Salmonella typhi/paratyphi A, B & C Test Device
For detection of Salmonella typhi and paratyphi A, B & C antigens in stool/serum/plasma.

**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 acquired typically 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.

Serovar paratyphi A is the second most prevalent cause of Typhoid. Paratyphi A and typhi cause a similar illness, with relapsing fever. The diagnosis of typhoid and Paratyphoid 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.

Our test employs a combination of monoclonal antibody/colloidal gold dye conjugate and a polyclonal antibody and 20 minutes.

**Specimen Collection, Storage and Precautions**

1. Stool should be collected in the specimen collection container.
2. Separate the Serum or Plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

**Test Procedure**

Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

For Stool Samples Only:

**SAMPLE COLLECTION METHOD**

(Please refer to illustration)

1. Loosen cap of extraction tube and remove cap with the spiral stick.
2. Introduce the spiral stick into the stool sample six times at six different sites of the sample. Try to avoid getting clumps of sample into the spiral stick. Collect about ½ gram of stool.
3. Return the spiral stick into the extraction tube.
4. Tighten cap and shake the tube to disperse the sample evenly into the buffer.
5. Remove the test cassette from the sealed pouch.
6. Hold the extraction tube upright with the tip pointed away from the person performing the test and snap off the tip.
7. Hold the bottle in a vertical position over the sample well of the test device, deliver 3 drops (150 µL) of diluted stool sample to the sample well.
8. If the flow of the buffer along the test cassette appears to have stopped, lightly tap the test cassette on a hard flat surface. If flow does not continue then dispense one drop at a time until flow continues.0and 20 minutes. DO NOT INTERPRET RESULTS AFTER 30 MINUTES.

For Serum or Plasma Samples:

1. Add 100 µLs of serum/plasma into the sample well.
2. The result should be read between 10 to 20 minutes but not more than 30 minutes.

Interpretation of Test Results (Refer to Figure)

POSITIVE:  
- S. typhi/paratyphi: Three distinct red lines appear. One line should be in the control region (C) and the other two lines should be in both test regions (1&2).
- S. typhi: Two distinct red lines appear. One line should be in the control region (C) and one line in test region 1.
- paratyphi: Two distinct red lines appear. One line should be in the control region (C) and one line in test region 2.

NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of S. typhi and/or paratyphi A antigen(s) present in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE: A low S. typhi/paratyphi A, B & C concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 30 minutes.

Limitations of the Test
1) The Salmonella typhi/paratyphi Test Device is for in vitro diagnostic use only. This test should be used for the detection of S. typhi/paratyphi A antigen in specimen.

Suggested Readings

REF
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