FilmArray[®] Meningitis/Encephalitis Panel

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



Bacteria

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 <u>www.BioFireDX.com</u> or call 1-800-735-6544.





Panel Specifications				
Sample Requirements	Performance Parameters			
Sample Type: Cerebrospinal Fluid (CSF)	Hands-on time: Approx. 2 minutes			
 Sample Volume: 200 μL 	Run turnaround time: About 1 hour			

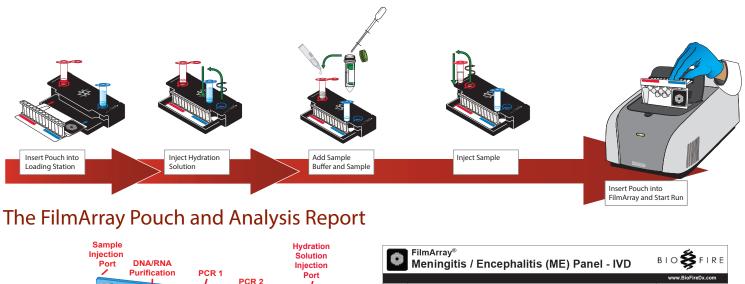
How Does the FilmArray Work?

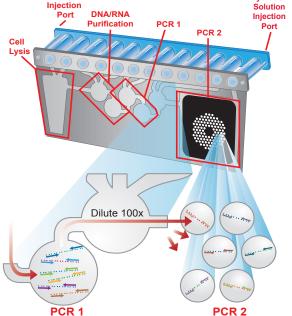
The FilmArray reagent pouch stores all the necessary reagents for sample preparation, reverse transcription, PCR and detection in a freeze-dried format. Prior to a run, the user injects hydration solution and sample combined with sample buffer into the pouch. The FilmArray instrument does the rest.

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 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





Men 🖉	ingitis / Encephalitis (ME)	Panel - IVD	В	
				www.BioFireDx.com
Run Summary				
Sample ID:	14067-0295	Ru	un Date:	21 Jun 2015
				1:47 PM
Detected:	Human herpesvirus 6	c	ontrols:	Passed
viruses may ind in conjunction w	FilmArray ME panel does not distinguish between lat icate primary infection, secondary reactivation, or the ith other clinical, laboratory and epidemiological data.			
Result Summary	Bacteria			
Not Detected	Escherichia coli K1			
Not Detected	Haemophilus influenzae			
Not Detected	Listeria monocytogenes			
Not Detected	Neisseria meningitidis			
Not Detected	Streptococcus agalactiae			
Not Detected	Streptococcus pneumoniae			
	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	Cryptococcus neoformans/gattii			
Run Details				
Pouch:	ME Panel v1.4	Protocol:	CSF v2.0)
	Completed	Operator:	Achlov H	lunter (ah)
Run Status:	Completed			
		Instrument:	ITI FA "F	A2430"

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.

A BIOMÉRIEUX COMPANY

The information contained in this document is subject to change without notice. No part of this to document may be reproduced or transmitted in any form you propose, without the express written permission of BioFire Diagnostics, LLC. FilmArray LegalNotices/) and owned by BioI

The purchase of this product includes a limited, nontransferable license under specific claims of one or more U.S. patents as listed on BioFire Diagnostics' Web site (http://www.biofiredx.com/ LegalNotices/) and owned by BioFire and the University of Utah Research Foundation.

Software, Detector, and Metacall software modules ©2002–2015 BioFire Diagnostics, LLC. BioFire Diagnostics, BioFire, the BioFire logo, FilmArray and LCGreen are trademarks of BioFire Diagnostics, LLC or BioFire Defense, LLC and are registered trademarks of BioFire Diagnostics,

LLC or BioFire Defense, LLC in the United States. All other names of products and brands appearing in this manual are trademarks or registered trademarks of their respective owners.