One-Step Salmonella *typhi/paratyphi* A Test Device (Stool/Serum/Plasma) Package Insert Catalog Number: B802C

A rapid, one step test for the qualitative detection of Salmonella typhi and paratyphi A antigens in stool/serum/plasma.

For professional in vitro diagnostic use only.

Intended Use

TELL ME FAST One Step Salmonella *typhi/paratyphi* A Test Device is a rapid chromatographic immunoassay for the qualitative detection of Salmonella *typhi and paratyphi* A antigens in stool/serum/plasma.

Summary

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 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.

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. Other tests include the Widal reaction. Biocan has developed a test that takes only 10-20 minutes and requires serum, plasma or a small amount of stool to perform. It is the easiest and most specific method for detecting S. *typhi* and *paratyphi* infection. 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 the S. *typhi* and *paratyphi* A antigens associated Salmonella *typhi* (typhoid) and salmonella *paratyphi* (paratyphoid) infections with a high degree of sensitivity and specificity.

Principle

The TELL ME FAST One Step Salmonella *typhi/paratyphi* A Test Device is a qualitative, lateral flow immunoassay for the detection of Salmonella *typhi and paratyphi* in stool/serum/plasma. The membrane is pre-coated with anti-salmonella antibodies on the test line region of the strip. During testing, the stool/serum/plasma specimen reacts with the particle coated with anti-Salmonella antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-Salmonella antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

Reagents

The test cassette contains anti-Salmonella conjugated to Gold particles and anti-Salmonella coated on the membrane.

Precautions

- For *in vitro* diagnostic use only.
- Do not use beyond the expiration date.
- Use separate syringe or clean pipette tips for different specimens. Do not pipette by mouth.
- Do not smoke, eat or drink in areas in which specimens or kits are handled.
- Wear disposable gloves while handling specimens and running the tests, and thoroughly wash hands afterwards.
- All patient samples should be handled as if they are capable of transmitting diseases. Observe established good laboratory procedures for proper disposal of specimens, used pipette tips or syringes, and used test devices.
- Humidity and temperature can adversely affect results.

Storage & Stability

Store as packaged in the sealed pouch at 4-30 °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.

Materials

Materials Provided:

- Test cassette
- Instructions for use

Materials Required but not Provided:

- Specimen Collection Container
- Timer
- Plastic or glass extraction tube/Pipette
- Phosphate Buffer Saline (PBS) or normal saline

Specimen Collection & Preparation

- Stool should be collected in the specimen collection container.

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- Separate the Serum or Plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- 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. For long-term storage, specimens should be kept below -20°C.
- 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.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

Directions for Use:

Allow test device, stool/serum/plasma and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

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. Best results will be obtained if the assay is performed within one hour.

For Stool Samples Only:

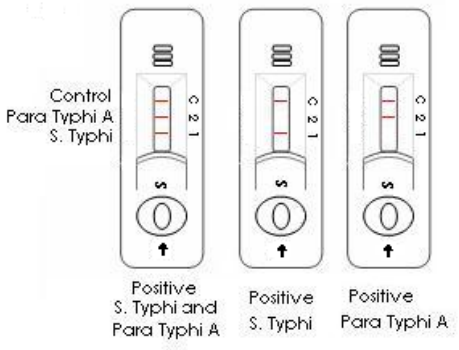
2. Add about ½ gram of stool specimen to approximately 1000µLs (1 mL) Phosphate Buffer Saline (PBS). Mix well and allow to sit for 5 minutes or to allow the large particles to settle.

For All Samples:

3. Add 100µLs from the upper layer of the extract or 100µLs of serum/plasma into the sample well.
4. The result should be read between 10 to 20 minutes but not more than 30 minutes.

Interpretation of Results:

(Please refer to the illustration)



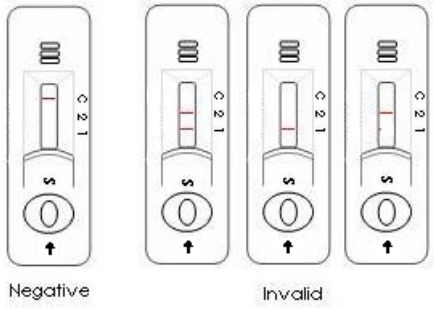
POSITIVE:

S. *typhi/para typhi*: 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* A**: 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 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

1. The TELL ME FAST One Step 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.
2. The TELL ME FAST One Step Salmonella *typhi/paratyphi* ATest Device will only indicate the presence of *S. typhi/paratyphi* A antigen in the specimen and should not be used as the sole criteria for the diagnosis of Typhoid and Paratyphoid infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Typhoid/ Paratyphoid infection.

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