minutes Run turnaround time: 1 hour

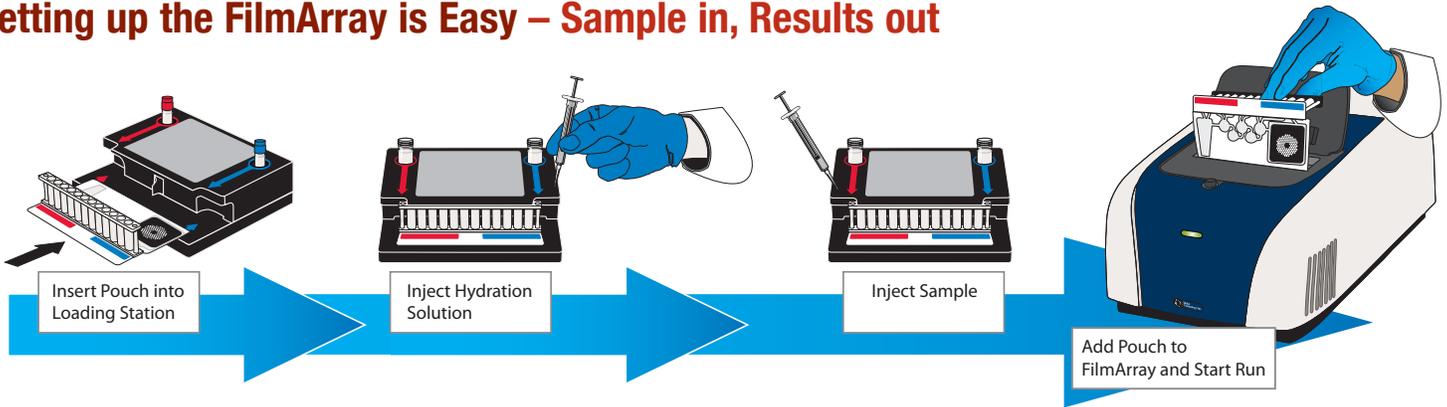
How Does the FilmArray Work?

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

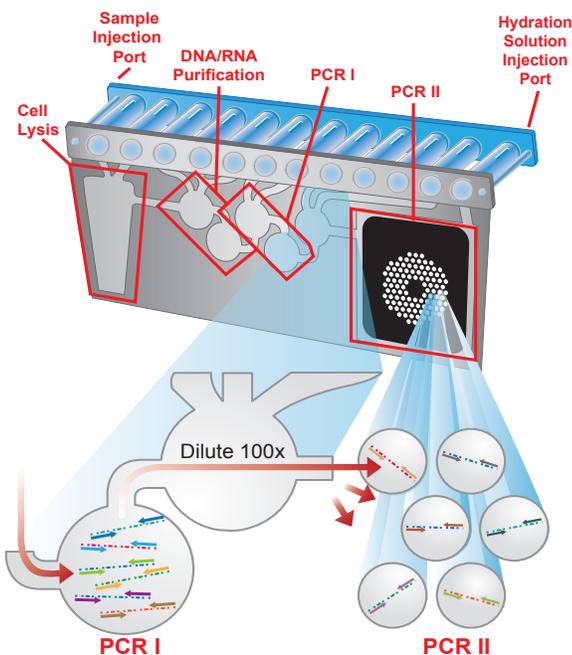
First, the FilmArray extracts and purifies all nucleic acids from the sample. Next, the FilmArray performs a nested multiplex PCR. During the first-stage PCR, the FilmArray performs a single, large volume, massively multiplexed reaction. Last, individual single-plex second-stage PCR reactions detect 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 Report		BIO F I R E	
www.biofire.com			
Run Summary			
Sample ID:	Example	Run Date:	26 Apr 2012
Organisms Detected:	<i>Giardia lamblia</i> STEC stx1/stx2	Time:	5:03 PM
Controls:	Passed		
Results Summary			
Bacteria			
Not Detected	<i>Aeromonas</i>		
Not Detected	<i>Clostridium difficile</i>		
Not Detected	<i>Campylobacter</i>		
Not Detected	<i>Plesiomonas shigelloides</i>		
Not Detected	<i>Salmonella</i>		
Not Detected	<i>Yersinia enterocolitica</i>		
Not Detected	<i>Vibrio</i>		
Not Detected	<i>Vibrio cholerae</i>		
Viruses			
Not Detected	Adenovirus 40/41		
Not Detected	Human Astrovirus		
Not Detected	Norovirus GI/GII		
Not Detected	Rotavirus A		
Not Detected	Sapovirus		
Protozoa			
Not Detected	<i>Cryptosporidium</i>		
Not Detected	<i>Cyclospora cayatanensis</i>		
Not Detected	<i>Entamoeba histolytica</i>		
✓ Detected	<i>Giardia lamblia</i>		
Diarrheagenic <i>E. coli</i>/Shigella Genetic Factors			
Not Detected	Enterotoxigenic <i>E. coli</i> (ETEC) <i>lt/st</i>		
Not Detected	Enteropathogenic <i>E. coli</i> (EPEC)		
✓ Detected	Shiga toxin producing <i>E. coli</i> (STEC) <i>stx1/stx2</i>		
Not Detected	<i>E. coli</i> O157		
Not Detected	<i>Shigella</i> /Enteroinvasive <i>E. coli</i> (EIEC)		
Not Detected	Enteraggregative <i>E. coli</i> (EAEC)		
NOTE: See package insert for a detailed description of diarrheagenic <i>E. coli</i> /Shigella and detected genetic factors.			
Run Details			
Pouch:	GI Panel v1.8	Protocol:	GI v 2.1
Run Status:	Complete	Operator:	EM
Serial No.:	00190177	Instrument:	ITI FA "FA1231"
Lot No.:	120321C		

The purchase of FilmArray System includes a limited, non-transferable license under U.S. Patent No. 5,871,908, owned by Evotec Biosystems GmbH and licensed to Roche Diagnostics GmbH, to use only the enclosed amount of product according to the specified protocols. No right is conveyed, expressly, by implication, or by estoppel, to use any instrument or system under any claim of U.S. Patent No. 5,871,908, other than for the amount of product contained herein.

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.'s 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.