OraQuick Ebola 2.0 Rapid Antigen Test

OraSure Technologies, Inc.

July 21, 2026

All individuals whose specimens are tested with this product will receive the Fact Sheet for Patients for the product.

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the OraQuick Ebola 2.0 Rapid Antigen Test.

WHERE CAN I GO FOR GENERAL INFORMATION ON EBOLA DISEASE?

For general information on Ebola disease, caused by a group of viruses known as orthoebolaviruses[1], including case definitions, symptoms, screening guidance, infection control precautions, and other information please check the CDC Ebola Disease webpage (see links provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdiction's website for the most up to date information.

If you have a patient that you suspect may have Ebola disease due to clinical signs or symptoms or epidemiological risk factors, consult your State, Local, Tribal or Territorial health department immediately. In the U.S., coordination and consultation with your health department and CDC are required prior to, during, and after testing for viruses that cause Ebola disease.

WHAT DO I NEED TO KNOW ABOUT VIRUS TESTING WITH THIS PRODUCT?

- The OraQuick Ebola 2.0 Rapid Antigen Test can be used to test venipuncture whole blood and fingerstick whole blood specimens from individuals meeting clinical and/or epidemiological criteria for testing as an aid in the diagnosis of Ebola disease.
- The OraQuick Ebola 2.0 Rapid Antigen Test can also be used to test cadaveric oral fluid collected from recently deceased individuals with epidemiological risk factors who are suspected to have had Ebola disease at the time of death (please review the Fact Sheet for Response Teams for additional information).
- Clinical and epidemiological criteria include individuals with signs and symptoms associated with Ebola disease and/or with epidemiological risk factors, such as contact with a probable or confirmed Ebola disease case and/or other epidemiologic links for which *Orthoebolavirus* testing may be indicated as part of a public health investigation.
- Testing for Ebola disease must be performed in accordance with current guidelines provided by the appropriate public health authorities that address appropriate biosafety conditions, interpretation of test results, and coordination of testing, results, and patient management.
- Test results from the OraQuick Ebola 2.0 Rapid Antigen Test are presumptive. Definitive identification of Ebola disease requires additional testing and confirmation procedures in consultation with CDC or your local public health and/or other appropriate authorities to whom reporting is required.
- The OraQuick Ebola 2.0 Rapid Antigen Test is only authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high complexity tests, or in similarly qualified non-U.S. laboratories and facilities adequately equipped, trained, and capable of testing for *Orthoebolavirus* infection.
- The OraQuick Ebola 2.0 Rapid Antigen Test is intended for use by experienced personnel who have received specific training on the use of the test, training in the correct use of recommended personal protective equipment (PPE), and expertise in infectious disease diagnostic testing, including the safe handling of clinical specimens potentially containing *Orthoebolavirus*.

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

Specimens should be collected with appropriate infection control precautions for orthoebolaviruses following public health authority guidance for case investigation and specimen collection. When collecting and handling specimens from individuals suspected of being infected with an *Orthoebolavirus*, appropriate personal protective equipment should be used as outlined on the CDC VHF Clinical Specimen webpage. For additional information, refer to the CDC *Infection Prevention and Control Recommendations for Patients in U.S. Hospitals who are Suspected or Confirmed to have Selected Viral Hemorrhagic Fevers (VHF)* guidance and CDC *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007)* (see links provided in "*Where can I go for updates and more information?*" section at the end of this document).

WHAT DOES IT MEAN IF THE SPECIMEN TESTS POSITIVE FOR A VIRUS THAT CAUSES EBOLA DISEASE?

A positive test result for Ebola disease indicates that antigen from an *Orthoebolavirus* was detected, and therefore the patient is presumptive positive for infection with the virus and presumed to be contagious. A positive result with the OraQuick Ebola 2.0 Rapid Antigen Test is presumptive. Definitive identification of Ebola disease requires additional testing and confirmation procedures in consultation with public health and/or other appropriate authorities to whom reporting is required. A positive test result does not preclude the possibility of other infectious pathogens (e.g., bacterial infection or co-infection with other viruses) contributing to the patient's symptoms. Healthcare providers should always consider laboratory test results in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in determining individual diagnosis and patient management decisions and should follow current CDC guidelines, or the guidelines of their local public health authorities.

The OraQuick Ebola 2.0 Rapid Antigen Test has been designed to minimize the likelihood of false positive test results. However, it is still possible that this test can give a false positive result. In the event of a false positive result, risks to patients could include a recommendation for isolation of the patient and monitoring of household or other close contacts for symptoms. Patient isolation may increase contact with other potentially infected patients and might limit contact with family or friends, the ability to work or seek care for other conditions, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, stigmatization, or other unintended adverse effects.

WHAT DOES IT MEAN IF THE SPECIMEN TESTS NEGATIVE FOR A VIRUS THAT CAUSES EBOLA DISEASE?

A negative test result means that antigen from an *Orthoebolavirus* was not present in the specimen above the limit of detection of the test. However, a negative result does not rule out Ebola disease and should not be used as the sole basis for treatment or patient management decisions. It is possible for a test to miss infection with an *Orthoebolavirus* if testing a person occurs too early (e.g., less than 72 hours post-symptom onset) or too late during their illness. Inadequate or improper specimen collection and handling may yield false negative results with the OraQuick Ebola 2.0 Rapid Antigen Test. It is unknown if vaccination or treatment targeting Ebola disease may affect the performance of this test. It is also unknown if this test might miss infections with novel strains of *Orthoebolavirus* which may develop significant genetic variation from the strains for which this test was developed.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of an individual's previous laboratory testing results, recent exposures, presence of clinical signs and symptoms consistent with Ebola disease, and stage of illness. The possibility of a false negative result should especially be considered if the individual's recent exposures or clinical presentation indicate that Ebola disease is likely, and diagnostic tests for other causes of illness (e.g., other illnesses with similar symptoms) are negative. If Ebola disease is still suspected based on exposure history together with other clinical findings, re-testing should be considered by healthcare providers in consultation with public health authorities. Additional testing may be helpful to ensure testing was not conducted too early and that an adequate specimen was collected.

Risks to a patient of a false negative test result include delayed or lack of treatment (if available), stopping treatment too soon, lack of isolation leading to transmission of the virus to others, lack of monitoring of household or other close contacts for symptoms resulting in increased risk of spread of Ebola disease within the community, unnecessary additional testing and treatment for other conditions, or other unintended adverse events.

WHAT IS AN EUA?

The United States (U.S.) Food and Drug Administration (FDA) has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of *in vitro* diagnostics (IVDs) for the detection of Ebola virus.[2]

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing Ebola disease.

The EUA for this test is in effect for the duration of the FDA declaration justifying emergency use of IVDs, unless the declaration is terminated or authorization is revoked sooner.

WHAT ARE THE APPROVED AVAILABLE ALTERNATIVES?

Any tests that have received full marketing status (e.g., cleared, approved) 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/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

WHERE DO I REPORT ADVERSE EVENTS?

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

WHERE CAN I GO FOR UPDATES AND MORE INFORMATION?

CDC WEBPAGES:

General Ebola Disease Page: https://www.cdc.gov/ebola/about/index.html

Public Health Guidance: https://www.cdc.gov/viral-hemorrhagic-fevers/php/public-health-strategy/index.html

Information for Clinicians: https://www.cdc.gov/ebola/hcp/clinical-guidance/index.html

Information for Laboratories: https://www.cdc.gov/viral-hemorrhagic-fevers/php/laboratories/index.html

Specimen Collection: https://www.cdc.gov/viral-hemorrhagic-fevers/php/laboratories/specimen-collection.html

Infection Control: https://www.cdc.gov/viral-hemorrhagic-fevers/hcp/infection-control/index.html; and https://www.cdc.gov/infection-control/hcp/isolation-precautions/index.html#e

[2] The nomenclature of the family Filoviridae, including the viruses that cause Ebola disease, has changed over time. Recently, the genus name *Ebolavirus* was changed to *Orthoebolavirus,* and the species name Zaire ebolavirus (including the strain of Ebola virus detected in the 2014 West African outbreak) was changed to *Orthoebolavirus zairense.* Refer to*: Biedenkopf N., et al, Renaming of genera Ebolavirus and Marburgvirus to Orthoebolavirus and Orthomarburgvirus, respectively, and introduction of binomial species names within family Filoviridae. Arch Virol., 2023 Aug 3;168(8):220. doi: 10.1007/s00705-023-05834-2. PMID: 37537381.*

FDA WEBPAGES:

General: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#ebola

EUAs: (includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices#ebola

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