

OraQuick Ebola 2.0 Rapid Antigen Test

OraSure Technologies, Inc.

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For the most up to date Ebola disease information, including symptoms, please visit:

<https://www.cdc.gov/ebola/about/>

Your loved one's sample(s) was tested for a virus that causes Ebola disease using the OraQuick Ebola 2.0 Rapid Antigen Test.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of Ebola disease. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

WHAT IS EBOLA DISEASE?

Ebola disease is caused by a group of viruses¹ that can be spread from person-to-person by contact with blood and body fluids (such as saliva, sweat, urine, semen, feces, or vomit) from a person who is sick or has died from Ebola disease. Ebola disease can also be spread by handling objects (like needles, syringes, bedding, or clothing) that have been contaminated with these viruses. The viruses may also be spread by handling sick or dead animals and/or contact with infected bats collected from or within areas where Ebola disease has occurred previously. People are only contagious once they begin showing signs or symptoms of illness (such as fever, diarrhea, vomiting, etc.). These viruses can cause serious illness that, without treatment, can cause death.

WHAT IS THE ORAQUICK EBOLA 2.0 RAPID ANTIGEN TEST?

The OraQuick Ebola 2.0 Rapid Antigen Test is designed to detect proteins from viruses that cause Ebola disease in the oral fluid of a deceased individual.

WHY WAS MY LOVED ONE'S SPECIMEN TESTED?

Your loved one's sample(s) were tested to help determine whether they may have been infected with a virus that causes Ebola disease. The deceased individual may have:

- Lived in or have recently traveled to a place where an Ebola disease outbreak is occurring, and/or
- Had typical signs and symptoms of Ebola disease before they passed, such as fever, severe headache, joint and muscle aches, weakness, diarrhea, vomiting, stomach pain, and lack of appetite. Some individuals may also have developed a rash, red eyes, hiccups, cough, sore throat, chest pain, difficulty breathing, difficulty swallowing, or unexplained bleeding inside and outside of the body.
- Had another possible exposure to one of the viruses that can cause Ebola disease.

The results of this test, along with other information, will inform decisions on safe and dignified burial procedures to prevent transmission of Ebola disease to you, your family and anybody that may come in contact with the deceased individual's body.

WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?

Potential risks include:

- Possible incorrect/wrong test result (see below for more information).

¹ Orthoebolaviruses that cause Ebola disease include *Orthoebolavirus zairense*, *Orthoebolavirus bundibugyoense*, *Orthoebolavirus sudanense*, and *Orthoebolavirus taiense*.

Potential benefits include:

- The results, along with other information, can help make informed recommendations on safe and dignified burial procedures for your deceased loved one to limit the spread of Ebola disease to you, your family and anybody that may have or will come in contact with the deceased individual's body.

WHAT DOES A POSITIVE TEST RESULT MEAN?

If the test result is positive, it is very likely that the deceased individual had Ebola disease at the time of death. 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. Additionally, you should contact your healthcare 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). There is a small chance that this test can give a positive result that is wrong (called a false positive result).

WHAT DOES A NEGATIVE TEST RESULT MEAN?

A negative test result means that protein from a virus that causes Ebola disease was not found in the deceased's sample. If the test is negative, the deceased individual may not have had Ebola disease at the time of death. It is possible that this test can give a negative result that is wrong (called a false negative result) meaning the deceased could have had Ebola disease at the time of death even though the test is negative.

WHAT IS AN EUA?

This test has been issued an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA). FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternative tests. The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of laboratory tests for the detection and/or diagnosis of Ebola virus.² This EUA will remain in effect (meaning this test can be used) for the duration of the Ebola virus declaration justifying the emergency use of in vitro diagnostics, unless the declaration is terminated, or authorization is revoked sooner. An EUA is NOT an FDA-approval or clearance.

WHAT ARE THE APPROVED AVAILABLE ALTERNATIVES?

Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at:

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices#ebola>

² The names of the viruses that cause Ebola disease have changed over time. Recently, the species name of the virus that includes the strain of Ebola virus detected in the 2014 West African outbreak was changed to *Orthoebolavirus zairense*.