Typhoid IgG/IgM Test Device

Rapid Test for qualitative detection of IgM & IgG Antibody of S.typhi in human serum / plasma / whole blood

40 Tests

INTENDED USE

TYPHOID IgG / IgM TEST DEVICE is an in vitro diagnostic rapid test based on the principle of immunochromatography on a membrane for differential detection of IgM and IgG antibodies to *Salmonella typhi* (S. typhi) in human serum, plasma or whole blood. For professional use only.

SUMMARY

Typhoid fever is caused by gram negative bacteria *Salmonella typhi* transmitted through ingestion of contaminated food or water. Typhoid fever is characterized by prolonged fever, headache, bowel dysfunction, malaise and in early stage cough is also common. In chronic cases the bacteria is detected in the stool even after an year of the onset of disease. Typhoid is one of the major cause of morbidity and mortality worldwide. Immuno compromised patients and patients with *Helicobacter pylori* infection are at a high risk. Diagnosis of Typhoid fever at an early stage is of great importance not only for etiological reasons but to identify potential carriers and prevent acute typhoid fever outbreaks. Detectable levels of antibodies appear after the onset of disease. During the initial acute phase in the second week of infection IgM antibodies are detected and persists for four months. IgG antibodies are detected thereafter and remain in the blood for about two years . The detection of IgM reveals initial acute phase of infection, detection of both IgG and IgM suggests the middle phase of infection , while the detection of increased level of specific IgG suggests a potential carrier and high rate of typhoid transmission.

Isolation of serotype Typhi from blood, urine, or stool is the most reliable means of confirming an infection. The most commonly used Widal test for testing of typhoid has certain limitations , the interpretation of the test is done against a base line level of titer in the same geographical area, but this cannot be used as a thumb rule as different endemic or non–endemic areas will have different titers. Paired sera with a four fold rise in titer is needed for a meaningful interpretation of results. The limitations of Widal test lead to the development of rapid tests that can qualitatively detect and differentiate antibodies.

TEST PRINCIPLE

TYPHOID IgG / IgM TEST DEVICE is a two site sandwich immunoassay based on the principle of immunochromatography on a membrane. The test device comprises of two membrane assemblies , one for IgM detection and the other for IgG detection. The IgM detection test assembly has a conjugate pad of anti human IgM colloidal gold conjugate, nitrocellulose membrane predispensed with S. typhi antigen (LPS) at test line region 'T' and a control line protein at control line region 'C'. The IgG membrane assembly has a conjugate pad of Protein - A colloidal gold conjugate, nitrocellulose membrane predispensed with S. typhi antigen (LPS) at test line region 'T' and a control line protein at control line region 'C'.

As the test sample is added to sample well (S), it flows through the respective membrane test assemblies. The anti human IgM /anti human IgG colloidal gold forms a complex with the S.typhi specific antibodies (IgM/IgG) in the sample, moves along the membrane by capillary action and come in contact with S.typhii specific antigens coated on the test regions (T) leading to the formation of a colored band at the test regions of the respective test assembly, which confirms a positive test result for IgM/IgG test. Absence of this colored band in either of the test region indicates a negative test result. The unreacted conjugate and unbound complex if any moves further up on the membrane and is subsequently immobilized at the control region C predispensed with control line protein, forming a colored band. This control band serves as a procedural control and helps to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

Each kit has

A. 40 tests individually sealed pouches containing:

1. **Double Test Assembly card: IgM Test Assembly:** comprising of a nitro cellulose membrane assembly predispensed with S. typhi antigen (LPS) at test line region 'T', a control line protein at control line region 'C and Conjugate pad containing anti human IgM colloidal gold conjugate. **IgG Test Assembly:** comprising of a nitro cellulose membrane assembly predispensed with S. typhi antigen (LPS) at test line region 'T', control line protein at control line region 'C and Conjugate pad containing Protein - A colloidal gold conjugate
2. Disposable plastic dropper
3. Desiccant pouch.

B. Sample Running Buffer

C. Product insert

MATERIAL REQUIRED BUT NOT PROVIDED

Blood collection tubes, syringes, lancing device, lancets, swabs, gloves and timer etc.

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 2-30°C till the duration of shelf life as indicated on the pouch. Do not freeze. Once the pouch is opened, test card must be used immediately.

PRECAUTIONS

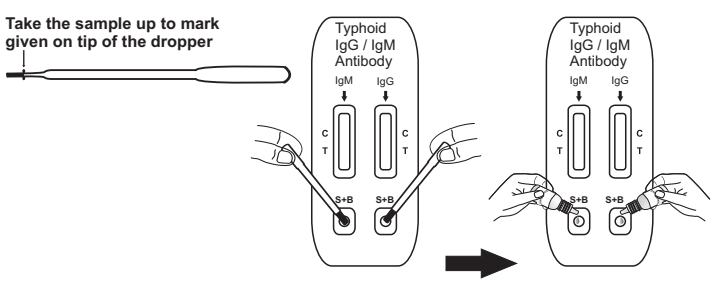
1. For professional use only, not to be used by the general public.
2. The test must be carried out by or under the direction of a registered medical practitioner or by a technician at the request of registered medical practitioner.
3. Bring all reagents and specimen to room temperature before use.
4. Do not pipette any material by mouth.
5. Do not eat, drink or smoke in the area where testing is done.
6. Use protective clothing and wear gloves when handling samples.
7. Use absorbent sheet to cover the working area.
8. Immediately clean up any spills with sodium hypochlorite.
9. Dispose off all the reagents and material used as if they contain infectious agent.
10. Neutralize acid containing waste before adding hypochlorite.
11. Do not use kit after the expiry date.
12. Do not mix components of one kit with another
13. Sample running buffer contains sodium azide (0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build-up in the plumbing.

SPECIMEN COLLECTION AND STORAGE

1. No prior preparation of the patient is required.
2. Collect blood specimen by venipuncture according to the standard procedure.
3. Specimen should be free of particulate matter and microbial contamination.
4. Preferably use fresh sample. However, specimen can be stored refrigerated for 24 hours. For long storage, freeze at -20°C or below. Specimen should not be frozen and thawed repeatedly. Maximum of two freeze/thaw cycles are allowed.
5. Do not use heat inactivated specimen.
6. Specimen containing precipitate or particulate matter should be clarified by centrifugation prior to use.
7. Do not use turbid, lipaemic, haemolysed, clotted or contaminated specimen.

TEST PROCEDURE

1. Bring the sealed pouch to room temperature, if the pouch of the test card is damaged discard the card and take a new one for the test. Open the pouch and remove the test card. Check the color of the desiccant. It should be blue, if it has turned colorless or faint blue, discard the card and use another card.
2. Label the card appropriately with patient identity. Once opened, the card must be used immediately. Refrigerated specimen must be bought to room temperature prior to use.
3. Add **5µl of serum / plasma or 10 µl of whole blood** using micropipette into the S + B well or use the provided disposable plastic dropper filling up specimen to the mark indicated on dropper.

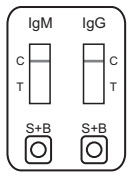


4. Add 2 drops of buffer into S + B well and wait for appearance of coloured lines in the result window. Additional drop of buffer may be added if sample movement is not observed on membrane.
5. Read results within 5-15 minutes. Do not read result after 15 minutes.

INTERPRETATION OF RESULT

Negative:

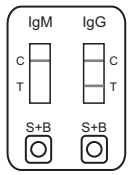
Appearance of only one colored band at control line region 'C'. The result should be considered negative.



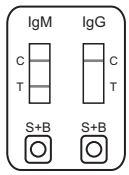
Negative for IgM & IgG

Positive:

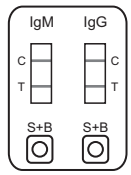
Appearance of two colored bands, one at test region 'T' and other at control line region 'C'. The result should be considered positive.



Negative for IgM Positive for IgG



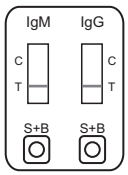
Negative for IgG Positive for IgM



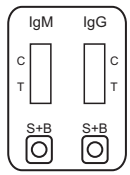
Positive for IgM Positive for IgG

Invalid

Appearance of no colored band at the control region C, the result should be considered as invalid. Repeat the test with a new test card.



Invalid



Invalid

QUALITY CONTROL

The control line serves as an internal control for integrity of reagents. It is recommended to use known positive and negative samples to check performance.

PERFORMANCE CHARACTERISTICS

Internal Evaluation

In an in- house study the performance of TYPHOID IgG / IgM TEST DEVICE was evaluated using a panel of WIDAL positive of different reactivity and WIDAL negative sera. The result of the evaluation show:

1. **Sensitivity:** 92 % for IgM antibody and 93 % for IgG antibody.
2. **Specificity:** Normally, healthy men and women do not have detectable levels of *S typhi* antibodies. Homologous and other potentially interfering substances did not cross react with TYPHOID IgG / IgM TEST DEVICE. The results showed Relative Specificity of 99 % for IgM antibody and 99 % for IgG antibody
3. **Accuracy:** The results obtained by Typhoid IgM/IgG Test Device correlated very well when run in parallel with other commercially available tests, using known positive and negative specimens. Relative Sensitivity: 92% Relative Specificity : 93%
4. **Precision:** Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of negative and positive samples. No variations were found in the outcome of the different tests.

LIMITATIONS

1. The tests procedure and the interpretation of the result must be followed closely when testing the presence of antibodies to S. typhi in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. TYPHOID IgG / IgM TEST DEVICE is limited to the qualitative detection of antibodies to S. typhi in human serum / plasma / whole blood The intensity of the test band does not have any correlation with the antibody titer in the specimen.
3. 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. 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 the sample is collected.
4. As with all other diagnostic tests TYPHOID IgG / IgM TEST DEVICE should be interpreted in conjunction with other diagnostic procedures and clinical findings.
5. Samples with positive results should be confirmed with alternative testing method (s) and clinical findings before a positive determination is made.

DISCLAIMER

Every precaution has been taken to ensure diagnostic ability and accuracy of this product. This product is used outside the control of manufacturer and distributors. Various factors including storage temperature, environmental conditions, and procedural errors may affect the result. A person who is subject of the diagnosis should consult a doctor for further confirmation.

WARNING

The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether direct or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

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 or Salmonella paratyphi in an endemic typhoid area. Archives of Internal Medicine 1991; 151: 381-2.
3. Clegg A, Passey M, Omena MK, et al. Re-evaluation of the Widal agglutination test in response to the changing pattern of typhoid fever in the highlands of Papua New Guinea. Acta Tropica 1994;57:255-63
4. Pang T. False positive Widal test in nontyphoid Salmonella infection. Southeast Asian Journal of Tropical Medicine and Public Health 1989; 20: 163-4.
5. Ismail A, Hai OK, Kader ZA. Demonstration of an antigenic protein specific for Salmonella typhi. Biochem Biophys Res Commun. 1991;181(1):301-5.

SYMBOLS USED ON LABELS

	Consult instructions for use	REF	Catalogue number
	Do not reuse	IVD	In vitro diagnostic medical device
	Storage temperature	CARD	Test Card
	Use by	PIPETTE	Disposable Plastic Dropper
LOT	Batch code		Date of Manufacture
	Manufactured By	Σ	Contains sufficient for <n> tests
EC REP	Authorized Representative		

For *in vitro* Diagnostic use only

Manufactured by:

Asritha Diatech India Pvt. Ltd.

Marketed by:

Euro Diagnostic Systems Pvt.Ltd

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