Typhoid Antibody Test (IgM/IgG)

Rapid card test for qualitative detection of IgM and IgG antibodies to Salmonella typhi/paratyphi in human serum / plasma

INTENDED USE

Typhoid Antibody Test is a rapid immunoassay for the qualitative detection of IgM and IgG antibodies to Salmonella typhi/paratyphi in human serum / plasma, an aid in the diagnosis of infection with Salmonella typhi/paratyphi. For professional and in-vitro diagnostic use only.

INTRODUCTION

Typhoid fever and paratyphi fever are bacterial infections caused by salmonella typhi and paratyphi A,B,C respectively, which is transmitted through the ingestion of tainted food and water. Patients who are infected with HIV at significantly increased risk of clinical infection. 1-5% of patients become chronic carriers harboring S.typhi and paratyphi from blood, bone marrow or specific anatomic lesion. In facilities that can not afford to perform this procedure Widal test is used to facilitate diagnosis. However, many limitations lead to difficulties in the interpretation of the Widal test. In contrast, the Typhoid IgG/IgM Rapid Test is a simple, fast laboratory test that simultaneously detects and differentiates IgG and IgM antibodies to S.typhi and paratyphi. IgG positive suggests late stage of infection, or previous infection, or latent infection or immunization.

TEST PRINCIPLE

Typhoid antibody test is based upon the principle of immunochromatography, a two site immunoassay on nitrocellulose membrane. Each card contains a strip composed with absorbent pad, nitrocellulose membrane, conjugate pad and sample pad. The nitrocellulose membrane is coated with anti-human IgM at test line region "T1" and anti-human IgG at test line region "T2" and anti mouse / rabbit IgG at control line region "C". the conjugate pad contains colloidal gold is conjugated with recombinant protein of S.typhi/ S. paratyphi and rabbit/mouse IgG.

When specimen containing typhoid antibodies is applied along with assay buffer on the sample pad area, it reacts with colloidal gold conjugate with recombinant protein of S. typhi / S.paratyphi and makes an immune complex. The immune complex flows laterally on the nitrocellulose membrane where it captured by the anti-human IgM at test line "T1" and anti-human IgG at test line region "T2" coated on the nitrocellulose membrane leading to the formation pink / purple line in the test line region "T" confirms a positive result.

The un-reacted conjugate and unbound complex of colloidal gold and unbounded complex, if any further on the nitrocellulose membrane and are subsequently captured by the control line protein forming a pink/purple line at the control line region "C". The control line serves as an internal control to validate the test result. If the control line region 'C' does not appear, the result of the test should be considered as invalid and the specimen must be retested using a new test card/device.

PRESENTATION

Pack size : As provided

KIT COMPONENTS

1. Test device
2. Assay buffer
3. Plastic dropper
3. Product insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Disposable gloves
2. Marking Pen
3. Timer
4. Extra lancets and alcohol swabs, if needed
5. Sharps box
6. Non sharps disposal container
7. Venipuncture blood collection materials and precision pipette plus tips
8. Refrigerator
9. Centrifuge

STORAGE & STABILITY

The sealed pouches in the test kit may be stored between 2-40°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.

WARNING AND PRECAUTIONS

1. This package insert must be read completely before performing the test.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all the reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolysed blood specimen for testing.
7. Apply standard biosafety precautions for handling and disposal of potentially infective material.
   - Handle all specimens as potentially infectious.
   - Wear gloves while handling specimens and performing test.
   - Avoid splashing and aerosol formation.
   - Clean up spills thoroughly using an appropriate disinfectant.
   - The buffer contains 0.095% sodium azide as a preservative which may be toxic if ingested. When disposed of through a sink, flush, with large quantities of water.
8. Do not use if the product has been exposed to excessive heat or humidity.
10. Perform the test immediately after opening of the cassette packaging.
11. Do not re-use the test.
12. Do not smoke, drink, or eat in areas where specimens or kits regents are being handled.
13. Dispose of all specimens and materials used to perform the test as biohazards waste.
14. The testing results should be read within 15-20 minutes after a specimen is applied to the sample well or sample pad of the device. Reading the test after 20 minutes may give erroneous results.
15. Do not perform the test in a room with strong air flow, ie. An electric fan or strong air conditioning.

SPECIMEN COLLECTION & STORAGE

Test should be performed with freshly collected human serum/ plasma as specimen for testing of Typhoid antibody test.

For Plasma

Collect blood specimen into tube containing EDTA by venipuncture.Separate the plasma by centrifugation (centrifuge at 5000 r.p.m. for 5 minutes at room temperature).
Collect supernatant as plasma after centrifugation into a new pre-labeled tube.

For Serum

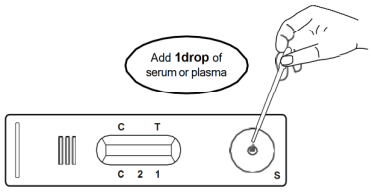
Collect blood specimen into a tube containing no anticoagulants by venipuncture.
Allow blood to clot.Separate the serum by centrifugation (centrifuge at 5000 r.p.m. for 5 minutes at room temperature).Collect supernatant as serum after centrifugation into a new pre-labeled tube.

Storage

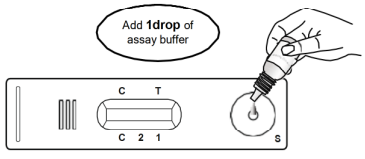
Test the specimens as soon as possible after collection, store specimen at 2-8°C if not tested immediately. Specimens can be stored at 2-8°C up to 7 days. The specimens should be frozen at -20°C for longer storage up to 12 months. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Centrifuge specimens containing visible particulate and discard the pellet. Use supernatant for testing. Do not use specimens demonstrating gross lipemia, gross haemolysis or turbidity in order to avoid interference with test result..

TEST PROCEDURE

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
2. Checked the expiration date the test. If expired, do not use it but take another test.
3. Check the test packaging for any damage. If damaged, discard the test and use another test.
4. When ready to test, open the pouch at the notch and remove device and check the desiccant. If color of desiccant does not show any change (Remains blue) you can use the test. Perform the test immediately after opening of cassette packaging.
5. Place the test device on clean, flat surface.
6. Be sure to label the device with specimens's ID number.
7. Prior to testing open buffer bottle correctly by breaking seal of the cap and pierce the nozzle by tightly screwing the cap of the bottle.
8. Add **1 drop or 25µl** of serum or plasma into sample well (S) using provided sample dropper.



9. Add 1 drop of assay buffer provided in the dropper bottle into the same sample well (S).

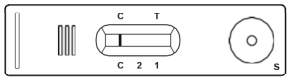


10. Interpret test results within **15-20 minutes**.

INTERPRETATION OF RESULTS

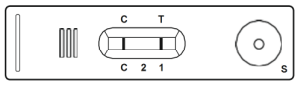
Negative:

Only the control band is visible at control region 'C' and no band in front of T1 or T2, Indicates that no anti-S. typhi or paratyphi antibody is detected in the specimen. The result is negative or non-reactive.

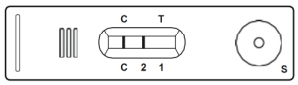


Positive:

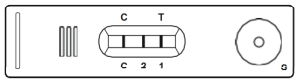
(A) Along with the control band 'C', if the T1 band appears, the test indicates for the presence of anti-S.typhi or paratyphi IgM in the specimen. The result is positive or reactive.



(B) In presence of control band 'C', if the T2 band appears, the test indicates for the presence of anti-S.typhi or paratyphi IgG in the specimen. The result is positive or reactive.



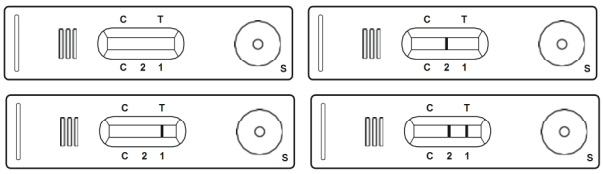
(C) Along with the control band 'C', if both T1 & T2 band appears, the test indicates for the presence of anti-S.typhi or paratyphi IgM and IgG in the specimen. The result is positive or reactive for IgM & IgG



Samples with positive or reactive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

Invalid:

If control band does not appear, the test is invalid. In this case, please repeat the test, following the test procedure exactly using new test card.



INTERNAL QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. External controls are not supplied with this kit. It is recommended that positive and negative controls should be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Handle the negative and positive controls in the same manner as patient specimens.

PERFORMANCE CHARACTERISTIC

Internal Evaluation

In an in-house study, the performance of device was evaluated using a panel of twenty known positive (of varying reactivity) and hundred known negative specimens in comparison to licensed competitor Typhoid Antibody (IgM/IgG) test. The results of the evaluation are as follows:

RESULTS					
Type of Specimens	Numbers	Precision Typhoid Antibody test		Competitor Typhoid Antibody test	
		Positive	Negative	Positive	Negative
Positive (IgM)	10	10	0	10	0
Positive (IgG)	10	10	0	10	0
Negative	100	0	100	0	100
Sensitivity:100%		Specificity:100%			

Based on this internal evaluation:

Sensitivity of : 100%

Specificity of : 100%

DISPOSAL

Consider all test devices run with human specimen as potentially infectious and discard using standard biosafety practices.

LIMITATIONS

1. The assay procedure and the test result interpretation must be followed closely when testing the presence of antibodies to S. Typhi or paratyphi in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The typhoid antibody test is limited to the qualitative detection of antibodies to S. typhi or paratyphi in human serum or plasma. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable anti S.typhi or paratyphi antibodies. However, a negative test result does not preclude the possibility of exposure to S. typhi or paratyphi.
4. A negative result can occur if the quantity of anti-S. typhi or paratyphi 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 a sample is collected.
5. If the symptom persists, while the result from typhoid antibody test is negative or non-reactive result, it is recommended to re-sample the patient few days later or test with an alternative test method, such as bacterial culture method.
6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.
8. Invalid tests and problems of background clearing may occur in lipaemic and icteric specimens.
9. The presence of the C line only means that migration of the test occurred. It does not guarantee that
   - The correct specimen has been used
   - The specimen has been applied correctly
   - The specimen and test ha been stored correctly
   - The test procedure was followed correctly
10. False positive results may occur in high titre of rheumatoid arthiritis antibodies may show cross reactivity.
11. False Negative result may occur in following condition - In early infections and some secondary infections, detectable levels of IgM antibodies may be low. Some patient may not produce detectable levels of antibody within the first seven to ten days after infection. Where symptoms persist, patient should be re-tested 3-5 days after the first testing date.

DISCLAIMER

Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the Manufacture and Distributor and the result may accordingly be Affected by environmental factors and user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

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

REFERENCES

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4. Pang T. False positive Widal test in nontyphoid Salmonella infection. Southeast Asian Journal of Tropical Medicine and Public Health 1989;20:163-4.
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Version : TYP/01

IVD In Vitro Diagnostic Use | See Pack Insert For Procedure | Single Use only | CE

Temperature Limit | Manufacturer's Address | Manufacturing Date | Expiry Date | LOT Lot Number

Manufactured in India by :

Precision Biomed Pvt. Ltd.

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