

# Salmonella typhi IgG/IgM Rapid Test

For detection of *Salmonella typhi* antibodies in Human Serum, Plasma or Whole Blood.



In-vitro diagnostic use only



Not reuse

## Introduction

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. It is common in developing countries where it affects about 12.5 million persons annually. 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 the lamina and submucosa. They are then phagocytosed there by polymorphs and mesenteric lymph nodes, where they multiply and, via the thoracic duct, enter the blood stream. A transient bacteremia follows, during which the bacilli are seeded in the liver, gall bladder, spleen, bone marrow, lymph nodes, and kidneys, where further multiplication takes place. Towards the end of the incubation period, there occurs a massive bacteremia from these sites, heralding the onset of the clinical symptoms. The diagnosis of typhoid consists of isolation of the bacilli and the demonstration of antibodies. The isolation of the bacilli is very time consuming and antibody detection is not very specific. Other tests include the Widal reaction.

## Intended Use

The typhoid Test Device is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to *Salmonella typhi* in serum plasma, or whole blood.

## Principle

The *Salmonella typhi* IgG/IgM Test Device (Serum/Plasma/Whole Blood) is a qualitative test for the detection of IgG and IgM antibodies to *S. typhi* in human serum, plasma, or whole blood. The test provides a differential detection of anti-*S. typhi*-IgG and anti-*S. typhi*-IgM antibodies and can be used for the presumptive distinction between a current, latent and/or carrier *S. typhi* infection. Serum, plasma or whole blood samples may be used with this test.

First a specimen is dispensed into the sample well of the test device. If IgG or IgM antibodies to *S. typhi* are present in the specimen they will bind to the colloidal gold-antigen conjugate and travel up the membrane chromatographically. The antibody-Antigen-colloidal gold complex will then bind to the immobilized anti-Human IgG and/or anti-Human IgM coated on the membrane. This will cause pale to dark colored lines to form at the IgG or IgM test region and can be seen in the results window. The intensity of the lines will vary depending upon the amount of antibody present in the sample. The appearance of a colored line in a specific test region should be considered as positive for that particular antibody (IgG and/or IgM).

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 proper membrane wicking has occurred.

## Kit Precautions and Storage Instructions

- 1) For best results, adhere to instructions provided
- 2) All specimens should be handled as potentially infectious
- 3) The test device should be stored at room temperature
- 4) The test device is sensitive to humidity as well as heat
- 5) Do not use beyond expiration date
- 6) Do not use test kit if pouch is damaged or seal is broken
- 7) Use test device immediately after removing from the pouch
- 8) The components (test device and assay diluents) in this kit have been quality control tested as a standard batch unit. Do not mix components from different lot numbers.
- 9) Store kit at room temperature (2 -30 °C). Do not expose the kit to temperature over 30 °C.

## Warnings

- 1) For in vitro diagnostic use only. DO NOT RE-USE test device
- 2) The instructions must be followed to obtain accurate results. Anyone performing an assay with this product must be trained in its use and laboratory procedures.
- 3) Do not eat or smoke while handling specimens
- 4) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.

- 5) Avoid splashing or aerosol formation
- 6) Clean up spills thoroughly using an appropriate disinfectant
- 7) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- 8) Do not mix with other specimens.

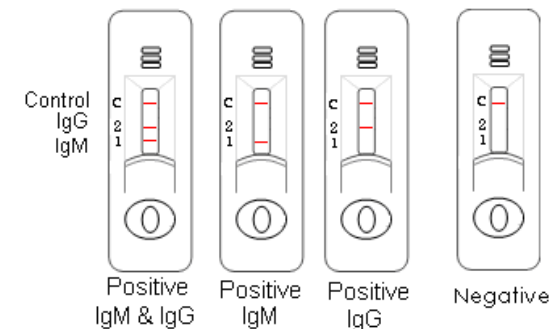
## Specimen Collection, Storage and Precautions

- 1) Serum (S): Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant .
- 2) Plasma (P): Collect the whole blood into a collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.
- 3) Whole Blood (WB): Collect the whole blood by lancing devices. WB can be delivered by pipette directly to the test card.
- 4) If serum or plasma specimens are not tested immediately, they should be refrigerated at 2-8 °C . For storage periods longer than 2 weeks, freezing is recommended. They should be brought to room temperature (1-30 °C) prior to use.
- 5) Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
- 6) Anticoagulants such as heparin, EDTA and sodium citrate do not affect the test results.
- 7) Use separately disposable capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.
- 8) As known relevant interference, hemolytic samples, rheumatoid factors-contained samples and lipaemic, icteric samples can lead to impair the test results.

## Test Procedure

- 1) Bring the pouch to room temperature before opening it. Remove the test device 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) Dispense 35µL of serum/plasma or whole blood into the sample well of the cassette.
- 3) Dispense 1 drop of buffer directly from buffer bottle or use a calibrated pipette to deliver 40µL of buffer to the sample well.
- 4) The result should be read between 10 and 20 minutes but not longer than 30 minutes.

## Interpretation of Test Results (Refer to Figure)



**IgG POSITIVE: Two distinct lines appear.**

The control line (C) and IgG line (2) are visible on the test cassette. The test is positive for IgG antibodies.

**IgM POSITIVE: Two distinct lines appear.**

The control line (C) and IgM line (1) are visible on the test cassette. The test is positive for IgM antibodies.

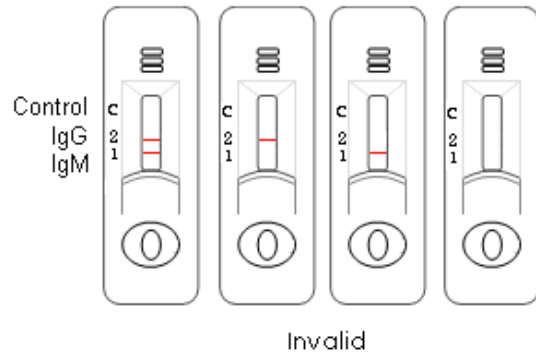
**IgM and IgG POSITIVE: Three distinct lines appear.**

The control line (C), IgM (M) and IgG (G) lines are visible on the test cassette. The test is positive for IgM and IgG antibodies.

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

**NEGATIVE: One red line appears in the control region (C).** No apparent 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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



**NOTE:** A low *S. typhi* antibody concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 30 minutes.

### Limitations of the Test

1. The *S. typhi* Antibody Test Device is for *in vitro* diagnostic use only. This test should be used for the detection of *S. typhi* Antibody in specimen.
2. The *S. typhi* Antibody Test Device will only indicate the presence of *S. typhi* Antibody in the specimen and should not be used as the sole criteria for the diagnosis of Typhoid infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Typhoid infection.

### Internal Quality Control

The "Control Line" is used for procedural control. Control line should always appear if the test procedure is performed

properly and the test reagents of control line are working. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required

### Suggested Reading List

- 1) Hatta M et al. Simple dipstick assay for the detection of salmonella typhi-specific IgM antibodies and the evolution of the immune response in patients with typhoid fever. *Am. J Trop. Med. Hyg.*, 66(4), 2002, pp. 416–421.
- 2) Gopalkrishna V., Sekhar W. Y., Soo E. H., Vinsent R. A. & Devi S., *Singapore Med J.* 2002 Vol. 43(7) 354-358.
- 3) House Deborah, Wain John, Ho Vo A., Diep To S., Chinh Nguyen, Bay Phan V., Vinh Ha, DueMinh, Parry Christopher M., Dougan Gordon, White Nicholas J., Hien Tran Tinh & Farrar, Jeremy J. J. *of Clin. Microbiol.* 2001 Vol. 39 (3) 1002-1007
- 4) Bhutta ZA et al. Rapid Serologic Diagnosis Of Pediatric Typhoid Fever In An Endemic Area: A Prospective Comparative Evaluation Of Two Dot-Enzyme Immunoassays And The Widal Test. *Am. J. Trop. Med. Hyg.* 61(4), 1999, pp. 654–657.

**REF**

RTST1211-1

**BIOGATELABS**

Manufactured & Quality Controlled by  
Biogate Laboratories Ltd.  
110-4238 Lozells Avenue, Burnaby, BC  
Canada, V5A 0C4  
Tel: 1-604-322-2955 Fax 1-604-322-2955  
[www.biogatelab.com](http://www.biogatelab.com)