D-Dimer Rapid Test Kit
Instructions For Use

PRODUCT NAME

FRENOVO D-Dimer Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

FRENOVO D-Dimer Rapid Test is a lateral flow immunoassay intended for the qualitative of D-Dimer in human plasma, whole blood specimens. The test is used as an aid in the assessment and evaluation of patients with suspected disseminated intravascular coagulation (DIC), deep vein thrombosis (DVT), and pulmonary embolism (PE).

SUMMARY AND PRINCIPLES OF THE PROCEDURE

The concentration of D-dimer increases during the activation of thrombosis and the fibrinolysis activity in blood vessels. Myocardial infarction, cerebral infarction, pulmonary embolism, venous thrombosis, surgery, tumor, diffuse intravascular coagulation, infection and tissue necrosis, etc all can lead to an raised D-dimer.

FRENOVO D-Dimer Rapid Test is a sandwich immunoassay. when test, samples of D-Dimer antigen and D-Dimer antibody on the conjugate first occur immune reaction, form immune complex . Immune complex flow as the sample in the nitrocellulose membrane , And react with the in advance coating D-Dimer antibodies ,then be fixed. The more D-Dimer in the blood ,the more compound exit in the test line , optical density in the test line will be higher accordingly . Meantime , in the test process , internal controled Combination will also chromatography along with the sample in the nitrocellulose membrane, react with the coated antibody ,then fixed . When sample not include D-Dimer or D-Dimer concentration ＜500ng/ml ,while showed Control line only .When D-Dimer concentration ≥500ng/ml, Test line will be showed clearly . The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS PROVIDED

Each kit contains:

1. test cassettes: 20 pieces test cassettes individually pouched.
2. Wash Buffer Solution: 2.0 ml in dropper bottle.
3. Droppers: 20 pieces droppers of 20 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 D-Dimer 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/Plasma.
2. Separate plasma from whole blood as soon as possible to avoid hemolysis.
   Use only clear non-hemolysis 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. Plasma specimens may be stored at 2~8 ℃ for up to 7 days, for long term storage, 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 Plasma Specimens

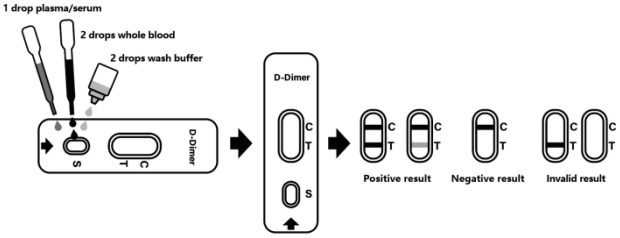
   To use a dropper: Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (one drop/approximately 20ul), then squeeze the wash buffer solution bottle, add two drops wash buffer solution inside (approximately 60ul) to the sample well and start the 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 two drops wash buffer solution inside (approximately 60ul) 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 40ul), then squeeze the wash buffer solution bottle, add two drops wash buffer solution inside (approximately 60ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.

   To use a micro-pipette: Pipette and dispense 40ul of specimen to the sample well of the test cassette, then squeeze the wash buffer solution bottle, add two drops wash buffer solution inside (approximately 60ul) 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

Negative result: if there is only a quality control line C, the detection line is colorless, indicating that D-Dimer has been lower than 500ng/ml in the specimens and the result is negative.

Positive result: if both the quality control line C and the detection line T appear, D-Dimer has been equalled to or higher than 500ng/ml in the specimens and the result is positive.

Invalid result: 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 D-Dimer in plasma or whole blood specimens only.
2. This product only indicates the existence of D-Dimer in the specimen and cannot be regard as the sole indicator of the diagnosis of disease. The testing results should be integrated confirmed by the clinician to determine the combination of clinical symptoms and other laboratory indicators.
3. Unstable D-Dimer antigen will variation by time and temperature, even not in combination with an antibody, resulting in erroneous test results, and using damp products may also lead to incorrect results, it is recommended to provide good laboratory reagents and specimen storage environment.

PERFORMANCE CHARACTERISTICS

REFERENCE RANGE

Normal negative reference values : < 500ng/ml

Coincidence rate of negative reference

Visual test negative reference, coincidence rate of negative reference should be 100%.

Sensitivity

Visual test can detect no less than the 500ng /ml concentration of D-dimer positive reference.

Coincidence rate of positive reference

Visual test positive reference, coincidence rate of positive reference should be 100%

Specificity

This product has no cross reactivity with 200mg/L bilirubin, 2500mg/L triglyceride and 2500mg/L hemoglobin.

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
CE	CE mark		Biological risks

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INSTRUCTION APPROVAL AND REVISION DATE

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