TruQuick™ Salmonella Typhi Ag 25T

A rapid test for the qualitative detection of *Salmonella typhi* antigen in feces.

REF **TQ5625** IVD **Rx Only**

INTENDED USE

TruQuick Salmonella Typhi Ag is a rapid chromatographic immunoassay for the qualitative detection of *Salmonella typhi* antigens in feces specimens to aid in the diagnosis of *Salmonella typhi* infection.

SUMMARY AND EXPLANATION OF THE TEST

Typhoid fever is a life threatening illness caused by the bacterium *Salmonella typhi*, and was observed by Eberth (1880) in the mesenteric nodes and spleen of fatal cases of typhoid fever.[1] The infection is acquired typically by ingestion. On reaching the gut, the bacilli attach themselves to the epithelial cells of the intestinal villi and penetrate to the lamina and submucosa. They are then phagocytosed there by polymorphs and macrophages. The ability to resist intracellular killing and to multiply within these cells is a measure of their virulence. They enter the mesenteric lymph nodes, where they multiply and, via the thoracic duct, enter the blood stream.[2]

TruQuick Salmonella Typhi Ag is a rapid immunoassay for the qualitative detection of *Salmonella typhi* antigens in feces specimens, providing results in five minutes. The test utilizes antibodies specific for *Salmonella typhi* antigens to selectively detect *S. typhi* antigens in feces.

BIOLOGICAL PRINCIPLES

TruQuick Salmonella Typhi Ag is a qualitative, lateral flow immunoassay for the detection of *S. typhi* antigens in feces. In this test, the membrane is precoated with anti-*S. typhi* antibodies on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-*S. typhi* antibodies. The mixture migrates upward on the membrane by capillary action to react with anti-*S. typhi* 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.

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 monoclonal anti-*S. typhi* antibodies coated particles and monoclonal anti-*S. typhi* antibodies coated on the membrane.
- Specimen Collection Tubes with Extraction Buffer: A buffered Extraction Buffer containing Proclin 300 as a preservative. The Extraction Buffer is supplied ready for use.
- Package insert

MATERIALS NOT PROVIDED

- Specimen collection containers
- Pipette and disposable tips (optional)
- Centrifuge
- Timer
- Droppers

PRECAUTIONS

1. For in vitro diagnostic use only. Do not use after expiration date.
2. The test should remain in the sealed pouch until use.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
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 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.

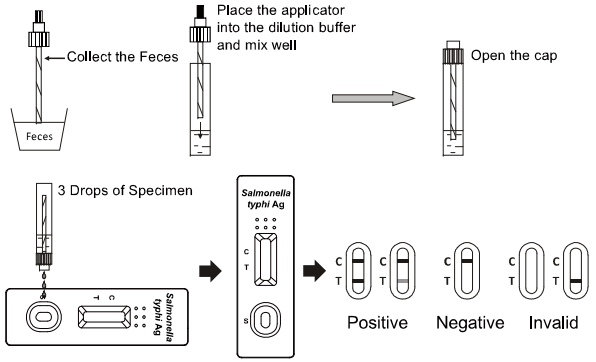
SPECIMEN COLLECTION AND PREPARATION

1. The feces specimen must be collected in clean, dry, waterproof container containing no detergents, preservatives or transport media.
2. Bring the necessary reagents to room temperature before use.
3. 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, Buffer and/or controls to reach room temperature (15-30 C) prior to testing.

1. To collect fecal specimens:
   Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8 C if not tested within 6 hours. For long term storage, specimens should be kept below -20 C.
2. To process fecal specimens:
   For Solid Specimens:
   Unscrew the cap of the Specimen Collection Tube，then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
   For Liquid Specimens:
   Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops (approximately 100 µL) into the Specimen Collection Tube containing the Extraction Buffer. Tighten the cap onto the Specimen Collection Tube, then shake the Specimen Collection Tube vigorously to mix the specimen and the Extraction Buffer.
3. Bring the pouch to room temperature before opening it. Remove the Test Cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
4. Hold the Specimen Collection Tube upright and open the cap onto the Specimen Collection Tube. Invert the Specimen Collection Tube and transfer 3 full drops of the extracted specimen (approximately 120 µL) to the specimen well (S) of the Test Cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
5. Read results at 5 minutes after dispensing the specimen. Do not read results after 15 minutes.
   Note: If the specimen does not migrate (presence of particles), centrifuge the extracted specimens contained in the Extraction Buffer vial. Collect 120 µL of supernatant, dispense into the specimen well (S) of a new Test Cassette and start afresh following the instructions mentioned above.



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 *S. typhi* antigen 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 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 colored line appearing in the control region (C) is an internal valid 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 Salmonella Typhi Ag has been compared with other Rapid Test Cassettes, demonstrating an overall accuracy of 98.3%.

LIMITATIONS OF THE PROCEDURE

1. TruQuick Salmonella Typhi Ag is for in vitro diagnostic use only. The test should be used for the detection of *S. typhi* antigens in feces specimens only. Neither the quantitative value nor the rate of increase in *S. typhi* antigen concentration can be determined by this qualitative test.
2. TruQuick Salmonella Typhi Ag will only indicate the presence of *S. typhi* in the specimen.
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 *Salmonella typhi* infection.
5. Following certain antibiotic treatments, the concentration of *S. typhi* antigens may decrease to the concentration below the minimum detection level of the test. Therefore, diagnosis should be made with caution during antibiotic treatment.

SPECIFIC PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

TruQuick Salmonella Typhi Ag has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. The result shows that the sensitivity of TruQuick Salmonella Typhi Ag is 96.2% and the specificity is 99.2% relative to other Rapid Test Cassettes.

Method		Other Test Cassette		Total Result
	Results	Positive	Negative	
TruQuick Salmonella Typhi Ag	Positive	51	1	52
	Negative	2	125	127
Total Result		53	126	179

Sensitivity: 96.2% (95% CI*: 87.0%-99.5%) *Confidence Interval
Specificity: 99.2% (95% CI*: 95.7%-100%)
Correlation: 98.3% (95% CI*: 95.2%-99.7%)

REPRODUCIBILITY

Intra-Assay Precision

Within-run precision was determined by using 15 replicates of four specimens: negative, low positive, middle positive and high positive specimens. The specimens were correctly identified > 99% of the time.

Inter-Assay Precision

Between-run precision was determined by 15 independent assays on the same four specimens: negative, low positive, middle positive and high positive specimens. Three different lots of TruQuick Salmonella Typhi Ag have been tested using these specimens. The specimens were correctly identified > 99% of the time.

CROSSREACTIVITY

Crossreactivity with the following organisms were studied at 1 x 10^9 org/mL. The following organisms were found negative when tested with TruQuick Salmonella Typhi Ag:

Acinetobacter calcoaceticus	*Acinetobacter spp*	*Branhamella catarrhalis*
Candida albicans	*Chlamydia trachomatis*	*Enterococcus faecium*
E. coli	*Enterococcus faecalis*	*Gardnerella vaginalis*
Group A *Streptococcus*	Group B *Streptococcus*	Group C *Streptococcus*
Hemophilus influenza	*Klebsiella pneumonia*	*Neisseria gonorrhea*
Neisseria meningitides	*Proteus mirabilis*	*Proteus vulgaris*
Pseudomonas aeruginosa	*Rotavirus*	*Helicobacter pylori*
Staphylococcus aureus	*Adenovirus*	

REFERENCES

1. Ivanoff B. Typhoid fever, global situation and WHO recommendations. SE Asia J Trop Med. Public Health. 1995;26:supp2 1-6.
2. Parry CM, Hien TT, Dougan G, et al. Typhoid fever. N Engl J Med. 2002;347:1770-82.

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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	R_x 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.