Diagnostic Kit for C-reactive Protein （Immunochromatographic assay）
User manual

【Product name】
Diagnostic Kit for C-reactive Protein （Immunochromatographic assay）

【Package specification】
25 Tests/kit

【Intended use】
It is used for quantitative detection of C-reactive protein (CRP) in human serum, plasma and whole blood. CRP is mainly used as a non-specific inflammatory index.

【Test principle】
The kit is used the principle of fluorescence immunochromatography. The CRP antigen in the sample first combines with the fluorescent labeled CRP monoclonal antibody conjugate, and then continues to move and combine with another CRP monoclonal antibody fixed on the nitrocellulose membrane to form a double antibody sandwich immune complex at the detection line of nitrocellulose membrane. The quantitative detection results are obtained by NIR-1000 dry fluoroimmunoassay analyser.

【Main components】

name	Loading capacity	component
Test card	25	It is composed of fluorescent pad (coated with fluorescent labeled CRP monoclonal antibody), nitrocellulose membrane (coated with CRP monoclonal antibody and Goat anti mouse IgG antibody), absorbent paper and backing
Sample diluent	25	Phosphate buffer
ID card	1	Record the standard curve information of this batch of reagents

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

【Storage conditions and validity period】
4℃ - 30℃, dry, dark, no freezing, sealed in aluminum foil bag, valid for 18 months. The test card should be returned to room temperature (15-30)℃ before use, and should be used within 15 minutes after unsealing under the environment of temperature (15-30) ℃ and relative humidity (20% - 90%).
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. Serum and EDTA•Na2 anticoagulant plasma and whole blood, EDTA•K2 anticoagulant plasma and whole blood, sodium citrate anticoagulant plasma and whole blood can be used.
2. Venous blood was collected according to routine laboratory methods, and hemolysis was avoided as much as possible in the process of treatment.
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)℃ without freezing; Serum and plasma samples can be stored for 7 days at 2-8℃;Serum and plasma samples - 20℃ for 30 days.
4. The sample must return to room temperature (15-30)℃ before testing. The frozen samples should be completely thawed, rewarming and mixed evenly before use, and repeated freezing and thawing should be avoided.
5. Do not test samples with severe hemolysis, severe lipidemia and jaundice.

【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 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. Add 5μL sample to sample diluent (1500μL), mix well and add 100μL diluted sample to the sampling hole.
6. Insert the test card into dry fluoroimmunoassay analyser, press the “timing test” key, automatically time for 3 minutes, automatically judge the test results, and display the quantitative results on the screen. Or insert the test card into the analyzer after 3 minutes, and press the “Instant test” key, and the instrument will automatically interpret the results.

【Reference interval】
252 healthy people aged 19-80 were tested. The upper limit of CRP reference value was 10mg/L at 95th percentile. Reference interval: CRP<10mg/L.
It is suggested that each laboratory should establish its reference range according to the characteristics of local population.

【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 CRP concentration lower than 0.5mg/L and higher than 200mg/L, the test results were reported as "<0.5mg/L " and ">200mg/L" respectively.

【Limitations of test methods】

1. This kit is only used to detect human serum / plasma / whole blood samples.
2. Due to the limitations of serological methods for antigen and antibody reactions, the results obtained by detection cannot be used as the only basis for clinical diagnosis, but should be evaluated together with all existing clinical and experimental data.
3. The contents of triglyceride, hemoglobin and bilirubin in the samples were not more than 20 mg/ml, 10 mg/ml and 0.4 mg/ml, respectively, and the relative deviation of the test results was not more than 0.5%±10%。
4. When the concentration of C-reactive protein was less than 400 mg/L, there was no hook effect.
5. When the concentration of human anti mouse in the sample is less than 50ng/ml, HAMA effect will not be produced.
6. When the RF concentration in the sample is less than 2000 IU/ml, the relative deviation of the detection results is not more than±10%。

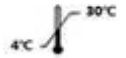
【Performance】

1. Detection limit: No higer than 0.5mg/L.
2. Accuracy: the relative deviation from the target value is not more than±10%。
3. Repeatability: coefficient of variation (CV) should be no more than 10%.
4. Inter batch difference: the relative range (R) between batches should be no more than 15%.
5. Linear range: within the specified linear range of 0.5mg/l-200mg/l, the linear correlation coefficient R ≥ 0.990.The absolute deviation of the linear range in [0.5-5] mg/L is not more than ±5 mg/L, the linear range is (5-200] mg/L, the relative deviation is less than±10%。

【Note】

1. The kit is only used for in vitro diagnosis.
2. The test card is 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 test card should be taken out from the aluminum foil bag and tested within 15 minutes to avoid being placed in the air for a long time and causing damp.
5. The requirements of specimen collection and storage should be strictly observed. If the specimen is turbid, it should be centrifuged and discarded before use.
6. The kit contains products from animals. The qualified information of animal source and health status cannot guarantee the existence of infectious pathogens. Therefore, it is suggested that these products 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.
7. Hematocrit too high or too low may affect the results of whole blood test, it is recommended to use other detection methods for verification.

【Interpretation of signs】

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

【Reference】

[1] Zhang Shanchun, Li Lin, Huang Xuan. Clinical significance of C-reactive protein in patients with coronary heart disease [J]. Chinese Journal of Cardiology, 2002, (07): 15-17doi:10.3969/j.issn.1007-5410.2002.01.006.

[2] Chu Yixing, Zhang Jinfeng, fan Jinnong. The value of C-reactive protein level in judging the outcome of inflammation and trauma[J]. Shanghai Journal of medical laboratory, 2000, (03): 155-156doi:10.3969/j.issn.1673-8640.2000.03.016.

[3] Role of wubo C-reactive protein in monitoring acute infection of COPD [J]. Journal of clinical pulmonary medicine 2012 (10)

【Basic information】

Registered person / manufacturer name: WWHS Biotech. Inc

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Production license No.: ysyjx production license No. 20193464

【medical device registration certificate No. / product technical requirements No.】 CFDA No. 20192401040

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