SPECTRUM

The Creative Approach to Bioscience

S. Typhi/Para Typhi A Antigen

REF: 1154 001 25 Card Test
REF: 1154 002 50 Card Test

Intended Use

It is the easiest and most specific method for detecting S.typhi-S.paratyphi infection (For professional use only)

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.

Principle

Spectrum 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 (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.

Reagents

The test cassette contains anti-salmonella conjugated to gold particles and anti-salmonella coated on the membrane.

Material Provided: Test Cassette, 25 ml Phosphate Buffer Saline and Instruction for Use

Storage and Stability

Spectrum S.typhi-S.paratyphi test kit is stable at any room temperature between 8 – 30 °C when in the unopened pouches.

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

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.

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

Spectrum S.typhi-S.paratyphi 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.

Procedure

1. Remove as many test cards from the pouches as needed. Lay on a clean flat surface.

   For stool samples: Add about 0.5 gm stool to approximately 1 ml of Phosphate Buffered Saline PBS. Mix well and allow to sit for 5 minutes or so to allow the large particles to settle.
   Then add 200 µl **from the upper layer of the extract** to the well (A).

   For serum samples: Using the pipette, add 100 µl of serum/plasma to the sample well (A)

   The amount of S.typhi-S.paratyphi 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 first and a negative result is obtained and typhoid is still suspected A second test run on a stool sample should be performed.

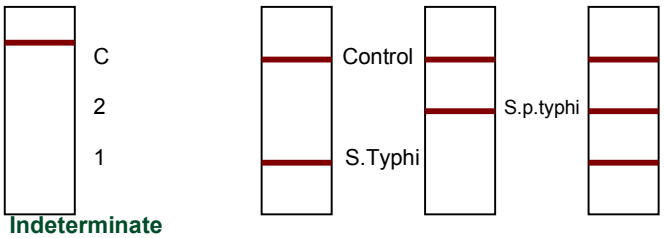
2. Results are then read in as little as10 minutes for strong positives or up to 20 minutes for weaker positives and to make sure negatives are confirmed.

Reading the Test Results

Negative
Only one pink/purple band appears in the C (Control) area of the test card.

POSITIVE

S. typhi S. paratyphi S.typhi & Paratyphi



Indeterminate

If only one band appears in the 1 or 2 – Test area, or no band appears at all in the C well – Control area. It is then recommended that a fresh device be used and the test repeated carefully following the directions in this insert.

Quality Control

A known positive and negative control should be run to ensure proper performance. All controls should be handled in the same manner as patient samples.

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 **Spectrum** S.typhi-S.paratyphi test is designed to detect S.typhi-S.paratyphi antigen in stool or serum samples. Testing of any other body fluids has not been validated and may not yield appropriate results.
For samples that test positive (reactive) by the **Spectrum** S.typhi-S.paratyphi 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-S.paratyphi infection even if antigen is present. Also, a negative result does not preclude the possibility of infection with S.typhi-S.paratyphi.

Performance Characteristics

Specificity:
The antibodies used in the **Spectrum** S.typhi-S.paratyphi assay were developed specifically against Salmonella typhi and Salmonella paratyphi LPS antigen.

Sensitivity:
Spectrum S.typhi-S.paratyphi assay was run using serum and stool samples versus culture positive samples and found to give positive results in all cases.