N-terminal prohormone of brain natriuretic peptide (NT-proBNP) Rapid Quantitative Test（Fluorescence immunoassay)

User manual

【Product name】

N-terminal prohormone of brain natriuretic peptide (NT-proBNP) Rapid Quantitative Test（Fluorescence immunoassay)

【Package specification】

25 Tests/kit

【Intended use】

This kit is used for quantitative determination of N-terminal prohormone of brain natriuretic peptide (NT-proBNP) in human whole blood and plasma.

【Inspection principle】

The principle of immunofluorescence chromatography was applied to the kit. The NT-proBNP antigen in the sample was first bound with the conjugated compound of fluorescent labeled NT-proBNP monoclonal antibody, then moved and combined with another NT-proBNP 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.

【Main components】

Name	Quantity	Component
Test card	25	It is composed of fluorescent pad (coated with fluorescent labeled N-terminal prohormone of brain natriuretic peptide (NT-proBNP) monoclonal mouse antibody), nitrocellulose membrane (coated with N-terminal prohormone of brain natriuretic peptide (NT-proBNP) monoclonal mouse antibody and Goat anti mouse IgG antibody), absorbent paper and backing
Sample buffer	25（300μL/tube）	Phosphate buffer
ID card	1	Record the standard curve information of this kit

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

【Storage conditions and validity】

The test card should be stored at 4℃~30℃, dry, dark and no freezing. It should be stored in sealed aluminum foil bag and valid for 18 months. The test card should be returned to room temperature (15℃~30℃) before opening. It 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 instruments】

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

【Sample requirements】

1. The sample types of this product are EDTA·K2 anticoagulant plasma, EDTA·Na2 anticoagulant plasma, sodium citrate (anticoagulant tube with the ratio of sodium citrate volume to blood collection volume of 1:9), EDTA·K2 anticoagulant whole blood, EDTA·Na2 anticoagulant whole blood and sodium citrate (anticoagulant tube with the ratio of sodium citrate volume to blood collection volume of 1:9).
2. Venous blood was collected according to routine laboratory methods to avoid hemolysis.
3. After clinical samples were collected, the detection was completed within 4 hours at room temperature (15℃~30℃). The whole blood sample can be stored for 24 hours at 2℃~8℃; Plasma samples can be stored at 2℃ to 8℃ for 7 days; The plasma sample was at - 20℃. It can be stored for 30 days at room temperature.
4. Before testing, the sample must return to room temperature (15℃~30℃). The frozen samples should be completely thawed, rewarming and mixed evenly before use, and repeated freezing and thawing should be avoided.

【Test procedure】

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 information card. The information card is inserted before use, so it is not necessary to calibrate again, and 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 100μL of patient sample with 300μL of sample diluent. Apply 100μL of diluted samples to the well of the test card.
6. Insert the test card into NIR-1000 dry fluoroimmunoassay analyser, press the [timing detection] key, automatically time for 10 minutes, automatically judge the test results, and display the quantitative results on the screen. Or insert the test card into the analyzer after timing for 10 minutes, and press the [real time detection] key, and the instrument will automatically interpret the

test results.

【Reference interval】

Healthy subjects under 75 years old have assay values below 347pg/mL. Healthy subjects over 75 years old have assay values below 449pg/mL.

【Interpretation of 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 NT-proBNP concentration lower than 18pg/mL and higher than 35000pg/mL, the detection results are reported as "< 18pg/mL " and ">35000pg/mL ", respectively.

【Limitations of methods】

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 15mg/ml, the content of hemoglobin shall not exceed 5mg/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 NT-proBNP in the sample is less than 35000pg/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 in the sample is less than 2000IU/ml, the relative deviation of the test results is within ±15%.

【Performance】

1. Analysis sensitivity

No more than 18pg/mL.

2. Accuracy

The relative deviation from the target value is within ±10%.

3. Precision

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

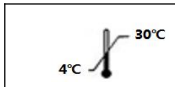
4. Linear range

Within the linear range (20-35000pg/mL), the linear correlation coefficient R≥0.990.

【Note】

1. This kit is only used for in vitro diagnosis.
2. The test card and sample diluent are disposable and 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. The requirements of specimen collection and storage should be strictly observed. If the specimen is turbid, it should be centrifuged and discarded before use.
5. The used kits should be treated as potential infectious substances, and all samples, reagents and potential pollutants should be disinfected and treated according to the relevant local regulations.

【Interpretation of signs】

	Storage temperature		Non reusable
	Avoid light	IVD	In vitro diagnostic reagents
	moisture-proof		See instruction manual

【Reference】

[1] McCullough PA, Hollander JE, Nowak RM, et al.: Uncovering heart failure in patients with a history of pulmonary disease: rationale for the early use of B-type natriuretic peptide in the emergency department.Acad Emerg Med 2003, 10(3):198-204.

【Essential information】

Registered / manufacturer name: WWHS Biotech. Inc

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

Contact: 0755-84235529

Name of after sales service unit: WWHS Biotech. Inc

Contact: 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 CFDA No. 20212400541

[Registration certificate No.] 20192401077

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