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Salmonella typhi IgG/IgM Ab Rapid Test Kit (Serum/Plasma/Whole blood)

QBL/SAL/RPT_38

The *Salmonella typhi* IgG/IgM Ab Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to *Salmonella typhi* in human serum/plasma/whole blood specimens.

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
01 Test	PTYB 01
05 Tests	PTYB 05
10 Tests	PTYB 10
25 Tests	PTYB 25
50 Tests	PTYB 50

CLINICAL SIGNIFICANCE

Typhoid fever and paratyphi fever are bacterial infections caused by Salmonella Typhi and paratyphoid A, B, C respectively, which is transmitted through the ingestion of tainted food and water. World-wide an estimated 17 million cases and 600,000 associated deaths occur annually. Patients who are infected with HIV are at significantly increased risk of clinical infection. 1-5% of patients become chronic carriers harboring S. typhi in the gallbladder. The clinical diagnosis of infections depends on isolation of S. typhi and paratyphi from blood, bone marrow or a specific anatomic lesion. In facilities that cannot afford to perform this complicated and time-consuming procedure, Filix-Widal test is used to facilitate diagnosis. However, many limitations lead to difficulties in the interpretation of the Widal test in contrast, the Typhoid IgG/IgM Rapid Test is a simple, fast laboratory test that simultaneously detects and differentiates IgG and IgM antibodies to S. typhi and paratyphi antigen thus aiding in the determination of current or previous exposure to S. typhi and paratyphi. IgM positive or IgM /IgG both positive suggest current infection, while IgG positive suggests late stage of infection, or previous infection, or latent infection.

PRINCIPLE

Typhoid IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy-colored conjugate pad containing recombinant H antigen and O antigen conjugated with colloid gold (HO conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing two test bands (G and M bands) and a control band (C band). The M band is pre-coated with monoclonal anti-human IgM for the detection of IgM anti-S. typhi and paratyphi, G band is pre-coated with reagents for the detection of IgG anti-S. typhi and paratyphi, and the C band is pre-coated with goat anti rabbit IgG.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the test specimen migrates by capillary action across the test cassette. IgM antibodies if present in the patient specimen will bind to the HO conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a burgundy-colored M band, indicating a S. typhi or paratyphi IgM positive test result. IgG antibodies if present in the patient specimen will bind to the HO conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a burgundy-colored G band, indicating a S. typhi or paratyphi IgG positive test result. Absence of any test bands (M and G) suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy-colored band of the immunocomplex goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid and the specimen must be retested with another device

KIT COMPONENTS

• Test Cassettes • Droppers • Buffer • Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

• Specimen Collection Containers • Centrifuge (For plasma only) • Timer

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

The S.typhi IgG/IgM Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum and plasma specimen.

- **Serum (S):** Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by vein puncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
- **Plasma (P):** Collect the whole blood into a collection tube (containing anticoagulants such as EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium) by vein puncture and then centrifuge blood to get plasma specimen.
- **Whole Blood (WB):** Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.

DIRECTIONS FOR USE

Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.
3. **For Serum or Plasma specimen**: 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 25 µL) to the specimen well, then add 1 drop of buffer (approximately 40 µL) and start the timer
4. **For Venipuncture Whole Blood specimen**: Hold the dropper vertically and transfer 1 drop of whole blood (approximately 25µL) to the specimen well, then add 1 drops of buffer (approximately 40 µL) and start the timer
   For Fingerstick Whole Blood specimen: Take sample using sample dropper and transfer approximately 25 µL (1 drop) of fingerstick whole blood specimen to the specimen well of test cassette, then add 1 drop of buffer (approximately 40 µL) and start the timer.
5. Wait for the colored line(s) to appear. Read results at 15 minutes.
   Note: Do not interpret the result after 20 minutes.

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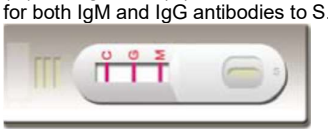
INTERPRETATION OF RESULTS

1) **IgG POSITIVE:** Two distinct red lines appear. The control line (c) and IgG (G) line are visible on the test cassette. This is positive for IgG antibodies to S. typhi.

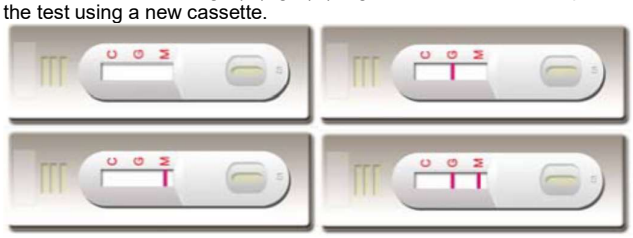
2) **IgM POSITIVE:** IgM Positive the control line (C) and IgM line (M) are visible on the test device. This is positive for IgM antibodies to S. typhi.

3) **IgG/IgM POSITIVE:** IgG and IgM Positive The control line (C), IgM (M) and IgG line (G) are visible on the test device. This is positive for both IgM and IgG antibodies to S. typhi



4) **NEGATIVE:** One distinct red line appears. The control line (c) is the only line visible on the test cassette. No IgM/IgG antibodies were detected. The result does not exclude S. typhi infection.

5) **INVALID:** Control line fails to appear. The test results are INVALID, if no control line (C) is visible, regardless of the presence or absence of line in the IgM(M)/IgG(G) region of the cassette. Repeat the test using a new cassette.



Quality Control

Internal procedural controls are included in the test individually. A colored line appearing in control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test

1. The test procedure, precautions and interpretation of results for this test must be followed when testing.
2. The S. typhi IgG/IgM Ab Rapid Test (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of antibodies for S. typhi in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of S. typhi can be determined by this qualitative test.
3. A negative result can occur if the quantity of the anti- S. typhi antibodies present in the specimen is below the detection limits of the assay or the antibodies that are detected are not present during the stage of disease. Other clinically available tests are required. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

Performance characteristics

A total of 350 specimens were collected from susceptible subjects and tested by S. typhi IgG/IgM Ab Rapid Test and a commercial S. typhi IgG and IgM Ab EIA Test as reference. Comparison for all subjects is showed in the following table.

	Clinical performance for IgM Test		
IgM EIA	Positive	Negative	Total
Positive	50	0	50
Negative	0	230	230
Total	50	230	280

	Clinical performance for IgG Test		
IgG EIA	Positive	Negative	Total
Positive	70	0	70
Negative	0	230	230
Total	70	230	300

IgM Relative Sensitivity: 100% (95% CI: 98.8-99.9%), IgG Relative Sensitivity: 100% (95% CI: 98.8-99.9%), Relative Specificity: 100% (95% CI: 98.8-99.9%), Overall Agreement: 100% (95% CI: 98.8-99.9%)

Cross-reactivity

The S. typhi IgG/IgM Ab Rapid Test Cassette (Serum/Plasma/Whole Blood) has been tested HBsAg, anti-HIV, anti-HCV, anti-RF, anti-Spyhilis, anti-H.pylori, anti-Toxo IgG positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the S. typhi IgG/IgM Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed. Caffeine: 20mg/dl, Creatine: 200mg/dl, Acetylsalicylic Acid: 20mg/dl, Gentisic Acid: 20mg/dl, Albumin: 2000mg/dl, Ascorbic Acid: 2g/dl, Hemoglobin: 1000mg/dl, Oxalic acid: 600mg/dl, Bilirubin: 1000mg/dL, Triglycerides: 1600mg/dl & Cholesterol: 800mg/dl

BIBLIOGRAPHY

1. Ivanoff BN, Levine MM, Lambert PH. Vaccination against typhoid fever: present status. Bulletin of the World Health Organization 1994; 72: 957-71.
2. Gotuzzo E, Frisancho O, Sanchez J, Liendo G, Carillo C, Black RE, Morris JG. Association between the acquired immunodeficiency syndrome and infection with Salmonella typhi or Salmonella paratyphi in an endemic typhoid area. Archives of Internal Medicine 1991; 151: 381-2.

GLOSSARY OF SYMBOL

	Consult Instruction for Use
REF	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2, Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.

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