Fastep®

TYP-W23

Typhoid fever Rapid Test Device (Whole Blood/Serum/Plasma)

INTENDED USE

Typhoid fever Rapid Test Device is an immunochromatographic assay designed for the qualitative detection of specific IgG and IgM andodies against a specific *Salmonella typhi* antigen（1-3） in human serum, plasma or whole blood. It is intended to be used as in vitro diagnostic of typhoid fever. The results obtained should not be the sole determinant for clinical decision.

INTRODUCTION

Typhoid fever is an infectious disease caused by a bacterium, *Salmonella typhi*. It continues to be a major health problem especially in the Asia Pacific region, the Indian subcontinent, Central Asia, Africa and South America (4). Definitive clinical diagnosis of typhoid is unreliable because typhoid fever symptoms mimic other diseases with fever that are common in this part of the world. Clinical presentations vary tremendously among patients and cover a wide spectrum, hence the need for a good laboratory test (5). In additional, an accurate diagnosis of typhoid at an early stage is important not only for an aetiological diagnosis for the patient but also to identify individuals that might serve as a source of infection6. Thus all cases of fever should be tested for typhoid and a rapid laboratory tests will be required. Typhoid fever Rapid Test Device offers early and specific diagnosis of typhoid.

PRINCIPLE

Typhoid fever Rapid Test Device (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of specific IgM antibodies against a specific *Salmonella typhi* antigen in whole blood, serum, or plasma. During testing, the specimen reacts with Goat anti-Human IgM/IgG -coated particles in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the *Salmonella typhi* antigen in test line region. If the specimen contains IgM antibodies against a specific *Salmonella typhi* antigen, a colored line will appear in test line region. If the specimen does not contain IgM antibodies against a specific *Salmonella typhi* antigen, no colored line will appear in the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

- Individually packed test devices
- Disposable pipettes
- Package insert
- Chase buffer

Materials Required but Not provided

- Specimen collection container
- Centrifuge
- Micropipette
- Timer
- Lancets

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use the test if the pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

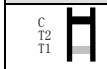
- Typhoid fever Rapid Test Device (Whole Blood/Serum/Plasma) is intended for use with human whole blood, serum or plasma specimens only.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.

PROCEDURE

Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.
2. Using the provided disposable pipette, transfer 2 drops of serum/plasma (approximately 50 µl) **or** 3 drops of whole blood (approximately 75 µl) to the specimen well (S) of the device and add 1 drop of buffer to the sample well, then start the timer.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
   As the test begins to work, color will migrate across the membrane.
3. The result should be read in 15 minutes. Do not interpret the result after 15 minutes.

INTERPRETATION OF RESULTS

Result	Test Line (T) Intensity	Possible Interpretation
POSITIVE	Three distinct red lines appear.	
	**Two colored bands appear on the membrane.** One band appears in the control region (C) and another band appears in the test region (T1).	A Test Line (T1) appears that means IgG is positive.
	**Two colored bands appear on the membrane.** One band appears in the control region (C) and another band appears in the test region (T2).	A Test Line (T2) appears that means IgM is positive.
	**Three colored bands appear on the membrane**	T1、T2 both appear mean IgG、IgM both are positive.
NEGATIVE	**Only one colored band appears, in the control region (C),** and no apparent red or pink line appears in the test region (T).	
	No Test Line (T)	A No Test Line result could be interpreted as IgG、IgM both are negative.
INVALID		
	Control line fail(s) to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for failure of reference lines to develop. 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:

1. A negative result can occur if the quantity of *Salmonella typhi* specific antibodies present in the specimen is below the detection limits of the assay, or the antigens that are detected are not present during the stage of disease in which a sample is collected.
2. A negative test result cannot exclude a recent infection.
3. The presence of detectable *Salmonella typhi* specific antibodies may mean positive for e Typhoid fever. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. This product is designed for use with human serum, plasma and whole blood only.

2. The test is a qualitative assay and is not for quantitative determination of antibodies concentration levels. The intensity of the band does not have linear correlation with the antibody titer of the specimen.

3. The results obtained should only be interpreted in conjunction with other diagnostic results and clinical information.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity and Specificity

The Typhoid fever Rapid Test Device (Whole Blood/Serum/Plasma) has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. Sensitivity and specificity Typhoid fever Rapid Test Device for are 90% and 80% respectively.

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of negative and positive specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the negative and positive specimens.Three different lots of the Typhoid fever Rapid Test Device (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >99% of the time.

LITERATURE REFERENCES

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4. Ivanoff B, Levine MM, Lambert PH (1994). Vaccination against typhoid fever: present status. Bull World Hlth Org 72: 957-71.
5. Levine MM, Grados O, Gilman RH, Woodward WE, Solis-Plaza R, Waldman W (1978). Diagnostic value of the Widal test in areas endemic for typhoid fever. Am J Trop Med Hyg 27: 785-800.
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GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse

Fastep®

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