K -Dengue NS1 Ag Test

PURPOSE OF USE

The K-Dengue NS1 Ag Test is used to detect NS1 antigens of all four dengue serotypes in serum, plasma, and whole blood specimens collected from suspected dengue infection.

TEST PRINCIPLES

The K-Dengue NS1 Ag Test is a colored chromatographic immunoassay. The test consisted of anti-NS1 and anti-mouse IgG antibodies coated on nitrocellulose membrane at the T and C line, respectively. The conjugate pad contains anti-NS1 antibody conjugated with colloidal gold nanoparticle. If the sample contains any dengue NS1 antigen, the antigen will bind specifically to the conjugate to form NS1 antigen-antibody complex. The complex then flow to the test line coated with anti-NS1 antibody, resulting in a visible appearing on the test line indicating a positive result. No color appearing on the test line indicates a negative result. A control line (C line), an internal control, develops after adding the running buffer. If the color of the control band ("C") is not visible after performing the test, the result is considered invalid.

PROVIDED MATERIALS

1. Individually foil pouched test cassettes, with a desiccant (30 packs)
2. Sample dropper (30 pieces)
3. Runing buffer 1 bottle
4. Instruction for Use

STORAGE AND STABILITY

The K-Dengue NS1 Ag Test can be stored at temperatures between 1-30°C. The test kit is stable until the expiration date specified on the package. The test should be kept in the sealed foil pouch until use. Do not keep the test in the freezer. Do not use after the expiration date.

PRECAUTION

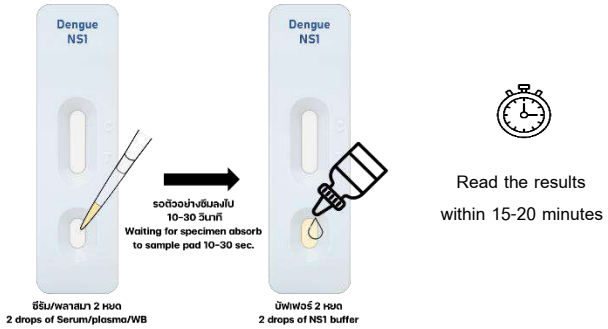
1. Test should be performed by professional healthcare providers or trained operators only.
2. Do not use the test kit after the expiration date.
3. Do not use the kit if the packaging is broken or pre-opened.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Read these Instructions for Use thoroughly before performing the test.
6. The test is for **one-time use** only, do not reuse the test.
7. The tested device and contaminated materials should be disposed of, following the standard regulation for biohazard material management.
8. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens.
9. Test should be performed immediately after opening the sealed pouch.
10. The test is intended for Dengue NS1 antigen detection only, no other viral antigens.

SPECIMEN COLLECTION

1. The K-Dengue NS1 Ag Test can be performed using serum, plasma, or venous whole blood specimens.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
3. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C for up to several months.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well before testing. Specimens cannot be freeze-thawed more than 3 times.

TEST PROCEDURE

1. Allow test cassette, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
2. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Place the test device on a clean and flat surface.
3. Use dropper to draw serum, plasma or venous whole blood and add 2 drops (40 µL) into the sample well. Then add 2 drops (about 60 µL) of running buffer to the same well. Avoid air bubbles.



4. Wait for the colored line(s) to appear. After 2 minutes, if the red color has not moved across the test window, add 1 additional drop of the running buffer to the sample well.
5. The result should be read in 10-15 minutes. Do not interpret the result after 30 minutes.
6. During 15 minutes of testing, if the result cannot be clearly read, add 1 additional drop of the running buffer to the sample well, wait for 5 minutes and then read the result.

Whole blood sample:

If whole blood sample is used, the heme residue may stain the nitrocellulose membrane. This phenomenon may affect the result reading especially in samples containing low-titer NS1 antigen. The result is clearer when testing with serum and plasma.

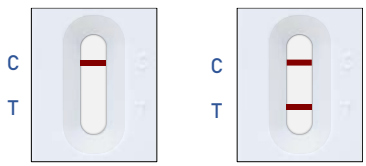
RESULT INTERPRETATION

NEGATIVE:

The presence of only one control line ("C" band). No line appears in the test line. The result is negative.

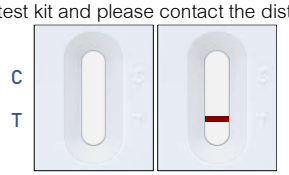
POSITIVE:

The presence of T and C lines. The result is positive.



INVALID:

The color of the control band ("C") is not visible, caused by various reasons. Repeating the test with a new device is recommended. If the same problem still occurs, stop using the test kit and please contact the distributor.



INTENDED USE

K -Dengue NS1 Ag Test

The K-Dengue NS1 Ag Test is intended for the detection of NS1 antigen of all four dengue serotypes in serum, plasma and whole blood specimens.

WARNING

The K-Dengue NS1 Ag Test is a screening test. If the test result is positive, a nucleic acid test or ELISA should always be performed further as a confirmatory test. If the result is negative, the patient's history, exposure period, time of infection, the presence of clinical signs and symptoms should also be considered for diagnosis.

QUALITY CONTROL

Procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen and buffer volume and correct procedural technique.

LIMITATIONS

1. The tests should be performed by professional healthcare providers or trained operators only.
2. This product is only for testing individual serum, plasma and whole blood. Other specimen types should not be used with this assay.
3. Use fresh samples whenever possible. Frozen and thawed samples (especially repeatedly) affect the result.
4. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
5. The result should be read in 15-20 minutes. Reading the test result too soon may yield erroneous interpretation.
6. The test is intended for dengue NS1 antigen detection only, no other viral antigens.
7. False positive results for NS1 antigen may occur due to cross-reactivity to unexpected antigens or other possible causes. Samples with positive results should be confirmed with standard testing method(s) and clinical findings before a diagnostic conclusion is made.
8. False negative result can occur if the quantity of the NS1 antigen present in the specimen is below the detection limits of the assay.
9. The K-Dengue NS1 Ag Test is limited to the qualitative detection of Dengue NS1 antigens. The intensity of the test line does not necessarily correlate to the titer of the NS1 antigens in the specimen.
10. Moisture affects the sensitivity of the test. The test should be performed immediately or within 1 hour after opening the sealed pouch.

PERFORMANCE CHARACTERISTIC

1. Sensitivity and specificity

The K-Dengue NS1 Ag Test was evaluated by testing a total of 172 samples: 52 positive serum samples (frozen), and 120 negative samples from healthy persons. Overall study results are shown in the table below.

Reference assay (ELISA)	K-Dengue NS1 Ag Test		Total
	Positive	Negative	
Positive	51	1	52
Negative	1	119	120
Total	52	120	172

Sensitivity: 98.08 % (51/52), 95%CI = 89.74-99.95%
Specificity: 99.2% (19/120), 95%CI = 95.44-99.98%
Accuracy: 98.8% (170/172), 95%CI = 95.86-99.86%

2. Cross Activity Assay

Cross-reactivity of the K-Dengue NS1 Ag Test was evaluated using 25 serum samples which contain antigens of the pathogens listed below. No false positives were found with the following:

Sample Categories	Sample Number
HBsAg	10
HCV	7
Rheumatoid factor	5
Chikungunya	3

3. Precision testing

Within-run precision and between-run precision of three different lots of the K-Dengue NS1 Ag Test have been determined by using ten replicates of three specimens: a negative, a low positive and a strong positive. The specimens were correctly identified >99% of the time.

4. Interference substance

Fourteen interference substances were used to evaluate the K-Dengue NS1 Ag Test. All of the tested substances were found to have no effect on test performance. The tested substances included acetaminophen, acetylsalicylic acid, amoxicillin, ampicillin, ascorbic acid, bilirubin, caffeine, chloramphenicol, chloroquinine, erythromycin, hemoglobin, ibuprofen, nicotinic acid, and triglycerides.

LIMIT OF DETECTION

The limit of detection (LoD) of K-Dengue NS1 Ag Test was evaluated with NS1 antigen of all four dengue serotypes. The test result is shown in the table below.

REFERENCES

1. Muhammad S., *et al*. NS1 antigen: A new beam of light in the early diagnosis of dengue infection. Asian Pac J Trop Med. 2016; 9(12):1212-1214.
2. Fauziah MK., *et al*. Use of dengue NS1 antigen for early diagnostic of dengue virus infection. Southeast Asian J Trop Med Public Health. 2011; 42(3):562-569.

NS1 antigen of dengue serotypes	Unit: ng/mL
DV1 NS1	8
DV2 NS1	4
DV3 NS1	8
DV4 NS1	64

3. Ashwini MA., *et al*. Evaluation of NS1 antigen detection for early diagnosis of dengue in tertiary hospital in Southern India. J Clin Diagn Res. 2016; 10(4):DC01-DC04.

Manufactured by

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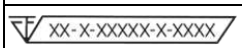
Symbols and abbreviations

Symbol	Meaning
	One time use only, do not reuse the test
	Temperature limitation
	*in vitro* diagnostic use only
	Consult instructions for use
	Manufacturer
	Registered number. FDA approved.
Lot No.	Batch code
MFD	Manufacturing date
EXP	Expiration date