
INTENDED USE

The DRG S. Typhi Antigen Rapid Test is an in vitro qualitative immunochromatographic assay for the rapid detection of S. Typhi antigens in human stool or serum specimen. The test results are intended to help in the diagnosis of S. Typhi infection and, to monitor the effectiveness of therapeutic treatment.

INTRODUCTION

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 infection.

PRINCIPLE OF THE TEST

The DRG S. Typhi Antigen 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 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 (B) or test area of the card. If no antigen is present, there is no line formation in the (B) 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.

MATERIALS PROVIDED

Each kit contains:

1. The DRG S. Typhi Antigen Rapid Test - 25 each
Each cassette contains a test strip with S. Typhi specific antibody on the test region of the membrane and colored S. Typhi antibody-gold conjugate pad.
2. Fecal sample buffer - 2 bottles, 8 mL each
3. Instruction for use

MATERIALS NOT PROVIDED

1. Specimen collection container
2. Timer.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Wear protective glove while handling kit components and test specimens.
3. Patient specimens and inactivated Positive Control may contain infectious agents and should be handled and disposed of as potential biohazards.
4. Do not use kit components beyond expiration date.
5. Dispose all used materials in appropriate container. Treat as potential biohazard.

STORAGE INSTRUCTION

1. The expiration date is indicated on the package label.
2. Test device can be stored at 4-30 °C.

SPECIMEN COLLECTION AND STORAGE

The DRG S. Typhi Antigen Rapid Test can be run on stool or serum samples. 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.

Shipment of samples should comply with local regulations for transport of etiologic agents.

Stool and serum specimens should be collected in containers that do not contain media, preservatives, animal serum or detergents as any of these additives may interfere with the DRG S. Typhi Antigen Rapid Test.

REAGENT PREPARATION

Bring all reagents, including test device, to room temperature (20-30°C) before use.

STOOL SPECIMEN PREPARATION

Add about 1/4 gram to approximately 500 µl of the extraction reagent provided (about 12 drops from the dropper vial provided). Mix well and allow to sit for 5 minutes or so to allow the large particles to settle.

Note: Watery or diarrhea specimens are inappropriate for testing.

Procedure

1. Bring all materials and specimens to room temperature (8 - 30°C).
2. Remove the test card from the sealed foil pouch.
3. For stool samples: use the provided pipet to transfer sample from the upper layer of the stool extract and add 3 drops to the sample well (marked as "A").
For serum samples: use the provided pipet to transfer the serum sample and add 3 drops to the sample well (marked as "A").
4. Read the result at 20 minutes. A strong positive sample may show test band earlier. However, to confirm a result is negative, it must wait 20 minutes to read the results.

Note: The amount of S. typhi antigens present in serum is typically less than that in stool. This may decrease the sensitivity of the test when using serum depending how soon after the onset of the infection the test is performed. Early infection typically exhibits greater levels of the antigen in the serum than in later infection. To confirm serum results: The use of a stool sample is recommended if serum is used

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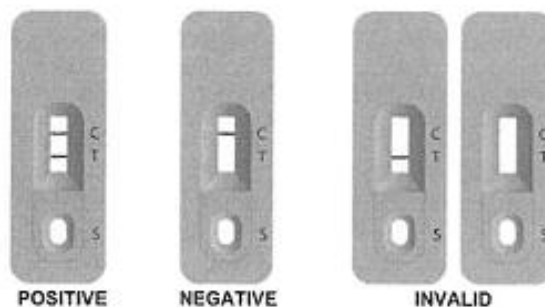
first and a negative result is obtained and typhoid is still suspected A second test run on a stool sample should be performed.

INTERPRETATION OF RESULTS

Positive result: A distinct pink colored band appears on test line regions, in addition to a pink line on the control line region.

Negative result: No line appears in the test line region. A distinct pink line shows on the control line region.

Invalid: The control line next to the test line does not become visible within 20 minutes after the addition of the sample.



QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials, which are not provided with this test kit, may be commercially available.

LIMITATIONS

1. The test is for qualitative detection of S.Typhi antigen in stool or serum sample and does not indicate the quantity of the antigens.
2. The test is for *in vitro* diagnostic use only.
3. For samples that test positive (reactive) by the DRG S. Typhi Antigen Rapid Test, more specific confirmatory testing should be done. A definitive clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated. 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.

PERFORMANCE CHARACTERISTICS

Sensitivity

To determine the sensitivity of the S. typhi rapid test, stool samples obtained from symptomatic, culture-positive patients (1st week) were used. These were tested in 50 duplicates according to the test procedure described in the package insert.

S. typhi	Positive	Negative	Percentage of Positive
Negative	0	50	0%
Positive	49	1	98%

The sensitivity of the test was determined to be 98 percent versus stool culture positive samples from symptomatic patients (1st week).

Correlation study

The DRG S. typhi Antigen Rapid Test was compared to results from laboratory supplied stool samples from patients who were stool culture positive and antibody positive via the Widal test for S. typhi.

50 positive and 50 negative specimens were then tested with the S. typhi rapid test.

Test results showed 98 percent overall correlations on positive samples and 100 percent correlation on negative samples.

Specificity

Negative stool samples from patients in areas where typhoid is relatively rare and would yield a typical negative population, showed no false positives when the test was read within 20 minutes as specified. Samples that were positive for s. paratyphi however were also negative as the antibodies used in the S. typhi rapid test are specific for S. typhi only.

REFERENCES

1. Ivanoff B. Typhoid fever, global situation and WHO recommendations. Southeast Asia J. Trop. Med. Public Health, 1995, 26:sup2 1-6
2. Parry CM, Hien TT Dougan G et al., Typhoid fever, N. Eng. J. Med. 2002, 347:1770-82.

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