

**2 Minutes Hands-on-Time. Results in about 1 Hour.**

 **FilmArray BioThreat-E Kit**

Detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) in whole blood and urine specimens.

**Authorized by the US FDA: Oct. 25, 2014**  
**For Use Under the Emergency Use Authorization (EUA) by**  
**CLIA Moderate and High Complexity Laboratories.**

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an Emergency Use Authorization for use by CLIA Moderate and High Complexity Laboratories;
- This test has been authorized only for the detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) and not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection of Ebola Zaire virus under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.



**1**  
**Hour**

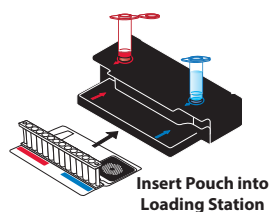
## Simple Ebola Zaire Detection

The easy-to-use, PCR test is performed on the FilmArray Instrument to detect RNA from the Ebola Zaire virus.

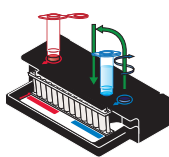
- **Fully Automated:** Sample prep, amplification, identification, and reporting.
- **Single Instrument Integration:** Minimal equipment and consumables.
- **Freeze-dried Reagents:** Room temperature stable.



# Setting up the FilmArray® is Easy – Sample in, Results out



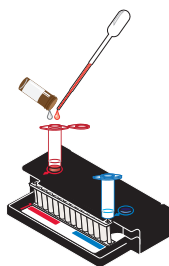
Insert Pouch into Loading Station



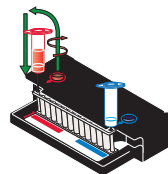
Inject Hydration Solution into Pouch



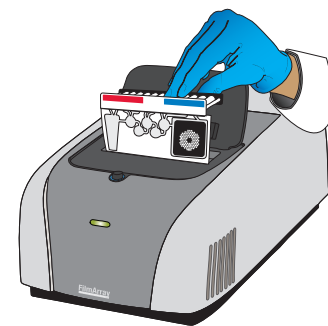
Add Sample Buffer to Protease



Add Protease and Sample



Inject Sample into Pouch



Insert Pouch into FilmArray and Start Run

## Fully Automated Operation

The FilmArray test contains all the required reagents for sample preparation, reverse transcription-PCR, PCR, and detection in a freeze-dried, room temperature stable format. Prior to a run, the operator injects hydration solution and the unknown sample into the pouch. The FilmArray instrument does the rest.

- First, the FilmArray extracts and purifies all nucleic acids from the unknown sample.
- Next, the FilmArray performs reverse transcription followed by nested multiplex PCR. During this first-stage PCR, the FilmArray performs a single, large volume, 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 the target.

## Easy-to-Read Reporting

www.BioFireDefense.com			
<b>Run Summary</b>			
Sample ID:	011409390-0939	Run Date:	05 Nov 2014 4:01 PM
Detected:	Ebola Zaire	Controls:	Passed
<b>Result Summary</b>			
Viruses			
✓ Detected	Ebola Zaire		
<b>Run Details</b>			
Pouch:	BioThreat-E v2.5	Protocol:	BT Blood v2.0
Run Status:	Completed	Operator:	agnes c
Serial No.:	02039119	Instrument:	ITI FA "FA2576"
Lot No.:	141031E		

## Kit Specifications

### Sample Handling

	<b>FilmArray BioThreat-E Kit</b> Part No: RFIT-ASY-0122
Sample Types	Blood and Urine
Sample Volume	200 µL
Tests per Kit	6 Pack Kit

### Reagents

- Freeze-dried in durable plastic pouches
- Room temperature storage

## Instrument Specifications

### Footprint

- Weight: 9 kg (20 lbs)
- Size: 25.4 x 39.3 x 16.5 cm (10 x 15.5 x 6.5 in.)

### Power Requirements

- 90-264 VAC, 10 A

### Performance Parameters

- Hands on time: Approx. 2 minutes
- Run turn-around time: Approx. 1 hour

### Environmental Specification

- Operating: 15 °C to 30 °C at 20 to 80% humidity
- Storage: -30 °C to 65 °C

### Software (Pre-loaded on supplied laptop)

- Windows-based instrument control and data analysis software
- Barcode reader for data input
- Automated qualitative analysis and reporting
- Separate advanced analysis software