

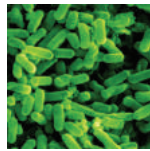
FilmArray[®] Blood Culture Identification Panel

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



Gram-Positive Bacteria

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



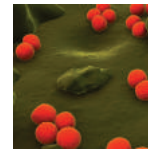
Gram-Negative Bacteria

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

27
Targets

Simultaneous Identification of 27 Targets

For *In-vitro* Diagnostic Use
FDA-cleared | CE-IVD Marked

The FilmArray Blood Culture Identification (BCID) Panel tests for a comprehensive list of 24 pathogens and 3 antibiotic resistance genes. 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 time

Easy: No precise measuring or pipetting required

Fast: Turnaround time of about 1 hour

Comprehensive: 27 target BCID Panel

FilmArray[®] Torch



FilmArray[®] 2.0 System



Panel Specifications

Sample Handling	Workflow Parameters
Sample Type: Positive Blood Culture	Hands-on time: Approximately two minutes
Sample Volume: 200 µL	Run time: About an hour

How Does the FilmArray Work?

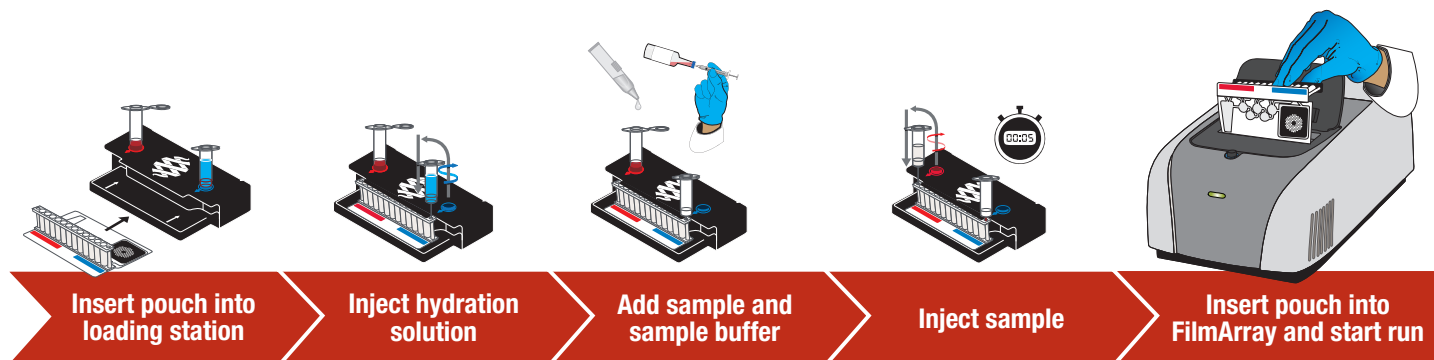
The FilmArray reagent pouch stores all the necessary reagents for sample preparation, PCR and detection in a freeze-dried format. Prior to a run, the user injects hydration solution and sample combined with sample buffer mix into the pouch. The FilmArray® Instrument does the rest.

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

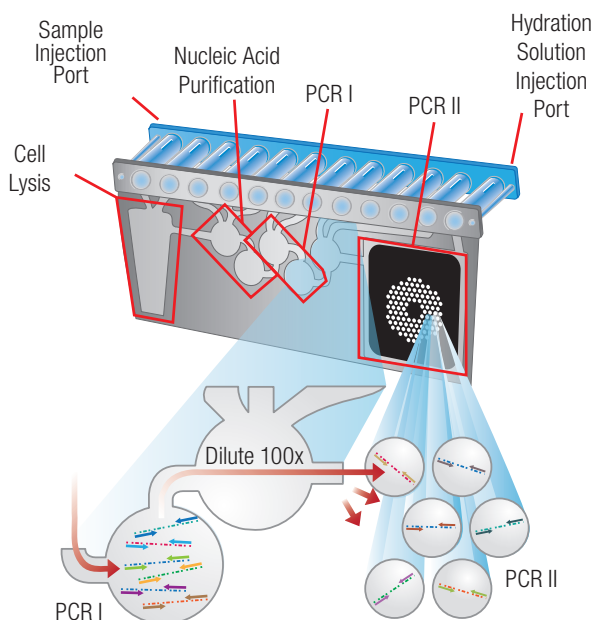
Next, the FilmArray performs a nested multiplex PCR. During the first-stage PCR, the FilmArray performs a single, large volume, massively multiplexed reaction. Last, individual singleplex second-stage PCR reactions detect the products from the first stage PCR.

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 simple Load and Go system



The FilmArray Pouch and Analysis Report



FilmArray® BCID Panel		BIOFIRE
www.BioFireDx.com		
Run Summary		
Sample ID:	Anonymous	Run Date: 04 Dec 2014 5:03 AM
Organisms Detected:	Enterobacteriaceae Klebsiella pneumoniae	Controls: Passed
Applicable Antimicrobial Resistance Genes:	KPC - Not Detected	
<small>WARNING: A Not Detected result for the KPC gene does not indicate susceptibility to carbapenems. Gram negative bacteria can be resistant to carbapenems by mechanisms other than carrying the KPC gene.</small>		
Result Summary - Interpretations		
Antimicrobial Resistance Genes		
Not Detected	KPC (carbapenem-resistance gene)	
Not Detected	meclA (methicillin-resistance gene)	
Not Detected	vanA/B (vancomycin-resistance genes)	
<small>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.</small>		
Gram Positive Bacteria		
Not Detected	Enterococcus	
Not Detected	Listeria monocytogenes	
Not Detected	Staphylococcus	
Not Detected	Staphylococcus aureus	
Not Detected	Streptococcus	
Not Detected	Streptococcus agalactiae (Group B)	
Not Detected	Streptococcus pneumoniae	
Not Detected	Streptococcus pyogenes (Group A)	
Gram Negative Bacteria		
Not Detected	Acinetobacter baumannii	
Not Detected	Enterobacteriaceae	
Not Detected	Enterobacter cloacae complex	
Not Detected	Escherichia coli	
Not Detected	Klebsiella oxytoca	
Not Detected	Klebsiella pneumoniae	
Not Detected	Proteus	
Not Detected	Serratia marcescens	
Not Detected	Haemophilus influenzae	
Not Detected	Neisseria meningitidis	
Not Detected	Pseudomonas aeruginosa	
Yeast		
Not Detected	Candida albicans	
Not Detected	Candida glabrata	
Not Detected	Candida krusei	
Not Detected	Candida parapsilosis	
Not Detected	Candida tropicalis	
Run Details		
Pouch:	BCID Panel v2.0	Protocol: BC v2.1
Run Status:	Completed	Operator: ADMIN ADMIN (ADMIN)
Serial No.:	01775458	Instrument: ITI FA "FA3014"
Lot No.:	172914	

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