Salmonella Typhi/Paratyphi Rapid Test Kit

Cat No. S007-08

In vitro Diagnostics

INTENDED USE

Sensit is a one step rapid Card Test for detection of both Salmonella typhi and Paratyphi A antigen in human serum and stool sample**.**

SUMMARY

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.

TEST DESCRIPTION & PRINCIPLE

Sensit S.typhi-S.paratyphi rapid test is a qualitative one step immunochromatographic assay. The test employs a conation of monoclonal antibody/colloidal gold dye conjugate and a polyclonal antibody immobilized on the solid phase. This will selectively identify S.typhi-S.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- S.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 S. paratyphi, the monoclonal antibody captures the complex. This forms a visible pink/purple band in the test region of the card. If no antigen is present, there is no line formation in the test region. The remaining complex continues to migrate to another immobilized antibody on the membrane in the (C) or Control region of the card, and is captured which then forms a band indicating proper performance of the test.

MATERIALS PROVIDED

- Test Cassette
- 25 ml Phosphate Buffer Saline
- Instruction for Use

STORAGE & STABILITY

1. The kit can be stored at room temperature or refrigerated (2- 30°C). The test device must remain in the sealed aluminum pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test strip, if the pouch is damaged or seal is broken.

PRECAUTION & WARNING

1. For professional *In-vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens and tested device.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Read the Instruction for use carefully before performing the test.

SAMPLE COLLECTION

1. **Sensit** S.typhi-S.paratyphi test can be run on stool or serum samples.
2. The test works best on fresh samples. If testing cannot be done immediately, they should be stored at 2-8'C after collection for up to 3 days. If testing cannot be done within 3 days, serum can be stored frozen at -20 °C or colder.
3. If specimens are to be shipped, it should be packed in compliance with federal regulations for transportation of etiologic agents.

TEST PROCEDURE

1. Allow test device, Assay Buffer and specimen equilibrates to room temperature (15-30□C) prior to testing.
2. Remove the test device from the aluminum foil 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:
   Add about 0.5gram of stool specimen to approximately 1000 µl of assay buffer provided. Mix well and allow to settle for 5 minutes or to allow the large particles to settle. Then add 4 drops (100 µL) **from the upper layer of the extract** to the Sample well 'S' using the dropper provided.

   For serum samples:
   Add 2 drops (50 µl) of serum specimen to approximately 1000 µl of Assay Buffered provided. Mix well and allow to sit for 5 minutes or to allow the large particles to settle. Then add 4 drops (100 µL) **from the upper layer of the extract** to the Sample well 'S' using the dropper provided.

3. Allow reaction to occur and read the result between 10 to 20 minutes. Do not interpret after 30 minutes.

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

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INTERPRETATION OF TEST RESULT

1. POSITIVE

- If two color lines appear, one at control region 'C' and other at test region '1', the specimen is positive for Salmonella Typhi.

- If two color lines appear, one at control region 'C' and other at test region '2', the specimen is positive for Salmonella Paratyphi 'A' Antigen.

- If three color line appear, one at control line 'C', one at test region '1' and one at test line '2', the specimen is positive for both Salmonella Typhi & Salmonella Paratyphi 'A' Antigen.

2. NEGATIVE

If only one color band appear at control line 'C' as the specimen is Negative for Salmonella Typhi & Salmonella Paratyphi 'A' Antigen.

3. INVALID

If no color band appear, at control line 'C' within the stipulated time then result is invalid. Repeat the test using a fresh Test Device.

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.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in Sensit S.typhi-S.paratyphi rapid test for single-step detection of S. typhi and S. parathyphi are the most common signs appearing on medical devices and their packaging. They are explained in more detail in the European Standards EN 980: 2008 and INTERNATIONAL Standard ISO 15223-1:2016

Key to symbols used			
	Manufacturer		Expiration/use by date
	Do not reuse		Date of manufacture
	Consult IFU [Instructions For Use]	LOT	Batch code
	Temperature limitation 2-30°C	IVD	In Vitro diagnostic medical device
Σ X	Contains sufficient for 'X ' kits		Do not use if package is damaged
REF	Catalogue No		Keep dry

Please read the user manual carefully before operating to ensure proper use

Manufactured by,

ubio Biotechnology Systems Pvt Ltd
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