Salmonella Typhi IgG/IgM Rapid Test Kit

(Immunochromatography)

Product Name

Salmonalla Typhi IgG/IgM Rapid Test Kit (Immunochromatography)

Intended Use

The Typhoid IgG/IgM Rapid Test is a lateral flow immunoassay for the simultaneous detection and differentiation of anti-*Salmonella typhi* (*S. typhi*) IgG and IgM in human serum, plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with *S. typhi.* Any reactive specimen with the Typhoid IgG/IgM Rapid Test must be confirmed with alternative testing method(s).

Test Principle

The Typhoid IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant *S. typhoid* H antigen and O antigen conjugated with colloid gold (Typhoid conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing two test bands (M and G bands) and a control band (C band). The M band is pre-coated with monoclonal anti-human IgM for the detection of IgM anti-*S. typhi*, G band is pre-coated with reagents for the detection of IgG anti-*S. typhi*, and the C band is pre-coated with goat anti rabbit IgG.

When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. Anti-*S. typhi* IgM if present in the specimen will bind to the Typhoid conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a burgundy colored M band, indicating a *S. typhi* IgM positive test result.

Anti-*S. typhi* IgG if present in the specimen will bind to the Typhoid conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a burgundy colored G band, indicating a *S. typhi* IgG positive test result.

Absence of any test bands (M and G) suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

Main Components

Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board.

Storage and Expiry

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.

Sample Requirement

1. The reagent can be used for the serum, plasma samples.
2. A sample must be collected in a clean and dry container. EDTA, sodium citrate, sodium oxalate, heparin can be used as the anticoagulants.
3. Samples may be stored at 2-8℃ for 3 days prior to assay, and at -20 ℃ for 2 years. Repeat freeze and thaw for no more than 3 times.

Test Procedure

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20℃-30℃) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10℃-50℃)

1. Take off the outer packing, put the cassette onto the desk with the sample window up.
2. Drop 1 drop (25 μL) of serum/plasma vertically into the sample hole of the cassette(S). Add 2 drops (80-100μl) of sample buffer into the diluents hole of the cassette(D).
3. Observe the test results immediately within 10-20 minutes, the result is invalid over 20 minutes.

Don't read result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

Result Judgment

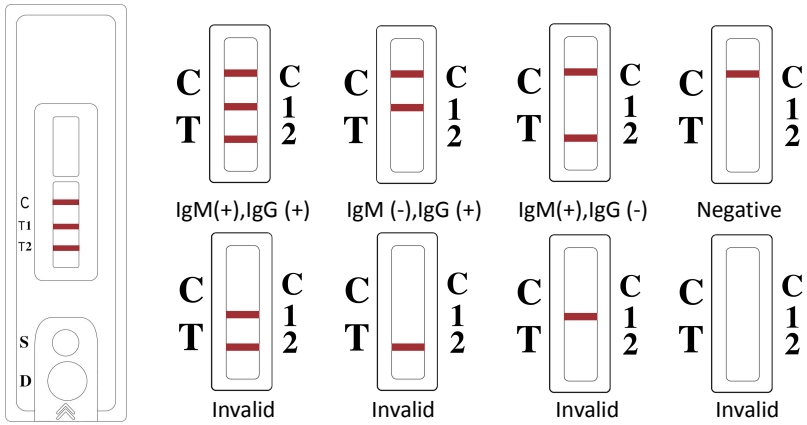
POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the T1 test region (T1), indicating the IgG positive.

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the T2 test region (T2), indicating the IgM positive.

POSITIVE: Three distinct red lines appear in the control region (C), the T1 test region (T1) and the T2 test region (T2), indicating the IgG and IgM positive.

NEGATIVE: One red line appears in the control region(C). No apparent red or pink line appears in the test region (T1 and T2).

INVALID: No red bands appear or control line fails to appear, indicating that the operator error or reagent failure.



Performance Characteristics

1. Clinical Performance For IgM Test

A total of 234 samples from susceptible subjects were tested by the Typhoid IgG/IgM Rapid Test and by a commercial S. typhi IgM EIA. Comparison for all subjects is showed in the following table:

IgM EIA	Positive	Negative	Total
Positive	31	3	34
Negative	2	198	200
Total	33	301	234

Relative Sensitivity: 91% , Relative Specificity: 99.3%, Overall Agreement: 97.9%

2. Clinical Performance For IgG Test

A total of 214 samples from susceptible subjects were tested by the Typhoid IgG/IgM Rapid Test and by a commercial S. typhi IgG EIA kit. Comparison for all subjects is showed in the following table:

IgG EIA	Positive	Negative	Total
Positive	13	1	14
Negative	2	198	200
Total	15	199	214

Relative Sensitivity: 92.9%, Relative Specificity: 99.0 %, Overall Agreement: 99.0%

Limitation

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to S. typhi in serum,plasma from individual subjects. Failure to follow the procedure may give inaccurate results.

2. The Typhoid IgG/IgM Combo Rapid Test is limited to the qualitative detection of antibodies to S. typhi in human serum, plasma. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.

3. A negative result for an individual subject indicates absence of detectable anti-S. typhi antibodies. However, a negative test result does not preclude the possibility of exposure to S. typhi.

4. 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.

5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

Precaution

1. For IN VITRO diagnose only.

2. Do not use after the expiration date.

3. The test result is invalid over 20 minutes.

4. The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.

5. All samples and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.

6. Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results.