TYPHOID ANTIGEN

METHOD – LATERAL FLOW IMMUNOASSAY
PRODUCT CODE – RC07

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

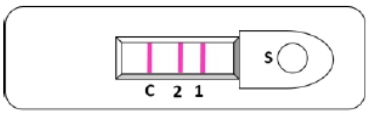
INTENDED USE: Test for qualitative detection of *S. typhi* and *S. paratyphi* antigens in human faeces and serum samples.

EXPLANATION OF TEST

Typhoid fever is a life threatening illness caused by the bacterium *Salmonella typhi*, and was observed by Eberth (1880) in the mesenteric nodes and spleen of fatal cases of typhoid fever. It is common in developing countries where it affects about 12.5 million persons annually. The infection is acquired typically by ingestion. On reaching the gut, the bacilli attach themselves to the epithelial cells of the intestinal villi and penetrate to the lamina and submucosa. They are then phagocytosed there by polymorphs and macrophages. The ability to resist intracellular killing and to multiply within these cells is a measure of their virulence. They enter the mesenteric lymph nodes, where they multiply and, via the thoracic duct, enter the blood stream. A transient bacteremia follows, during which the bacilli are seeded in the liver, gall bladder, spleen, bone marrow, lymph nodes and kidneys, where further multiplication takes place. Towards the end of the incubation period, there occurs a massive bacteremia from these sites, heralding the onset of the clinical symptoms. The diagnosis of typhoid consists of isolation of the bacilli and the demonstration of antibodies. The isolation of the bacilli is very time consuming and antibody detection is not very specific. Other tests include the Widal reaction. has developed a test that takes only 10-20 minutes and requires only a small quantity of stool or one drop of serum to perform. It is the easiest and most specific method for detecting S.typhi-S.paratyphi infection.

PRINCIPLE

S. typhi and *paratyphi* rapid test is a qualitative one step immunochromatographic assay. The test employs a combination of monoclonal antibody/colloidal gold dye conjugate and a polyclonal antibody immobilized on the solid phase. This will selectively identify *S. typhi* and *paratyphi* antigen associated with typhoid infection with a high degree of sensitivity and specificity.



As the specimen flows through the absorbent pad in the sample well and through the antibody/colloidal gold complex any *S. typhi* and *paratyphi* antigen present in the sample binds to the conjugate forming an antigen/antibody complex. The sample and dye complex continue to migrate along the membrane to the immobilized monoclonal antibody. In the presence of *S. typhi* and *paratyphi*, the monoclonal antibody captures the complex. This forms a visible pink/purple band in the test area of the card. If no antigen is present, there is no line formation. The remaining complex continues to migrate to another immobilized antibody on the membrane in the (C) or Control area of the card, and is captured which then forms a band indicating proper performance of the test.

MATERIALS PROVIDED

1. Pouch contents - Test cassette, Desiccant.
2. Specimen Collection tube with assay buffer.
3. Package Insert.

WARNING & PRECAUTIONS

1. For professional in vitro diagnostic use only.
2. Do not reuse.
3. Do not use if the pouch seal or its packaging is compromised.
4. Do not use after the expiration date shown on the pouch.
5. Do not mix and interchange different specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
7. Wash hands thoroughly after finishing the tests.
8. Do not eat, drink or smoke in the area where the specimens or kits are handled.
9. Clean up spills thoroughly with appropriate disinfectants.
10. Handle all specimens as if they contain infectious agents.
11. Observe established precautions against microbiological hazards throughout testing procedures.
12. Dispose off all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.

STORAGE & STABILITY

Store as packaged in the sealed pouch at 2-30 ^{0}C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. Do not freeze.

SPECIMEN COLLECTION AND STORAGE

The *S. typhi* and *paratyphi* test can be run on stool or serum samples. The test works best on fresh samples. If testing cannot be done immediately, they should be stored at 2-8 ^{0}C after collection for up to 3 days. If testing cannot be done within 3 days, serum can be stored frozen at –20 ^{0}C or colder.

TEST PROCEDURE

A. For Stool samples only:

1. Take a device from the pouch and bring it to room temperature. Use clean, dry containers for specimen collection.
2. Unscrew the cap of the specimen collection tube and take out specimen collection stick.
3. Add about 0.5 gram stool specimen to approximately 1000µl of Assay buffer provided.
4. Mix well and allow to sit for 5 minutes or to allow the large particles to settle. Then add 100 µL **from the upper layer of the extract** to the 'S' well of the test card using the droppers provided.
5. Read the result in 15-20 minutes. Do not interpret results after 30 minutes.

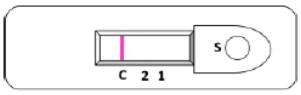
NOTE: One more drop of diluent of the previously prepared stool sample may be added if the membrane does not clear sufficiently within 10 minutes.

B. For serum samples:

1. Take a device from the pouch and bring it to room temperature. Use clean, dry containers for specimen collection.
2. Using the droppers OR pipette, add 4 drops (100 µL) of serum/plasma to the sample well 'S'.
3. The result should be read between 10 to 20 minutes but not more than 30 minutes.

INTERPRETATION OF THE RESULTS

NEGATIVE RESULT:



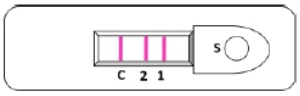
A pink coloured band appears only at the control region (C), indicating a negative result for S. *typhi* and *paratyphi* infections.

POSITIVE RESULT:

***S. typhi* Positive:** A clear pink control line (C) and a detectable test line 1 appears, as seen in the image below, it indicates positive result for *S. typhi* infection.

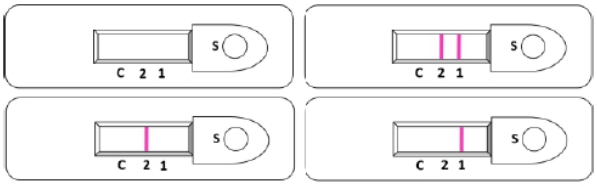
***S. paratyphi* Positive:** A clear pink control line (C) and a detectable test line 2 appears, as seen in the image below, it indicates positive result for *S. paratyphi* infection.

***S. typhi* and *S. paratyphi* Positive:** A clear pink control line (C) and two detectable test line 1 and 2 appears, as seen in the image below, it indicates positive results for *S. typhi* and *paratyphi*, mixed infection.



INVALID TEST:

No visible band at the control region. Repeat with a new test device.



QUALITY CONTROL

Although the testing device contains an internal quality control (pink coloured band in the control region), good laboratory practice recommends to run a known positive and negative control sample to ensure proper performance. All controls should be handled in the same manner as patient

PERFORMANCE CHARACTERISTICS

SPECIFICITY

The antibodies used in the *S. typhi* and *paratyphi* assay were developed specifically against *Salmonella typhi* and *Salmonella paratyphi* LPS antigen.

SENSITIVITY

S. typhi and *paratyphi* assay was run using serum and stool samples versus culture positive samples and found to give positive results in all cases.

LIMITATIONS OF THE TEST

1. The instructions for use and reading of the test instructions must be followed carefully for the test to perform properly.
2. The *S. typhi* and *paratyphi* test is designed to detect *S. typhi* and *paratyphi* antigen in stool or serum samples. Testing of any other body fluids has not been validated and may not yield appropriate results.
3. For samples that test positive (reactive) by the *S. typhi* and *paratyphi* test, more specific confirmatory testing should be done. A clinical evaluation of the patient's situation and history should also be made before a final diagnosis is established. The use of a rapid test alone is not sufficient to diagnose *S. typhi* and *paratyphi* infection even if antigen is present. Also, a negative result does not preclude the possibility of infection with *S. typhi* and *paratyphi*.

BIBLIOGRAPHY

1. 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.
2. Ivanoff BN, Levine MM, Lambert PH. Vaccination against typhoid fever: present status. Bulletin of the World Health Organization 1994; 72: 957-71.

SYMBOLS:


Read Instruction for use

In Vitro Diagnostic Use Only


Manufactured by


Expiry Date


Storage Temperature

ANAMOL LABORATORIES PVT. LTD.
61, Genesis Industrial Township, Kolgaon,
Palghar – 401 404. India.
Customer Care: +91-9823388695.

admin@anamollabs.com
exports@anamollabs.com
www.anamollabs.com

ISO 9001 : 2015
ISO 13485 : 2003
GMP
CE