S. Typhi IgG/IgM Antibody
Antibody Detection Card Test
Serum/Plasma/Whole Blood

INTENDED USE:

S. Typhi IgG/IgM device is rapid and qualitative test for the detection of IgG and IgM Antibody against S. typhi in human Serum and Plasma or whole blood.

PRINCIPLE OF THE TEST:

After addition of the sample and the assay buffer to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with recombinant S. Typhi specific antigens and streptavidin. If the sample contains detectable levels of the S. Typhi specific IgM and IgG antibodies, it reacts with the gold conjugated recombinant S. Typhi specific antigens to form a complex. This complex moves further and S. Typhi specific IgM antibodies conjugate complex reacts with anti-human IgM test line and the S. Typhi specific IgG antibodies react with the anti-human IgG antibodies test line on the nitrocellulose membrane area to form coloured band/s. The unbound complex and the Streptavidin conjugated colloidal gold particles move further to the Biotin coated control area to form a coloured band (Control line). The appearance of test line/s and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result. The control line acts as a procedural control. Control line should always appear if the test is performed as per the procedure and reagents are working properly.

MATERIALS PROVIDED:

S. Typhi IgG/IgM kit contains the following items:

1. Test devices individually foil-pouched with a desiccant.
2. Assay Solution.
3. Product insert.

MATERIALS REQUIRED BUT NOT PROVIDED:

1. Specimen collection container/tube.
2. Timer.

PRECAUTIONS:

1. For *in-vitro* diagnostic use only . IVD
2. Wear protective gloves while handling samples and wash hands thoroughly after the test.
3. The presence of humidity may decrease the stability of the reagents. Thus, please carry out the test immediately after removing the device from the foil pouch.
4. Do not use the kit after the expiration date and do not freeze the kit.
5. Dispose all the specimens and kits properly after test, in accordance with GLP.
6. Never use reagents from another kit.
7. Discard the Assay Solution if it is contaminated with bacteria or mold.

SPECIMEN COLLECTION AND STORAGE:

1. Specimen to be tested should be obtained and handled by standard methods for their collections.

A. Serum: allow the blood to clot, then centrifuge to separate the serum.

B. Plasma: collect the whole blood into the tube contained anticoagulants such as heparin, citrate, or EDTA. Centrifuge

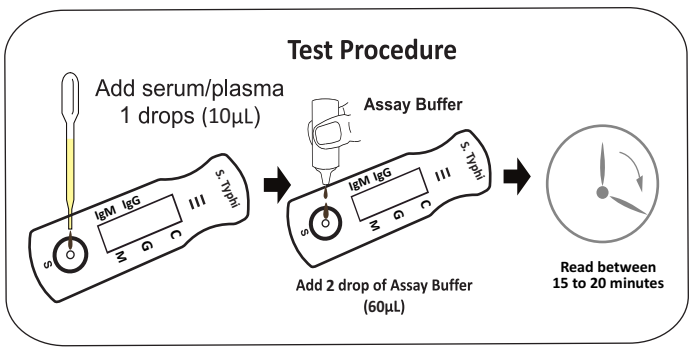
the blood and separate the plasma.

2. All specimens should be tested as soon as they are prepared. If necessary, they may be stored at 2-8˚C for up to 24 hours or at -20˚C for longer periods.

TEST PROCEDURE:

1. Place all specimens, test devices, and Assay Solution and allow them to room temperature prior to testing (15~30 min).
2. Prepare the test device as you need, and then mark the patient's ID onto the device. Please perform the test immediately after removing the device from foil pouch.
3. Dispense one drop (10 µl) of Serum or Plasma and 2 drops (20 µl) of whole blood sample into the sample well (S) in the test device using dropper provided in the kit.
4. Add two drops (60 µl) of Assay Solution into sample well (S).
5. Interpret the test results in 15 to 20 minutes.
6. Do not read the results after 30 minutes.

*Results are invalid after 30 minutes.

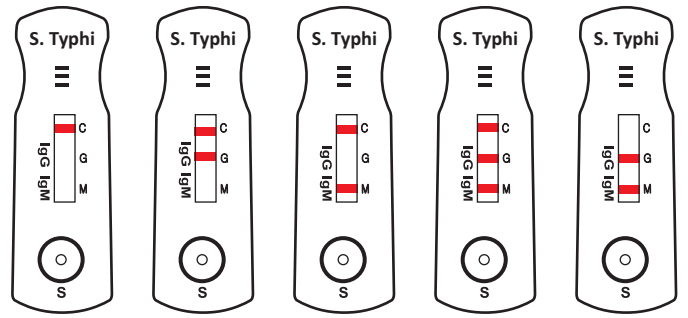


INTERPRETATION OF THE RESUS:

1. **Negative:** If only the control line (C) is visible. It indicates that there are no S. Typhi antibodies detectable in the sample.
2. **IgM Positive:** If along with the control line (C), the band for S. Typhi IgM (M) is also visible. It indicates that the sample

contains detectable levels of S. Typhi IgM antibodies in the sample.

3. **IgG Positive:** If along with the control line (C), the band for S. Typhi IgG (G) is also visible. It indicates that the sample contains detectable levels of S. Typhi IgG antibodies in the sample.
4. **IgG & IgM Positive:** If along with the control line (C), both the bands for S. Typhi IgG (G) and S. Typhi IgM (M) are also visible. It indicates that the sample contains detectable levels of S. Typhi IgG and S. Typhi IgM antibodies in the sample..
5. **Invalid result:** If the control line (C) does not appear. In this case, the test should be repeated following the exact test procedure.



Negative S. Typhi IgG/IgM | IgG Positive S. Typhi IgG/IgM | IgM Positive S. Typhi IgG/IgM | IgG & IgM Positive S. Typhi IgG/IgM | Invalid S. Typhi IgG/IgM

STORAGE & EXPIRATION:

1. S. Typhi IgG/IgM Antibody kit should be stored between 4 to 30°C.
2. Expiry date of this kit is as mentioned on the label.

QUALITY CONTROL:

A procedural control is included in the test. A coloured line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking 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:

S. Typhi IgG/IgM is designed for primary screening test of IgG and IgM antibodies against S. typhi (not to S. paratyphi species). Although, this kit can provide fast and easy way to get a result, however, it does not completely exclude the possibility of false positive or false negative result caused by various factors. Results obtained should be correlated clinically.

PERFORMANCE CHARACTERISTICS:

Relative Sensitivity: 97.3%

Relative Specificity: 99.3%

REFERENCES:

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 in an endemic typhoid area. Archives of Internal Medicine 1991; 151: 381-2.

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