



Asan Easy Test® Dengue NS1 Ag 100

IVD

One step kit for the detection of NS1 against dengue virus using human serum, plasma or whole blood

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

Immunochromatography

INTENDED USE

Asan Easy Test® Dengue NS1 Ag 100 is rapid and qualitative test for the detection dengue virus NS1 antigen in human serum, plasma or whole blood. This kit is for professional use and only for the initial screening test and reactive samples should be conrmed by a supplemental assay such as nucleic acid test and other immunological assays.

EXPLANATION OF THE TEST

Asan Easy Test® Dengue NS1 Ag 100 device is a chromatographic immunoassay kit for rapid detection kit of dengue virus NS1 antigen using human blood. Dengue-specic 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-specic antibodies-gold complex to make visible band in the test line.

MATERIALS PROVIDED

Asan Easy Test® Dengue NS1 Ag 100 contains following items to perform the assay.

1. Test device individually foil-pouched with a desiccant.....25units
2. Disposable dropper25units
3. Instruction for use 1sheet

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Anyone performing an assay with this product must be trained in its use and must be experienced in laboratory procedures.
3. Do not eat or smoke while handling specimens.
4. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
5. Avoid splashing or aerosol formation.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Decontaminate and dispose of all specimens and reaction waste after test, according to GLP or other applicable national standards and / or laws.
8. Do not mix and interchange different specimen.
9. The presence of humidity may decrease the stability of the reagents. Thus, carry out the test immediately after removing the device from the foil pouch.
10. Do not use it beyond the expiration date.
11. Do not change the usage of the product or components.
12. Do not re-use the product becuse it is disposable.

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°C and should be used within 3days.
- ③ The stored specimen need pre-warm step at room temperature before its testing.

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.

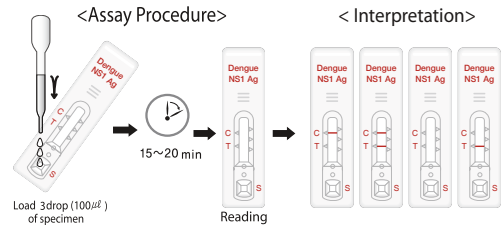
- 3) If serum or plasma specimens are not tested immediately, they should be refrigerated at 2~8 °C For storage period longer than 2 weeks, freezing is recommended. They should be brought to room temperature prior to use.
- 4) Serum or plasma specimens containing a precipitate may yield inconsistent 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 capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous result.

TEST PROCEDURE

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 (100µl) 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.

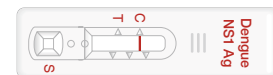


INTERPRETATION OF THE TEST

1. A color band will appear in the upper section ("C" zone) of the window to show that the test is working properly. This band is the control band.
2. The down section ("T" zone) of the window indicates the test results, test band. If another color band appears in the down section of the window, this band is the test band.

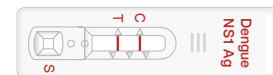
A. NEGATIVE RESULTS:

The presence of only one purple band (control band) within the window indicate a negative result.



B. POSITIVE RESULTS:

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



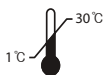
C. INVALID RESULTS:

If no band or only T band 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. It is recommended that the specimen should be retesting using a new test kit.



STORAGE & EXPIRATION

1. Asan Easy Test Dengue NS1 Ag 100 should be stored between 1~30°C (33.8~86 °F).
2. Expiration date of this kit is 24 months after its manufacture date.



PERFORMANCE CHARACTERISTIC

This clinical test was performed using a total of 243 specimens. Each specimens were tested with Asan Easy Test® Dengue NS1 Ag 100 and RT-PCR. The results are summarized in the following tables.

n= 243		RT-PCR		Total
		Dengue	No disease	
Asan Easy Test® Dengue NS1 Ag 100	Positive	137	0	137
	Negative	4	102	106
Total		141	102	243

※ Relative Sensitivity : 97.16%, Relative Specificity : >99.9%

LIMITATIONS OF THE TEST

Asan Easy Test Dengue NS1 Ag 100 is designed for primary screening test of dengue virus 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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