NAME AND INTENDED USE

The OraQuick® Ebola Rapid Antigen Test for cadaveric oral fluid is a single-use immunoassay intended for the qualitative detection of antigens from Ebola Zaire virus (detected in the West Africa outbreak in 2014). The test is intended for use with oral fluid swab specimens from individuals with epidemiological risk factors for Ebola virus infection and suspected to have died of Ebola. The test is intended to aid in diagnosing Ebola Zaire virus infection as the cause of death in order to inform decisions on safe and dignified burial procedures to prevent transmission of the Ebola Zaire virus in the community. The test may also detect antigens from Sudan Ebola virus and Bundibugyo Ebola virus; however, it does not distinguish between these different Ebola virus species.

The OraQuick® Ebola Rapid Antigen Test for cadaveric oral fluid may be used with direct testing or in conjunction with recommended swabs in viral transport media.

The authorized OraQuick® Ebola Rapid Antigen Test for cadaveric oral fluid is not intended for use as a diagnostic test for oral fluid swabs of living individuals. This test is not intended for general Ebola infection screening, such as airport screening or contact tracing of individuals without signs of symptoms of Ebola infection.

The OraQuick® Ebola Rapid Antigen Test for cadaveric oral fluid is authorized for use by personnel who are adequately equipped, trained, and capable of testing for Ebola infection in laboratories, facilities, and in field surveillance and response teams acting under the direction of public health authorities.

In a limited number of cases, a negative result may not preclude Ebola virus disease. The OraQuick® Ebola Rapid Antigen Test was evaluated in a limited clinical study using retrospective clinical specimens from deceased individuals with EVD confirmed by RT-PCR.

SUMMARY AND EXPLANATION OF THE TEST

Ebola hemorrhagic fever is a severe, often-fatal disease in humans and nonhuman primates that has appeared sporadically since its initial recognition in 1976. Ebola virus is one of three, genera of the family of RNA viruses called Filoviridae. There are four species of Ebola virus affecting humans: Bundibugyo virus (BDBV), Sudan virus (SUDV), Taï Forest virus (TAFV), and Ebola virus (EBOV). The presence of Ebola virus antigens indicate that the individual may be currently infected and capable of transmitting the virus.

The OraQuick® Ebola Rapid Antigen Test uses a sandwich capture lateral flow immunoassay method to detect Ebola virus 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 Rapid Antigen Test is a manually performed, visually read immunoassay for the qualitative detection of Ebola virus in human cadaveric oral fluid. The OraQuick® Ebola Rapid Antigen Test is comprised of both a single-use test device and a 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 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 blockier pad, the conjugate pad, the nitrocellulose membrane, and finally the absorbent pad. The performance of the assay occurs by hydration and transport of reagents as they interact with the specimen across the strip via chromatographic lateral flow. The conjugate pad contains salts, buffers, and a signal generating reagent consisting of Ebola antibodies conjugated to colloidal gold. Ebola antibodies in the sample are captured by Ebola antibodies at the Test (T) Zone, which become immobilized on the nitrocellulose membrane and visualized by colloidal gold labeled Ebola antibodies. The Control (C) Zone immobilized onto the nitrocellulose membrane is visualized by colloidal gold ensuring component elution, reagent activity, and adequate device performance.

For cadaveric oral fluid specimens, there are two ways to collect specimens: 1. Swab the gum line or the soft palate tissue in the back of the throat and then insert the device directly into the developer solution. 2. Swab the gum line or the soft palate tissue in the back of the throat with a recommended swab and insert into a recommended viral transport media. Refer to the Cadaveric Oral Fluid Procedure – Direct Collection or Cadaveric Oral Fluid Procedure – Transport Media sections in this package insert for the specimen collection instructions. When using viral transport media, collect the specimen from the transport media tube by using the plastic micropipette included in the kit. Transfer the specimen to the device through the sample port. Insert the device into the developer solution. 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 Ebola antibody labeled gold colorimetric reagent present on the assay strip. If the specimen contains Ebola antigens, the resulting labeled complexes bind to the Test (T) Zone resulting in a purple line. If the specimen does not contain Ebola virus, no labeled complexes 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 C Zone during the performance of all valid tests whether or not the sample is positive or negative for Ebola virus (refer to the Test Result and Interpretation of Test Result section in this package insert). Positive results may be interpreted as soon as lines are visible at the Test (T) Zone and Control (C) Zones. Negative results have to be read 30 minute after inserting the device into the Developer Vial.

MATERIALS PROVIDED

OraQuick® Ebola Rapid Antigen Test Kits are available in the following packaging configurations:

<table>
<thead>
<tr>
<th>Components of Kit</th>
<th>Catalog Number</th>
<th>25 Count Kit 1001-0426</th>
<th>100 Count Kit 1001-0427</th>
</tr>
</thead>
<tbody>
<tr>
<td>Divided Pouch, each containing: Test Device (1)</td>
<td>25</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Absorbent Packet (1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Developer Solution Vial (1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(each vial contains 1.0 mL of a buffered saline solution with an antimicrobial agent)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reusable Test Stands</td>
<td>25</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Plastic Micropipettes</td>
<td>30</td>
<td>120</td>
<td></td>
</tr>
<tr>
<td>Package Insert</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Cadaveric Oral Fluid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quick Reference Guide</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

Note: An additional Package Insert and Quick Reference Guide for use of the device with Venipuncture, Whole Blood or Fingerstick Whole Blood may be present in the Kit.

MATERIALS REQUIRED AND AVAILABLE AS AN ACCESSORY TO THE KIT

OraQuick® Ebola Rapid Antigen Oral Fluid Test Kit Controls 1001-0425
Ebola Positive Control (1 vial, orange cap, 0.25 mL)
Ebola Negative Control (1 vial, white cap, 0.25 mL)
Package Insert

OraQuick® Ebola Visual Reference Panel 1001-0428
Ebola Limit of Detection (1 device)
Ebola Low Positive (1 device)
Ebola Negative (1 device)
Package Insert

Foil Transfer Pouch 1001-0494

MATERIALS REQUIRED BUT NOT PROVIDED

Timer or watch capable of timing 30 minutes
Biohazard waste container

OPTIONAL MATERIALS NOT PROVIDED WITH KIT

BD Universal Viral Transport for Viruses, Chlamydia, Mycoplasmas and Ureaplasmas
∑-Virocult® System (MW951S)

WARNINGS AND PRECAUTIONS

For in vitro Diagnostic Use under Emergency Use Authorization only

- For prescription use only.
- 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.
- Specimens should 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 should be appropriately trained of the donning and doffing of personal protective equipment.
- All personnel conducting testing MUST read and be familiar with Universal Precautions*, Infection Control for Viral Hemorrhagic Fevers in the African Health Care Setting² 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.
• All equipment and biohazardous waste should be discarded in accordance with country, state, and local laws and policies.
• This test kit is for use with venipuncture and fingerstick whole blood and cadaveric oral fluid swab specimens only. Please refer to the whole blood Instructions for Use for information on whole blood testing.
• 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 for cadaveric oral fluid testing.
• Follow the instructions carefully when performing the OraQuick® Ebola Rapid Antigen Test. Failure to do so may cause an inaccurate test result.
• The use of any viral transport media for cadaver testing other than BD Universal Viral Transport for Viruses, Chlamydia, Mycoplasmas and Ureaplasmas (220528) or ∑-Virocult® System (MW951S) has not been evaluated and has not been authorized under this EUA.
• 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 (15°-40°C, 59°-104°F) before performing testing.
• Do not use this test beyond the expiration date printed on the Divided Pouch. Always check expiration date prior to testing.

Device Handling Precautions
• Use all Pipettes, Test Devices, and Developer Solution Vials only once and dispose of properly (see Safety 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
Store unused OraQuick® Ebola 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 Safety Precautions section in this package insert.
2. Gather the materials you will need.
3. Allow the OraQuick® Ebola Rapid Antigen Tests to come to operating temperature (15°- 40°C, 59°- 104°F) before use. Refer to the External Quality Control section in this package insert to determine when the Kit Controls should be run.
4. Set an OraQuick® Test Stand at your workspace, using only the stand provided.
5. Open the two chambers of the OraQuick® Divided Pouch (“Pouch”) by tearing at the notches on the top of each side of the Pouch (see pictures 1 and 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 (see picture 3).

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 (see picture 4 ).
CADAVERIC ORAL FLUID PROCEDURE – DIRECT COLLECTION

STEP 1: COLLECT
1. Remove the Device from its Pouch. DO NOT touch the Flat Pad (see picture 5). Check to make sure that an Absorbent Packet is included with the Device (see picture 6). If no Absorbent Packet is present, discard the Device and obtain a new Pouch for testing.
2. Open the mouth of the cadaver and collect a sample from the posterior oral cavity by swiping the flat pad around the back of the soft palate (see pictures 7 and 8). If collection in this manner is not feasible due to rigor mortis, collection of cadaveric oral fluid can be taken from the gum line. To obtain a sample from the gum line, swipe the flat pad once around the top and once around the bottom of the gum line (see pictures 9 and 10).

NOTE: Both sides of the Flat Pad may be used during this procedure.
3. If the device cannot be placed immediately in the Developer Vial for Testing (Step 2 below), the device may be placed in a foil Transfer Pouch. Only those pouches provided by OraSure Technologies as an accessory as part number (1001-0494) should be used to ensure proper stability of the sample.
4. The sealed Transfer Pouch may be stored at 15° - 40°C (59° - 104°F) for 60 minutes or at 2° - 8°C (36° - 46°F) for up to 22 hours prior to testing.

STEP 2: TEST
1. If testing samples were stored on ice, remove the Transfer Pouch from storage and allow it to come to room temperature for 15 minutes prior to testing.
2. Insert the Flat Pad of the Device all the way into the Vial (see picture 11). Make sure that the Flat Pad touches the bottom of the Vial. The Result Window on the Device should be facing towards you (see picture 12).
3. Start timing the test (see picture 13). DO NOT remove the Device from the Vial while the test is running. Red fluid will appear and travel up the Result Window. The red fluid will gradually disappear as the test develops (see picture 14). Positive results may be interpreted as soon as lines are visible at the Test (T) Zone and Control (C) Zone. Negative results have to be read 30 minutes after inserting the device into the Developer Vial.
4. Refer to the Test Result and Interpretation of Test Result section in this Package Insert.

CADAVERIC ORAL FLUID PROCEDURE – TRANSPORT MEDIA

STEP 1: COLLECT
1. Cadaveric oral fluid specimens should be collected and handled following the instructions for use of the swab/viral transport media. Once a swab specimen is collected, it should be placed in the transport media vial. Specimens may be stored at 2° - 40°C (36° - 104°F) for up to 24 hours. If the sample cannot be tested within 24 hours of collection, the transport media can be frozen at -70°C (-94°F) with a maximum of 3 freeze/thaw cycles.

STEP 2: TEST
1. Prior to testing, mix the transport media tube gently by inversion several times to ensure a homogeneous sample.
2. Remove the Device from the Pouch. DO NOT touch the Flat Pad (see picture 15). 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 (see picture 16). 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 (see picture 17).
3. Pick up an unused micropipette by the handle (see picture 18). Hold the micropipette, place it in the transport media tube, and slowly draw the sample up. Filling of the micropipette is automatic, do not squeeze while sampling (see picture 19). Make sure that the micropipette is filled up to the indicator line with the sample and there are no bubbles present (see picture 20). If a bubble is present, discard collected sample and obtain a new sample using a new micropipette.

4. Deposit the cadaveric sample through the sample port on the device by compressing the micropipette directly above the sample port (see picture 21).

5. Insert the Flat Pad of the Device all the way into the Vial (see picture 22). Make sure that the Flat Pad touches the bottom of the Vial. The Result Window on the Device should be facing towards you (see picture 23).

6. Start timing the test (see picture 24). **DO NOT** remove the Device from the Vial while the test is running. Red fluid will appear and travel up the Result Window. The red fluid will gradually disappear as the test develops (see picture 25). Positive results may be interpreted as soon as lines are visible at the Test (T) Zone and Control (C) Zone. Negative results have to be read 30 minutes after inserting the device into the Developer Vial.

7. Refer to the Test Result and Interpretation of Test Result section in this Package Insert.

**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 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. The Control line will appear on all valid tests, whether or not the sample is positive or negative for Ebola Antigens. (Refer to Test Result and Interpretation of Test Result section of this package insert).

**External Quality Control**

OraQuick® Ebola Rapid Antigen Test Kit Controls must be used with the OraQuick® Ebola 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 Positive Control will produce a positive test result and has been manufactured to produce a faint Test ("T") line. The Ebola Negative Control will produce a negative test result (Refer to Test Result and Interpretation of Test Result section of this package insert). Use of kit control reagents manufactured by any other source may not produce the required results, and therefore, will not meet the requirements for an adequate quality assurance program for the OraQuick® Ebola Rapid Antigen Test. If external controls do not produce expected results, cadaver testing should not be performed. Contact OraSure Technologies' Customer Care if the Kit Control reagents do not produce the expected results.

**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,
- Whenever a new shipment of test kits is received,
- If the temperature of the test kit storage area falls outside of 2°C-30°C (36°F-86°F),
- If the temperature of the testing area falls outside of 15°C-40°C (59°F-104°F), and
- At periodic intervals as dictated by local, state and country laws and by the user facility.
Test Procedure for External Controls:

Refer to the OraQuick® Ebola Rapid Antigen Test Kit Control package insert for full instruction on the use of these reagents. 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.

Qualification for New Operators

The OraQuick® Ebola Visual Reference Panel is available separately for use with the OraQuick® Ebola Rapid Antigen Test. The OraQuick® Ebola Visual Reference Panel includes potential test results including negative, low positive, and the limit of detection of the device. New operators must be able to correctly interpret all devices in the OraQuick® Ebola Visual Reference Panel prior to using the OraQuick® Ebola Rapid Antigen Test device with cadaver samples. Failure to read at low intensities can result in the inability to detect specimens near the limit of detection of the OraQuick® Ebola Rapid Antigen Test and may result in false negative results.

TEST RESULT AND INTERPRETATION OF TEST RESULT

Positive results may be interpreted as soon as lines are visible in the Test (T) Zone and the Control (C) Zone. Negative results have to be read 30 minutes after inserting the device into the Developer Vial.

NEGATIVE

A test is Negative if:
- A purple line appears in the C Zone and NO line appears next to the T Zone (see picture 26).

A Negative test result is interpreted as Ebola antigen not detected in the specimen. The cadaver is presumed negative for Ebola antigen.

A Negative result does not preclude Ebola virus infection.

POSITIVE

A test is Positive if:
- A purple line appears in the C Zone and a purple line appears in the T Zone. Lines may vary in intensity. The test is positive regardless of how faint these lines appear (see pictures 27, 28, and 29).

A Positive test result is interpreted as Ebola antigen detected in the specimen. The cadaver is presumed positive for Ebola antigen.

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 (http://apps.who.int/iris/bitstream/10665/185258/1/WHO_EVD_Guidance_Contact_15.1_eng.pdf?ua=1) issued by the World Health Organization (WHO) and the Centers for Disease Control (CDC).³

INVALID

A test is Invalid if any of the following occurs:
- NO purple line appears in the C Zone (see picture 30), or
- a purple background in the Result Window makes it difficult to read the result at 30 minutes (see picture 31), or
- any partial line on one side of the C or T Zones (see picture 32 and 33).

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.
LIMITATIONS OF THE TEST
1. Weak positive samples may take longer to develop and can take the entire 30 minutes for a test line to be present. Therefore, all negative test results must be read 30 minutes after inserting the device in the Developer Vial. Negative test results must not be reported prior to reading the device at 30 minutes.
2. Reading any test result after 30 minutes may yield inaccurate test results.
3. Clinical performance of this device was evaluated with a limited number of retrospective cadaveric oral fluid samples.
4. Negative results do not preclude Ebola virus infection.
5. Potential cross reactivity of the OraQuick® Ebola Rapid Antigen Test with Ebola vaccines and therapeutics has not been evaluated. Specimens from cadavers who have received therapeutics or vaccines against Ebola virus may exhibit false positive or other confounding test results.
6. Testing samples with concentrations of mucin above 15mg/mL may result in false positive results.
7. Cross-Reactivity with organisms other than those tested in the Cross Reactivity Study have not been assessed and may lead to erroneous results.

CADAVERIC ORAL FLUID CLINICAL PERFORMANCE
A total of 277 retrospective cadaveric specimens (collected in VTM) were tested in a study conducted by the World Health Organization; all samples were originally tested with the RealStar Filovirus Screen Test. Prior to testing with the OraQuick® Ebola Rapid Antigen Test, all samples were re-tested with the Xpert Ebola Assay (Cepheid) to confirm the original Ebola PCR result.
A total of 222 RealStar Filovirus Screen RT-PCR negative specimens were tested on the Xpert Ebola Assay (Cepheid). Of these specimens 29 gave an invalid result, possibly because of a failure of the human gene target internal control due to poor specimen quality, and were excluded. Therefore, a total of 193 PCR negative specimens were included in the RDT evaluation.
Of the 55 RealStar Filovirus Screen RT-PCR positive specimens tested on Xpert Ebola Assay (Cepheid), 51 specimens passed as positive; 3 were negative and 1 gave an invalid result and were therefore excluded. Of the 51 positive specimens, 16 were tested in a manner inconsistent with the instructions for use and were therefore excluded from the study. A total of 35 positive specimens were included in the performance evaluation.
Using the Xpert Ebola Test (Cepheid) as the comparator assay, the performance of the OraQuick® Ebola Rapid Antigen Test is shown in the following table:

<table>
<thead>
<tr>
<th></th>
<th>Positive Percent Agreement (PPA) (95% CI)</th>
<th>Negative Percent Agreement (NPA) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OraQuick® Ebola Rapid Antigen Test</td>
<td>34/35</td>
<td>193/193</td>
</tr>
<tr>
<td></td>
<td>97.1%</td>
<td>100.00%</td>
</tr>
<tr>
<td></td>
<td>(85.5 - 99.5)</td>
<td>(98.1 - 100)</td>
</tr>
</tbody>
</table>

Note: The study also included testing of 16 samples that were diluted 1:4 in distilled water. The OraQuick® Ebola Rapid Antigen test correctly detected 14 out of these 16 samples as positive. The two samples that were incorrectly detected as being negative had high PCR Ct values representative of Ebola virus concentrations below the assay’s LOD.

i. CDC Study – Sierra Leone
CDC in collaboration with the Ministry of Health (MOH) has conducted a Field Evaluation of New Rapid Diagnostic Tests for Ebola Virus Disease in Sierra Leone that included the testing of cadavers. A total of 111 samples were tested with the OraQuick® Ebola Rapid Antigen Test according to the instructions for use with cadaveric oral fluid using the direct sampling method. The 111 samples tested by OraQuick® RDTs were all negative by PCR (the 50 specimens collected in Kenema were tested with the Trombley PCR assay on the Cepheid Smartcycler II). Three samples initially produced invalid results and were re-tested according to the instructions for use; two of these samples were re-tested as negative. One of the invalid results could not be resolved by re-testing as it gave another invalid result and was therefore excluded from the performance calculation. The following table includes a summary of the field study data:

<table>
<thead>
<tr>
<th>Date of testing</th>
<th>Region</th>
<th>RDTs tested</th>
<th>Reactive</th>
<th>Non-reactive</th>
<th>Invalid</th>
<th>PCR</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 10, 2016</td>
<td>Kenema</td>
<td>50</td>
<td>0</td>
<td>50A</td>
<td>0</td>
<td>50A</td>
</tr>
<tr>
<td>January 6 - 13, 2016</td>
<td>Western</td>
<td>61</td>
<td>1C</td>
<td>59B</td>
<td>1C</td>
<td>61</td>
</tr>
<tr>
<td>Total</td>
<td>111</td>
<td>1</td>
<td>109</td>
<td>1</td>
<td>1</td>
<td>111</td>
</tr>
</tbody>
</table>

A) The control line on the OraQuick® device was not visualized and the test was interpreted as invalid. Upon repeat testing the OraQuick® test was non-reactive. A swab for PCR was collected and the samples were negative by PCR.
B) PCR is currently performed in conjunction with the OraQuick® tests for all cadavers. The 111 samples tested by OraQuick® RDTs were all negative by PCR (Trombley PCR assay on the Cepheid Smartcycler II). Three samples initially produced invalid results and were re-tested according to the instructions for use; two of these samples were re-tested as negative. One of the invalid results could not be resolved by re-testing as it gave another invalid result and was therefore excluded from the performance calculation. The following table includes a summary of the field study data:

This study provided a Negative Percent Agreement (NPA) for the OraQuick® Ebola Rapid Antigen Test of 109/110 = 99.1% with a 95% Confidence Interval of 95.0 - 100%.
ii. CDC Study – Guinea

In Guinea 334 oral swab samples were taken from cadavers and tested in parallel with PCR and with the OraQuick® Ebola Rapid Antigen Test. Samples were collected between June 2015 and August 2015. All samples were negative by PCR and by the OraQuick® Ebola Rapid Antigen Test. This study provided a Negative Percent Agreement (NPA) for the OraQuick® Ebola Rapid Antigen Test of 334/334 = 100% with a 95% Confidence Interval of 98.9 - 100%.

iii. CDC Study – Liberia

Additionally, 97 specimens from cadavers in Liberia were tested with the OraQuick® Ebola Rapid Antigen Test. Samples were parallel tested with either the CDC or the DOD EUA PCR. Samples were collected between May and June 2015 and tested with the OraQuick® Ebola Rapid Antigen Test according to the instructions for use with cadaveric oral fluid. All samples tested were negative by PCR; three of these PCR negative samples resulted in an invalid test result with the OraQuick® Ebola Rapid Antigen Test. The samples were not retested with the OraQuick® Ebola Rapid Antigen Test and were therefore excluded from the performance calculation below. All other PCR negative samples also resulted in a negative OraQuick® Ebola Rapid Antigen Test result. This study provided a Negative Percent Agreement (NPA) for the OraQuick® Ebola Rapid Antigen Test of 94/94 = 100% with a 95% Confidence Interval of 96.1 to 100%.

iv. OraSure Technologies Inc. Study – Ebola Positive Contrived Oral Fluid Samples

The performance of the device was evaluated using twenty (20) Ebola contrived positive saliva samples as a surrogate for direct collect oral fluid and spiking the sample onto the device collection pad. Samples were contrived positive using gamma-irradiated Zaire ebolavirus, Mayinga, NR-31807 from BEI Resources. Ebola negative samples were included in the blinded test reads to control for bias. Percent Positive Agreement was 95%. One contrived positive sample at the 1.5 x LoD level was recorded as a non-reactive result. The negative samples yielded expected results with 100% concordance. This study provided a Positive Percent Agreement (PPA) of 19/20 = 95% with a 95% Confidence Interval of 75.13 to 99.87%.

v. OraSure Technologies Inc. Study – Cadaver Oral Fluid Samples in Viral Transport Media (VTM)

The specificity performance of the OraQuick® Ebola Rapid Antigen Test in cadaveric oral fluid samples collected in Becton Dickinson (BD) Universal Viral Transport for Viruses, Chlamydiae, Mycoplasmas and Ureaplasmas and ∑-Virocult® Swab and Virus Transport Medium for the Collection of Virus Specimens was evaluated with 63 negative cadaveric oral fluid samples blinded with contrived positive oral fluid samples. OraQuick® Ebola Rapid Antigen Test results were non-reactive for all cadaveric oral fluid samples tested in both the BD VTM and ∑-Virocult VTM. All contrived samples were correctly identified as reactive by the operators. The Negative Percent Agreement (NPA) for the OraQuick® Ebola Rapid Antigen Test was determined to be 63/63 = 100% with a 95% Confidence Interval of 94.3 to 100.0% in both the BD VTM and ∑-Virocult VTM.

LIMIT OF DETECTION – LIVING DONORS

A Limit of Detection (LoD) range finding study was conducted with oral fluid collected from living donors with the BD Universal Transport System (3mL medium), the ∑-Virocult Transport System (1mL medium), and directly collected with the OraQuick® Ebola Rapid Antigen Test. For the direct collection with the OraQuick® Ebola Rapid Antigen Test recombinant VP40 antigen was spiked directly on to the collection pad of the OraQuick® Ebola Rapid Antigen Test after oral fluid collection and prior to insertion in to the Developer Vial. Recombinant VP40 antigen was spiked on the swab of the respective transport system after oral fluid collection and prior to placement in the transport medium. A total of 20µL was then placed in the sample port of the OraQuick® Ebola Rapid Antigen Test prior to insertion of the device into the Developer Vial.

The tentative LoD for oral fluid directly collected from living donors with the OraQuick® Ebola Rapid Antigen Test was 0.53 ng/test with a VP40 antigen concentration in oral fluid of 7.6 ng/mL. This concentration was confirmed as the LoD by 19 out of 20 replicates testing positive with the same recombinant VP40 antigen at this concentration.

The tentative LoD for oral fluid collected from living donors with the BD Universal Transport System was 0.217 ng/test with a VP40 antigen concentration in oral fluid of 465 ng/mL. This concentration was confirmed as the LoD by 20 out of 20 replicates testing positive with the same recombinant VP40 antigen at this concentration.

The tentative LoD for oral fluid collected from living donors with the ∑-Virocult® Transport System was 3.20 ng/test with a VP40 antigen concentration in oral fluid of 3200 ng/mL. This concentration was confirmed as the LoD by 20 out of 20 replicates testing positive with the same recombinant VP40 antigen at this concentration.

<table>
<thead>
<tr>
<th>Collector</th>
<th>LoD/Test [Amount of rAG per Test]</th>
<th>LoD [Concentration of rAG in Oral Fluida]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Collection OraQuick®</td>
<td>0.53 ng/test</td>
<td>7.6 ng/mL</td>
</tr>
<tr>
<td>BD Universal Viral Transport for Viruses</td>
<td>0.217 ng/test</td>
<td>465 ng/mL</td>
</tr>
<tr>
<td>∑-Virocult® Transport System</td>
<td>3.20 ng/test</td>
<td>3200 ng/mL</td>
</tr>
</tbody>
</table>

aRecombinant antigen, live and inactivated virus were tested in parallel with the OraQuick® Ebola Rapid Antigen Test for use with whole blood. With whole blood the LoD of 0.53ng/test corresponded to an LoD of 1.64 x 10^6 TCID50/mL.

bLoD concentration in oral fluid was calculated using the average volumes of oral fluid that is absorbed by each of the swabs/devices (i.e., 70 µl for the OraQuick® Ebola Rapid Antigen Test flat pad, 70 µl for the BD swab diluted into 3 mL of VTM and 50µl for the ∑-Virocult® swab diluted in 1 mL VTM) and the subsequent volume of 20µL of the VTM solution that was transferred to the device.

Additional testing has established that the analytical LoD in cadaveric oral fluid and live donor derived oral fluid is equivalent.
**CROSS REACTIVITY**

Cross reactivity of the OraQuick® Ebola Rapid Antigen Test was evaluated by testing additional viral and bacterial pathogens. In this study, three (3) replicates were tested with the pathogens spiked into Ebola negative oral fluid (saliva as surrogate) at the concentrations listed below. None of the tested organisms produced false positive results in the OraQuick® Ebola Rapid Antigen Test at the concentration tested.

<table>
<thead>
<tr>
<th>Virus/Bacteria</th>
<th>Inactivated or Live</th>
<th>Type/Strain</th>
<th>Concentration Tested</th>
<th>Reactivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herpes Simplex Virus Type 1</td>
<td>Live</td>
<td>ATCC VR-260</td>
<td>2.7 x 10^6 TCID&lt;sub&gt;50&lt;/sub&gt;/mL</td>
<td>None</td>
</tr>
<tr>
<td>Herpes Simplex Virus Type 2</td>
<td>Live</td>
<td>ATCC VR-734</td>
<td>1.0 x 10^6 TCID&lt;sub&gt;50&lt;/sub&gt;/mL</td>
<td>None</td>
</tr>
<tr>
<td>Actinomyces viscosus</td>
<td>Live</td>
<td>ATCC 43146</td>
<td>2.9 x 10^7 CFU/mL</td>
<td>None</td>
</tr>
<tr>
<td>Candida albicans</td>
<td>Live</td>
<td>ATCC 18804</td>
<td>6.1 x 10^8 CFU/mL</td>
<td>None</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>Live</td>
<td>ATCC 6538</td>
<td>3.6 x 10^8 CFU/mL</td>
<td>None</td>
</tr>
<tr>
<td>Staphylococcus epidermis</td>
<td>Live</td>
<td>ATCC 12228</td>
<td>3.9 x 10^8 CFU/mL</td>
<td>None</td>
</tr>
<tr>
<td>Streptococcus pyogenes</td>
<td>Live</td>
<td>ATCC 19615</td>
<td>1.4 x 10^9 CFU/mL</td>
<td>None</td>
</tr>
<tr>
<td>Streptococcus salivarius</td>
<td>Live</td>
<td>ATCC 7073</td>
<td>7.7 x 10^9 CFU/mL</td>
<td>None</td>
</tr>
<tr>
<td>Streptococcus mutans</td>
<td>Live</td>
<td>ATCC 25175</td>
<td>2.0 x 10^10 CFU/mL</td>
<td>None</td>
</tr>
<tr>
<td>Lactobacillus johnsonii</td>
<td>Live</td>
<td>ATCC 33200</td>
<td>1.9 x 10^10 CFU/mL</td>
<td>None</td>
</tr>
<tr>
<td>Porphyromonas gingivalis</td>
<td>Live</td>
<td>ATCC 49417</td>
<td>1.7 x 10^10 CFU/mL</td>
<td>None</td>
</tr>
<tr>
<td>Mycobacterium tuberculosis</td>
<td>Live</td>
<td>ATCC 25177</td>
<td>1.0 x 10^10 CFU/mL</td>
<td>None</td>
</tr>
<tr>
<td>Moraxella catarrhalis</td>
<td>Live Ne 11 [CCUG 353, LMG 11192, NCTC 11020] ATCC 25238</td>
<td>2.7 x 10^7 CFU/mL</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Corynebacterium diphtheriae</td>
<td>Live 5159 ATCC 13812</td>
<td>8.4 x 10^7 CFU/mL</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Nocardia sp.</td>
<td>Live N1408 [QN360] ATCC 700034</td>
<td>5.4 x 10^8 CFU/mL</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Bacteroides oralis</td>
<td>Live VPI D27B-24 [NCTC 11459] ATCC 33269</td>
<td>5.1 x 10^8 CFU/mL</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Chlamydomphila pneumoniae</td>
<td>Live AR-39 ATCC 53592</td>
<td>2.6 x 10^7 IFU/mL</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Mycoplasma pneumonia</td>
<td>Live FH strain of Eaton Agent [NCTC 10119] ATCC 15531</td>
<td>2.6 x 10^7 IFU/mL</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Bordetella pertussis</td>
<td>Live Tohama I ATCC BAA-589</td>
<td>6.9 x 10^7 IFU/mL</td>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

Additional cross reactivity with the following organisms was performed for the OraQuick® Ebola Rapid Antigen Test for use with whole blood and no cross reactivity was observed at the tested concentration: Marburg, Crimean Congo Hemorrhagic Fever, Lassa, Rift Valley Fever, Yellow Fever (Vaccine Strain), Chikungunya virus, Influenza A, Influenza B, Rotavirus, Adenovirus, RSV, Enterovirus, Salmonella enterica, Salmonella typhi, Shigella dysenteriae, Pseudomonas aeruginosa, Vibrio cholera, Streptococcus pneumonia, Haemophilus influenza (meningitis), Leptospira, Neisseria meningitides, Yersinia enterocolitica, Plasmodium falciparum (malaria), Plasmodium vivax (malaria), Trypanosoma cruzi, Rickettsia africae (protein), Bacteroides fragilis, Klebsiella pneumoniae, Enterococcus faecium. E. Coli, Vesicular Stomatitis Virus, HIV-1, Hepatitis A, Hepatitis B, Hepatitis C, Cytomegalovirus, Epstein-Barr Virus, West Nile, Mumps, Measles, Rubella, Borrelia hermsii, Yersinia pseudotuberculosis, Rickettsia australis, Dengue. However, the test reacts with Ebola Sudan and Ebola Bundibugyo. Please refer to the instructions for use for the OraQuick® Rapid Antigen Test for whole blood for further information.
INTERFERING SUBSTANCES

The OraQuick® Ebola Rapid Antigen Test was evaluated with the following interfering substances present in negative oral fluid and oral fluid spiked with recombinant antigen (rAg) at 2.0 X the LoD in order to assess their potential effect on the assay performance as per CLSI guidelines EP17-A24. For Toothpaste, Mucin and Leukocytes testing was completed on three (3) oral fluid samples each tested at n=2 replicates for each condition.

The concentration for toothpaste could not be analytically quantified, but duration of interference use was two (2) minutes and then a thirty (30) minute wait before direct collection with the OraQuick® Ebola Rapid Antigen Test. At the Mucin 20mg/mL test concentration there was one (1) false positive in negative oral fluid test group and (1) false negative in the rAg spiked oral fluid test group. No interference was noted at the 15mg/mL test concentration.

<table>
<thead>
<tr>
<th>Interfering Substances</th>
<th>Target Testing Concentration</th>
<th>Reactivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toothpaste</td>
<td>n/a</td>
<td>None</td>
</tr>
<tr>
<td>Mucin</td>
<td>20 mg/mL</td>
<td>Reactive</td>
</tr>
<tr>
<td></td>
<td>15 mg/mL</td>
<td>None</td>
</tr>
<tr>
<td>Leukocytes</td>
<td>6.12 x 10^9 cells / L</td>
<td>None</td>
</tr>
</tbody>
</table>

REPRODUCIBILITY

The reproducibility of the OraQuick® Ebola Rapid Antigen Test was tested at 3 sites using 3 lots of test devices twice a day for 5 days with 9 operators (3 per site). Three VTM Oral Fluid (live donor saliva as surrogate) panel member types (negative, low positive - 2x limit of detection (LoD), and moderate positive — 5x LoD) were tested. Panel members were blinded per operator, run, and device lot to ensure that the results of the panel member types were unpredictable to the operator. Overall concordance across operators, sites, and device lots for VTM oral fluid was 99.9% (95% CI 99.3-100.0%) for the negative specimen, 99.8% (95% CI 99.1-100.0%) for the low positive specimen and 100.0% (95% CI 99.5-100.0%) for the moderate positive specimen.

Three Direct Collect Oral Fluid (live donor saliva as surrogate) panel member types (negative, low positive - 2x limit of detection (LoD), and moderate positive — 5x LoD) were also tested. Panel members were blinded per operator, run, and device lot to ensure that the results of the panel member types were unpredictable to the operator. Overall concordance across operators, sites, and device lots for direct collect oral fluid was 98.1% (95% CI 97.0-99.0%) for the negative specimen, 95.2% (95% CI 93.5-96.5%) for the low positive specimen and 99.4% (95% CI 98.6-99.8%) for the moderate positive specimen.

BIBLIOGRAPHY

3. EMERGENCY GUIDELINE Implementation and management of contact tracing for Ebola virus disease (http://apps.who.int/iris/bitstream/10665/185259/1/WHO_EVD_Guidance_Contact_15.1_eng.pdf?ua=1) issued by the World Health Organization (WHO) and the Centers for Disease Control (CDC).
EXPLANATION OF SYMBOLS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOT</td>
<td>Batch Code</td>
<td><strong>In Vitro Diagnostic Medical Device</strong></td>
</tr>
<tr>
<td>REF</td>
<td>Catalog Number</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>⚠️</td>
<td>Caution, Consult</td>
<td><strong>Part Number</strong></td>
</tr>
<tr>
<td></td>
<td>Accompanying Documents</td>
<td></td>
</tr>
<tr>
<td>🕒</td>
<td>Use By</td>
<td><strong>Temperature Limitation</strong></td>
</tr>
</tbody>
</table>

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
Critical reagents in the OraQuick® Ebola Rapid Antigen Test are being supplied by:

- the Viral Hemorrhagic Fever Consortium, or "VHFC" (www.VHFC.org). The VHFC reagents were developed with the support of the National Institute of Allergy and Infectious Diseases of the National Institutes of Health ("NIH/NIAID"). VHFC members Autoimmune Technologies LLC and Zalgen Labs LLC manufacture the critical reagents.
- the Biological Defense Research Directorate at the United States Navy Medical Research Center (NMRC).
Step 1a. – Specimen Collection
Direct Specimen Collection

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

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

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

OR

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

Step 1b. – Specimen Collection
Viral Transport Media

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

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

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

NOTE: If a bubble is present discard the sample and obtain a new sample using a new micropipette.

Step 2. Perform the Test

Insert device into vial

Start timer

Purple fluid travels through the Result Window

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

Step 3. Read Results

Positive results may be interpreted as soon as lines are visible in the Test (T) Zone and the Control (C) Zone. Read negative results 30 minutes after inserting the device into the Developer Vial.

Negative: Line in C Zone

No Ebola Antigens detected

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

Invalid: Repeat with a Fresh Sample

No line in C Zone

Purple background obscures results

Any partial line at C or T Zone

Positive: Lines in C and T Zones

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

Line in T Zone

Line in T Zone

Faint line in T Zone

• A Positive test result is interpreted as Ebola Antigen detected in the specimen. The cadaver is positive for Ebola Antigen.

• Individuals with a positive result with the OraQuick® Ebola Rapid Antigen Test should, in accordance with CDC and WHO recommendations, be subjected to safe and dignified burial procedure. Contacts of an Ebola positive cadaver should be identified and followed up on.

Order Information and Description
1001-0426 Box of 25 tests
1001-0427 Box of 100 tests
1001-0425 Kit Controls
1001-0428 Visual Reference Panel

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OraQuick® Ebola is a registered trademark of OraSure Technologies, Inc.

For Use Under Emergency Use Authorization (EUA) Only


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

OraSure Technologies
220 East First Street
Bethlehem, PA 18015 USA
phone: 800.ORASURE
web: www.OraSure.com
Made in the USA
Ebola Positive Control

The Ebola Positive Control will produce a Positive test result and has been manufactured to produce a very faint line 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


EXPLANATION OF SYMBOLS

<table>
<thead>
<tr>
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<th>Description</th>
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<tbody>
<tr>
<td>CB</td>
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www.OraSure.com

CONTREÔLES DE TRousse

Réservé à une utilisation dans le cadre d’une autorisation d’utilisation d’urgence (EAU)

Lire entièrement cette notice et celle de l’OraQuick® Ebola Rapid Antigen Test avant d’effectuer le test sous peine de résultats incorrects.

Suivre scrupuleusement ces instructions sous peine de fauser les résultats. Avant de commencer le test, tout le personnel de l’étude DOIT lire et se familiariser avec les documents Universal Precautions1, Infection Control for Viral Haemorrhagic Fever in the African Health Care Setting et Information for Healthcare Worker in the United States (http://www.cdc.gov/vhf/ebola/hcp/) selon le pays dans lequel a lieu le test.

NOM ET INDICATION

Les contrôles de la trousse OraQuick®, Ebola Rapid Antigen Test sont des réactifs de contrôle qualité uniquement destinés à une utilisation avec l’OraQuick® Ebola Rapid Antigen Test.

Doser les contrôles de la trousse dans les cas suivants :

- Tout nouvel opérateur avant d’effectuer un test sur des échantillons patient,
- À l’ouverture d’un nouveau lot de trousse de tests,
- À chaque réception d’un nouvel évent de trousse de tests,
- Si la température de la zone de stockage de la trousse de test se situe en dehors de la plage 2–30 °C,
- Si la température de la zone de test se situe en dehors de la plage 15–40 °C et
- 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 l’OraQuick® Ebola Rapid Antigen Test pour s’assurer que le test est effectué correctement.

RÉSUMÉ ET EXPlication DES CONTRÔLES DE LA TRousse

MÉTHODES FOURNIES

Contrôles de la trousse OraQuick® Ebola Rapid Antigen Test

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

Contrôle positif Ebola


Contrôle négatif Ebola

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

MÉTHODES ET FOURNISSES

MATERIELS FOURNIS

Minuterie ou montre capable de compter entre 20 et 30 minutes

Gants jetables en latex, vinyle ou nitrile

Micropipettes

MÉTHODES REQUISES ET FOURNISSES

Minuterie ou montre capable de compter entre 20 et 30 minutes

Gants jetables en latex, vinyle ou nitrile

Récipient pour déchets biologiques dangereux

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'OraQuick® Ebola Rapid Antigen Test 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, Infection Control for Viral Hemorrhagic Fevers in the African Health Care Setting et Information for Healthcare Worker in the United States (http://www.cdc.gov/vhf/ebola/hcp/), selon la zone dans laquelle est effectué le test.

PRÉCAUTIONS

Consignes de sécurité

• Manipuler les contrôles de la trousse et les matériaux en contact avec les contrôles comme s'ils étaient capables de transmettre des agents infectieux.

• Jeter tous les contrôles de trousse et matériaux 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 lois et politiques 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 réactifs 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'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 Controls only when you are performing tests. Recap and store the tubes 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 Test to come to operating temperature (15° - 40°C; 59° - 104°F) before use.

2. Open an OraQuick® Test Stand at your workpace, 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 OraQuick® Divided Pouch ("Pouch") from the Pouch. Hold the Pouch firmly in your hand. Carefully remove the cap from the Pouch by gently rocking the back and forth while pulling it out. Set the cap on your workspace cover.

5. Slide the Pouch into the top of one of the slots in the Stand. DO NOT force the pouch into the stand from the front of the slot as splashing may occur. Make sure the pouch is pulled all the way to the bottom of the slot in the stand.

6. Remove the Device from the pouch. DO NOT touch the Flat Pouch. 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)

7. Check to make sure that an Absorbent Packet is included with the Device. If no Absorbent Packet is present, discard the Device and order 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.

8. Open a kit control vial containing the control reagent.

9. Insert the micropipette into the vial and draw out a sample until it reaches the indicated line. Filling of the micro pipette is automatic. Never squeeze the micro pipette while sampling. Visually inspect the tipette to make sure there are no bubbles. If bubbles are present, discard the sample and obtain a new sample.

10. Immediately deposit the kit control sample through the sample port on the device by compressing the micro pipette directly above the sample port. Use separate unused micro pipettes for each control reagent.

11. Insert the Test Device, flat pad first, into the Development Vial. Be sure that the Result Window is facing toward you and the flat pad touches the bottom of the Development Vial.

12. Leave the Test Device in the Development 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 lit 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 insertion of the device into the Development 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.

13. Discard the used test materials in a biohazard waste container.

14. Recap the Kit Control reagent vials and store them in the original container at 2° - 8°C (36° - 46°F).

EXPECTED RESULTS

Etoila Negative Control

The Etoila 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.

INSTRUCTIONS DE CONSERVATION

Conserver les contrôles de la trousse OraQuick® Ebola Rapid Antigen Test pour sang total entre 2 et 8 °C. Ne pas utiliser les contrôles de la trousse au-delà de la date de péremption imprimée sur la boîte extérieure. Ouvrir les tubes de contrôles uniquement au moment d’effectuer les tests. Recouper et conserver les tubes dans leur boîte d’origine entre 2 et 8 °C après usage. Après ouverture, les contrôles de la trousse devront être jetés après huit (8) semaines.

MODE D’EMPLOI

Préparatifs généraux

Effectuer les procédures conformément à la section Préparatifs généraux de la notice OraQuick® Ebola Rapid Antigen Test.

PROCEDURE DE TEST

1. Avant utilisation, laisser la température de l’OraQuick® Ebola Rapid Antigen Test monter entre 15 et 40 °C.

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 étiquettes en haut, de chaque côté du sachet.


5. Glisser le flacon par haut dans les logements du support. NE PAS insérer le tube dans le logement par l’avant en forçant sous peine d’entrainer des problèmes. S’assurer que le flacon est posé 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 plate 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 dessiccant est inclus avec le dispositif. Dans le cas contraire, jeter le tout et se procurer un nouveau sachet déshydraté 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 réactif de contrôle.

8. Installer la micro pipette dans le tube et prélever un échantillon jusqu’à ce qu’elle atteigne le trait indicateur. Le remplissage de la micro pipette se fait automatiquement. Ne jamais pincer la micro pipette durant le prélèvement. Inspecter visuellement la pipette pour s’assurer qu’elle ne contient pas de bulles. Si des bulles sont présentes, jeter l’échantillon et en prélever un autre.


10. 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.

11. Laisser le dispositif de test dans le flacon de solution révélatrice et mettre la minuterie en marche. Ne pas retirer le dispositif de test du flacon avant d’avoir lu les résultats. Les résultats à un endroit très bien éclairé. Les résultats positifs peuvent être interprétés dès que des traits sont visibles dans la zone d’interprétation (T) et la zone de contrôle (C) (sous 4 minutes parfois). Les résultats négatifs doivent être lus 30 minutes après avoir inséré le dispositif dans le flacon de solution révélatrice. Les résultats comme indiqué à la section « Résultat du test et interprétation » de la notice de la trousse OraQuick® Ebola Rapid Antigen Test

12. Jeter le matériau de test utilisé dans un récipient pour déchets biologiques dangereux.

13. Réfrigérer les tubes de réactifs de contrôle de la trousse et les conserver dans leur carton d’origine entre 2 et 8 °C.

RÉSULTATS ESCOMPÉTÉS

Contrôle négatif Ebola

Le contrôle négatif Ebola produit 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.

**EXPLANATION OF SYMBOLS**

<table>
<thead>
<tr>
<th>Code (CO)</th>
<th>Catalog Number (REF)</th>
<th>In Vitro Diagnostic (IVD)</th>
<th>Manufacturer (Manufacturer)</th>
<th>Temperature Limitation (Caution)</th>
<th>Use By (PN)</th>
</tr>
</thead>
</table>

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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**BIBLIOGRAPHY**


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**FOR USE UNDER EMERGENCY USE AUTHORIZATION (EUA) ONLY**

All new operators must be able to correctly interpret all devices provided within the OraQuick® Ebola Visual Reference Panel prior to using the OraQuick® Ebola Rapid Antigen Test.

Failure to read at low intensities can result in the inability to detect specimens near the limit of detection of the OraQuick® Ebola Rapid Antigen Test and may result in false negative results.

This package insert and the OraQuick® Ebola Rapid Antigen Test package insert must be read completely before using the product. Follow the instructions carefully; failure to do so may cause an inaccurate test result.

**NAME AND INTENDED USE**

The OraQuick® Ebola Visual Reference Panel is intended to assist new operators in becoming proficient at reading specimens with antigen levels near the limit of detection of the device. The OraQuick® Ebola Visual Reference Panel is comprised of OraQuick® Ebola Rapid Antigen Test devices that have been designed to represent reading intensities of limit of detection, low positive, and negative test results. The limit of detection test device is indicative of specimens with antigen levels at the limit of detection of the device.

It is the responsibility of each laboratory using the OraQuick® Ebola Rapid Antigen Test to establish an adequate quality assurance program to ensure proficiency of new operators in their ability to interpret test results. The clinical performance of this device was established based on an operator’s ability to read visual intensities at the “T” Zone at all levels including very weak lines representing low antigen levels.

**SUMMARY AND EXPLANATION OF THE EBOLA VISUAL REFERENCE PANEL**

The OraQuick® Ebola Visual Reference Panel consists of three devices that have been manufactured to represent limit of detection, low positive, and negative test results. The devices are specifically formulated and manufactured to assist new operators in becoming proficient at reading specimens with antigen levels near the limit of detection of the device. The Ebola Limit of Detection Device has a very faint purple line at the Test (T) Zone. The Ebola Low Positive Device has a purple line at the Test (T) Zone. The Ebola Negative Device does not have a purple line at the Test (T) Zone. All devices have a purple line at the Control (C) Zone. Refer to Test Result and Interpretation of Test Result section of the OraQuick® Ebola Rapid Antigen Test package insert for instructions on how to interpret the devices.

This panel is to be used to assist new operators with becoming proficient at reading and interpreting OraQuick® Ebola Rapid Antigen Test results at or near the limit of detection of the device. The OraQuick® Ebola Visual Reference Panel is NOT to be used as a quality control device to set intensity values used as a cutoff for reading and interpreting OraQuick® Ebola Rapid Antigen Test devices. Any line at the T Zone is considered a positive result regardless of how faint the line appears.

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**EXPLIQUAISON DES SYMBOLES**

| Code de lot (CO) | Numéro de référence (REF) | Dispositif médical pour diagnostic in vitro (IVD) | Fabricant (Manufacturer) | Température limite (Caution) | Utiliser avant le (PN) |

Pour un support technique ou un service clientèle aux États-Unis, appeler le (800) ORASURE (800-672-7873). Clients en dehors des États-Unis : appeler le +(001) 610 882 1820 ou aller sur le site www.OraSure.com

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**FOR USE UNDER EMERGENCY USE AUTHORIZATION (EUA) ONLY**


Une impossibilité de lecture à faible intensité peut se solder par une impossibilité de détection des échantillons proches du seuil de détection de l’OraQuick® Ebola Rapid Antigen Test pour sang total et engendrer des faux négatifs.

Lire entièrement cette notice d’utilisation et celle de l’OraQuick® Ebola Rapid Antigen Test avant d’utiliser ce produit. Suivre scrupuleusement ces instructions sous peine de résultats inexacts.

**NOM ET INDICATION**


Il incombe à chaque laboratoire utilisant l’OraQuick® Ebola Rapid Antigen Test de définir un programme d’assurance qualité adéquat afin de garantir les compétences des nouveaux opérateurs en matière d’interprétation des résultats de tests. La performance clinique de ce dispositif a été établie à partir d’un laboratoire dédié à l’interprétation des résultats de tests de laboratoire. Pour les instructions d’interprétation des tests, voir la section Élaboration de la lecture et l’interprétation dans la notice de l’OraQuick® Ebola Rapid Antigen Test.

Ce panel est destiné à aider les nouveaux opérateurs à maîtriser la lecture et l’interprétation des résultats de l’OraQuick® Ebola Rapid Antigen Test au seuil de détection du dispositif au prouche de celui-ci. L’OraQuick® Ebola Visual Reference Panel NE DOIT PAS servir de dispositif de contrôle qualité pour définir les valeurs d’intensités utilisées comme limites de lecture et d’interprétation des dispositifs OraQuick® Ebola Rapid Antigen Test. Un trait quelconque dans la zone T est considéré comme un résultat positif, même s’il est de faible intensité.
MÉTIERIERS FOURNIS

OraQuick® Ebola Visual Reference Panel

Le sachet contient une notice d’utilisation et trois dispositifs (un dispositif correspondant au seuil de détection du virus Ebola, un dispositif faiblement positif au virus Ebola et un dispositif négatif au virus Ebola), comme décrit ci-dessous.

Dispositif correspondant au seuil de détection du virus Ebola

Dispositif OraQuick® Ebola Rapid Antigen Test qui a été fabriqué à un niveau de réactivité prédéterminé pour produire un résultat de test positif conforme au seuil de détection du dispositif.

Dispositif faiblement positif au virus Ebola

Dispositif OraQuick® Ebola Rapid Antigen Test qui a été fabriqué à un niveau de réactivité prédéterminé pour produire un résultat de test positif.

Dispositif négatif au virus Ebola

Dispositif OraQuick® Ebola Rapid Antigen Test qui a été fabriqué pour produire un résultat de test négatif.

MÉTIERIERS ET FOURNIS dans l’OraQuick® EBOLA Visual Reference Panel

Sac sachet contenant trois dispositifs OraQuick® Ebola Rapid Antigen Test prédéterminant représentant des résultats correspondant au seuil de détection, à un échantillon faiblement positif et à un échantillon négatif.

Notice d’utilisation

MÉTIERIERS REQUIS, MAIS NON FOURNIS

Gants jetables en latex, vinyle ou nitrile

AVERTISSEMENTS

• Lire intégralement la notice d’utilisation avant d’utiliser le produit.


• Pour les instructions d’interprétation des dispositifs, voir la section Résultats du test et interprétation dans la notice de l’OraQuick® Ebola Rapid Antigen Test.

• Lorsqu’il est stocké à l’abri de la lumière (dans le sachet ou non), l’OraQuick® Ebola Visual Reference Panel et l’OraQuick® Ebola Rapid Antigen Test sont stables pendant 5 mois. S’il n’est pas protégé de la lumière ou qu’il est stocké en dehors de l’intervalles de température indiqué, le dispositif non stocké dans sachet devrait être jeté après 15 jours.

• L’OraQuick® Ebola Visual Reference Panel NE DOIT PAS servir de dispositif de contrôle qualité pour définir les valeurs d’intensité utilisées comme limites de lecture et d’interprétation des dispositifs OraQuick® Ebola Rapid Antigen Test. Un trait quelconque dans la zone C est considéré comme un résultat positif, même s’il n’est pas de faible intensité.

• Tous les tests DOIVENT être réalisés dans des conditions de biosécurité appropriées, conformément aux directives du CDC. Tout le personnel de l’étude réalisant le test DOIT lire et se familiariser avec les documents Universal Precautions, Infection Control for Viral Hemorrhagic Fevers in the African Healthcare Setting and Information for Healthcare Worker in the United States (http://www.cdc.gov/ebola/healthcare-us/index.html), selon le pays dans lequel il a lieu le test.

PRÉCAUTIONS

Consignes de sécurité

• Jeter tous les dispositifs OraQuick® Ebola Visual Reference Panel dans un récipient pour déchets biologiques dangereux.

• L’OraQuick® Ebola Visual Reference Panel ne contient pas de matériau potentiellement infectieux ; toutefois, les dispositifs seront utilisés dans des zones contenant du matériau infectieux, ils devront être jetés dans un récipient pour déchets biologiques dangereux.

• L’utilisation de panneaux de référence visuelle d’un autre fabricant risque de ne pas satisfaire les exigences d’un programme d’assurance qualité adéquat pour l’OraQuick® Ebola Rapid Antigen Test.

STORAGE INSTRUCTIONS

Stora l’OraQuick® Ebola Visual Reference Panel at 15°-30°C (59°-86°F). Do not use the OraQuick® Ebola Visual Reference Panel beyond the expiration date printed on the foil pouch. Open the OraQuick® Ebola Visual Reference Panel pouch only when qualifying new operators in interpreting test results. Re- seal and store the devices in their original foil pouch at 15°-30°C (59°-86°F) after use. If not protected from light or stored above indicated temperatures, the unpouched device should be discarded after 15 days.

DIRECTIONS FOR USE

Test Procedure

Note: The OraQuick® Ebola Visual Reference Panel should be read and interpreted in the same location that testing and interpreting the OraQuick® Ebola Rapid Antigen Test occurs.

1. Open the foil pouch containing the OraQuick® Ebola Visual Reference Panel.
2. Pull out the three devices contained within the foil pouch.
3. Note the date the pouch was opened on the device labels or the pouch label.
4. Follow the Test Result and Interpretation of Test Result section of the OraQuick® Ebola Rapid Antigen Test package insert for instructions on how to interpret the devices.
5. Store the OraQuick® Ebola Visual Reference Panel Devices in the original re-sealable foil pouch at 15°-30°C (59°-86°F).

EXPECTED RESULTS

Ebola Limit of Detection Device

The OraQuick® Ebola Limit of Detection Device has been manufactured to have a very faint line at the Test (T) Zone. A line should be present in the Result Window in both the C Zone and the T Zone. This indicates a weakly positive test result consistent with the limit of detection of the device. The C Zone and the T Zone lines will not be the same intensity.

Ebola Low Positive Device

The OraQuick® Ebola Low Positive Device has been manufactured to have a line at the Test (T) Zone. A line should be present in the Result Window in both the C Zone and the T Zone. This indicates a positive test result. The C Zone and the T Zone lines will not be the same intensity.

Ebola Negative Device

The OraQuick® Ebola Negative Device has been manufactured to have a line at the Control (C) Zone. 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.

NOTE: If a new operator is unable to interpret all devices provided as part of the OraQuick® Ebola Visual Reference Panel, they are not considered to be proficient at reading and interpreting the OraQuick® Ebola Rapid Antigen Test. Failure to read low intensities can result in the inability to detect specimens near the limit of detection of the OraQuick® Ebola Rapid Antigen Test and may result in false negative results.

LIMITATIONS

The OraQuick® Ebola Visual Reference Panel is for use only with the OraQuick® Ebola Rapid Antigen Test.

INSTRUCTIONS DE CONSERVATION


MODE D’EMPLOI

Procédure de test

Remarque : L’OraQuick® Ebola Visual Reference Panel doit être lu et interprété au même endroit que là où auront lieu le test et l’interprétation de l’OraQuick® Ebola Rapid Antigen Test.

2. Sortir les trois dispositifs contenus dans le sachet au.
4. Pour les instructions d’interprétation des dispositifs, voir la section Résultat du test et interprétation dans la notice de l’OraQuick® Ebola Rapid Antigen Test.

RÉSULTATS ESCOMPTÉS

Dispositif correspondant au seuil de détection du virus Ebola

Le dispositif OraQuick® correspondant au seuil de détection du virus Ebola a été fabriqué pour produire un trait de très faible intensité dans la zone de test (T). Un trait doit apparaître dans la fenêtre de résultat dans la zone C et dans la zone T. Ceci indique un résultat de test faiblement positif, dans la logique du seuil de détection du dispositif. Les traits des zones C et T ne seront pas nécessairement de la même intensité de couleur.

Dispositif faiblement positif au virus Ebola

Le dispositif OraQuick® fabriqué au virus Ebola a été fabriqué pour produire un trait dans la zone de test (T). Un trait doit apparaître dans la fenêtre de résultat dans la zone C et dans la zone T. Ceci indique un résultat de test positif. Les traits des zones C et T ne seront pas nécessairement de la même intensité de couleur.

Dispositif négatif au virus Ebola

Le dispositif OraQuick® fabriqué au virus Ebola a été fabriqué pour produire un trait dans la zone de test (T). Un trait doit apparaître dans la fenêtre de résultat dans la zone C et dans la zone T. Ceci indique un résultat de test négatif.

REMARQUE : Si un nouvel opérateur est incapable d’interpréter tous les dispositifs fournis dans le cadre de l’OraQuick® Ebola Visual Reference Panel, il n’est pas considéré compétent pour lire et interpréter l’OraQuick® Ebola Rapid Antigen Test. Une impossibilité de lecture à faible intensité peut se solder par une impossibilité de détection des échantillons proches du seuil de détection de l’OraQuick® Ebola Rapid Antigen Test pour sang total et engendrer des faux négatifs.

LIMITES

L’OraQuick® Ebola Visual Reference Panel est uniquement destiné à une utilisation avec l’OraQuick® Ebola Rapid Antigen Test pour sang total.