ASTAM DIAGNOSTICS

PRODUCT INSERT

REF TATD

PRATHAM®

ONE STEP SALMONELLA TYPHI IgG & IgM TEST KIT / DEVICE

INTENDED USE

Pratham® One step Salmonella typhi IgG & IgM Test kit/Device is a lateral flow through immunochromatographic assay designed for the qualitative detection and differentiation of specific IgM and IgG antibodies against specific salmonella typhi OMP antigen in human serum, plasma or whole blood. For professional use only.

INTRODUCTION

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 fourfold 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 PRINCIPAL

Pratham® One step Salmonella typhi IgG & IgM Test kit/ Device is produced in cassette format. The device containing a membrane sheet. The membrane is coated with anti-human IgG for Test line "G" and anti-human IgM for Test line "M", and goat anti-mouse IgG for control line "C" and recombinant typhoid antigen colloid gold conjugate. The human serum, plasma or whole blood sample migrate upward on the membrane chromatographically by capillary action to react with antibodies on the test line and generate a line on test device as the antibody-antigen-antibody gold particle complex forms. The device Indicating test line "G" & "M" and control line "C" on window of test device. The Test line "G" & "M" indication positive results of sample and control line "C" indicating proper functioning of test device and proper volume of specimen has been added.

KIT COMPONENTS

1. Pouch contents: Test Cassette, Sample Dropper, Desiccant
2. Assay Buffer
3. Instruction for use

MATERIAL REQUIRED BUT NOT PROVIDED

Timer, Gloves Micropipette, tips & centrifuge etc.

STORAGE AND STABILITY

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

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 (serum / plasma / whole blood) should be free of particulate matter and microbial contamination.
4. Preferably use fresh sample. However, specimen can be stored refrigerated for short duration. For long storage, freeze at -200C or below. Do not freeze whole blood samples. Specimen should not be frozen and thawed repeatedly.
5. Do not heat inactivate before use.
6. Turbid sample (microbial contamination) should not be used.
7. Specimens containing precipitate or particulate matter should be centrifuged prior to use.

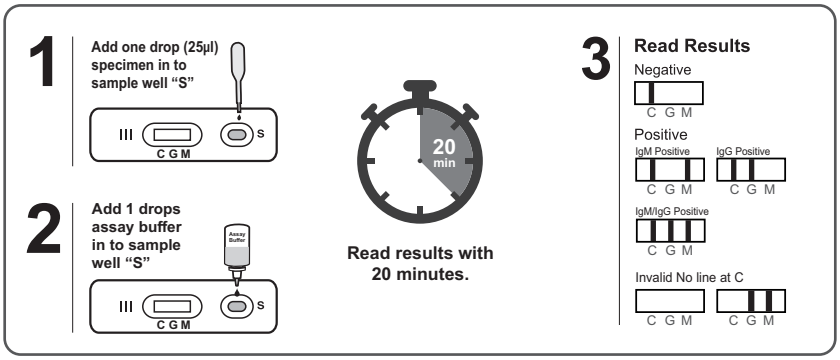
WARNING AND PRECAUTIONS

- Use product insert to perform the assay. Failure to follow the insert gives inaccurate test results.
- Do not use expired kit.
- Use separate sample collection tube or micropipette tips for each sample to avoid cross contamination.
- Do not use haemolysed blood specimens for testing.
- Do not throw away used device, sample tube and tips anywhere discard it in proper way as bio hazardous waste.
- Use of disposable gloves and bio-hazardous clothing while running the test.
- The Test shall be performed by competent person only.
- Bring all reagents and specimen to room temperature before use.
- Spills should be decontaminated promptly with IPA or any other suitable disinfectant.
- Do not unwrap the packed until it attains room temperature.
- Do not re-use the test device.

TEST PROCEDURE

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible
2. Check the packaging is not damaged. If damaged, discard the test and use another test.
3. Open the pouch & check the desiccant. If colour of desiccant does not show any change (Remains blue) you can use the test. If colour changes then discard the test and use another test.
4. Add **1 drop (25µl)** of serum, plasma or whole blood into the sample well.
5. Add **1 drop (35-40µl)** of assay/running buffer into the sample well using provided buffer vial.
6. Interpret test results within 20 minutes. Don't interpret results after 20 minutes.

TEST PROCEDURE & INTERPRETATION OF RESULTS



Negative: A pink coloured band appears only at the control region "C", indicating a negative result. There is no S.typhi antibody present in specimen.

Positive: Along with the control band, if the "M" band appears, the specimen is infected with IgM. If "G" band appears, the specimen is infected with IgG. If both "M" & "G" band appears, the specimen is infected with both IgM and IgG.

Invalid: No visible band at the control region. Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

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 CHARACTERISTICS

Internal Evaluation

In an in- house study the performance of **Pratham® One step Salmonella typhi IgG & IgM Test kit/ 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 93.2 % for IgG antibody.
2. **Specificity:** Normally, healthy men and women do not have detectable levels of S typhiantibodies. Homologous and other potentially interfering substances did not cross react with **Pratham® One step Salmonella typhi IgG & IgM Test kit/ Device.** The results showed Relative Specificity of 99.5 % for IgM antibody and 99 % for IgG antibody.
3. **Accuracy:** The results obtained by **Pratham® One step Salmonella typhi IgG & IgM Test** 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 OF THE TEST

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. **Pratham® One step Salmonella typhi IgG & IgM Test** is limited to the qualitative detection of antibodies to S. typhi in human serum, plasma or 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 **Pratham® One step Salmonella typhi IgG & IgM Test** 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.

DISPOSAL

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

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, environment 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 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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SYMBOLS

Read instructions for use	Name of Manufacturer	For single use only
No. of test	Expiry Date of Kit.	Date of manufacturing of IVD Kit
IVD In-vitro diagnostic use	Keep away from Sunlight	REF Reference Catalogue Number
Storage Condition		

ASTAM DIAGNOSTICS

Manufactured By:
ASTAM DIAGNOSTICS PVT. LTD.
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