

# Fact Sheet for Health Care Providers: Interpreting Idylla™ Ebola Virus Triage Test Results

May 26, 2016

## 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 Biocartis Idylla™ Ebola Virus Triage Test with the Biocartis Idylla™ Instrument System to test for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) in EDTA venous whole blood specimens obtained from individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors.

The FDA issued this EUA based on data submitted by Biocartis NV 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 to inform you of the significant known and potential risks and benefits of the emergency use of the Idylla™ Ebola Virus Triage 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. Biocartis NV has developed the Idylla™ Ebola Virus Triage 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 Idylla™ Ebola Virus Triage 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 EDTA whole blood collected by venipuncture. Specimens should be collected with appropriate infection control precautions for Ebola viruses, in accordance with the instructions for the specimen collection device.

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having Ebola virus infection. The specimens should be shipped for analysis only to laboratories in the United States 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, please 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), which can be 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 regularly check the CDC Ebola (Ebola Virus Disease) website 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 Idylla™ Ebola Virus Triage Test 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 epidemiological data in making a final diagnosis.

The Idylla™ Ebola Virus Triage 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 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 Idylla™ Ebola Virus Triage Test 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 the illness are negative.

## Reporting Adverse Events

Any adverse events should be sent to the following email address:  
[customerservice@biocartis.com](mailto:customerservice@biocartis.com)

**Give patients the *Fact Sheet for Patients: Understanding Results from the Idylla™ Ebola Virus Triage Test*.**

### **Contact Information for Biocartis Idylla™ Instrument System and the Idylla™ Ebola Virus Triage Test:**

E-Mail: [customerservice@biocartis.com](mailto:customerservice@biocartis.com)

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**Contact information for other Biocartis offices is available on the website at**  
[www.biocartis.com](http://www.biocartis.com)

Health care providers will be contacted by Biocartis in the event of any significant new findings that negatively impact the performance of the test and that are observed during the course of the emergency use of the Idylla™ Ebola Virus Triage Test.