IVD

Dengue NS1 Rapid Test Kit (Colloidal Gold)

Instruction for Use

Read this instruction carefully before use

A rapid test for the qualitative detection of Human Dengue NS1 in human serum ,plasma or whole blood.*For professional medical institutions use only,Not for self testing.*

PRODUCT NAME

Dengue NS1 Rapid Test-Cassette (Colloidal Gold)

SPECIFICATION

25 tests/kit;5 tests/kit;1 test/kit

INTENDED USE

The Dengue NS1 Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of dengue virus antigen (Dengue Ag) in human serum ,plasma or whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Dengue viruses. Any reactive specimen with the Dengue Ag Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION THE TEST

Dengue viruses, a family of four distinct serotypes of viruses (Den 1,2,3,4), are single-strained, enveloped, positive-sense RNA viruses. The viruses are transmitted by mosquitoes of the daytime-bitting Stegemyia family, principally Aedes aegypti, and Aedes albopictus. Today, more than 2.5 billion people living in the areas of tropical Asia, Africa, Australia, and the Americas are at risk for dengue infection. An estimated 100 million cases of dengue fever and 250,000 cases of life-threatening dengue hemorrhagic fever occur annually on a worldwide basis.

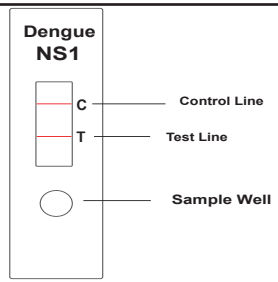
Serological detection of IgM antibody is the most common method for the diagnosis of dengue virus infection. Lately, detection of antigens released during virus replication in the infected patient showed very promising result. It enables diagnosis from the first day after the onset of fever up to day 9, once the clinical phase of the disease is over, thus allows early treatment in placed promptly4-.The Dengue NS1 Rapid Test is developed to detect circulating dengue antigen in serum ,plasma or whole blood. The test can be performed by untrained or minimally skilled personnel, without laboratory equipment.

PRINCIPLE

The Dengue NS1 Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing mouse anti-dengue NS1 antigen conjugated with colloid gold (Dengue Ab conjugates), 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with mouse anti-dengue NS1 antigen, and the C band is pre-coated with goat anti-mouse IgG antibody. The antibodies to dengue antigen recognize the antigens from all the four serotypes of the dengue virus.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the test cassette. Dengue NS1 Ag if present in the specimen will bind to the Dengue Ab conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti-NS1 antibody, forming a burgundy colored T band, indicating a Dengue Ag positive test result.

Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-mouse IgG/mouse IgG-gold conjugate regardless of the presence of colored T band. Otherwise, the test result is invalid and the specimen must be retested with another device.



REAGENTS AND MATERIALS PROVIDED

Components	25tests/kit	5tests/kit	1test/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Sample Diluent Solution with dropper	25tubes (300ul/tube)	5tubes (300ul/tube)	300ul/tube
Transfer tube	25 pcs	5 pcs	1 pcs
Package insert	1	1	1

MATERIALIS REQUIRED BUT NOT PROVIDED

Clock or Timer

WARNINGS AND PRECAUTIONS

For in Vitro Diagnostic Use

1.This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2.Do not open the sealed pouch, unless ready to conduct the assay.
3.Do not use expired devices.
4.Bring all reagents to room temperature (15°C-30°C) before use.
5.Do not use the components in any other type of test kit as a substitute for the components in this kit.
6.Do not use hemolized blood specimen for testing.
7.Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8.Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9.Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10.Dispose of all specimens and materials used to perform the test as biohazardous waste.
11.Handle the Negative and Positive Control in the same manner as patient specimens.
12.The testing results should be read within 25 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 25 minutes may give erroneous results.
13.Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. The positive and negative controls should be kept at 2°C-8°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Plasma

1.Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.
2.Separate the plasma by centrifugation.
3.Carefully withdraw the plasma into new pre-labeled tube.

Serum

1.Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
2.Allow the blood to clot.
3.Separate the serum by centrifugation.
4.Carefully withdraw the serum into a new pre-labeled tube.
5.Test specimens as soon as possible after collecting. Store specimens at 2°C to 8°C if not tested immediately.
6.Store specimens at 2°C to 8°C up to 5 days. The specimens should be frozen at -20°C for longer storage

Blood

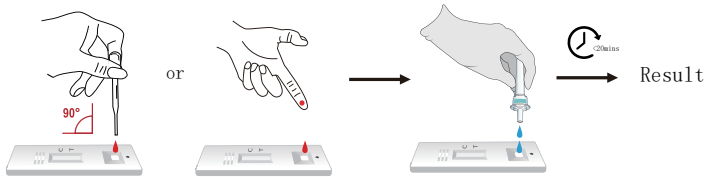
Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use any hemolized blood for testing.

ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to assay.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
Step 3: Be sure to label the device with specimen's ID number.

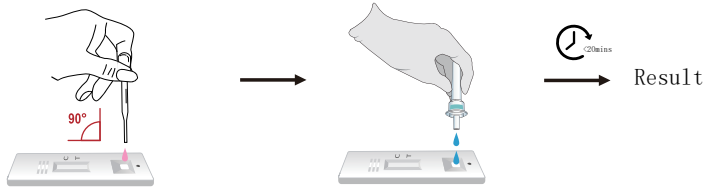
Step 4: For whole blood test
- Apply 1 drop of whole blood (about 30-35 μL) into the sample well.
- Then add 2 dropS (about 60-70 μL) of Sample Diluent immediately.



1 drop of Whole Blood 2 drops of Buffer

For serum or plasma test

- Fill the pipette dropper with the specimen.
- Holding the dropper vertically, dispense 1 drop (about 30-35 μL) of specimen into the sample well making sure that there are no air bubbles.
- Then add 2 dropS (about 60-70 μL) of Sample Diluent immediately.



1 drop of serum/plasma 2 drops of Buffer

Step 5: Set up timer.
Step 6: Results can be read in 20 minutes. Positive results can be visible in as short as 1 minute.

Don't read results after 30 minutes.To avoid confusion, discard the test device after interpreting the result.

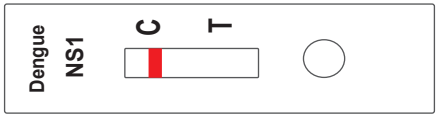
QUALITY CONTROL

Using individual Dengue NS1 Rapid Test kit as described in the Assay Procedure above, run 1 Positive Control and 1 Negative Control (provided upon request) under the following circumstances to monitor test performance:
1.A new operator uses the kit, prior to performing testing of specimens.
2.A new test kit is used.
3.A new shipment of kits is used.
4.The temperature used during storage of the kit falls outside of 2°C -30°C.

5.The temperature of the test area falls outside of 15°C -30°C
Expected results are as follows:

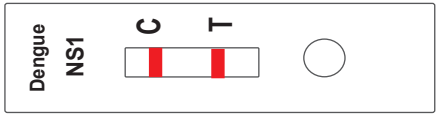
Negative Control

Only the C band shows color development. The T band shows no color development.



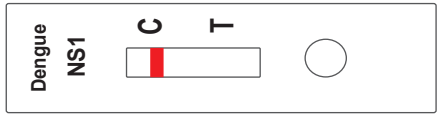
Positive Control

Both C and T bands show color development.The appearance of any burgundy color in the T band, regardless of intensity, must be considered as presence of the band.



INTERPRETATION OF ASSAY RESULT

1.NEGATIVE RESULT: If only the C band is developed, the test indicates that the level of dengue Ag in the specimen is undetectable. The result is negative or non-reactive.



2.POSITIVE RESULT: If both C and T bands are developed, the test indicates that the specimen contains dengue Ag. The result is positive or reactive.Samples with positive results should be confirmed with alternative testing method(s) such as PCR or ELISA and clinical findings before a positive determination is made.

3.INVALID: If no C band is developed, the assay is invalid regardless of color development on the T band as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

Clinical Performance

A total of 654 patient samples from susceptible subjects were tested by the Dengue NS1 Rapid Test and by a commercial EIA. Comparison for all subjects is showed in the following table:

	Dengue NS1 Rapid Test		
Dengue NS1 EIA Test	Positive	Negative	Total
Positive	289	3	292
Negative	1	361	362
Total	290	364	654

Relative Sensitivity: 98.97%, Relative Specificity: 99.72%, Overall Agreement: 99.39%

LMITATIONS OF TEST

1.The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of dengue Ag in serum ,plasma or whole blood. from individual subjects. Failure to follow the procedure may give inaccurate results.
2.The Dengue NS1 Rapid Test is limited to the qualitative detection of dengue Ag in human serum ,plasma or whole blood.. The intensity of the test band does not linear correlate with dengue Ag titer of the specimen.
3.A negative test result does not preclude the possibility of exposure to or infection with dengue viruses.
4.A negative result can occur if the quantity of dengue Ag present in the specimen is below the detection limits of the assay, or the dengue Ag that are detected are not present during the stage of disease in which a sample is collected.
5.Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6.If the symptom persists, while the result from Dengue NS1 Rapid Test is negative or non-reactive result, it is recommended to re-sample the patient few days late or test with an alternative test device such as PCR, ELISA.
7.The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
LOT	Batch code	IVD	In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don't use the product when the package is damaged		Keep dry
	Date of manufacture	Σ	Tests per kit
CE	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

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