Cadaveric Oral Fluid Quick Reference Guide

OraQuick® Ebola Rapid Antigen Test

The OraQuick® Ebola Rapid Antigen Test is intended for the qualitative detection of antigens from viruses within the *Ebolavirus* genus in whole blood from individuals with epidemiological risk factors with signs and symptoms of EVD or cadaveric oral fluid from recently deceased individuals with epidemiological risk factors who are suspected to have died of EVD. For the full intended use, limitations, and warnings see the instructions for use inside the box.

POUCH CONTENTS: 1 developer vial, 1 device and 1 absorbent packet

STEP 1a. – Specimen Collection [1,2,3]
Direct Specimen Collection

For direct collection, swab the cadaver using the flat pad of the device. If direct collection from the soft palate is not possible due to rigor mortis, collect sample from the gum line. After collection go to Step 2.


Collect sample from the soft palate (back of the oral cavity) using the flat pad of the device.

OR


Collect sample from gum line. Swab lower and upper gum once.

OR

STEP 1b. – Specimen Collection [1,2,3]
Viral Transport Media

For specimen collection in viral transport media follow instruction of the Swab/ Transport media manufacturer. Prior to testing, mix the transport media tube gently by inversion several times. Store at 2°-25°C (36°-77°F) for transport. If sample cannot be tested within 48 hours of collection, store specimen at -70°C (-94°F).

Remove the collection swab from the tube. Using a calibrated laboratory pipette, slowly draw up 20µL of viral transport media sample.

NOTE: If a bubble is present, discard the sample and obtain a new sample using a new pipette tip.


Deposit the cadaveric sample into the sample port on the device. Go to Step 2.

STEP 2. – Perform the Test

Insert device into developer vial

Start the timer for 30 minutes

Purple fluid travels through the Result Window

DO NOT remove the device from the developer vial while the test is running.

STEP 3. – Read Results

Positive results may be interpreted as soon as lines are visible in the Test (T) Zone and the Control (C) Zone and have been observed as early as 4 minutes. Negative results **MUST** be read 30 minutes after inserting the device into the Developer vial. To report a device problem, contact OraSure Technologies Customer Service (1-800-orasure) within the US or +(001) 610-882-1820 for outside the US. You can also go to http://www.orasure.com/contact/contact-customer-service.asp.

Negative: Line in C Zone

Line in C Zone
No Ebola Antigens detected

- A Negative test result means that Ebola Antigens were not detected in the specimen.
- The test result is interpreted as Ebola Antigen was not detected. The cadaver is Negative for Ebola Antigen.

Invalid: Repeat with a Fresh Sample

No line in C Zone

Purple background obscures results

Any partial line at C or T Zone


Positive: Lines in C and T Zones

Examples of positive results – Line in C Zone in each test

Line in T Zone

Line in T Zone

Faint line in T Zone

- A Positive test result means that Ebola Antigen has been detected in the specimen. The cadaver is presumed positive for Ebola.
- Individuals with a positive result with the OraQuick® Ebola Rapid Antigen Test should, in accordance with CDC and WHO recommendations, be subjected to safe and dignified burial procedure. Contacts of an Ebola positive cadaver should be identified and followed up on.

Order Information and Description

1001-0509 Box of 25 tests
1001-0508 Kit Controls
1001-0537 Visual Reference Panel

Item# 3001-2930 rev. 10/19

1 See "Universal Precautions," CDC, MMWR, 1988; 37(24):377-388. 2 Centers for Disease Control and Prevention and World Health Organization. Infection Control for Viral Haemorrhagic Fevers in the African Health Care Setting. Atlanta, Centers for Disease Control and Prevention, 1998:1-198. 3 Information for Health Care Workers in the United States: http://www.cdc.gov/vhf/ebola/healthcare-us/index.html

Please refer to the package insert for complete information and instructions on the proper use of the OraQuick® Ebola Rapid Antigen Test.

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