

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 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 the 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 whole blood samples.

WHY WAS MY SAMPLE TESTED?

Your sample(s) were tested because your healthcare provider believes you may have been exposed to one of the viruses that can cause Ebola disease based on your signs and symptoms, and/or because:

- You live in or have recently traveled to a place where an Ebola disease outbreak is occurring, and/or
- Because you have another possible exposure to one of the viruses that can cause Ebola disease.

Typical signs and symptoms of Ebola disease include fever, severe headache, joint and muscle aches, weakness, diarrhea, vomiting, stomach pain, and lack of appetite. Some individuals may also develop a rash, red eyes, hiccups, cough, sore throat, chest pain, difficulty breathing, difficulty swallowing, or unexplained bleeding inside and outside of the body.

The sample(s) collected from you were tested to help find out whether you may be infected with one of the viruses that can cause Ebola disease.

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

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect 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 your healthcare provider make informed recommendations about your care, including appropriate treatment.
- The results of this test may help limit the spread of Ebola disease to your family, intimate partners, medical personnel, and others you come into close contact with.

WHAT DOES A POSITIVE TEST RESULT MEAN?

If you have a positive test result, it is very likely that you are infected with a virus that causes Ebola disease. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive result). However, your healthcare provider will work with you to determine how best to care for you based on the test results along with other factors such as your medical history, symptoms, possible exposures, geographic location of places you have recently traveled, and advice from your local public health authorities.

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 your sample. If your test result is negative, something else may be responsible for your illness. There is a chance that this test can give a negative result that is wrong (called a false negative result) meaning that you could possibly still have Ebola disease even though the test result is negative. Therefore, 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 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 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*.