

Guidance for Using Rapid Diagnostic Tests for Ebola in the United States



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Summary

In October 2019, the U.S. Food and Drug Administration (FDA) allowed marketing of the OraQuick® Ebola Rapid Antigen Test, a rapid diagnostic test (RDT) for detecting Ebola virus in both symptomatic patients and recently deceased people. This is the first Ebola RDT that FDA has allowed for marketing in the United States. The RDT should be used only in cases where more sensitive molecular testing is not available. All OraQuick® Ebola Rapid Antigen Test results are presumptive; all test results (positive and negative) must be verified through real-time reverse transcriptase polymerase chain reaction (rRT-PCR) testing at a Laboratory Response Network (LRN) laboratory located in 49 states and at the Centers for Disease Control and Prevention (CDC). Interpretation of RDT results should be done with caution and in consultation with relevant public health authorities to ensure appropriate testing and interpretation of results. RDT results should not be used to rule out Ebola infection or to determine the use or type of infection prevention and control precautions when managing a patient with Ebola compatible symptoms and epidemiologic risk factors. Healthcare providers with a patient with possible Ebola virus infection should first contact their local or state public health authorities before any testing is performed. CDC is available to provide consultation, technical assistance, and confirmatory testing as necessary.

Background

[Ebola virus disease](#) (Ebola) is a rare and deadly disease caused by infection with viruses within the genus *Ebolavirus*. There are four known species within genus *Ebolavirus* that are known to cause disease in humans: Ebola virus (species *Zaire ebolavirus*), Sudan virus (species *Sudan ebolavirus*), Bundibugyo virus (species *Bundibugyo ebolavirus*), and Tai Forest virus (species *Tai Forest ebolavirus*). People can become infected through contact with blood or body fluids of a person

infected with or who has died of Ebola. Ebola virus can also be spread through contact with contaminated objects or infected animals. Symptoms of Ebola can include fever, headache, muscle and joint pain, abdominal pain, weakness and fatigue, gastrointestinal symptoms including diarrhea and vomiting, and bleeding or bruising.

An outbreak of Ebola (associated with *Zaire ebolavirus*) is occurring in the South Kivu, North Kivu, and Ituri provinces in northeastern Democratic Republic of the Congo (DRC). First declared on August 1, 2018, the outbreak is the second largest Ebola outbreak in history and the largest that has ever occurred in DRC. As of December 9, 2019, more than 3,200 confirmed cases and more than 2,000 confirmed deaths have been reported. Despite this, the risk of Ebola virus infection for most U.S.-based travelers to DRC is low, and the risk of global spread of Ebola to the United States and elsewhere is also low. Only those going to the outbreak area or who otherwise have contact with an Ebola-infected person (living or deceased) are at risk. Family and friends caring for people with Ebola and health care workers who do not use correct infection control precautions are at higher risk (1).

The OraQuick® Ebola Rapid Antigen Test was originally developed as a tool for rapid presumptive diagnosis of Ebola in outbreak settings and is useful in low-resource areas where access to more sensitive molecular testing is difficult. This test is not intended to be used for general Ebola infection screening or testing of asymptomatic people or those without risk factors and compatible symptoms of Ebola. The test has shown to be capable of detecting antigens for three species of *Ebolavirus*: *Zaire ebolavirus*, *Bundibugyo ebolavirus*, and *Sudan ebolavirus* (2).; however, the test cannot differentiate between species. In the United States, presumptive testing for Ebola virus (*Zaire ebolavirus*) is available at 69 Laboratory Response Network (LRN) laboratories located in 49 states using rRT-PCR, accessible through coordination with state or local public health authorities. Molecular testing at CDC is available to confirm these results and is also required to differentiate between species of *Ebolavirus*.

Recommendations

CDC recommends that Ebola virus testing be conducted only for people who have an epidemiologic risk factor within 21 days of symptom onset and who have an Ebola compatible clinical syndrome. The signs and symptoms of Ebola are non-specific, both in the early and advanced clinical course. Because most travelers are at low to no risk of becoming infected with Ebola, other more common differentials with similar clinical symptomatology such as malaria, dengue, influenza, or typhoid should be considered. Since August 1, 2018, CDC has received clinical inquiries from state and local health departments for 49 ill returning travelers from DRC or the surrounding countries. Of these, testing for Ebola virus was recommended for one returning traveler. The traveler tested negative for Ebola and was subsequently diagnosed with malaria.



Healthcare providers interested in testing for Ebola virus in ill returning travelers should isolate the patient and contact their state or local public health authorities. An assessment of epidemiologic risk factors for Ebola and clinical presentation and history

should be made as quickly as possible to ensure patient care is not compromised. CDC is available to provide consultation, technical assistance, and confirmatory testing as necessary.

State public health authorities or healthcare facilities in the United States considering integrating the OraQuick® Ebola Rapid Antigen Test into their Ebola testing algorithms or preparedness protocols should consider the following:

1. The RDT should be used only in circumstances where more sensitive molecular testing is not available.
2. RDTs should be used only in collaboration and consultation with relevant public health authorities to ensure appropriate testing and interpretation of results.
3. All results (positive and negative) from the OraQuick® Ebola Rapid Antigen Test are presumptive and must be verified through rRT-PCR testing that is available at 69 LRN laboratories located in 49 states and at CDC. Testing at LRN laboratories is coordinated through state or local public health authorities.
4. Per existing protocols, specimens that test positive by the Ebola virus rRT-PCR assay at an LRN laboratory must be forwarded to CDC for confirmatory testing.
5. Negative RDT results alone should not be used to rule out Ebola virus infection or to determine the use or type of infection prevention and control precautions when managing a patient with compatible symptoms and epidemiologic risk factors.
6. The OraQuick® Ebola Rapid Antigen Test may result in false positive results in patients that have elevated rheumatoid factor levels (2). Additionally, potential cross-reactivity of the test with Ebola vaccines or therapeutics is possible and has not been evaluated, and patients who have received vaccines or therapeutics against Ebola virus may have false positive or other confounding results (2). It is important to consult with public health authorities prior to the use of RDTs and to aid in the interpretation of RDT results.
7. Facilities that collect and handle specimens from patients with suspected cases of Ebola should ensure adequate biosafety protocols are in place for the handling and disposal of all potentially infectious materials to avoid risk of inadvertent exposure (3). For healthcare providers collecting specimens, appropriate personal protective equipment should be used (4,5).

References

1. CDC. Traveler's Health – Ebola in Democratic Republic of the Congo, 29 Oct. 2019. <https://wwwnc.cdc.gov/travel/notices/alert/ebola-democratic-republic-of-the-congo>.
2. OraSure Technologies, Inc. OraQuick® Ebola Rapid Antigen Test customer letter. Bethlehem, PA. 2019. https://www.orasure.com/docs/pdfs/products/ebola/Ebola_Instruction_PI-ENG.pdfpdf 
3. 2019 US Government Guidance on Managing Solid Waste Contaminated with a Category A Infectious Substance. <https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/docs/transporting-infectious-substances/6821/cat-waste-planning-guidance-final-2019-08.pdfpdf> 


4. CDC. Guidance on Personal Protective Equipment (PPE) To Be Used by Healthcare Workers during Management of Patients with Confirmed Ebola or Persons under Investigation (PUIs) for Ebola who are Clinically Unstable or Have Bleeding, Vomiting, or Diarrhea in U.S. Hospitals, Including Procedures for Donning and Doffing PPE. <https://www.cdc.gov/vhf/ebola/healthcare-us/ppe/guidance.html>.
5. CDC. For U.S. Healthcare Settings: Donning and Doffing Personal Protective Equipment (PPE) for Evaluating Persons Under Investigation (PUIs) for Ebola Who Are Clinically Stable and Do Not Have Bleeding, Vomiting, or Diarrhea. <https://www.cdc.gov/vhf/ebola/healthcare-us/ppe/guidance-clinically-stable-puis.html>.

For More Information

OraSure product information

<https://www.orasure.com/products-infectious/products-infectious-OraQuick®-ebola.asp> 

FDA press release

<https://www.fda.gov/news-events/press-announcements/fda-allows-marketing-first-rapid-diagnostic-test-detecting-ebola-virus-antigen> 

CDC Ebola information

<https://www.cdc.gov/vhf/ebola/index.html>

CDC Traveler's Health: Ebola in Democratic Republic of the Congo

<https://wwwnc.cdc.gov/travel/notices/alert/ebola-democratic-republic-of-the-congo>

Ebola Case Definition and Criteria for Person Under Investigation

<https://www.cdc.gov/vhf/ebola/clinicians/evaluating-patients/case-definition.html>

CDC Assessing Viral Hemorrhagic Fever Risk in a Returning Traveler

<https://www.cdc.gov/vhf/abroad/assessing-vhf-returning-traveler.html>

The Laboratory Response Network Partners in Preparedness

<https://emergency.cdc.gov/lrn/>

WHO Ebola information

<https://www.who.int/en/news-room/fact-sheets/detail/ebola-virus-disease> 

CDC-INFO

<https://www.cdc.gov/cdc-info/index.html> or 1-800-232-4636

CDC Emergency Operations Center (24 Hour EOC)

770-488-7100

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, HAN coordinators, and clinician organizations.

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