



Kit Controls

This package insert and the OraQuick® HCV Rapid Antibody 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. Before proceeding with testing, all operators MUST read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis A Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings.¹

NAME AND INTENDED USE

The OraQuick® HCV Rapid Antibody Test Kit Controls are quality control reagents for use only with the OraQuick® HCV Rapid Antibody Test.

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°-30°C (36°-86°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® HCV Rapid Antibody Test to establish an adequate quality assurance program to ensure the performance of the device under its specific locations and conditions of use.

SUMMARY AND EXPLANATION OF THE KIT CONTROLS

The OraQuick® HCV Rapid Antibody Test Kit Controls are human plasma-based reagents. The Kit Controls are specifically formulated and manufactured to ensure proper performance of the test. The HCV Positive Control will produce a reactive reddish-purple line at the Test (T) Zone. The HCV Negative Control will generate a non-reactive test result (no reddish-purple line at the Test (T) Zone). Refer to *Test Result and Interpretation of Test Result* section of the OraQuick® HCV Rapid Antibody Test package insert. Use of kit control reagents manufactured by any other source will not meet the requirements for an adequate quality assurance program for the OraQuick® HCV Rapid Antibody Test.

MATERIALS PROVIDED

OraQuick® HCV Rapid Antibody Test Kit Controls

Each Kit Control box contains a package insert and two vials (one HCV Positive Control and one HCV Negative Control) as described below:

HCV Positive Control

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

HCV Negative Control

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

MATERIALS REQUIRED AND PROVIDED in the OraQuick® HCV Rapid Antibody Test Kit

Divided Pouches, each containing a Test Device, an Absorbent Packet, and a Developer Solution Vial
Reusable Test Stands
Specimen Collection Loops
OraQuick® HCV Rapid Antibody Test Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

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

WARNINGS

For *in vitro* Diagnostic Use

- **This package insert must be read completely before using the product.**
- **Follow the instructions carefully when performing the OraQuick® HCV Rapid Antibody Test, failure to do so may cause an inaccurate test result.**
- **Before proceeding with testing, all operators MUST read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis A Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings.¹**

PRECAUTIONS

Safety Precautions

- Handle Kit Controls and materials in contact with Kit Controls as if capable of transmitting infectious agents.
- Dispose of all Kit Controls and materials used in the test procedure in a biohazard waste container.
- Wear disposable gloves while handling and testing the Kit Controls. Dispose of used gloves in a biohazard waste container.
- Use of kit control reagents manufactured by any other source will not meet the requirements for an adequate quality assurance program for the OraQuick® HCV Rapid Antibody Test.

STORAGE INSTRUCTIONS

Store the OraQuick® HCV Rapid Antibody Test Kit Controls at 2°-8°C (36°-46°F). Do not use Kit Controls beyond the expiration date printed on the outer box. Open the Kit Control vials only when you are performing tests. Recap and store the vials in their original box at 2°-8°C (36°-46°F) after use. Once opened, Kit Controls should be discarded after eight weeks.

DIRECTIONS FOR USE

General Test Preparation

Perform procedures according to the *General Test Preparation* section of the OraQuick® HCV Rapid Antibody Test package insert.

TEST PROCEDURE

1. Open a Kit Control vial containing the control reagent.
2. Insert the rounded 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.**
3. Immediately immerse the control-reagent-filled Specimen Collection Loop into the Developer Vial. Use the Specimen Collection Loop to stir the specimen in the developer solution. Remove the Specimen Collection Loop from the Developer 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 Vial containing the specimen. **Be sure that the Result Window is facing towards you and the flat pad touches the bottom of the Developer 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 in a fully lighted area after 20 minutes, but no more than 40 minutes. Read the results as described in the *Test Result and Interpretation of Test Result* section of the OraQuick® HCV Rapid Antibody Test Kit Package Insert.
6. Dispose of the used test materials in a biohazard waste container.
7. Reseal the Kit Control reagent vials and store them in the original container at 2°-8°C (36°-46°F).

EXPECTED RESULTS

HCV Negative Control

The HCV Negative Control will produce a Non-Reactive 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 Non-Reactive test result.

HCV Positive Control

The HCV Positive Control will produce a Reactive test result and has been manufactured to produce a line at the Test (T) Zone. A line should be present in the Result Window in the (C) Zone and a line should appear in the (T) Zone. This indicates a Reactive test result. The lines will not necessarily be the same intensity.

NOTE: If the test result for either the HCV Negative Control or the HCV 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® HCV Rapid Antibody Test Kit Controls are quality control reagents for use only with the OraQuick® HCV Rapid 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.

EXPLANATION OF SYMBOLS

 Batch Code	 <i>In Vitro</i> Diagnostic Medical Device
 Catalog Number	 Kit Controls
 Caution, Consult Accompanying Documents	 Manufacturer
 Contents	 Part Number
 Control Negative	 Temperature Limitation
 Control Positive	 Use By
 Developer Solution Vial	



OraSure Technologies, Inc.

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