OraQuick Ebola 2.0 Rapid Antigen Test

OraSure Technologies, Inc.

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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.

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

- This test was designed to be used for the detection of orthoebolaviruses in cadaveric oral fluid specimens collected from recently deceased individuals with epidemiological risk factors who are suspected to have had Ebola disease at the time of death.
- This test is intended to aid in determining Ebola disease at the time of death to inform decisions on safe and dignified burial procedures in order to prevent transmission of Ebola disease in the community.
- 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*.

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 having had Ebola disease at the time of death, appropriate personal protective equipment should be used.

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 cadaver is likely infected with the virus and presumed to be contagious. Cadavers with a positive result should be subjected to safe and dignified burial procedures and contacts of an *Orthoebolavirus* positive cadaver should be identified and followed up. Contact testing should be conducted in accordance with appropriate public health authority guidelines.

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,

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

risks could include a recommendation for safe and dignified burial procedures for the cadaver, and unnecessary monitoring of household or other close contacts for symptoms, 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 cadaver management decisions. The possibility of a false negative result should especially be considered if the deceased individual's recent exposures or clinical presentation indicate that *Orthoebolavirus* infection was likely. Risks of a false negative test result include an increased risk of spreading Ebola disease within the community 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

[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*.

OTHER WEBPAGES:

How to conduct safe and dignified burial of a patient who has died from suspected or confirmed Ebola virus disease: http://apps.who.int/iris/bitstream/10665/137379/1/WHO_EVD_GUIDANCE_Burials_14.2_eng.pdf

Infection Control for Viral Hemorrhagic Fevers in the African Health Care Setting: https://iris.who.int/handle/10665/65012

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

OraSure Technologies, Inc.

220 East First Street
Bethlehem, PA 18015

E-mail: customercare@orasure.com
Telephone: 1-800-ORASURE (within the US) or +(001) 610-882-1820 (outside the US)