TruQuick™ HCV 40T

A rapid test for the qualitative detection of antibodies to Hepatitis C Virus in serum or plasma.

REF **TQ5040** IVD **Rx Only**

INTENDED USE
TruQuick HCV is a rapid chromatographic immunoassay for the qualitative detection of antibody to Hepatitis C Virus in serum or plasma.

SUMMARY AND EXPLANATION OF THE TEST
Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA virus. HCV is now known to be the major cause of parenterally transmitted non-A, non-B hepatitis. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis.

Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens.[1, 2] Compared to the first generation HCV EIAs using single recombinant antigen, multiple antigens using recombinant protein and/or synthetic peptides have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests.[3, 4]

TruQuick HCV is a rapid test to qualitatively detect the presence of antibody to HCV in a serum or plasma specimen. The test utilizes colloid gold conjugate and recombinant HCV proteins to selectively detect antibody to HCV in serum or plasma. The recombinant HCV proteins used in the test kit are encoded by the genes for both structural (nucleocapsid) and non-structural proteins.

BIOLOGICAL PRINCIPLES
TruQuick HCV is a qualitative, membrane based immunoassay for the detection of antibody to HCV in serum or plasma. The membrane is precoated with recombinant HCV antigen on the test line region of the Cassette. During testing, the serum or plasma specimen reacts with recombinant HCV antigen conjugated colloid gold. The mixture migrates upward on the membrane chromatographically by capillary action to react with recombinant HCV antigen on the membrane and generate a colored line. Presence of this colored line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS/MATERIALS PROVIDED
The maximum number of tests obtained from this test kit is listed on the outer box.
- Test Cassettes: The Test Cassette contains recombinant HCV antigen-conjugated colloid gold and HCV antigen coated on the membrane.
- Buffer: A buffered solution containing Proclin 300 as a preservative. The Buffer is supplied in a dropper vial ready for use.
- Droppers
- Package insert

MATERIALS NOT PROVIDED
- Specimen collection containers
- Timer
- Centrifuge (for plasma only)

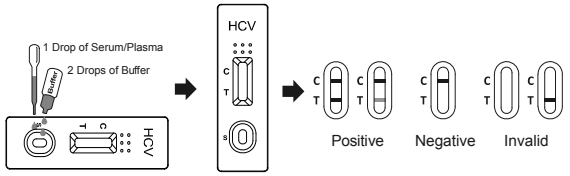
PRECAUTIONS
1. All reagent are for in vitro diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Humidity and temperature can adversely affect results.

HAZARD and PRECAUTIONARY STATEMENTS
Refer to the SDS, available at www.meridianbioscience.com for Hazard and Precautionary Statements.

SHELF LIFE AND STORAGE
The kit can be stored at room temperature or refrigerated (2-30 C). The Test Cassette is stable through the expiration date printed on the sealed pouch. The Test Cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION
1. TruQuick HCV can be performed using serum or plasma.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 C for up to three days. For long term storage, specimens should be kept at - 20 C.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

TEST PROCEDURE
Allow Test Cassette, specimen, Buffer and/or controls to equilibrate to room temperature (15-30 C) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the Test Cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the cassette on a clean and level surface.
3. Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 25 µL) to the specimen area, then **add 2 drops of Buffer** (approximately 80 µL),and start the timer. See illustration below.
4. Wait for the colored line(s) to appear. The test result should be read at **10 minutes**. Do not interpret the result after **20 minutes**.



INTERPRETATION OF RESULTS
(Please refer to the illustration above.)
POSITIVE:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).
***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of HCV antibodies present in the specimen. Therefore, any shade of red in the test region should be considered positive.
NEGATIVE: One color line appears in the control region (C). No red or pink line appears in the test region (T).
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new Test Cassette. If the problem persists, discontinue using the test kit immediately and contact Meridian's Technical Services Department at 800-343-3858 or your local distributor.

QUALITY CONTROL
This test should be performed per applicable local, state, or federal regulations or accrediting agencies.
Internal procedural controls are included in the test. A color line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

External controls are not supplied with this kit; however, it is recommended that positive and negative external controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

If the expected control reactions are not observed, repeat the control tests as the first step in determining the root cause of the failure. If control failures are repeated please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.

EXPECTED VALUES
TruQuick HCV has been compared with a leading commercial HCV EIA test. The correlation between these two systems is 99.0%.

LIMITATIONS OF THE PROCEDURE
1. TruQuick HCV is for in vitro diagnostic use only. This test should be used for the detection of antibodies to HCV in serum or plasma specimen.
2. TruQuick HCV will only indicate the presence of antibodies to HCV in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis C viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of Hepatitis C Virus infection.

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity and Specificity
The recombinant antigen used for TruQuick HCV is encoded by genes for both structural (nucleocapsid) and non-structural proteins. TruQuick HCV as passed a seroconversion panel and compared with a leading commercial HCV EIA test using clinical specimens.

The results show that the relative sensitivity of TruQuick HCV is 98.7%, and the relative specificity is 99.1%.

Method		EIA		Total Result
	Results	Positive	Negative	
TruQuick HCV	Positive	235	6	241
	Negative	3	692	695
Total Result		238	698	936

Sensitivity: 98.7% (95% CI:*96.4%-99.7%)
Specificity: 99.1% (95% CI:*98.1%-99.7%)
Correlation: 99.0% (95% CI:*98.2%-99.6%) *Confidence Intervals

REPRODUCIBILITY
Intra-Assay Precision
Within-run precision was determined by using 20 replicates of three specimens: a negative, a HCV low titer positive and a HCV high titer positive. The negative, HCV low titer positive and HCV high titer positive values were correctly identified 100% of the time.
Inter-Assay Precision
Between-run precision was determined by 20 independent assays on the same three specimens: a negative, a HCV low titer positive and a HCV high titer positive. Three different lots of TruQuick HCV were tested. The specimens were correctly identified 100% of the time.

CROSSREACTIVITY
TruQuick HCV was tested with patient samples containing IgM to the following: HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-Syphilis, anti-HIV, anti-*H. pylori*, Mononucleosis, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive specimens. The samples showed no crossreactivity.

TESTS FOR INTERFERING SUBSTANCES
The following potentially interfering substances were added to HCV negative and positive specimens.

Acetaminophen 20 mg/dL	Caffeine 20 mg/dL
Acetylsalicylic Acid 20 mg/dL	Gentisic Acid 20 mg/dL
Ascorbic Acid 2 g/dL	Albumin 2 g/dL
Creatine 200 mg/dL	Hemoglobin 1000 mg/dL
Bilirubin 1 g/dL	Oxalic Acid 60 mg/dL

None of the substances at the concentration tested interfered in the assay.

REFERENCES

1. Choo QL, Kuo G, Weiner AJ, Overby LR, Bradley DW, Houghton M.. Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome. Science. 1989;244:359.
2. Kuo G, Choo QL, Alter HJ, Houghton M. An assay for circulating antibodies to a major etiologic virus of human non-A, non-B hepatitis. Science. 1989;44:362.
3. van der Poel CL, Cuypers HTM, Reesink HW, Lelie PN. Confirmation of hepatitis C virus infection by new four-antigen recombinant immunoblot assay. Lancet. 1991;337:317.
4. Wilber JC. Development and use of laboratory tests for hepatitis C infection: a review. J Clin Immunoassay. 1993;16:204.

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SYMBOL USAGE
You may see one or more of these symbols on the labeling/packaging of this product:
Key guide to symbols

	Use By	CONTROL +	Positive control
LOT	Batch Code	CONTROL −	Negative control
IVD	In vitro diagnostic medical device	EC REP	Authorized Representative in the European Community
CE	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices	SMP PREP DIL SPE	Sample Preparation Apparatus containing Sample Diluent
REF	Catalogue number		Do not freeze
	Consult Instructions for Use	BUF RXN	Reaction Buffer
	Manufacturer		For IVD Performance Evaluation Only
Σ	Contains sufficient for <n> tests	SOLN STOP	Stopping Solution
	Temperature limitation	CONJ ENZ	Enzyme Conjugate
SN	Serial number	CONTROL	Assay Control
TEST	Test Device	REAG	Reagent
	Date of manufacture	BUF WASH	Wash Buffer
BUF	Buffer		Warning
CONJ	Conjugate	DIL SPE	Specimen Diluent (or Sample Diluent)
SUBS	Substrate	BUF WASH 20X	Wash Buffer Concentration: 20X
RUO	Research Use Only	DET REAG	Detection Reagent
IUO	Investigational Use Only	R_x Only	Prescription Use Only
	Do not use if package is damaged		

For technical assistance, call Technical Support Services at 800-343-3858 between the hours of 8AM and 6PM, USA Eastern Standard Time. To place an order, call Customer Service Department at 800-543-1980.