IVD

Asan Easy Test® Dengue IgG/IgM

ASAN

One step kit for the differential detection of IgG and IgM against dengue virus type Ⅰ, Ⅱ, Ⅲ and Ⅳ from 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® Dengue IgG/IgM device is a chromatographic immunoassay kit for rapid and differential detection kit of immunoglobulin G (IgG) and immunoglobulin M (IgM) against all types of dengue viruses from human serum, plasma or whole blood.
Dengue antibody complexed with gold conjugate is placed in the conjugate pad and dengue specific antigen 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-antibody gold complex to make visible band in the test line.

PROPERTIES

Asan Easy Test® Dengue IgG/IgM device can detect dengue-specific antibodies so that the device is suitable for the diagnosis of 4 types of dengue infections.

MATERIALS PROVIDED

Asan Easy Test® Dengue IgG/IgM device kit contains the following items:
1. Test device individually foil-pouched with a desiccant ..... 25 units
2. 10㎕ Capillary pipette ..... 25 units
3. Assay solution ..... 1 vial
4. Instruction manual ..... 1 sheet

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) 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℃.
③ When stored at 2~8℃, the blood specimens should be used within 3days.

[Collection using a lancet]

① Clean the area to be lanced with an alcohol swab.
② Squeeze the end of the fingertip and pierce with a sterile lancet provided.
③ Take a 10㎕ capillary pipette provided, immerse the open end in the blood drop and then release the pressure to draw blood into the capillary pipette to black line.

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℃ 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.

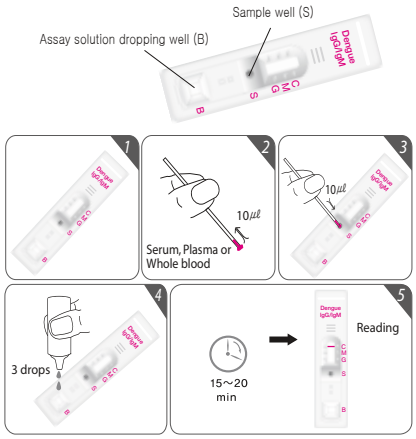
2. Precaution

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

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

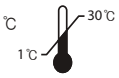
TEST PROCEDURE

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



STORAGE & EXPIRATION

1. Asan Easy Test® Denuge IgG/IgM kit should be stored between 1 to 30℃ (33.8-86 ℉).
2. Expiration date of this kit is 24 months after its manufacture date.



INTERPRETATION OF THE TEST

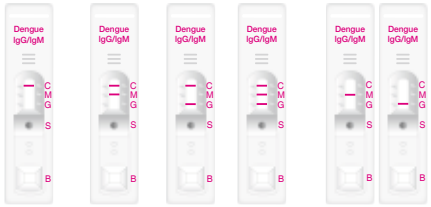
1. Negative
The control line is only visible on the test device. No dengue-specific IgG and IgM antibodies were dectected. Retest in 3~5 days if dengue infection is suspected.

2. IgM Positive
The control line (C) and IgM line (IgM) 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
The control line (C) and IgG line (IgG) 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
The control line (C), IgM (IgM) and IgG (IgG) 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
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.



Negative | IgM Positive | IgG Positive | IgM/IgG Positive | Invalid

PERFORMANCE CHARACTERISTIC

The Asan Easy Test® Dengue IgG/IgM have tested with positive and negative clinical samples confirmed by ELISA. The results are summarized in the following tables.

n= 251		Commercial ELISA		Total
		Positive	Negative	
Asan Easy Test® Dengue IgG	Positive	115	3	118
	Negative	2	131	133
Total		117	134	251

*Dengue IgG sensitivity: 98.29% (115/117)
*Dengue IgG specificity: 97.76% (131/134)

n= 247		Commercial ELISA		Total
		Positive	Negative	
Asan Easy Test® Dengue IgM	Positive	47	0	47
	Negative	1	199	200
Total		48	199	247

*Dengue IgM sensitivity: 97.92% (47/48)
*Dengue IgM specificity: 100% (199/199)

LIMITATIONS OF THE TEST

Asan Easy Test® Dengue IgG/IgM Device is designed for primary screening test of dengue 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.

ASAN
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