Cardiac Troponin I (cTnI) Rapid Quantitative Test（Fluorescence immunoassay)

User manual

[Product Name]

Cardiac Troponin I (cTnI) Rapid Quantitative Test（Fluorescence immunoassay)

[Packing Specification]

25 Tests/kit

[Intended Use]

The product is used to determine the content of cardiac troponin I (cTnI) in whole blood, plasma and serum of human body and is mainly used clinically for auxiliary diagnosis of myocardial infarction.

[Test Principle]

The kit uses immunochromatographic assay. First, cTnI antigen in the sample combines with the fluorescently-labeled cTnI monoclonal antibody conjugate. Then, it continues to move and combines with another cTnI monoclonal antibody fixed on the nitrocellulose membrane to form double-antibody sandwich immune complex in the position of the nitrocellulose membrane test line and analyze and obtain quantitative test result using NIR-1000 dry fluoroimmunoassay analyser.

[Main Ingredients]

Name	Loading capacity	Ingredient
Test card	25	The product consists of fluorescent mat (coated with fluorescently-labeled cTnI monoclonal murine antibody), nitrocellulose membrane (coated with cTnI monoclonal murine antibody and goat anti mouse IgG antibody), absorbent paper and bottom lining.
Sample diluent	25	Phosphate buffer
ID card	1	Record standard curve information of this batch of reagents

Ingredients of kits of different batch numbers cannot be exchanged.

[Storage Conditions and Validity]

The product should be stored at 4℃-30℃ in a dry and dark place, sealed using aluminum foil bag and must not be frozen. The storage life is 12 months. The test card should be unpacked at room temperature (15℃-30℃) and should be used in 15min after unpacked at a temperature of (15-30)℃ and relative humidity of 20%-90%.

See outer packing for production date, batch number and expiry date.

[Applicable Instrument]

NIR-1000 dry fluoroimmunoassay analyser produced by WWHS Biotech. Inc.

[Sample Requirements]

1. Serum and EDTA·Na_2 anticoagulant plasma and whole blood, EDTA·K_2 anticoagulant plasma and whole blood, sodium citrate anticoagulant plasma and whole blood can be used.
2. Collect venous blood using conventional laboratory method and avoid hemolysis in the treatment process.
3. Clinical samples should be tested at room temperature (15-30)℃ in 4h after collected. Whole blood specimens can be stored at (2-8)℃ for 24h and should not be frozen; serum or plasma specimens can be stored at (2-8)℃ for 7 days and at -20ºC for 30 days.
4. The sample must be re-warmed to room temperature (15-30)℃ before test. Frozen samples should be completely melted, re-warmed and mixed before use and should not be frozen repeatedly.
5. Please do not test samples of severe hemolysis, severe lipoidemia and icterus.

[Test Method]

1. Please thoroughly read the specification before test. Frozen test card and sample should be placed at room temperature (15-30)℃ for at least 30min before use.
2. Start NIR-1000 dry fluoroimmunoassay analyser and verify quality control according to the specification. (Note: Reagent has been calibrated in advance and calibration curve parameters of each batch of reagents have been stored in the information card. Insert the information card before use and carry out test without re-calibration after passing quality inspection; otherwise, identify the cause before test.)
3. Take out the test card from the aluminum foil bag and use it within 15min
4. Place the test card on a clean horizontal table top and label it.
5. Serum, plasma or whole blood specimen: Take 100μL of sample and add it into 300μL of buffer solution (1:3). Then, mix the solution evenly, take 100μL of the solution and add it into the test card well.
6. Insert the test card into NIR-1000 dry fluoroimmunoassay analyser and press “Timing test” to keep time for 12min automatically. The analyser will judge and read the test result automatically and display it in the screen. Or insert the test card into the analyser after 12min and press “Instant test”, the instrument will judge and read the result automatically.

[Reference Interval]

Determine 252 healthy people aged 18-68 and carry out statistical analysis using 95th percentile method. Result shows that cTnI reference interval＜0.3ng/mL.

The laboratory should establish a reference range according to characteristics of local people.

[Interpretation of Test Results]

1. The kit can be used for auxiliary test only. If test result is abnormal, retest timely and judge combined with clinical symptoms.
2. For samples whose cTnI concentration is lower than 0.1ng/mL and higher than 40ng/mL, test result is "＜0.1ng/mL" and "＞40ng/mL" respectively.

[Limitation of Test Method]

1. The kit can be used to test serum/plasma/whole blood specimens of human body only.
2. Due to limitations of serological methods for antigen and antibody response, the test result cannot be used as the only basis for clinical diagnosis and should be evaluated together with all existing clinical and experimental data.
3. The content of triglyceride contained in the sample is no more than 15mg/mL, that of hemoglobin is no more than 5mg/mL and that of hemoglobin is no more than 0.5mg/mL, and the relative deviation is limited to ±15%.
4. When cTnI concentration of samples is less than 250ng/mL, Hook effect is not observed.
5. When human anti mouse concentration of samples is less than 50ng/mL, HAMA effect will not be observed.
6. When RF concentration of samples is less than 2000IU/mL, relative deviation of test result is limited to ±15%.

[Product Performance Indicators]

1. Limit of detection

   No more than 0.1ng/mL.
2. Accuracy

   The relative deviation to the target value is limited to ±15%.
3. Precision

   Within-run precision CV≤15%; between-run relative limit R≤15%.
4. Linearity range

   Within the specified linearity range cTnI (0.1-40) ng/mL, linearly dependent coefficient r≥0.990.
5. Analytical Specificity

Determine cardiac troponin T, cardiac troponin C and skeletal muscle troponin I samples whose concentration is 1000ng/mL and the result does not exceed 0.1ng/mL.

[Precautions]

1. Test card and buffer solution are single-use and they cannot be reused.
2. Please inspect packaging integrity and validity of kit before use and then unpack the product. If the product is stored at low temperature, restore to room temperature (15℃-30℃) before unpacking and use. Reagent cannot be used if packaging is damaged and the validity period expires.
3. Take the test card out of the aluminum foil bag and carry out experiment in 15min. Do not place it in the air for a long time to avoid dampness.
4. It is required to strictly comply with the requirements for sample collection and storage. If the sample is turbid, please centrifuge and precipitate it before use.
5. The kit contains products from animals. Eligible information about animal source and sanitary condition cannot absolutely ensure inexistence of infectious pathogen. Therefore, these products should be disposed of as latent infective material, and all samples, reagents and latent contaminants should be disinfected and disposed of according to relevant local regulations.
6. Too high or too low hematocrit of red cells may affect whole blood test result, so verification should be conducted using other methods .

【Interpretation of Signs】

	Storage temperature		Single-use
	Keep in dark place	IVD	IVD Reagents
	Dampproof		Refer to the specification

[References]

[1] Ma Qiang, Li Yanmei, Bi Lili. Sensitivity and Specificity of Troponin I, Myohemoglobin and Creatine Kinase Isoenzyme for Early Diagnosis of Acute Myocardial Infarction[J]. Chinese Contemporary Medicine, 2006, 4(4): 60-61.

[2] Wang Yang, Zhao Yuan. Diagnostic Value of Joint Test of Troponin and Myohemoglobin for Myocardial Infarction[J]. CHINESE JOURNAL OF LABORATORY MEDICINE, 2010, 11(3): 156-157.

[3] Huang Shuiming, Fang Yucai. Diagnostic Value of Joint Test of Cardiac Troponin, Myohemoglobin and Creatine Kinase Isoenzyme for Acute Chest Pain Patients [J]. Prevention and Treatment of Cardio-cerebral-vascular Disease, 2005, 5(5): 28-30.

[Basic Information]

Registrant/Manufacturer Name: WWHS Biotech. Inc

Domicile: Rm505, 1st building, Shenzhen Biomedical Innovation Industrial Park, No. 14th, Jinhui Road, East Jinxiu Road, Kengzi Street, Pingshan District, Shenzhen

Contact information: 0755-84235529

After-sales Service Center: WWHS Biotech. Inc

Contact information: 0755-84235529

Production address: Rm505, 1st building, Shenzhen Biomedical Innovation Industrial Park, No. 14th, Jinhui Road, East Jinxiu Road, Kengzi Street, Pingshan District, Shenzhen

Production License No.: CFDA No. 20193464

[Medical Device Registration Certificate No. /Product Technical Requirement No.] YXZZ 20192401041

[Date of Approval and Revision] September 30, 2019