Troponin I (cTnI) Rapid Test Kit
Instructions For Use

PRODUCT NAME

FRENOVO Troponin I (cTnI) Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

FRENOVO Troponin I (cTnI) Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of human cardiac Troponin I (cTnI) in whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction (MI).

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa. Troponin I is part of a three subunit complex comprising of Troponin T and Troponin C. Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle. After cardiac injury occurs, Troponin I is released into the blood 4-6 hours after the onset of pain. The releasepattern of cTnI is similar to CK-MB, but while CK-MB levels return to normal after 72 hours, Troponin I remain elevated for 6-10 days, thus providing for a longer window of detection for cardiac injury. The high specificity of cTnI measurements for the identification of myocardial damage has been demonstrated in conditions such as the perioperative period, after marathon runs, and blunt chest trauma. cTnI release has also been documented in cardiac conditions other than acute myocardial infarction (AMI) such as unstable angina, congestive heart failure, and ischemic damage due to coronary artery bypass surgery. Because of its high specificity and sensitivity in the myocardial tissue, Troponin I has recently become the most preferred biomarker for myocardial infarction.

FRENOVO Troponin I (cTnI) Rapid Test is a qualitative, membrane based immunoassay for the detection of cTnI in whole blood, serum or plasma. The membrane is pre-coated with capture reagent on the test line region of the test. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with anti-cTnI antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with capture reagent on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that 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 Troponin I (cTnI) 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 (two drops/approximately 40ul), then squeeze the wash buffer solution bottle, add one drop wash buffer solution inside (approximately 30ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.

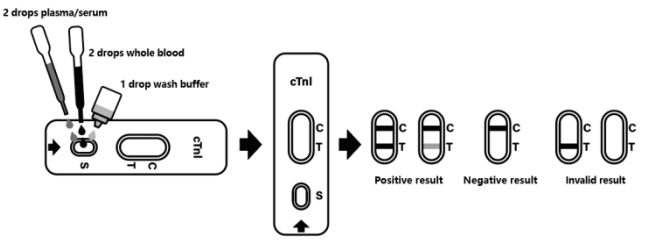
   To use a micro-pipette: Pipette and dispense 40ul of specimen to the sample well of the test cassette, then squeeze the wash buffer solution bottle, add one drop wash buffer solution inside (approximately 30ul) to the sample well and start the timer.

   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 one drop wash buffer solution inside (approximately 30ul) 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 one drop wash buffer solution inside (approximately 30ul) 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 Troponin I (cTnI) has not been detected and the result is negative.

Positive result: if both the quality control line C and the detection line appear, Troponin I (cTnI) has been detected 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.

NOTE: The intensity of the color in the test line region(s) will vary depending on the concentration of Troponin I (cTnI) in the specimen.

LIMITATIONS

1. The kit is for in vitro diagnostic use only. The test should be used for the detection of Troponin I (cTnI) antibodies in serum, plasma or whole blood specimens only. The intensity of the test line does not have a linear correlation with the cTnI level in the specimen.
2. A negative result for an individual subject indicates the level of cTnI is not detectable. However, a negative test result does not preclude the possibility of AMI.
3. A negative result can occur if the level of cTnI present in the specimen is below the detection limits of the assay or cTnI that is detected is not present during the stage of AMI in which a sample is collected.
4. AMI progresses rapidly. If symptoms are suspicious or persist while the result from the test is negative or non-reactive, it is recommended to test with an alternative test method, such as ECG.
5. Unusually high titers of heterophile antibodies or rheumatoid factor present in specimens may affect the expected results.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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:

cTnI Clinical Study		PCR		
FRENOVO Troponin I (cTnI) Rapid Test	Results	Positive	Negative	Total Results
	Positive	158	7	165
	Negative	2	603	605
Total Results		160	610	770

Summary Results:

Clinical sensitivity =98.75% (95%CI*95.56%～99.85%)

Clinical specificity = 98.85% (95%CI*97.65%～99.54%)

Accuracy=98.83% (95%CI*97.79%～99.46%)

Minimum Detection Level

The minimum detection limit for FRENOVO Troponin I (cTnI) Rapid Test is 1.0ng/ml.

Hook effect

No hook effect was found with cTnI concentration up to 3,521 ug/ml.

Cross Reaction

Amounts of antibodies to cTnI have been tested with10,000 ng/ml Skeletal Troponin I, 2,000 ng/ml Troponin T, and 20,000 ng/ml CardiacMyosin. No cross-reactivity was observed, indicating that FRENOVO Troponin I (cTnI) Rapid Test has a high degree of specificity for cardiacTroponin I.

Interference Substances

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

Substance	Tested Concentration
Acetaminophen	20 mg/dl
Albumin	10.5 g/dl
Bilirubin	1,000 mg/dl
Cholesterol	Cholesterol
Acetylsalicylic acid	20 mg/dl
Ascorbic acid	20 mg/dl
Caffeine	20 mg/dl
Creatinine	200 mg/dl

Immunoglobin A	2.20 mg/mL
Gentistic acid	20 mg/dl
Hemoglobin	1000 mg/dl
Oxilic acid	600 mg/dl
Triglycerides	1,600 mg/dl

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

Revision Date:
Date of Issue: