



SAFETY STATEMENT

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

PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test Kit Controls

GENERAL USE: OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test 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 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.

ORASURE PRODUCT NUMBERS: 1001-0077, 1001-0288, 1001-0354.

MANUFACTURER

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

HAZARD IDENTIFICATION

The OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test Kit Controls do not meet the criteria for classification according to Regulation EC No. 1272/2008 (EU CLP), WHS (Australia) regulations, USA (OSHA) regulations, MOEL public notice No. 2016-19 (South Korea) and ABNT NBR 14725 (Brazil).

The OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test Kit Controls individual components should be used only 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 applicable USA, EU, Australian, Korean or Brazilian regulations.

Components	Contents
1 vial of 0.2ml HIV-1 Positive Control (Black Cap)	0.2ml BPUV treated human plasma, positive for HIV-1 antibodies, diluted in a defibrinated pool of human plasma. Preservative: ProClin 950.
1 vial of 0.2ml HIV-2 Positive Control (Red Cap)	0.2ml BPUV treated human plasma, positive for HIV-2 antibodies, diluted in a defibrinated pool of human plasma. Preservative: ProClin 950.
1 vial of 0.2ml Negative Control (White Cap)	0.2ml of defibrinated pool of human plasma negative for HIV-1 & HIV-2. Preservative: ProClin 950.

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

HANDLING AND STORAGE

HANDLING: The individual components within this 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).

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 applicable USA, EU, Australian, Korean and Brazilian regulations, we are not required to supply an SDS for a product which is not classified as hazardous.

SUMMARY OF CHANGES:

11/11/16-New Safety Statement for USA, EU, Australia, Korea and Brazil.