CRP Test Kit User Manual

(Dry Fluorescence Immunoassay)

[PRODUCT NAME]

CRP Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

1 test/kit
5 tests/kit
25 tests/kit
50 tests/kit
100 tests/kit

[INTENDED USE]

CRP Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro quantitative measurement of CRP in human serum,plasma and whole blood.

Creactive protein (CRP) is a typical acute-phase reactive protein synthesized by the liver,named for its ability to bind to the capsular C polysaccharide of Streptococcus pneumoniae.Under normal conditions, CRP molecules exist in the form of pentamers,which can also be decomposed into monomers in acidic or alkaline environments,which can cause certain immune reactions.However,because CRP monomers exist in cell membranes instead of serum,it is difficult Detection. In inflammation,infection, tissue damage,CRP is rapidly synthesized in the liver under the stimulation of cytokines (such as interleukin-6,tumor necrosis factor),and 20% of the liver's ability to synthesize protein at the peak of the acute phase reaction is directly It points to the synthesis of CRP,which can be used for routine verification and the detection of cardiovascular inflammation.

Full-scale CRP includes conventional hypersensitive CRP (hs-CRP) and regular CRP.The common use of hs-CRP can be used as an auxiliary means of cardiovascular disease risk identification.Used in conjunction with traditional clinical diagnosis of acute coronary syndrome,it can be used as an early warning indicator for recurrence of coronary artery disease or acute coronary syndrome. Common uses of regular CRP can be used to evaluate infection, tissue damage and inflammatory diseases.Commonly used clinical and laboratory testing methods include immunoturbidimetric method, immunofluorescence method, latex enhanced immunoturbidimetric method and so on.

[TEST PRINCIPLE]

CRP Test Kit (Dry Fluorescence Immunoassay) uses immunofluorescence double antibody sandwich method quantitatively detect the content of CRP.Two highly specific and sensitive monoclonal antibodies, of which CRP mouse monoclonal antibody 1 is a capture antibody, are coated on the test area on a nitrocellulose membrane, and CRP mouse monoclonal antibody 2 is labeled as fluorescent microspheres and fixed on the binding pad. The detection buffer is mixed with the sample, the antigen in the sample is combined with the CRP mouse monoclonal antibody 2 labeled fluorescent microspheres in the binding pad, and the complex is then captured by the CRP mouse monoclonal antibody 1 immobilized on the test area to form fluorescent microspheres Sandwich structure; the chicken IgY-labeled fluorescent particle complex in the binding pad combines with the goat anti-chicken IgY immobilized on the quality control area of the nitrocellulose membrane to form a quality control area. The compound can be measured and analyzed by supporting equipment, which can quantitatively detect the content of CRP in human blood.

[MAIN COMPONENTS]

1. CRP test strip in a sealed pouch with desiccant.....25 tests
2. Sample diluent.....25 pieces
3. QR code card for calibration.....1 piece
4. User Manual.....1 piece
5. Quantitative suction and dropping tube (Optional).

Note: Do not mix or interchange different batches of kit.

[STORAGE AND VALIDITY]

Store the test kit at 4°C-30°C, with a valid period of 18 months.
Test strip should be used within 30 minutes once the foil pouch is opened.

[APPLICABLE DEVICES]

1. LS-1000 Dry Fluorescence Immunoassay Analyzer
2. LS-2000 Dry Fluorescence Immunoassay Analyzer
3. LS-1100 Dry Fluorescence Immunoassay Analyzer
4. LS-2100 Dry Fluorescence Immunoassay Analyzer
5. LS-4000 Hand-Held Dry Fluorescence Immunoassay Analyzer
6. LS-7000 Dry Fluorescence Immunoassay Analyzer
7. LS-7100 Microfluidic and Dry Fluorescence Immunoassay Analyzer
8. LS-7800 Automatic Microfluidic and Dry Fluorescence Immunoassay Analyzer
9. LS-3000 Automatic Fluorescence Immunoassay Analyzer
10. LS-3100 Automatic Fluorescence Immunoassay Analyzer

[SAMPLE REQUIREMENT]

1. Used for human **serum, plasma and whole blood**. Other bodily fluids and samples may not get the accurate result.
2. Whole blood and plasma sample can be anticoagulant with EDTA ,heparin and sodium citrate under aseptic conditions.
3. At room temperature, the test should be performed within 4 hours after the sample collection. Serum or plasma sample can be stored at 2°C-8°C for 3 days at most. If more than 3 days, it should be stored at -20°C. It is suggested to use fresh sample to test. Stale blood sample may not get accurate result.Whole blood samples cannot be stored in freezing, only can be stored for 3 days under the conditions of 2℃-8℃.
4. Avoid using microbial contamination samples.
5. Frozen samples must be completely melted, restored to room temperature, and mixed well before use. Avoid repeated freezing and thawing. It is recommended that the sample be frozen and thawed no more than once. If there is sediment in the thawed sample, the sample should be centrifuged before testing.

[TEST PROCEDURE]

1. Collect samples according to user manual.
2. Before the test, the sample and test strip should be recovered to room temperature (15°C-30°C).

For LS-1100

3. Perform QR code calibration when necessary. (Details refer to LS-1100 User Manual)
4. On the main interface of LS-1100, press "Test" icon to enter testing interface. Input patient information, sample information, doctor information when necessary. (Details refer to LS-1100 User Manual)
5. Remove test strip from sealed pouch and put it on a clean table, horizontally placed.
6. Using pipette to deliver 5μL of sample into one tube of sample diluent. Mix gently and thoroughly. And then drop 100μL of mixed fluid into the sample port in the test strip.
7. **Reaction Time: 3 minutes**

For panel inside: Insert the test strip into the analyzer immediately after sample dispensing. Then click "Test".

For panel outside: After reaction time 3 minutes is elapsed, insert the test strip into the analyzer and then click "Test".

8. The result will be shown on the screen and printed automatically.

Notes: It is required to perform QR code calibration when starting to use one new batch of kit.

[EXPECTED VALUE]

Cut-Off Value: CRP≤10μg/mL；hs-CRP≤3μg/mL

CRP concentration is determined using samples obtained from 178 apparently healthy individuals. hs-CRP concentration was determined using samples obtained from 158 apparently healthy individuals.

It is recommended that each laboratory establish its own reference range for the population it serves.

[INTERPRETATION OF RESULT]

1. If the test result of the sample is more than 200μg/mL, the analyzer displays ">200μg/mL", and if the result is less than 0.5μg/mL, the analyzer displays "<0.5μg/mL". Specific data can be exported through related software as needed.The results of regular CRP and hs-CRP are shown separately. When the test result is greater than 10 mg/L, the specific value is displayed in the CRP; when the test result is less than 5 mg/L, the specific value is displayed in the hs-CRP.
2. When the sample concentration exceeds the detection limit, the maximum dilution ratio is 2 times when the sample is diluted with calf serum or negative sample.

[LIMITATION]

1. The test result of this kit are only one of the diagnostic aids for the clinicians.
2. Samples containing interfering substances can affect test results. The maximum allowable concentration is: hemoglobin 3 mg/ mL bilirubin 0.25 mg/ mL and triglyceride 10 mg/ mL.

[PRODUCT PERFORMANCE]

1. Measuring Range: 0.5-200μg/mL,r≥0.990.
2. Lower Detection Limit: ≤0.5μg/mL.
3. Accuracy: Verify with comparison experiments, the relative deviation ≤15%.
4. Within-Run Precision: ≤15%.
5. Between-Run Precision: ≤15%.

[PRECAUTIONS]

1. Only used for in vitro diagnostics,and it is for one-time use, please do not reuse it.
2. After the test strip is removed from the sealed pouch, it should be tested as soon as possible to avoid excessive time in the air, resulting in dampness.
3. The damaged test strip or package cannot be used.
4. Do not mix the components of different kits.
5. All samples from patients should be treated as potential sources of infection.
6. Used reagent cards should be properly disposed of in accordance with local regulations to avoid contamination.

[REFERENCES]

1. Zhao heping, xiao qunfeng. Quantitative determination of c-reactive protein. Journal of practical medicine, 2006, 13(21):3908.
2. Yang zhenxiu. Detection of c-reactive protein. Shanghai journal of medical examinations, 1999, 14(5):261-263.

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Production date and expiration see the label.

IVD	For in vitro diagnostic use only
REF	Catalog number
	Manufacturer
LOT	Lot number
EC REP	European Authorized Representative
	Date of Manufacture
	Use by date
	Consult instructions for use
4℃ 30℃	Store between 4-30℃
Σ 25	Contents Sufficient for < n > Tests
	Do not reuse
	Keep away from sunlight
	Fragile handle with care
	Keep dry
	Forbidden to inversion