

# Fact Sheet for Health Care Providers: Interpreting Xpert® Ebola Assay Test Results

March 23, 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 Cepheid Xpert® Ebola Assay (hereafter referred to as the Xpert Ebola Assay) with the Cepheid GeneXpert® Instrument Systems to test for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) in EDTA venous whole blood specimens from individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors.

FDA issued this EUA based on data submitted by Cepheid 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 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 in conjunction with epidemiological risk factors.

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 Xpert Ebola 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 can detect Ebola Zaire virus (detected in the West Africa outbreak in 2014) in clinical specimens are available. Cepheid has developed the Xpert Ebola Assay 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 Xpert Ebola 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 EDTA whole blood collected by venipuncture. Specimens should be collected with appropriate infection control precautions for Ebola viruses, according to instructions for the specimen collection device.

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having Ebola virus infection. These specimens should be shipped for analysis only to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform moderate complexity and high complexity tests or to similarly qualified non-U.S. laboratories. For additional information, refer to the U.S. Centers for Disease Control and Prevention (CDC) *Guidance for Collection, Transport and Submission of Specimens for Ebola Virus Testing* (<http://www.cdc.gov/vhf/ebola/healthcare-us/laboratories/specimens.html>).

Current information about Ebola virus disease for health care workers, including case definitions and infection control, is available in the guideline, *Infection Control for Viral Hemorrhagic Fevers in the African Health Care Setting*, developed by the 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 virus laboratory testing, may change as we continue to learn more about this virus. Please check the CDC Ebola (Ebola Virus Disease) 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 virus?**

A positive test result from the Xpert Ebola Assay indicates that the patient is presumptively infected with 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 virus species. Laboratory test results should always be considered in the context of clinical observations and epidemiologic data in making a final diagnosis.

The Xpert Ebola 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. Isolation measures may likely already be in place for symptomatic persons meeting the case definition. 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 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 virus infection and should not be used as the sole basis for treatment, public health, 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 Xpert Ebola Assay result should not be interpreted as demonstrating that the patient does not have Ebola 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 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 email address:  
[TechSupport@cepheid.com](mailto:TechSupport@cepheid.com)

**Give patients the *Fact Sheet for Patients: Understanding Results from the Cepheid® Xpert® Ebola Assay*.**

**Contact Information for Cepheid GeneXpert Instrument Systems:**

Mail: [TechSupport@cepheid.com](mailto:TechSupport@cepheid.com)

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089-1189  
USA  
Technical Services Phone: +1 888 838 3222

**Contact Information for Technical Assistance for the Xpert Ebola Assay:**

Mail: [TechSupport@cepheid.com](mailto:TechSupport@cepheid.com)

Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089-1189  
USA  
Technical Services Phone: +1 888 838 3222

Contact information for other Cepheid offices is available on the website at [www.cepheid.com](http://www.cepheid.com) or [www.cepheidinternational.com](http://www.cepheidinternational.com) under the **SUPPORT** tab. Select the **Contact Us** option.

Health care providers will be contacted by Cepheid in the event of any significant new findings observed during the course of the emergency use of the Xpert Ebola Assay.