TruQuick™ Typhoid 40T

A rapid test for the qualitative detection of IgG and IgM antibodies to *Salmonella typhi* (*S. typhi*) in whole blood, serum or plasma.

REF **TQ5840** IVD **Rx Only**

INTENDED USE
TruQuick Typhoid is a rapid immunoassay for the simultaneous detection and differentiation of IgG and IgM antibodies against *Salmonella typhi* (*S. typhi*) in whole blood, serum or plasma. It is intended to be used as a screening test as an aid in the diagnosis of infection with *S. typhi*. Any reactive specimen with TruQuick Typhoid needs to be confirmed with alternative testing method and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST
Typhoid fever is caused by *S. typhi*, a Gram-negative bacterium. World-wide, an estimated 17 million cases and 600,000 associated deaths occur annually.[1] Patients who are infected with HIV are at significantly increased risk of clinical infection with *S. typhi*.[2] Evidence of *H. pylori* infection also presents an increase risk of acquiring typhoid fever. Approximately 1-5% of patients become chronic carriers harboring *S. typhi* in the gallbladder.

The clinical diagnosis of typhoid fever depends on the isolation of *S. typhi* from blood, bone marrow or a specific anatomic lesion. In the facilities that cannot afford to perform this complicated and time consuming procedure, a Widal test (also referred as Weil-Felix Test) is used to facilitate the diagnosis. However, many limitations lead to difficulties in the interpretation of the Widal test.[3, 4]

In contrast, TruQuick Typhoid is a simple and rapid laboratory test. The test simultaneously detects and differentiates IgG and the IgM antibodies to *S. typhi*-specific antigen[5] in whole blood, serum or plasma as an aid in the determination of current or previous exposure to *S. typhi*.

BIOLOGICAL PRINCIPLES
TruQuick Typhoid consists of a Test Cassette containing two components: an IgG component and an IgM component. The IgG test line region is precoated with reagents for the detection of anti-*S. typhi* IgG. The IgM test line region is precoated with monoclonal anti-human IgM for detection of anti-*S. typhi* IgM.

During testing, specimen dispensed into the sample well of the Test Cassette binds with Typhoid conjugates impregnated in the reagent area if the specimen contains anti-Typhoid antibodies. The immunocomplex thus formed migrates by capillary action. If the antibodies in the specimen are of the IgG type, the immunocomplex is then captured by the precoated reagents on the membrane, forming a colored IgG line, indicating a *S. typhi* IgG positive test result. If the antibodies in the specimen are of IgM type, the immunocomplex would be captured on the membrane by the precoated anti-human IgM antibody, forming a colored IgM line, indicating a *S. typhi* IgM positive test result. Absence of any test lines (IgM and IgG) indicates a negative result. A colored control line (C) should always appear in case of a positive or a negative result. Its absence indicates invalid test results.

REAGENTS/MATERIALS PROVIDED
The maximum number of tests obtained from this test kit is listed on the outer box.
- Test Cassettes: The test contains mouse anti-human IgM, mouse anti-human IgG and Typhoid antigen. A goat antibody is employed in the control line system. Each cassette is enclosed 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.
- Sample droppers
- Package insert

MATERIALS NOT PROVIDED
- Specimen collection containers
- Centrifuge
- Timer

PRECAUTIONS
1. All reagents are for in vitro diagnostic use only. Do not use after the expiration date.
2. Do not smoke, drink, or eat in areas where specimens or kits reagents are handled.
3. Dispose of all specimens and materials used to perform the test as biohazardous waste.
4. This package insert must be read completely before performing the test.
5. Bring all reagents to room temperature (15 C–30 C) before use.
6. Do not interchange the Buffer and Test Cassettes of different lots.
7. Do not use hemolyzed blood specimens for testing.

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

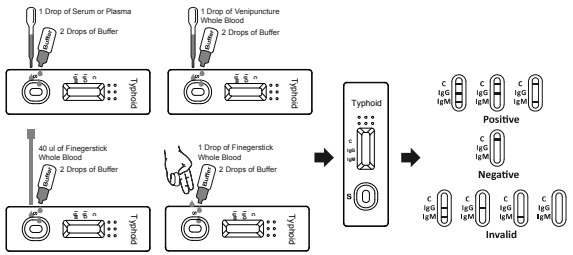
SHELF LIFE AND STORAGE
Store as packaged in the sealed pouch at room temperature or refrigerated (4-30 C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION
1. TruQuick Typhoid 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 40 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 1 hanging drop 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 the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
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 federal regulations for transportation of etiologic agents

TEST PROCEDURE
Allow Test Cassette, Buffer, specimen, 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 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 2 drops of Buffer** (approximately 80 µL) and start the timer. See illustration below.
   For **Venipuncture Whole Blood** specimen: Hold the dropper vertically and **transfer 1 drop of whole blood** (approximately 40 µL) to the specimen area, then **add 2 drops of Buffer** (approximately 80 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 40 µL of fingerstick whole blood specimen** to the specimen area of Test Cassette, then **add 2 drops of Buffer** (approximately 80 µL) and start the timer. See illustration below.
   - To use hanging drops: Allow **1 hanging drop of fingerstick whole blood specimen** (approximately 40 µL) to fall into the specimen area of Test Cassette, then **add 2 drops of Buffer** (approximately 80 µL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. Read the result at 15 minutes, do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS
(Please refer to the illustration above.)
POSITIVE:* Two or three lines appear. One colored line should always appear in the control line region (C) and another one or two colored line(s) should be in the test line region(s) (IgM and/or IgG).
IgM Positive: Along with line in Control region (C), a line appears in IgM region. It indicates a positive Test result for antibodies to *S. typhi* (Isotype IgM)
IgG Positive: Along with line in Control region (C), a line appears in IgG region. It indicates a positive Test result for antibodies to *S. typhi* (Isotype IgG)
***NOTE:** The intensity of the color in the test line regions (IgM and IgG) may vary depending on the concentration of Typhoid antibodies present in the specimen. Therefore, any shade of color in the test line region (IgM and/or IgG) should be considered positive.
NEGATIVE: **One colored line appears in the control line region (C)**. No line appears in the test line regions (IgM and IgG).

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.
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 Typhoid was compared with a leading commercial Typhoid ELISA test. The correlation between these two systems is over 98%.

LIMITATIONS OF THE PROCEDURE
1. The TEST PROCEDURE and INTERPRETAION OF RESULTS sections must be followed closely when performing the assay. Failure to follow the procedure may give inaccurate results.
2. TruQuick Typhoid is for the qualitative detection of antibodies to *S. typhi* in whole blood, serum or plasma. The intensity of the test band has no linear correlation with the antibody titer in the specimen.
3. A negative result only indicates absence of anti-*S. typhi* antibodies at detectable levels. A negative test result does not preclude the possibility of exposure to *S. typhi* as a negative result can occur if the quantity of anti-*S typhi* antibodies present in the specimen is below the detection limit of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
4. Specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
5. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity and Specificity
A clinical evaluation was conducted comparing the results obtained using TruQuick Typhoid to Typhoid IgG/IgM EIA. The study included 15 IgG specimens and 33 IgM specimens. Both assays identified 298 negative and 13 IgG positive results. Both assays identified 298 negative and 31 IgM positive results.

IgM Results

Method		*S. typhi* EIA (IgM)		Total Results
	Results	Positive	Negative	
TruQuick Typhoid for IgM	Positive	31	3	34
	Negative	2	298	300
Total Results		33	301	334

Sensitivity: 93.9% (95% CI*: 79.8%~99.2%)
Specificity: 99.0% (95% CI*: 97.1%~99.8%)
Correlation: 98.5% (95% CI*: 96.5%~99.5%) *Confidence Intervals

IgG Results

Method		*S. typhi* EIA (IgG)		Total Results
	Results	Positive	Negative	
TruQuick Typhoid for IgG	Positive	13	1	14
	Negative	2	298	300
Total Results		15	299	314

Sensitivity: 86.7% (95% CI*: 59.5%~89.3%)
Specificity: 99.6% (95% CI*: 98.2%~99.9%)
Correlation: 99.0% (95% CI*: 97.2%~98.8%) *Confidence Intervals

REPRODUCIBILITY
Intra-Assay Precision
Within-run precision was determined by using 10 replicates of serum and plasma samples for five specimens: a negative, an IgM low positive, an IgG low positive, an IgM high positive and an IgG high positive. The samples were correctly identified > 99% of the time.
Inter-Assay Precision
Between-run precision was determined by 10 independent assays on serum and plasma for the same five specimens: a negative, an IgM low positive, an IgG low positive, an IgM high positive and an IgG high positive. Five different lots of TruQuick Typhoid were tested. The specimens were correctly identified > 99% of the time.

CROSSREACTIVITY
TruQuick Typhoid was tested with specimens from patients diagnosed with HIV, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, HCV Syphilis, *H. pylori*, Rubella, CMV and Toxoplasmosis. The samples showed no crossreactivity.

TESTS FOR INTERFERING SUBSTANCES

The following potentially interfering substances were added to Typhoid negative and positive serum and plasma specimens.

Acetaminophen 20 mg/dL	Caffeine 200 mg/dL
Acetylsalicylic Acid 20 mg/dL	Gentisic Acid 20 mg/dL
Ascorbic Acid 20 mg/mL	Albumin 2 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. Ivanoff BN, Leivne MM, Lambert PH. Vaccination against typhoid fever: Present status. Bulletin of the WHO. 1994;72:957-71.
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4. Pang T. False positive Widal test in non-typhoid Salmonella infection. SE Asian J Trop Med and Public Health. 1989;20:163-4.
5. Ismail A, Hai OK, Kader ZA. Demonstration of an antigenic protein specific for *Salmonella typhi*. Biochem Biophys Res Commun. 1991;181(1):301-5.

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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.