FACT SHEET FOR HEALTH CARE PROVIDERS

# Interpreting FilmArray NGDS BT-E Assay Results for Ebola

FACT
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March 2, 2015

**Dear Health Care Provider:**

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to authorize the use of the BioFire Defense FilmArray NGDS BT-E Assay with the FilmArray Instrument to test for the presumptive presence of Ebola Zaire virus (detected in the West Africa outbreak in 2014) in whole blood, plasma and serum specimens from individuals with signs and symptoms of Ebola virus infection or who are at risk for exposure or may have been exposed to the Ebola Zaire virus (detected in the West Africa outbreak in 2014) in conjunction with epidemiological risk factors.

FDA issued this EUA based on data submitted by BioFire Defense, LLC., to FDA and on the U.S. Secretary of Health and Human Services' (HHS) declaration that circumstances exist to justify the emergency use of *in vitro* diagnostic tests for the detection of the Ebola virus. This EUA will terminate when the HHS Secretary's declaration terminates, unless FDA revokes it sooner.

This test should be performed only on individuals with signs and symptoms of Ebola virus infection or who are at risk for exposure or may have been exposed to the Ebola Zaire virus (detected in the West Africa outbreak in 2014).

The information in this Fact Sheet is the minimum necessary to inform you of the significant known and potential risks and benefits of the emergency use of the NGDS BT-E Test. For more information on this EUA, please see FDA's website at: http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm.



## Why is this test needed at this time?

At this time, no FDA-approved/cleared tests that can detect Ebola Zaire virus (detected in the West Africa outbreak in 2014) in clinical specimens are available. BioFire Defense has developed the NGDS BT-E Test to detect Ebola Zaire virus (detected in the West Africa outbreak in 2014) infections in the specified population.

If infection with Ebola Zaire virus (detected in the West Africa outbreak in 2014) is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, the NGDS BT-E Test should be ordered only to presumptively diagnose Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection. This test is authorized for use with whole blood, plasma and serum. Specimens should be collected with appropriate infection control precautions for Ebola viruses, according to the manufacturer's instructions for the specimen collection device.

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having Ebola Zaire virus infection. These specimens should be shipped according to the specified shipping protocol only to a laboratory designated by DoD for analysis.

Current Guidance on Personal Protective Equipment To Be Used by Healthcare Workers During Management of Patients with Ebola Virus Disease in U.S. Hospitals, Including Procedures for Putting On (Donning) and Removing (Doffing) is found at://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html. All information and guidelines, including those on Ebola Zaire virus laboratory testing, may change as we continue to learn more about this virus. Please check the CDC Ebola website regularly for the most current information http://www.cdc.gov/vhf/ebola/index.html.

## What does it mean if the specimen tests positive for Ebola Zaire virus?

A positive test result from the NGDS BT-E Test indicates that the patient is presumptively infected with the Ebola Zaire virus (detected in the West Africa outbreak in 2014). The test does not indicate the stage of infection nor does it distinguish between different Ebola Zaire virus strains. Laboratory test results should always be considered in the context of clinical observations and epidemiologic data in making a final diagnosis.

The NGDS BT-E Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, the patient may be placed in isolation or in contact with other potentially infected/infected patients. While isolation or quarantine measures may likely already be in place for symptomatic persons meeting the case definition, there is a chance that quarantine may also be used for asymptomatic persons who test positive. Any positive test obtained in a laboratory designated by DoD should be immediately reported to USAMRIID, Diagnostics Services Division (1-301-619-4357/1202). All laboratories using this test must follow the recommended or standard confirmatory testing and reporting guidelines.

## What does it mean if the specimen tests negative for Ebola Zaire virus?

A negative test presumes that Ebola Zaire virus (detected in the West Africa outbreak in 2014) is not present at the detection level of the assay. However, negative results do not preclude Ebola Zaire virus infection, and should not be used as the sole basis for treatment or other patient management decisions. The clinical features of the illness and the type and risk of exposure are the keys to making patient management and isolation decisions. A negative NGDS BT-E Test result should not be interpreted as demonstrating that the patient does not have Ebola Zaire virus infection. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that Ebola Zaire virus infection is likely, and diagnostic tests for other causes of illness are negative.

## Reporting Adverse Events

Any adverse events should be sent to the following website: http://biofiredefense.com/support/filmarray-support/BioThreat-E Report

Give patients the **Fact Sheet for Patients: Understanding Results from the FilmArray NGDS BT-E Test for Ebola. (MRKT-PRT-0306)**

## Contact Information for Technical Assistance for the NGDS BT-E Test

**BioFire Defense Technical Assistance**
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Health care providers will be contacted by the DoD's Joint Project Management Office, Medical Countermeasures System (MCS), in the event of any significant new findings observed during the course of the emergency use of the NGDS BT-E Test.



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For additional information about technology and other BioFire Defense products, please visit us at www.BioFireDefense.com or call 1-801-262-3592.

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