Fact Sheet for Relatives and Caregivers: Understanding Results from the OraQuick® Ebola Rapid Antigen Test

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What is the OraQuick® Ebola Rapid Antigen Test?

If you have received this Fact Sheet, oral fluid samples from your deceased loved one were tested to help determine whether he/she 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 the oral fluid sample is called the OraQuick® Ebola Rapid Antigen Test.

The OraSure Technologies, Inc. OraQuick® Ebola Rapid Antigen Test is a laboratory test designed to help detect Ebola virus in individuals suspected to have died of Ebola. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). However, due to the recent 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 authorities have determined that this virus is contagious and can spread from person-to-person.

Why was the deceased tested using the OraQuick® Ebola Rapid Antigen Test?

The deceased's oral fluid was tested using the OraQuick® Ebola Rapid Antigen Test to help determine whether he/she was infected with Ebola virus. The results of this test, along with other information, will inform decisions on safe and dignified burial procedures to prevent transmission of the Ebola Zaire virus to you, your family and anybody that may have come in contact with the body.

What are the known risks and benefits of the OraQuick® Ebola Rapid Antigen Test?

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, will allow for safe and dignified burial procedures to prevent the spread of the virus to your family or others. The test result can help to determine whether you, your family or any other person that came in contact with the deceased during his/her illness or after his/her death are at risk for having contracted the Ebola virus from the deceased.

If this test is positive, does that mean that the deceased died of Ebola infection?

If the test is positive, it is very likely that the person tested died from Ebola virus infection. If the result is positive, you, your family and any other person that had contact with the deceased during his/her illness or after his/her death may be contacted by public health authorities for further guidance. There is a small chance that this test can give a positive result that is wrong; this is called a false positive result. If the result is positive you should contact your health care provider who will decide how to care for you based on the test results, along with other factors (such as symptoms, possible exposures to the virus, and geographic location).

If this test is negative, does that mean that the deceased did not have Ebola infection?

Most, but not all, people with Ebola virus infection will have a positive test. Therefore, if the test is negative, something else may have been responsible for the death of the deceased. There is a small chance that this test can give a negative result that is wrong (called a false negative result) meaning the deceased could have died from an Ebola virus infection even though the test is negative.

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 OraQuick® Ebola Rapid Antigen 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 OraQuick® Ebola Rapid Antigen Test to test for the presence of Ebola virus in oral fluid specimens of individuals suspected to have died of Ebola. 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 necessary to inform you of the significant known and potential risks and benefits of the OraQuick® Ebola Rapid Antigen Test.

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.