# Asan Easy Test® Dengue DUO

IVD

One step kit for the detection of differential IgG/IgM antibodies and NS1 antigen against dengue virus using human serum, plasma or whole blood

Caution: Please read the precautions and test procedure in this manual before using.

Immunochromatography

## EXPLANATION OF THE TEST

Asan Easy Test ® De n g ue DUO device is a chromatographic immunoassay kit for simultaneous detection of di erential immunoglobulin G(IgG)/ immunoglobulin M(IgM) antibodies and NS1 antigen against dengue virus using human serum, plasma or whole blood.

[Dengue IgG/IgM] Dengue - specific antigen complexed with gold conjugate is placed in the conjugate pad and anti-human IgG and anti-human IgM are immobilized on the membrane. When dengue 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 dengue-specific antigen-gold complex to make visible band in the test line.

[Dengue NS1 Ag] Dengue-specific antibodies complexed with gold conjugate are placed in the conjugate pad and anti-dengue NS1 antibodies are immobilized on the membrane. When dengue antigen-positive specimen is loaded into sample injection point, the antigen is captured the immobilized anti-dengue NS1 antibodies. And then, the antigen is reacted with dengue-specific antibodies-gold complex to make visible band in the test line.

This kit is for professional use and only for the initial screening test and reactive samples should be con rmed by a supplemental assay such as nucleic acid test and other immunological assays.

## MATERIALS PROVIDED

Asan Easy Test® Dengue DUO contains following items to perform the assay.

1. Test device in aluminum pouch with a desiccant
2. Assay solution for Dengue IgG/IgM test
3. Capillary pipette for Dengue IgG/IgM test
4. Disposable dropper for Dengue NS1 Ag test
5. Instruction manual

## PRECAUTIONS

1. For *in vitro* diagnostic use only. Do not re-use the product because it is disposable.
2. Read the instructions for use thoroughly in order to attain the accurate result.
3. Only the persons well-trained about the how-to-use of the kit are qualified to perform the test.
4. Do not eat or smoke during handling specimens.
5. Wear protective gloves while handing specimens and wash hands thoroughly after test.
6. During specimens handling, be careful to avoid the powder sample material in liquid form.
7. The contaminated area stained with spilled specimen must be cleaned thoroughly by using a surfactant.
8. Dispose all the samples and devices properly after test, in accordance with GLP.
9. Do not mix with other specimens.
10. Do not hold the pipette in the mouth and use the reagent of the other lots.
11. 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.
12. Do not use the kit after the expiration date.
13. The buffer solution contains sodium azide as a preserving agent. Be careful not to contact it in your eyes or onto your skin. if it does, flush it away with plenty of water, and go to see a doctor if necessary.
14. As the possibility of false positive or false negative cannot be completely eliminated due to several factors in this product, final diagnosis shall not be solely based on the result of this product, and the final diagnosis shall be decided by the results of other test methods and the judgement of a medical specialist based on clinical opinions.
15. Do not expose the product at 45℃ or higher for more than 1 week during storage or transportation of the product.
16. If the aluminium pouch of a product is damaged before use, or the packing is not well-sealed, the product shall not be used.
17. Do not change the usage of the product or components.

## SPECIMEN COLLECTION AND STORAGE

1.Specimen Collection and Storage

1) 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℃ and should be used within 3days.

③ The stored specimen need pre-warm step at room temperature before its testing.

**[Collection using lancet]**

① Clean the area to be lanced with an alcohol swab. Squeeze the end of the fingertip and pierce with lancet. Using a proper pipette, the blood can be loaded into the test device.

2) 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.

3) If serum or plasma specimens are not tested immediately, they should be refrigerated at 2~8 ℃ For storage period longer than 2 weeks, freezing is recommended.

They should be brought to room temperature prior to use.

4) Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

2. Precaution

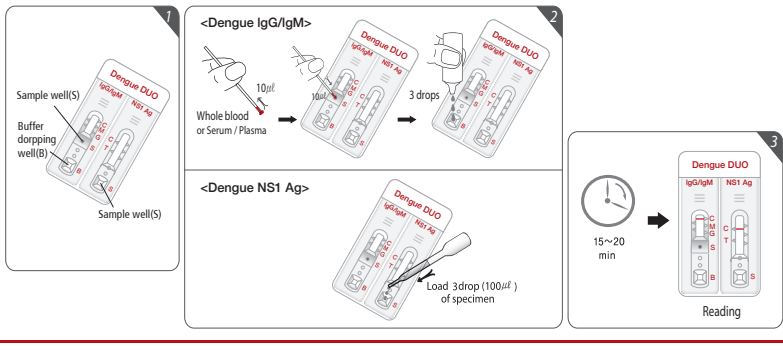
1) Anticoagulants such as heparin, EDTA, and citrate do not affect the test result.

2) Use separately disposable capillay pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous result.

## TEST PROCEDURE

**[Asan Easy Test® Dengue IgG/IgM]**

1. Take a device from the pouch and place it on a flat.
2. [Capillary pipette use] Using a capillary pipette, add 10㎕ of specimen drawn to black line into the sample well (S).
   [Micropipette use] Add 10㎕ of specimen into the sample well (S) directly.
3. Add 3drop (120㎕) of assay solution into the square shape of buffer dropping well (B).
4. Interpret the test results in 15~20 minutes after dropping assay solution. Do not read the test result after 20minutes, the reading too late can give false results.





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Immunochromatography

**[Asan Easy Test® Dengue NS1 Ag]**

1. Place all specimens, test device and allow them to room temperature prior to testing(15~30 min).
2. Please perform the test immediately after removing the device from the foil pouch.
3. With a disposable dropper, load 3 drops (100㎕) of specimen into the sample well (S) in the test device.
4. Interpret the test results between 15~20 minutes. Do not read the results after 20 minutes.

## ◎ INTERPRETATION OF THE TEST

**[Asan EasyTest® Dengue IgG/IgM]**

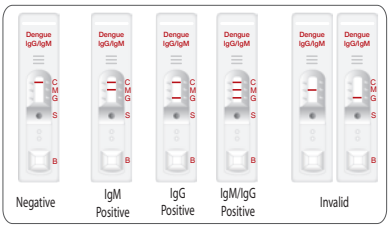
**1. Negative Results :**
The control line is only visible on the test device. No dengue-speci c IgG and IgM antibodies were detected. Retest in 3~5days if dengue infection is suspected.

**2. IgM Positive Results :**
The control line (C) and IgM line (M) are visible on the test device. This is positive for IgM antibodies to dengue virus. This is indicative of a primary dengue infection.

**3. IgG Positive Results :**
The control line (C) and IgG line (G) are visible on the test device. This is positive for IgG antibodies. This is indicative of a secondary or previous dengue infection.

**4. IgG and IgM Positive Results :**
The control line (C), IgM (M) and IgG (G) are visible on the test device. This is positive for both IgM and IgG antibodies. This is indicative of a late primary or early secondary dengue infection.

**5. Invalid Results :**
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.



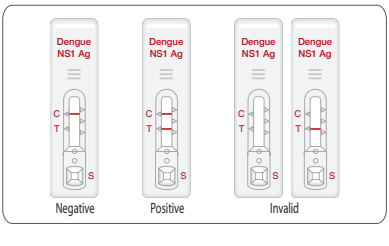

**[Asan EasyTest® Dengue NS1 Ag]**

**1. Negative Results:**
The presence of only one purple band (control band) within the window indicate a negative result.

**2. Positive Results:**

Two bands (“T” band and “C” band) are appeared in the test line and control line.

**3. Invalid Results:**
If no band or only T line are visible within the window after performing the test, the result is considered invalid. Some causes of invalid results are: not following the directions correctly or the test may have deteriorated beyond the expiration date.




## ◎ STORAGE & EXPIRATION


1. Asan Easy Test® Dengue DUO should be stored between 1~30℃ (33.8~86 ℉).
2. Expiration date of this kit is 24 months after its manufacture date.

## ◎ LIMITATIONS OF THE TEST

Asan Easy Test Dengue DUO is designed for primary screening test of dengue virus IgG/IgM antibodies and NS1 antigen. Although this can provide fast and easy way to get a result, the testing do not completely exclude the possibility of false and positive or negative result caused by various factor. So, refer to the result of the kit, please make a final decision with clinical manifestation, other test results and doctor’s view, collectively.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