WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: OraQuick HIV 1/2 Rapid Antibody Test
WHO reference number: PQDx 0159-055-00

OraQuick HIV 1/2 Rapid Antibody Test with product codes 5x4-0010, 5x4-0012, 5x4-0014
5x4-0015 and 5X4-0062 manufactured in Thailand for OraSure Technologies, Inc., Rest-of-
World regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics
and was listed on 8 April 2016.

Summary of WHO prequalification assessment for
OraQuick HIV 1/2 Rapid Antibody Test

<table>
<thead>
<tr>
<th>Date</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>PQ listing</td>
<td>8-Apr-2016 listed</td>
</tr>
<tr>
<td>Dossier review</td>
<td>26-Jan-2016 MR</td>
</tr>
<tr>
<td>Site inspection of quality management system</td>
<td>3-5-Nov-2014 MR</td>
</tr>
<tr>
<td>Laboratory evaluation</td>
<td>28-Jan-2016 MR</td>
</tr>
</tbody>
</table>

MR: Meets requirements

Report amendments and/or product changes

This public report has since been amended. Amendments may have arisen because of
changes to the prequalified product for which WHO has been notified and has undertaken
a review. Amendments to the report are summarized in the following table, and details of
each amendment are provided below.

<table>
<thead>
<tr>
<th>Version</th>
<th>Summary of amendment</th>
<th>Date of report amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>Changes in relation to the manufacturing process, facility or equipment, manufacturing quality control procedures and materials.</td>
<td>11-Oct-2016</td>
</tr>
<tr>
<td>3.0-6.0</td>
<td>Correction of typographical errors.</td>
<td>20-Jun-2018</td>
</tr>
<tr>
<td>7.0</td>
<td>Addition of two new generic product codes 5x4-0014 and 5x4-0015 and to make changes to product labelling, country specific (Ghana, Nigeria and Russia).</td>
<td>27-Jul- 2018</td>
</tr>
<tr>
<td>8.0</td>
<td>1. Addition of a paediatric claim for intended use population from 2 years of age and above of the OraQuick Rapid HIV-1/2 Antibody Test for professional use.</td>
<td>24-Jan-2020.</td>
</tr>
</tbody>
</table>
2. Increasing warehousing capacity to meet the ongoing increase in demand for the OraQuick HIV Self-Test. The new facility will be used for raw material storage, warehousing and distribution.

3. Addition of a product code for a Thailand-specific, oral fluid only variant (product code 5X4-0062) of the OraQuick Rapid HIV-1/2 Antibody Test”.

Intended use:¹

According to the claim of the manufacturer, “OraQuick HIV-1/2 Rapid Antibody Test is a qualitative, in vitro immunoassay. It detects antibodies to the human immunodeficiency virus types 1 and 2 (HIV-1/2) in human oral fluid, whole blood, serum or plasma (EDTA). The assay is read visually, and is intended for the detection of such antibodies from individuals infected by HIV-1 or HIV-2”.

Assay description:

According to the claim of the manufacturer, “OraQuick HIV-1/2 is a visually read, qualitative immunochromatographic test for the detection of IgG antibodies to HIV-1 and HIV-2. The flat pad that contacts the gums is treated with a mild surfactant, and no materials of viral origin are used in the manufacture of the test. One cannot become infected with HIV by taking this test. The device is placed into the subject’s mouth, so that the flat pad is between the cheek and the outer gums, then swabbed across the outer gum line (see oral fluid procedure in the IFU). The device is then placed into a vial containing a premeasured amount of developer solution, and allowed to develop. Use only the stand provided to hold the developer vial. Fluid from the surface of the gums enters the device through the flat pad, then flows onto a test strip. As it migrates across the strip, it hydrates and mixes with a red-colored reagent (protein A bound to colloidal gold). IgG antibodies in the specimen bind to the reagent. If in turn the bound IgG antibody recognizes synthetic HIV-1 or HIV-2 antigen immobilized on the strip enclosed in the housing, a colored line forms in the ‘T’ (test) area of the result window. If not, no line forms there.

Further up the strip, the colored reagent encounters an immobilized biochemical that recognizes human antibodies. The line that forms in this ‘C’ area of the result window is the control line. It demonstrates assay validity, indicating that the oral fluid contains IgG, that the strip is functioning properly, and that fluid is migrating appropriately through the device.

Alternatively, a whole blood, serum or plasma specimen can be collected using a loop. The loop is immersed into the developer and stirred to mix. See the test procedure for whole

¹ This product is one that uses Protein A to detect human IgG antibodies. Protein A is also able to detect other classes of human antibody (IgA, IgD, IgE and IgM) but not as reliably as it does IgG. This product has been prequalified with respect to its ability to detect human IgG antibodies. Any claim to detect other types of antibodies on this kind of product has not been validated based on WHO prequalification requirements.
blood, serum or plasma in the IFU.

Kit controls for OraQuick HIV-1/2 are available separately. These serve to demonstrate that the test is maintaining adequate performance (see Kit Control insert).

### Test kit contents:

<table>
<thead>
<tr>
<th>Configuration</th>
<th>100 tests</th>
<th>500 tests</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product code</strong></td>
<td><strong>5x4-0010</strong></td>
<td><strong>5x4-0014</strong></td>
</tr>
<tr>
<td><strong>Pouch</strong> containing 1 test device, 1 desiccant, 1 developer solution vial containing 1ml of phosphate buffer saline solution containing polymers and an antimicrobial agent.</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td><strong>Test stands</strong></td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td><strong>Specimen collection loops, 5µl</strong></td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td><strong>Instructions for use</strong></td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

### Items required but not provided:

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Consumables, for testing on fingerstick whole blood specimen</strong></td>
<td>Alcohol swabs, Sterile lancets</td>
</tr>
<tr>
<td><strong>Equipment</strong></td>
<td>Timer or watch</td>
</tr>
</tbody>
</table>

### Accessories:

<table>
<thead>
<tr>
<th>Item</th>
<th>Product code</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OraQuick ADVANCE Rapid HIV-1/2 Antibody Test Kit Controls</strong></td>
<td>1001-0077</td>
</tr>
<tr>
<td>3 Vials</td>
<td>1001-0144</td>
</tr>
<tr>
<td>Vial 1 - 1x HIV-1 positive control;</td>
<td>1001-0145</td>
</tr>
<tr>
<td>Vial 2 - 1x HIV-2 positive control; and</td>
<td></td>
</tr>
<tr>
<td>Vial 3 - 1x Negative control.</td>
<td></td>
</tr>
<tr>
<td>Sufficient to run approximately 25 tests.</td>
<td></td>
</tr>
<tr>
<td>Unopened expiry date: 12-months</td>
<td></td>
</tr>
<tr>
<td>Opened expiry date: 8-weeks when stored at 2 - 8 °C.</td>
<td></td>
</tr>
<tr>
<td><strong>Loop</strong></td>
<td></td>
</tr>
<tr>
<td>package of 5;</td>
<td>1001-0144</td>
</tr>
<tr>
<td>package of 25.</td>
<td>1001-0145</td>
</tr>
<tr>
<td><strong>Test Stand</strong></td>
<td>004-0002</td>
</tr>
<tr>
<td>package of 5</td>
<td></td>
</tr>
</tbody>
</table>
Storage:
The test kit should be stored at 2 - 30 °C.

- Store unopened and unused tests at 2 - 30 °C. Do not open the foil pouch until you are ready to perform a test.
- This test should be performed at temperatures in the range of (15 - 37 °C). If stored in a refrigerator, ensure that the Divided Pouch is brought to operating temperature (15 - 37 °C) before performing testing.
- If the test kit is stored at temperatures outside of ambient temperature (2 - 27 °C) or used outside of the operating temperature (15 - 37 °C), use the Kit Controls to ensure performance of the test.

Shelf-life upon manufacture:
30 months.

Warnings:

- Handle specimens and materials contacting specimens as if potentially infectious biological materials in accordance with Universal Precautions. It has been reported that infectious HIV can be isolated from the oral fluid of some HIV infected individuals. When detectable in oral fluid, infectious virus is present at low levels compared with blood and may be inactivated by salivary inhibitors.
- Clean and disinfect any oral fluid- or blood-containing spills. Use a 0.5% sodium hypochlorite (1:10 household bleach) solution, or other appropriate disinfectant.
- Dispose of all potentially contaminated materials in accordance with local regulations for disposal of biohazardous materials.
- If an oral fluid test must be repeated (following the gum-swab procedure), wait 15 minutes and start the process over using a new test device, and use the whole blood test procedure.
- Use adequate lighting to visually check a test result. If two lines are present at any visible intensity, the test result is interpreted as reactive.
- Do not cover or otherwise obstruct the two small holes on the back of the test device. The flow of fluid can be impaired.
- Individuals infected with HIV-1 and/or HIV-2 who are receiving antiretroviral therapy (ART) may produce false negative results.
- Individuals undergoing preventive treatment for HIV may produce false negative results.
- Do not use the test beyond the expiration date printed on the Divided Pouch. Always check expiration date prior to testing.
Limitations

1. The OraQuick HIV-1/2 Rapid Antibody Test must be used in accordance with these instructions to obtain an accurate result.
2. Oral fluid specimens for testing must be freshly collected, as detailed in the procedure. For blood-based testing, aged specimens or specimens, which have undergone repeated freeze-thaw cycles may give incorrect results.
3. Blood-based specimens that have been heat or chemically inactivated may not give accurate results.
4. The test is not for use with body fluids not specified here, with oral fluid collected by other methods or with other commercially available oral fluid collectors, or with pooled specimens.
5. Clinical data has not been collected to demonstrate the performance of OraQuick HIV-1/2 Rapid Antibody Test in persons under 13 years of age.
6. Do not use this test as the sole basis for a diagnosis of AIDS, ARC or HIV infection. Any reactive result should be confirmed.
7. For a reactive result, the intensity of the test line does not necessarily correlate to the titer of antibody in the specimen.
8. A non-reactive result does not preclude the possibility of exposure to HIV or infection by HIV. An antibody response to recent exposure may take some time to reach detectable levels.
9. If a red background in the result window makes it difficult to read the test at 20 minutes, wait until the background clears to read the result (but not more than 40 minutes total time).

Prioritization for prequalification

Based on the established eligibility criteria, OraQuick HIV 1/2 Rapid Antibody Test was given priority for WHO prequalification assessment.

Product dossier assessment

The manufacturer submitted a product dossier for OraQuick HIV 1/2 Rapid Antibody Test as per the “Instructions for compilation of a product dossier” (PQDx_018 v1). The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

The manufacturer's responses to the nonconformities found during dossier screening and assessment findings were accepted on 26 January 2016.

Based on the product dossier screening and assessment findings, the product dossier for OraQuick HIV 1/2 Rapid Antibody Test meets WHO prequalification requirements.
Manufacturing site inspection

A comprehensive inspection was performed at the site of manufacture (220 East First Street, Bethlehem, PA, 18015-1360, USA) of OraQuick HIV 1/2 Rapid Antibody Test, on 3-5 November 2014 as per the “Information for manufacturers on prequalification inspection procedures for the sites of manufacture of diagnostics” (PQDx_014). In addition, an inspection was undertaken at a key supplier (Pacific Biotech, 42M004 Phetchabun Chalianglub Rd., Napa, Muang, Petchabun 6700, Thailand). The inspections found that the manufacturer had an acceptable quality management system and good manufacturing practices in place that ensured the consistent manufacture of a product of good quality.

The manufacturer’s responses to the nonconformities found at the time of the inspection were accepted on 8 January 2015. A desk review of the quality management system was conducted 22 January 2016.

Based on the site inspections, desk review and corrective action plan review, the quality management system for OraQuick HIV 1/2 Rapid Antibody Test meets WHO prequalification requirements.

Product performance evaluation

OraQuick HIV-1/2 Rapid Antibody Test was evaluated at the Institute of Tropical Medicine on behalf of WHO in 2014 on serum/plasma specimens and in 2015 for oral fluid specimens. From this evaluation, we drew the following conclusions:

OraQuick HIV-1/2 Rapid Antibody Test is a qualitative rapid immunochromatographic test for the detection of antibodies to HIV 1/2 in oral fluid, whole blood, serum or plasma specimens. This type of assay requires no sophisticated equipment and can therefore be performed in laboratories with limited facilities and non-laboratory settings. Reading of the results can be done visually i.e. subjectively read.

In the evaluation on a panel of 1,118 clinically-derived stored serum and plasma specimens, compared to the reference algorithm (Vironostika HIV Ag/Ab [bioMérieux] and Enzygnost Anti-HIV 1/2 [Siemens Healthcare Diagnostics] in parallel; followed by INNO-LIA HIV I/II Score [Fujirebio]), the following performance characteristics were obtained:
### Performance characteristics in comparison with an agreed reference standard: serum/plasma specimens (N=1118)

<table>
<thead>
<tr>
<th></th>
<th>Initial (95% CI)</th>
<th>Final (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity % (N=460)</td>
<td>99.1% (97.8% - 99.8%)</td>
<td>99.1% (97.8% - 99.8%)</td>
</tr>
<tr>
<td>Specificity % (N=658)</td>
<td>99.8% (99.2% - 100%)</td>
<td>99.8% (99.2% - 100%)</td>
</tr>
<tr>
<td>Invalid rate %</td>
<td>0.1%</td>
<td></td>
</tr>
<tr>
<td>Inter-reader variability %</td>
<td>0%</td>
<td></td>
</tr>
</tbody>
</table>

### Performance characteristics in comparison with an agreed reference standard: oral fluid specimens (N=596)

<table>
<thead>
<tr>
<th></th>
<th>Initial (95% CI)</th>
<th>Final (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity % (N=106)</td>
<td>*99.1% (94.8% - 100%)</td>
<td>Repeat testing was not conducted</td>
</tr>
<tr>
<td>Specificity % (N=376)</td>
<td>100% (99.0% - 100%)</td>
<td>Repeat testing was not conducted</td>
</tr>
<tr>
<td>Invalid rate %</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Inter-reader variability %</td>
<td>0.4%</td>
<td></td>
</tr>
</tbody>
</table>

*For patients not on antiretroviral therapy (ART)*

The instructions for use includes a warning that individuals infected with HIV-1 and/or HIV-2 who are receiving antiretroviral therapy (ART) may produce false negative results and individuals undergoing preventive treatment for HIV may produce false negative results.
### Additional performance characteristics for serum/plasma evaluation

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity during seroconversion on 8 seroconversion panels in comparison with a benchmark assay; Enzygnost Anti-HIV 1/2 Plus (Siemens Healthcare Diagnostics)</td>
<td>Seroconversion sensitivity index of + 1.375, therefore detection is 1.375 later than the benchmark assay.</td>
</tr>
<tr>
<td>Analytical sensitivity on a mixed titer panel in comparison with an agreed reference standard</td>
<td>24 of 25 specimens were correctly classified.²</td>
</tr>
<tr>
<td>Lot to lot variation on a dilution panel</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>

### Key operational characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validated specimen types</td>
<td>Serum, plasma (EDTA), venous whole blood (EDTA, Sodium heparin and sodium citrate), capillary whole blood, oral fluid</td>
</tr>
<tr>
<td>Number of steps</td>
<td>2, without precision required.</td>
</tr>
<tr>
<td>Time to result</td>
<td>20 minutes</td>
</tr>
<tr>
<td>Endpoint stability</td>
<td>20 minutes (no more than 40 minutes after specimen added to developer vial)</td>
</tr>
<tr>
<td>Internal QC</td>
<td>Yes, internal quality control in form of control line for detection of IgG.</td>
</tr>
<tr>
<td>In-use stability of reagents</td>
<td>The foil pouch should be opened just before use.</td>
</tr>
</tbody>
</table>

² All anti-HIV positive/HIV-1 antigen positive and anti-HIV negative/HIV-1 antigen negative specimens were correctly classified. One out of the eleven anti-HIV positive/HIV-1 antigen negative specimens was not detected by the assay. All six anti-HIV indeterminate/HIV-1 antigen positive specimens were not detected by the assay.
Labelling

1. Labels
2. Instructions for use
1. Labels

1.1 Pouch labels

Generic pouch label
Pouch label for the Ghana variant
Pouch label for the Russian variant
1.2 Shipper box labels

100 Tests box label
500 Tests box label
1.3 Kit control box label

![Kit control box label image]

1.4 Developer vial label

![Developer vial label image]
1.5 Device label

Item# 3001-3035-70
rev. 03/17
2.0 Instructions for use

3 English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.
PN 204-7052 rev. 12/19 (Oral Fluid, Whole blood, Plasms or Serum)
as part of the oral-fluid clinical trials, information was collected from the participants regarding concurrent diseases or medical conditions, pathogens, non-HIV viral infections, and other factors (e.g., use of certain medications, dental/facial, and/or a history of intravenous/pelvic therapy). To test for these disease states, medical conditions or other factors interfering with test specificity in a separate study of 60 individuals, consumption of alcohol, smoking habit, use of medication or smoking at 5 minutes before testing, as well as factors that could affect test specificity. Namely, it is not recommend that subjects observed a period prior to the last food, coffee, or other beverages before the test. As part of the oral-fluid clinical trials, information was collected from the participants regarding concurrent diseases or medical conditions, pathogens, non-HIV viral infections, and other factors (e.g., use of certain medications, dental/facial, and/or a history of intravenous/pelvic therapy). To test for these disease states, medical conditions or other factors interfering with test specificity in a separate study of 60 individuals, consumption of alcohol, smoking habit, use of medication or smoking at 5 minutes before testing, as well as factors that could affect test specificity. Namely, it is not recommend that subjects observed a period prior to the last food, coffee, or other beverages before the test.
The OraQuick® device may not detect HIV infections that have occurred within the last 3 months. If you are using this test earlier than 3 months since a risk event and your test result is reactive, get a second test using an approved alternative testing method and refer the individual to a health care provider. The test kit is not stored at temperatures outside of ambient temperature 2-30 °C (36-86 °F) or as plasma for up to 7 days at 2-8 °C (36-46 °F). Other anticoagulants have not been tested for this collection of the plasma sample.

Limitations of the Procedure

The OraQuick® HIV-1/2 test does not recognize the presence of HIV-1 antibody present in the absence of detectable HIV-1 RNA. It suggests the presence of anti-HIV antibodies in the specimen. Reactive results should be confirmed by another method.

Reactive - lines may appear

If a complete line appears on the test strip, adjacent to the T and/or C lines, regardless of whether or not a positive control line is present, the test result must be considered invalid. The test kit is not compatible with all HIV-1/2 blood samples. A lack of one line in the result window indicates a valid result. If no line appears in the result window, the test result is invalid. If one line appears in the result window, the result is considered invalid.

Invalid - no line present in T or C area

If there is a line in the C area and no line is present in the T area, this is considered an invalid result. This indicates that the test did not capture a positive result. The test kit is not compatible with all HIV-1/2 blood samples. If there is a line in the T area and no line is present in the C area, the result is considered invalid. If no line appears in the result window, the test result is invalid. If one line appears in the result window, the result is considered invalid.

Interpretation of Results - Refer to the result window

Reactive - two lines appear

If two complete lines appear in the result window, adjacent to the C area and anywhere above or below the C area, the test result is considered reactive. The diagram at the right shows a reactive result. This indicates that a strong positive test result is present.

Reactive - lines may appear

If a complete line appears on the test strip, adjacent to the T and/or C lines, regardless of whether or not a positive control line is present, the test result must be considered invalid. The test kit is not compatible with all HIV-1/2 blood samples. A lack of one line in the result window indicates a valid result. If no line appears in the result window, the test result is invalid. If one line appears in the result window, the result is considered invalid.

Invalid - no line present in T or C area

If there is a line in the C area and no line is present in the T area, this is considered an invalid result. This indicates that the test did not capture a positive result. The test kit is not compatible with all HIV-1/2 blood samples. If there is a line in the T area and no line is present in the C area, the result is considered invalid. If no line appears in the result window, the test result is invalid. If one line appears in the result window, the result is considered invalid.

Interpretation of Results - Refer to the result window

Reactive - two lines appear

If two complete lines appear in the result window, adjacent to the C area and anywhere above or below the C area, the test result is considered reactive. The diagram at the right shows a reactive result. This indicates that a strong positive test result is present. A control line in the ‘C’ area of the result window indicates a valid result. A valid result indicates a positive sample was collected and the test performed properly. The test is not appropriate for all testing sites. These tests are not intended for public health performance. Kit controls should be used only with the kit manufacturer’s kit. Inert the kit controls present when using these reagents.

Interpretation of Results - Refer to the result window

Reactive - two lines appear

If two complete lines appear in the result window, adjacent to the C area and anywhere above or below the C area, the test result is considered reactive. The diagram at the right shows a reactive result. This indicates that a strong positive test result is present. A control line in the ‘C’ area of the result window indicates a valid result. A valid result indicates a positive sample was collected and the test performed properly. The test is not appropriate for all testing sites. These tests are not intended for public health performance. Kit controls should be used only with the kit manufacturer’s kit. Inert the kit controls present when using these reagents.

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Interpretation of Results - Refer to the result window

Reactive - two lines appear

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Interpretation of Results - Refer to the result window

Reactive - two lines appear

If two complete lines appear in the result window, adjacent to the C area and anywhere above or below the C area, the test result is considered reactive. The diagram at the right shows a reactive result. This indicates that a strong positive test result is present. A control line in the ‘C’ area of the result window indicates a valid result. A valid result indicates a positive sample was collected and the test performed properly. The test is not appropriate for all testing sites. These tests are not intended for public health performance. Kit controls should be used only with the kit manufacturer’s kit. Inert the kit controls present when using these reagents.
PN # 3001-3074 rev. 03/19 (Oral fluid only)
package Insert
Pouched Devices
Catalog Number
Part Number
Contents
Manufacturer
Do Not Reuse

3.
6.
7.
6.
2.

BIBLIOGRAPHY

7.


1986; 224:500-3.
QUALITY CONTROL
A control line (C) and an internal control line (IC) are visible in the result window. A valid result indicates a visible test result and the test function properly. The control line will appear on all valid tests, whether or not the test result is reactive. (See Interpretation of Results below.)

Kit control strips are available separately. These should be used one strip per test to detect contamination and/or as a quality assurance measure. If the Kit Control product insert is not used, results cannot be interpreted.

INTERPRETATION OF RESULTS
Non-reactive:
The result window is empty.

Reactive:
If a single line appears on the test strip, adjacent to the T and C labels, the result is considered reactive. The absence of a line shows a non-reactive result, which suggests the absence of anti-HIV antibodies in the specimen.

NOTE: Using the Negative Kit Control gives this result (see insert for OraQuick ADVANCE® HIV-1/2 Rapid Test).

REACtIVE - two lines appear

If two lines appear on the test strip, adjacent to the T and C labels, the result is considered reactive. One or more lines may not be the same color. At least one line is an example of reactive results, which suggests the presence of anti-HIV antibodies in the specimen.

Read results should be confirmed by another method.

NOTE: Using the HIV-1 Kit Control or HIV-2 Kit Control gives this result (the lines shown in the center panel were tested in OraQuick ADVANCE® HIV-1/2 Controls).

INVALID - no lines appear
If there is no line in the area labeled T, the result is invalid. An invalid test should be repeated using a new test device. At the right are examples of invalid results, which are caused by procedural errors.

LIMITATIONS OF THE PROCEDURE
- The OraQuick ADVANCE® HIV-1/2 Test is made in accordance with the instructions to obtain an accurate result.
- Oral fluid specimens for OraQuick HIV-1/2 testing must be freshly collected, as described in the STATEMENT CONCERNING BLOOD-BASED TESTING WAS REMOVED.
- Do not re-use test devices.
- OraQuick ADVANCE® HIV-1/2 Test only detects anti-HIV antibodies at detectable levels.
- A non-reactive result does not exclude the possibility of exposure to HIV or by the test window.
- Results should be verified using other assays to confirm the HIV diagnosis.
- A reactive result does not provide the possibility of exposure to HIV or infection by the test window.
- A negative test result does not provide the possibility of exposure to HIV or by the test window.
- A non-reactive result does not exclude the possibility of exposure to HIV or by the test window.
- A reactive result does not provide the possibility of exposure to HIV or by the test window.

DATA FROM CLINICAL STUDIES CONDUCTED WITH THE US VERSION OF THE OraQuick ADVANCE® HIV-1/2 Test

To meet the blood-borne pathogen standard (21 CFR 860.550) and the voluntary standard for oral fluid collection devices (ISO 18186:2008), a clinical study was conducted in the United States to determine the performance of the OraQuick ADVANCE® HIV-1/2 Test. A total of 1,006 previously unscreened individuals at low risk for HIV infection were enrolled. Of the 1,006 specimens, 606 were collected from oral fluid using OraQuick ADVANCE® HIV-1/2 Test, 779 were collected from oral fluid using OraQuick HIV-1/2 Test, and 40 were collected from oral fluid using other commercial oral fluid collection devices.

Performance characteristics:

Sensitivity

True Positive (95% CI) True Negative (95% CI)

Specificity

95% CI

Data from clinical studies conducted with the US version of the OraQuick HIV-1/2 Test

STATEMENT CONCERNING BLOOD-BASED TESTING WAS REMOVED."