Dengue IgG/IgM Rapid Test Kit
Instructions For Use

PRODUCT NAME

FRENOVO Dengue IgG/IgM Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

FRENOVO Dengue IgG/IgM Rapid Test is an in vitro qualitative immunochromatographic assay for the rapid detection of anti-dengue IgG/IgM antibodies in human blood, serum and plasma specimens simultaneously. The test results are intended to aid in the diagnosis of dengue infection.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Dengue fever is one of the most important mosquito-borne diseases in the world in the terms of morbidity, mortality. Dengue fever virus (serotypes 1 – 4) belongs to the group flavivirus, and is transmitted in nature by day-biting Aceder mosquitos. The most important mosquito vector is highly domesticated and urban species, Aedes aegypti. Primary Dengue infection, also known as Dengue Fever, is the most common type of dengue illness. It is associated with mild to high fever, headache, muscle pain and skin rash. Secondary infection is known as Dengue Hemorrhagic Fever (DHF) or Dengue Shock Syndrome, and often results in high fever and in many cases, with hemorrhagic events and circulatory failure. The fatality rate in patients with Dengue Shock Syndrome can be as high as 44%. Dengue presents typically as a fever of sudden onset with headache, retrobullar pain, pain in the back and limbs (break-bone fever), lymphaderopathy and maculopaplar rash. Patients diagnosed with dengue in endemic areas generally have secondary infection, whereas patients in non-endemic areas are usually diagnosed with primary infection. Specific antibody responses to Dengue virus enable serodiagnosis and differentiation between primary and secondary dengue infections.

FRENOVO Dengue IgG/IgM Rapid Test utilizes the principle of Immunochromatography. Mouse anti-human IgM and human IgG antibodies are immobilized on the nitrocellulose membrane respectively, as two individual test lines (IgM line and IgG line) in the test window of the test device. As the test sample flows through the membrane within the test device, the colored–Dengue specific recombinant antigen-colloidal gold conjugate complexes with specific antibodies (IgM and/or IgG) of Dengue virus, if present in the sample. This complex moves further on the membrane to the test region where it is captured by the antihuman IgM and/or human IgG antibodies coated on the membrane leading to formation of a colored band, which indicates a positive test results. Absence of this colored band in the test window indicates a negative test result. A built-in control line will always appear in the test window when the test has performed properly, regardless of the presence or absence of anti-Dengue virus antibodies in the specimen.

MATERIALS PROVIDED

Each kit contains:

1. test cassettes: 20 pieces test cassettes individually pouched.
2. Wash Buffer Solution: 3.0 ml in dropper bottle.
3. Droppers: 20 pieces droppers of 10 ul.
4. Package insert: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves and/or protective clothing
- Centrifuge(for plasma only)
- Micro-pipette

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 kits for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. FRENOVO Dengue IgG/IgM Rapid Test Kit is for professional use only.
2. The package insert instructions must be followed to ensure optimum test performance.
3. The kit is 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°C 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 solution, 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 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 cassettes 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 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 whole 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 as soon as possible . 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. 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.
7. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
8. 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 cassette, specimen, buffer 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. For Serum or Plasma Specimens

   To use a dropper: Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (one drop/approximately 10ul), then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.

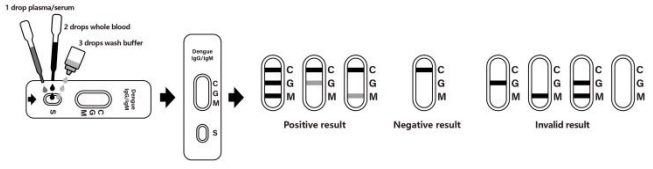
   To use a micro-pipette: Pipette and dispense 10ul of specimen to the sample well of the test cassette, then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer.

   For Whole Blood Specimens

   To use a dropper: Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (two drops/approximately 20ul), then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.

   To use a micro-pipette: Pipette and dispense 20ul of specimen to the sample well of the test cassette, then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer.

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

IgG and IgM POSITIVE: Three lines appear. One colored line should be in the control line region(C), and two colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not have to match. the result is positive for IgG & IgM antibodies and is indicative of secondary Dengue infection.

IgG POSITIVE: Two lines appear. One colored line should be in the control line region(C), and a colored line appears in IgG test line region. The result is positive for Dengue specific-IgG and is probably indicative of secondary Dengue infection.

IgM POSITIVE: Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for Dengue specific-IgM antibodies and is indicative of primary Dengue infection.

NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of Dengue antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s)should be considered positive

NEGATIVE: One colored line should be in the control line region (C). No line appears in IgG and IgM test line region(s)

INVALID: Control line fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The kit is for in vitro diagnostic use only. The test should be used for the detection of Dengue IgG/IgM antibodies in serum, plasma or whole blood specimens only.
2. A negative test result cannot exclude a recent infection. A positive result may not indicate previous Dengue infection. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.
3. Results from immunosuppressed patients should be interpreted with caution.
4. Results from this test should not be used to diagnose or to exclude acute Dengue infection or to inform infection status.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

Clinical study was performed to compare the results obtained by The kit and PCR. The results indicated that The kit has a high sensitivity and specificity as summarized below:

Dengue IgM Study		PCR		
Dengue IgM Rapid test	Results	IgM Positive	IgM Negative	Total Results
	IgM Positive	249	9	258
	IgM Negative	12	771	783
Total Results		261	780	1041

Dengue IgM Study Summary Results:

Clinical sensitivity =95.40% (95%CI*92.11%～97.60%)

Clinical specificity = 98.85% (95%CI*97.82%～99.47%)

Accuracy=97.98% (95%CI*96.93%～98.75%)

Dengue IgG Study		PCR		
Dengue IgM Rapid test	Results	IgG Positive	IgG Negative	Total Results
	IgG Positive	128	12	140
	IgG Negative	12	889	901
Total Results		140	901	1041

Dengue IgG Study Summary Results:

Clinical sensitivity =91.43% (95%CI*85.51%～97.60%)

Clinical specificity = 98.85% (95%CI*97.82%～99.47%)

Accuracy=97.98% (95%CI*96.93%～98.75%)

Interference Substances

The following potential interfering substances have been tested using The kit and no interference was observed :

Substance	Tested Concentration
Acetaminophen	136 µg/mL
Albumin	47 mg/mL
Bilirubin	7.40 mg/mL
Cholesterol	260 mg/mL
Creatinine	6.90 mg/mL

Digoxin	3.00 ng/mL
Ethanol	2.10 mg/mL
Glucose	3.90 mg/mL
Immunoglobin A	2.20 mg/mL
Immunoglobin G	10.00 mg/mL
Immunoglobin M	1.10 mg/mL
Total Protein	70.40 mg/mL
Triglycerides	1.90 mg/mL
Urea nitrogen	700 μg/mL
Uric acid	92 μg/mL

Cross Reaction

Cross-reactivity of The kit was evaluated using serum samples containing antibodies to other pathogens., which has no effect on the negative and positive test results, and there is no cross-reaction.

IgM potential cross-reactant	IgG potential cross-reactant
Influenza A virus (H1N1, H3N2)	Influenza A virus (H1N1, H3N2)
Influenza B virus (Yamagata IgM,Victoria IgM)	Influenza B virus (Yamagata IgG, Victoria IgG)
Endemic human coronavirus (OC43, 229E)	Endemic human coronavirus (OC43, 229E)
CMV IgM	CMV IgG
Rubella IgM	Rubella IgG
Toxo IgM	Toxo IgG
HSV IgM	HSV IgG
Coxsackie virus group B IgM	Coxsackie virus group B IgG
Epstein-Barr virus IgM	Epstein-Barr virus IgG
Enterovirus 71 IgM	Enterovirus 71 IgG
Coxsackie virus type A16 IgM	Coxsackie virus type A16 IgG
Varicella zoster virus IgM	Varicella zoster virus IgG
Mumps Virus IgM	Mumps Virus IgG
Respiratory syncytial virus IgM	Respiratory syncytial virus IgG
Adenovirus IgM	Adenovirus IgG
Chlamydia pneumoniae IgM	Chlamydia pneumoniae IgG
Mycoplasma pneumoniae IgM	Mycoplasma pneumoniae IgG
Measles virus IgM	Measles virus IgG

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	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
CE	CE mark		Biological risks

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INSTRUCTION APPROVAL AND REVISION DATE

Revision Date:
Date of Issue: