Myoglobin (Myo) Rapid Quantitative Test (Fluorescence immunoassay)
User manual

【Product name】
Myoglobin (Myo) Rapid Quantitative Test (Fluorescence immunoassay)

【Packing specification】
25 Tests/kit

【Intended use】
The kit is used for quantitative determination of Myoglobin (Myo) in human whole blood, plasma and serum.
Myoglobin (Myo) is a binding protein composed of a peptide chain and a heme prosthetic group. It is a protein used to store oxygen in the muscle. It can be elevated as soon as 2 hours after the onset of chest pain, and the level of Myo in patients with severe congestive heart failure and cardiac surgery will also be increased due to myocardial damage. Therefore, Myo is a sensitive indicator for the diagnosis of acute myocardial infarction, Myo has become one of the current markers of myocardial infarction.

【Test principle】
The Myo Rapid Quantitative Test is is a one-step chromatographic sandwich immunoassay designed for the quantitative measurement of Myo. The Myo antigen in the sample was first bound with the conjugated compound of fluorescent labeled Myo monoclonal antibody, then moved and combined with another Myo monoclonal antibody fixed on the nitrocellulose membrane, and the double antibody sandwich complex was formed at the detection line of the cellulose nitrate membrane. The quantitative detection results were obtained by NIR-1000 dry fluoroimmunoassay analyser.

【Components】

Name	Quantity	Component
Test cards	25	It is composed of fluorescent pad (coated with fluorescently-labeled Myo monoclonal antibody), nitrocellulose membrane (coated with Myo monoclonal antibody and Goat anti mouse IgG antibody), absorbent paper and backing.
Sample diluent	25 (0.3mL/ tube)	Phosphate buffer
ID card	1	With specific stand curve file

The components in different batches of kits cannot be used interchangeably.

【Storage conditions and validity】
The kit should be stored at 4℃~30℃, out of direct sunlight. It is valid for 18 months. The test card should be used within 15 minutes after unsealing under the environment of 15℃~30℃ and 20% ~ 90% relative humidity.
The production date, batch number and expiration date are shown in the outer package of the product.

【Applicable instrument】
NIR-1000 dry fluoroimmunoassay analyser produced by WWHS Biotech. Inc.

【Sample requirements】
1. Plasma, serum and whole blood can be used as samples. The whole blood should be collected in a tube containing heparin, citrate or EDTA as the anticoagulant. If the serum procedure is used, collect blood in a tube without anticoagulant and allow clotting. Hemolyzed samples should not be used.
2. Venous blood was collected according to routine laboratory methods to avoid hemolysis.
3. It is highly recommended to use fresh samples instead of keeping the samples at room temperature for a long time. After samples were collected, the detection should be completed within 4 hours at room temperature (15℃~30℃). The whole blood sample can be stored at 2℃~8℃ for 24 hours. Plasma and serum samples can be stored at 2℃~ 8℃ for 7 days, -20℃ for 30 days.
4. Before testing, the sample should return to room temperature (15℃~30℃). The frozen samples should be completely thawed, rewarming and mixed evenly before use. Repeated freeze-thaw cycles should be avoided.

【Test method】
1. Before the test, please read the instructions completely. If the test card and sample are stored in cold storage, they should be balanced at room temperature (15-30)℃ for not less than 30min before use.
2. Start NIR-1000 dry fluoroimmunoassay analyser according to the instruction manual of the instrument, and carry out quality control verification according to the instruction manual of the instrument（Note: the reagent has been calibrated in advance, and the calibration curve parameters of each batch of reagent have been stored in the ID card. The test can be carried out only after the quality control is passed. Otherwise, the cause should be found out before testing.)
3. Remove the test card from the aluminum foil bag and use it within 15 minutes.
4. Place the test card on a clean horizontal table and mark it horizontally.
5. Mix 10 μL of patient sample with 300μL of sample diluent. Apply 100 μL of diluted samples to the well of the test card.
6. Insert the test card into NIR-1000 dry fluoroimmunoassay analyser, read and record the results at 12 minutes after addition of samples, then dispose of used test appropriately.

【Reference interval】
The normal reference value is less than 58ng/mL in this assay. It is strongly recommended that each

laboratory should determine its own normal and abnormal values.

【Interpretation of test results】

1. This reagent is only used for auxiliary detection. If the test results are abnormal, it should be reviewed in time and judged in combination with clinical symptoms.
2. For samples with Myo concentration lower than 5.00ng/mL and higher than 400.00ng/mL, the detection results are reported as "＜5.00ng/mL "and "＞400.00ng/mL ", respectively.

【Limitation of method】

1. This kit is only used to detect human plasma/whole blood samples
2. Due to the limitations of immunoassay methods of antigen and antibody reaction, the results cannot be used as the only basis for clinical diagnosis, but should be evaluated with all the existing clinical and experimental data.
3. The content of triglyceride in the sample shall not exceed 10mg/ml, the content of hemoglobin shall not exceed 10mg/ml, and the content of bilirubin shall not exceed 0.5mg/ml, and the relative deviation of the test results shall not exceed ±15%。
4. When the concentration of Myo in the sample is less than 4000.00ng/mL, there is no hook effect.
5. HAMA effect was not produced when the concentration of human anti rat in the sample was less than 50ng/ml.
6. When RF concentration of samples is less than 2000IU/mL, relative deviation of test result is limited to ±10.0%.

【Performance】

1. Limits of detection

No higher than 5.00 ng/mL.

2. Accuracy

The relative deviation from the target value is limited to ±15.0%.

3. Repeatability

The within and between assay coefficient of variations are within 15%.

4. Linearity range

Within the linear range (5.00~ 400.00ng/mL), the linear correlation coefficient R≥0.990.

【Note】

1. The kit can be used for in vitro diagnosis only.
2. Test card and buffer solution are single-use and they cannot be reused.
3. Please check the integrity and validity of the kit package before use, and then open the package. When it is stored at low temperature, it should be restored to room temperature (15℃ ~ 30℃) before opening the package for use. The reagents with damaged inner package and beyond the validity period cannot be used.
4. 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.
5. 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.
6. The kit used 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.

【Interpretation of signs】

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

【References】

[1] Nadeau L , Baril P , Turcotte G , et al. Myoglobin (MYO) and cardiac troponin I (CTNI) in diagnosis of suspected acute myocardial infarct (AMI)[J]. Clinical Biochemistry, 1997, 30(4):369-370.
[2] Wu A , Feng Y J , Contois J H , et al. Comparison of myoglobin, creatine kinase-MB, and cardiac troponin I for diagnosis of acute myocardial infarction[J]. Annals of Clinical & Laboratory Science, 1900, 26(4):291-300.

【 Essential information】

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