ACCUCARE®
ONE STEP S.TYPHI / S.PARATYPHI 'A' DIRECT ANTIGEN RAPID TEST (Serum/Stool)

One step rapid Card Test for detection of both Salmonella typhi and Paratyphi A antigen in human serum and stool sample

Store at 2-30°C. DO NOT FREEZE.
For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
01 Tests	TAGC 01
10 Tests	TAGC 10
25 Tests	TAGC 25

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

The ACCUCARE® ONE STEP S.TYPHI / S.PARATYPHI 'A' DIRECT ANTIGEN RAPID TEST is a qualitative one step immuno chromatographic 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.

CONTENTS

Test Device
Instruction for Use (IFU)
Assay Buffer
Disposable (Dropper) 25 µl sampling device

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 device/strip, if the pouch is damaged or seal is broken.

PRECAUTIONS

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.

LIMITATIONS

1. The ACCUCARE® ONE STEP S.TYPHI / S.PARATYPHI 'A' DIRECT ANTIGEN RAPID 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.
2. For samples that test positive (reactive) by the ACCUCARE® ONE STEP S.TYPHI / S.PARATYPHI 'A' DIRECT ANTIGEN RAPID TEST, more specific confirmatory testing should be done.
3. A clinical evaluation of the patient's situation and history should also be made before a final diagnosis is established.
4. 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.
5. The instructions for use and reading of the test instructions must be followed carefully for the test to perform properly.

SPECIMEN COLLECTION & PREPARATION

1. The ACCUCARE® ONE STEP S.TYPHI / S.PARATYPHI 'A' DIRECT ANTIGEN RAPID TEST can be performed using either serum or stool.
2. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
3. Bring specimens to room temperature prior to testing.
4. If specimens are to be shipped, it should be packed in compliance with federal regulations for transportation of etiologic agents.

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.

ISO 13485:2016

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For Stool Samples Only:
Add about ½ gram 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.

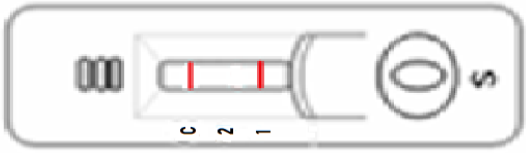
3. Allow reaction to occur and read the result between 10 to 20 minutes. Do not interpret after 30 minutes.

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.

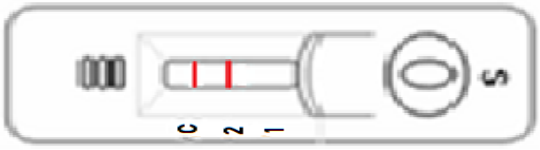
INTERPRETATION OF RESULTS

1. POSITIVE

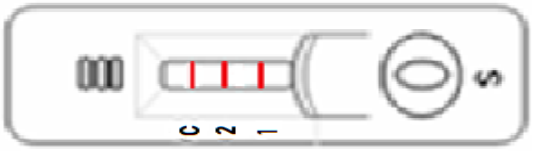
- If two color lines appear, one at control region 'C' and other at test region '1', the specimen is positive for Salmonella Typhi.



- 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.

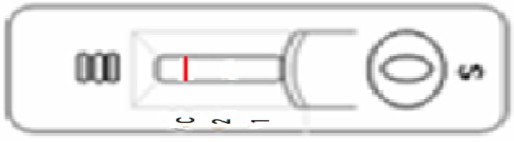


- If three color line appear, one at control line 'C', one at test region '1' and one at test line '2', the specimen is positive for both Salmonella Typhi & Salmonella Paratyphi 'A' Antigen.



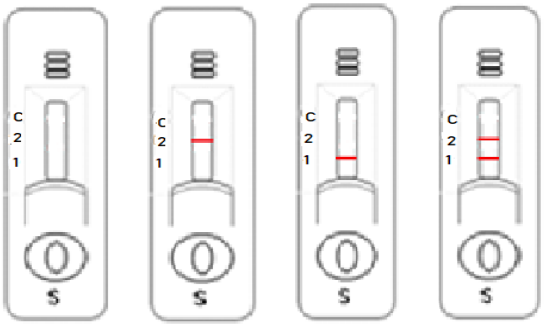
2. NEGATIVE

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.

PERFORMANCE CHARACTERISTICS

The ACCUCARE® ONE STEP S. TYPHI / S. PARATYPHI 'A' DIRECT ANTIGEN RAPID TEST has been evaluated with positive and negative and data are as below:

Specimen	Positive	Negative	Total
Positive	24	2	26

Sensitivity: 92.3 %

Specimen	Positive	Negative	Total
Negative	3	97	100

Specificity: 97.0 %

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.

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		Do not reuse
IVD	For *in vitro* Diagnostic use only		Keep Dry
Σ	Tests per Kit		Do Not Use if Damaged

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