OraQuick® Rapid Antibody Test HCV

ENGLISH

Read the Package Insert 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 assay. 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, if not all, 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 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.

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 0.75 mL phosphate buffered saline solution containing polymers and an antimicrobial agent.
- Reusable test stands
- Collection loops
- Package insert

MATERIALS REQUIRED, AVAILABLE AS AN ACCESSORY TO THE KIT

OraQuick® HCV Rapid Antibody Test Kit Controls

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

WARNINGS

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

- Read the Package Insert 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.
- 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.
- If the test kit is exposed to temperatures outside of the recommended storage temperature (2°-30°C), or is tested outside of the operating temperature (15°-37°C), use the Kit Controls to ensure performance of the test.

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. Test administrators 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, plasma or serum: Insert the test device into the Developer Solution within 60 minutes of adding the sample.
- 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

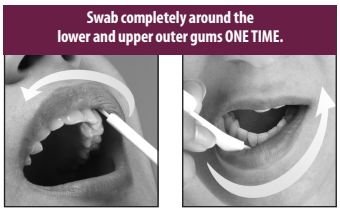
GENERAL TEST PREPARATION

- 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.

1. SAMPLE COLLECTION

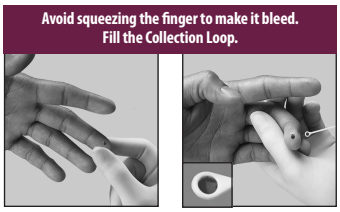
1a. Oral Fluid

- 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.
- 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.
- If the loop is dropped or contacts any other surface, discard it. Use a new Loop to collect the blood.

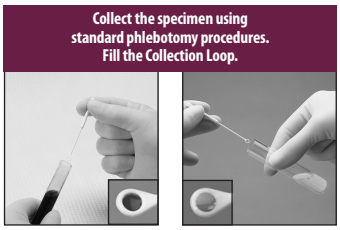


1c. Venipuncture Whole Blood

- 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.

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.



2. RUN TEST

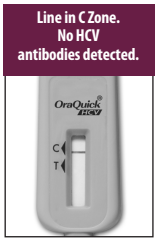
- Insert the Test Device into the Developer Solution Vial.
- Set the timer for 20 to 40 minutes.

TEST RESULT AND INTERPRETATION

Refer to the Result Window on the Test Device.

NON-REACTIVE

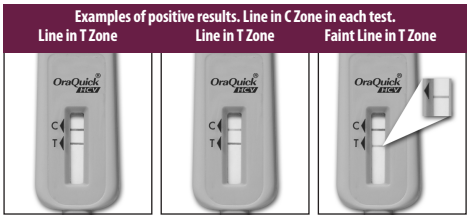
A test is Non-Reactive if a line appears in the C Zone and NO line appears in the T Zone. A Non-Reactive test result means that HCV antibodies were not detected in the specimen. Patient is presumed not to be infected with HCV.



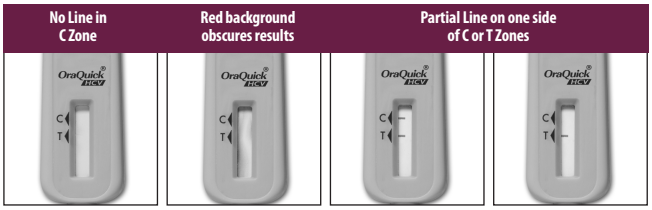
REACTIVE

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.



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 the instructions in this package insert 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 that 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 test. 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 test 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 test 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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EC REP
QARAD bvba
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B-2440 GEEL
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Item# 3001-2124 rev. 05/13 ENG