

Fact Sheet for Patients: Understanding Results from the Idylla™ Ebola Virus Triage Test

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Dear Patient:

What is the Idylla™ Ebola Virus Triage Test?

If you have received this Fact Sheet, your blood samples were tested to help determine whether you may be infected with the Ebola Zaire virus (detected in the West Africa outbreak in 2014). The test that has been used on your blood is called the Idylla™ Ebola Virus Triage Test.

The Biocartis Idylla™ Ebola Virus Triage Test is a laboratory test designed to help detect Ebola Zaire virus in certain individuals. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). However, due to the ongoing Ebola emergency in West Africa, FDA has authorized the emergency use of this test under an Emergency Use Authorization (EUA).

What is the Ebola Zaire virus?

The Ebola Zaire virus is one of the four Ebola viruses that cause Ebola virus disease. Ebola virus disease is a severe, often-fatal disease in humans that has appeared sporadically since it was first recognized in 1976. Recently, a large number of human cases of Ebola Zaire virus infection have been identified in West Africa. Public health officials have determined that this virus is contagious and can spread from person-to-person.

Why was my sample tested using the Idylla™ Ebola Virus Triage Test?

Your blood sample was tested using the Idylla™ Ebola Virus Triage Test to help determine whether you are infected with Ebola Zaire virus. The results of this test, along with other information, could help your health care provider make decisions about how to take care of you. The test results could also help public health officials identify and limit the spread of this virus in your community.

What are the known risks and benefits of the Idylla™ Ebola Virus Test?

Besides minimal potential discomfort during sample collection, there is a very small risk that the reported test result would be incorrect (see next paragraphs for more information). The benefit of having this test is that the results of this test, combined with other information, can help your health care provider to take better care of you. Moreover, by knowing whether or not you are infected, you can help to prevent the spread of the virus to your family and others.

If the test result is positive, does that mean that I have Ebola infection?

If you have a positive test result, it is very likely that you have Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection. Therefore, it is also likely that you may be placed in isolation to avoid transmitting the virus to others. There is a very small chance that this test can give a positive result that is wrong; that is called a false positive result. However, your health care provider will decide how to care for you, based on the test results, along with other factors of your illness (such as symptoms, possible exposures to the virus, and geographic location).

If the test result is negative, does that mean that I do not have Ebola infection?

Most - but not all - people with Ebola Zaire virus infection will have a positive test result. Therefore, if your test is negative, something else may be responsible for your illness. There is a very small chance that this test can give a negative result that is incorrect (called a false negative), meaning that you could possibly still have an Ebola Zaire virus infection, even though the test result is negative. Therefore, while a negative test result most likely means that you do not have an Ebola Zaire virus infection, your health care provider must consider the test result together with all other aspects of your illness (such as symptoms, possible exposures, and geographical location) in deciding how to treat you.

What is an Emergency Use Authorization (EUA)?

An EUA is a tool that the FDA can use to allow the use of certain medical products for emergencies based on available scientific data. The U.S. Secretary of Health and Human Services (HHS) has declared that circumstances exist to allow the emergency use of *in vitro* diagnostics, such as the Idylla™ Ebola Virus Triage Test, for detecting the Ebola virus. At this time, there are no FDA-approved/cleared alternative tests available that can detect Ebola virus.

FDA has authorized the emergency use of the Idylla™ Ebola Virus Triage Test to test for the presence of Ebola Zaire virus in blood specimens. Use of the test is authorized only for the duration of the threat of the emergency, unless it is revoked by FDA sooner.

This Fact Sheet contains information to help you understand the significant known and potential risks/benefits of the use of the Idylla™ Ebola Virus Triage Test. You may want to discuss with your health care provider the benefits and risks described in this Fact Sheet.

How can I learn more?

Updates about Ebola Zaire virus infection or significant new findings observed during the course of the emergency use of this test will be made available at:

<http://www.cdc.gov/vhf/ebola/index.html> .

Please also contact your doctor if you have any questions.