TruQuick™ HBsAg/HCV/HIV/Syp 25T

A rapid test for the qualitative detection of Hepatitis B surface antigen (HBsAg), antibodies to Hepatitis C Virus, antibodies to HIV type 1, type 2 and syphilis- antibodies (IgG and IgM) to *Treponema Pallidum* (TP) in serum or plasma.

REF **TQ5525** IVD **Rx Only**

INTENDED USE

TruQuick HBsAg/HCV/HIV/Syp is a rapid immunoassay for the qualitative detection of Hepatitis B surface antigen (HBsAg),antibodies to Hepatitis C Virus, antibodies to HIV type 1, type 2 and syphilis antibodies (IgG and IgM) to *Treponema Pallidum* (TP) in serum or plasma.

SUMMARY AND EXPLANATION OF THE TEST

TruQuick HBsAg Component 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 Component 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]

TruQuick HIV 1.2 Component is a rapid test to qualitatively detect the presence of antibody to HIV 1 and/or HIV 2 in whole blood, serum or plasma specimen. The test utilizes latex conjugate and multiple recombinant HIV proteins to selectively detect antibodies to the HIV 1.2 in serum or plasma.

HIV is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virion is surrounded by a lipid envelope that is derived from host cell membrane. Several viral glycoproteins are on the envelope. Each virus contains two copies of positive-sense genomic RNAs. HIV 1 has been isolated from patients with AIDS and AIDS-related complex, and from healthy people with high potential risk for developing AIDS.[6] HIV 2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals.[7] Both HIV 1 and HIV 2 elicit immune response.[8] Detection of HIV antibodies in serum, plasma is the most efficient and common way to determine whether an individual has been exposed to HIV and to screen blood and blood products for HIV.[9] Despite the differences in their biological characteristics, serological activities and genome sequences, HIV 1 and HIV 2 show strong antigenic cross-reactivity.[10, 11] Most HIV 2 positive sera can be identified by using HIV 1 based serological tests.

TruQuick Syphilis Component utilizes a double antigen combination of a Syphilis antigen-coated particle and Syphilis antigen immobilized on membrane to detect TP antibodies (IgG and IgM) qualitatively and selectively in serum or plasma.

Treponema pallidum (TP) is the causative agent of the venereal disease Syphilis. TP is a spirochete bacterium with an outer envelope and a cytoplasmic membrane.[12] Relatively little is known about the organism in comparison with other bacterial pathogens. According to the Center for Disease Control (CDC), the number of cases of Syphilis infection has markedly increased since 1985.[13] Some key factors that have contributed to this rise include the crack cocaine epidemic and the high incidence of prostitution among drug users. One study reported a substantial epidemiological correlation between the acquisition and transmission of the HIV virus and Syphilis.

Multiple clinical stages and long periods of latent, asymptomatic infection are characteristic of Syphilis. Primary Syphilis is defined by the presence of a chancre at the site of inoculation. The antibodies response to the TP bacterium can be detected within four to seven days after the chancre appears. The infection remains detectable until the patient receives adequate treatment.[14]

BIOLOGICAL PRINCIPLES

TruQuick HBsAg Component is a qualitative, solid phase, two-site sandwich immunoassay for the detection of HBsAg in serum or plasma. The membrane is precoated 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 Component 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.

TruQuick HIV 1.2 Component is a qualitative, membrane based immunoassay for the detection of antibodies to HIV 1.2 in whole blood, serum or plasma. The membrane is precoated with recombinant HIV antigens. During testing, the whole blood, serum or plasma specimen reacts with HIV antigen coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with recombinant HIV antigen on the membrane in the test line region. If the specimen contains antibodies to HIV 1 and/or HIV 2, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain HIV 1 and/or HIV 2 antibodies, a colored line will not appear in the test line region, indicating 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 Syphilis Component is a qualitative membrane based immunoassay for the detection of TP antibodies (IgG and IgM) in serum or plasma. In this test procedure, recombinant Syphilis antigen is immobilized in the test line region of the test. After specimen is added to the specimen well of the test Cassette, it reacts with Syphilis antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized Syphilis antigen. The double antigen test format can detect both IgG and IgM in specimens. If the specimen contains TP antibodies, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain TP antibodies, a colored line will not appear in this region, indicating 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.

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 anti-HBsAg conjugated particles, anti-HBsAg coated on the membrane; recombinant HCV antigen conjugated particles, HCV antigen coated on the membrane; HIV 1/2 recombinant antigens conjugated particles, HIV 1/2 recombinant antigens coated on the membrane and Syphilis antigen coated particles and Syphilis 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. All reagents are for in vitro diagnostics 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.

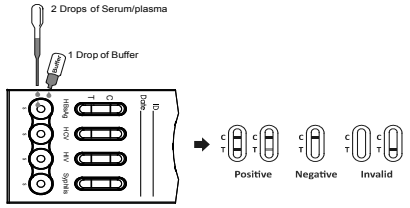
SPECIMEN COLLECTION AND PREPARATION

1. TruQuick HBsAg/HCV/HIV/Syp 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. Hold the dropper vertically and transfer **2 drops of serum or plasma (approximately 50 µL)** to the specimen area, then add **1drop of Buffer (approximately 40 µL)**, respectively. Start the timer. 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**.



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 HBsAg antigen and/or HCV antibodies and/or HIV 1.2 antibodies and/or Syphilis antibody 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

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 HBsAg/HCV/HIV/Syp has been 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 not designed to determine the quantitative concentration of HBsAg, HCV antibody, HIV 1.2 antibody or syphilis antibody.
4. TruQuick HBsAg Component 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 and/or HIV 1.2 and/or syphilis infection.

SPECIFIC PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

HBsAg

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

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

Method		EIA		Total Results
TruQuick HBsAg Component	Results	Positive	Negative	
	Positive	129	1	130
	Negative	0	370	370
Total Results		129	371	500

Sensitivity: > 99.9% (95% CI*: 97.7%-100%)
Specificity: 99.7% (95% CI*: 98.5%-100%)
Correlation: 99.8% (95% CI*: 98.9%-100%) *Confidence Intervals

HCV
The recombinant antigen used for TruQuick HCV Component is encoded by genes for both structural (nucleocapsid) and non-structural proteins. TruQuick HCV Component 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 Component is 99.9%, and the specificity is 99.8%.

Method		EIA		Total Results
TruQuick HCV Component	Results	Positive	Negative	
	Positive	163	1	164
	Negative	0	336	336
Total Result		163	337	500

Sensitivity: > 99.9% (95% CI*: 98.2%-100%)
Specificity: 99.7% (95% CI*: 98.4%-100%)
Correlation: 99.8% (95% CI*: 99.0%-100%) *Confidence Intervals

HIV 1.2
TruQuick HIV 1.2 Component has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial ELISA HIV test using clinical specimens. The results show that the sensitivity of TruQuick HIV 1.2 Component is > 99.9% and the specificity is 99.7%.

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Method		ELISA		Total Results
TruQuick HIV 1.2 Component	Results	Positive	Negative	
	Positive	100	1	101
	Negative	0	399	399
Total Result		100	400	500

Sensitivity: > 99.9% (95% CI*: 97.0%-100%)
Specificity: 99.8% (95% CI*: 98.6%-100%);
Correlation: 99.8% (95% CI*: 99.0%-100%). *Confidence Intervals

Syphilis
TruQuick Syphilis Component has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial TPPA Syphilis test using clinical specimens. The results show that the sensitivity of TruQuick Syphilis Component is > 99.9% and the specificity is 99.7%.

Method		ELISA		Total Results
TruQuick Syphilis Component	Results	Positive	Negative	
	Positive	164	1	165
	Negative	0	335	335
Total Result		164	336	500

Sensitivity: > 99.9% (95% CI*: 98.2%-100%)
Specificity: 99.7% (95% CI*: 98.4%-100%)
Correlation: 99.8% (95% CI*: 99.0%-100%) *Confidence Intervals

REPRODUCIBILITY
Intra-Assay Precision
Within-run precision was determined by using 20 replicates of four different specimens containing different concentrations of HBsAg, HCV antibody, HIV 1.2 antibody and syphilis antibody. The negative, positive values were correctly identified 100% of the time.
Inter-Assay Precision
Between-run precision was determined by 20 independent assays on the same four different specimens containing different concentrations of HBsAg, HCV antibody, HIV 1.2 antibody and syphilis antibody. Three different lots of TruQuick HBsAg/HCV/HIV/Syp have been tested over a 3-month period using above negative and positive specimens. The specimens were correctly identified 100% of the time.

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

TruQuick HIV 1.2 Component was tested by HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, HCV, Syphilis, HAMA, RF, *H. pylori*, Mononucleosis, CMV, Rubella and Toxoplasmosis positive specimens. The results showed no crossreactivity.

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

TESTS FOR INTERFERING SUBSTANCES
The following potentially interfering substances were added to HBsAg, HCV antibody, HIV 1.2 antibody and syphilis antibody 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 interfered in the assay at the concentration tested.

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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	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.