TruQuick™ HBV Combo 25T

A rapid test for the qualitative detection of Hepatitis B Surface Antigen (HBsAg), Hepatitis B Surface Antibody (HBsAb), Hepatitis B Envelope Antigen (HBeAg), Hepatitis B Envelope Antibody (HBeAb), and Hepatitis Core Antibody (HBcAb) in serum or plasma.

REF **TQ5325** IVD **Rx Only**

INTENDED USE
TruQuick HBV Combo is a rapid chromatographic immunoassay for the qualitative detection of HBsAg, HBsAb, HBeAg, HBeAb and HBcAb in serum or plasma. The results of this test should be considered with other tests and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST
Chronic hepatitis B is a serious, debilitating illness that can cause cirrhosis of the liver, liver cancer and death. Chronic hepatitis B is the main cause of liver cancer and the tenth leading cause of death worldwide, with 400,000,000 people infected with the virus. Every year, one million people worldwide are expected to die from this infection. Most people fight off the infection themselves, but approximately 5-10 percent of those infected with the virus become carriers, and an additional 5-10 percent of those infected each year will progress to chronic liver disease, cirrhosis and possibly liver cancer.

TruQuick HBV Combo is a rapid qualitative test to detect the presence of HBsAg, HBsAb, HBeAg, HBeAb and HBcAb in serum or plasma without the use of an instrument.[1]

BIOLOGICAL PRINCIPLES
HBsAg and HBeAg
HBsAg and HBeAg tests are qualitative, two-site sandwich immunoassays for the detection of HBsAg or HBeAg in serum or plasma. The membrane is precoated with anti-HBsAg or anti-HBeAg antibodies on the test line region of the strip. During testing, the serum or plasma specimen reacts with particles coated with anti-HBsAg or anti-HBeAg antibodies.[2] The mixture migrates along the membrane by capillary action to react with anti-HBsAg or anti-HBeAg antibodies on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result.

HBsAb
Hepatitis B surface Antibody (HBsAb) is also known as anti-Hepatitis B surface Antigen (anti-HBs). This test is a qualitative, lateral flow immunoassay for the detection of HBsAb in serum or plasma. The membrane is precoated with HBsAg on the test line region of the strip. During testing, the serum or plasma specimen reacts with particles coated with HBsAg. The mixture migrates along the membrane by capillary action to react with HBsAg on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result.

HBeAb and HBcAb
Hepatitis B envelope Antibody (HBeAb) is also known as anti-Hepatitis B envelope Antigen (anti-HBe). Hepatitis B core Antibody (HBcAb) is also known as anti-Hepatitis B core Antigen (anti-HBc). These tests are immunoassays based on the principle of competitive binding.

During testing, the mixture migrates along the membrane by capillary action. The membrane is precoated with HBeAg or HBcAg on the test line region of the strip. During testing, anti-HBe antibody or anti-HBc antibody, if present in the specimen, will compete with particles coated anti-HBe antibody or anti-HBc antibody for limited amount of HBeAg or HBcAg on the membrane, and no line will form in the test line region, indicating a positive result. A visible colored line will form in the test line region if there is no anti-HBe antibody or anti-HBc antibody in the specimen because all the antibody coated particles will be captured by the antigen coated in the test line region.

To serve as a procedural control, a colored line will always appear in the control line region of each strip 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: Each Test Cassette contains five test strips. Depending on the test each strip is coated with specific antibody-coated particles and specific antibodies at the test line.
- Droppers
- Package insert

MATERIALS NOT PROVIDED
- Specimen collection containers
- Centrifuge
- Timer

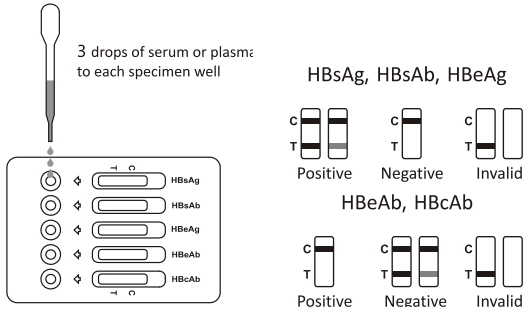
PRECAUTIONS
Please read all the information in this package insert before performing the test.
1. All reagents are for in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Hand all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing 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 being tested.
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
Store as packaged at room temperature or refrigerated (2-30 C). The Test Cassette is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION
1. TruQuick HBV Combo can be performed using either serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, nonhemolyzed specimens.
3. Testing should be performed immediately after specimen collection. 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 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 covering the transportation of etiologic agents.

TEST PROCEDURE
Allow the test, specimen and/or controls to reach room temperature (15-30 C) prior to testing.
1. Remove the Test Cassette from the sealed foil 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 clean and level surface. Hold the dropper vertically and transfer 3 full drops of serum or plasma (approx.75 µL) to each sample well of the Test Cassette respectively, then start the timer. Avoid trapping air bubbles in the specimen well. See the illustration below.
3. Wait for the red line to appear. The result should be read at 15 minutes. Do not interpret the results after 20 minutes.



INTERPRETATION OF RESULTS
(Please refer to the illustration above.)
Warning: Do not interpret all five tests with the same criterion. Carefully follow the directions below.
HBsAg, HBsAb, HBeAg
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, HBsAb, or HBeAg present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.
NEGATIVE: One colored line appears in the control region (C). No apparent colored 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.
HBeAb, HBcAb
NEGATIVE:* 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) may vary. But it should be considered negative whenever there is even a faint pink line.
Positive: One colored line appears in the control region (C). No apparent colored 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.
A procedural control is included in the test. A red line appearing in the control line region (C) is the internal 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 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.

LIMITATIONS OF THE PROCEDURE
1. TruQuick HBV Combo is for in vitro diagnostic use only. The test should be used for the detection of HBsAg, HBsAb, HBeAg, HBeAb and HBcAb in serum or plasma specimens. Neither the quantitative value nor the rate of HBsAg, HBsAb, HBeAg, HBeAb, HBcAb concentration can be determined by this qualitative test.
2. TruQuick HBV Combo will only indicate the presence of HBsAg, HBsAb, HBeAg, HBeAb and HBcAb in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity and Specificity
TruQuick HBV Combo was compared with leading commercial EIA/RIA HBsAg, HBsAb, HBeAg, HBeAb, HBcAb tests. The results show that TruQuick HBV Combo has a high sensitivity and specificity.

HBsAg

Method		EIA		Total Results
TruQuick HBsAg Component	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

HBsAb

Method		RIA		Total Results
TruQuick HBsAb Component	Results	Positive	Negative	
	Positive	194	9	203
	Negative	7	391	398
Total Results		201	400	601

Sensitivity: 96.5% (95% CI*: 93.0%-98.6%)
Specificity: 97.8% (95% CI*: 95.89%-99.0%)
Correlation: 97.3% (95% CI*: 95.7%-98.5%) *Confidence Intervals

HBeAg

Method		RIA		Total Results
TruQuick HBeAg Component	Results	Positive	Negative	
	Positive	154	9	163
	Negative	6	429	435
Total Results		160	438	598

Sensitivity: 96.3% (95% CI*: 92.1%-98.6%)
Specificity: 97.9% (95% CI*: 96.1%-99.1%)
Correlation: 97.5% (95% CI*: 95.9%-98.6%) *Confidence Intervals

HBeAb

Method		EIA		Total Results
TruQuick HBeAb Component	Results	Positive	Negative	
	Positive	146	7	153
	Negative	4	329	333
Total Results		150	336	486

Sensitivity: 97.3% (95% CI*: 93.3%-99.3%)
Specificity: 97.9% (95% CI*: 95.8%-99.2%)
Correlation: 97.7% (95% CI*: 96.0%-98.9%) *Confidence Intervals

HBcAb

Method		EIA		Total Results
TruQuick HBcAb Component	Results	Positive	Negative	
	Positive	358	4	362
	Negative	8	167	175
Total Results		366	171	537

Sensitivity: 97.8% (95% CI*: 95.7%-99.1%)
Specificity: 97.7% (95% CI*: 94.1%-99.4%)
Accuracy: 97.8% (95% CI*: 96.1%-98.8%) *Confidence Intervals

REPRODUCIBILITY
Intra-Assay Precision
Within-run precision was determined by using 15 replicates of three specimens for each analyte (HBsAg, HBsAb, HBeAg, HBeAb, HBcAb) negative, low positive, high positive. The negative and positive samples were correctly identified 99% of the time.
Inter-Assay Precision
Between-run precision was determined in 15 independent assays using the same three specimens for each analyte of negative, low positive, high positive. Three different lots of TruQuick HBV Combo were tested. The specimens were correctly identified 99% of the time.

CROSSREACTIVITY
TruQuick HBV Combo was tested with samples from patients diagnosed with HAMA, Rheumatoid factor (RF), HAV, Syphilis, HIV, *H. pylori*, Mononucleosis, CMV, Rubella and Toxoplasmosis. The samples showed no crossreactivity

ANALYTICAL SENSITIVITY
The Limit of Detection for TruQuick HBV Combo, as determined by dilutions of either HBsAg recombinant antigen or HBsAb antibody in plasma, is 1 ng/mL HBsAg and 10 mIU/mL HBsAb.

TESTS FOR INTERFERING SUBSTANCES

TruQuick HBV Combo was tested with the following potential interferents:

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

None of the substances interfered with the assay at the concentrations listed.

REFERENCES

1. Chizzali-Bonfadin C, Addlassnig KP, Kreihsl M, Hatvan A, Horak W. Knowledge-based interpretation of serologic tests for hepatitis on the World Wide Web. Clin Perform Qual HealthCare 1997 Apr-Jun 5:61-3.
2. ter Bog F. et al. Relation between laboratory results and histological hepatitis activity in individuals postitve for hepatitis B surface antigen and antibodies to hepatitis B e antigen. Lancet 1998 June;351:1914-8.

SNTQ5325 **REV. 05/17**

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	Rx 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.