PATHKITS

SIMPLE Typhoid IgG/IgM

Product Code: **PKRK018**
Kit Contents (**25 Kits**)
Shelf Life: **24 Months**

Kit Components	Quantity (Units)
Test Strips	25
Assay Buffer	1 Bottle
Sample Dropper	25
IFU	1

Introduction

The Typhoid Rapid Test Cassette is a lateral flow immunoassay for the simultaneous detection and differentiation of IgG and IgM antibodies against *Salmonella typhi* (*S.typhi*) in human whole blood, serum or plasma (1). 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 the Typhoid rapid test cassette needs to be confirmed with an alternative testing method. Typhoid fever is caused by *S. typhi,* a Gram-negative bacterium. WHO estimates the global typhoid fever disease burden at 11-20 million cases annually, resulting in about 128 000–161 000 deaths per year (2). Patients who are infected with HIV are at significantly increased risk of clinical infection with *S. typhi*. Evidence of *H. Pylori* infection also presents an increased risk of acquiring typhoid fever. 1- 5% of patients become chronic carriers harboring *S. typhi* in the gallbladder (3).

Intended Use

A rapid test for the qualitative detection of IgG and IgM antibodies to *Salmonella typhi* (*S.typhi*) in human whole blood, serum or plasma. For professional *in vitro* diagnostic use only.

Test Principle

The Typhoid Rapid Test Cassette is a qualitative, membrane-based immunoassay for the detection of antibodies (IgG and IgM) to *Salmonella typhi (S.typhi)* in human whole blood, serum/plasma. The diagnostic test cassette consists of two components: an IgG component and an IgM component. The IgG line region is pre-coated with reagents for the detection of anti-*S. typhi* (IgG). The IgM line region is pre-coated with monoclonal anti human IgM for detection of anti-*S. typhi* (IgM). During testing, a 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(4).

The immunocomplex thus formed migrates by capillary action. If the present antibodies in specimen are of IgG types, the immunocomplex is then captured by the pre-coated reagents on the membrane, forming a colored IgG line, indicating a *S. typhi* IgG positive test result. If the present antibodies in the specimen are of IgM type, the immunocomplex would be captured on the membrane by the pre-coated anti-human IgM antibody, forming a colored IgM line, indicating a *S. typhi* IgM positive test result. Absence of any T 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.

Warnings and Precautions

1. Read these Instructions for Use completely before performing the test. Failure to follow the instructions could lead to inaccurate test results.
2. Do not use if the pouch is damaged or broken.
3. Test is for single use only. Do not reuse under any circumstances.
4. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. Do not open the sealed pouch, unless ready to conduct the assay.
7. Do not use expired devices.
8. Bring all reagents to room temperature (15-30°C) before use.
9. Do not use the components in any other type of test kit as a substitute for the components in this kit.
10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.

Reagent Preparation and Storage Instructions

All reagents are ready to use as supplied. Store unused test devices unopened at 2-40°C. If stored at 2-8°C, ensure that the test device is brought to room temperature (15-30°C) before opening. The test device is stable through the expiration date printed on the pouch. Do not freeze or expose the kit to temperatures above 40°C.

Specimen Collection and Handling

Specimen to be tested should be obtained and handled by standard methods for their collections.

1. **Serum:** allow the blood to clot, then centrifuge to separate the serum.
2. **Plasma:** collect the whole blood into the tube containing anticoagulants such as heparin, citrate, or EDTA. Centrifuge the blood and separate the plasma
3. **Whole blood:** Fresh blood from finger prick/puncture may be used as a test specimen for collection of whole blood as a test specimen

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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 3 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 2 days of collection.
5. Do not freeze whole blood specimens.
6. Whole blood collected by fingerstick should be tested immediately.
7. Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.
8. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

Materials Required but not provided

1. Timer or Stopwatch
2. PPE and other consumables for collection and disposal of samples

Limitations of Test

1. The assay procedure and the test result interpretation must be followed closely when performing the assay. Failure to follow the procedure may give inaccurate results.
2. The Typhoid IgG/IgM Rapid Test is limited to the qualitative detection of antibodies to *S.typhi* in human whole blood, serum or plasma. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable anti-*S. typhi* antibodies. However, a negative test result does not preclude the possibility of exposure to *S. typhi*.
4. A negative result can occur if the quantity of *anti-S. typhi* antibodies present in the specimen are 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.
5. If the symptom persists, while the result from Typhoid IgG/IgM Rapid Test is negative or non-reactive, it is recommended to re-sample the patient a few days late or test with an alternative test method, such as bacterial culture method.
6. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factors may affect expected results.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

Procedure

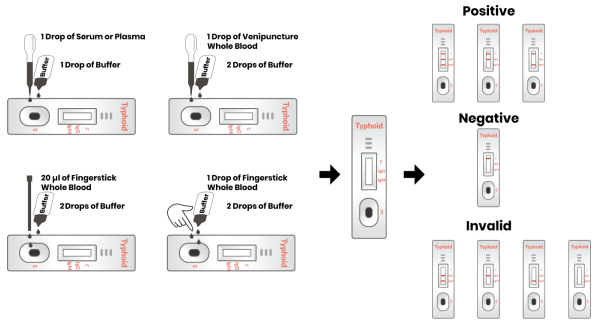
1 Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch. Prior to testing.

2 Place the test cassette on a clean and level surface.

- **For Serum or Plasma specimen**: Hold the dropper vertically and transfer 1 drop of serum/plasma (approximately 25µl) to the specimen well of test Cassette, then add 1 drop of buffer (approximately 40µl) and start the timer. Avoid trapping air bubbles in the specimen well. See the illustration below.
- **For Venipuncture Whole Blood specimen:** Hold the dropper vertically and transfer 1 drop of whole blood to the specimen well, then add 2 drops of buffer (approximately 80µl), and start the timer. See illustration below.
- **For Fingerstick Whole Blood specimen**: To use a capillary tube: Fill the capillary tube and transfer approximately 20µl of fingerstick whole blood specimen to the specimen area of test cassette, then add 2 drops of buffer (approximately 80µl) and start the timer. See illustration below.

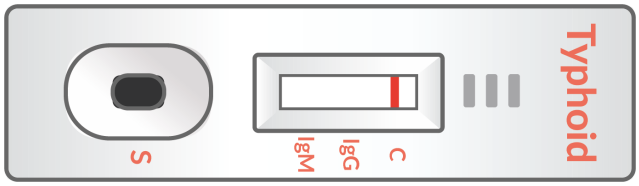
3 Wait for the colored line(s) to appear. The result should be read in 15 minutes.

4 Do not interpret the results after 15 minutes.



Interpretation of results

NEGATIVE RESULT: One colored line appears in the control line region (C). No line appears in the test line regions (IgM and IgG)



POSITIVE RESULT*: Two or three lines appear. One colored line should always appear in the control line region (C) and another

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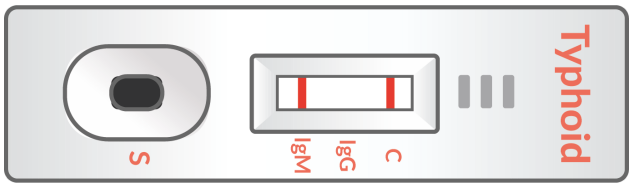
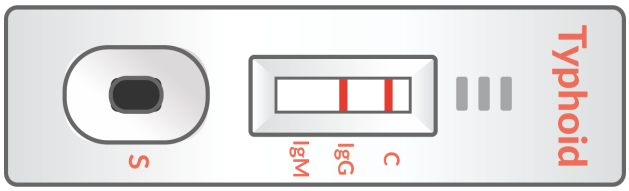
one or two apparent colored line(s) should be in the test line region(s) (IgM and/or IgG).

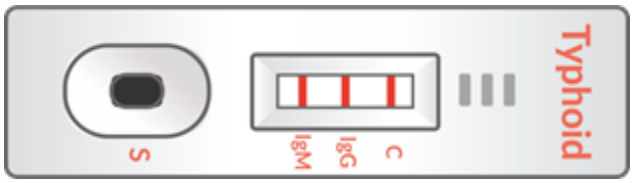
IgM Positive*: Along with a line in Control region (C), a line appears in IgM region. It indicates a positive Test result for antibodies to *S. typhi* (Isotype IgM) and is probably indicative of primary Typhoid infection.



IgG Positive*: Along with a line in Control region (C), a line appears in IgG region. It indicates a positive Test result for antibodies to *S. typhi* (Isotype IgG) and is indicative of secondary Typhoid infection.

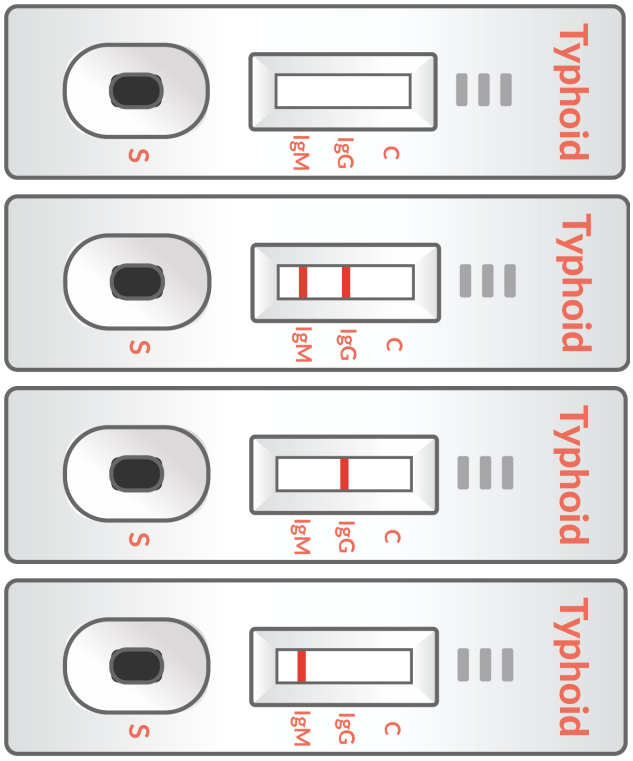


IgG and IgM Positive*: The colored line in the control line region (C) appears and two colored lines should appear in test line regions IgG and IgM. The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies and is indicative of secondary Typhoid infection.



***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.

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 your local distributor.



Quality Control

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.

References

1. Walper, S.A., Lasarte Aragonés, G., Sapsford, K.E., Brown III, C.W., Rowland, C.E., Breger, J.C. and Medintz, I.L., 2018. Detecting biothreat agents: From current diagnostics to developing sensor technologies. *ACS sensors*, *3*(10), pp.1894-2024.
2. https://www.who.int/news-room/fact-sheets/detail/typhoid
3. Gal-Mor, O., 2019. Persistent infection and long-term carriage of typhoidal and nontyphoidal Salmonellae. *Clinical microbiology reviews*, *32*(1), pp.e00088-18.
4. Ong, P.S., Yusof, N.A., Bwatanglang, I.B., Rashid, J.I., Nordin, N. and Azmi, I.A., 2018. Impact of nanotechnology on diagnosis and therapy in biomedical industry. In *Handbook of nanomaterials for industrial applications* (pp. 662-695). Elsevier.

Technical Assistance

For customer support, please contact our Technical Support:
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