Diagnostic Kit for Serum Ferritin（Immunochromatographic assay）
User manual

【Product name】

Diagnostic Kit for Serum Ferritin（Immunochromatographic assay）

【Package specification】

25 Tests/kit

【Intended use】

It is used to quantitatively detect the content of ferritin in human serum. Clinically, it is mainly used for the auxiliary diagnosis of iron metabolism related diseases, such as hemochromatosis and iron deficiency anemia.

【Test principle】

The principle of immunofluorescence chromatography was applied to the kit. The Ferr antigen in the sample was first bound with the conjugated compound of fluorescent labeled Ferr monoclonal antibody, then moved and combined with another Ferr 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 Ferr monoclonal antibody), nitrocellulose membrane (coated with Ferr monoclonal antibody and Goat anti mouse IgG antibody), absorbent paper and backing
Sample buffer	25（400μL/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 12 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 20 μL of patient sample with 400μL 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, press the [timing detection] key, automatically time for 5 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 5 minutes, and press the [real time detection] key, and the instrument will automatically interpret the test results.

【Reference interval】

Through the determination of serum samples from 301 healthy people aged 10 ~ 87, the results were statistically analyzed.

Gender	2.5th (ng/mL)	97.5 percentile (ng/mL)
Male	24	335
Female	11	307

【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 Ferr concentration lower than 5ng/ml and higher than 500ng/ml, the detection results are reported as "< 5ng/ml" and "> 500ng/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 Ferr in the sample is less than 1000ng/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 higher than 5ng/ml.

2. Accuracy

The relative deviation from the target value is within ±15%.

3. Precision

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

4. Linear range

Within the linear range (5 ~ 500ng/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] State Food and drug administration. YY / T 1456-2016 ferritin quantitative detection kit [S]. Beijing: China Standards Press, 2017:1-7

[2] Shu Qiang, Zhang man. Application of ferritin detection in clinic [J]. Labeled immunoassay and clinic, December 2012, Volume 19 (6): 378-379

[3] Zhu LAN, Zhou Yan, Huang Biao, Guo Mingming, Dong Xiaoli. Establishment and clinical application of ferritin time-resolved immunofluorescence chromatography [J]. Modern immunology 2016, Vol. 36 (1): 50-53

【Essential information】

Registered / manufacturer name: WWHS Biotech. Inc.

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