TruQuick™ Tuberculosis 40T

A rapid test for the qualitative detection of anti-TB antibodies (Isotypes IgG, IgM and IgA) in whole blood, serum or plasma specimens.

REF **TQ5640** IVD **Rx Only**

INTENDED USE
TruQuick Tuberculosis is a rapid immunoassay for the qualitative detection of anti-TB antibodies (Isotypes IgG, IgM and IgA) in whole blood, serum or plasma specimens. The results of this test should be considered in conjunction with other test results and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST
Tuberculosis (TB) is spread primarily via airborne transmission of aerosolized droplets developed by coughing, sneezing and talking. Areas of poor ventilation pose the greatest risk of exposure to infection. TB is a major cause of morbidity and mortality worldwide, resulting in the greatest number of deaths due to a single infectious agent. The World Health Organization reports that more than 8 million new cases of active tuberculosis are diagnosed annually. Almost 3 million deaths are attributed to TB as well.[1, 2] Timely diagnosis is crucial to TB control, as it provides early initiation of therapy and limits further spread of infection. Several diagnostic methods for detecting TB have been used over the years including skin test, sputum smear, and sputum culture and chest x-ray. All of these methods have some limitations. Newer tests, such as PCR-DNA amplification or interferon-gamma assays, have been recently introduced. However, the turn-around time for these tests is long, they require laboratory equipment and skilled personnel, and some are neither cost effective nor easy to use.[3] These tests are also expensive and not practical for developing countries. Serological methods constitute an attractive alternative, since TB serodiagnosis is simple, inexpensive, relatively noninvasive, and it does not depend on detection of mycobacteria.[4- 6]

TruQuick Tuberculosis is a rapid test for qualitative detection of anti-TB antibodies (Isotypes IgG, IgM and IgA) in whole blood, serum or plasma specimens. The test utilizes a combination of recombinant antigens to detect elevated levels of anti-TB antibodies.

BIOLOGICAL PRINCIPLES
The membrane of the Test Cassette is precoated with TB recombinant antigen on the test line region of the Cassette. During testing, anti-TB antibodies, if present the specimen react with particles coated with TB recombinant antigen. The mixture migrates along the membrane by capillary action to react with TB recombinant antigen 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.

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 TB recombinant antigen-coated particles and TB recombinant antigen coated on the membrane. Each cassette is packaged in a foil pouch.
- Buffer (for whole blood only): A buffered solution containing ProClin 300 as a preservative. The Buffer is supplied in a dropper vial ready for use.
- Disposable specimen droppers
- Package insert

MATERIALS NOT PROVIDED
- Specimen collection containers
- Centrifuge
- Lancets (for fingerstick whole blood only)
- Timer

PRECAUTIONS
1. All reagents 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. Do not use test if the package is damaged.
4. Handle 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.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
6. Humidity and temperature can adversely affect results.
7. The used test should be discarded according to local regulations.
8. Do not use potassium oxalate as anticoagulant to collect plasma or venous blood samples.

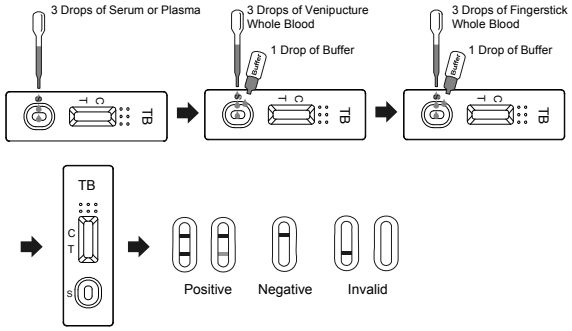
HAZARD and PRECAUTIONARY STATEMENTS
Refer to the SDS, available at www.meridianbioscience.com for Hazard and Precautionary Statements.

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 Tuberculosis can be performed using whole blood (from venipuncture or fingerstick) serum, or plasma specimens.
2. To collect Venipuncture Whole Blood Specimens: Collect anticoagulated blood sample (EDTA, heparin, and sodium citrate) following standard laboratory procedures.
   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 Cassette by using hanging drop:
   - Position the patient's finger so that the drop of blood is just above the specimen well (S) of the Test Cassette.
   - Allow 3 hanging drops of fingerstick whole blood to fall into the center of specimen well (S) on the Test Cassette, or move the patient's finger so that the hanging drop touches the center of the specimen well (S). Avoid touching the finger directly to the specimen well (S).
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 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. 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 federal regulations covering the transportation of etiologic agents.

TEST PROCEDURE
Allow the Test Cassette, specimen, Buffer, and/or controls to equilibrate to 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 immediately after opening the foil pouch.
2. Place the cassette on a clean and level surface.
   For **Serum or Plasma** Specimens:
   Hold the dropper vertically, transfer 3 drops of serum or plasma (approximately 75 µL) to the specimen well (S) of Test Cassette and then start the timer. See illustration below.
   For **Venipuncture Whole Blood** Specimens:
   Hold the dropper vertically and transfer 3 drops of venipuncture whole blood (approximately 75 µL) to the specimen well (S) of Test Cassette, then add 1 drop of Buffer (approximately 40 µL) and start the timer. See illustration below.
   For **Fingerstick Whole Blood** Specimens:
   Allow 3 hanging drops of fingerstick whole blood (approximately 75 µL) to fall into the center of the specimen well (S) 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. The result should be read at 10 minutes. Do not interpret the result after 30 minutes.



INTERPRETATION OF RESULTS
(Please refer to the illustration above.)
POSITIVE:* Two distinct colored lines appear. One line should be in the control region (C) and another 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 anti-TB antibodies 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.

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 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 a good laboratory practice to confirm the test procedure and to verify proper test performance. Some preservatives may interfere with the operation of the test. External controls should be validated before use to ensure valid results.

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 Tuberculosis was compared to smear/culture procedures with 615 specimens from symptomatic patients. There was 96.7% correlation between the two methods.

LIMITATIONS OF THE PROCEDURE
1. TruQuick Tuberculosis is for in vitro diagnostic use only.
2. The test should be used for the detection of anti-TB antibodies in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in anti-TB antibodies concentration can be determined by this qualitative test.
3. TruQuick Tuberculosis will only indicate the presence of anti-TB antibodies in the specimen and should not be used as the sole criteria for the diagnosis of active tuberculosis infection.
4. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

SPECIFIC PERFORMANCE CHARACTERISTICS
Clinical Sensitivity and Specificity
TruQuick Tuberculosis has been evaluated using specimens that have been collected from individuals found to be either smear positive/negative or culture positive/negative. The results show that the sensitivity of TruQuick Tuberculosis is 86.4%, the specificity is 99.0%.

TruQuick Tuberculosis vs. Smear/Culture

Method		Smear/Culture		Total Results
	Results	Positive	Negative	
TruQuick Tuberculosis	Positive	95	5	100
	Negative	15	500	515
Total Results		110	505	615

Sensitivity: 86.4% (95% CI*: 78.5%~92.2%);
Specificity: 99.0% (95% CI*: 97.7%~99.7%);
Correlation: 96.7% (95% CI*: 95.0%~98.0%). *Confidence Intervals

REPRODUCIBILITY
Intra-Assay Precision
Within-run precision was determined by using 20 replicates of serum and plasma for four specimens: a negative, a low positive, a middle positive and a high positive. The specimens were correctly identified > 99% of the time.
Inter-Assay Precision
Between-run precision was determined by 5 independent assays on serum and plasma for the same four specimens: negative, low positive, middle positive, high positive. Three different lots of TruQuick Tuberculosis were tested. The specimens were correctly identified > 99% of the time.

CROSSREACTIVITY
TruQuick Tuberculosis was tested with specimens from patients diagnosed with the following: BCG vaccine, HBV, HCV, HIV, HAMA, Pulmonary diseases, RF, CMV. No crossreactivity was observed, indicating that the performance of TruQuick Tuberculosis is unaffected by the presence of these factors.

TESTS FOR INTERFERING SUBSTANCES
TruQuick Tuberculosis was tested with the following potentially interfering substances:

Ascorbic acid 20 mg/mL	Acetaminophen 20 mg/dL
Hemoglobin 500 mg/dL	Acetylsalicylic acid 20 mg/dL
Gentisic acid 20 mg/dL	Methanol 10%
Oxalic acid 60 mg/dL	Creatine 200 mg/dL
Bilirubin 30 mg/dL	Albumin 2000 mg/dL
Uric acid 20 mg/mL	Caffeine 20 mg/dL

None of the substances interfered at the concentrations tested.

REFERENCES

1. Global tuberculosis control. WHO Report. 2003:1-40.
2. Raviglione MC, Snider Jr DE, Kochi A. Global epidemiology of tuberculosis. JAMA.1995;273:220-225.
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4. Bothamley GH. Serological diagnosis of tuberculosis. Eur Resp J. 1995;8:676s-688s.
5. Lyashchenko K, Colangeli R, Houde M, et al. Heterogenous antibody responses in tuberculosis. Infect Immun. 1998;66:3936-3940.
6. Lyashchenko KP, Singh M, Colangeli R, Gennaro ML. A multi-antigen print immunoassay for the serological diagnosis of infectious diseases. J Immunol Methods 2000;242:91-100.

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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.