


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. – Collect the Specimen<sup>1,2,3</sup> Fingerstick Whole Blood


Cleanse finger. Air dry. Puncture with lancet.



Micropipette



Wipe away first drop of blood. Fill micropipette to black lines.




NOTE: Touch the tip of the micropipette to the drop of blood. Filling of the pipette is automatic, never squeeze the micropipette while sampling. To prevent bubbles, the tip of the pipette must maintain uninterrupted contact with the blood sample until filled.

### STEP 1b. – Collect the Specimen<sup>1,2,3</sup> Venipuncture Whole Blood


Collect blood using standard phlebotomy procedures.

- Prior to testing, mix blood tube gently by inversion several times to ensure homogenous specimen.
- Remove tube cap.
- Whole blood may be stored at 2°-30°C (36°-86°F) for up to 24 hours.

Slowly fill the micropipette.

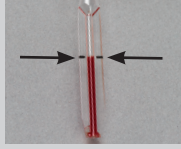


NOTE: Place the tip of the micropipette in the blood tube. Filling of the pipette is automatic, never squeeze the micropipette while sampling. To prevent bubbles, the tip of the pipette must maintain uninterrupted contact with the blood sample until filled.



NOTE: A calibrated lab pipette may be used in place of the micropipette to draw up 20µL of sample from the blood tube.

If using a micropipette, make sure it is filled with blood up to the indicator line and no bubbles are present.



**Go to Step 2**

### STEP 2. – Perform the Test Fingerstick Whole Blood and Venipuncture Whole Blood

Deposit the blood sample by compressing the pipette bulb



Insert device into developer vial



Start the timer for 30 minutes



Fluid travels through the Result Window




• DO NOT remove the device from the Developer Solution 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 patient is presumed Negative for Ebola Antigen.

#### Invalid: Repeat Test


No line in C Zone



Background obscures results




Any partial line at C or T Zones




#### Positive: Lines in C and T Zones.

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


Line in T Zone



Line in C Zone



Faint line in T Zone



- A Positive test result means that Ebola Antigen has been detected in the specimen. The patient is presumed Positive for Ebola Antigen. Follow up testing with PCR to confirm test result.
- Some pink may remain visible in the background as a result of the whole blood specimen.
- Immediately follow the CDC guidelines for at-risk exposure patient management.

#### Order Information and Description

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

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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