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) *It/st* Shiga-like toxin-producing *E. coli* (STEC) *stx1/stx2 E. coli* 0157 *Shigella/*Enteroinvasive *E. coli* (EIEC)



Cryptosporidium Cyclospora cayetanensis Entamoeba histolytica Giardia lamblia



Adenovirus F 40/41 Astrovirus Norovirus GI/GII Rotavirus A Sapovirus (I, II, IV and V)



Simultaneous Identification of 22 Targets

The FilmArray Gastrointestinal (GI) Panel tests for a comprehensive panel of 22 viruses, bacteria and parasites that cause infectious diarrhea. The FilmArray instrument integrates sample preparation, amplification, detection and analysis into one simple system that requires two minutes of hands-on time and has a total run time of about an hour.

Simple: 2 minutes of hands-on timeEasy: No precise measuring or pipetting requiredFast: Turnaround time of about 1 hourComprehensive: 22 target GI Panel

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



PIONEERING DIAGNOSTICS

Panel Specifications		
Sample Handling	Performance Parameters	
Sample Type: Stool in Cary Blair	Hands-on time: Approximately two minutes	
Sample Volume: 200 µL	Run time: About an hour	



How Does the FilmArray Work?

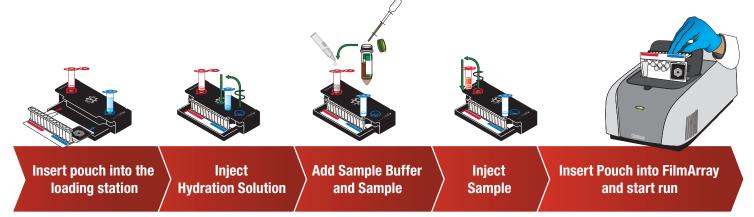
The FilmArray reagent pouch stores all the necessary reagents for sample preparation, reverse transcription, PCR and detection in a freeze-dried format. Sample is collected in Cary Blair transport media. Prior to a run, the user injects hydration solution and sample combined with sample buffer mix into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

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

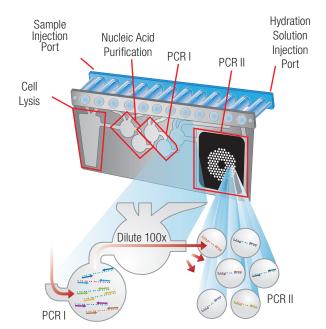
Next, the FilmArray performs a nested multiplex PCR. During the first-stage PCR, the FilmArray performs a single, large volume, massively multiplexed reaction. Last, individual singleplex second-stage PCR reactions detect the products from the first stage PCR.

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 — a true Load and Go system.



The FilmArray Pouch and Analysis Report



GI P			~ ~	
			www.BioFireDx.cor	
Run Summary				
Sample ID:	009196-03-0790	R	un Date: 27 Sep 2013 12:03 PM	
Detected:	Giardia lamblia		Controls: Passed	
Result Summary	/			
	Bacteria			
Not Detected	Campylobacter			
Not Detected	Clostridium difficile toxin A/B			
Not Detected	Plesiomonas shigelloides			
Not Detected	Salmonella			
Not Detected	Vibrio			
Not Detected	Vibrio cholerae			
Not Detected	Yersinia enterocolitica			
	Diarrheagenic E. coli/S	Shigella		
Not Detected	Enteroaggregative E. coli (EAEC)			
Not Detected	Enteropathogenic E. coli (EPEC)			
Not Detected	Enterotoxigenic E. coli (ETEC) It/st			
Not Detected	Shiga-like toxin-producing E. coli (STEC)	stx1/stx2		
Q N/A	E. coli O157			
Not Detected	Shigella/Enteroinvasive E. coli (EIEC)			
	Parasites			
Not Detected	Cryptosporidium			
Not Detected	Cyclospora cayetanensis			
Not Detected	Entamoeba histolytica			
 Detected 	Giardia lamblia			
	Viruses			
Not Detected	Adenovirus F 40/41			
Not Detected	Astrovirus			
Not Detected	Norovirus GI/GII			
Not Detected	Rotavirus A			
Not Detected	Sapovirus			
Run Details				
	GI Panel v2.1	Protocol:	Stool FA v2.3	
	Completed	Operator:		
Serial No.:	00788640	Instrument:	ITI FA "FA1315"	

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