Typhoid Antigen Rapid Test Kit

INTENDED USE

The Typhoid Antigen Rapid Test rapid immunoassay for the qualitative detection of Salmonella Typhi (S.Typhi) antigen in human faeces specimens to aid in the diagnosis of typhoid infection.

INTRODUCTION

Typhoid fever is a life-threatening illness caused by the bacterium Salmonella typhus, 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 typically acquired by ingestion. On reaching the gut, the bacilli attach themselves to the epithelial cells of the intestinal Villi and penetrate the lamina and submucosa. They are then phagocytosed there by polymorphs and mesenteric lymph nodes, where they multiply and, via the thoracic duct, enter the bloodstream. 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.

PRINCIPLE

The Typhoid Antigen Rapid Test kit is a qualitative membrane strip-based immunoassay for the detection of Salmonella typhi (S.Typhi) antigen in human faeces. The test cassette consists of: 1) a burgundy colored conjugate pad containing anti-S.Typhi antibody conjugated with colloid gold, 2) a nitrocellulose membrane strip containing one test band (T band) and a control band (C band). The T band is pre-coated with the anti-typhoid antibody, and the C band is pre-coated with goat anti-mouse IgG. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. S.Typhi antigen, if present in the specimen, will bind to the anti-typhoid conjugates. The immunocomplex is then captured by the reagent pre-coated on the T band, forming a colored T band, indicating a typhoid antigen-positive test result. A colored line will not form in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region, indicating that a proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS AND METHODS

1. Individual sealed pouches, each containing:
   a. 1 × Test Kit
   b. 1 × Desiccant Pouch
   c. 1 × Dropper
2. Buffer Tube

STORAGE AND STABILITY

- Keep the test kit between 2 - 30°C in a dry, cool place. Avoid freezing.
- The kit is stable within the expiry date printed on the product label and outer packaging. Do not use later than the specified date.
- The package should be sealed until it is required for use.

SPECIMEN COLLECTION

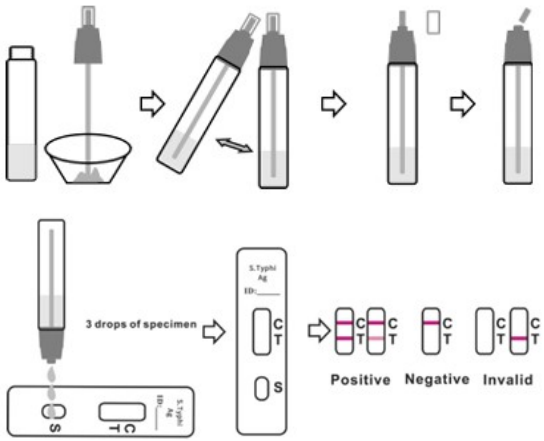
The Typhoid Antigen Rapid Test Kit can be used on human faeces.

- Collect adequate faeces (1-2 mL or 1-2 g) in a sterile, dry specimen collecting container to obtain maximum antigen as possible (if any). For the best results, the assays should be performed within six hours after collection.
- If the specimen is not examined within six hours, it can be kept for three days at 2–8°C. The specimens should be stored at or below -20°C for long-term storage.

- To collect the specimen, unscrew the cap of the specimen collection tube and jab the specimen collecting applicator into the faecal specimen at least five times to collect around 50 mg of faeces.
- Screw on and tighten the specimen collection tube's cap, then shake to mix the specimen into the dilution buffer. Allow the tube to rest for two minutes.
- Before testing, bring the specimens to room temperature. Frozen specimens need to be thoroughly thawed and mixed. It is not recommended to repeatedly freeze and thaw specimens.

TEST PROCEDURE

1. Allow the test kits and specimens to equilibrate to room temperature (15-30°C).
2. Bring the pouch to room temperature, and after removing the kit from the pouch, use it as soon as possible.
3. Ensure the test kit is situated on a clean surface, and while holding the specimen collection tube upright, remove the tip with caution. Then, add 3 drops (approximately 100 µL) to the specimen well of the test kit and set the timer.
4. Wait until the colored lines appear. Examine the results after 15 minutes. The results should not be interpreted after 20 minutes. The test is positive if a colored line appears in the top section (C) and lower section (T) of the result window.



RESULT:

1. Two Pink Lines - (POSITIVE)
2. One Pink Line at (C) - (NEGATIVE)
3. No Pink Line - (INVALID)

LIMITATIONS

1. The Typhoid Antigen Rapid Test Cassette is for in vitro diagnostic use only. The test should be used for the detection of S.Typhi antigen in human faeces only. Neither the quantitative value nor the rate of increase in S.Typhi antigen can be determined by this qualitative test.
2. The test is limited to the qualitative detection of S.Typhi antigen level in the specimen. The exact concentration of the S.Typhi antigen cannot be determined by this assay.

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: 381-389.
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