

Typhoid IgG/IgM Rapid Test

Only for in vitro use in clinical laboratory

(IVD) Intended Use

Salmonella typhi IgG/IgM Rapid Test Kit is a qualitative immunochromatographic assay for the detection of IgG and IgM antibodies produced against Salmonella Typhi in human blood/Serum.

Salmonella typhi IgG/IgM Rapid Test is only intended for initial screening and reactive samples should be confirmed by a supplemental assay such as ELISA or Widal test.

Clinical Significance

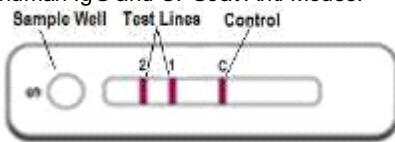
Typhoid fever, also known as enteric fever, is a potentially fatal multisystemic illness caused primarily by *Salmonella typhi*. The protein manifestations of typhoid fever make this disease a true diagnostic challenge. Symptoms include fever, malaise, diffuse abdominal pain, and constipation. Untreated, typhoid fever is a grueling illness that may progress to delirium, obtundation, intestinal hemorrhage, bowel perforation, and death within one month of onset. Survivors may be left with long-term or permanent neuropsychiatric complications.

Typhoid fever is a global health problem. Its real impact is difficult to estimate because the clinical picture is confused with those of many other febrile infections. Additionally, the disease is underestimated because there are no bacteriology laboratories in most areas of developing countries. These factors are believed to result in many cases going undiagnosed. It has been estimated that approximately 17 million cases of typhoid fever and 600 000 associated deaths occur annually.

Euro *Salmonella typhi* IgG/IgM Rapid test utilizes Anti human IgG and Anti human IgM as the capture molecules. *Salmonella Typhi* O and H antigen colloidal gold conjugate is used as the detection antibody for *Salmonella Typhi* IgG/IgM rapid test.

Principle

Salmonella typhi IgG/IgM Rapid test works on chromatographic immunoassay. Basic components of each test strip includes: a) Conjugate pad which contains colloidal gold conjugate; b) a nitrocellulose membrane strip containing two lines T2: Anti human IgM, T1: Anti human IgG and C: Goat Anti Mouse.



Test sample that is added to the sample well (S), with adequate amount of buffer migrates from the sample pad along the conjugate pad where *Salmonella Typhi* specific IgG/IgM present in the sample will bind to Colloidal Gold conjugate to form a complex. The sample then continues to migrate across the membrane until it reaches the capture zones where the complex accordingly will bind to the immobilized Anti Human IgG/IgM (on test lines) producing visible lines on the membrane. If the respective antibody is not present in the sample, no reaction occurs in the capture zones and no test line is formed. The sample then migrates further along the strip until it reaches the control zone, where it produces another visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended.

Kit Components

1. Each test pouch contains :
 - a. One test card and dropper
 - b. Desiccant
2. Assay Diluent- In dropper bottle
3. Instruction Leaflet

Storage and Stability

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

Precaution and Warning

1. Use within 10 minutes after opening pouch.
2. Do not touch result window.
3. Use only the buffer supplied along with the kit.
4. Do not mix components from different kits.
5. Use only for in-vitro diagnostic purpose.
6. Treat all specimens, used tests and other contaminated materials as infectious, and dispose accordingly.
7. Do not use with hemolytic, lipemic or bacterially contaminated specimen.
8. Do not use with specimen containing precipitates

Materials Required but not provided

Specimen Collection tubes, Centrifuge, Timer

Specimen Collection and Preparation

Blood, Serum/plasma

Blood:

Collect the whole blood using a syringe or vacutainer into a container containing anticoagulants such as heparin, EDTA or sodium citrate by venipuncture.

Serum:

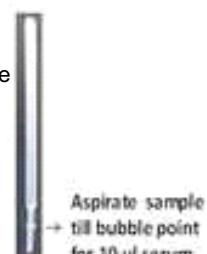
Collect the whole blood using a syringe or vacutainer (NOT containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Leave the syringe or vacutainer, preferably at an angle, to settle for 30 minutes. Once blood coagulates, centrifuge the blood to get serum specimen as supernatant.

- If the specimen is not used for testing immediately, they should be refrigerated at 2~8°C.
- For storage period longer than 5 days, freezing is recommended. Store at -20°C
- The specimen should be brought to room temperature prior to use.

Treat the specimen as infectious and handle with standard biosafety measures.

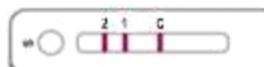
Procedure:

1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 10 µl of Whole Blood/ Serum/Plasma to the Sample well "S"
3. When the sample is fully absorbed, add 2 drops of the diluent provided with the assay to the sample hole.
4. Wait for 15 minutes and interpret results. All results where control band does not appear are considered invalid.



Results

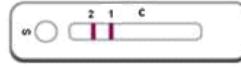
Typhoid IgG & IgM Positive



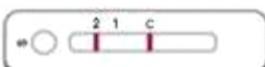
Typhoid IgG Positive



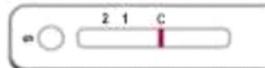
Invalid



Typhoid IgM Positive



Typhoid Negative



Reference:

Sensitivity and specificity of typhoid fever rapid antibody tests for laboratory diagnosis at two sub-Saharan African sites.

Karen H Keddy, Arvinda Sooka, Maipi E Letsoalo, Greta Hoyland, Claire Lise Chaignat, Anne B Morrissey & John A Crump

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