# TruQuick™ HBsAg /HCV Combo 25T

**A rapid test for the qualitative detection of Hepatitis B surface antigen (HBsAg) and antibodies to Hepatitis C Virus in serum or plasma.**

REF **TQ5425** IVD **Rx Only**

## INTENDED USE
TruQuick HBsAg/HCV Combo is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B surface antigen (HBsAg) and antibodies to Hepatitis C Virus in serum or plasma.

## SUMMARY AND EXPLANATION OF THE TEST
TruQuick HBsAg is a rapid test to qualitatively detect the presence of HBsAg in serum or plasma specimen. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in serum or plasma.

Viral hepatitis is a systemic disease primarily involving the liver. Most cases of acute viral hepatitis are caused by Hepatitis A virus, Hepatitis B virus (HBV) or Hepatitis C virus. The complex antigen found on the surface of HBV is called HBsAg. Previous designations included the Australia or Au antigen.[1] The presence of HBsAg in serum or plasma is an indication of an active Hepatitis B infection, either acute or chronic. In a typical Hepatitis B infection, HBsAg will be detected two to four weeks before the ALT level becomes abnormal and three to five weeks before symptoms or jaundice develop. HBsAg has four principal subtypes: adw, ayw, adr and ayr. Because of antigenic heterogeneity of the determinant, there are 10 major serotypes of Hepatitis B virus.

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.

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.[2, 3] 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.[4,5]

## BIOLOGICAL PRINCIPLES
TruQuick HBsAg is a qualitative, solid phase, two-site sandwich immunoassay for the detection of HBsAg in serum or plasma. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the cassette. During testing, the serum or plasma specimen reacts with the particle coated with anti-HBsAg antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-HBsAg antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

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
- Test Cassettes: The Test Cassette contains anti-HBsAg conjugated particles, anti-HBsAg coated on the membrane and recombinant HCV antigen conjugated particles, 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
- Centrifuge (for plasma only)
- Timer

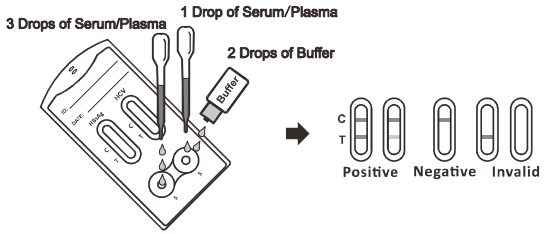
## PRECAUTIONS
1. For in vitro diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout 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.

## 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 HBsAg/HCV Combo can be performed using either 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. Specimens may be stored at 2-8 C for up to three days. For long term storage, specimens should be kept below -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 Test Cassette on a clean and level surface.
   **For TruQuick HBsAg**
   - Place the test device on a clean and level surface. Hold the dropper vertically and transfer **3 drops of serum or plasma specimen (approximately 75 µL)** into the sample well of the Test Cassette, then start the timer immediately. See the illustration below.

   **For TruQuick HCV**
   - Place the test device on a clean and level surface. Hold the dropper vertically and transfer **1 drop of serum or plasma (approx. 25 µL)** into the sample well of the Test Cassette then add 2 drops of Buffer **(approx. 80 µL)** and start the timer immediately. See the illustration below.
3. 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**.




## INTREPRETATION 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 HBsAg antigen and/or HCV antibodies present in the specimen. Therefore, any shade of red in the test region should be considered positive.
**NEGATIVE**: One colored 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
Internal procedural controls are included in the test. A colored 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 HBsAg/HCV Combo was compared with a leading commercial EIA test, respectively. The correlation between these two systems is 99%.

## LIMITATIONS OF THE PROCEDURE
1. This test is for in vitro diagnostic use only.
2. This test has been developed for testing serum /plasma specimens only. The performance of the test using other specimens has not been substantiated.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of HBsAg or HCV antibody,
4. TruQuick HBsAg cannot detect less than 1 PEI ng/mL of HBsAg in specimens.
5. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
6. 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 HBsAg and/or Hepatitis C Virus.

## SPECIFIC PERFORMANCE CHARACTERISTICS
**Sensitivity and Specificity**

**1. HBsAg**

TruQuick HBsAg was tested with a sensitivity panel ranging from 0 to 300 ng/mL. All 10 HBsAg subtypes produced positive results on TruQuick HBsAg. The test can detect 1 PEI ng/mL of HBsAg in serum/plasma.

Antibodies used for TruQuick HBsAg were developed against whole Hepatitis B antigen isolated from Hepatitis B virus. Specificity of TruQuick HBsAg was also tested with laboratory strains of Hepatitis A and Hepatitis C. They all yielded negative results.

| Method | | EIA | | Total Results |
|---|---|---|---|---|
| TruQuick HBsAg | Results | Positive | Negative | |
| | Positive | 241 | 2 | 243 |
| | Negative | 0 | 359 | 359 |
| Total Results | | 241 | 361 | 602 |

Sensitivity: > 99.9% (95% CI:*98.8%-100%)
Specificity: 99.4% (95% CI:*98.0%-100%)
Correlation: 99.7% (95% CI:*98.8%-100%) *Confidence Intervals

**2. HCV**

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

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

| Method | | EIA | | Total Results |
|---|---|---|---|---|
| TruQuick HCV | Results | Positive | Negative | |
| | 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 four different specimens containing negative, HBsAg low positive, HBsAG middle positive, HBsAg high positive, HCV low positive, HCV middle positive, HCV high positive at different concentrations. The negative, positive values were correctly identified 100% of the time.
**Inter-Assay Precisio2**
Between-run precision was determined by 20 independent assays on the same four different specimens containing negative, HBsAg low positive, HBsAg middle positive, HBsAg high positive, HCV low positive, HCV middle positive and HCV high positive samples . Three different lots of the TruQuick HBsAg/HCV Combo were tested over a three month period using above negative and positive specimens. The specimens were correctly identified 100% of the time.

## CROSSREACTIVITY
TruQuick HBsAg/HCV Combo was tested by HIV, Syphilis, HAMA, RF, HAV, *H. pylori*, HCV, HEV, Mononucleosis, CMV, Rubella, and Toxoplasmosis positive specimens. The results showed no crossreactivity.

TruQuick HCV was tested by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, Syphilis, HIV, *H. pylori*, Mononucleosis, CMV, Rubella and Toxoplasmosis positive specimens. The results showed no crossreactivity.

## TESTS FOR INTERFERING SUBSTANCES
TruQuick HBsAg/HCV Combo was tested with the following potentially interfering substances :

| | |
|---|---|
| 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 interfered in the assay at the concentration tested.

**REFERENCES**


1. Blumberg BS. The discovery of Australian antigen and its relation to viral hepatitis. Vitro. 1971;7:223.
2. 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.
3. 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;244:362.
4. van der Poel C L, Cuypers HTM, Reesink HW, Lelie PN.Confirmation of hepatitis C virus infection by new four-antigen recombinant immunoblot assay. Lance.t 1991;337:317.
5. Wilber JC. Development and use of laboratory tests for hepatitis C infection: a review. J Clin Immunoassay. 1993;16:204.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Manufactured By

Meridian Bioscience, Inc.
Corporate Office
3471 River Hills Drive
Cincinnati, Ohio 45244 USA
Telephone: 513.271.3700
Orders/Customer Service:
800.543.1980
Technical Support Center:
800.343.3858
Information Fax: 513.272.5432
Ordering Fax: 513.271.0124


**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. 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.