

Fact Sheet for Patients: Understanding Results from the CDC Ebola Virus VP40 Real-Time RT-PCR (EBOV VP40 rRT-PCR) Assay

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Dear Patient:

If you have received this Fact Sheet, your blood or urine specimen(s) have been tested to help determine whether you may be infected with Ebola virus, including the strain causing the current West African outbreak. The test that was used on your specimen(s) is called the Centers for Disease Control and Prevention (CDC) Ebola Virus VP40 Real-Time RT-PCR (EBOV VP40 rRT-PCR) Assay, which is a laboratory test designed to help detect Ebola virus in humans. Although the test has not been cleared or approved by the U.S. Food and Drug Administration (FDA), the FDA has authorized its use on an emergency basis, due to the ongoing Ebola emergency in West Africa.

What is Ebola?

Ebola is caused by infection with Ebola virus. Recently, many human cases of Ebola have been identified in West Africa. When infection occurs, symptoms usually begin between 2 and 21 days after exposure to Ebola virus although 8-10 days is typical. Ebola is transmitted to people by contact with blood and body fluids (such as saliva, sweat, urine, semen, feces, or vomit) of other infected person(s) and objects (like needles and syringes) that have been contaminated with the virus. Ebola is not spread through the air or by water, or in general, through food. However, in Africa, Ebola may be spread as a result of handling bushmeat (wild animals hunted for food) and contact with infected bats. Ebola virus only spreads when people are sick. A patient must have symptoms to spread the virus to others.

Most confirmed patients with Ebola develop fever, severe headache, joint and muscle aches, weakness, diarrhea, vomiting, stomach pain, and lack of appetite. Some experience a rash, red eyes, hiccups, cough, sore throat, chest pain, difficulty breathing, difficulty swallowing, or unexplained bleeding inside and outside of the body.

Why was my specimen tested using the EBOV VP40 rRT-PCR?

The blood or urine specimen(s) collected from you was tested using the EBOV VP40 rRT-PCR 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 and potential risks and benefits of the EBOV VP40 rRT-PCR?

Besides minimal potential discomfort during specimen collection, there is a very small risk that the test result is incorrect (see next paragraphs for more information). The benefit of having this test is that the test results, along with other information, can help your health care provider take better

care of you. Also, knowing your test results may help prevent the spread of the virus to your family or others.

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

If you have a positive test, it is very likely that you have Ebola, and you will likely be placed in isolation to prevent transmission of the virus to others. There is a very small chance that this test can give a positive result that is wrong; this is called a false positive result. If your result from this test is positive, your health care provider can use this information together with all other characteristics of your illness (such as symptoms, possible exposures to the virus, and places you have traveled recently) to determine how to best care for you.

If this test is negative, does it mean that I do not have Ebola?

If you have a negative test, you probably do not have Ebola and are most likely sick with something else. 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 Ebola, even though the test is negative. A false negative result might cause any or all of the following: delayed treatment, potential lack of treatment, or stopping treatment too soon. While a negative test most likely means you do not have Ebola, your health care provider must consider the test result together with all other aspects of your illness (such as symptoms, time since onset of symptoms, possible exposures, and places you have traveled recently) in deciding how to treat you.

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 EBOV VP40 rRT-PCR. You may want to discuss with your health care provider the benefits and risks of the EBOV VP40 rRT-PCR test.

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 certain 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 Ebola diagnostic tests, such as the EBOV VP40 rRT-PCR test, for detecting the Ebola virus.

At this time, there are no FDA approved/cleared alternative tests available that detect Ebola virus. Therefore, FDA has authorized the emergency use of the EBOV VP40 rRT-PCR to test for the presence of Ebola virus in blood and urine specimens. Use of this test is authorized only for the duration of the threat of the emergency, unless it is terminated or revoked by FDA sooner.

How can I learn more?

Information about Ebola and any significant new findings observed during the course of the emergency use of the EBOV VP40 rRT-PCR Assay will be made available at <http://www.cdc.gov/vhf/ebola/resources/index.html>. Please also contact your health care provider if you have any questions.