OraQuick™ Rapid Antigen Test EBOLA 2.0

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Instructions for Use

For Use Under Emergency Use Authorization (EUA) Only
For in vitro diagnostic use

CLIA COMPLEXITY: High (U.S.)

NAME AND INTENDED USE

The OraQuick™ Ebola 2.0 Rapid Antigen Test is an in vitro diagnostic single-use immunoassay intended for the presumptive qualitative detection of antigens from viruses within the *Orthoebolavirus* genus (such as *Orthoebolavirus zairense, Orthoebolavirus bundibugyoense, Orthoebolavirus sudanense*, and *Orthoebolavirus taiense*); however, it does not differentiate among these viruses.

Testing with the OraQuick™ Ebola 2.0 Rapid Antigen Test must only be performed when public health authorities have determined the need for this test. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high complexity tests, or in similarly qualified non-U.S. laboratories and facilities adequately equipped, trained, and capable of testing for *Orthoebolavirus* infection. The test is intended for use by experienced personnel who have received specific training on the use of the OraQuick™ Ebola 2.0 Rapid Antigen Test, training in the correct use of recommended personal protective equipment (PPE), and expertise in infectious disease diagnostic testing, including the safe handling of clinical specimens potentially containing *Orthoebolavirus*. Testing for Ebola disease must be performed in accordance with current guidelines provided by the appropriate public health authorities that address appropriate biosafety conditions, interpretation of test results, and coordination of testing, results, and patient management.

The OraQuick™ Ebola 2.0 Rapid Antigen Test is intended for use in:

- Venipuncture whole blood and fingerstick whole blood specimens as an aid in the diagnosis of Ebola disease in patients suspected of and with signs and symptoms consistent with Ebola disease and who have epidemiological risk factors for *Orthoebolavirus* exposure.
- Cadaveric oral fluid collected from recently deceased individuals with epidemiological risk factors who are suspected to have had Ebola disease at the time of death. The test is intended as an aid in determining Ebola disease at the time of death to inform decisions regarding the safe handling of cadavers to prevent disease transmission.

The OraQuick™ Ebola 2.0 Rapid Antigen Test results are presumptive. Definitive identification of Ebola disease requires additional testing and confirmation procedures in consultation with public health and/or other appropriate authorities to whom reporting is required. The diagnosis of Ebola disease must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence in addition to the identification of *Orthoebolavirus*. Positive results indicate the presence of *Orthoebolavirus* antigens; clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results do not preclude *Orthoebolavirus* infection and should not be used as the sole basis for treatment of patient management decisions. Negative results should be considered in the context of history, signs, symptoms, and exposure likelihood.

The OraQuick™ Ebola 2.0 Rapid Antigen Test is not intended for general *Orthoebolavirus* infection screening, such as airport screening or contract tracing of individuals at risk of exposure without signs or symptoms of infection. The OraQuick™ Ebola 2.0 Rapid Antigen Test is not intended for use as a diagnostic test for oral fluid samples of living individuals.

The OraQuick™ Ebola 2.0 Rapid Antigen Test is authorized for use under the U.S. Food and Drug Administration's Emergency Authorization.

SUMMARY AND EXPLANATION OF THE TEST

Ebola disease is a severe, often-fatal disease in humans and nonhuman primates that has appeared sporadically since its initial recognition in 1976. *Orthoebolavirus* species are in the *Filoviridae* family. There are four species of *Orthoebolavirus* affecting humans: *Orthoebolavirus zairense, Orthoebolavirus bundibugyoense, Orthoebolavirus sudanense, and Orthoebolavirus taiense*. The presence of *Orthoebolavirus* antigens indicates that the individual may be currently infected and capable of transmitting the virus.

The OraQuick™ Ebola 2.0 Rapid Antigen Test utilizes a sandwich capture lateral flow immunoassay method to detect *Orthoebolavirus* antigens. Ebola antigens are captured and visualized by colloidal gold labeled with Ebola antibodies generating a visible line in the test zone for a positive sample.

PRINCIPLES OF THE TEST

The OraQuick™ Ebola 2.0 Rapid Antigen Test is a manually performed, visually read immunoassay for the qualitative detection of *Orthoebolavirus* antigens in human venipuncture whole blood, fingerstick whole blood, and cadaveric oral fluid. The OraQuick™ Ebola 2.0 Rapid Antigen Test is comprised of both a single-use test device and vial containing a pre-measured amount of a buffered developer solution. The test consists of a sealed pouch with two separate compartments for each component. The OraQuick™ Ebola 2.0 Rapid Antigen Test utilizes a proprietary lateral flow immunoassay procedure.

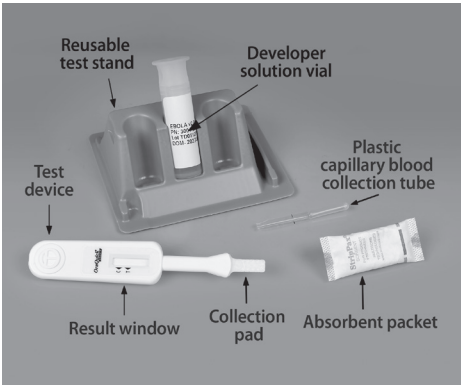
The assay test strip, which can be viewed through the test device result window, is comprised of a series of components: the blocker pad, the conjugate pad, the nitrocellulose membrane, and finally the absorbent pad. The performance of the assay occurs through hydration and transport of reagents as they interact with the specimen across the strip via chromatographic lateral flow. As the specimen migrates through the device, *Orthoebolavirus* antigens, if present, are captured by antibodies located in the blocker pad and subsequently form complexes with antibody-labeled gold colorimetric reagent on the assay strip. These labeled complexes are immobilized at the test (T) zone, producing a visible purple line. In the absence of *Orthoebolavirus* antigens, no complexes form at the test (T) zone, and no line is observed. The intensity of the test line is not directly proportional to the concentration of the virus in the specimen.

Fifty microliters (50 µL) of a fingerstick or venipuncture whole blood specimen are transferred to the integrated collection pad on the device, followed by the insertion of the device into the developer vial. For cadaveric oral fluid testing, swab the oral cavity with the integrated with the integrated flat collection pad of the device and then insert the device directly into the developer solution to run the test. The developer solution facilitates the capillary flow of the specimen into the device and onto the assay strip. As the specimen flows through the device, antigens from the specimen are bound by the *Orthoebolavirus* antibody-labeled gold colorimetric reagent present on the assay strip. If the specimen contains *Orthoebolavirus* antigens, the resulting labeled complexes bind to the test (T) zone resulting in a purple line. If the specimen does not contain *Orthoebolavirus* antigens, the labeled complexes do not bind at the test zone and no line is observed. The intensity of the line color is not directly proportional to the amount of virus present in the specimen. The remaining colloidal gold is transported and bound to the control (C) zone. This procedural control serves to demonstrate that the fluid has migrated adequately through the device. A purple line will appear at the control (C) zone during the performance of all negative tests (refer to the *Test Result and Interpretation of Test Result* section on page 6 of in this package insert). Positive results may be interpreted as soon as purple lines are visible at the test (T) zone and control (C) zone. In instances of very high virus concentrations, the control line may not appear. If there is a test line present, the test should be interpreted as positive even if the control line is not present. Negative results MUST be read 30 to 40 minutes after inserting the device into the developer vial.

MATERIALS PROVIDED

The OraQuick™ Ebola 2.0 Rapid Antigen Test Kit is available in the following packaging configuration:

Components of Kit Catalog Number	25 count/kit 1001-0708_EUA
Divided pouch Each pouch containing: Test device (1) Absorbent packet (1) Developer solution vial (1) (each vial contains 1.0 mL of a buffered saline solution with an antimicrobial agent)	25
Test stands	25
Plastic capillary blood collection tubes	30
Instructions for use	1
Cadaveric oral fluid quick reference guide	1
Whole blood quick reference guide	1
Visual Reference card	1
Fact sheet for relatives and caregivers	1 (pack of 5)
Fact sheet for patients	1 (pack of 5)
Fact sheet for healthcare providers	1
Fact sheet for response team	1



MATERIALS REQUIRED AND AVAILABLE AS AN ACCESSORY TO THE KIT

OraQuick™ Ebola 2.0 Rapid Antigen Kit Controls 1001-0709_EUA

Ebola 2.0 Positive Control (1 vial, 0.5 mL); Ebola 2.0 Negative Control (1 vial, 0.5 mL); Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

Timer or watch capable of timing 30 to 40 minutes
Biohazard waste container
Materials required for venipuncture whole blood specimen collection or
Materials required to obtain a fingerstick whole blood specimen
Pipette capable of delivering 50 µL
Disposable pipette tips

WARNINGS AND PRECAUTIONS

- **For prescription use only.**
- **This product has not been U.S. FDA cleared or approved, but has been authorized for emergency use by U.S. FDA under an EUA for use by the authorized laboratory.**
- **This product has been authorized only for the detection of antigens from orthoebolaviruses including *Orthoebolavirus zairense*, *Orthoebolavirus bundibugyoense*, *Orthoebolavirus sudanense*, and *Orthoebolavirus taiense*, not for any other viruses or pathogens.**
- **The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for the detection of Ebola virus under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.**
- **All testing MUST be conducted under appropriate biosafety conditions in accordance with applicable country, state and local laws and with CDC and/or WHO guidelines.**
- **In the U.S., Ebola disease is a nationally notifiable condition and must be reported to public health authorities in accordance with local, state, and federal regulations.**
- **Specimens MUST always be treated as infectious and/or biohazardous. The use of all possible universal precautions is highly recommended when handling specimens with this test.**
- **Use personal protective equipment (PPE) consistent with current guidelines including safety goggles and / or face shields, masks or respiratory equipment, disposable gowning, boots, and gloves. Users performing this test MUST be appropriately trained on the donning and doffing of personal protective equipment.**
- **All personnel conducting testing 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 (https://www.cdc.gov/vhf/Ebola/healthcare-us/index.html) depending upon their location of testing.**
- **All equipment and biohazardous waste MUST be discarded in accordance with country, state, and local laws and policies.**
- **This test kit is for use with venipuncture and fingerstick whole blood specimens and cadaveric oral fluid swab specimens only.**
- **Cadaveric oral swab specimens should not be stored and should be tested immediately after collection.**
- **If samples are suspected of hemolysis, another venous whole blood should be collected and tested.**
- **Do not freeze whole venous whole blood samples.**
- **Results must be read no earlier than 30 minutes and no later than 40 minutes.**
- **Read times below 30 minutes significantly affect performance of the device with low positive samples.**
- **Reducing the read time below 30 minutes can prevent correct identification of low positive samples.**
- **Reading any test result after 40 minutes may yield inaccurate test results.**
- **Samples MUST NOT be pre-diluted. Such pre-dilution can result in false negative results.**
- **This test is not intended to be used as a screening test on patients without signs and symptoms of Ebola infection or to monitor individuals who are undergoing treatment.**
- **Do not smoke, eat, or drink in areas where specimens or kit reagents are handled.**
- **This package insert must be read completely before using the product.**
- **Follow the instructions carefully when performing the OraQuick™ Ebola 2.0 Rapid Antigen Test. Failure to do so may cause an inaccurate test result.**
- **This test should be performed at temperatures in the range of 15°-40°C (59°-104°F). If stored refrigerated, ensure that the divided pouch is brought to operating temperature of 15°-40°C (59°-104°F) before performing testing.**
- **Do not use this test beyond the expiration date printed on the outer packaging. Always check expiration date prior to testing.**
- **Individuals who have received an Ebola vaccine may produce false results.**

Device Handling Precautions

- Use all capillary tubes, pipette tips, test stands, test devices, and developer solution vials only once and dispose of properly (see *Warnings and Precautions*). **Do not reuse any test components.**
- Inspect the divided pouch. If the divided pouch has been damaged, discard the divided pouch and its contents and select a new divided pouch for testing.
- Do not interchange test devices and developer solution vials from kits with different lot numbers.
- Avoid microbial contamination and exercise care in handling the kit components.
- Adequate lighting is required to read a test result.

STORAGE INSTRUCTIONS AND SHELF LIFE

Store unused OraQuick™ Ebola 2.0 Rapid Antigen Tests unopened at 2°-30°C (36°-86°F). Do not open the divided pouch until you are ready to perform a test. If stored refrigerated, ensure that the divided pouch is brought to operating temperature 15°-40°C (59°-104°F) before opening.

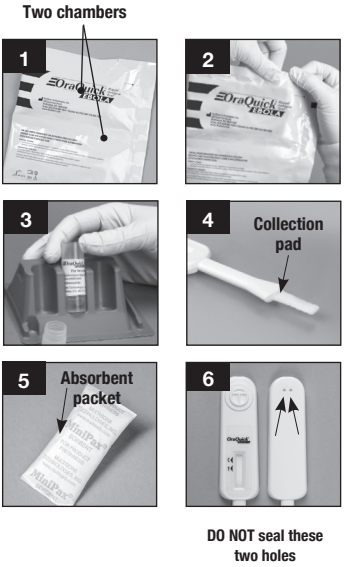
DIRECTIONS FOR USE

GENERAL TEST PREPARATION

1. Follow the *Warnings and Precautions* section in this instructions for use.
2. Gather the materials you will need.
3. Allow the OraQuick™ Ebola 2.0 Rapid Antigen Test to come to operating temperature 15°-40°C (59°-104°F) before use.

4. Set a test stand at your workspace, using only the stand provided.
5. Open the two chambers of the divided pouch ("pouch") by tearing at the notches on the top of each side of the pouch (Picture 1, 2).
6. 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.
7. 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 (Picture 3).
8. Remove the device from the pouch. Handle the device by the plastic housing, **NOT** the collection pad (Picture 4). Place the device on a flat clean surface. Check to make sure that an absorbent packet is included with the device (Picture 5). If no absorbent packet is present, discard the device and obtain a new pouch for testing.

   NOTE: DO NOT seal the two holes in the back of the device with labels or other materials. Doing so may cause an invalid result (Picture 6).



SPECIMEN COLLECTION AND TESTING PROCEDURE

The OraQuick™ Ebola 2.0 Rapid Antigen Test can be used for testing venipuncture whole blood and fingerstick whole blood specimens or cadaveric oral fluid specimens. Refer to the specific testing procedures below.

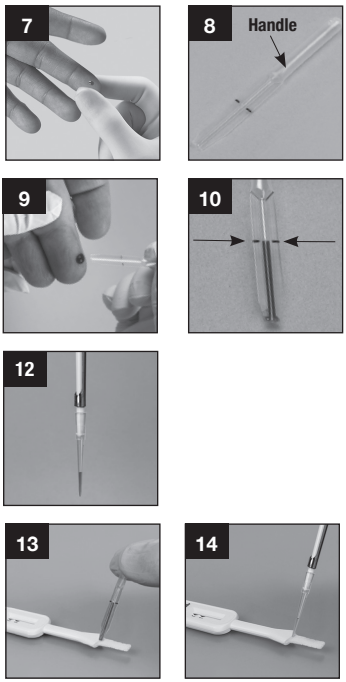
FINGERSTICK WHOLE BLOOD AND VENIPUNCTURE PROCEDURE

STEP 1: COLLECT THE SPECIMEN

STEP 1A: FINGERSTICK WHOLE BLOOD

1. Using an antiseptic wipe, clean the finger of the person being tested. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad. Using a sterile lancet, puncture the skin just off the center of the finger pad and perpendicular to the fingerprint ridges. Apply slight pressure beside the point of the puncture (Picture 7). Avoid aggressive squeezing of the finger to make it bleed. Wipe away this first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
2. Hold the capillary blood collection tube (Picture 8) horizontally and touch the tip of the tube to blood drop on the finger (Picture 9). The capillary tube fills automatically; do not squeeze the bulb during blood collection. To avoid air bubbles, keep the tube tip in continuous contact with the blood until the fill is complete. Confirm that the capillary tube is filled to the indicator line and that no bubbles are present (Picture 10). If bubbles are observed, discard the sample and collect a new one using a new capillary tube.

   NOTE: If the capillary tube is dropped or comes in contact with any other surface, discard it in a biohazard waste container and obtain a new one. If blood is still flowing, attempt to collect 50 µL. If not, a new puncture may need to be performed. Get a new capillary tube for the collection of the blood sample.



STEP 1B: VENIPUNCTURE WHOLE BLOOD

1. Using standard venous phlebotomy procedures collect a whole blood sample using a tube containing EDTA (lavender top) anticoagulant. If the specimens are not tested at the time of collection, the specimen may be stored at 2°-8°C (36°-46°F) for up to 6 days.
2. Prior to testing, mix the blood tube gently by inversion several times to ensure a homogeneous sample.
3. Using a calibrated pipettor, pipette 50 µL of sample and inspect the tip for bubbles (Picture 12). If a bubble is present, discard the collected sample and obtain a new sample.

STEP 2: TEST

1. Deposit the blood sample onto the integrated collection pad at the position shown in the photos. (Pictures 13-14). **Samples MUST only be applied directly to the device and should not be pipetted into the developer vial.**

   Note: Pipetting the sample at a location other than that shown in the photo could result in failure to detect a low positive sample.

2. Insert the collection pad of the device all the way into the developer vial (Picture 15). Make sure that the collection pad touches the bottom of the vial. The result window on the device should be facing you (Picture 16).
3. Start timing the test (Picture 17). **DO NOT** remove the device from the vial while the test is running. Fluid will appear and travel up the result window. The fluid may gradually lighten as the test develops (Picture 18). Read the results in a fully lit area. Read results between 30 and 40 minutes to obtain an accurate result. DO NOT read before 30 minutes or after 40 minutes.
4. Refer to the *Test Result and Interpretation of Test Result* section on page 6 of in this package insert.

CADAVERIC ORAL FLUID PROCEDURE – DIRECT COLLECTION

STEP 1: COLLECT THE SPECIMEN

1. Remove the device from its pouch. Handle the device by the plastic housing, **NOT** the collection pad (Picture 19). Check to make sure that an absorbent packet is included with the device (Picture 20). If no absorbent packet is present, discard the device and obtain a new pouch for testing.
2. Collect a sample from oral cavity by swiping the integrated flat collection pad across the upper and lower gum lines once (Pictures 21-22). Samples can also be collected by swabbing once across the inner cheek (Picture 23) or once across the soft palate (Picture 24). Only one sample location should be used when swabbing with the device. **NOTE: Both sides of the flat pad may be used during this procedure.**

STEP 2: TEST

1. Insert the collection pad of the device all the way into the vial (Picture 25). Make sure that the collection pad touches the bottom of the vial. The result window on the device should be facing you (Picture 26).
2. Start timing the test (Picture 27). DO NOT remove the device from the vial while the test is running. Purple fluid will appear and travel up the result window. The purple fluid will gradually disappear as the test develops (Picture 28). Read results between 30 and 40 minutes to obtain an accurate result. DO NOT read before 30 minutes or after 40 minutes.
3. Refer to the *Test Result and Interpretation of Test Result* section on page 6 of this package insert.

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 (Picture 29).

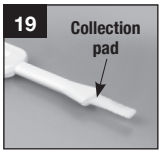
GENERAL TEST CLEAN-UP

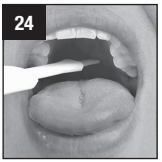
1. Dispose of the used test materials in a biohazard waste container. All equipment and biohazardous waste should be discarded in accordance with country, state, and local laws and policies.
2. Change your gloves between each test to prevent contamination. Throw away the used gloves in a biohazard waste container.
3. Use a freshly prepared 10% solution of bleach to clean up any spills.

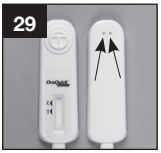
QUALITY CONTROL PROCEDURES

Built-in Control Features

The OraQuick™ Ebola 2.0 Rapid Antigen Test has a built-in procedural control that demonstrates assay validity. A purple line in the control (C) zone of the result window indicates that the fluid migrated appropriately through the test device. In some patients with high levels of virus, a line in the C zone will be absent, but the line in the T zone will be positive. In this case, the T zone line serves as the built in procedural control. Refer to the *Test Result and Interpretation of Test Result* section on page 6 of this package insert.







Do NOT seal these two holes

External Quality Control

OraQuick™ Ebola 2.0 Rapid Antigen Test Kit Controls must be used with the OraQuick™ Ebola 2.0 Rapid Antigen Test. The kit controls are specifically formulated and manufactured to ensure performance of the Test, and are used to verify your ability to properly perform the test and interpret the results. The Ebola 2.0 positive control will produce a positive test result and the Ebola 2.0 negative control will produce a negative test result. Refer to the *Test Result and Interpretation of Test Result* section on page 6 of this package insert. Use of kit control reagents manufactured by any other source may not produce the required results, and therefore, may not meet the requirements for an adequate quality assurance program for the OraQuick™ Ebola 2.0 Rapid Antigen Test. If external controls do not produce expected results, patient testing should not be performed. Contact OraSure Technologies' Customer Care if the kit control reagents do not produce the expected result.

Run the External Controls under the following circumstances:

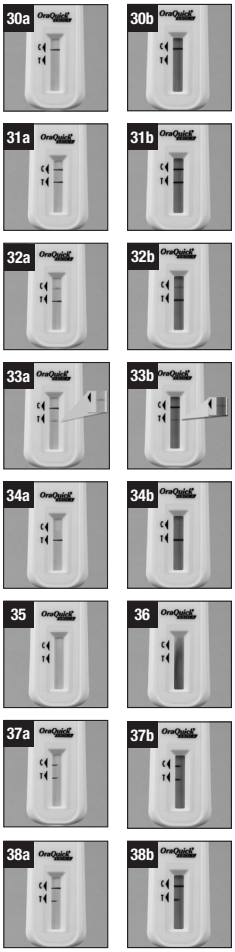
- Each new operator prior to performing testing on patient specimens,
- When opening a new test kit lot,
- When a new shipment of test kits is received,
- When test kit storage conditions fall outside of 2°-30°C (36°-86°F), and
- At periodic intervals as dictated by the user facility, country, state or local regulations and policies.

Test Procedure for External Controls:

Refer to the OraQuick™ Ebola 2.0 Rapid Antigen Test Kit Control package insert for full instruction on the use of these controls. It is the responsibility of each laboratory using the OraQuick™ Ebola 2.0 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.

TEST RESULT AND INTERPRETATION OF TEST RESULT

Interpret results 30 to 40 minutes after inserting the device into the developer vial. **Please refer to the Visual Reference Card provided in the kit to see colored images of the varying intensity levels that may be observed while running and interpreting the OraQuick™ Ebola 2.0 Rapid Antigen Test.**



NEGATIVE

A test is **Negative** if:

A purple line appears in the C zone and NO line appears next to the T zone (Picture 30a/b)

A negative test result is interpreted as Ebola antigen not detected in the specimen.

The patient/cadaver is presumed negative for Ebola antigen.

A negative result does not preclude Ebola disease.

POSITIVE

A test is **Positive** if:

A purple line appears in the T zone. Lines may vary in intensity. The test is positive regardless of how faint these lines appear (Picture 31a/b, 32a/b, 33a/b). In some cases the purple line in the C zone may not be present or may be very faint if there are high levels of virus in the sample (Picture 34a/b).

A positive test result is interpreted as Ebola antigen detected in the specimen. The patient/cadaver is presumed positive for Ebola antigen. Definitive identification of Ebola disease requires additional testing and confirmation procedures in consultation with public health and/or other authorities to whom reporting is required.

In accordance with CDC and WHO recommendations, cadavers with a positive result should be subjected to safe and dignified burial procedures and contacts of an Ebola positive cadaver should be identified. Follow up testing of possible contacts should be conducted in accordance with, EMERGENCY GUIDELINE Implementation and management of contact tracing for Ebola virus disease (https://iris.who.int/server/api/core/bitstreams/1be2b0a4-ecaa-442d-af2b-709dae0dae58/content) issued by the World Health Organization (WHO) and the Centers for Disease Control (CDC).

INVALID

A test is **Invalid** if any of the following occurs:

- **NO** purple lines are present. (Picture 35), or
- A purple background in the result window makes it difficult to read the result at a time between 30 and 40 minutes (Picture 36), or
- Any partial line on one side of the C or T zones (Picture 37a/b, 38a/b).

An invalid test result means that there was a problem running the test, related either to the specimen or to the test device. **An invalid result cannot be interpreted. An invalid test result needs to be repeated with a fresh sample and a new device. Please contact OraSure Technologies' Customer Care if you are unable to obtain a valid test result upon repeat testing.**

To report a device problem, contact OraSure Technologies Customer Service (1-800-ORA-SURE) within the United States or +(001) 610-882-1820 for outside the United States. You can also go to https://orasure.com/inquiry.html.

LIMITATIONS OF THE TEST

1. U.S. hospitals or clinical laboratories concerned about a patient with potential *Orthoebolavirus* exposure should contact their local and/or state public health authorities. These agencies will work with CDC to determine whether a patient is or is not a person under investigation (PUI); only PUI should be tested for Ebola.
2. Testing with the OraQuick™ Ebola 2.0 Rapid Antigen Test should not be performed unless the patient meets clinical and epidemiologic criteria for testing suspect specimens.
3. All results with the OraQuick™ Ebola 2.0 Rapid Antigen Test are presumptive; definitive diagnosis of Ebola disease requires performing additional testing with molecular testing in consultation with public health and/or other authorities to whom reporting is required. The diagnosis of Ebola disease must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence in addition to the identification of *Orthoebolavirus*.
4. Negative results do not preclude *Orthoebolavirus* infection and should not be used as the sole basis for patient management decisions.
5. Potential cross-reactivity of the OraQuick™ Ebola 2.0 Rapid Antigen Test with Ebola vaccines or therapeutics has not been evaluated. Specimens from patients who have received therapeutics or vaccines against *Orthoebolavirus* may exhibit false positive or other confounding test results.
6. The OraQuick™ Ebola 2.0 Rapid Antigen Test is a qualitative test; therefore, the intensity of the line for positive results should not be correlated with viral concentration.
7. The performance of this test was evaluated with a limited number of clinical specimens for whole blood, fingerstick blood, and cadaveric fluid.
8. The OraQuick™ Ebola 2.0 Rapid Antigen Test is not intended for use as a diagnostic test for oral fluid samples of living individuals nor is it intended for use with cadaveric samples stored in viral transport media.
9. False negative results have been observed with hemolyzed venous whole blood samples.
10. Testing of whole blood samples with concentrations of Rheumatoid Factor above 544 IU/mL may result in false positive results.
11. Cross-reactivity with organisms other than those tested in the cross-reactivity study have not been assessed.
12. The level of *Orthoebolavirus* antigens present in clinical specimens from individuals with early systemic infection is unknown. Test performance is associated with the level of antigen in the patient; therefore, the test is not intended for use in asymptomatic populations for mass screening purposes (e.g., as the sole means of Ebola disease control at airports or border crossings) or for testing individuals at risk of exposure without observable signs or symptoms of infection (e.g., contact tracing).

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The OraQuick™ Ebola 2.0 Rapid Antigen Test, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, the authorized Fact Sheet for Response Teams, the authorized Fact Sheet for Relatives and Caregivers and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices#ebola.

To assist clinical laboratories running OraQuick™ Ebola 2.0 Rapid Antigen Test, the relevant Conditions of Authorization are listed verbatim below, and are required to be met by laboratories performing the EUA test.

- Authorized laboratories* that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories using your product must include with test result reports, all authorized fact sheets. Under exigent circumstances, other appropriate methods for disseminating these fact sheets may be used, which may include mass media.
- Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories must have a process in place to track adverse events and report to OraSure Technologies and to U.S. FDA pursuant to 21 CFR Part 803. For customers within the U.S., phone: 1-800-ORASURE (800-672-7873). For customers outside the U.S., phone +(001) 610-882-1820 or go to www.orasure.com.
- All laboratory personnel using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate laboratory and personal protective equipment when handling your product, and use your product in accordance with the authorized labeling.
- OraSure Technologies, Inc., authorized distributor(s), and authorized laboratories must collect information on the performance of your product and must report any significant deviations from the established performance characteristics of your product of which they become aware to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov). In addition, authorized distributor(s) and authorized laboratories report to OraSure Technologies. For customers within the U.S. phone: 1-800-ORASURE (800-672-7873). For customers outside the U.S., phone +(001) 610-882-1820 or go to www.orasure.com.
- OraSure Technologies, Inc., authorized distributor(s), and authorized laboratories using this product must ensure that any records associated with this EUA, are maintained until otherwise notified by U.S. FDA. Such records must be made available to U.S. FDA for inspection upon request.

*Authorized laboratories are laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high-complexity tests, or in similarly qualified non-U.S. laboratories and facilities adequately equipped, trained, and capable of testing for *Orthoebolavirus* infection, by experienced personnel who have received specific training on the use of the OraQuick™ Ebola 2.0 Rapid Antigen Test, training in the correct use of recommended personal protective equipment (PPE), and expertise in infectious disease diagnostic testing, including the safe handling of clinical specimens potentially containing *Orthoebolavirus*.

PERFORMANCE CHARACTERISTICS

WHOLE BLOOD CLINICAL PERFORMANCE

BUNDIBUGYO POSITIVE CONTRIVED BLOOD SAMPLES

Fifty (50) unique venous whole blood samples including 6 from febrile individuals (> 100.4°F) were collected and spiked with inactivated Bundibugyo virus (200706291 Uganda Prototype, lot 815371) to prepare contrived positive samples. Ten (10) samples were spiked at the LoD, fifteen (15) were spiked at < 2x LoD and twenty-five (25) were spiked in the range of 3x LoD to 5x LoD. Overall positive percent agreement (PPA) for venous whole blood was 100% (95% CI, 93.6%-100%). Results are summarized in the table below.

Sample type	Concentration Tested	Positive percent agreement (n/N)	95% CI
Contrived positive venous whole blood	LoD	100% (10/10)	72.2%-100%
	1.9 x LoD	100% (15/15)	79.6%-100%
	3 x LoD	100% (10/10)	72.2%-100%
	4 x LoD	100% (10/10)	72.2%-100%
	5 x LoD	100% (5/5)	56.6%-100%

n = number in agreement; N = sample size; CI = confidence interval
Six (6) febrile samples were tested as spiked positive samples

SPECIFICITY PERFORMANCE IN NON-ENDEMIC POPULATION

To support venous whole blood and fingerstick whole blood claims, specificity studies were conducted on a total of 245 subjects (166 venous whole blood, 29 febrile venous whole blood and 50 fingerstick whole blood) in the United States. Of the venous whole blood samples, seventy-three (73) unique whole blood samples were also tested for specificity as part of the contrived whole blood samples (prior to spiking). A summary of all results is provided in table below.

Sample type	Negative percent agreement (n/N)	95% CI
Venous whole blood[a]	98.2% (163/166)	94.8%-99.4%
Venous whole blood - febrile[b]	100% (29/29)	89.0%-100%
Fingerstick whole blood	98% (49/50)	88.5%-99.9%

n = number in agreement; N = sample size; CI = confidence interval

[a]Sixty-six (66) negative samples from the contrived sample study have been incorporated into the total for venous whole blood.

[b]Seven (7) febrile samples were tested as part of contrived specimen study.

WHOLE BLOOD ANALYTICAL PERFORMANCE

LIMIT OF DETECTION

A limit of detection (LoD) range-finding study in venous whole blood identified 1.76 x 10^4 $TCID_{50}$/mL as the tentative LoD for inactivated Bundibugyo virus (200706291 Uganda Prototype, lot 815371, 3.51 x 10^6 $TCID_{50}$/mL). This tentative LoD was confirmed as the LoD by 19/20 replicates testing positive with the same inactivated Bundibugyo virus at this concentration. The range finding study in venous whole blood identified 1.43 x 10^4 $TCID_{50}$/mL as the tentative LoD for Ebola Zaire (Mayinga). This tentative LoD was confirmed as the LoD by 19/20 replicated testing positive with the same Mayinga inactivated virus at this concentration. The tentative LoD for Taï Forest (Côte D'Ivoire) was determined to be 1.11 x 10^3 $TCID_{50}$/mL in venous whole blood and confirmed in 20/20 replicates. Refer to the table below.

Additionally, a LoD range-finding study was performed using recombinant Mayinga VP40 antigen spiked into pooled venous whole blood. This LoD range-finding study determined the tentative LoD of the OraQuick™ Ebola 2.0 Rapid Antigen Test in venous whole blood with the recombinant antigen to be 0.5 ng/mL. The tentative LoD was confirmed as the LoD by 20/20 replicates testing positive with the same recombinant VP40 antigen at this concentration.

Ebola strain	Concentration tested	Positive
Bundibugyo (200706291 Uganda Prototype)	1.76 x 10^4 $TCID_{50}$/mL	19/20
Ebola Zaire (Mayinga)	1.43 x 10^4 $TCID_{50}$/mL	19/20
Taï Forest (Côte D'Ivoire)	1.11 x 10^3 $TCID_{50}$/mL	20/20

WHOLE BLOOD ANALYTICAL REACTIVITY (INCLUSIVITY)

Analytical reactivity of the OraQuick™ Ebola 2.0 Rapid Antigen Test was evaluated for additional strains of the *Orthoebolavirus*. Testing was performed using negative whole blood as the testing sample matrix. The OraQuick™ Ebola 2.0 Rapid Antigen Test detects all *Orthoebolavirus* strains tested. The results provided below represent the lowest concentration in which all replicates were positive.

Ebola strain	Inactivated or live	Concentration tested	Positive
Sudan (200011676 Gulu)	Inactivated	1.04 x 10^4 $TCID_{50}$/mL	3/3
	Live	1.04 x 10^5 $TCID_{50}$/mL	3/3
Reston (119876 Pennsylvania Strain)	Inactivated	3.16 x 10^7 PFU/mL	5/5

HIGH-DOSE HOOK EFFECT

A high-dose hook effect is a false negative result due to very high concentrations of the target analyte. Antigens at excessive concentrations could quench the specific antibodies in the assay, decreasing complexes between the antibody on the gold conjugate and the biotinylated antibody. Insufficient binding of the gold conjugate could occur at the test line, and the result could be interpreted falsely as a negative result. Testing of live virus stocks at high concentrations of *Orthoebolavirus* species Bundibugyo, Zaire (Mayinga), Sudan and Taï Forest, were evaluated and demonstrated acceptable performance of the OraQuick™ Ebola 2.0 Rapid Antigen Test. A decrease in the visual intensity of the control line was observed; however, the control line remained visible. Refer to table for concentrations tested.

Ebola strain	Concentration tested ($TCID_{50}$/mL)
Bundibugyo (200706291 Uganda Prototype)	3.51×10^6
Zaire (Mayinga)	2.85×10^7
Sudan (200011676 Gulu)	4.14×10^7
Taï Forest (Cote D'Ivoire)	1.00×10^6

An analytical study was conducted, and the results demonstrated acceptable performance of the OraQuick™ Ebola 2.0 Rapid Antigen Test when evaluating samples at excessive antigen concentrations. No decrease in visual intensity was observed at the test line for VP40 antigen concentrations up to 50 µg/mL, 100,000 times the established LoD. A decrease in the visual intensity of the control line was observed at higher concentrations; however, the control line remained visible up to 50 µg/mL.

WHOLE BLOOD INTERFERING SUBSTANCES

The OraQuick™ Ebola 2.0 Rapid Antigen Test was evaluated with the following interfering substances present in negative whole blood and whole blood spiked with Zaire Mayinga recombinant antigen (rAg) at ≤ 3x LoD, in order to assess their potential effect on the assay performance. If the substance interfered with the performance of the OraQuick™ Ebola 2.0 Rapid Antigen Test, additional dilutions were prepared to determine at what concentration the substance did not cause interference.

Interfering substance	Target testing concentration	N	Negative samples		Positive rAg-spiked samples	
			Positive	Negative	Positive	Negative
Unconjugated bilirubin	25 mg/dL	3	0/3	3/3	3/3	0/3
Serum protein	5 g/dL	3	0/3	3/3	3/3	0/3
Rheumatoid factor	544 IU/mL	3	2/3	1/3	3/3	0/3
Rheumatoid factor – dilution 1	272 IU/mL	3	0/3	3/3	Not tested	
Cholesterol	13 mmol/L	3	0/3	3/3	3/3	0/3
HAMA	1016 ng/mL	3	0/3	3/3	3/3	0/3
Hemoglobin (hemolyzed blood)	20 g/dL	3	0/3	3/3	1/3	2/3
Hemoglobin (hemolyzed blood) - dilution 1	10 g/dL	3	Not tested		3/3	0/3
ANA	≥ 8.0 AI	3	0/3	3/3	3/3	0/3
Chloroquine	18 µg/mL	3	0/3	3/3	3/3	0/3
Proguanil/Atovaquone	2.8/89.1 µg/mL	3	0/3	3/3	3/3	0/3
Ibuprofen	2425 µmol/L	3	0/3	3/3	3/3	0/3
Acetaminophen	1324 µmol/L	3	0/3	3/3	3/3	0/3
Quinine	148 µmol/L	3	0/3	3/3	3/3	0/3
Amoxicillin	206 µmol/L	3	0/3	3/3	3/3	0/3
Tetracycline	34 µmol/L	3	0/3	3/3	3/3	0/3
Ribavirin	11.04 µg/mL	3	0/3	3/3	3/3	0/3
Biotin	3.6 µg/mL	3	0/5	5/5	5/5	0/5

There was no interference from the exogenous substances tested, including pain relievers, antivirals, antimalarials, or antibiotics. From the endogenous substances tested, false positives were seen with rheumatoid factor (RF) samples at 544 IU/mL; however, rheumatoid factor (RF) samples at 272 IU/mL did not cause interference. False negatives were seen with hemoglobin (hemolyzed blood) samples at 20 g/dL; however, hemoglobin (hemolyzed blood) samples at 10 g/dL did not cause interference. The remaining endogenous substances including bilirubin, cholesterol, serum protein, HAMA (human anti-mouse antibodies), and ANA (antinuclear antibody) did not cause interference with the performance of the OraQuick™ Ebola 2.0 Rapid Antigen Test.

WHOLE BLOOD CROSS-REACTIVITY

The cross-reactivity of the OraQuick™ Ebola 2.0 Rapid Antigen Test evaluated the impact of various virus, bacteria, and parasitic pathogens. In this study, multiple replicates were tested with the pathogens spiked into whole blood at the concentrations listed in table. None of the tested organisms produced false positive results in the OraQuick™ Ebola 2.0 Rapid Antigen Test at the tested concentrations.

Organism	Tested concentration	Units	Positive	Negative
Plasmodium falciparum	unknown	N/A	0/5	5/5
Plasmodium vivax	unknown	N/A	0/5	5/5
Salmonella enterica subsp. *enterica* serovar Typhi	2.0E+06	CFU/mL	0/5	5/5
Salmonella enterica subsp. *enterica,* serovar Choleraesuis	8.4E+07	CFU/mL	0/5	5/5
Dengue virus serotype 1	5.00E+06	$TCID_{50}$/mL	0/5	5/5
Dengue virus serotype 2	8.9E+04	$TCID_{50}$/mL	0/5	5/5
Dengue virus serotype 3	1.6E+06	$TCID_{50}$/mL	0/5	5/5
Dengue virus serotype 4	2.8E+07	$TCID_{50}$/mL	0/5	5/5
Measles virus	8.9E+04	$TCID_{50}$/mL	0/5	5/5
Leptospira biflexa, serotype *Patoc*	unknown	N/A	0/5	5/5
Simian rotavirus A	1.6E+07	$TCID_{50}$/mL	0/5	5/5
Adenovirus type 4	2.8E+06	$TCID_{50}$/mL	0/5	5/5
Escherichia coli serotype O157:H7	2.30E+07	CFU/mL	0/5	5/5
Shigella dysenteriae	>2E+03	CFU/mL	0/5	5/5
Clostridioides difficile	2.8E+08	CFU/mL	0/5	5/5
Rickettsia africae	1.6E+05	$TCID_{50}$/mL	0/5	5/5
Rickettsia australis	8.9E+05	$TCID_{50}$/mL	0/5	5/5
SARS-CoV-2	1.4E+05	$TCID_{50}$/mL	0/5	5/5
Marburg Ravn	3.39E+05	$TCID_{50}$/mL	0/5	5/5
Marburg Musoke	3.16E+06	PFU/mL	0/5	5/5
Marburg Voege *	3.6E+06	PFU/mL	0/5	5/5
Marburg Angola	Unknown	N/A	0/5	5/5
Crimean-Congo hemorrhagic fever virus	5.6E+04	$TCID_{50}$/mL	0/5	5/5
Lassa Josiah	3.16E+05	PFU/mL	0/5	5/5
Rift Valley fever virus	5.43E+06	PFU/mL	0/5	5/5
Yellow fever virus, vaccine strain 17D	1.6E+06	$TCID_{50}$/mL	0/5	5/5
Influenza virus A	3.0E+06	$CEID_{50}$/mL	0/5	5/5
Influenza virus B	2.8E+06	$TCID_{50}$/mL	0/5	5/5
RSV	1.6E+05	$TCID_{50}$/mL	0/5	5/5
Chikungunya	8.9E+06	$TCID_{50}$/mL	0/15	15/15
Coxiella burnetii	1.6E+04	$TCID_{50}$/mL	0/15	15/15
Enterovirus	8.9E+05	$TCID_{50}$/mL	0/5	5/5
Borrelia recurrentis	unknown	N/A	0/5	5/5
Pseudomonas aeruginosa	1.12E+08	CFU/mL	0/5	5/5
Vibrio cholerae	>2E+03	CFU/mL	0/5	5/5
Streptococcus pneumoniae	>1E+03	CFU/mL	0/5	5/5
Hemophilus influenzae	1.8E+07	CFU/mL	0/5	5/5
Neisseria meningitidis	7.2E+05	CFU/mL	0/5	5/5
Yersinia pestis	2.9E+06	CFU/mL	0/5	5/5
Yersinia enterocolitica	1.4E+08	CFU/mL	0/5	5/5
Rickettsia prowazekii	1.6E+03	$TCID_{50}$/mL	0/15	15/15
Rickettsia conorii	2.8E+06	$TCID_{50}$/mL	0/15	15/15
Trypanosoma cruzi	unknown	N/A	0/5	5/5

* *Marburg Voege* is an isolate from a patient infected during the 1967 Marburg outbreak.

CADAVERIC ORAL FLUID

CADAVERIC ORAL FLUID CLINICAL PERFORMANCE

BUNDIBUGYO POSITIVE CONTRIVED ORAL FLUID SAMPLES

Fifty (50) unique oral fluid samples from live donors were collected and spiked with Bundibugyo inactivated virus (200706291 Uganda Prototype, lot 815371) to prepare contrived positive samples as a surrogate for direct collect cadaveric oral fluid samples. Ten (10) samples were spiked at the LoD, fifteen (15) were spiked at < 2x LoD and twenty (25) were spiked in the range of 3x LoD to 5x LoD. Overall positive percent agreement (PPA) for oral fluid from live donors was 100% (95% CI, 93.6%-100%). Results are summarized in table.

Sample type	Concentration Tested	Positive percent agreement (n/N)	95% CI
Contrived positive oral fluid	LoD	100% (10/10)	72.2%-100%
	1.9 x LoD	100% (15/15)	79.6%-100%
	3 x LoD	100% (10/10)	72.2%-100%
	4 x LoD	100% (10/10)	72.2%-100%
	5 x LoD	100% (5/5)	56.6%-100%

n = number in agreement; N = sample size; CI = confidence interval

SPECIFICITY PERFORMANCE IN NON-ENDEMIC POPULATION

To support cadaveric oral fluid claims, specificity studies were conducted on 108 living donors (oral fluid) and 80 cadavers in the United States. Oral fluid from living donors was tested as a surrogate for cadaveric oral fluid. For living donors, the specificity demonstrated was 100% (108/108; 95% CI, 96.6%-100%) for direct collection. For cadaver samples, the direct collection method demonstrated 100% (80/80; 95% CI, 95.5%-100%). A summary of all results is provided in table.

Sample type	Negative percent agreement (n/N)	95% CI
Oral fluid – live donors[a]	100% (108/108)	96.6%-100%
Cadaveric oral fluid	100% (80/80)	95.5%-100%

n = number in agreement; N = sample size; CI = confidence interval

[a]Fifty-eight (58) negative samples were collected and tested as part of the contrived sample study.

CADAVERIC ORAL FLUID ANALYTICAL PERFORMANCE

LIMIT OF DETECTION

A limit of detection (LoD) range-finding study was conducted in oral fluid collected from living donors spiked onto the collection pad of the OraQuick™ Ebola 2.0 Rapid Antigen Test. The range-finding study identified 8.78 x 10^3 $TCID_{50}$/mL as the tentative LoD for Bundibugyo inactivated virus (200706291 Uganda Prototype, lot 815371, 3.51 x 10^6 $TCID_{50}$/mL). This tentative LoD was confirmed as the LoD by 19/20 replicates testing positive with the same Bundibugyo inactivated virus at this concentration.

CROSS-REACTIVITY — CADAVERIC ORAL FLUID

The cross-reactivity of the OraQuick™ Ebola 2.0 Rapid Antigen Test was evaluated by testing additional viral and bacterial pathogens. In this study, five (5) replicates were tested with the pathogens spiked into Ebola negative oral fluid (saliva as a surrogate) at the concentrations listed in table. None of the tested organisms produced false positive results in the OraQuick™ Ebola 2.0 Rapid Antigen Test.

Organism	Tested concentration	Units	Positive	Negative
Moraxella (Branhamella) catarrhalis	3.8E+06	CFU/mL	0/5	5/5
Corynebacterium diphtheriae	3.2E+07	CFU/mL	0/5	5/5
Nocardia spp.	Unknown	N/A	0/5	5/5
Hoylesella (Bacteroides) oralis	>2E+03	CFU/mL	0/5	5/5
Chlamydophila pneumoniae	2.9E+07	IFU/mL	0/5	5/5
Mycoplasma pneumoniae	2.6E+07	CFU/mL	0/5	5/5
Bordetella pertussis	8.0E+07	CFU/mL	0/5	5/5
Clostridioides difficile	2.8E+08	CFU/mL	0/5	5/5
Cytomegalovirus (human herpesvirus 5)	2.8E+04	$TCID_{50}$/mL	0/5	5/5
Epstein-Barr virus (human gammaherpes virus 4)	Unknown	N/A	0/5	5/5

Additional cross-reactivity was performed for the OraQuick™ Ebola 2.0 Rapid Antigen Test for use with whole blood and no cross-reactivity was observed at the tested concentrations. Refer to the Whole Blood Cross-Reactivity testing section for the list of organisms.

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
3. *EMERGENCY GUIDELINE Implementation and management of contact tracing for Ebola virus disease* (https://iris.who.int/server/api/core/bitstreams/1be2b0a4-ecaa-442d-af2b-709dae0dae58/content) issued by the World Health Organization (WHO) and the Centers for Disease Control (CDC).

EXPLANATION OF SYMBOLS

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

For Technical or Customer Service within the United States, 1-800-ORASURE (1-800-672-7873).
For customers outside the United States, phone +(001) 610-882-1820 or go to www.orasure.com.

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3001-3961_EUA v1/07-26

Whole Blood Quick Reference Guide

OraQuick™ Ebola 2.0 Rapid Antigen Test

For use under Emergency Use Authorization (EUA) only.
For in vitro diagnostic use.

The OraQuick™ Ebola 2.0 Rapid Antigen Test is an in vitro diagnostic single-use immunoassay for the qualitative detection of antigens from viruses within the *Orthoebolavirus* genus but does not differentiate between these viruses.

This product has not been U.S. FDA cleared or approved, but has been authorized for emergency use by U.S. FDA under an EUA for use by the authorized laboratory.

This product has been authorized only for the detection of antigens from orthoebolaviruses including *Orthoebolavirus zairense*, *Orthoebolavirus bundibugyoense*, *Orthoebolavirus sudanense*, and *Orthoebolavirus taiense*, not for any other viruses or pathogens.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of Ebola virus under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

This Quick Reference Guide is designed to provide a basic guideline for testing. Please refer to the package insert for complete information on proper collection of samples and procedural use of the OraQuick™ Ebola 2.0 Rapid Antigen Test. Deviation from these procedures may result in inaccurate results.

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

STEP 1a. – Collect the Specimen [1,2,3]
Fingerstick Whole Blood

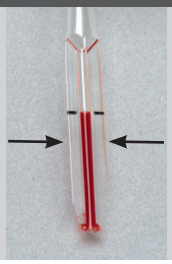
Cleanse finger. Air dry. Puncture with lancet.

Capillary blood tube

Wipe away first drop of blood. Fill capillary blood tube to black lines.

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

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



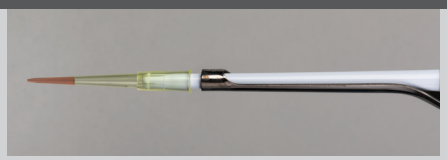
OR

STEP 1b. – Collect the Specimen [1,2,3]
Venipuncture Whole Blood

Collect blood using standard phlebotomy procedures.

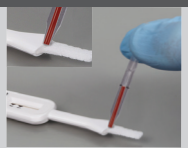
- Prior to testing, mix blood tube gently by inversion several times to ensure homogenous specimen.
- Remove tube cap.
- Whole blood may be stored for 6 days refrigerated at 2°C-8°C (36°F-46°F).

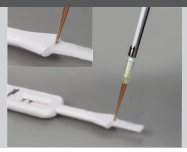
Using a calibrated pipette, pipette 50 µL of sample and inspect the tip for bubbles. If a bubble is present, discard the collected sample and obtain a new sample.



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

Deposit the blood sample by compressing the bulb on the capillary blood tube, or from the calibrated pipette onto the collection pad at the location shown in the photo. Samples MUST only be applied directly to the device and should not be pipetted into the developer vial. **Note: Pipetting the sample at a location other than that shown in the photo could result in failure to detect a low positive sample.**





Insert the collection pad of the device all the way into the developer vial. Make sure that the collection pad touches the bottom of the vial. The result window on the device should be facing you.

Set a timer for 30 minutes and start timing the test.

Fluid will appear and travel up the result window. The fluid may gradually lighten as the test develops.

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

STEP 3. – Read Results

Read the results in a fully lit area. Read results between 30 and 40 minutes to obtain an accurate result. DO NOT read before 30 minutes or after 40 minutes.
To report a device problem, contact OraSure Technologies Customer Service (1-800-orasure) within the U.S. or +(001) 610-882-1820 for outside the U.S. You can also go to www.orasure.com/inquiry.html.

Negative: Line in C zone

Line in C zone.

- A negative test result means that Ebola antigens were not detected in the specimen.
- The test result is interpreted as Ebola antigens were not detected. The patient is presumed negative for Ebola antigens.

Invalid: Repeat test

No lines present

Background obscures results

Any partial line at C or T zone

Positive: Lines in T zones

Examples of positive results.

Line in T zone

Line in T zone

Faint line in T zone

No line in C zone

- A positive test result means that Ebola antigens have been detected in the specimen. The patient is presumed positive for Ebola antigens. 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.
- In some cases, the purple line in the C zone may not be present or may be very faint if there are high levels of virus in the sample.

Order Information and Description

1001-0708 25 Count kit
1001-0709 Kit Controls

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: https://www.cdc.gov/ebola/about/index.html

3001-3963_EUA v2/07-26

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Made in the USA

Cadaveric Oral Fluid Quick Reference Guide

OraQuick™ Ebola 2.0 Rapid Antigen Test

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The OraQuick™ Ebola 2.0 Rapid Antigen Test is an in vitro diagnostic single-use immunoassay for the qualitative detection of antigens from viruses within the *Orthoebolavirus* genus but does not differentiate between these viruses.

This product has not been U.S. FDA cleared or approved, but has been authorized for emergency use by U.S. FDA under an EUA for use by the authorized laboratory.

This product has been authorized only for the detection of antigens from orthoebolaviruses including *Orthoebolavirus zairense*, *Orthoebolavirus bundibugyoense*, *Orthoebolavirus sudanense*, and *Orthoebolavirus taiense*, not for any other viruses or pathogens.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of Ebola virus under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

This Quick Reference Guide is designed to provide a basic guideline for testing. Please refer to the package insert for complete information on proper collection of samples and procedural use of the OraQuick™ Ebola 2.0 Rapid Antigen Test. Deviation from these procedures may result in inaccurate results.

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

STEP 1. – Specimen Collection [1,2,3]

Using the flat pad of the test device, swab the upper and lower gum line as shown in the photos below. Swab the cadaver using the flat pad of the device. After collection, go to Step 2.

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

OR

Collect sample from one inner cheek. Swab once.

OR

Collect sample from the soft palate. Swab once.

STEP 2. – Perform the Test

Insert the collection pad of the device all the way into the developer vial. Make sure that the collection pad touches the bottom of the vial. The result window on the device should be facing you.

Set a timer for 30 minutes and start timing the test.

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

Fluid will appear and travel up the result window. The fluid may gradually lighten as the test develops.

STEP 3. – Read Results

Read the results in a fully lit area. Read results between 30 and 40 minutes to obtain an accurate result. DO NOT read before 30 minutes or after 40 minutes.
To report a device problem, contact OraSure Technologies Customer Service (1-800-orasure) within the U.S. or +(001) 610-882-1820 for outside the U.S. You can also go to www.orasure.com/inquiry.html.

Negative: Line in C zone

Line in C zone

- A negative test result means that Ebola antigens were not detected in the specimen.
- The test result is interpreted as Ebola antigens were not detected. The cadaver is negative for Ebola antigens.

Invalid: Repeat with a fresh sample

No lines present

Purple background obscures results

Any partial line at C or T zone

Positive: Lines in T zones

Example of positive results.

Line in T zone

Line in T zone

Faint line in T zone

No line in C zone

- A positive test result means that Ebola antigens have been detected in the specimen. The cadaver is presumed positive for Ebola.
- Individuals with a positive result with the OraQuick™ Ebola 2.0 Rapid Antigen Test should, in accordance with CDC and WHO recommendations, be subjected to a safe and dignified burial procedure. Contacts of an Ebola-positive cadaver should be identified and monitored.
- In some cases, the purple line in the C Zone may not be present or may be very faint if there are high levels of virus in the sample.

Order Information and Description

1001-0708 25-ct kit
1001-0709 kit controls

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

3001-3962_EUA v2/07-26

OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015 USA
phone: 800.ORASURE
web: www.orasure.com

Made in the USA

POSITIVE TEST RESULTS
VISUAL REFERENCE CARD

OraQuick™ Rapid Antigen Test
EBOLA 2.0

For Use Under Emergency Use Authorization (EUA) Only

This product has not been U.S. FDA cleared or approved, but has been authorized for emergency use by U.S. FDA under an EUA for use by the authorized laboratory.

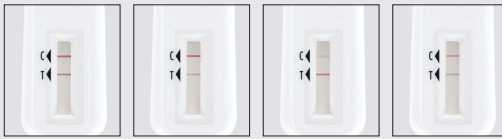
This product has been authorized only for the detection of antigens from orthoebolaviruses including *Orthoebolavirus zairense*, *Orthoebolavirus bundibugyoense*, *Orthoebolavirus sudanense*, and *Orthoebolavirus taiense*, not for any other viruses or pathogens.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of Ebola virus under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

This card provides examples of what a positive result could look like, including combinations of strong and weak lines, to help guide interpretation.

All new operators must be able to visualize all lines in the images below, prior to using the OraQuick™ Ebola 2.0 Rapid Antigen Test. Failure to read faint lines may result in false negative results.

EXAMPLES OF POSITIVE TEST RESULTS



These photos show how faint the line next to the "T" may be. These are all positive test results. In some cases, the line next to the "C" may also be very faint.

Look very closely!
The bottom line may be very faint.

Any line next to the "T" means Ebola antigens have been detected in the specimen, even if the line is very faint.

THE TEST RESULT IS ALSO POSITIVE IF:

There is a line next to the "T" and NO line next to the "C"

If your test does not look like any of these, see Instructions for Use for more examples of test results. Be sure to follow all instructions.

Pour des informations en français, voir au verso.

Ebola 2.0 positive control
The Ebola 2.0 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 2.0 negative control or the Ebola 2.0 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 2.0 Rapid Antigen Test Kit Controls are quality control samples for use only with the OraQuick™ Ebola 2.0 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 1-800-ORASURE (1-800-672-7873).
For customers outside the United States, phone +(001) 610-882-1820 or go to www.orasure.com.

OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015 USA
ORASURE (1-800-672-7873) • (610) 882-1820
www.orasure.com

3001-3956_EUA v1/07-26

OraQuick™ Rapid Antigen Test EBOLA 2.0

Rx

KIT CONTROLS

For use under Emergency Use Authorization (EUA) only.
For in vitro diagnostic use.

This product has not been U.S. FDA cleared or approved, but has been authorized for emergency use by U.S. FDA under an EUA for use by the authorized laboratory.
This product has been authorized only for the detection of antigens from orthoebolaviruses including *Orthoebolavirus zairense, Orthoebolavirus bundibugyoense, Orthoebolavirus sudanense,* and *Orthoebolavirus taiense,* not for any other viruses or pathogens.
The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of Ebola virus under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Read this package insert and the OraQuick™ Ebola 2.0 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 (https://www.cdc.gov/ebola/about/index.html), depending upon their location of testing.

NAME AND INTENDED USE
The OraQuick™ Ebola 2.0 Rapid Antigen Test Kit Controls are quality control samples for use only with the OraQuick™ Ebola 2.0 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 2.0 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 2.0 Rapid Antigen Test Kit Controls are human plasma-based samples. The kit controls are specifically formulated and manufactured to ensure proper performance of the test. The Ebola 2.0 positive control will produce a red to purple line at the Test (T) zone. The Ebola 2.0 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 2.0 Rapid Antigen Test Quick Reference Guide. Use of kit control samples manufactured by any other source may not meet the requirements for an adequate quality assurance program for the OraQuick™ Ebola 2.0 Rapid Antigen Test.

Contrôle positif Ebola 2.0
Le contrôle positif Ebola 2.0 produira un résultat de test positif dans la zone de test (T). Deux traits doivent être présents dans la fenêtre de résultat. Un trait doit apparaître dans la zone C et un autre doit être présent dans la zone T. Ceci indique un résultat de test positif. Les traits ne seront pas nécessairement de la même intensité de couleur.
REMARQUES: Si le résultat de test pour le contrôle négatif Ebola 2.0 ou le contrôle positif Ebola 2.0 ne correspond pas au résultat escompté, reprendre le test en utilisant un nouveau dispositif de test, un nouveau tube de solution révélatrice et un nouveau contrôle. Si les réactifs de contrôle de la trousse ne donnent pas le résultat escompté, contacter le service clientèle OraSure Technologies.

LIMITES
Les contrôles de la trousse du Test de Dépistage Rapide des Antigènes OraQuick™ Ebola 2.0 sont des réactifs de contrôle qualité uniquement destinés à une utilisation avec le Test de Dépistage Rapide des Antigènes OraQuick™ Ebola 2.0.

BIBLIOGRAPHIE

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

EXPLICATION DES SYMBOLES

LOT	Code de lot	IVD	Dispositif médical pour diagnostic in vitro
REF	Numéro de référence		Fabricant
	Attention, consulter les documents connexes		Température limite
PN	Numéro de référence		Utiliser avant le
		Rx	Ordonnance médicale

Pour un support technique ou un service clientèle aux États-Unis, appeler le 1-800-ORASURE (1-800-672-7873).
Clientsendehors des États-Unis: appeler le +(001) 6 0l-88 2-1820 ou aller sur le site www.orasure.com.

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3001-3956_EUA v1/07-26

OraQuick™ Rapid Antigen Test EBOLA 2.0

Rx

CONTRÔLES DE TROUSSE

À utiliser uniquement dans le cadre d'une autorisation d'utilisation d'urgence (EUA).
À usage diagnostique in vitro.

Ce produit n'a pas été homologué ni approuvé par la FDA, mais son utilisation a été autorisée à titre d'urgence par la FDA dans le cadre d'une autorisation d'utilisation d'urgence (EUA) pour une utilisation par le laboratoire agréé.
Ce produit a été autorisé uniquement pour la détection d'antigènes d'orthoebolavirus, notamment l'*Orthoebolavirus zairense, l'Orthoebolavirus bundibugyoense, l'Orthoebolavirus sudanense* et l'*Orthoebolavirus taiense,* et non pour tout autre virus ou agent pathogène.
L'utilisation d'urgence de ce produit n'est autorisée que pour la durée de la déclaration selon laquelle il existe des circonstances justifiant l'autorisation d'utilisation d'urgence de diagnostics in vitro pour la détection du virus Ebola en vertu de la section 564(b)(1) de la loi, 21 U.S.C. § 360bbb-3(b)(1), à moins que la déclaration ne soit levée ou que l'autorisation ne soit révoquée plus tôt.

Lire entièrement cette notice et celle du Test de Dépistage Rapide des Antigènes OraQuick™ Ebola 2.0 avant d'effectuer le test sous peine de résultats incorrects.

Suivre scrupuleusement ces instructions sous peine de fausser les résultats. Avant de commencer le test, tous les utilisateurs DOIVENT lire et se familiariser avec les documents Universal Precautions1, Infection Control for Viral Hemorrhagic Fevers in the African Health Care Setting[2] et Information for Healthcare Worker in the United States (https://www.cdc.gov/ebola/about/index.html), selon le pays dans lequel a lieu le test.

NOM ET INDICATION
Les contrôles de la trousse du Test de Dépistage Rapide des Antigènes OraQuick™ Ebola 2.0 sont des échantillons de contrôle qualité uniquement destinés à une utilisation avec le Test de Dépistage Rapide des Antigènes OraQuick™ Ebola 2.0.

Doser les contrôles de la trousse dans les cas suivants:
- Tout nouvel opérateur avant d'effectuer un test sur des échantillons patient/cadavre,
- À l'ouverture d'un nouveau lot de trousses de tests,
- À chaque réception d'un nouvel envoi de trousses de tests,
- Si la température de la zone de stockage de la trousse de test se situe en dehors de la plage 5°-30°C (41°-86°F),
- À intervalles périodiques, comme indiqué dans l'établissement utilisateur et par les politiques et réglementations nationales, régionales ou locales.

Il incombe à chaque laboratoire d'utiliser le Test de Dépistage Rapide des Antigènes OraQuick™ Ebola 2.0 afin de définir un programme d'assurance qualité adéquat capable de garantir la performance du dispositif dans ses conditions d'utilisation et lieux spécifiques.

RÉSUMÉ ET EXPLICATION DES CONTRÔLES DE LA TROUSSE
Les contrôles de la trousse de Test de Dépistage Rapide des Antigènes OraQuick™ Ebola 2.0 sont des échantillons à base de plasma humain. Ces contrôles sont spécialement formulés et fabriqués pour garantir la performance du test. Le contrôle positif Ebola 2.0 produira un trait rouge à violet dans la zone de test (T). Le contrôle négatif Ebola 2.0 produira un résultat de test négatif (pas de trait rouge à violet dans la zone de test T). Les deux contrôles produiront un trait violet dans la zone de contrôle (C). Voir la section Résultat du test et interprétation dans la notice du Test de Dépistage Rapide des Antigènes OraQuick™ Ebola 2.0 Guide de référence rapide. L'utilisation d'échantillons de contrôle de la trousse d'un autre fabricant risque de ne pas satisfaire les exigences d'un programme d'assurance qualité adéquat pour le Test de Dépistage Rapide des Antigènes OraQuick™ Ebola 2.0.

MATERIALS PROVIDED

OraQuick™ Ebola 2.0 Rapid Antigen Test Kit Controls

Each kit control box contains a package insert and two vials (one Ebola 2.0 positive control and one Ebola 2.0 negative control) as described below:

Ebola 2.0 positive control

One vial containing 0.500 mL of Ebola 2.0 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 2.0 negative control

One vial containing 0.500 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 2.0 Rapid Antigen Test Kit

- Divided pouches, each containing a test device, an absorbent packet, and a developer solution vial
- Test stands
- Quick Reference Guide

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or watch capable of timing 30 minutes
- Latex, vinyl, or nitrile disposable gloves
- Biohazard waste container
- Pipette capable of delivering 50 µL

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 2.0 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 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 samples manufactured by any other source may not meet the requirements for an adequate quality assurance program for the OraQuick™ Ebola 2.0 Rapid Antigen Test.

STORAGE INSTRUCTIONS

Store unopened OraQuick™ Ebola 2.0 Rapid Antigen Test Kit Controls at 2°–25°C (36°–77°F). After opening and use, store control vials at 2°–8°C (36°–46°F).

Do not use previously opened kit control vials if they were stored above 2°–8°C (36°–46°F). Do not use kit controls after the expiration date printed on the outer box.

DIRECTIONS FOR USE

General Test Preparation

Perform procedures according to the "General Test Preparation" section of the OraQuick™ Ebola 2.0 Rapid Antigen Test Quick Reference Guide.

TEST PROCEDURE

1. Allow the OraQuick™ Ebola 2.0 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 sample.
8. Pipette 50 µL of control sample onto the collection pad at the location shown in the photo.

9. 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.**
10. 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 and as described in the Test Result and Interpretation of Test Result section of the OraQuick™ Ebola 2.0 Rapid Antigen Test Kit.
11. Dispose of the used test materials in a biohazard waste container.
12. Reseal the kit control sample vials and store them in the original container at 2°-8°C (36°-46°F) or discard after initial use if storage at 2°-8°C (36°-46°F) is not available.

EXPECTED RESULTS

Ebola 2.0 negative control

The Ebola 2.0 negative control will produce a negative test result. A single line should be present in the result window in the C zone and NO line should be present in the T zone. This indicates a negative test result.

MATÉRIEL FOURNI

Contrôles de la trousse Test de Dépistage Rapide des Antigènes OraQuick™ Ebola 2.0

Chaque boîte de contrôles de trousse contient une notice d'utilisation et deux tubes (un contrôle positif Ebola 2.0 et un contrôle négatif Ebola 2.0) comme indiqué ci-dessous :

Contrôle positif Ebola 2.0

Un tube à contenant 0,500 ml de VP40 recombinant Ebola 2.0 dilué dans un pool défibriné de plasma humain normal négatif pour Ebola 2.0. Conservateur : 2-méthyl-4-isothiazoline-3-one. Négatif pour les antigènes de surface de l'hépatite B et les anticorps dirigés contre le VIH-1/2.

Contrôle négatif Ebola 2.0

Un tube à contenant 0,25 ml de pool défibriné de plasma humain normal négatif pour Ebola 2.0. Conservateur : 2-méthyl-4-isothiazoline-3-one. Négatif pour les antigènes de surface de l'hépatite B et les anticorps dirigés contre le VIH-1/2.

MATÉRIEL REQUIS ET FOURNI dans la trousse du Test de Dépistage Rapide des Antigènes OraQuick™ Ebola 2.0

- Sachets compartimentés contenant chacun un dispositif de test, un sachet dessicatif et un flacon de solution révélatrice
- Supports de test
- Guide de Référence Rapide

MATÉRIEL REQUIS, MAIS NON FOURNI

- Minuterie ou montre capable de compter entre 20 et 30 minutes
- Gants jetables en latex, vinyle ou nitrile
- Récipient pour déchets biologiques dangereux
- Pipette permettant de distribuer 50 µL

AVERTISSEMENTS

Pour usage diagnostique in vitro

- **Lire intégralement la notice d'utilisation avant d'utiliser le produit.**
- **Suivre scrupuleusement ces instructions lors de l'utilisation de l'Test de Dépistage Rapide des Antigènes OraQuick™ Ebola 2.0 sous peine de fausser les résultats.**
- **Avant de commencer le test, tout le personnel de l'étude DOIT lire et se familiariser avec les documents Universal Precautions[1], Infection Control for Viral Hemorrhagic Fevers in the African Health Care Setting[2] et Information for Healthcare Worker in the United States , slon le pays dans lequel a lieu le test.**

PRÉCAUTIONS

Consignes de sécurité

- Manipuler les contrôles de la trousse et les matériels en contact avec les contrôles comme s'ils étaient capables de transmettre des agents infectieux.
- Jeter tous les contrôles de trousse et matériels utilisés pour la procédure de test dans un récipient pour déchets biologiques dangereux. Tout le matériel et tous les déchets biologiques dangereux doivent être éliminés conformément aux politiques et lois nationales, régionales et locales.
- Porter des gants jetables pour manipuler et doser les contrôles de la trousse. Jeter les gants usagés dans un récipient pour déchets biologiques dangereux.
- L'utilisation de échantillons de contrôle de la trousse d'un autre fabricant risque de ne pas satisfaire les exigences d'un programme d'assurance qualité adéquat pour l'du Test de Dépistage Rapide des Antigènes OraQuick™ Ebola 2.0.

INSTRUCTIONS DE CONSERVATION

Conservez les flacons de contrôle non ouverts du kit de test antigénique rapide OraQuick™ Ebola 2.0 à une température comprise entre 2 °C et 25 °C (36 °F et 77 °F). Après ouverture et utilisation, conservez les flacons de contrôle à une température comprise entre 2 °C et 8 °C (36 °F et 46 °F).

N'utilisez pas les flacons de contrôle du kit déjà ouverts s'ils ont été conservés à une température supérieure à 2 °C à 8 °C (36 °F à 46 °F). N'utilisez pas les contrôles du kit après la date de péremption indiquée sur l'emballage extérieur.

MODE D'EMPLOI

Préparatifs généraux

Effectuer les procédures conformément à la section « Préparation générale du test » du Guide de référence rapide du Test de Dépistage Rapide des Antigènes OraQuick™ Ebola 2.0

PROCÉDURE DE TEST

1. Avant utilisation, laisser la température du Test de Dépistage Rapide des Antigènes OraQuick™ Ebola 2.0 monter entre 2° et 25°C (36° et 77°F).
2. Installer un support de test OraQuick™ dans l'espace de travail, en utilisant seulement le support fourni.
3. Ouvrez les deux compartiments du sachet OraQuick™ (« sachet ») en déchirant au niveau des encoches en haut, de chaque côté du sachet.
4. Retirer le flacon de solution révélatrice (« flacon ») du sachet. Tenir le flacon fermement dans la main. Déboucher le flacon avec précaution en imprimant un mouvement de va-et-vient au bouchon tout en tirant dessus. Poser le bouchon sur la protection de l'espace de travail.
5. Glisser le flacon par le haut dans l'un des logements du support. **NE PAS** insérer le tube dans le logement par l'avant en forçant sous peine d'entraîner des projections. S'assurer que le flacon est poussé jusqu'au fond du logement du support.
6. Retirer le dispositif du sachet. **NE PAS** toucher à la spatule. Placer le dispositif sur une surface plane propre. **(Remarque: pour que le tampon de prélèvement reste propre, éviter tout contact avec des surfaces de laboratoire ou d'autres surfaces, y compris les mains de l'opérateur.)** S'assurer qu'un sachet dessicatif est inclus avec le dispositif. Dans le cas contraire, jeter le tout et se procurer un nouveau sachet compartimenté pour le test.
   REMARQUE : NE PAS couvrir les deux trous à l'arrière du dispositif avec des étiquettes ou un objet quelconque sous peine de fausser le résultat.
7. Ouvrir un tube de contrôle contenant le échantillons de contrôle.
8. Pipetez 50 µl d'échantillon de contrôle sur le tampon de prélèvement, à l'endroit indiqué sur la photo.

9. Insérer le dispositif de test, la spatule en premier, dans le flacon de solution révélatrice. **S'assurer que la fenêtre de résultat est tournée vers soi et que la spatule touche le fond du flacon de solution révélatrice.**
10. Laissez le dispositif de test dans le flacon de solution révélatrice et démarrez un chronomètre. Ne retirez pas le dispositif de test du flacon avant d'avoir lu les résultats. Lisez les résultats dans un endroit bien éclairé et en suivant les instructions fournies dans la section « Résultats du test et interprétation des résultats » du kit de test antigénique rapide OraQuick™ Ebola 2.0.
11. Jeter le matériel de test utilisé dans un récipient pour déchets biologiques dangereux.
12. Refermer les tubes de échantillons de contrôle de trousse et les conserver dans leur carton d'origine entre 2° et 8°C (36° et 46°F) à défaut, jetez-les après la première utilisation.

RÉSULTATS ESCOMPTÉS

Contrôle négatif Ebola 2.0

Le contrôle négatif Ebola 2.0 produira un résultat de test négatif. Un seul trait doit apparaître dans la fenêtre de résultat dans la zone C et AUCUN trait ne doit être présent dans la zone T. Ceci indique un résultat de test négatif.