# TYPHOID CARD (IgG/IgM)

**IMMUNOPAK**

(Serum/Plasma)

Last update 04-2026

Ref. RDT-TYP.111, 25 Test

## INTENDED USE

The Typhoid IgG/IgM Rapid Test is a lateral flow immunoassay for the simultaneous detection and differentiation of anti-Salmonella typhi (S. typhi) IgG and IgM in human serum / plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with S. typhi. Any reactive specimen with the Typhoid IgG/IgM Rapid Test must be confirmed with alternative testing method(s).

## INTRODUCTION

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. 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 carrier harboring S. typhi in the gall bladder.

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 can not afford to perform this complicated and time-consuming procedure, Felix-Widal test is used to facilitate the 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 and rapid laboratory test. The test simultaneously detects and differentiates the IgG and the IgM antibodies to S. typhi specific antigen thus to aid in the determination of current or previous exposure to the S. typhi.

## PRINCIPLE

The Typhoid IgG/IgM Rapid Test is a lateral flow immunochromatographic assay. The test cassette consists of: 1) a pink-purple colored conjugate pad containing recombinant S. typhi H antigen and O antigen conjugated with colloid gold (Typhoid conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing two test region (Test line M and G) and a control region (control line). The test line 'M' is pre-coated with monoclonal anti-human IgM for the detection of IgM anti-S. typhi, test line 'G' is pre-coated with monoclonal anti-human IgG for the detection of IgG anti-S. typhi , 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. Anti-S. typhi IgM if present in the patient specimen will bind to the Typhoid conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody at test region 'M', forming a pink-purple line at 'M' region, indicating a S. typhi IgM positive test result.

Anti-S. typhi IgG if present in the patient specimen will bind to the Typhoid conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a pink-purple line at test region 'G', indicating a S. typhi IgG positive test result. Absence of any pink-purple line at test region (M and G) suggests a negative result. The test contains an internal control (control line) which should exhibit a pink-purple line of the immunocomplex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the test region. Otherwise, the test result is invalid and the specimen must be retested with another device.

## PRESENTATION

| | 25 Tests |
|---|---|
| Typhoid Card (IgG/IgM) | 25 Cards |
| Assay Buffer | 1 bottle |

## PRECAUTION

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15°C-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolysed blood specimen for testing. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as biohazardous waste.
10. Handle the Negative and Positive Control in the same manner as patient specimens.
11. The testing results should be read within 20 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 20 minutes may give erroneous results.
12. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

## STORAGE AND STABILITY

Typhoid IgG/IgM test card should be stored at 2°C-40°C. The card may be stored at room temperature but not exceeding 40°C in the original sealed pouch. The shelf life or expiry of the card is printed on Pouch as well as carton label. The test kit should be kept away from direct sunlight, moisture and heat.

## SPECIMEN COLLECTION AND STORAGE

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

**Plasma**

1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer® ) by veinpuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into new pre-labeled tube.

**Serum**

1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.

Test the specimens as soon as possible after collecting. Store specimens at 2-8°C if not tested immediately.

Store specimens at 2°C-8°C up to 5 days. The specimens should be frozen at -20°C for longer storage.

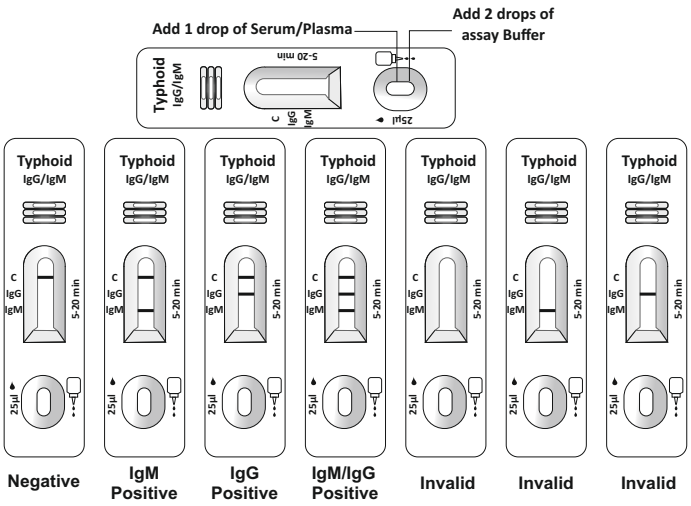
Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

## PROCEDURE

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
2. When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
3. Fill the pipette dropper with the specimen. Holding the dropper vertically, add 1 drop (25µl) of specimen (Serum/Plasma) into the sample well making sure that there are no air bubbles. Then add 2 drops (60µl) of Assay buffer immediately.
4. Read the results within 20 minutes. Positive results can be visible in as short as 1 minute. Don't read result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

## INTERPRETATION OF TEST RESULTS




- **NEGATIVE:** If only the C band is present, the absence of any pink-purple color in the both test bands (M and G) indicates that no anti-S. typhi antibody is detected in the specimen. The result is negative.
- **IgM POSITIVE:** In addition to the presence of C band, if only test band at 'M' region is developed, the test indicates for the presence of anti- S. typhi IgM in the specimen. The result is IgM positive or reactive.
- **IgG POSITIVE:** In addition to the presence of C band, if only test band at 'G' region is developed, the test indicates for the presence of anti- S. typhi IgG in the specimen. The result is IgG positive or reactive.
- **IgM/IgG POSITIVE:** In addition to the presence of C band, both test band at 'M' region and test band at 'G' region are developed, the test indicates for the presence of anti-S. typhi IgM and IgG in the specimen. The result is both IgM and IgG positive or reactive.
- **INVALID:** The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques may be reason for control line failure. Repeat the test using a new test device.

Samples with positive or reactive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

## Limitations of Test

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to S. typhi in serum or plasma from individual subjects. 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 serum or plasma. The intensity of the test band does not have linear correlation with the antibody titer in the specimen .
3. The Typhoid IgG/IgM Rapid Test also detects para-typhi antibodies.
4. 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.
5. 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.
6. If the symptom persists, while the result from Typhoid IgG/IgM Rapid Test is negative or non-reactive result, it is recommended to re-sample the patient few days late or test with an alternative test method, such as bacterial culture method.
7. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
8. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

## References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