Salmonella Ab Rapid Test

Cat. No. S007-07

INTENDED USE

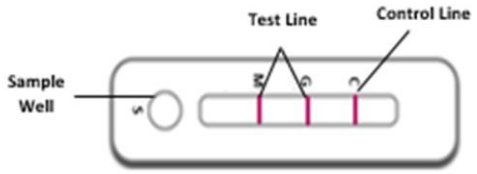
Sensit Salmonella typhi IgG/IgM Rapid Test Kit is a qualitative immuno chromatographic assay for the detection of IgG and IgM antibodies produced against Salmonella Typhi in human blood/Serum.
Sensit Salmonella typhi IgG/IgM Rapid Test is only intended for initial screening and reactive samples should be confirmed by a supplemental assay such as ELISA or widal test.

SUMMARY &TEST DESCRIPTION

Typhoid fever, also known as enteric fever, is a potentially fatal multisystemic illness caused primarily by Salmonella typhi. The protean 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.
Sensit 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.

TEST PRINCIPLE

Sensit Salmonella typhi IgG/IgM Rapid test works on chromatographic immunoassay. The test provides a differential detection of anti-S. typhi-lgG and anti-S. typhi -lgM antibodies and can be used for the presumptive distinction between a current, latent and/or carrier S. typhi infection. 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 antibody.



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 a 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.

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REAGENTS & MATERIALS PROVIDED

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

STORAGE & 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 & 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

SAMPLE PREPARATION

- Specimen: Blood, Serum

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 0 C
- The specimen should be brought to room temperature prior to use.

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

TEST PROCEDURE

1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 35 µl of Whole Blood/Serum to the sample well “S”.
3. When the sample is fully absorbed, add 1 drop of the diluent provided with the assay to the sample hole.
4. Wait for 10-15 minutes and interpret results. All results where control band does not appear are considered invalid.

INTERPRETATION OF TEST RESULT

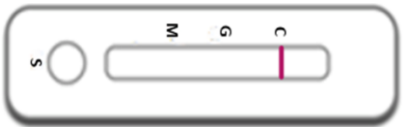
IMPORTANT NOTE: INTERPRET THE RESULTS WITH RESPECT TO THE WRITINGS 'C' , 'M,' &'G' ON THE DEVICE AS SHOWN BELOW. DONOT CONSIDER 'C' & 'T')

Typhoid IgG Positive: A clear pink control band ("C") and a detectable test band ("IgG") appear, indicating the presence of Typhoid specific IgG antibody in the sample, probably a secondary Typhoid infection.

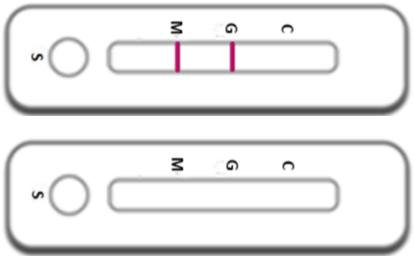
Typhoid IgM Positive: A clear pink control band ("C") and a detectable test band ("IgM") appear, indicating the presence of Typhoid specific IgM antibody in the sample, probably a primary Typhoid infection.

Typhoid IgG & IgM Positive: A clear pink control band ("C") and detectable test bands ("IgG and IgM") appear, indicating the presence of Typhoid IgG or IgM antibodies in the sample, probably a secondary Typhoid infection.

Negative: A pink colored band appears only at control region ("C") indicating the absence of Typhoid antibodies in the sample.



Invalid: If the control line fails to appear within the result window, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be retested.



DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in Typhoid IgG/IgM Rapid Test for single-step detection of Typhoid IgG/IgM antibodies are the most common signs appearing on medical devices and their packaging. They are explained in more detail in the European Standards EN 980: 2008 and INTERNATIONAL Standard ISO 15223-1:2016

Key to symbols used			
	Manufacturer		Expiration/use by date
	Do not reuse		Date of manufacture
	Consult IFU [Instructions For Use]	LOT	Batch code
	Temperature limitation 2-30°C	IVD	In Vitro diagnostic medical device
Σ X	Contains sufficient for 'X ' kits		Do not use if package is damaged
REF	Catalogue No		Keep dry

Please read the user manual carefully before operating to ensure proper use

Manufactured by,

ubio Biotechnology Systems Pvt Ltd
Plot # 15A,Biotechnology Zone
Kalamassery, Cochin, Kerala, India 683503
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