Dignity Health Central Coast Service Area

**SUBJECT**: OraQuick ADVANCE Rapid HIV-1/2

ORIGIN: Clinical Laboratory/Hematology

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| **Document Category:** |
| [x]  Policy | [x] Procedure | [ ] Standardized Procedure | [ ] Other:  |

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| **Applies to:** |
| [x]  Santa Maria Campus,Marian Regional Medical Center | [x] Arroyo Grande Campus,Marian Regional Medical Center | [x] French Hospital Medical Center |
| [ ] St. John’s Pleasant Valley Hospital | [ ] St. John’s Regional Medical Center |

# purpose:

The OraQuick Advance Rapid HIV-1/2 Antibody test is a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2.

# REAGENTS/SUPPLIES:

OraQuick© test kit containing:

1. Test device
2. Developer solution vial
3. Reusable test stand
4. Specimen collection loop
5. Timer

# SPECImen requirements:

Venipuncture whole blood: Collect a whole blood specimen, with one of the following anticoagulants: Ethylenediaminetetraacetic acid (EDTA), sodium heparin, sodium citrate or ACD. Whole blood may be stored up to 5 days in 2-30° C. Test specimens and controls are to be run at room temperature (15-27° C).

# QUALITY CONTROL:

The OraQuick© Advance Rapid HIV-1/2 antibody test has its own internal controls. External Positive and Negative Controls are in a separate kit and are stored at 2-8 C. The controls have a 21 day expiration date.

1. The OraQuick© Test Device has a built-in procedural control that demonstrates assay validity.
2. A reddish-purple line in the Control C zone of the result window indicates that a specimen was added and 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 HIV-1/2 antibodies.
1. OraQuick© controls are used to verify the lab's ability to properly perform the test and interpret results.
2. Kit Controls should be run under the following circumstances:
* By each new operator prior to performing testing on patient specimens.
* Whenever a new lot of the OraQuick© test kit is used for the first time.
* If there is a change in the conditions of testing (e.g., new location, lighting, temperature, etc.)

# procedure:

## Use a new specimen collection loop each time you perform the test. Touch the round end of the loop to the drop of blood.

## Visually inspect the loop to make sure that it is completely filled with blood.

## Put the blood-filled loop into the developer solution inside the vial.

## Use the loop to stir the specimen in the developer solution. Solution will appear pink indicating the blood specimen was properly introduced.

## Remove the disposable loop and discard as infectious waste.

## Place the vial into the top of the slot in the blue angled test stand.

## The testing device must be inserted into the developer solution vial within 1 hour after collection.

1. Note: Do not cover the two holes in the back of the test device after placing it into the developer solution. Doing so may cause an invalid result.

H. Leave the device in the vial and start timing the test.

1. Do not remove the device from the vial until you have read the results.

2. Read the results after 20 minutes.

3. Do not exceed 40 minutes.

4. Read and record results.

# INTERPRETATION OF RESULTS:

Refer to the result window on the test device.

1. NON-REACTIVE: A reddish-purple line appears in the result window in the area adjacent to the triangle labeled “C” and no line appears in the area adjacent to the triangle labeled “T”, the result is Non-reactive.
* The test result is interpreted as negative for HIV-1 antibodies.
* Note: A non-reactive result does not preclude the possibility of exposure to HIV or infection with HIV.
* An antibody response to recent exposure may take several months to reach detectable levels.
1. REACTIVE: A reddish-purple line appears in the result window in the area adjacent to the triangle labeled “C” and a reddish-purple line appears in the area adjacent to the triangle labeled “T”, the result is considered Reactive.
* One of these lines may be darker than the other.
* The presence of any reddish-purple line in the area adjacent to the “T” and in the area adjacent to the “C”, no matter how faint these lines are, is considered to be a Reactive result.
* NOTE: As this is a screening test, a result of REACTIVE is not reported out. If the test result is REACTIVE, report result as “Sent to Ref Lab”. The laboratory information system will automatically reflex an HIV with confirmation to one of Dignity’s reference laboratories.
1. INVALID: A test is Invalid if any of the following occurs:
* No reddish-purple line is present in the area adjacent to the “C” triangle.
* A red background in the result window makes it difficult to read the results after 20 minutes.
* Any of the lines appear outside of the areas adjacent to the “C” or “T” triangles.
* An invalid test should be repeated with a new test device and developer solution.

# LIMITATIONS:

1. Reading the test results earlier than 20 minutes or later than 40 minutes may yield erroneous results.
2. A reactive result using the OraQuick Antibody test suggests the presence of anti-HIV-1 and/or HIV-2 antibodies in the specimen.

1. Any reactive specimens are to be sent to our reference lab for confirmation.
C. For a Reactive result, the intensity of the test line does not necessarily correlate with the titer of antibody in the specimen.
D. A Non-Reactive result does not preclude the possibility of exposure to HIV or infection with HIV.

1. An antibody response to recent exposure may take several months to reach detectable levels.

# references:

OraQuick Advance Rapid HIV-1/2 Test Product Insert, OraSure Technologies, Inc. Bethlehem, PA, 18015