



**Rapid Test for *S. typhi***

A One Step Assay for the Detection of *Salmonella typhi* antigen in stool specimens, or whole blood

*For In Vitro Diagnostic Use  
Not for Sale in U.S.*

**Description**

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 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. 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. The ABI 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* infection.

**Principle of the Test**

The ABI *S. typhi* 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 the *S. typhi* antigen associated *Salmonella typhi* (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* 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 polyclonal antibody. In the presence of *S. typhi*, the polyclonal antibody captures the complex. This forms a visible pink/purple band in the (T) or test area of the card. If no antigen is present, there is no line formation in the (T) area. 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.

**Kit Components**

Each test kit contains:

1. 25 test cassettes
2. Extraction reagent
3. Directions for use

**Stability and Storage Conditions**

The ABI *S. typhi* test kit is stable at any room temperature between 15-30°C when in the unopened pouches. DO NOT FREEZE the kit or expose to temperature extremes.

Stability of the kit is 24 months from the date of manufacture – dating is indicated on the kit label.

**General Precautions**

- The test is for In Vitro Diagnostic use only.
- Appropriate infection control and handling procedures should be followed – do not smoke, eat, or drink in the area where the test is to be performed. Use suitable clothing and gloves when handling samples and when performing the test.
- Do not pipette any samples or reagents by mouth.
- All materials should be considered as potentially infectious. To disinfect, either autoclave materials at 121.5°C for 1 hour or treat with Sodium hypochlorite (1 percent solution).
- Do not use test beyond the expiration date indicated.

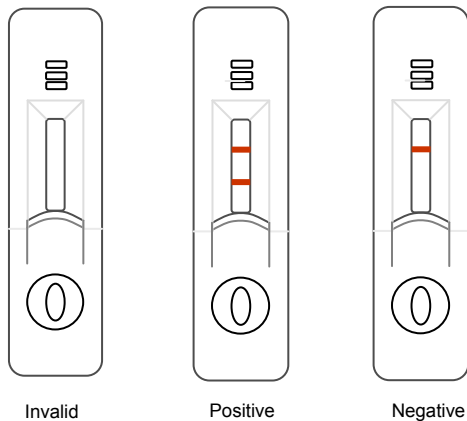
**Sample Collection**

The ABI *S. typhi* test works best on fresh stool samples. If testing can not be done immediately, they should be stored at 2-8°C after collection for up to 3 days. If testing can not be done within 3 days, serum can be stored frozen at -20°C or colder. Shipment of samples should comply with local regulations for transport of etiologic agents.

**Test Procedure**

1. Remove as many test strips from the pouches as needed.
2. For stool samples:
3. Add about ½ gram to approximately 1ml of the extraction reagent provided. Mix well and allow approx. 5 minutes to allow the large particles to settle.
4. Transfer approx. 100 ul from the top clear layer of the stool suspension to the sample port of the cassette.
5. For whole blood, serum or plasma samples:
6. Transfer 10 ul of whole blood or 20 ul of serum or plasma to the sample port of the cassette.
7. Add 100 ul of diluent to sample port.
8. Place the cassette on a flat surface, start the timer and wait for the red line(s) to appear. The result should be read between 10 to 20 minutes.
9. Results are may be read in as little as 10 minutes for strong positive specimens or up to 20 minutes for weaker positives and to make sure negatives are confirmed.

## Interpretation of Test Results



**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.

**POSITIVE:** Two bands will appear in the control and test areas, which indicate a positive result for *S. typhi*.

**NEGATIVE:** A color band will appear only in the control area, which indicates a negative result.

### Limitations of the Test

The instructions for use and reading of the test instructions must be followed carefully for the test to perform properly. The ABI *S. typhi* test is designed to detect *S. typhi* antigen in serum, plasma, whole blood or stool specimens. Testing of any other type of body fluid has not been validated and may not yield appropriate results. For samples that test positive (reactive) by The ABI *S. typhi* 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* infection even if antigen is present. Also, a negative result does not preclude the possibility of infection with *S. typhi*.