

FilmArray

The Fastest Way to Better Results

FilmArray[®]
The fastest way to better results.

BioFire Over 20 Years of Innovations

FilmArray[®]
The fastest way to better results.

Molecular Biology Tools

•LightCycler[®]

1996

2000

Applied PCR

- BioThreat Testing
- Food Testing

Idaho
Technology,
Inc.

1990

2014

Acquired by
bioMérieux

2012

Becomes BioFire
Diagnostics

2011

FilmArray RP
Comprehensive – Fast – Easy₂

2005

JBAIDS United States
Government Contract

•FDA-cleared



FilmArray

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- **Easy** – Two minutes of hands-on time
- **Fast** – Results in about 1 hour
- **Comprehensive** –
 - RP(호흡기)- 20 targets (17 viruses & 3 bacteria)
 - BCID(혈액배양)- 27 targets (19 bacteria, 4 yeast & 3 antibiotic resistance genes)
 - GI(장관)- 22 targets (13 bacteria, 4 parasites & 5 viruses)
 - ...
- **Closed System** – risk of contamination is reduced
- **Molecular Diagnostics** – Increased sensitivity and specificity

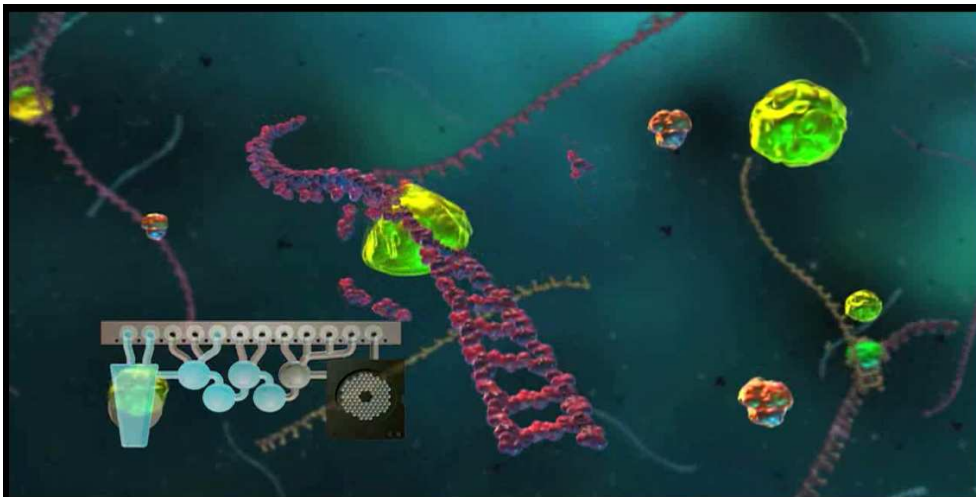


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FilmArray 동영상

FilmArray®
The fastest way to better results.

- 유튜브 : bioMerieux, 장비이름으로 검색!
: 비오메리외의 다양한 제품 동영상을 보실 수 있습니다~
예) filmarray
https://www.youtube.com/watch?v=7Vq4S9_EHHg



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The Fastest Way to Better Results

Presentation Overview

- The Product Knowledge
- The Panels
- The System
- The Workflow
- The advantage

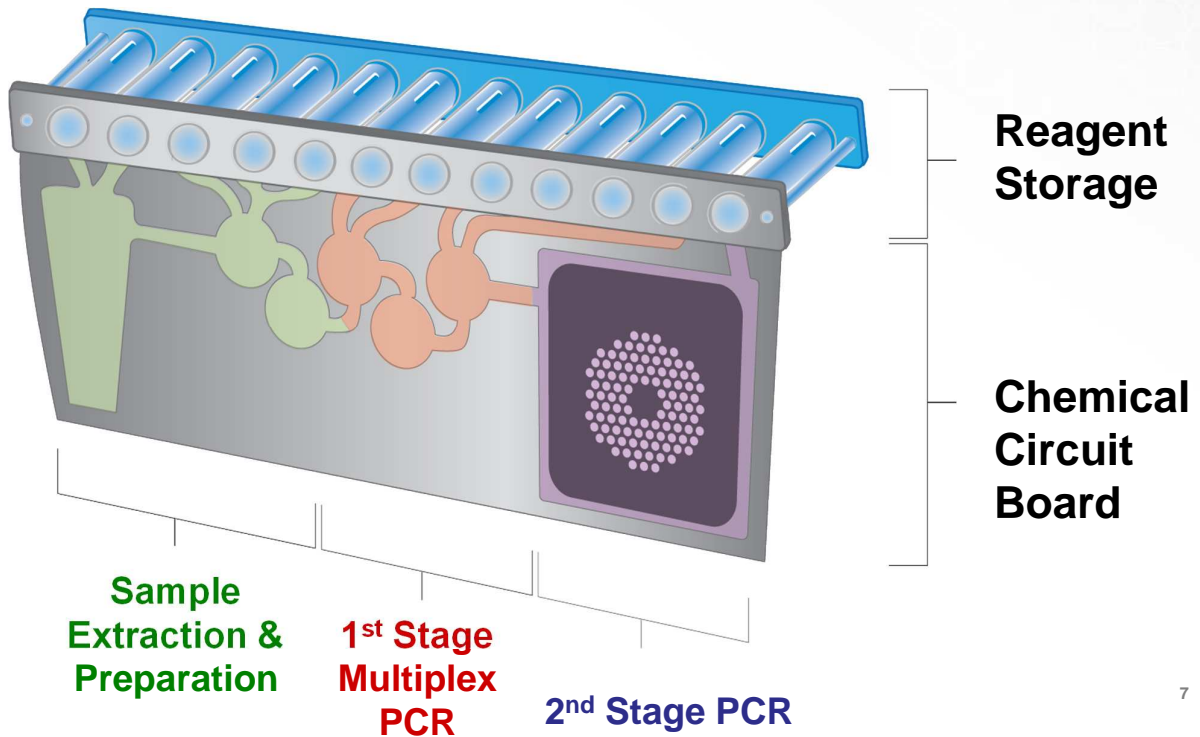
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THE PRODUCT KNOWLEDGE

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The FilmArray Pouch

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Sample Prep - Hydration

Hydration Solution:

- Molecular grade water
- Used to Hydrate the pouch



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Sample Prep - Lysis

Sample Buffer:

- Breaks open virus particles
- Weakens cell walls
- Contains Guanidinium HCL and detergent
 - One of the most **chaotropic** substances

*chaotropic이란?

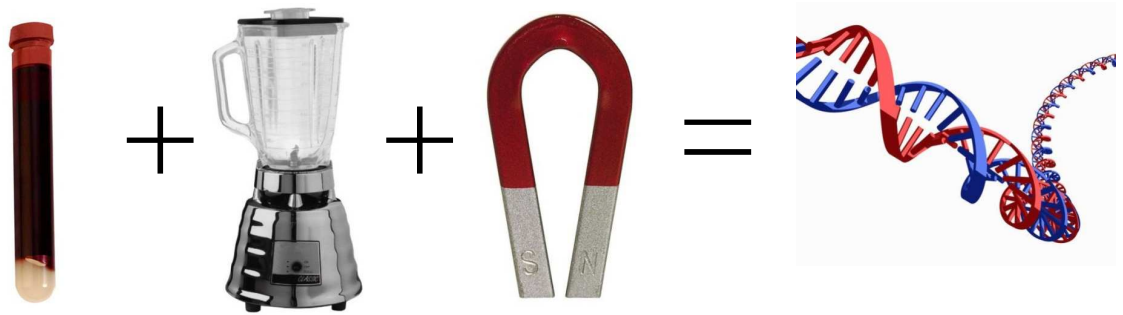
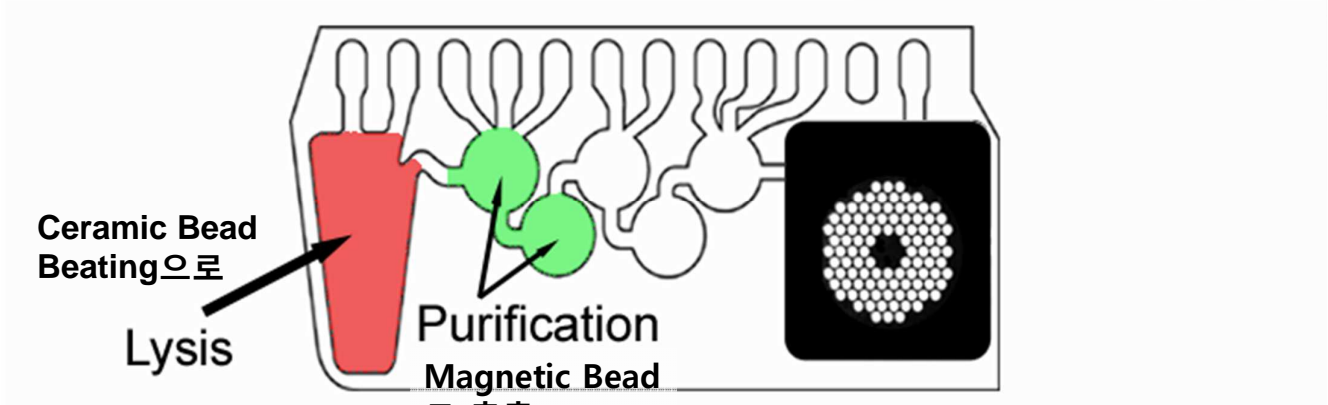
disrupts the structure of, and denatures, macromolecules such as proteins and nucleic acids

(e.g. DNA and RNA).



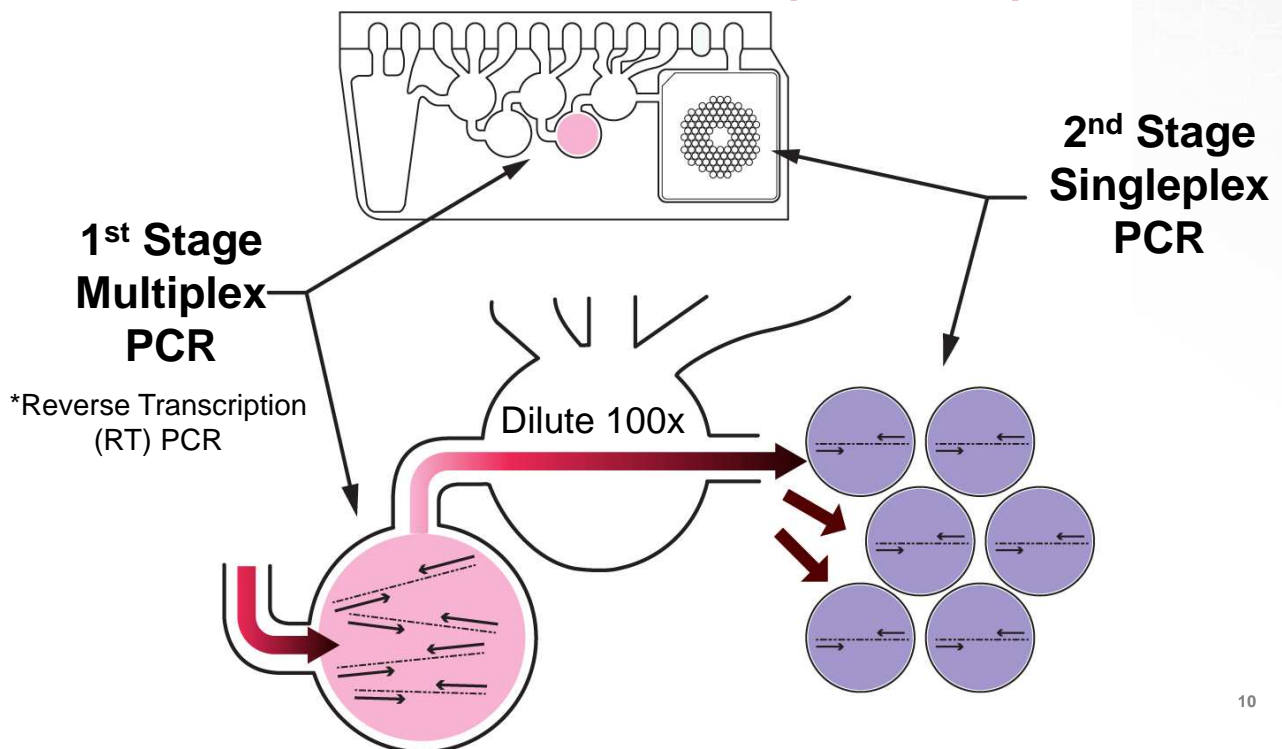
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(Step1.) Purification Nucleic Acids



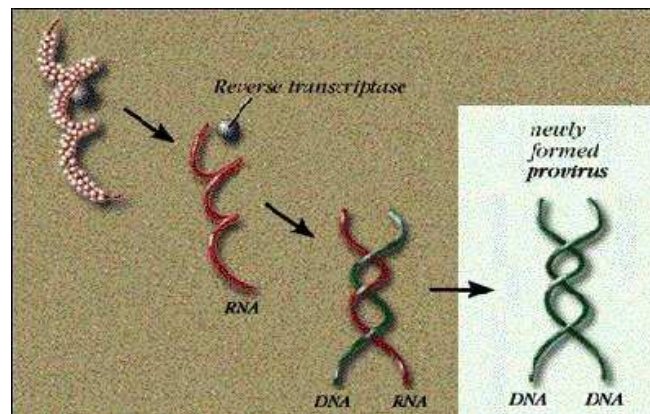
(Step2.) Amplification

: Nested MultiPlex PCR (nmPCR)



Reverse Transcription:

- Enzymatic conversion of RNA to DNA
- Required because PCR will not work on RNA



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Amplification - nmPCR

1st Stage PCR:

- 1 large (140ul) reaction
- Massively Multiplexed
 - 36 primer pairs (RP)
- Occurs in 2 blisters
- 1 peltier device uniformly heats both blisters
- 27 cycles
- No detection

*Reverse Transcription(RT) PCR로
2nd stage PCR에 필요한 Template를
만드는 단계

2nd Stage PCR:

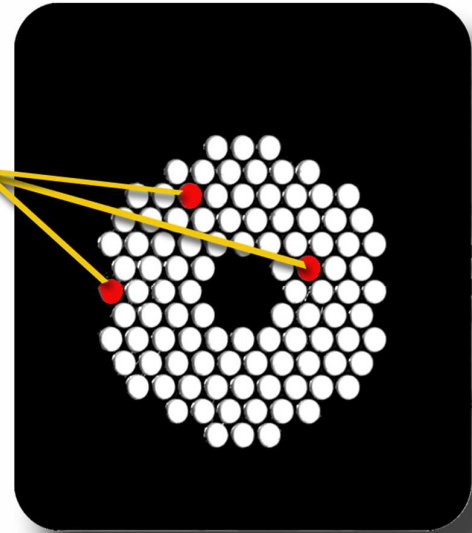
- 102 (1ul) reactions
- Nested singleplex reaction
 - 1 primer pair in each
- Occurs in 102 wells in the array
- 1 peltier device uniformly heats entire array
- 30 cycles
- Melting analysis using LC Green Plus Detection

*실제 target 검출을 위한 PCR 단계

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Automated Results Analysis

- Detection using LC Green Plus like SYBR Green
- 102 individual 2nd stage PCR wells
- Each well contains one reaction **RSV**
- Melt curves generated for each well
- All targets tested in triplicate
- Internal Control(IC) control whole process
 - ✓ RNA Process Control
 - ✓ 2nd stage PCR



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THE PANELS

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Respiratory Panel(RP) FDA Cleared FilmArray® The fastest way to better results.

(상기도 호흡기 패널)

Viral (감기 및 독감바이러스)

Adenovirus

Coronavirus 229E

Coronavirus HKU1

Coronavirus OC43

Coronavirus NL63

Human Metapneumovirus

Human Rhinovirus/
Enterovirus

Influenza A

Influenza A/H1

Influenza A/H1-2009

Influenza A/H3

Influenza B

Parainfluenza 1

Parainfluenza 2

Parainfluenza 3

Parainfluenza 4

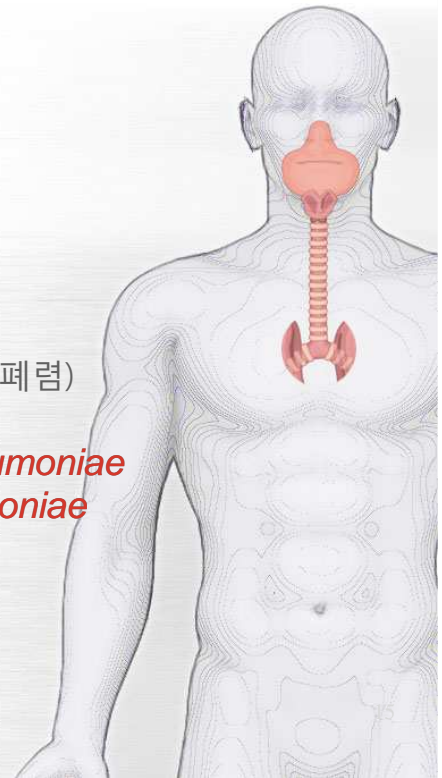
RSV

Bacterial (백일해 및 폐렴)

Bordetella pertussis

Chlamydomphila pneumoniae

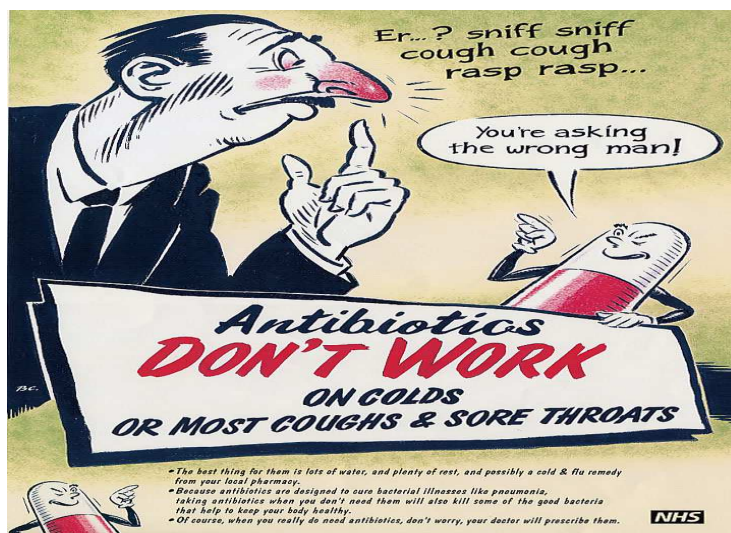
Mycoplasma pneumoniae



* FDA-Cleared for the first time

RP Market Need Cont. FilmArray® The fastest way to better results.

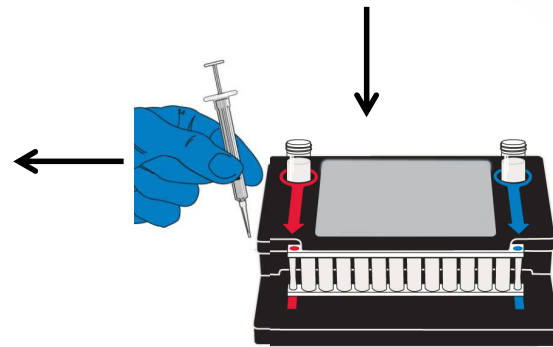
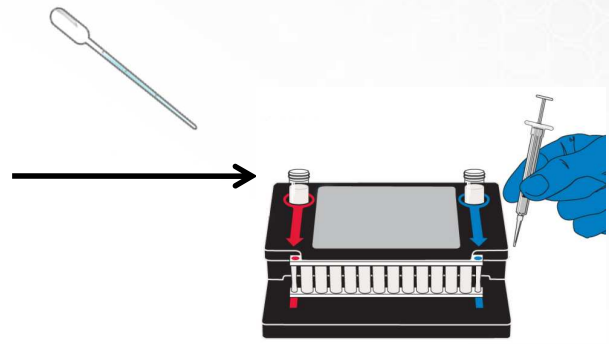
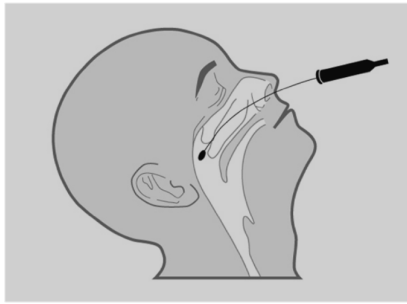
- Respiratory bacteria and viruses have very similar symptoms, but are treated differently!
 - Bacteria: Antibiotics(항생제) Viruses: Antivirals(항바이러스제)



Symptoms Include:

- Acute pharyngitis
- Pain in joints
- Fever
- Chills
- Malaise and fatigue
- Headache
- Shortness of breath
- Wheezing
- Cough
- Painful respiration

RP 시료 swap 방법



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Blood Culture Identification Panel FilmArray® The fastest way to better results.

Panel FDA Cleared (혈액배양 패널)

Gram + Bacteria:

Enterococcus
L. monocytogenes
Staphylococcus
S. aureus
Streptococcus
S. agalactiae
S. pyogenes
S. pneumoniae

Antibiotic Resistance

(항생제내성 유전자 검출)
mecA (methicillin)
Van A/B (vancomycin)
KPC (Carbapenem)

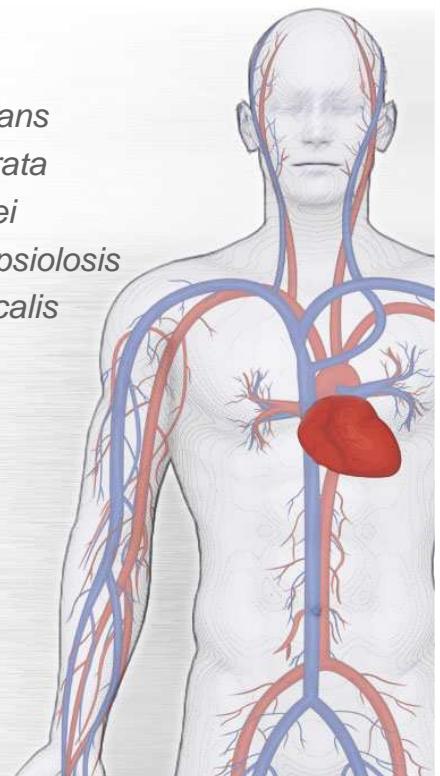
* FDA-Cleared for the first time

Gram - Bacteria:

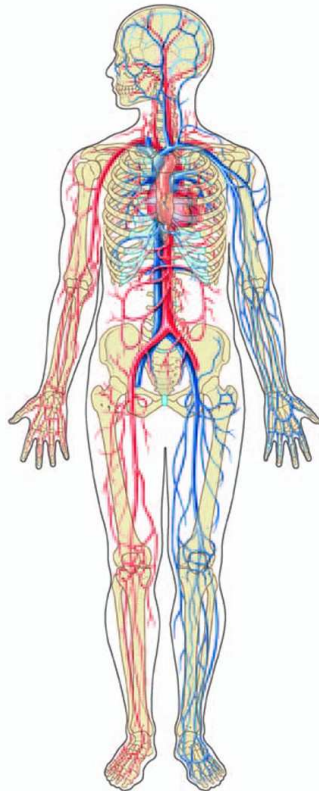
A. baumannii
H. influenzae
N. meningitidis
P. aeruginosa
Enterobacteriaceae
Enterobacter cloacae complex
E. coli
K. oxytoca
K. pneumoniae
Proteus
S. marcescens

Yeast:

C. albicans
C. glabrata
C. krusei
C. parapsiiosis
C. tropicalis



BCID Market Need: Sepsis (패혈증)



Systemic inflammatory response syndrome (SIRS) in response to infection

- can lead to organ failure and death
- : 패혈증으로 죽음에 이를 수도 있음!

Sepsis is the 11th leading cause of death in U.S.

Caused primarily by three main groups of microbes:

gram-positive bacteria

gram-negative bacteria

yeast (*Candida* sp.)

Complicated by antimicrobial resistance

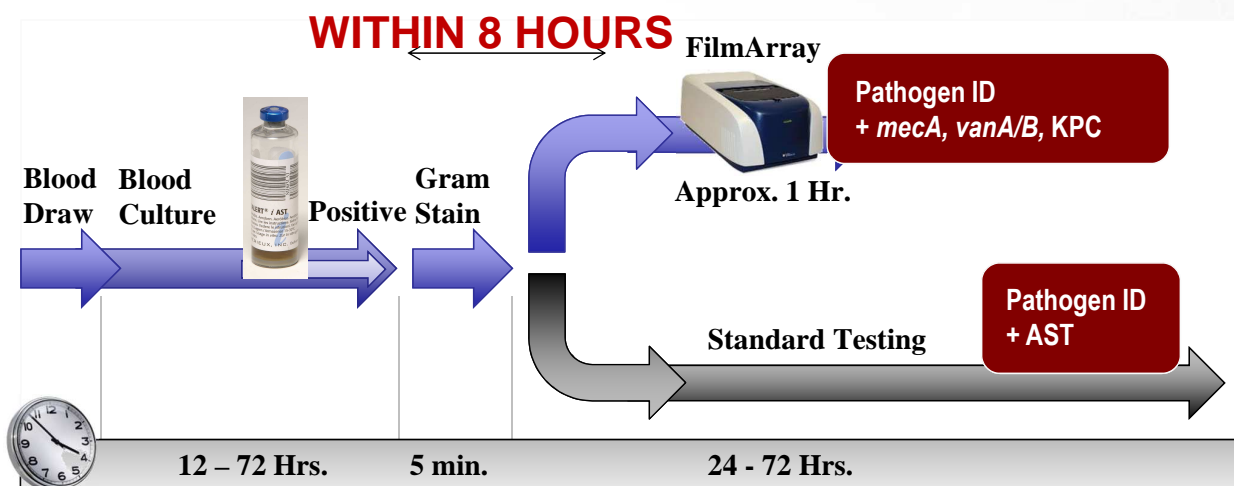
Other terms: septicemia, bacteremia, fungemia (candidemia), bloodstream infection

*패혈증이란?

: 미생물에 감염되어 전신에 심각한 염증 반응이 나타나는 상태

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FilmArray BCID Workflow



FilmArray BCID gives answers faster – but cannot give all of the answers. Standard testing must be completed, especially for antimicrobial susceptibility testing. **BCID can NOT determine susceptibility to antimicrobials.**

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GI Panel FDA Cleared(장관 패널)*식중독균포함

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Bacteria:

Campylobacter

Clostridium difficile (Toxin A/B)

Plesiomonas shigelloides

Salmonella

Vibrio (*parahaemolyticus*, *vulnificus* and *cholerae*)

Vibrio cholerae

Yersinia enterocolitica

Diarrheagenic *E. coli* / *Shigella*

Enteraggregative *E. coli* (EAEC)

Enteropathogenic *E. coli* (EPEC)

Enterotoxigenic *E. coli* (ETEC)

Shiga-like toxin-producing *E. coli* (STEC)

E. coli O157

Shigella/Enteroinvasive *E. coli* (EIEC)

Protozoa:

Cryptosporidium

Cyclospora cayetanensis

Entamoeba histolytica

Giardia lamblia

Viruses:

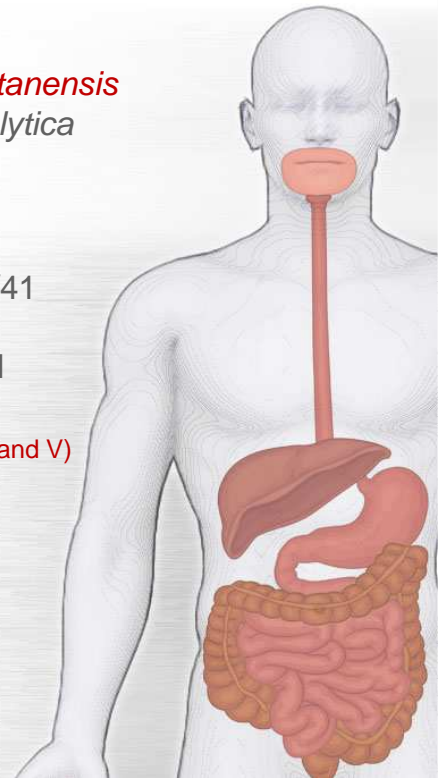
Adenovirus F 40/41

Astrovirus

Norovirus GI/GII

Rotavirus A

Sapovirus (I, II, IV and V)

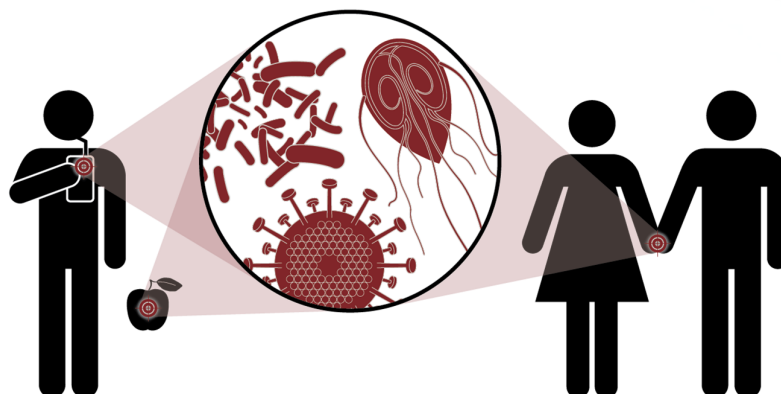


* FDA-Cleared for the first time

Market Needs: Gastrointestinal Infections

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- Diarrhea(설사) is defined as an alteration in normal bowel movement, and is characterized by an increase in water content, volume or frequency of stools¹
 - “Acute diarrhea” is an episode lasting ≤ 14 days¹
 - “Persistent diarrhea” describes episodes lasting >14 days¹
- Diarrhea is usually caused by infection of the gastrointestinal (GI) tract¹
: 설사는 주로 환경 및 음식물에 있는 세균 또는 바이러스가 위장관을 통해 감염되어 발병



- Infection of the GI tract may also produce symptoms of nausea, vomiting and/or abdominal cramps¹

Sample Type

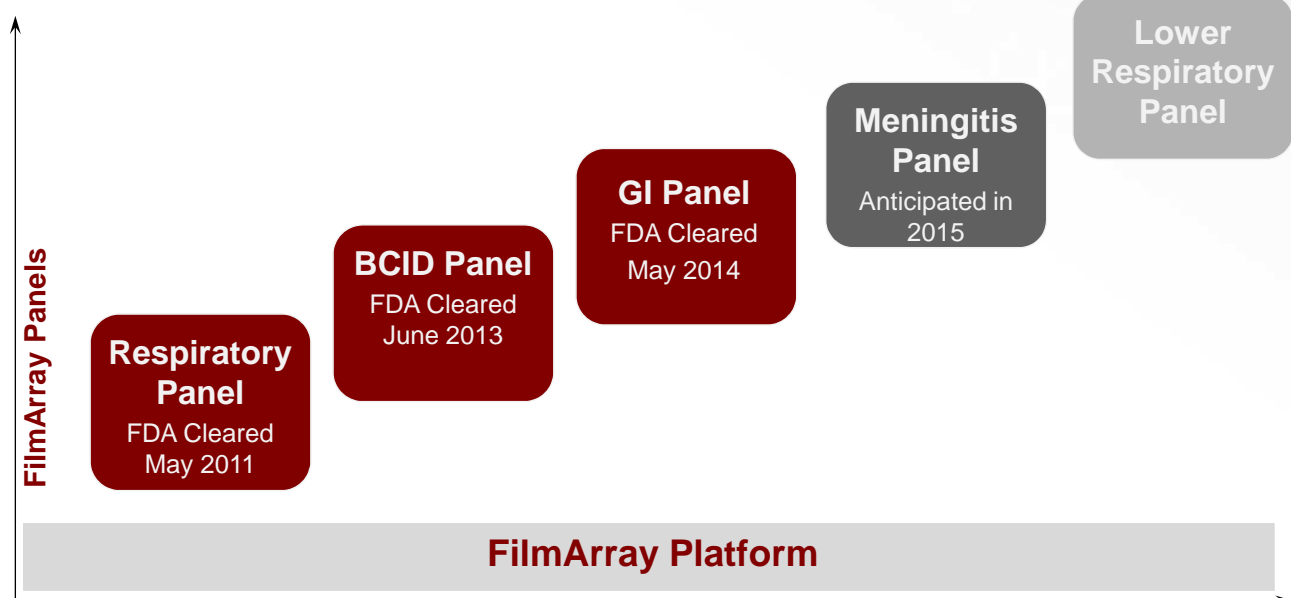


시료는 Stool



시료 채취 및 운반은 stool용 배지인 Cary-Blair Transport medium이용

The Panels



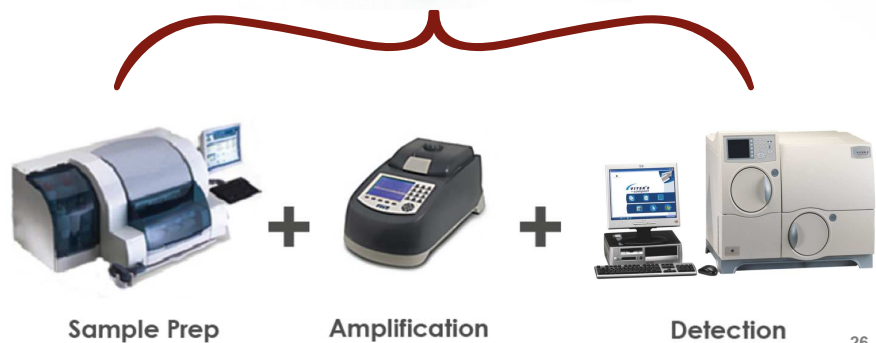
After all panels are FDA-cleared, FilmArray will have assays covering 125 of the most common pathogens that cause death and disease.

THE SYSTEM

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The System How the FilmArray Works

- FilmArray는 '추출 & 증폭 & 검출' 을 한번에 할 수 있는 system,
- Running time 1hr!
- PC 1대에 장비 ~8대까지 연결 가능



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The System

How Results are Reported

FilmArray™ GI Panel		BIOFIRE www.BioFireDx.com	
Run Summary			
Sample ID:	009196-03-0790	Run Date:	27 Sep 2013 12:03 PM
Detected:	<i>Giardia lamblia</i>	Controls:	Passed
Result Summary			
Bacteria			
Not Detected	<i>Campylobacter</i>		
Not Detected	<i>Clostridium difficile</i> toxin A/B		
Not Detected	<i>Plesiomonas shigelloides</i>		
Not Detected	<i>Salmonella</i>		
Not Detected	<i>Vibrio</i>		
Not Detected	<i>Vibrio cholerae</i>		
Not Detected	<i>Yersinia enterocolitica</i>		
Diarrheagenic E. coli/Shigella			
Not Detected	Enteraggregative <i>E. coli</i> (EAEC)		
Not Detected	Enteropathogenic <i>E. coli</i> (EPEC)		
Not Detected	Enterotoxigenic <i>E. coli</i> (ETEC) <i>lt/st</i>		
Not Detected	Shiga-like toxin-producing <i>E. coli</i> (STEC) <i>stx1/stx2</i>		
⊗ N/A	<i>E. coli</i> O157		
Not Detected	<i>Shigella</i> /Enteroinvasive <i>E. coli</i> (EIEC)		
Parasites			
Not Detected	<i>Cryptosporidium</i>		
Not Detected	<i>Cyclospora cayetanensis</i>		
Not Detected	<i>Entamoeba histolytica</i>		
✓ Detected	<i>Giardia lamblia</i>		
Viruses			
Not Detected	Adenovirus F 40/41		
Not Detected	Astrovirus		
Not Detected	Norovirus GI/GII		
Not Detected	Rotavirus A		
Not Detected	Sapovirus		
Run Details			
Pouch:	GI Panel v2.1	Protocol:	Stool FA v2.3
Run Status:	Completed	Operator:	John Madison (jrm)
Serial No.:	00788640	Instrument:	ITI FA "FA1315"
Lot No.:	133813		

• PCR raw data도 볼 수 있음

- ✓ Amplification curve
- ✓ Melting peak

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The System

- Throughput and capacity

		Number of Instruments			
		1	2	3	4
Lab Operating Hours	8 hours	7	14	21	28
	16 hours	14	28	42	56
	24 hours	21	42	63	84

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THE WORKFLOW

Procedure

FilmArray™ Gastrointestinal Panel Quick Guide

To avoid contamination always wear gloves and work behind a protective shield.

Step 1: Prepare Pouch

- Insert pouch into Pouch Loading Station.
- Place **Sample Injection Vial** into **red well**.
- Place **Hydration Injection Vial** into **blue well**.



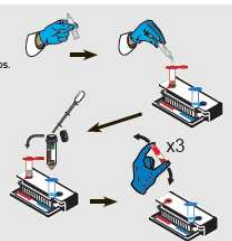
Step 2: Hydrate Pouch

- Twist off **Hydration Injection Vial** cap in Pouch Loading Station, and insert into **pouch hydration port**.
- Forcefully push down to puncture seal and wait as **Hydration Solution** is drawn into pouch.



Step 3: Prepare Sample Mix

- Add **Sample Buffer** to **Sample Injection Vial**:
 - Invert **Sample Buffer Ampoule** so that tip is facing up.
 - Note: Do not touch the tip of the ampoule.
 - Firmly pinch textured plastic tab on side of ampoule until seal snaps.
 - With the tip facing down, dispense **Sample Buffer** into **Sample Injection Vial** using a slow, forceful squeeze, followed by a 2nd squeeze. Avoid generating excessive bubbles.
- Thoroughly mix stool specimen in transport media.
- Using transfer pipette, draw up specimen to 2nd line.
- Add to **Sample Injection Vial**.
- Tightly close lid of **Sample Injection Vial**.
- Mix sample by gently inverting **Sample Injection Vial** 3 times.
- Return **Sample Injection Vial** to **red well** of Pouch Loading Station.



Warning: The Sample Buffer is harmful if swallowed, can cause serious eye damage and/or skin irritation.

Step 4: Load Sample Mix

- Unscrew **Sample Injection Vial** from cap.
- Pause for 3-5 seconds, then remove **Sample Injection Vial**, leaving cap in Pouch Loading Station.
- Insert **Sample Injection Vial** into **pouch sample port**.
- Forcefully push down to puncture seal.
- Wait as **Sample Mix** is drawn into pouch.



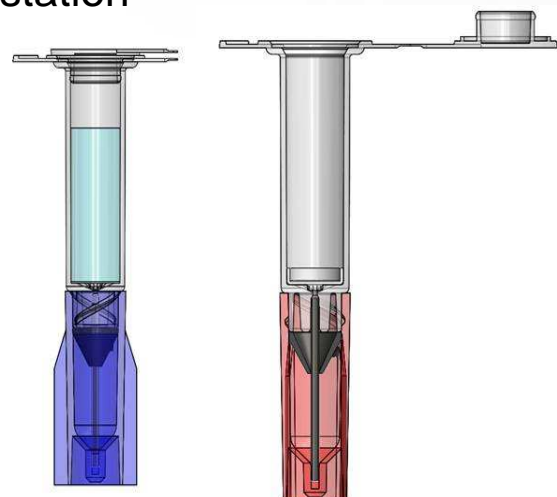
Step 5: Run Pouch

- Follow instructions on computer for initiating a test.
- The pouch will click into place when properly seated.

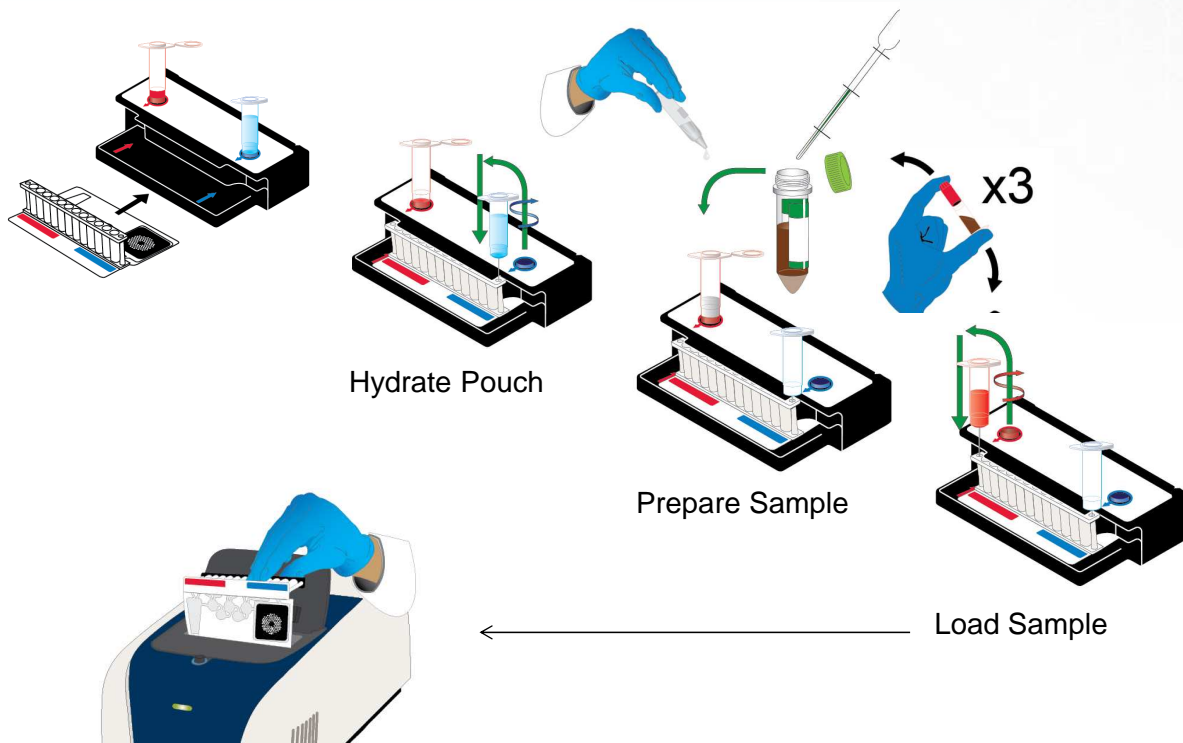
Note: If the pouch does not insert easily, ensure that the lid is opened completely.



FilmArray Injection Vials (FAIVs) and new loading station



Workflow

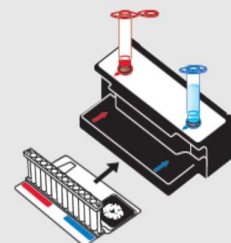


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To avoid contamination always wear gloves and work behind a protective shield.

Step 1: Prepare Pouch

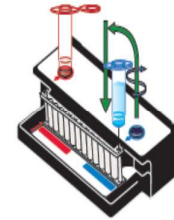
- Insert pouch into Pouch Loading Station.
- Place **Sample Injection Vial** into **red well**.
- Place **Hydration Injection Vial** into **blue well**.



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Step 2: Hydrate Pouch

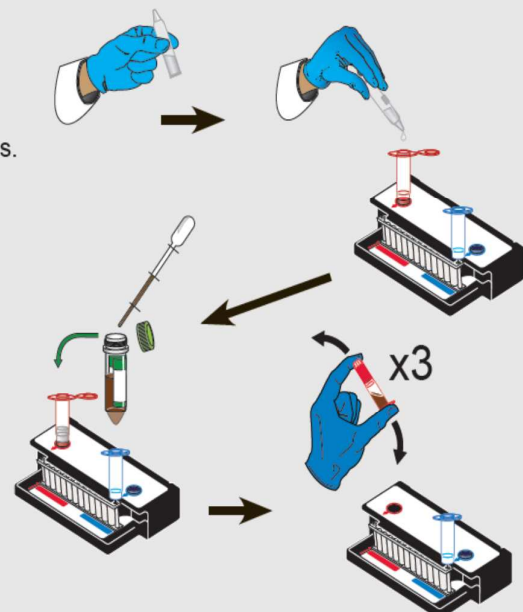
- Twist off **Hydration Injection Vial**, leaving cap in Pouch Loading Station, and insert into **pouch hydration port**.
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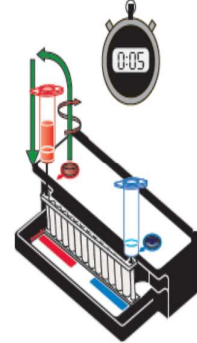


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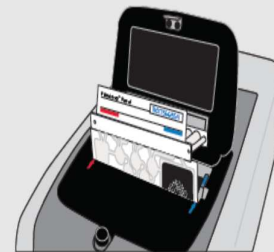


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THE ADVANTAGE

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FilmArray Advantage

- Time
 - Cost
 - Labor
- } saving
- Multiple tests at once
 - Easy to use

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