PARAMCARE™ Salmonella typhi Ag Rapid Test Kit for detection of Salmonella typhi antigen in human Stool

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
01 Test	PTYA 01
05 Tests	PTYA 05
10 Tests	PTYA 10
25 Tests	PTYA 25
50 Tests	PTYB 50

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 to perform. It is the easiest and most specific method for detecting S. typhi infection.

PRINCIPLE

The PARAMCARE™ Salmonella typhi Ag Rapid Test Kit 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 S. typhi 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 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, the monoclonal antibody captures the complex. This forms a visible pink/purple band in the test region of the rapid test. If no antigen is present, there is no line formation in the test regions. The remaining complex continues to migrate to another immobilized antibody on the membrane in the

Control region (C) of the card, and is captured, which then forms a band indicating proper performance of the test.

CONTENTS

Test Device
Extraction tube filled with Assay Buffer
Instruction for Use (IFU)
Desiccant

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 PARAMCARE™ Salmonella typhi, Ag Rapid Test Kit is designed to detect S. typhi antigen in human Stool samples only. Testing of any other body fluids has not been validated and may not yield appropriate results.
2. For samples that test positive (reactive) the PARAMCARE™ Salmonella typhi Ag Rapid Test Kit, 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 infection even if antigen is present. Also, a negative result does not preclude the possibility of infection with S. typhi.
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 PARAMCARE™ Salmonella typhi Ag Rapid Test Kit can be performed using human 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.
3.

For Stool Samples Only:

Poke the stool sample in at least 3 places using the sample applicator of the extraction tube.
Mix the sample in 1000 µl of Buffer provided in the pre-filled extraction tube.
Mix well and allow to settle for 5 minutes or to allow the large particles to settle.
Then add 3 drops (75-80 µL) to the Sample well using same extraction tube.

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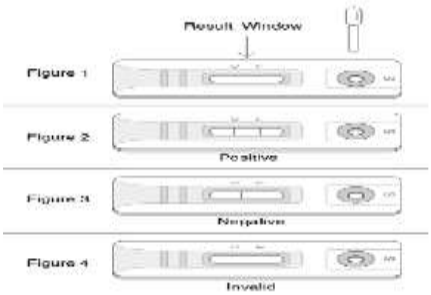
NOTE: One more drop of diluent from the previously prepared stool sample may be added if the membrane does not clear sufficiently within 10 minutes.

INTERPRETATION OF RESULTS



1) Positive
The control line (C) and test line (T) lines are visible on the test device. This is positive for S. typhi antigen. This is indicative of presence of S. typhi antigen.
2) Negative
The control line is the only visible line on the test device. No S. typhi antigens were detected.
3) Invalid
No line appears at 'C' and 'T' side.
No line appears at 'C' side and the line appears only at 'T' side.
Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.

NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of *S. typhi* antigen present in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.

PERFORMANCE CHARACTERISTICS

The PARAMCARE™ Salmonella typhi Ag Rapid Test Kit has been evaluated with known positive and negative samples for which data is as below:

Specimen	Positive	Negative	Sensitivity
S. Typhi Positive	60	00	100%

Specimen	Positive	Negative	Specificity
Negative	03	217	98.63%

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
REF	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2, Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.
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