

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、40 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 | 25/40 | 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 | 25/40 | 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】

Mod: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 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 5 μL of sample with 1000μL of sample diluent. Apply 100 μL of diluted samples to the well of the test card.
7. At 3 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】

252 healthy people aged 19-80 were tested. The upper limit of CRP reference value was 10.0mg/L at 95th percentile. The upper limit of high sensitive CRP was 1.0mg/L at 95th percentile. Reference interval: CRP<10.0mg/L, hsCRP<1.0mg/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 15 mg/ml, 5 mg/ml and 0.5 mg/ml, respectively, and the relative deviation of the test results was not more than ±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】

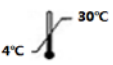





1. Detection limit: No higher than 0.5mg/L.

2. Accuracy: the relative deviation from the target value is not more than $\pm 10\%$ 。
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 $R \geq 0.990$. The absolute deviation of the linear range in [0.5-5] mg/L is not more than ± 0.5 mg/L, the linear range is (5-200) mg/L, the relative deviation is less than $\pm 10\%$ 。

【Precaution】

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) °C 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】

| | | | |
|---|-------------------------|---|------------------------------------|
|  | Temperature limit |  | Do not re-use |
|  | Keep away from sunlight |  | In vitro diagnostic medical device |
|  | Keep dry |  | Consult instructions for use |

【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】

Registrant/Manufacturer: WWHS Biotech.Inc.

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