OraQuick ADVANCE® Rapid Antibody Test HIV-1/2

Kit Controls

Read this package insert and the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit package insert completely before using the product. Follow the instructions carefully. Not doing so may result in inaccurate test results. Before performing testing, all operators MUST read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne Pathogens in Health-Care Settings.[1,2]

NAME AND INTENDED USE

The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit Controls are quality control reagents for use only with the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test and the OraQuick® Rapid HIV-1/2 Antibody Test (for outside USA use only).

Run the Kit 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°- 27°C (36°- 80°F),
- if the temperature of the testing area falls outside of 15°- 37°C (59°- 99°F), and
- at periodic intervals as dictated by the user facility.

It is the responsibility of each laboratory using the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test or the OraQuick® Rapid HIV-1/2 Antibody Test (for outside USA use only) to establish an adequate quality assurance program to ensure the performance of the device under its specific locations and conditions of use.

SUMMARY AND EXPLANATION OF THE KIT CONTROLS

OraQuick *ADVANCE*® Kit Controls are human plasma-based reagents. 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 HIV-1 and HIV-2 Positive Controls will produce a Reactive test result and have been manufactured to produce a very faint Test ("T") line. The Negative Control will produce a non-reactive test result. 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 OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test.

MATERIALS PROVIDED

OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit Controls

Each Kit Control box contains a package insert and three vials (one HIV-1 positive control, one HIV-2 positive control and one negative control) as described below:

HIV-1 Positive Control

One black-capped vial containing 0.2 mL of photochemically inactivated human plasma positive for antibodies to HIV-1, diluted in a defibrinated pool of normal human plasma. Preservative: 2-methyl-4-isothiazolin-3-one. Negative for Hepatitis B surface antigen and Hepatitis C antibody.

HIV-2 Positive Control

One red-capped vial containing 0.2 mL of photochemically inactivated human plasma positive for antibodies to HIV-2, diluted in a defibrinated pool of normal human plasma. Preservative: 2-methyl-4-isothiazolin-3-one. Negative for Hepatitis B surface antigen and Hepatitis C antibody.

Negative Control

One white-capped vial containing 0.2 mL of defibrinated pool of normal human plasma negative for antibodies to HIV-1 and HIV-2. Preservative: 2-methyl-4-isothiazolin-3-one. Negative for Hepatitis B surface antigen and Hepatitis C antibody.

MATERIALS REQUIRED AND PROVIDED in the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit

Divided Pouches, each containing a Test Device, an Absorbent Packet, and a Developer Solution Vial
Reusable Test Stands
Specimen Collection Loops
Subject Information Pamphlets
OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Package Insert with Customer Letter

MATERIALS REQUIRED BUT NOT PROVIDED

Timer or watch capable of timing 20 to 40 minutes
Latex, vinyl or nitrile disposable gloves
Biohazard waste container
Clean, disposable, absorbent workspace cover

WARNINGS AND PRECAUTIONS

For *in vitro* Diagnostic Use

1. Read this package insert and the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test package insert completely before using the product. Follow the instructions carefully. Not doing so may result in inaccurate test results.
2. Handle specimens, and materials contacting specimens, as if potentially infectious biological materials in accordance with "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Blood-borne Pathogens in Health-Care Settings".[1,2]
3. Handle the Kit Controls, and materials contacting the Kit Controls, as if capable of transmitting infectious agents.
4. Do not drink, eat, or smoke in areas where the Kit Controls are being handled.
5. Wear disposable gloves while handling specimens. Wash hands thoroughly after performing each test. Dispose of gloves in a biohazard waste container after use.
6. Dispose of all Kit Controls and materials used in the test procedure in a biohazard waste container. The recommended method of disposal of biohazard waste is autoclaving for a minimum of 1 hour at 121°C. Disposable materials may be incinerated. Liquid wastes may be mixed with appropriate chemical disinfectants. A freshly prepared solution of 10% bleach (0.5% solution of sodium hypochlorite) is recommended. Allow 60 minutes for effective decontamination. **NOTE: Do not autoclave solutions that contain bleach.** For additional information on biosafety, refer to "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Blood-borne Pathogens in Health-Care Settings".[1,2]
7. Wipe all spills thoroughly with a freshly prepared solution of 10% bleach or other appropriate disinfectant.[3]
8. 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 *ADVANCE*® Rapid HIV-1/2 Antibody Test.

STORAGE INSTRUCTIONS

Store the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit Controls at 2°- 8°C (36°- 46°F). Do not use Kit Controls beyond the expiration date printed on the outer carton. Open the Kit Control vials only when you are performing tests. Recap and store the vials in their original container at 2°- 8°C (36°- 46°F) after use.

Dispose of unused portions of opened Kit Control vials after eight weeks.

DIRECTIONS FOR USE

General Test Preparation

Perform procedures indicated in the *Set-Up Your Workspace* and *General Test Preparation* sections of the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test package insert or the Test Procedure sections of the OraQuick® Rapid HIV-1/2 Antibody Test package insert.

TEST PROCEDURE

1. Open a Kit Control vial containing the control reagent.
2. Insert the round end of an unused Specimen Collection Loop into the vial of control reagent. Visually inspect the loop to make sure that it is completely filled with the control reagent. **Use separate unused Specimen Collection Loops for each control reagent.**
   NOTE: The Kit Control reagents are clear to straw-colored. Do not use if the reagent appears visually cloudy or discolored.
3. Immediately immerse the control-reagent-filled Specimen Collection Loop in the developer solution inside the Developer Solution Vial. Use the Specimen Collection Loop to stir the specimen in the developer solution. Remove the Specimen Collection Loop from the Developer Solution Vial and discard the used loop in a biohazard waste container.
4. Remove the Test Device from the Divided Pouch without touching the flat pad. Insert the Test Device, flat pad first, into the Developer Solution Vial containing the specimen. **Be sure that the result window faces forward and the flat pad touches the bottom of the Developer Solution Vial**.
5. Leave the Test Device in the Developer Solution Vial and start a timer. **Do not remove the Test Device from the vial until you have read the results.** Read the results after 20 minutes but not more than 40 minutes in a fully lighted area. Read the results as described in the *Test Result* and *Interpretation of Test Result* sections of the test kit product insert.
6. Dispose of the used Developer Solution Vial and the Test Device in a biohazard waste container.
7. Reseal the Kit Control reagent vials and store them in their original container at 2°- 8°C (36°- 46°F).

EXPECTED RESULTS

Negative Control:
The Negative Control will produce a Non-Reactive test result. A line should be present in the Result Window in the area adjacent to only the triangle labeled "C." This indicates a Non-Reactive test result.

HIV-1 Positive Control:
The HIV-1Positive Control will produce a Reactive test result and has been manufactured to produce a very faint Test ("T") line. A line should be present in the Result Window in the area adjacent to the triangle labeled "C" **and** a line should appear in the area adjacent to the triangle labeled "T." This indicates a Reactive test result. The lines will not necessarily be the same intensity.

HIV-2 Positive Control:
The HIV-2 Positive Control will produce a Reactive test result and has been manufactured to produce a very faint Test ("T") line. A line should be present in the Result Window in the area adjacent to the triangle labeled "C" **and** a line should appear in the area adjacent to the triangle labeled "T." This indicates a Reactive test result. The lines will not necessarily be the same intensity.

NOTE: If the test result for either the Negative Control or the HIV-1 Positive Control or the HIV-2 Positive Control is not as expected, the test should be repeated using a new Test Device, Developer Solution Vial and control specimen. If the test result for any of the controls is not as expected upon repeat testing, discontinue testing and contact OraSure Technologies Customer Service.

LIMITATIONS
The OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit Controls are quality control reagents for use only with the OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test and the OraQuick® Rapid HIV-1/2 Antibody Test.

BIBLIOGRAPHY

1. CDC. Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. *MMWR* 1988; 37(24):377-388.
2. CDC. Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. *HICPAC* 2007; 12-93.
3. Sehulster LM, Hollinger FB, Dreesman GR, and Melnick JL. Immunological and biophysical alteration of hepatitis B virus antigens by sodium hypochlorite disinfection. *Appl Env Microbiol* 1981; 42:762-7.

EXPLANATION OF SYMBOLS

LOT Batch Code	IVD *In Vitro* Diagnostic Medical Device
REF Catalog Number	Manufacturer
Caution, Consult Accompanying Documents	Temperature Limitation
HIV CONTROL – HIV Negative Control	Use By
HIV-1 CONTROL + HIV-1 Positive Control	HIV-2 CONTROL + HIV-2 Positive Control
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