# One Step Typhoid IgG/IgM Test (Whole Blood/Serum/Plasma)

FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY

**Intended Use**
The One Step Typhoid IgG/IgM Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to Typhoid virus in Whole Blood /Serum / Plasma to aid in the diagnosis of Typhoid viral infection.

**Summary**
Typhoid fever is a bacterial disease, caused by Salmonella typhi. It is transmitted through the ingestion of food or drink contaminated by the faeces or urine of infected people. Symptoms usually develop 1–3 weeks after exposure, and may be mild or severe. They include high fever, malaise, headache, constipation or diarrhoea, rose-coloured spots on the chest, and enlarged spleen and liver. Healthy carrier state may follow acute illness. One step Typhoid IgG/IgM Test is a simple, visual qualitative test that detects Typhoid antibodies in human Whole Blood/serum/plasma. The test is based on immunochromatography and can give a result within 15 minutes.

**Principle**
The One Step Typhoid IgG/IgM Test is a qualitative membrane strip based immunoassay for the detection of Typhoid antibodies (IgG and IgM) in Whole Blood /Serum / Plasma. The test device consists of: 1) a burgundy coloured conjugate pad containing Typhoid recombinant envelope antigens conjugated with Colloid gold (Typhoid conjugates) and rabbit IgG-gold conjugates,2) a nitrocellulose membrane strip containing two test bands (T1 and T2 bands) and a control band (C band). The T1 band is pre-coated with the antibody for the detection of IgG anti-Typhoid, T2 band is coated with antibody for the detection of IgM anti-Typhoid, 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 test cassette, the specimen migrates by capillary action across the cassette. IgM anti-Typhoid, if present in the specimen, will bind to the Typhoid conjugates. The immunocomplex is then captured by the reagent pre-coated on the T2 band, forming a burgundy coloured T2 band, indicating a Typhoid IgM positive test result and suggesting a fresh infection. IgG anti-Typhoid if present in the specimen will bind to the Typhoid conjugates. The immunocomplex is then captured by the reagent coated on the T1 band, forming a burgundy coloured T1 band, indicating a Typhoid IgG positive test result and suggesting a recent or repeat infection. Absence of any T bands (T1 and T2) suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy coloured band of the immunocomplex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the colour development on any of the T bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

**Storage and Stability**
- Store as packaged in the sealed pouch at room temperature or refrigerated (4-30℃ or 40-86℉). The test device is stable through to the expiration date printed on the sealed pouch.
- The test must remain in the sealed pouch until used.

**Additional Special Equipment**

**Materials Provided**
- Test device
- Buffer (for whole blood only)
- 2 x Single Use Lancets
- Alcohol Wipe
- Pipette
- Package insert
- Capillary Tube

***Please note that the blood sampling equipment (lancets, capillary tube & alcohol wipe) are only included in the 1 test pack***

**Materials that may be required but are not provided**
- Timer
- Specimen collection containers
- Centrifuge

**Precautions**
- For professional in vitro diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- 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.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Follow standard biosafety guidelines for handling and disposal of potential infective material.
- Humidity and temperature can adversely affect results.

**Specimen Collection and Preparation**
1. The One Step Typhoid IgG/IgM Test can be performed using on Whole Blood / Serum / Plasma.
2. To collect whole blood, serum or plasma specimens follow regular clinical laboratory procedures.
3. For immediate near patient testing, please follow the finger prick testing procedure overleaf.
4. Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear non-haemolysed specimens
5. 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℃ for up to 3 days. For long term storage, specimens should be kept below -20℃. Whole blood should be stored at 2-8℃ if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.
6. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

**Test Procedure**
Allow the test, specimen, buffer and/or controls to reach room temperature 15-30℃ (59-86℉) prior to testing.

1. Wash hands with soap and rinse with warm water.
2. Remove the test device from the sealed pouch and use it as soon as possible.
3. Place the test device on a clean and level surface.

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4. Medical professionals should obtain a 35µl blood sample following their own clinical methods and proceed to point 9. Alternatively, take the safety lancet holding the body and twist off the protective cap until you feel it has been separated from the device. Don't pull, just twist.

5. Clean the end of the forefinger or middle finger with an alcohol wipe. Massage the finger to enhance the blood flow.

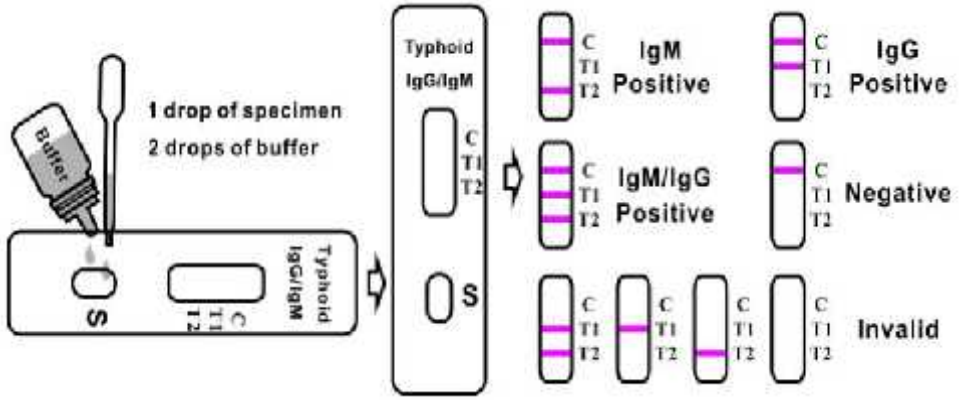
6. Press the safety lancet platform firmly against the chosen site.

7. Keeping the hand down, massage the finger to obtain a blood drop.

8. Without pressing the bulb, put the capillary tube in contact with the blood drop. The blood will migrate into the tube by capillary action. Fill to the black line indicated on the capillary tube trying to avoid getting any air bubbles in the tube.

If necessary you may massage your finger again or use the second provided lancet to obtain more blood in order to fill the capillary tube.

9. Transfer 1 drop of the collected blood (approximately 35µl) to the specimen well (S) of the test device, then add 2 drops of buffer (approximately 70µl) and start the timer. See illustration below:




10. Wait for the coloured line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.

11. Replace the protective cap and then dispose of lancet in a suitable container.

**Notes**
Applying sufficient amount of specimen is essential for a valid test result. If migration (the wetting of membrane) is not observed in the test window after one minute, add one more drop of buffer (for whole blood) or specimen (for serum or plasma) to the specimen well.

**Interpretation of Results**
**Positive:** Control line and at least one test line appear on the membrane. The appearance of T2 test line indicates the presence of Typhoid specific IgM antibodies. The appearance of T1 test line indicates the presence of Typhoid specific IgG antibodies. And if both T1 and T2 line appear, it indicates that the presence of both Typhoid specific IgG and IgM antibodies. The lower the antibody concentration is, the weaker the result line is.

**Negative:** One coloured line appears in the control region (C). No apparent coloured line appears in the test line region.

**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.

**Limitations**
The One Step Typhoid IgG/IgM Test is for in vitro diagnostic use only. The test should be used for the detection of Typhoid antibodies in Whole Blood /Serum / Plasma specimens only. Neither the quantitative value nor the rate of increase in Typhoid antibodies can be determined by this qualitative test.
As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
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 Typhoid infection.

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