Diagnostic Kit for C-reactive Protein and Serum Amyloid A protein
（Immunochromatographic assay）
User manual

【Product name】

Diagnostic Kit for C-reactive Protein and Serum Amyloid A protein（Immunochromatographic assay）

【Packing specification】

25 Tests/kit

【Intended use】

The kit is used for quantitative determination of C-reactive protein (CRP) and Serum Amyloid A protein (SAA) in human whole blood, plasma and serum. SAA and CRP are sensitive indicators reflecting infectious diseases.

【Test principle】

The CRP/SAA Rapid Test is a one-step chromatographic sandwich immunoassay designed for the quantitative measurement of CRP and SAA. The CRP or SAA antigen in the sample was first bound with the conjugated compound of fluorescent labeled CRP or SAA monoclonal antibody, then moved and combined with another CRP or SAA 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 CRP/SAA monoclonal antibody), nitrocellulose membrane (coated with CRP/SAA monoclonal antibody and Goat anti mouse IgG antibody), absorbent paper and backing
Sample diluent	25 (1.0mL/ 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. 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℃~30℃). The whole blood sample can be stored at 2℃~8℃ for 48 hours. Plasma and serum samples can be stored at 2℃~ 8℃ for 7 days, -20℃ for 30 days.
4. Before testing, the sample should return to room temperature (15℃~30℃). 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)℃ 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 10 μL of patient sample with 1.0mL 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 5 minutes after addition of samples.

【Reference interval】

CRP normal reference value is less than 10.0mg/L and SAA normal reference value is less than 10.0mg/L. 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 CRP concentration lower than 1.00mg/L and higher than 200.00mg/L, the detection results are reported as "＜1.00mg/L"and "＞200.00mg/L", respectively.
3. For samples with SAA concentration lower than 1.00mg/L and higher than 200.00mg/L, the detection results are reported as "＜1.00mg/L"and "＞200.00mg/L", respectively.

【Limitation of rest 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 15mg/mL, the content of hemoglobin shall not exceed 5mg/mL, and the content of bilirubin shall not exceed 0.5mg/mL, and CRP relative deviation of the test results shall not exceed ±10%, SAA relative deviation of the test results shall not exceed ±15%。
4. When the concentration of CRP in the sample is less than 400mg/L, the concentration of SAA in the sample is less than 400mg/L, there is no hook effect.
5. There was no HAMA effect 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, CRP relative deviation of the test results shall not exceed ±10%, SAA relative deviation of the test results shall not exceed ±15%。

【Performance】

1. Limits of detection

CRP：No higher than 1.00mg/L; SAA：No higher than 1.00mg/L.

2. Accuracy

CRP：the relative deviation from the target value is limited to ±10.0%;

SAA：the relative deviation from the target value is limited to ±15.0%.

3. Repeatability

CRP：the within assay coefficient of variations are within 10.0%;

SAA：the within assay coefficient of variations are within 15.0%.

4. Batch-to-batch variation

CRP：the extreme difference are within 15.0%; SAA：the extreme difference are within 15.0%.

5. Linearity range

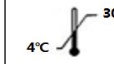
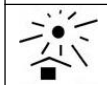
CRP: Within the linear range(1.00~200.00)mg/L, the linear correlation coefficient R≥0.990； Within the linear range(1.00~ 5.00)mg/L, the linear absolute deviation is limited to ±0.50 mg/L； Within the linear range(5.00~ 200.00)mg/L, the linear relative deviation is limited to ±10.0%.

SAA: Within the linear range (1.00~ 200.00)mg/L, 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] Yamada T. Inflammatory markers; C-reactive protein (CRP) and serum amyloid A (SAA)]. [J]. Rinsho Byori the Japanese Journal of Clinical Pathology, 2005, 53(6):558.

【 Essential information】

Registered/manufacturer name: WWHS Biotech. Inc

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