

# TruQuick™ Syphilis 40T

A rapid qualitative test to detect antibodies (IgG and IgM) to *Treponema pallidum* (TP) in whole blood, serum or plasma.

REF TQ2440

IVD

Rx Only

## INTENDED USE

TruQuick Syphilis is a rapid immunoassay for the qualitative detection of antibodies (IgG and IgM) to *Treponema pallidum* (TP) in whole blood, serum or plasma to aid in the diagnosis of Syphilis. Positive results should be confirmed with other tests and clinical findings.

## SUMMARY AND EXPLANATION OF THE TEST

*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.<sup>1</sup> 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.<sup>2</sup> Some key factors that have contributed to this rise include the crack cocaine epidemic and the high incidence of prostitution among drug users.<sup>3</sup> One study reported a substantial epidemiological correlation between the acquisition and transmission of the HIV virus and Syphilis.<sup>4</sup>

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 4 to 7 days after the chancre appears. The infection remains detectable until the patient receives adequate treatment.<sup>5</sup>

The TruQuick Syphilis (Whole Blood/Serum/Plasma) 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 whole blood, serum or plasma.

## BIOLOGICAL PRINCIPLES

The TruQuick Syphilis (Whole Blood/Serum/Plasma) is a qualitative membrane based immunoassay for the detection of TP antibodies (IgG and IgM) in whole blood, 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 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 contains Syphilis antigen-coated particles and Syphilis antigen coated on the membrane. Each cassette is packaged in a foil pouch.
- 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
- Lancets
- Centrifuge
- Heparinized capillary tubes and dispensing bulb
- Timer

## PRECAUTIONS

1. All reagents are for in vitro diagnostic use. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use test if pouch is damaged.
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. The used test should be discarded according to local regulations.
7. Humidity and temperature can adversely affect results.

## HAZARD and PRECAUTIONARY STATEMENTS

Refer to the SDS, available at [www.meridianbioscience.com](http://www.meridianbioscience.com) for Hazard and Precautionary Statements.

## SHELF LIFE AND STORAGE

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 C). The test 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 after the expiration date.

## SPECIMEN COLLECTION AND PREPARATION

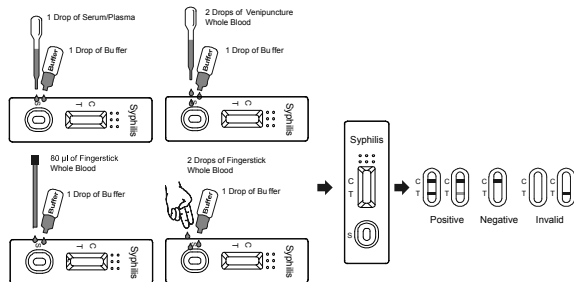
1. TruQuick Syphilis can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
2. To collect **Fingerstick Whole Blood specimens:**
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.

- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube:**
- Touch the end of the capillary tube to the blood until filled to approximately 80 µL. Avoid air bubbles.
  - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the Test Cassette.
- Add the Fingerstick Whole Blood specimen to the test by using **hanging drops:**
- Position the patient's finger so that the drop of blood is just above the specimen area of the Test Cassette.
  - Allow 2 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the Test Cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear nonhemolyzed specimens.
  4. 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 below -20 C. Whole blood collected by venipuncture should be stored at 2-8 C if the test is to be run within two days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
  5. 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.
  6. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

## TEST PROCEDURE

Allow the test, specimen, Buffer and/or controls to reach 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.
2. Place the cassette on a clean and level surface.  
For **Serum or Plasma** specimen: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 40 µL) to the specimen area, then add 1 drop of Buffer (approximately 40 µL) and start the timer. See illustration below.  
For **Venipuncture Whole Blood** specimen: Hold the dropper vertically and transfer 2 drops of whole blood (approximately 80 µL) to the specimen area, then add 1 drop of Buffer (approximately 40 µL), and start the timer. See illustration below.  
For **Fingerstick Whole Blood** specimen:
  - To use a capillary tube: Fill the capillary tube and transfer approximately 80 µL of fingerstick whole blood specimen to the specimen area of Test Cassette, then add 1 drop of Buffer (approximately 40 µL) and start the timer. See illustration below.
  - To use hanging drops: Allow 2 hanging drops of fingerstick whole blood specimen (approximately 80 µL) to fall into the specimen area of Test Cassette, then add 1 drop of Buffer (approximately 40 µL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. Read results at 5 minutes. Do not interpret the result after 20 minutes.



## INTERPRETATION OF RESULTS

(Please refer to the illustration above.)

**POSITIVE:** Two lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T).

**\*NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of TP antibodies present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

**NEGATIVE:** One colored line appears in the control line region (C). No line appears in the test line 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. 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 colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking 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

The TruQuick Syphilis (Whole Blood/Serum/Plasma) has been compared with a leading commercial TPPA Syphilis test, demonstrating an overall accuracy greater than or equal to 99.8%.

## LIMITATIONS OF THE PROCEDURE

1. TruQuick Syphilis is for in vitro diagnostic use only. The test should be used for the detection of TP antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in TP antibodies can be determined by this qualitative test.
2. TruQuick Syphilis will only indicate the presence of TP antibodies in the specimen and should not be used as the sole criteria for the diagnosis of TP infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of TP infection.

## SPECIFIC PERFORMANCE CHARACTERISTICS

### Sensitivity and Specificity

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

Method	TPPA			Total Result
	Results	Positive	Negative	
TruQuick Syphilis	Positive	200	1	201
	Negative	0	319	319
	Total Result	200	320	520

Sensitivity: > 99.9% (95%CI\*: 99.4%-100%)

Specificity: 99.7% (95%CI\*: 98.3%-100%)

Correlation: 99.8% (95%CI\*: 98.9%-100%) \*Confidence Interval

## REPRODUCIBILITY

### Intra-Assay Precision

Within-run precision was determined by using 10 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified > 99% of the time.

### Inter-Assay Precision

Between-run precision was determined by 10 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of TruQuick Syphilis have been tested over a three day period using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified > 99% of the time.

## CROSSREACTIVITY

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

## TESTS FOR INTERFERING SUBSTANCES

The following potentially interfering substances were added to Syphilis negative and positive specimens.

Acetaminophen 20 mg/dL	Caffeine 20 mg/dL
Acetylsalicylic Acid 20 mg/dL	Genistic Acid 20 mg/dL
Ascorbic Acid 2 g/dL	Albumin 2 g/dL
Creatine 200 mg/dL	Hemoglobin 1 g/dL
Bilirubin 1 g/dL	Oxalic Acid 600 mg/dL

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

## REFERENCES

1. Fraser CM. Complete genome sequence of *Treponema pallidum*, the syphilis spirochete. Science 1998;281 July: 75-381.
2. Center for Disease Control. Recommendations for diagnosing and treating syphilis in HIV-infected patients, MMWR Morb. Mortal Wkly Rep. 1988;37:601.
3. Marx AR. Crack, sex and STD. Sexually Transmitted Diseases. 1991;18:92-101.
4. Wasserheit JN. Epidemiological synergy: Interrelationships between human immunodeficiency virus infection and other sexually transmitted diseases. Sexually Transmitted Diseases. 1992;19:61-77.
5. Johnson PC. Testing for syphilis. Dermatologic Clinic. 1994 12 Jan;9:17.



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


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