Ebola Positive Control

The Ebola Positive Control will produce a Positive test result at the Test (T) Zone. Two lines should be present in the Result Window. A line in the C Zone and a line in the T Zone should be present. This indicates a Positive test result. The lines will not necessarily be the same intensity.

NOTE: If the test result for either the Ebola Negative Control or the Ebola Positive Control is not as expected, the test should be repeated using a new Test Device, Developer Solution Vial and control specimen. Contact OraSure Technologies' Customer Care if the Kit Control reagents do not produce the expected result.

LIMITATIONS

The OraQuick® Ebola Rapid Antigen Test Kit Controls are quality control reagents for use only with the OraQuick® Ebola Rapid Antigen Test.

BIBLIOGRAPHY

1. CDC. Universal Precautions For Prevention Of Transmission Of Human Immunodeficiency Virus, Hepatitis B Virus, And Other Bloodborne Pathogens In Health-Care Settings. *MMWR* 1988; 37(24):377-388.
2. Infection Control for Viral Haemorrhagic Fevers in the African Health Care Setting. Centers for Disease Control and Prevention and World Health Organization. Atlanta, Centers for Disease Control and Prevention, 1998: 1-198. WHO, September 2014: Ref: WHO/HIS/SDS/2014.4

EXPLANATION OF SYMBOLS

LOT	Batch Code	IVD	*In Vitro* Diagnostic Medical Device
REF	Catalog Number		Manufacturer
	Caution, Consult Accompanying Documents		Temperature Limitation
PN	Part Number		Use By
		Rx	Medical Prescription

For Technical or Customer Service within the United States, phone (800) ORASURE (800-672-7873).
For customers outside the United States, phone +(001) 610 882 1820 or go to www.OraSure.com

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Item# 3001-2927 rev. 10/19

OraQuick® Rapid Antigen Test EBOLA

Rx

KIT CONTROLS

Read this package insert and the OraQuick® Ebola Rapid Antigen Test Package Insert completely prior to performing the test; failure to do so may cause inaccurate test results.

Follow the instructions carefully; failure to do so may cause an inaccurate test result. Before proceeding with testing, all users MUST read and be familiar with Universal Precautions[1], Infection Control for Viral Hemorrhagic Fevers in the African Health Care Setting[2] and in Information for Healthcare Worker in the United States (http://www.cdc.gov/vhf/ebola/healthcare-us/index.html) depending upon their location of testing.

NAME AND INTENDED USE

The OraQuick® Ebola Rapid Antigen Test Kit Controls are quality control reagents for use only with the OraQuick® Ebola Rapid Antigen Test.

Run the Kit Controls under the following circumstances:

- Each new operator prior to performing testing on patient/cadaver specimens,
- When opening a new test kit lot,
- Whenever a new shipment of test kits is received,
- If the temperature of the test kit storage area falls outside of 5°-30°C (41°-86°F), and
- At periodic intervals as dictated by the user facility, country, state or local regulations and policies.

It is the responsibility of each laboratory using the OraQuick® Ebola Rapid Antigen Test to establish an adequate quality assurance program to ensure the performance of the device under its specific locations and conditions of use.

SUMMARY AND EXPLANATION OF THE KIT CONTROLS

The OraQuick® Ebola Rapid Antigen Test Kit Controls are human plasma-based reagents. The Kit Controls are specifically formulated and manufactured to ensure proper performance of the test. The Ebola Positive Control will produce a red to purple line at the Test (T) Zone. The Ebola Negative Control will generate a negative test result (no red to purple line at the T Zone). Both controls will produce a red to purple line in the Control (C) Zone. Refer to Test Result and Interpretation of Test Result section of the OraQuick® Ebola Rapid Antigen Test package insert. Use of kit control reagents manufactured by any other source will not meet the requirements for an adequate quality assurance program for the OraQuick® Ebola Rapid Antigen Test.

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MATERIALS PROVIDED

OraQuick® Ebola Rapid Antigen Test Kit Controls

Each Kit Control box contains a package insert and two vials (one Ebola Positive Control and one Ebola Negative Control) as described below:

Ebola Positive Control

One orange-capped vial containing 0.25 mL of Ebola recombinant VP40 diluted in a defibrinated pool of human plasma negative for Hepatitis B surface antigen, Hepatitis C virus, HIV-1 and HIV-2. A preservative of 2-methyl-4-isothiazolin-3-one is added.

Ebola Negative Control

One white-capped vial containing 0.25 mL of pooled defibrinated human plasma negative for Hepatitis B surface antigen, Hepatitis C virus, HIV-1 and HIV-2. A preservative of 2-methyl-4-isothiazolin-3-one is added.

MATERIALS REQUIRED AND PROVIDED in the OraQuick® Ebola Rapid Antigen Test Kit

Divided Pouches, each containing a Test Device, an Absorbent Packet, and a Developer Solution Vial

Test Stands

Package Insert

Micropipettes

MATERIALS REQUIRED BUT NOT PROVIDED

Timer or watch capable of timing 30 minutes

Latex, vinyl, or nitrile disposable gloves

Biohazard waste container

WARNINGS

For *in vitro* Diagnostic Use

- **This package insert must be read completely before using the product.**
- **Follow the instructions carefully when performing the OraQuick® Ebola Rapid Antigen Test. Failure to do so may cause an inaccurate test result.**
- **Before proceeding with testing, all study personnel MUST read and be familiar with Universal Precautions[1], Infection Control for Viral Hemorrhagic Fevers in the African Health Care Setting[2] and in Information for Healthcare Worker in the United States (http://www.cdc.gov/vhf/ebola/healthcare-us/index.html) depending upon their location of testing.**

PRECAUTIONS

Safety Precautions

- Handle Kit Controls and materials in contact with Kit Controls as if capable of transmitting infectious agents.
- Dispose of all Kit Controls and materials used in the test procedure in a biohazard waste container. All equipment and biohazardous waste should be discarded in accordance with country, state, and local laws and policies.
- Wear disposable gloves while handling and testing the Kit Controls. Dispose of used gloves in a biohazard waste container.
- Use of kit control reagents manufactured by any other source will not meet the requirements for an adequate quality assurance program for the OraQuick® Ebola Rapid Antigen Test.

STORAGE INSTRUCTIONS

Store the OraQuick® Ebola Rapid Antigen Test Kit Controls at 2° - 8°C (36° - 46°F). Do not use the Kit Controls beyond the expiration date printed on the outer box. Open the Kit Control vials only when you are performing tests. Recap and store the vials in their original box at 2° - 8°C (36° - 46°F) after use. Once opened, Kit Controls should be discarded after eight (8) weeks.

DIRECTIONS FOR USE

General Test Preparation

Perform procedures according to the General Test Preparation section of the OraQuick® Ebola Rapid Antigen Test package insert.

TEST PROCEDURE

1. Allow the OraQuick® Ebola Rapid Antigen Tests to come to operating temperature (15°- 40°C, 59°- 104°F) before use.
2. Set an OraQuick® Test Stand at your workspace, using only the stand provided.
3. Open the two chambers of the OraQuick® Divided Pouch ("Pouch") by tearing at the notches on the top of each side of the Pouch.
4. Remove the Developer Solution Vial ("Vial") from the Pouch. Hold the Vial firmly in your hand. Carefully remove the cap from the Vial by gently rocking the cap back and forth while pulling it off. Set the cap on your workspace cover.
5. Slide the Vial into the top of one of the slots in the Stand. **DO NOT** force the vial into the Stand from the front of the slot as splashing may occur. Make sure the Vial is pushed all the way to the bottom of the slot in the Stand.
6. Remove the Device from the Pouch. **DO NOT** touch the Flat Pad. Place the device on a flat clean surface. **(Note: to keep the collection pad clean, avoid contact with any laboratory or other surfaces including hands of the operator)** Check to make sure that an Absorbent Packet is included with the Device. If no Absorbent Packet is present, discard the Device and obtain a new Pouch for testing. **NOTE: DO NOT cover the two holes in the back of the Device with labels or other materials. Doing so may cause an Invalid result.**
7. Open a Kit Control vial containing the control reagent.
8. Insert the micropipette in the vial and draw out a sample until it reaches the 20µL indicator line. Filling of the micropipette is automatic. Never squeeze the micropipette while sampling. Visually inspect the pipette to make sure there are no bubbles. If bubbles are present, discard the sample and obtain a new sample.
9. Immediately deposit the kit control sample through the sample port on the device by compressing the micropipette directly above the sample port. **Use separate unused micropipettes for each control reagent.**
10. Insert the Test Device, flat pad first, into the Developer Vial. **Be sure that the Result Window is facing towards you and the flat pad touches the bottom of the Developer Vial.**
11. Leave the Test Device in the Developer Solution Vial and start a timer. Do not remove the Test Device from the vial until you have read the results. Read the results in a fully lighted area. Positive results can 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 have to be read 30 minutes after inserting the device into the Developer Vial. Read the results as described in the Test Result and Interpretation of Test Result section of the OraQuick® Ebola Rapid Antigen Test Kit package insert.
12. Dispose of the used test materials in a biohazard waste container.
13. Reseal the Kit Control reagent vials and store them in the original container at 2°-8°C (36°-46°F).

EXPECTED RESULTS

Ebola Negative Control

The Ebola Negative Control will produce a Negative test result. A single line should be present in the Result Window in the