

# Fact Sheet for Health Care Providers: Interpreting *Ebola Zaire (Target 1) Real-Time PCR (TaqMan<sup>®</sup>) (EZ1 rRT-PCR) Assay Results*

October 10, 2014

## Dear Health Care Provider:

If you have received this Fact Sheet, it is because the U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to authorize the use of the U.S. Department of Defense (DoD) EZ1 rRT-PCR Assay with specified instruments to test for the presumptive presence of Ebola Zaire virus (detected in the West Africa outbreak in 2014) in whole blood, plasma, Trizol-inactivated whole blood, or Trizol-inactivated plasma specimens from individuals in affected areas 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 DoD 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). Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having Ebola Zaire virus infection.

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 EZ1 rRT-PCR Assay. 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 identify the existence of the Ebola Zaire virus (detected in the West Africa outbreak in 2014) in clinical specimens are available. Therefore, DoD has developed the EZ1 rRT-PCR Assay to detect Ebola Zaire virus (detected in the West Africa outbreak in 2014) infections in the specified population.

Current information on hemorrhagic fever virus infections for health care workers, including case definitions and infection control guidelines, is available in the guideline, *Infection Control for Viral Hemorrhagic Fevers in the African Health Care Setting*, developed by the U.S. Centers for Disease Control and Prevention (CDC) in conjunction with the World Health Organization (WHO) and found at <http://www.cdc.gov/vhf/abroad/healthcare-workers.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/outbreaks/guinea/>).

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 EZ1 rRT-PCR Assay 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 or plasma, as well as with Trizol-inactivated whole blood or Trizol-inactivated plasma. Specimens should be collected with appropriate infection control precautions for Ebola viruses according to instructions for the specimen collection device and shipped according to the specified shipping protocol only to a laboratory designated by DoD for analysis.

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

A positive test result from the EZ1 rRT-PCR Assay 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 EZ1 rRT-PCR Assay 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 (1-301-619-6357/1202). 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 the Ebola Zaire virus?**

A negative test presumes that Ebola Zaire virus (detected in the West Africa outbreak in 2014) was 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 EZ1 rRT-PCR Assay 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 hemorrhagic illness are negative.

### **Reporting Adverse Events**

Any adverse events should be sent to the following website:  
[https://mrmc.amedd.army.mil/index.cfm?pageid=medical\\_r\\_and\\_d.regulated\\_activities.overview](https://mrmc.amedd.army.mil/index.cfm?pageid=medical_r_and_d.regulated_activities.overview)

**Give patients the *Fact Sheet for Patients: Understanding Results from the Ebola Zaire (Target 1) Real-Time PCR (TaqMan®) (EZ1 rRT-PCR) Test.***

**Contact Information for Instrument Manufacturers:**

JBAIDS Operators Help Line/Technical Assistance  
JBAIDS Training School  
3599 Winfield Scott Road  
Bldg. 2841, Suite 0310  
Ft. Sam Houston, TX 78234  
Phone (commercial): 1-210-221-7702 or 1-210-221-6048  
DSN: 471-7702 or 471-6048

LightCycler  
Roche Diagnostics Corporation  
9115 Hague Road  
P.O. Box 50414  
Indianapolis, IN 46250-0414 USA  
Phone: 1-800-262-4911

ABI7500 FAST DX  
Applied Biosystems  
850 Lincoln Centre Drive  
Foster City, CA 94404 USA  
Phone: 1-650-638-5800 | Toll Free: 1-800-327-3002

**Contact Information for Technical Assistance for the EZ1 rRT-PCR Assay:**

USAMRIID, Diagnostics Services Division  
Field Operations and Training  
1425 Porter Street  
Fort Detrick, MD 21702-5011  
Phone (commercial): 1-301-619-6357/1202  
DSN: 343-6357/1202

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 EZ1 rRT-PCR assay.