TYPHOID RAPID TEST

(Serum/Plasma/Whole Blood)

INTENDED USE

The Typhoid Rapid Test Cassette is a rapid chromatographic immunoassay for the simultaneous detection and differentiation of IgG and IgM types of antibodies against Salmonella typhi (S. typhi) in human serum or plasma. It is intended to be used as a screening test as an aid in the diagnosis of infection with S. typhi. Any reactive specimen with the Typhoid rapid test cassette needs to be confirmed with alternative testing method.

SUMMARY AND EXPLANATION OF THE TEST

Typhoid fever is caused by S. typhi, a Gram-negative bacterium. World-wide an estimated 17 million cases and 600,000 associated deaths occur annually'. Patients who are infected with HIV are at significantly increased risk of clinical infection with S. typhi2. Evidence of h. pylori infection also presents an increased risk of acquiring typhoid fever. 1-5% of patients become chronic carrier harboring S. typhi in the gallbladder.

The clinical diagnosis of typhoid fever depends on the isolation of S. typhi from blood, bone marrow or a specific anatomic lesion in the facilities that cannot afford to perform this complicated and time consuming procedure, Widal test (also referred as Weil-Felix Test) is used to facilitate the diagnosis. However, many limitations lead to difficulties in the interpretation of the Widal test 3'4.

In contrast, the Typhoid Rapid Test Cassette is a simple and rapid laboratory test. The test simultaneously detects and differentiates the IgG and the IgM antibodies to S. typhi specific antigens in whole blood, serum or plasma thus aid in the determination of current or previous exposure the S. typhi.

TEST PRINCIPLE

The Typhoid Rapid Test Cassette is a qualitative, membrane based immunoassay for the detection of antibodies (IgG and IgM) to Salmonella typhi (S. typhi) in human whole blood, serum or plasma. The diagnostic test cassette consists of two components: an IgG component and an IgM component. The IgG line region is pre-coated with reagents for the detection of anti-S. typhi (IgG). The IgM line region is pre-coated with monoclonal antihuman IgM for detection of anti-S. typhi (IgM).

During testing, specimen dispensed into the sample well of the test cassette binds with Typhoid conjugates impregnated in the reagent area, if the specimen contains anti-Typhoid antibodies. The immunocomplex thus formed migrates by capillary action. If the present antibodies in specimen are of IgG types, the immunocomplex is then captured by the pre-coated reagents on the membrane, forming a colored IgG line, indicating a S. typhi IgG positive test result. If the present antibodies in the specimen are of IgM type, the immunocomplex would he captured on the membrane hy the pre-coated antihuman IgM antibody, forming a colored IgM line, indicating a S. typhi IgM positive test result.

Absence of any T lines (IgM and IgG) indicates a negative result. A colored control line (C) should always appear in case of a positive or a negative result. Its absence indicates invalid test results.

REAGENTS AND MATEREIALS PROVIDED

Typhoid IgG/IgM Test cards contain the following:

- Test Device with activated silica gel
- Plastic Dropper.
- Assay Buffer Bottle
- Package Insert (Instruction for use)

MATERIALS MAY BE REQUIRED AND NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDE

- Timer
- Digital Clock
- Specimen collection container Tube

WARNINGS AND PRECAUTIONS:

For in Vitro Diagnostic Use

- This package insert must be read completely before performing the test.
- The test device should remain in the sealed pouch until use
- Do not use expired devices.
- Do not use the kit if the cassette package is damaged or the seal is broken.
- Bring all reagent to room temperature (15-30°C) before use.
- Do not use hemolyzed blood specimens for testing.
- Wear personal protective equipment,such as gloves and lab coats when handling kit reagents.wash hands thoroughly after performing the test.
- Do not smoke,drink or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and material used to perform the test as bio-hazardous waste.

REAGENT PREPARATION AND STORAGE

INSTRUCTIONS: All reagents are ready to use as supplied. Store unused test device unopened at 2-30 °C, ensure that the test device brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperature 30°C.

SPECIMEN COLLECTION, STORAGE AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

1. Plasma

- **Step 1:** Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively, in Vacutainer®) by venipuncture.
- **Step 2:** Separate the plasma by centrifugation.
- **Step 3:** Carefully withdraw the plasma into a new per-labeled tube.

2. Serum

- **Step 1:** Collect blood specimen into a red top collection tube (containing no anti coagulants in Vacutainer®) by venipuncture.
- **Step 2:** Allow the blood to clot.
- **Step 3:** Separate the serum by centrifugation.
- **Step 4:** Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store Specimens at 2-8°C if not tested immediately, for up to 5 days. The specimens should be frozen at -20°C for longer storage.

.3.Whole Blood

- Drops of whole blood can be obtained by either finger tip puncture or venipuncture. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®). Do not use hemolyzed blood for testing.
- Whole blood specimens should be store in refrigeration (2-8°C), if not tested immediately. The specimens must be tested within 24 hours of collection.

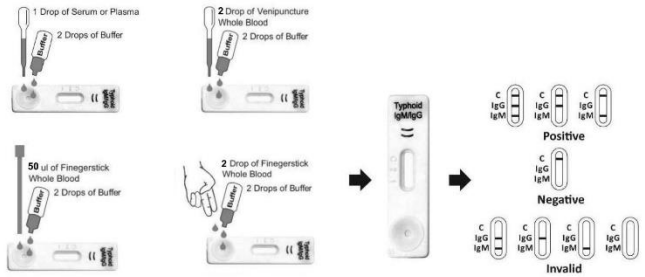
DIRECTIONS FOR USE

Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it.
2. Remove the test cassette from the sealed pouch and place it on flat dry surface.
3. **For Serum or Plasma Specimen**: Hold the dropper vertically and transfer **1 Drop** of serum or plasma (**approximately 25µl**) to the specimen area, then add **2 Drop** of buffer **(approximately 80µl),** and start the timer, see illustration below.

   .For Whole Blood Specimen: Hold the dropper vertically and transfer **2 Drop** of whole blood (**approximately 50µl**) to the specimen area, then add **2 drops** of buffer (**approximately 80µl**), and start the timer. See illustration below.

4. Wait for the colored line(s) to appear. The test result should be read at 15-20 minutes.
   Note. ***Do not interpret the result after 20 minutes*****.**



INTERPRETATION OF RESULT

(Please refer to the illustration above)

Positive: Two or three lines appear. One colored line should always appear in the control line region (C) and another one or two apparent colored line(s) should be in the test line region(s) (IgM and/or IgG).

IgM Positive: Along with line in Control region (C), a line appears in IgM region. It indicates a positive Test result for antibodies to S. typhi (Isotype IgM)

IgG Positive: Along with line in Control region (C), a line appears in IgG region. It indicates a positive Test result for antibodies to S. typhi (Isotype IgG)

Note: The intensity of the color in the test line regions (IgM and IgG) may vary depending on the concentration of Typhoid antibodies present in the specimen. Therefore, any shade of color in the test line region (IgM and/or IgG) should be considered positive.

Negative: One colored line appears in the control line region (C). No line appears in the test line regions (IgM and IgG).

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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

1. The assay procedure and the test result interpretation must be followed closely when performing the assay. Failure to follow the procedure may give inaccurate results.
2. The Typhoid Rapid Test Cassette is for qualitative detection of antibodies to S. typhi in human whole blood, serum or plasma. The intensity of the test band has not linear correlation with the antibody titer in the specimen.
3. A negative result only indicates absence of anti-S. typhi antibodies above detectable levels. A negative test result does not preclude the possibility of exposure to S. typhi as a negative result can occur if the quantity of anti- S typhi antibodies present in the specimen is below the detection limit of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
4. Specimens containing unusually high titer ot heterophile antibodies or rheumatoid factor may affect expected results.
5. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

EXPECTED VALUES

The Typhoid Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial Typhoid ELISA test. The correlation between these two systems is over 99%.

PERFORMANCE CHARACTERISTICS

1.Sensitivity and Specificity

A clinical evaluation was conducted comparing the results obtained using the Typhoid Rapid Test Cassette to Typhoid IgG/IgM ELISA Testing. The study included 314 IgG specimens and 334 IgM specimens, and about the IgG specimen both assays identified 298 negative and 13 positive results, about the IgM specimen both assays identified 298 negative and 31 positive results.

IgM Results

Method		S. typhi EIA (IgM)		Total Results
Typhoid Rapid Test Cassette for IgM	Results	Positive	Negative	
	Positive	31	3	34
	Negative	2	298	300
Total Results		33	301	334

Sensitivity: 93.9%
Specificity: 99.0%
Accuracy : 98.5%

IgG Results

Method		S. typhi EIA (IgG)		Total Results
Typhoid Rapid Test Cassette for IgG	Results	Positive	Negative	
	Positive	13	1	14
	Negative	2	298	300
Total Results		15	299	314

Sensitivity: 86.7%
Specificity: 99.6%
Accuracy : 99.0%

2. Cross-reactivity

The Typhoid Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for HBsAg, HBsAb, HbeAg, HBeAb, HBcAb, HCV.HIV, Syphilis, H. Pylori, CMV, Rubella and Toxo positive specimens. The results showed no cross-reactivity.

LIMITED EXPRESS WARRANTY DISCLAIMER

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REFERANCE

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