WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: OraQuick HCV Rapid Antibody Test Kit
WHO reference number: PQDx 0244-055-00

OraQuick HCV Rapid Antibody Test Kit with product codes **1001-0270** and **1001-0274**, manufactured by **OraSure Technologies, Inc.**, **CE-marked regulatory version**, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 1 March 2017.

Intended use:
OraQuick® HCV Rapid Antibody Test is a single-use, in vitro diagnostic medical device. It is an immunoassay for the qualitative detection of immunoglobin G (IgG) antibodies to hepatitis C virus (anti-HCV) in oral fluid, fingerstick whole blood, venipuncture whole blood, plasma specimens (EDTA, sodium heparin, lithium heparin, and sodium citrate), and serum (serum separator tube (SST), and from individuals 11 years or older. OraQuick® HCV Rapid Antibody Test assay results may be used to provide presumptive evidence of infection with HCV in individuals with signs and symptoms of hepatitis and in individuals at risk for hepatitis C infection.

The effectiveness of the OraQuick® HCV Rapid Antibody Test for use in screening whole blood, plasma, or tissue donors has not been established.

Assay description:
OraQuick® HCV Rapid Test is a manually performed, visually read, 20-minute immunoassay for the qualitative detection of HCV antibodies. The assay test strip contains synthetic peptides and recombinant proteins from the core, NS3, and NS4 regions of the HCV genome (test line) and a goat anti-human IgG (control line) immobilized onto a nitrocellulose membrane.

Test kit contents:

Component	**25 tests (product code 1001-0270)**	**100 tests (product code 1001-0274)**
Divided test pouch: Contains OraQuick® HCV Rapid Antibody Test plus Absorbent Packet and OraQuick® HCV Developer Solution	25	100
Reusable test stands, plastic	5	10
Collection loops, plastic, capable of holding 5 µl	25	100
Instructions for use	1	1

Items required but not provided:

Item	Product code
Consumables: OraQuick HCV Kit Controls 2 Vials Vial 1 - 1x HCV positive control; Vial 2 -1x HCV negative control. Sufficient to run approximately 50 tests	1001-0278
Equipment: Timer	

Storage:
The test kit should be stored at 2 to 30 °C.
OraQuick HCV Kit Controls should be stored at 2 to 8 °C

Shelf-life upon manufacture:
OraQuick HCV Rapid Antibody Test Kit has a shelf life of 18 months.
OraQuick HCV Kit Controls have a shelf life of 12 months.

Warnings/limitations:
It is not intended for use in screening whole blood, plasma, or tissue donors.

Summary of WHO prequalification assessment for OraQuick HCV Rapid Antibody Test Kit

	Date	Outcome
PQ listing	1 March 2017	listed
Dossier review	N/A	MR
Inspection(s) of quality management system	11 December 2015	MR
Laboratory evaluation of performance and operational characteristics	24 January 2017	MR

MR: Meets requirements
N/A: Not applicable

Prioritization for prequalification
Based on the established criteria, OraQuick HCV Rapid Antibody Test Kit was given priority for WHO prequalification.

Product dossier assessment
In accordance with the WHO procedure for abbreviated prequalification assessment, OraSure Technologies, Inc., was not required to submit a product dossier for OraQuick HCV Rapid Antibody Test Kit as per the "Instructions for compilation of a product dossier" (PQDx_018 v1). Notwithstanding, certain aspects of the product dossier previously submitted for stringent regulatory review were reviewed by an assessor during the site inspection.

Commitments for prequalification:

1. The essential principles relating to patient and user safety must be met. As such, it is not considered adequate to supply OraQuick HCV Kit Controls that have not been tested for HIV, HBV and HCV by nucleic acid testing (NAT) technologies.
   OraSure Technologies will introduce testing of OraQuick HCV Kit Controls by NAT technologies, as soon as possible.

Manufacturing site inspection
A Stage 1 inspection was performed on the quality management system for OraQuick HCV Rapid Antibody Test Kit on 11 December 2015 as per the "Information for manufacturers on prequalification inspection procedures for the sites of manufacture of diagnostics" (PQDx_014 v1). The Stage 1 inspection found that the manufacturer had an acceptable quality management system and good manufacturing practices in place that ensured the consistent manufacture of a product of good quality. The last inspection of this manufacturing site (220 East First Street, Bethlehem, PA, 18015-1360, USA) was 3 to 5 November 2014. At the time of inspection the site was found to be compliant with the requirements for prequalification and a subsequent inspection was not required.

The manufacturer's responses to the questions raised found at the time of the Stage 1 inspection were accepted on 1 February 2016.

Based on the Stage 1 inspection and response, the quality management system for OraQuick HCV Rapid Antibody Test Kit meets WHO prequalification requirements.

Laboratory evaluation

OraQuick HCV Rapid Antibody Test was evaluated by WHO in the fourth quarter of 2016 using plasma specimens. From this evaluation, we drew the following conclusions:

OraQuick HCV Rapid Antibody Test is an immunochromatographic assay for the detection of antibodies to HCV in human oral fluid, finger stick whole blood, venipuncture whole blood, plasma specimens (EDTA, sodium heparin, lithium heparin and sodium citrate), and serum (serum separator tube (SST), and from individuals 11 years or older. One collection loop (5µL) of specimen is needed to perform the assay. This type of assay does not require laboratory equipment (i.e. timer) and can be performed in laboratories with limited facilities.

Performance characteristics in comparison with an agreed reference standard		
	Initial (95% CI)	**Final (95% CI)**
Sensitivity %	100% (97.8% to 100.0%)	100% (97.8% to 100.0%)
Specificity %	99.4% (97.3% to 99.8%)	99.7% (98.3 to 100.0%)
Invalid rate %	0%	
Inter-reader variability %	0.09%	

Additional performance characteristics	
Sensitivity during seroconversion on 4 seroconversion panels in comparison with a benchmark assay; Murex anti-HCV (version 4.0) DiaSorin South Africa Pty Ltd.	Seroconversion sensitivity index of +2.75, therefore detection is 2.75 days later than the benchmark assay
Analytical sensitivity on a mixed titer panel in comparison with an agreed reference standard	20 of 25 antibody positive specimens were correctly classified
Lot to lot variation on a dilution panel in comparison with an agreed reference standard	Acceptable

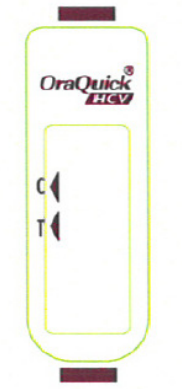
Key operational characteristics	
Validated specimen types	Serum (and serum separator tubes), plasma (EDTA, sodium heparin, lithium heparin and sodium citrate), venous whole blood, capillary whole blood, oral fluid
Number of steps	3 without precision required
Time to result	20 minutes
Endpoint stability	40 minutes
Internal QC	Yes, a control line appears when the reagents have flowed adequately along the device. Other HCV positive and negative test kit controls are supplied separately as an accessory to the OraQuick HCV Rapid Antibody Test kit.
In-use stability of reagents	0 days after opening

Labelling

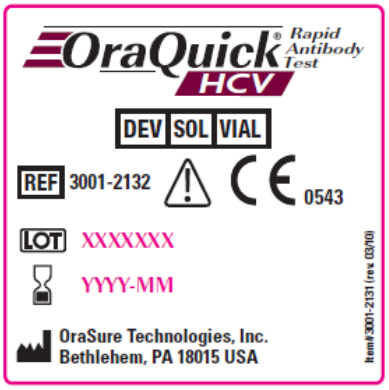
1. **Labels**
2. **Instructions for use**

1. Labels

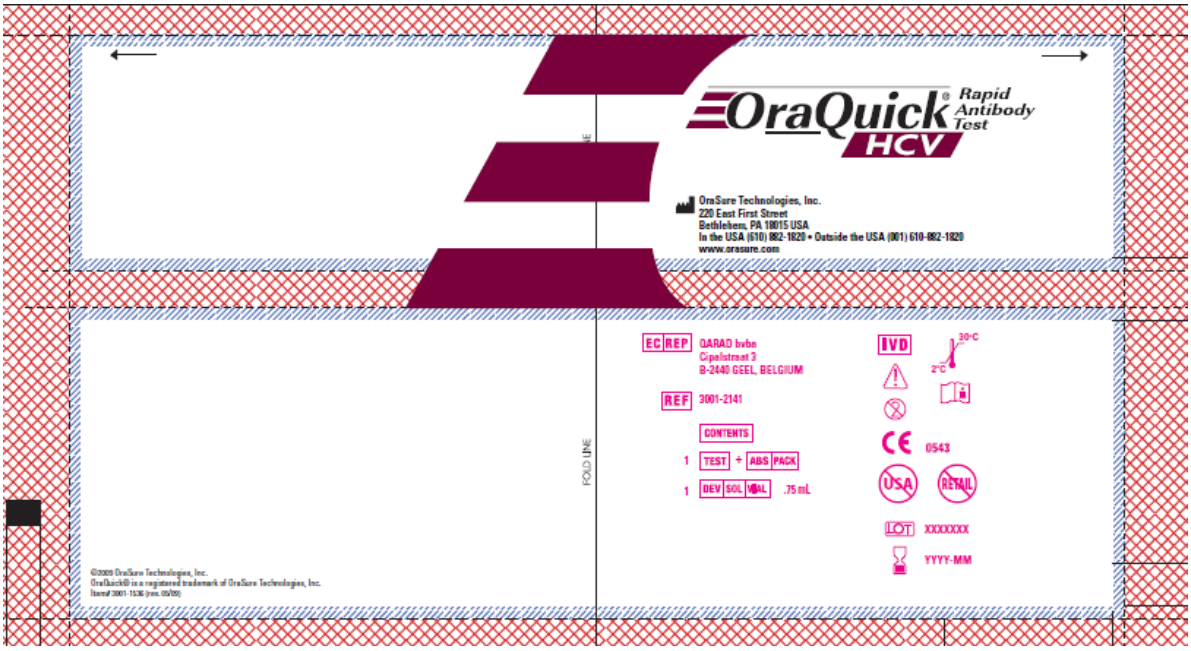
Device Label 3001-1537 rev 09/08



Developer Vial Label 3001-2131 rev 3/10

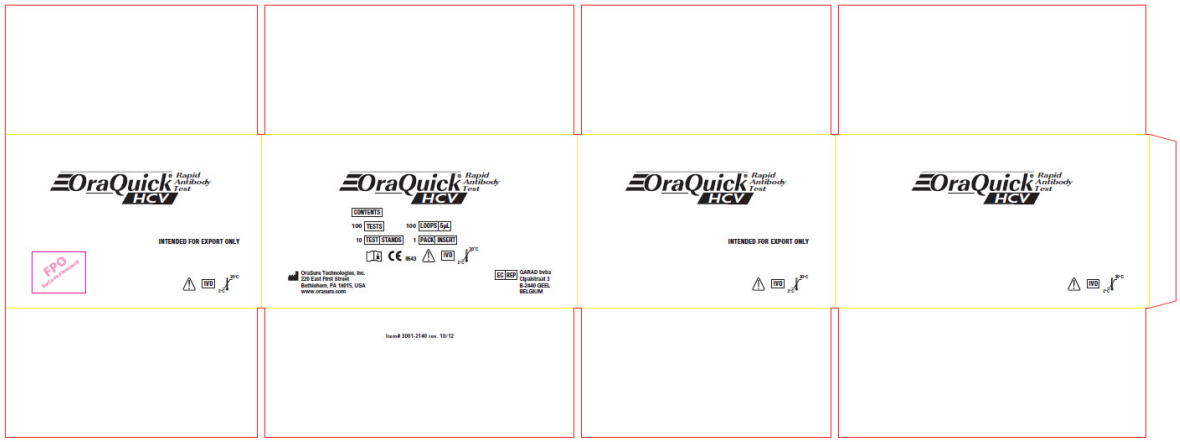


Foil Laminate Pouch 3001-1536 rev 05/09 with JIT

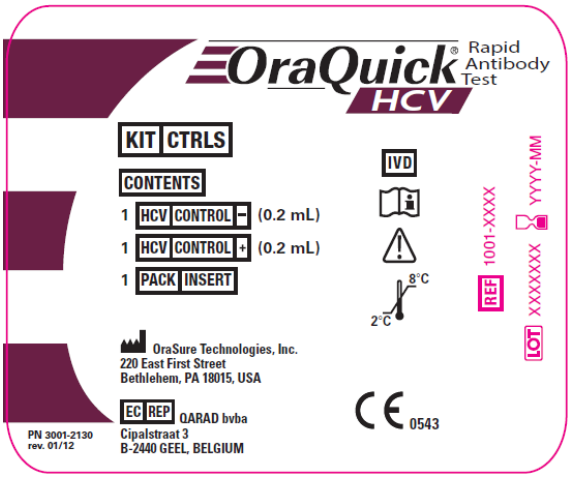


25 count Shipper Box 3001-2139 rev 10/12

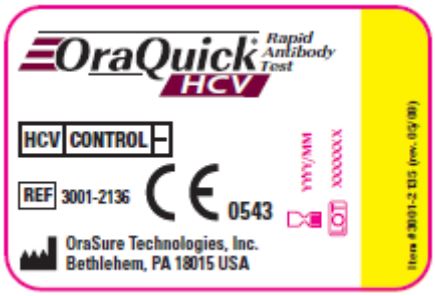
100 count Shipper Box 3001-2140 rev 10/12



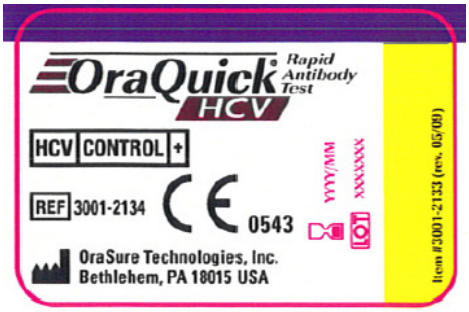
Kit Control Box Label 3001-2130 rev 11/12



Negative Kit Control Vial Label 3001-2135 rev 05/09



Positive Kit Control Vial Label 3001-2133 rev 05/09



2. Instructions for use

OraQuick® HCV Rapid Antibody Test Instructions for Use

OraQuick® HCV Kit Control Instructions for Use

OraQuick® Rapid Antibody Test HCV

ENGLISH

Read the instructions for use completely before using the product. Follow the instructions carefully when performing testing. Failure to do so may result in inaccurate test results.

INTENDED USE

IVD For use by healthcare professionals only.

The OraQuick® HCV Rapid Antibody Test is a single-use, anti-HCV *in vitro* diagnostic mecial device (IVD). It is an immunoassay for the qualitative detection of immunoglobin G (IgG) antibodies to hepatitis C virus (anti-HCV) in oral fluid, fingerstick whole blood, venipuncture whole blood, plasma specimens (EDTA, sodium heparin, lithium heparin, and sodium citrate), and serum (serum separator tube (SST)), and from individuals 11 years or older. The OraQuick® HCV Rapid Antibody Test assay results may be used to provide presumptive evidence of infection with HCV in individuals with signs and symptoms of hepatitis and in individuals at risk for hepatitis C infection.

Warning: Not intended for use in screening whole blood, plasma, or tissue donors. The effectiveness of the OraQuick® HCV Rapid Antibody Test for use in screening whole blood, plasma, or tissue donors has not been established.

SUMMARY AND EXPLANATION OF THE TEST

Hepatitis C virus (HCV) is the causative agent for most non-A, non-B hepatitis.[1] The presence of antibodies to HCV indicates that the individual may be currently infected and capable of transmitting the virus.

PRINCIPLES OF THE TEST

The OraQuick® HCV Rapid Antibody Test is a manually performed, visually read immunoassay for the qualitative detection of HCV antibodies in human oral fluid, fingerstick and venipuncture whole blood. The OraQuick® HCV Rapid Antibody Test is comprised of both a single-use test device and vial containing a pre-measured amount of a buffered developer solution. The test consists of a sealed pouch with two separate compartments for each component. The OraQuick® HCV Rapid Antibody Test utilizes a proprietary lateral flow immunoassay procedure.

The assay test strip, which can be viewed through the test device result window, contains synthetic peptides and recombinant proteins from the core, NS3, and NS4 regions of the HCV genome (test) and a goat anti-human IgG (procedural control) immobilized onto a nitrocellulose membrane at the Test (T) and the Control (C) Zone, respectively.

A fingerstick whole blood specimen or venipuncture whole blood specimen is collected using a specimen loop and transferred into the developer solution vial or an oral fluid specimen is collected using the flat pad of the device, followed by the insertion of the device. The developer solution facilitates the capillary flow of the specimen into the device and onto the assay strip. As the specimen flows through the device, antibodies from the specimen are bound to the protein A gold colorimetric reagent present on the assay strip. If the specimen contains anti-HCV antibodies, the resulting labeled complexes contain HCV antibody and bind to immobilized HCV antigens at the HCV Test Zone (T Zone) resulting in a reddish-purple line. If the specimen does not contain anti-HCV antibodies, the labeled complexes do not bind at the HCV Test Zone and no line is observed in the T Zone. The intensity of the line color is not directly proportional to the amount of HCV antibody present in the specimen. The remaining labeled complexes are transported to the Control Zone (C Zone) binding to a goat anti-human antibody fragment. The presence of IgG antibodies in the sample (regardless of their specificity) results in a reddish-purple line at the C Zone. This procedural control serves to demonstrate that a specimen was added to the vial and that the fluid has migrated adequately through the device. A reddish-purple line will appear at the C Zone during the performance of all valid tests; whether or not the sample is positive or negative for HCV antibodies (refer to the *Test Result and Interpretation* section in this instructions for use).

The test results are interpreted after 20 minutes, but not more than 40 minutes following the introduction of the device into the developer solution vial. No precision pipetting, pre-dilutions, or specialized instrumentation are required to perform the OraQuick® HCV Rapid Antibody Test.

MATERIALS PROVIDED (REF 1001-0270 25 TESTS, REF 1001-0274 100 TESTS)

- Divided pouch contains OraQuick® HCV Rapid Antibody Test plus Absorbent Packet and OraQuick® HCV Developer Solution: Vial containing 0.75mL phosphate buffered saline solution containing polymers and 0.1% 2-methyl-4-isothiazolin-3-one
- Reusable test stands
- 5µL Collection loops
- Instructions for use

MATERIALS REQUIRED, AVAILABLE AS AN ACCESSORY TO THE KIT

OraQuick® HCV Rapid Antibody Test Kit Controls (1001-0278)

MATERIALS REQUIRED BUT NOT PROVIDED

Timer capable of timing 20 to 40 minutes
Biohazard waste container

Additional Items Required for Fingerstick and Venipuncture Specimens

Antiseptic wipe, sterile lancet, disposable gloves (optional for oral fluid testing), sterile gauze pads or venipuncture supplies, centrifuge

WARNINGS

For *in vitro* Diagnostic Use. For use by healthcare professionals only.

- Read the instructions for use 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.
- Do not interchange Test Devices and Developer Solution vials from kits with different lot numbers
- This test kit has been approved for use with oral fluid, fingerstick whole blood, venous whole blood, serum and plasma specimens only. Use with other specimen types may cause inaccurate results.
- This test is not intended to be used to monitor individuals who are undergoing treatment.

PRECAUTIONS

- Handle specimens and materials in contact with specimens as if capable of transmitting infectious agents.
- Wear disposable gloves while handling and testing blood specimens. Change gloves and wash hands thoroughly after performing each test. Dispose of used gloves in a biohazard waste container.
- Use of gloves for oral fluid testing is recommended as any biologic specimen should be treated as potentially infectious. Testing providers with breaks in the skin (cuts, abrasions, or dermatitis) should wear gloves when performing oral fluid testing. Wash hands thoroughly after performing each oral fluid test and after contact with oral fluid.
- Do not reuse Specimen Collection Loops, Test Devices or Developer Solution. Dispose of these components properly. Reuse of these components is capable of transmitting infectious agents.
- Do not use the test beyond the expiration date printed on the pouch.

STORAGE

- Store unused OraQuick® HCV Rapid Antibody Test unopened at 2 - 30 °C.
- Do not open the pouch until you are ready to perform a test.
- If stored refrigerated, ensure that the pouch is brought to operating temperature (15 - 37 °C) before opening.

SPECIMEN HANDLING

- Oral Fluid: Ensure prior to testing that the subject has not had anything to eat, drink or has chewed gum for at least 15 minutes. Have the subject wait for at least 30 minutes prior to testing if they have used any oral care products. Collect specimen and place in Developer Solution immediately.
- Whole blood, serum or plasma may be stored at 15 - 30 °C for up to 3 days or at 2 - 8 °C for up to 7 days. Invert the tube several times to mix.
- Serum or plasma: Centrifuge at 1000-1300 x *g* for approximately 5 minutes.
- Serum and plasma specimens stored frozen at -20 °C may have up to 3 freeze-thaw cycles.

DIRECTIONS FOR USE

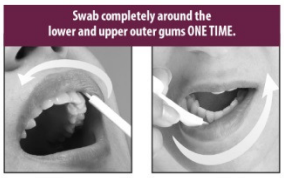
GENERAL TEST PREPARATION

- Allow all components to come to operating temperature (15 - 37 °C).
- Place the Reusable Test Stand on your work space. Use only the stand provided with the OraQuick® HCV Kit.
- Do not open the pouch until you are ready to perform a test. Check the pouch for damage or holes. Discard the pouch if it is damaged.
- After opening the pouch, check for an absorbent packet. If it is not present or appears damaged, discard the pouch and open a new one.
- Hold the OraQuick® HCV Developer Solution vial firmly in your hand. Remove the cap by rocking it back and forth while pulling it off. Set the cap aside. Slide the vial into the top of one of the slots in the Reusable Test Stand.
- **DO NOT** cover the 2 holes on the back of the test with labels or other materials. Blocking the holes may cause an invalid result.
- Adequate lighting is required to read a test result.

1. SPECIMEN COLLECTION

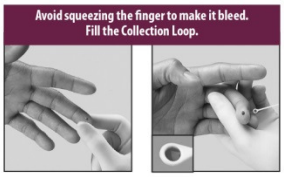
1a. Oral Fluid

- Ensure prior to collection of the oral fluid that the subject has not had anything to eat, drink or has chewed gum for at least 15 minutes. Have the subject wait for at least 30 minutes prior to testing if they have used any oral care products.
- Remove the OraQuick® HCV Rapid Antibody Test from the pouch. DO NOT touch the Flat Pad.
- Swab completely around the lower and upper outer gums **ONE TIME**. DO NOT swab the roof of the mouth, cheeks or tongue.



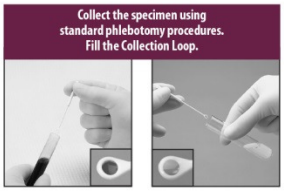
1b. Fingerstick Whole Blood

- Cleanse finger. Air dry.
- Puncture finger with a sterile lancet. Wipe away the first drop of blood with a sterile gauze. Hold the finger downward and apply gentle pressure beside the point of puncture. Avoid squeezing the finger to make it bleed.
- Fill the Specimen Collection Loop. Immediately insert the Loop into the Developer Solution Vial. Mix with the loop. Ensure the blood is thoroughly mixed in the solution. The solution should be a uniform shade of pink.
- If the loop is dropped or contacts any other surface, discard it. Use a new Loop to collect the blood.



1c. Venipuncture Whole Blood

- Collect the specimen using standard phlebotomy procedures into a tube containing EDTA, sodium heparin, lithium heparin, or sodium citrate. Other anticoagulants have not been tested and may cause an incorrect result.
- Mix the blood by inversion. Fill the Specimen Collection Loop. Immediately insert the Loop into the Developer Solution Vial. Mix with the Loop. Ensure the blood is thoroughly mixed in the solution. The solution should be a uniform shade of pink.



1d. Serum or Plasma

- Plasma: Collect the specimen using standard phlebotomy procedures into a tube containing EDTA, sodium heparin, lithium heparin, or sodium citrate. Serum: Collect into SST tube. Other anticoagulants have not been tested and may cause an incorrect result.
- Centrifuge at 1000-1300 x *g* for approximately 5 minutes.
- Fill the Specimen Collection Loop. Immediately insert the Loop into the Developer Solution Vial. Mix with Loop. Ensure the specimen is thoroughly mixed in the solution.

2. RUN TEST

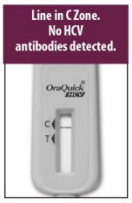
- Insert the Test Device into the Developer Solution Vial within 60 minutes of adding the blood, serum or plasma sample.
- Set the timer for 20 minutes.

TEST RESULT AND INTERPRETATION

Refer to the Result Window on the Test Device.

NON-REACTIVE

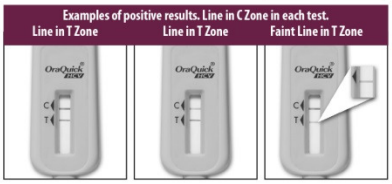
A test is Non-Reactive if a line appears in the C Zone and NO line appears in the T Zone. A Non-Reactive test result means that HCV antibodies were not detected in the specimen. Patient is presumed not to be infected with HCV.



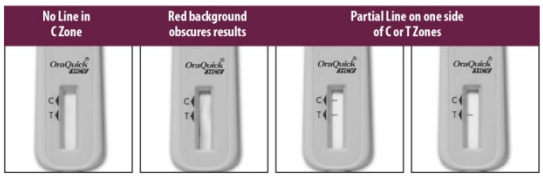
REACTIVE

A test is Reactive if a line appears in the C Zone and a line appears in the T Zone. Lines may vary in intensity. The test is reactive regardless of how faint these lines appear. A Reactive test result means that HCV antibodies have been detected in the specimen. Patient is presumed to be infected with HCV.

Follow appropriate guidelines for supplemental testing. A person who has HCV antibodies is presumed to be infected with the virus. Additional testing and medical evaluation is required to determine the state or associated disease.



INVALID



A test is Invalid if:

An Invalid test result means that there was a problem running the test either related to the specimen or to the Test Device. An Invalid result cannot be interpreted. Repeat the test with a new Pouch and a new specimen. Contact OraSure Technologies' Customer Service if you are unable to get a valid test result upon repeat testing.

GENERAL TEST CLEAN-UP

1. Dispose of the unused test material and gloves in a biohazard waste container.
2. When using gloves, change your gloves between each test to prevent contamination.
3. Use a freshly prepared 10% solution of bleach to clean up any spills.[2]

QUALITY CONTROL

The OraQuick® HCV Rapid Antibody Test has a built-in procedural control. A line in the C Zone after 20 minutes indicates assay validity. External controls are available separately. Run OraQuick® HCV Rapid Antibody Test Kit Controls according to the quality assurance policy of the facility.

LIMITATIONS OF THE TEST

1. The OraQuick® HCV Rapid Antibody Test must be used in accordance with this instructions for use to obtain an accurate result.
2. Reading test results earlier than 20 minutes or later than 40 minutes may yield inaccurate test results.
3. Clinical data has not been collected to demonstrate the performance of the OraQuick® HCV Rapid Antibody Test in individuals under 11 years of age.
4. A reactive result using the OraQuick® HCV Rapid Antibody Test suggests the presence of HCV antibodies in the specimen, and the intensity of the test line does not necessarily correlate with the HCV antibody titer in the specimen. The OraQuick® HCV Rapid Antibody Test is intended as an aid in the diagnosis of HCV infection.
5. A non-reactive result does not exclude the possibility of exposure to HCV or infection with HCV. An antibody response to recent exposure may take several months to reach detectable levels.
6. A person who has HCV antibodies is presumed to be infected with the virus. Additional testing and medical evaluation is required to determine the state or associated disease.

PERFORMANCE CHARACTERISTICS

SENSITIVITY

The sensitivity of OraQuick® HCV Rapid Antibody Test was assessed in symptomatic and/or at-risk individuals determined to be HCV infected. Sensitivity for each of the five specimen matrices was calculated by dividing the number of OraQuick® HCV Rapid Antibody Test reactive results by the total number of specimens tested from HCV infected individuals (N). Results with the 95% confidence intervals (CI) for all five specimen matrices are summarized in the table below.

Specimen	Reactive	Total N	Sensitivity	95% CI
Oral Fluid	739	753	98.1%	96.9-99.0%
Fingerstick WB	752	754	99.7%	99.0-100.0%
Venipuncture WB	753	755	99.7%	99.0-100.0%
Plasma	755	756	99.9%	99.3-100.0%
Serum	756	757	99.9%	99.3-100.0%

SPECIFICITY

Specificity of the OraQuick® HCV Rapid Antibody Test was assessed in symptomatic and/or risk individuals who were determined not to be HCV infected. The percent specificity of the OraQuick® HCV Rapid Antibody Test for each of the five specimen matrices was calculated by dividing the number of OraQuick® HCV Rapid Antibody Test non-reactive result by the total number of specimens tested that were derived from subjects determined not to be HCV infected (N). Results with the 95% confidence intervals (CI) for all five specimen matrices are summarized in the table below.

Specimen	Non-Reactive	Total N	Specificity	95% CI
Oral Fluid	1418	1423	99.6%	99.2-99.9%
Fingerstick WB	1421	1422	99.9%	99.6-100.0%
Venipuncture WB	1421	1423	99.9%	99.5-100.0%
Plasma	1420	1422	99.9%	99.5-100.0%
Serum	1422	1423	99.9%	99.6-100.0%

REACTIVITY WITH HCV SEROCONVERSION PANELS

Thirty panels containing sequential plasma specimens from individuals undergoing seroconversion as a result of HCV infection were evaluated with the OraQuick® HCV Rapid Antibody Test and compared with a CE approved anti-HCV EIA. The sensitivity of the OraQuick® HCV Rapid Antibody Test to detect seroconversion was similar to that of the CE approved EIA. The OraQuick® HCV Rapid Antibody Test detected anti-HCV antibodies to HCV 0.6 days (95% CIs 0.1 to 1.4) before the EIA at the 20-minute read time and the OraQuick® HCV Rapid Antibody Test detected antibodies to HCV 0.9 days (95% CIs 0.03 to 1.8) before the EIA at the 40-minute read time.

REACTIVITY WITH HCV SPECIMENS FROM VARIOUS GENOTYPES AND SUBTYPES

The ability of the OraQuick® HCV Rapid Antibody Test to detect infection derived from various genotypes and subtypes was assessed using two commercially available Worldwide HCV Performance panels. Thirty-two HCV-positive plasma specimens derived from multiple geographies, representing six genotypes and eleven subtypes (1, 1a, 1b, 1a/b, 2, 2a, 2a/c, 3, 3a, 3b, 3a/b, 4, 4a, 4c/d, 4h, 5a, and 6a) were tested. All specimens were reactive with the OraQuick® HCV Rapid Antibody Test. Three HCV-negative samples were included in the panel and all were non-reactive with the OraQuick® HCV Rapid Antibody Test.

MEDICAL CONDITIONS UNRELATED TO HCV INFECTION

The performance of the OraQuick® HCV Rapid Antibody Test was evaluated with commercially available HCV negative plasma and serum specimens derived from twenty-one medical conditions unrelated to HCV infection. Results are summarized in the table below.

Medical Condition	N	Non-Reactive (%)	Reactive (%)
Autoimmune Diseases			
Myasthenia Gravis	4	4(100)	0(0)
Rheumatoid Arthritis	10	10(100)	0(0)
Scleroderma	20	19(95)	1(5)
Sjögren's Syndrome	20	19(95)	1(5)
Systemic Lupus Erythematosus (SLE)	10	10(100)	0(0)
Other Medical Conditions			
Influenza Vaccination	10	10(100)	0(0)
Hepatitis A Virus (HAV)	20	19(95)	1(5)
Hepatitis B Virus (HBV)	20	19(95)	1(5)
Hepatitis D Virus (HDV)	2	2(100)	0(0)
Hepatitis E Virus (HEV)	8	8(100)	0(0)
Human T-Cell Lymphotropic Virus (HTLV I/II)	20	19(95)	1(5)
Epstein-Barr Virus (EBV)	10	10(100)	0(0)
Cytomegalovirus (CMV)	10	10(100)	0(0)
Herpes Simplex Virus (HSV)	10	10(100)	0(0)
Parvovirus B19	10	10(100)	0(0)
Rubella	10	10(100)	0(0)
Syphilis	10	10(100)	0(0)
Toxoplasmosis	10	10(100)	0(0)
Human Immunodeficiency Virus (HIV-1/2)	20	19(95)	1(5)
Heterophilic Antibodies	10	10(100)	0(0)
Multiparous Female	10	10(100)	0(0)
Total Samples Tested	254	248	6

Of the twenty-one unrelated conditions tested, six produced any consistently reactive result with the OraQuick® HCV Rapid Antibody Test that were not due to an HCV co-infection (Scleroderma, Sjögren's Syndrome, Hepatitis A, Hepatitis B, HTLV, and HIV). Each of these unrelated medical conditions produced only a single reactive result in the twenty specimens from patients with that condition. None of the medical conditions tested produced an unacceptably high rate of false positive results in the OraQuick® HCV Rapid Antibody Test device.

INTERFERING SUBSTANCES

The OraQuick® HCV Rapid Antibody Test was evaluated with the following interfering substance. None of these interfering substances had any impact on the OraQuick® HCV Rapid Antibody Test assay performance at the concentrations listed.

Interfering Substances	Concentration
Bilirubin	10 mg/dL
Hemoglobin	500 mg/dL
Lipid (Triolein)	3500 mg/dL
Protein	12 mg/dL

In addition, a study was performed to assess the potential effect of anticoagulants on assay performance. Venipuncture whold blood specimens were collected from 50 HCV negative subjects and tested for eleven (11) conditions that consisted of three (3) sample types: whole blood, plasma, and serum; two (2) tube types: glass and plastic; and four (4) anticoagulant types: EDTA, lithium heparin, sodium citrate, and sodium heparin, as well as serum in SST. Each of the sample types was aliquoted into vials marked positive and negative and then the positive aliquots were spiked with an HCV positive specimen. The aliquoted tubes were then stored either refrigerated (2°-8°C) or at room temperature (30°C ± 3°C). Serum and plasma aliquots were also stored frozen at (-10°C to -20°C) for up to three (3) freeze thaw cycles. There was no anticoagulant-specific effect observed on assay performance with samples held up to 7 days at 2°-8°C, 3 days at 30°C ± 3°C and up to 3 freeze thaw cycles at -10°C to -20°C.

ORAL INTERFERENCE

The OraQuick® HCV Rapid Antibody Test was evaluated with the following interfering substance: Gingivitis, Dentures, Tobacco (Smokeless), Food & Beverage (Standardized Food, Acidic Beverage, Common Beverage, Basic Beverage, Alcoholic Beverage), Oral Care Products (Tooth brushing, mouthwash, tooth whitening), and Medications (Aspirin, Warfarin/Coumadin/Jantoven). None of these interfering substances had any impact on the OraQuick® HCV Rapid Antibody Test assay performance with a wait period of 15 minutes for food and drink and 30 minutes for oral care products.

REPRODUCTIBILITY

The reproducibility of the OraQuick® HCV Rapid Antibody Test was tested at 3 sites using 3 lots of Test Devices on 5 different days with 9 operators (3 per site). A blinded panel was tested that consisted of 3 plasma specimens (1 negative, 1 low positive, and 1 moderate positive). Overall concordance across operators, sites and device lots was 100% (95% CIs 99,5-100%) for the negative specimen, 100% (95% CIs 99,5-100%) for the low positive specimen and 99,9% (95% CIs 99,3-100%) for the moderate positive specimen.

BIBLIOGRAPHY

1. Q-L Choo, A.J. Weiner, L.R. Overby, G. Kuo, M. Houghton, and D.W. Bradley, Hepatitis C Virus: The Major Causative Agent of Viral Non-A, Non-B Hepatitis. British Medical Bulletin. 1990; Vol. 46, No. 2:423-441.
2. L.M. Sehulster, F.B. Hollinger, G.R. Dreesman, and J.L. Melnick, Immunological and Biophysical Alteration of Hepatitis B Virus Antigens by Sodium Hypochlorite Disinfection. Appl. Environ. Microbiol. 1981; 42(5):762-767.

Explanation of Symbols					
	Use by	HCV CONTROL –	Negative HCV Control	TEST	Test Device
REF	Catalog Number	HCV CONTROL +	Positive HCV Control	TESTS	Test Devices
LOT	Batch Code	KIT CTRLS	Kit Controls	TEST STANDS	Test Stands
	Manufacturer	PACK INSERT	Package Insert	IVD	*In Vitro* Diagnostic Medical Device
	Consult Instructions for Use	LOOPS 5µL	5 µL Loops		Temperature Limitation
	Caution, Consult Accompany Documents	ABS PACK	Absorbent Packet		Do Not Reuse
CONTENTS	Contents	DEV SOL VIAL	Developer Solution Vial	EC REP	Authorized Representative in the European Country

CE
0543

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(001) 610.882.1820 • www.orasure.com

EC REP QARAD bvba
Cipalstraat 3
B-2440 GEEL
BELGIUM

Item# 3001-2124 rev. 05/14 ENG

OraQuick® Rapid Antibody Test HCV

ENGLISH

Kit Controls (1001-0278)

This instructions for use 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 test result and has been manufactured to produce a very faint 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.
- Use a freshly prepared 10% solution of bleach to clean up any spills.

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 (HCV 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 (HCV CONTROL +)

The HCV Positive Control will produce a Reactive test result and has been manufactured to produce a very faint reddish-purple line at the Test ("T") area. A reddish-purple line should be present in the Result Window in the area adjacent to the triangle labeled "C" **and** a second reddish-purple 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 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					
ABS PACK	Absorbent Packet	HCV CONTROL –	Negative HCV Control		Temperature Limitation
LOT	Batch Code	HCV CONTROL +	Positive HCV Control		Use by
REF	Catalog Number	KIT CTRLS	Kit Controls		Caution, Consult Accompany Documents
	Consult Instructions for Use		Manufacturer	IVD	*In Vitro* Diagnostic Medical Device
CONTENTS	Contents	PACK INSERT	Package Insert	EC REP	Authorized Representative in the European Country

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