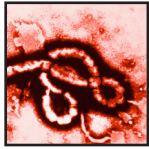




2 Minutes Hands-on-Time. Life Saving Results in 1 Hour.



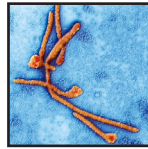
FilmArray NGDS BT-E Assay Kit

Part No: NGDS-ASY-0001

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

Authorized: Oct. 25, 2014
For Use Under the Emergency Use Authorization (EUA) by Laboratories Designated by US DoD.

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an Emergency Use Authorization for use by laboratories designated by DoD;
- 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.



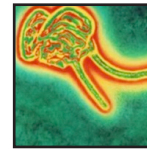
FilmArray BioThreat-E Kit

Part No: RFIT-ASY-0122

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

Authorized: 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.

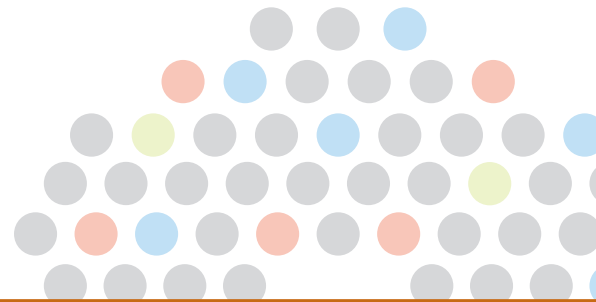


FilmArray BioThreat Kit

Part No: RFIT-ASY-0094

Detection of 16 BioThreat targets including Ebola, Marburg, Anthrax, Ricin and others.

Available Now
For research use only.



1
Hour

Comprehensive Ebola Detection

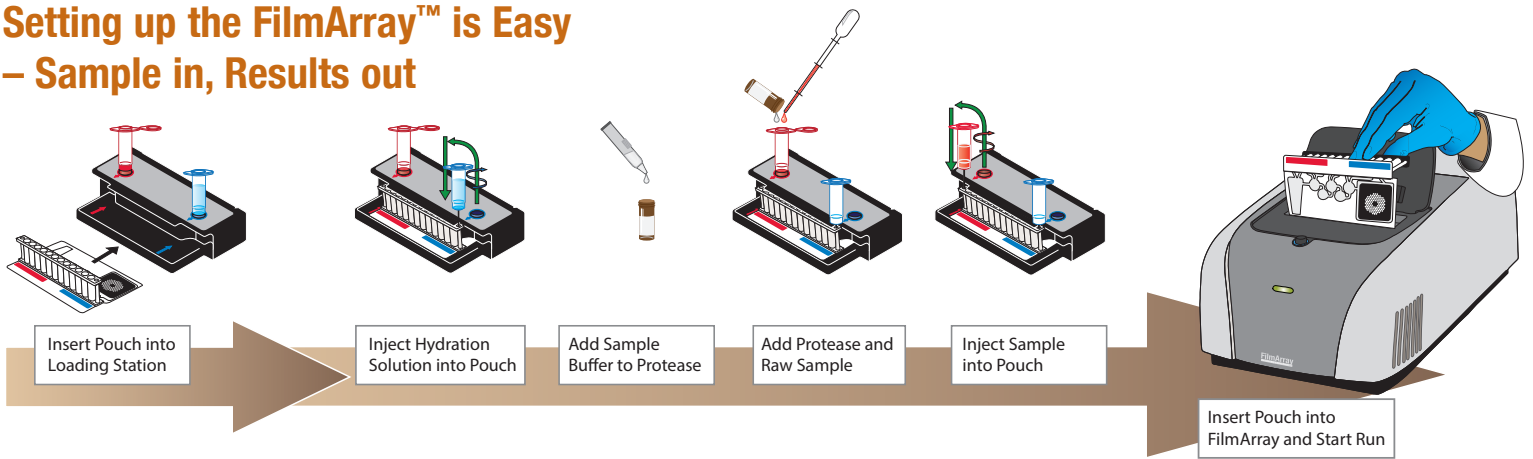
These FilmArray kits provide reliable PCR tests for the detection of Ebola Zaire virus.

The easy-to-use tests are 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



Fully Automated Operation

The FilmArray pouch 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 a nested multiplex PCR. During the 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 each target.

Easy-to-Read Reporting

www.BioFireDefense.com			
Run Summary			
Sample ID:	011409390-0939	Run Date:	05 Nov 2014 4:01 PM
Detected:	Ebola Zaire	Controls:	Passed
Result Summary			
Viruses			
✓ Detected	Ebola Zaire		
Run Details			
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

	BioThreat Kit Part No: RFIT-ASY-0094	NGDS BT-E Assay Part No: NGDS-ASY-0001	BioThreat-E Kit Part No: RFIT-ASY-0122
Sample Types	Swab, liquid, culture, powder	Blood	Blood and Urine
Sample Volume	100/200 µL	200 µL	200 µL
Tests per Kit	6 Pack Kit	30 Pack 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

Desktop 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