ACCUCARE™
S.typhi-S.paratyphi 'A' Direct Antigen Detection Test (Serum/Stool)

For rapid qualitative detection of both Salmonella typhi and Paratyphi A antigen in human serum and stool sample.
Only for *In Vitro* diagnostic use.

ORDER INFORMATION

REF	Cont.
TAGC 1	1 Test
TAGC 10	10 Test
TAGC 25	25 Test

CLINICAL SIGNIFICANCE

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.

PRINCIPLE

ACCUCARE 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.

KIT COMPONENTS

Test Device, Sample Dropper ,product insert and Phosphate buffer

PRECAUTIONS

For *in Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15°C-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as biohazardous waste.
10. Handle the Negative and Positive Control in the same manner as patient specimens.
11. The testing results should be read within 15 minutes after a specimen is applied to the sample well or sample pad of the device. Reading the test after 15 minutes may give erroneous results.

STORAGE & STABILITY

Store as packaged in the sealed pouch at 2-30 °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.

SPECIMEN COLLECTION & PRESERVATION

The ACCUCARE 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.

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 1000µl of Phosphate Buffered Saline provided. Mix well and allow to sit for 5 minutes or to allow the large particles to settle. Then add 100 µL **from the upper layer of the extract** to the ' S' well of the test card using the droppers provided.

For serum samples: Using the droppers OR pipette , add 40 µL of serum/plasma to approximately 1000µl of Phosphate Buffered Saline provided. Mix well and allow to sit for 5 minutes or to allow the large particles to settle. Then add 100 µL **from the upper layer of the extract** to the ' S' well of the test card using the droppers provided.

3. The result should be read between 10 to 20 minutes but not more than 30 minutes.

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

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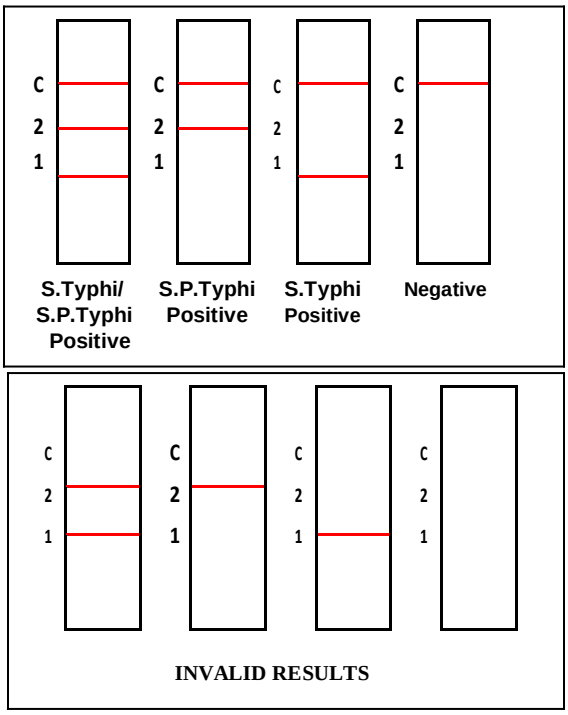
INTERPRETATION OF RESULTS



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.*

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

The instructions for use and reading of the test instructions must be followed carefully for the test to perform properly.
The ACCUCARE 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 ACCUCARE 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 ACCUCARE S.typhi-S.paratyphi assay were developed specifically against Salmonella typhi and Salmonella paratyphi LPS antigen.

Sensitivity:

ACCUCARE 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.

BIBLIOGRAPHY

1. Ivanoff BN, Levine MM, Lambert PH. Vaccination against typhoid fever: present status. Bulletin of the World Health Organization 1994; 72: 957-71.
2. Gotuzzo E, Frisancho O, Sanchez J, Liendo G, Carillo C, Black RE, Morris JG. Association between the acquired immunodeficiency syndrome and infection with Salmonella typhi or Salmonella paratyphi in an endemic typhoid area. Archives of Internal Medicine 1991; 151: 381-2.

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