

**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.**

## 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) area. The HCV Negative Control will generate a non-reactive test result (no reddish-purple line at the Test (T) area). 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.

## 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.**

## 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 OraQuick® HCV Rapid Antibody Test package insert.

## EXPECTED RESULTS

### HCV Negative Control ( )

The HCV Negative Control will produce a Non-Reactive test result. A single reddish-purple line should be present in the Result Window next to the triangle labeled "C." 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 reddish-purple Test (T) line. A reddish-purple line should be present in the Result Window next to the triangle labeled "C" and a second reddish-purple line should appear next 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 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.

## Explanation of Symbols

|  |   |  |
|--|---|--|
|  Use by                                     | <b>HCV CONTROL -</b> Negative HCV Control   | <b>TEST</b> Test Device  |
| <b>REF</b> Catalog Number  | <b>HCV CONTROL +</b> Positive HCV Control   | <b>TESTS</b> Test Devices  |
| <b>LOT</b> Batch Code  | <b>PACK INSERT</b> Package Insert           | <b>IVD</b> <i>In Vitro</i> Diagnostic Medical Device   |
|  Manufacturer                               | <b>LOOPS 5µL</b> 5 µL Loops                 |  Temperature Limitation |
|  Consult Instructions for Use               | <b>ABS PACK</b> Absorbent Packet            |  Do Not Reuse           |
|  Caution, Consult<br>Accompanying Documents | <b>DEV SOL VIAL</b> Developer Solution Vial | <b>EC REP</b> Authorized Representative in the<br>European Community                                       |
| <b>CONTENTS</b> Contents   | <b>TEST STANDS</b> Test Stands              | <b>KIT CTRLS</b> Kit Control   |

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0543



**OraSure Technologies, Inc.**

220 East First Street  
Bethlehem, PA 18015 U.S.A.  
(001) 610.882.1820 • [www.orasure.com](http://www.orasure.com)



Qarad b.v.b.a.  
Volmolenheide 13  
B-2400 Mol  
Belgium