CE IVD

FRENOVO

Dengue NS1 Rapid Test Kit

Instructions For Use

PRODUCT NAME

Dengue NS1 Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

The kit is a lateral flow, qualitative immunoassay. It is intended for use on qualitative detection of dengue virus NS1 antigen in human whole blood, serum or plasma by immunochromatography. Dengue virus NS1 antigen is a specific serological marker for dengue fever diagnosis. This product is suitable for early auxiliary diagnosis of dengue virus infection.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Dengue fever is caused by dengue virus (divided into four serotypes, denv-1-4).It is an acute infectious disease transmitted by Aedes aegypti and Aedes albopictus. Clinical types can be divided into dengue fever, dengue hemorrhagic fever and dengue shock syndrome. The main clinical manifestations include fever, headache, muscle and joint pain, extreme fatigue, rash, lymphadenopathy and leukopenia. The initial infection of dengue virus patients, generally mild clinical manifestations, can be manifested as asymptomatic recessive infection, or mild, typical dengue fever; re infection of heterogeneous dengue virus, the condition is more serious, clinical dengue hemorrhagic fever and shock syndrome increased probability, high mortality, is a serious infectious disease.In the early stage of infection, there was a high concentration of NS1 antigen in the serum of patients, which could be detected in 1-9 days after the onset of fever.

The nitrocellulose membrane test area (T) of dengue virus NS1 antigen test strip was coated with monoclonal antibody against dengue virus NS1 protein, and the quality control area (c) was coated with polyclonal antibody against chicken IgY, When the sample contains dengue virus NS1 antigen and the concentration is higher than the minimum detection limit, the anti dengue virus NS1 protein monoclonal antibody labeled with colloidal gold combines with dengue virus NS1 antigen in whole blood, serum or plasma to form a reactive complex. Under the action of chromatography, the reactive complex moves forward along the nitrocellulose membrane and interacts with the detection area (T) on the nitrocellulose membrane. When the pre-coated monoclonal antibody against dengue virus NS1 protein combines to form a complex, and finally forms a red reaction line visible to naked eyes, the result is positive; on the contrary, when the sample does not contain dengue virus NS1 antigen or the concentration is lower than the minimum detection limit, there is no red reaction line in the detection area (T), and the result is negative. Whether the sample contains NS1 antigen or not, a red reaction line will be formed in the quality control area (c).

MATERIALS PROVIDED

Each kit contains:

1. Test Devices: 20 pieces test devices individually pouched.
2. Wash Buffer Solution: 2.0ml in dropper bottle.
3. Droppers: 20 pieces droppers of 25 ul
4. Instructions For Use: 1 copy attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves and/or protective clothing
- Centrifuge(for plasma only)
- Micropipette
- Lancets(for fingertip whole blood only)

WARNINGS

1. Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kitis for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. The kit rapid test is for professional use only.
2. The package insert instructions must be followed to ensure optimum test performance.
3. The kitis intended for in vitro diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke, eat, drink, apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121℃ for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of wash buffer, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate dropper and device for each specimen tested.

Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix wash buffer solution/test devices from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 10 minutes incubation time following the addition of specimen and wash buffer solution. Do not read results beyond 15 minutes.

STORAGE INSTRUCTIONS

1. The kit kit should be stored between 2-30°C and the shelf life is 24 months.
2. The Kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the wash buffer solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

SAMPLE COLLECTION AND PREPARATION

1. Applicable samples： Whole Blood/Serum/Plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear nonhemolysis specimens.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.
4. Serum and plasma specimens may be stored at 2~8 ℃ for up to 7 days, for long term storage, serum/plasma specimens should be kept below -20℃.Whole blood collected by venipuncture should be stored at 2~8℃ if the test is to be run within 2 days of collection.
5. Do not freeze whole blood specimens.
6. Whole blood collected by finger stick should be tested immediately.
7. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
8. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
9. EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

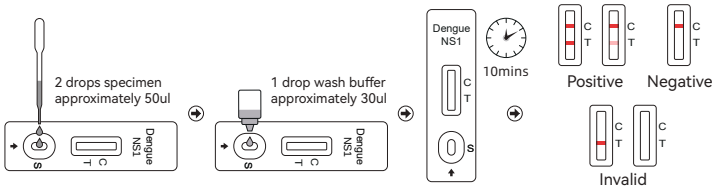
QUALITY CONTROL

An internal procedural control is included in the test. a colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

TEST PROCEDURE

Allow the test device, specimen, extraction solution to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed pouch and use it within one hour. Place the test cassette on a clean and level surface.
2. Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (two drops/approximately 50ul), then add one drop of buffer(approximately 30ul)to the sample well and start the timer. Avoid trapping air bubbles in the sample well.
3. Wait for the colored line(s)to appear. The test result should be read at 10 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

Negative result: if there is only a quality control line C, the detection line is colorless, indicating that Dengue NS1 antigen has not been detected and the result is negative.

Positive result: if both the quality control line C and the detection line appear, the Dengue NS1 antigen has been detected and the result is positive for antigen.

Invalid result: if the quality control line C is not observed, it will be invalid regardless of whether there is detection line (as shown in the figure above), and the test shall be conducted again.

LIMITATIONS

1. The kit is for in vitro diagnostic use only. The test should be used for the detection of Dengue NS1 antigen in serum, plasma or whole blood specimens only. Neither the quantitative value nor the rate of increase in Dengue NS1 antigen concentration can be determined by this qualitative test.
2. The kit will only indicate the presence of Dengue NS1 antigen in the specimen and should not be used as the sole criteria for the diagnosis of Dengue infection.
3. The continued presence or absence of antigen cannot be used to determine the success or failure of therapy.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. If the test result is negative and clinical symptoms persist additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Dengue infection.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

Clinical samples(serum/plasma) confirmed Dengue NS1 antigen positive or negative by PCR test with the kit.The results indicated that the kit has a high sensitivity and specificity as summarized below:

Clinical study		PCR		
Dengue NS1 Rapid Tes	Results	Positive	Negative	Total Results
	Positive	58	7	65
	Negative	4	93	97
Total Results		62	100	162

Accuracy Results:

Clinical sensitivity=93.55 % (95%CI* 84.30% to 98.21%)
Clinical specificity=93.00 % (95%CI* 86.11% to 97.14%)
Accuracy=93.21% (95%CI*88.18% to 96.56%)

Minimum detection limit

Dengue NS1 sub-type	minimum detection limit
Type I	$8.3xl0^2TCID^{50}/ml$
Type II	$8.3xl0^3TCID^{50}/ml$
Type III	$1.5xl0^3TCID^{50}/ml$
Type IV	$3.0xl0^3TCID^{50}/ml$

Cross Reaction

The following organisms were tested with FRENOVO The kit and has no effect on the negative and positive test results of this reagent, and there is no cross-reaction.

Encephalitis B	hepatitis C
measles	hepatitis B
rubella	leptospirosis
influenza A	hemorrhagic fever
epidemic cerebrospinal meningitis	sepsis
typhoid	tsutsugamushi
AIDS	

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use, Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2°C 30°C	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
	Biological risks	CE	CE mark

Hangzhou Frenovo Biotech Co., Ltd.
Address: Room 401,Building 26, Room 401&301,Building 27,No.488-1,Donghu North Road, Donghu Street,LinPing District,Hangzhou City,Zhejiang Province.China.
Tel: +86-571-89170657
Email: business@frenovo.com

EC REP
CMC Medical Devices & Drugs S.L
Address: C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Email: info@cmcmedicaldevices.com

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