

**WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT
Product: OraQuick Hepatitis C Self-Test
WHO reference number: PQDx 0244-055-01**

OraQuick Hepatitis C Self-Test Kit with product codes 3001-3217.###, 7X4-2001U.###, 7X4-1000.###, 7X4-1001.###, and 7X4-2001.###, manufactured by OraSure Technologies, Inc., **rest-of-world** regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 10 July 2024.

Summary of WHO Prequalification Assessment for OraQuick HCV Self-Test¹

	Date	Outcome
PQ listing	10 July 2024	listed
Dossier review	N/A	MR
Inspection(s) of the quality management system	10-12 August 2022	MR
Product performance evaluation	24 January 2017	MR

MR: Meets requirements

OraSure Technologies, Inc. submitted a change notification for their prequalified product, OraQuick HCV Rapid Antibody Test Kit, to introduce a new configuration with an intended use specific for HCV self-testing (OraQuick Hepatitis C Self-Test). The new configuration was adapted from the corresponding professional use product (OraQuick HCV Rapid Antibody Test Kit), for which a WHO prequalification assessment has already taken place. Additional data was generated to meet requirements for self-testing as set out in the WHO Technical Specifications Series document TSS-16 Immunoassays to detect HCV antibody and/or antigen².

¹ Dossier assessment and product performance evaluation for the OraQuick Hepatitis C Self-Test were considered from the previous assessment of the professional use product, OraQuick HCV Rapid Antibody Test Kit, which was prequalified in 2017. Based on the product dossier assessment and product performance evaluation, the OraQuick HCV Self-Test meets WHO prequalification requirements. Please refer to the WHO Prequalification of Diagnostics Programme PUBLIC REPORT for OraQuick HCV Rapid Antibody Test Kit at <https://extranet.who.int/prequal/WHOPR/public-report-oraquick-hcv-rapid-antibody-test-kit-pqdx-0244-055-00>

²<https://iris.who.int/bitstream/handle/10665/366073/9789240033757-eng.pdf>

Report amendments and product changes

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which the WHO has been notified and has undertaken a review. Amendments to the report are summarised in the following table, and details of each amendment are provided below.

Version	Summary of the amendments	Date of report amendment
2.0	Changed the wording on the shelf life upon the manufacturer of 18 months to "Device Shelf-life upon manufacture: 18 months. Finished Goods Shelf-life upon packaging completion: 15 months"	8 December 2025

Intended use

According to the intended use purpose from OraSure Technologies, Inc., "*OraQuick Hepatitis C Self-Test is an oral fluid self-test for Hepatitis C. This test works by detecting your body's response to Hepatitis C infection.*"

Test kit contents:

OraQuick Hepatitis C Self-Test (Community Version)	
Product Code 7X4-1000.### - 50 Pouched Kits	Product Code 7X4-1001.### - 250 Pouched Kits
Each pouched kit (3001-3217.####) contains: <ul style="list-style-type: none"> • 1 Divided Pouch (3001-3217) with <ul style="list-style-type: none"> ○ a single-use test device, ○ a preservative and ○ a developer solution vial containing 0.75mL of tris-buffered saline solution containing polymers and an antimicrobial agent • 1 Test Stand, • 1 Instructions for Use 	Each pouched kit (3001-3217.####) contains: <ul style="list-style-type: none"> • 1 Divided Pouch (3001-3217) with <ul style="list-style-type: none"> ○ a single-use test device, ○ a preservative and ○ a developer solution vial containing 0.75mL of tris-buffered saline solution containing polymers and an antimicrobial agent • 1 Test Stand, • 1 Instructions for Use
OraQuick Hepatitis C Self-Test (Pharmacy Version)	
Product Code 7X4-2001.### - 200 Boxed Kits	

Each boxed kit (7X4-2001U.###) contains:

- **1 Divided Pouch** (3001-3217) with
 - a **single-use test device**,
 - a preservative and
 - a developer solution vial containing 0.75mL of tris-buffered saline solution containing polymers and an antimicrobial agent
- **1 Test Stand,**
- **1 Instructions for Use**

Each kit contains the same pouched device configuration as the community version, except the contents are contained in a carton.

OraQuick Hepatitis C Self-Test (Individual Unit Product Code 3001-3217.###)

- **1 Divided Pouch** (3001-3217) with
 - a **single-use test device**,
 - a preservative and
 - a developer solution vial containing 0.75mL of tris-buffered saline solution containing polymers and an antimicrobial agent
- **1 Test Stand,**
- **1 Instructions for Use**

NOTE:

Country-specific variations are documented through a suffix “###” to the product code on the outer packaging (i.e. 3001-3217.###). Therefore, product codes 7X4-2001U.###, 7X4-1000.###, 7X4-1001.###, and 7X4-2001.### are prequalified product codes. The country-specific product code relates to the language of the IFU provided within the product.

Materials required but not provided:

- Clock, watch or timing device.

Storage:

- Store and perform this test in a cool area.
- DO NOT use this test if it has been stored outside the acceptable temperature of 2 to 30 °C (36 °- 86 °F).
- This test should be performed at 15 to 37 °C (59 °- 99 °F).

Shelf-life upon manufacture:

Device Shelf-life upon manufacture: 18 months.

Finished Goods Shelf-life upon packaging completion: 15 months.

Warnings/Limitations

Please refer to the current version of the manufacturer's instructions for use (IFU).

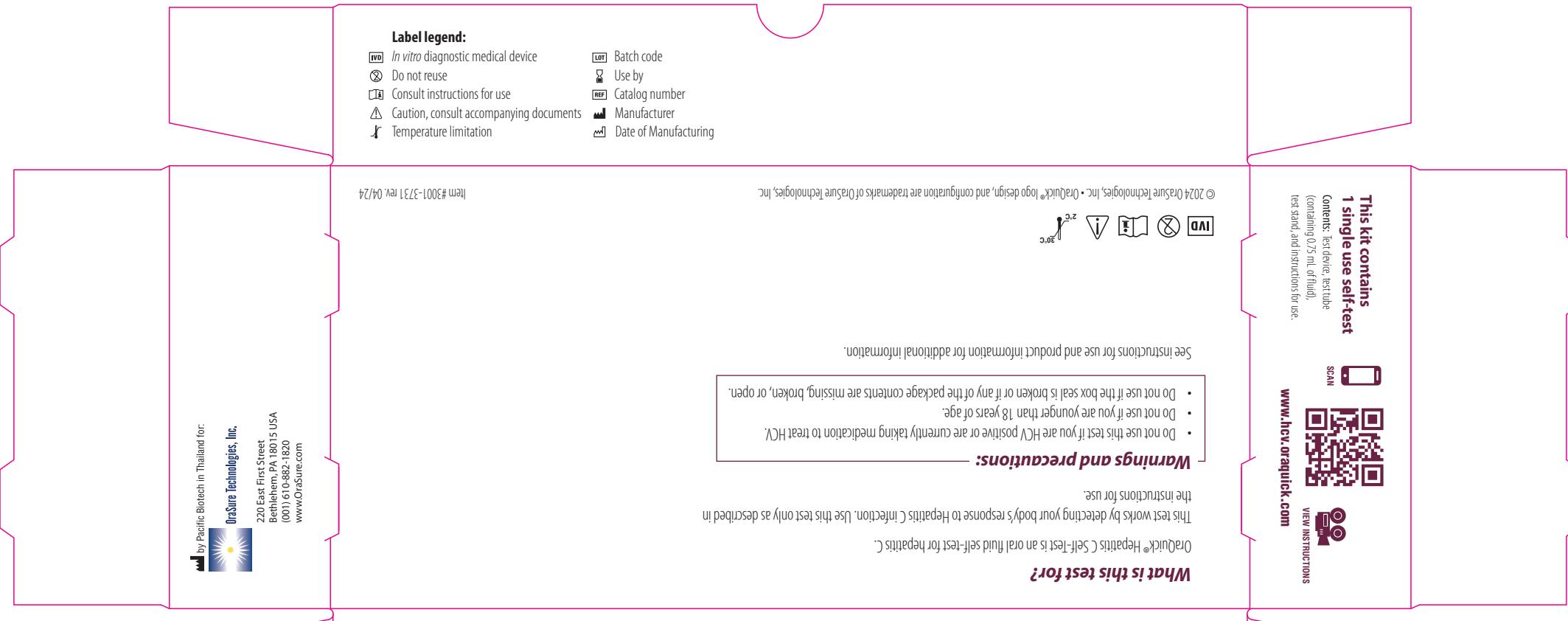
Prequalification assessments:

Dossier assessment, manufacturing site inspection and laboratory evaluation for the OraQuick Hepatitis C Self-Test were adapted from the professional use product, OraQuick HCV Rapid Antibody Test Kit, prequalified in 2017. Please refer to the WHO Prequalification of Diagnostics Programme PUBLIC REPORT for OraQuick HCV Rapid Antibody Test Kit (PQDx 0244-055-00) accessible at <https://extranet.who.int/prequal/WHOPR/public-report-oraquick-hcv-rapid-antibody-test-kit-pqdx-0244-055-00>.

Labelling

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

1.1 Unit Box



1.2 Outer Bag

3" allowance for gripper

8.5"



www.hcv.oraquick.com

ORAQUICK®

HEPATITIS C SELF-TEST

REFER TO TESTING DIRECTIONS INSIDE PACK

CONTENTS:

1 Instructions for Use	1 Developer Vial
1 Test Device	1 Test Stand
1 Preservative	

IVD



30 °C
2 °C

LOT

XXXXX-###



YYYY-MM-DD



YYYY-MM-DD

REF

3001-3217.XXX

by Pacific Biotech in Thailand for:



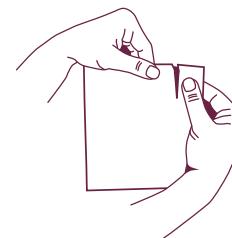
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Item# 3001-3730 rev. 04/24

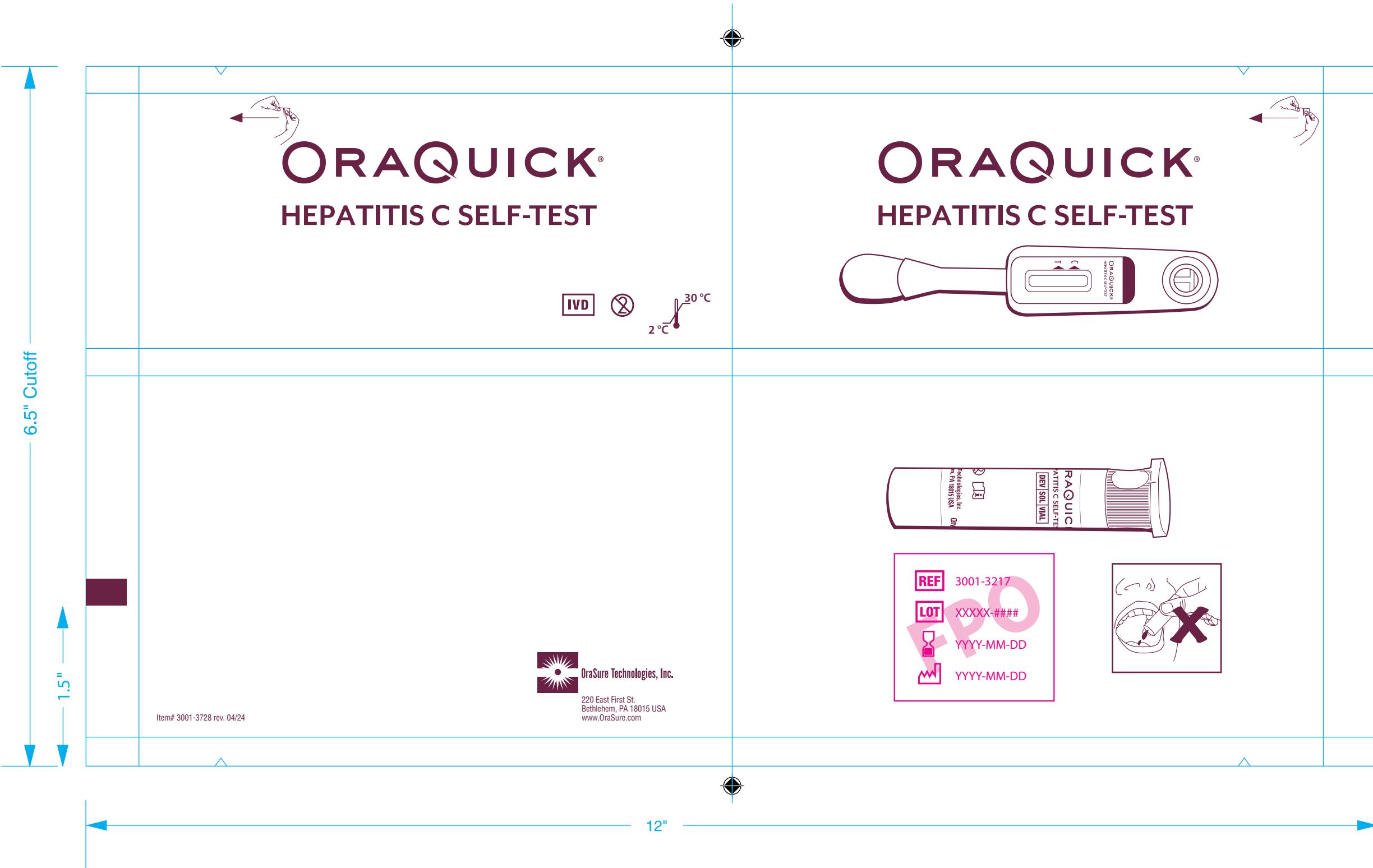


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1.3 Inner Pouch



2.0 Instructions for Use ³

³ English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.



In Vitro Diagnostic Use • Do Not Reuse

INSTRUCTIONS FOR USE

OraQuick® Hepatitis C Self-Test is an oral fluid self-test for hepatitis C. This test works by detecting your body's response to Hepatitis C infection.

You must follow the test directions carefully to get an accurate result.Do not eat or drink for at least 15 minutes before you start the test. Do not use mouth cleaning products for at least 30 minutes before you start the test. **WARNING:** Do not use this test if you have Hepatitis C or taking medication to treat Hepatitis C.VIEW INSTRUCTIONS
www.hcv.oraquick.com

HOW TO USE THE ORAQUICK® HEPATITIS C SELF-TEST KIT



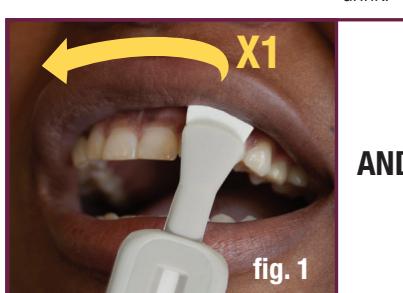
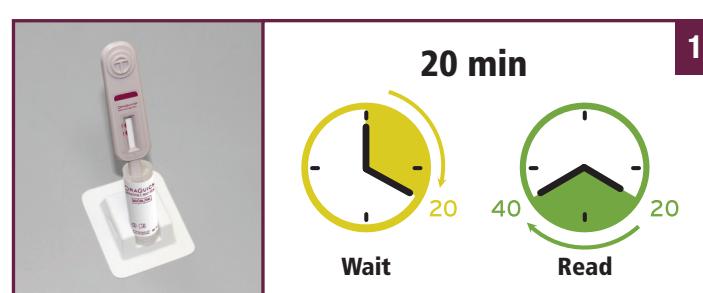
YOU WILL NEED A WAY TO TIME THE TEST

Kit contains: **test kit, test stand, and instructions for use.** Remove these items to begin testing.

Your test kit contains two pouches.

Tear open the pouch containing the **tube**.

Remove the cap.

The liquid in the tube is used in this test. Leave the liquid in the tube. **DO NOT** pour out the liquid. **DO NOT** drink.Slide the tube into the **stand**.Tear open pouch containing the **test device** and remove. **DO NOT** touch the flat pad with your fingers. **DO NOT** eat or swallow the preservative.Press the **Flat Pad** firmly against your gum and swab it along your **upper gum once** (fig. 1) and **your lower gum once** (fig. 2).Put the **flat pad** all the way into the tube until it touches the bottom.LEAVE IT THERE for 20 MINUTES before reading the results. **DO NOT** read the result after 40 minutes. You can read this test after 20 minutes but before 40 minutes.

INTERPRETING RESULTS Read test results in a well-lit area

HEPATITIS C POSITIVE RESULT

TWO COMPLETE LINES, even if the line is faint, means you may be Hepatitis C **POSITIVE**. A positive test means you have a current or past Hepatitis C infection and you need to seek confirmation testing.

98.7% of people (74/75) correctly reported their result as positive. This means that 1 out of 75 people with a past or current infection with HCV reported a negative test result. This is called a false negative.

**As soon as possible...**
Visit a nearby Healthcare Provider or Testing Facility.**fig. 1**
If there is no line next to the "C" (even when there is a line next to the "T"), the test line or control line are not complete (all the way across the window), or a red background makes it impossible to read the test, the test is not working and should be repeated.**You will need to obtain another test.**

0.9% of study subjects (9 out of 1,015) failed to obtain a test result.

HEPATITIS C NEGATIVE RESULT

IF READ BEFORE 20 MINUTES, RESULT MAY NOT BE CORRECT

ONE LINE next to the "C" and NO line next to the "T", your result is Hepatitis C **NEGATIVE**.

99.8% of people (927/929) correctly reported their result as negative. This means that 2 out of 929 people not infected with HCV reported a positive test result. This is called a false positive.

It may take several months from exposure for the test to detect your body's response to Hepatitis C infection. Consider following up with a nearby Healthcare Provider or Testing Facility if your test result is negative.

INVALID RESULT



If there is no line next to the "C" (even when there is a line next to the "T"), the test line or control line are not complete (all the way across the window), or a red background makes it impossible to read the test, the test is not working and should be repeated.

You will need to obtain another test.

0.9% of study subjects (9 out of 1,015) failed to obtain a test result.



The test did not work properly. Visit a nearby Healthcare Provider or Testing Facility to test again.

NOT SURE OF RESULT

If you do not understand your result or if you are unsure of what your result is, visit your nearest Healthcare Provider or Testing Facility.

DISPOSE

Remove the test stick, put the cap on the test tube and throw away all contents in the normal trash.



REF # 3001-3217, 7X4-1000, 7X4-1001, 7X4-2001

INTENDED USE

OraQuick® Hepatitis C Self-Test is an oral fluid self-test for Hepatitis C. This test works by detecting your body's response to Hepatitis C infection.

PRINCIPLES OF THE PROCEDURE

The OraQuick® Hepatitis C Self-Test is a single use qualitative immunoassay to detect antibodies to Hepatitis C virus in oral fluid. The OraQuick® Hepatitis C Self-Test is intended for use by lay users as a self-test to aid in the diagnosis of infection with Hepatitis C virus. The device is placed into the mouth, so that the flat pad is between the cheek and the outer gums, then swabbed across the outer gum line. The device is then placed into a tube containing a premeasured amount of solution. Fluid from the surface of the gums enters the device through the flat pad, then flows onto a test strip. As it flows across the strip, a colored line forms in the 'T' (test) area of the result window if Hepatitis C antibodies are detected. If no Hepatitis C antibodies are detected, no line forms there. If the test is performed correctly, a line forms in the 'C' area of the result window. This is called the control line.

KIT CONTENTS

One pouched device containing:

- Divided Pouch (3001-3217) with single use Test Device, Preservative and a Developer Solution Vial
- Test Stand
- Instructions for Use

Materials required, but not provided:

- Clock, watch or timing device

STORAGE AND OPERATING CONDITIONS

30°C • **DO NOT** use this test if it has been stored outside the acceptable temperatures of 2°-30°C (36°-86°F).

This test should be performed at temperatures in the range of 15°-37°C (59°-99°F).

WARNINGS AND PRECAUTIONS

- DO NOT** use the test if you know you are Hepatitis C positive or are taking medication to treat Hepatitis C.
- Use with oral fluid only. The test is not for use with blood, serum, breast milk, plasma, semen, urine, vaginal fluid or sweat.
- DO NOT** use the test if it has been exposed to household cleaning products (i.e. bleach).
- DO NOT** use if any of the package contents are missing, broken, or open.

- DO NOT** use this test if it has been stored outside the acceptable temperatures of 2°-30°C.
- DO NOT** use mouth cleaning products (such as mouthwash) for at least 30 minutes before you start the test.

- Remove dental products, such as dentures, or any other products that cover your gums prior to the oral fluid collection.
- If today is after the 'Use By' date on the outside of the pouch, do not use this test.
- DO NOT** open any of the pouches until you are ready to begin your test.
- You should not use this test if you are age 17 or younger.
- Individuals must have adequate lighting to read a test result.
- Visual aids, such as eyeglasses or contact lenses, are required for individuals who are visually impaired.

LIMITATIONS OF THE TEST

- The OraQuick® Hepatitis C Self-Test kit Instructions for Use must be followed carefully to get an accurate result.
- If you are taking medication to treat Hepatitis C, you may get a false result.
- A negative test does not exclude the possibility of infection with Hepatitis C. It may take several months from exposure for the test to detect your body's response to Hepatitis C infection.
- For a positive result, the intensity of the test line does not necessarily equal the amount of antibody in the specimen.
- Positive results should be verified using another test performed by a trained professional to confirm a Hepatitis C diagnosis.
- This product has not been evaluated for use in self-testing individuals younger than 18 years of age. You should not use this test if you are age 17 or younger.

INTERFERING SUBSTANCES

The following endogenous substances may produce false results with this test:

- HAMA
- Rheumatoid factor
- Multiple blood transfusions
- Sickle-cell disease
- Pregnant women (multiparous)
- Systemic lupus erythematosus ANA

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TEST PERFORMANCE

In a clinical study, 1,015 people who were unaware of their Hepatitis C status were given the OraQuick® Hepatitis C Self-Test to use. The results were compared to the OraQuick® Rapid HCV Antibody Test for professional use and to a blood-based laboratory EIA. Two (2) participants were excluded from the analysis and 0.9% (9 of 1,015) failed to obtain a test result and were also excluded from the analysis.

The table below summarizes the results from the clinical study:

	OraQuick Self-Test vs OraQuick Professional	OraQuick Self-Test vs Laboratory EIA*
Sensitivity	98.7% (74/75)	85.1% (74/87)
Specificity	99.8% (927/929)	99.8% (917/919)
Failed to obtain a result	0.9% (9/1,015)	0.9% (9/1,015)

*Of the 13 OraQuick Hepatitis C Self-Test false negative results, 10 had an EIA s/co less than 10. Confirmatory testing of the OraQuick Hepatitis C Self-Test false negative results was not performed.

If you have any questions or concerns about the OraQuick® Hepatitis C Self-Test, please contact a nearby Healthcare Provider or Testing Facility.

EXPLANATION OF SYMBOLS

LOT	Batch Code		Caution, Consult Accompanying Documents
	Do Not Reuse		Manufacturer
	Temperature Limitation		Consult Instructions for Use
REF	Catalog Number		Date of Expiration
IVD	In Vitro Diagnostic Medical Device		Date of Manufacturing
	Use By		

 by Pacific Biotech in Thailand for:
OraSure Technologies, Inc.

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