

Diagnostic Kit for Cystain C (Immunochromatographic assay)

User manual

【Product name】

Diagnostic Kit for Cystain C (Immunochromatographic assay)

【Package specification】

25 Tests/kit

【Intended use】

It is used to quantitatively detect the content of cystatin C in human serum, plasma and whole blood samples. It is mainly used as one of the indicators reflecting glomerular filtration rate

【Test principle】

The Cys-C Rapid Test is a one-step chromatographic sandwich immunoassay designed for the quantitative measurement of Cys-C. The Cys-C antigen in the sample was first bound with the conjugated compound of fluorescent labeled Cys-C monoclonal antibody, then moved and combined with another Cys-C 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 fluorescent labeled Cys-C monoclonal antibody), nitrocellulose membrane (coated with Cys-C monoclonal antibody and Goat anti mouse IgG antibody), absorbent paper and backing
Sample diluent	25 (1.50mL/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°C~30°C, 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°C~30°C 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. 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°C~30°C). The whole blood sample can be stored at 2°C~8°C for 24 hours. Plasma and serum samples can be stored at 2°C~8°C for 7 days, -20°C for 30 days.
4. Before testing, the sample should return to room temperature (15°C~30°C). The frozen samples should be completely thawed, rewarming and mixed evenly before use. Repeated freeze-thaw cycles 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)°C 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 5µL of sample with 1.50mL of sample diluent. Apply 100 µL of diluted samples to the well of the test card.
7. At 5 minutes after addition of samples, insert the test card into NIR-1000 dry fluoroimmunoassay analyser and click the "Instant test" button to read the results.

【Reference interval】

Healthy non-pregnant adults are expected to have serum Cys-C values 0.5mg/L~1.1mg/L. It is strongly recommended that each laboratory should determine its own normal and abnormal values based on population.

【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 Cys-C concentration lower than 0.4mg/L and higher than 9mg/L, the detection results are reported as "<0.4mg/L" and ">9mg/L", 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 $\pm 15\%$.
4. When the concentration of Cys-C in the sample is less than 15mg/L, 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 $\pm 15\%$.

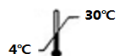

【Performance】





1. Limits of detection
No more than 0.40mg/L.
2. Accuracy
The relative deviation from the target value is within $\pm 15\%$.
3. Precision
The within and between assay coefficient of variations are within 15%.
4. Linear range
Within the linear range (0.40 ~ 9mg/L), the linear correlation coefficient $R \geq 0.990$.

【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°C ~ 30°C) 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
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	Avoid light		In vitro diagnostic reagents
	moisture-proof		See instruction manual

【Reference】

- [1] Tang Hongmei, Jiang Zhenwei. Clinical application of cystatin C. International Journal of laboratory medicine, 2011,32 (2): 216-218
- [2] Su Baoxin, Zhou Shuai. Determining the reference range of cystatin C by referring to C282A2. Sichuan Medical Journal, 2010,2 (31): 246-248

【Essential information】

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