Fact Sheet for Patients: Understanding Results from the ReEBOV™ Antigen Rapid Test

March 16, 2015

What is the ReEBOV™ Antigen Rapid Test?

If you have received this Fact Sheet, your blood samples were tested to help determine whether you may be infected with an Ebola virus (including the Zaire Ebola virus strain detected in the West Africa outbreak in 2014). The test that was used on your fingerstick (capillary) whole blood, venous whole blood or plasma is called the ReEBOV™ Antigen Rapid Test.

The Corgenix Inc. ReEBOV™ Antigen Rapid Test is a laboratory test designed to help detect Ebola viruses 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 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 ReEBOV™ Antigen Rapid Test?

Your blood sample was tested using the ReEBOV™ Antigen Rapid Test to help determine whether you are infected with Ebola virus. The results of this test, along with other information, may help your health care provider take better 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 ReEBOV™ Antigen Rapid Test?

Besides minimal potential discomfort during sample collection, there is a very small risk that the test result reported is incorrect (see next paragraphs for more information). The benefit of having this test is that the results of this test, along with other information, can help your health care provider take better care of you. Also, knowing your test results may help to prevent the spread of the virus to your family or others.

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

If you have a positive test, it is very likely that you have Ebola virus infection. Therefore, it is also likely that you may be placed in isolation to avoid transmitting the virus to others. There is a small chance that this test can give a result that is wrong; this 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 this test is negative, does that mean that I do not have Ebola infection?

Most, but not all, people with Ebola virus infection will have a positive test. Therefore, if your test is negative, something else may be responsible for your illness. There is a small chance that this test can give a negative result that is wrong (called a false negative) meaning you could possibly still have an Ebola virus infection even though the test is negative. Therefore, while a negative test most likely means you do not have an Ebola 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 FDA can use to allow the use of certain medical products for emergencies based on 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 ReEBOV™ Antigen Rapid 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 ReEBOV™ Antigen Rapid Test to test for the presence of Ebola virus in plasma specimens. Use of this test is authorized only for the duration of the threat of the emergency, unless it is revoked by FDA sooner.

The information in this Fact Sheet is the minimum necessary to inform you of the significant known and potential risks and benefits of the use of the ReEBOV™ Antigen Rapid 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.