Diagnostic Kit for Neutrophil gelatinase-associtated lipocalin（Immunochromatographic assay）
User manual

【Product name】
Diagnostic Kit for Neutrophil gelatinase-associtated lipocalin（Immunochromatographic assay）

【Packing specification】
25 Tests/kit

【Intended use】
The kit is used for quantitative determination of Neutrophil gelatinase-associtated lipocalin (NGAL) in human urine. Clinically, it is mainly used to assist in the diagnosis of renal function injury.

【Test principle】
The kit is a one-step chromatographic sandwich immunoassay designed for the quantitative measurement of NGAL. The NGAL antigen in the sample was first bound with the conjugated compound of fluorescent labeled NGAL monoclonal antibody, then moved and combined with another NGAL 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 NGAL monoclonal antibody), nitrocellulose membrane (coated with NGAL 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. Urine can be used as samples.
2. The middle urine samples of random urine were collected for detection.
3. After sample collection, clear urine samples can be stored at room temperature for 24 hours and at 2 ℃ ~ 8 ℃ for 7 days; It can be stored at - 20 ℃ for 30 days.

【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 and correctly select the corresponding sample type on the instrument.
3. Take out the ID card, make sure that the batch number of the ID card is consistent with that of the test card, and insert the ID card into the ID card port of the instrument.
4. Take out the test card from the aluminum foil bag and use it within 15 minutes.
5. Place the test card on a clean horizontal table and mark it horizontally.
6. Mix 100 μL of urine sample with 300μL of sample diluent. Apply 100 μL of diluted samples to the well of the test card.
7. Insert the test card into NIR-1000 dry fluoroimmunoassay analyser and click the “instant test” button to read the results at 10 minutes after addition of samples.

【Reference interval】
The normal reference value is less than 132ng/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 NGAL concentration lower than 10.00ng/mL and higher than 1500.00ng/mL, the detection results are reported as "＜10.00ng/mL "and "＞1500.00ng/mL ", respectively.

【Limitation of method】
1. This kit is only used to detect human serum/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 30mg/mL, the content of hemoglobin

shall not exceed 10mg/mL, and the content of bilirubin shall not exceed 0.25mg/mL, and the relative deviation of the test results shall not exceed ±15%。

4. When the concentration of NGAL in the sample is less than 2000ng/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 ±15.0%.

【Performance】

1. Limits of detection

No higher than 10.00 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 15.0%.

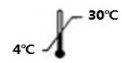
4. Linearity range

Within the linear range (10.00~ 1500.00)ng/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

【Reference】

[1] Yao X, Huang J, Zhong H, et al. Targeting Interleukin-6 in Inflammatory Autoimmune Diseases and Cancers[J]. Pharmacology Therapeutics, 2013, 141(2):125-139.

[2] Kang S, Narazaki M, Metwally H, et al. Correction: Historical overview of the interleukin-6 family cytokine[J]. Journal of Experimental Medicine, 2020, 217(5).

【 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

[Date of approval and revision] 2021-06-12