



# Asan Easy Test<sup>®</sup> S.Typhoid IgG/IgM

IVD

One step kit for the differential detection of IgG and IgM against *S. typhi* in human serum, plasma or whole blood

Immunochromatography

[Caution: Do not read the test result after 15 minutes, The too late can give false results]

## EXPLANATION OF THE TEST

Asan Easy Test S.Typhoid IgG/IgM device is a chromatographic immunoassay kit for simultaneous and differential detection kit of anti-Salmonella typhi (*S.typhi*) IgG and IgM in human serum, plasma or whole blood. *S.typhi*-specific antigen with gold conjugate is placed in the conjugate pad, and anti-human IgG and anti-human IgM are immobilized on the membrane. When *S.typhi* antibody-positive specimen is loaded into sample injection point, the antibodies are captured the immobilized anti-human antibodies. And then, the antibodies are reacted with *S.typhi* -specific antigen-gold complex to make visible and in the test line.

## MATERIALS PROVIDED

Asan Easy Test S.Typhoid IgG/IgM device kit contains the following items:

1. Test device individually foil-pouched with a desiccant
2. Assay solution
3. Instruction manual

## PRECAUTIONS

1. The device is sensitive to humidity as well as to heat. So, it's very important to take off the device from the sealed pouch when it use.
2. Do not use the kit after the expiration date.
3. For in vitro diagnostic use only.
4. Wear protective gloves while handling samples and wash hands thoroughly after the test.
5. Dispose all the samples and devices properly after test, in accordance with GLP.
6. Do not pipette reagent or blood by mouth.
7. Do not change the usage of the product or components.
8. Do not re-use the product because it is disposable.

## SPECIMEN PREPARATION AND STORAGE

### 1. Specimen Collection and Storage

- 1) Serum, plasma or whole blood samples may be used with this test.
- 2) Whole Blood

[Collection by venipuncture]

1. Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture.
2. If blood specimens are not immediately tested, they should be refrigerated at 2~8°C.
3. When stored at 2~8°C, the blood specimens should be used within 3days.
- 3) Serum or Plasma

**[Serum]** Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen or supernatant.

**[Plasma]** Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.

- 4) If serum or plasma specimens are not tested immediately, they should be refrigerated at 2~8°C. For storage period longer than 2 weeks, freezing is recommended. They should be brought to room temperature prior to use.
- 5) Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

### 2. Precaution

- 1) Anticoagulants such as heparin, EDTA, and citrate do not affect the test result.
- 2) Use separately disposable capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.

## TEST PROCEDURE

1. Take a device from the pouch and place it on a flat.
2. [Micropipette use] Add 30 µl of serum, plasma or whole blood into the square shape of sample dropping well(S) directly.
3. Add 1 drop (30~40 µl) of assay solution into the square shape of sample dropping well(S).
4. Interpret the test results in 10~15 minutes after dropping assay solution.

## INTERPRETATION

### A. NEGATIVE RESULTS:

The control line is only visible on the test device. No *S.typhi*-specific IgG and IgM antibodies were detected. Retest in 3~5 days if *S. typhi* infection is suspected



### B. POSITIVE RESULTS:

1) IgG positive: The control line (C) and test line1 (T1) are visible on the test device. This is positive for IgG antibodies. This is indicative for the presence of anti- *S.typhi* IgG positive or rective.



2) IgM positive: The control line (C) and test line (T2) are visible on the test device. This is positive for IgM antibodies to dengue virus. This is indicative for the presence of anti- *S.typhi* IgM positive or rective.

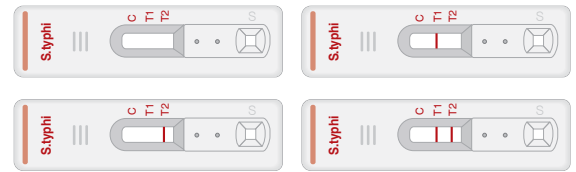


3) IgM, IgG positive: The control line (C), IgG (T1) and IgM (T2) are visible on the test device. This is positive for both IgM and IgG antibodies. This is indicative for the presence of anti-*S. typhi* IgG and IgM positive or rective.



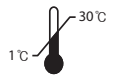
### C. INVALID RESULT:

The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques may be the reasons for control line failure. Repeat the test using a new test device.



## STORAGE & EXPIRATION

1. Asan Easy Test S.Typhoid IgG/IgM kit should be stored between 1 to 30°C (33.8-86 °F).
2. Expiration date of this kit is 24 months after it is manufacture date



## LIMITATIONS OF THE TEST

Asan Easy Test S.Typhoid IgG/IgM Device is designed for primary screening test of *S. typhi* infection. This kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive and false negative result caused by various factors. Therefore, please refer to the result of this kit and please make a final decision with clinical manifestation with other test results and doctor's view, collectively.



Manufactured & Sold by  
**ASAN PHARMACEUTICAL CO., LTD**  
Factory1: 163, Yeongcheon-ro, Hwaseong-si, Gyeonggi-do 18462, Korea  
Factory2: 122-26, Gieopdanji-ro, Gongdo-eup, Anseong-si, Gyeonggi-do, 17551, Korea

Tel: +82-31-376-5990~2  
Fax: +82-31-376-5993  
http://www.asanpharm.com  
REF Code No.: 022821  
Document Code: STYPHI-SOE00

