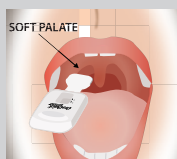


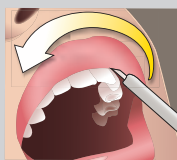
Step 1a. – Specimen Collection Direct Specimen Collection

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

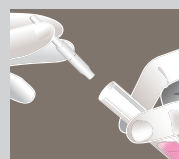


Collect sample from gum line. Swab lower and upper gum once. **DO NOT** swab the roof of the mouth, cheeks or tongue.

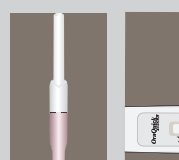
OR

Step 1b. – Specimen Collection 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).



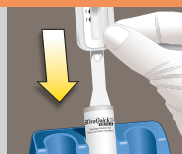
Slowly fill the micropipette. Place the tip of the micropipette in the vial transport media tube and slowly draw the sample up. Filling of the pipette is automatic, never squeeze the micropipette while sampling.



Deposit the cadaveric sample into the sample port on the device. Go to Step 2.
NOTE: If a bubble is present discard the sample and obtain a new sample using a new micropipette.

Step 2. Perform the Test

Insert device into vial



Start timer



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. Read negative results 30 minutes after inserting the device into the Developer Vial.

Negative: Line in C Zone

Line in C Zone
No Ebola Antigens detected

CDC recommendations for reporting Ebola negative results:^{1,2,3}



- 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 is interpreted as Ebola Antigen detected in the specimen. The cadaver is positive for Ebola Antigen.
- 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

1001-0426 Box of 25 tests
1001-0427 Box of 100 tests
1001-0425 Kit Controls
1001-0428 Visual Reference Panel
Item# 3001-2813 rev. 02/16

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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