

SAFETY STATEMENT

OraQuick[®] HCV Rapid Antibody Test Kit Controls**PRODUCT AND COMPANY IDENTIFICATION**

PRODUCT NAME: OraQuick[®] HCV Rapid Antibody Test Kit Controls

GENERAL USE: OraQuick[®] HCV Rapid Antibody Test Kit Controls are quality control reagents for use only with the OraQuick[®] HCV Rapid Antibody Test. The kit control components 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).

ORASURE PRODUCT NUMBERS: 1001-0182, 1001-0278

MANUFACTURER

OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015
Phone: 800-869-3538
www.orasure.com

HAZARD IDENTIFICATION

The OraQuick[®] HCV Rapid Antibody Test Kit Controls do not meet the criteria for classification according to Regulation EC No. 1272/2008 (EU CLP) and applicable US regulations.

The OraQuick[®] HCV Rapid Antibody Test Kit Controls individual components should only be used by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety.

COMPOSITION / INFORMATION ON INGREDIENTS

COMMENTS: To the best of our knowledge, this material does not contain any hazardous ingredients in quantities requiring reporting in this section, in accordance with USA or EU regulations.

Components	Contents
1 vial of 0.2ml HCV Positive Control (Purple Cap)	0.2ml of photochemically inactivated human plasma positive for antibodies to HCV, diluted in a defibrinated pool of normal human plasma. Preservative: ProClin 950.
1 vial of 0.2ml HCV Negative Control (White Cap)	0.2ml of defibrinated pool of normal human plasma negative for antibodies to HCV. Preservative: ProClin 950.

COMMENTS: The Positive Control (purple capped vial) contains 0.2ml of photochemically inactivated human plasma positive for antibodies to HCV, diluted in a defibrinated pool of normal human plasma. The Negative Control (white capped vial) contains 0.2ml of defibrinated pool of normal human plasma. All control vials contain the chemical ProClin 950 as a preservative. All control vials are negative for Hepatitis B surface antigen and HIV-1/2 antibody. The vials contain no known active viruses; the test indication is based on the response to the antibody only.

NOTE: This material and its container must be disposed of in a safe way and in accordance with Local, State and Federal Regulations. Unless otherwise stated no known or anticipated adverse health hazards are likely for the small amount of chemical provided within the mixtures of this product. Use proper decontamination methods (1:10 dilution of household bleach and water). Utilize Good Laboratory Practices.

HANDLING AND STORAGE

HANDLING: The individual components within the product should be handled only by qualified personnel. Utilize Good Laboratory Practices and safety guidelines for handling chemicals and other hazards. Wear appropriate Personal Protective Equipment (PPE) including gloves, lab coat or equivalent and eye/face protection. Keep containers tightly closed; avoid splashing, spills and the generation of aerosols. Handle all specimens, materials and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per universal precautions.

STORAGE: Store according to product and label instructions, 2-8°C (35-46°F). Open kit vials can be recapped and stored in their original containers at 2-8°C (35-46°F).

NOTE: Handling, storing or shipping of the complete packaged product should pose no threat to the individual. If no leak or excessive damage is noted there is no recommended Personal Protective Equipment (PPE) required. If the products' integrity is in question due to excessive damage or unforeseen circumstances, utilize proper safety procedures and handle using universal precautions including PPE (safety glasses/face protection and gloves) as per 29 CFR 1910.1030.

OTHER INFORMATION

The information contained herein is accurate to the best of our knowledge. OraSure Technologies Inc. makes no warranty of any kind, expressed or implied, concerning the safe use of this material in the process or in combination with other substances.

This is not a Safety Data Sheet (SDS). According to USA and EU regulations, we are not required to supply an SDS for a product which is not classified as hazardous.

SUMMARY OF CHANGES:

11/09/16 - New Safety Statement for USA and EU.