SAA/CRP Test Kit User Manual(Dry Fluorescence Immunoassay)

[PRODUCT NAME]

SAA/CRP Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

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

[INTENDED USE]

SAA/CRP Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro quantitative measurement of serum amyloid A (SAA)/ C-reactive protein (CRP) in serum, plasma and whole blood. This test is used for the detection and evaluation of infection and inflammation disorders.

[TEST PRINCIPLE]

SAA/CRP Test Kit (Dry Fluorescence Immunoassay) is used for in-vitro quantitative measurement of SAA/CRP by immunofluorescence double antibody sandwich method. The testing sample will migrate forward due to capillary action, then the SAA/ CRP of the sample will combine with antibody which is attached to fluorescence microspheres. This marked complex is attached to the detection area of immobilized antibody and the other fluorescence microspheres are attached to the control area. When the test strip is inserted into the analyzer, the analyzer automatically scans the ribbons and detected the fluorescence intensity of the composite emission from the testing area and the control area. Analyzing the fluorescence values was used to calculate the content of the detected substances.

[MAIN COMPONENTS]

1. SAA/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 is individually packaged. Test strip should be used within 1 hour 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. Plasma and whole blood can be anticoagulant with heparin, EDTA and sodium citrate under aseptic conditions.
3. At room temperature, clinical blood sample must be performed by within 4 hours after the sample collection. Serum or plasma sample can be stored at 2°C-8°C for 7days and -20°C for 6 months. Whole sample should not be frozen and can be stored at 2°C-8°C for 3 days.
4. The sample contaminated by microorganism should be avoided.
5. Frozen samples can be used after being melted, reheated and mixed thoroughly. Avoid repeated freezing-thawing. It is recommended that the freezing-thawing shall not more than one time.

[TEST PROCEDURE]

1. Preparation

The test card, sample and sample diluent should be recovered to room temperature(15°C-30°C) before testing.

2. Add the sample

Deliver 5μL of sample into one tube of sample diluent and mix gently and thoroughly. And then drop 100μL of mixture into the sample port in the test card and timing.

3. The test strip was left at room temperature for 5 minutes. After 5 minutes, insert the test strip into the analyzer for testing (For details, see the device user manual).
4. The analyzer performs analytical testing and displays the results.
5. Remove the used test strip.

6. Quality control: the test kit don't include control. The supporting devices and SAA/CRP Test Kit (Dry Fluorescence Immunoassay) is used to test the control (It is recommended to use the quality control provided by Lansionbio). If the test result is within the range of the target value of the control, the performance of the device and the kit meet the requirement.

[REFERENCE INTERVAL]

The following reference interval was obtained after statistical analysis of 95% the confidence interval for the tests of the level of SAA/CRP in serum, plasma and whole blood from 180 healthy people respectively:

SAA: <10μg/mL

CRP: ≤10μg/mL

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

[INTERPRETATION OF RESULT]

1. If the CRP 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. If the SAA test result of the sample is more than 300μg/mL, the analyzer displays ">300μg/mL", and if the result is less than 2μg/mL, the analyzer displays "<2μg/mL". Specific data can be exported through related software as needed.

2. When the sample concentration exceeds the upper detection limit, the maximum dilution ratio is 3 times when the sample is diluted with calf serum or negative sample.

[LIMITATION]

1. This kit is only for the serum, plasma and whole blood test.
2. The test result of this kit are only one of the diagnostic aids for the clinicians.
3. The result of the test should be evaluated in the context of all the clinical and laboratory data available. In those instances where the laboratory results do not agree with the clinical evaluation, additional tests should be performed accordingly.

[PRODUCT PERFORMANCE]

1. Measuring Range: SAA: 2-300μg/mL ; CRP: 0.5-200μg/mL
2. Limit of blank: SAA≤2μg/mL; CRP≤0.5μg/mL;
3. Accuracy: Verify with comparison experiments, the relative deviation ≤15%, the correlation coefficient r≥0.990.
4. Repeatability: CV≤15%.
5. Between-Run Precision: CV≤15%.

[PRECAUTIONS]

1. IVD: In vitro diagnostic medical device.
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 strips should be properly disposed according to local regulations to avoid contamination.

[REFERENCES]

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4. Yang Zhenxiu. Detection of c-reactive protein[J]. Laboratory medicine, 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
	Store between 4-30℃
	Contents Sufficient for < n > Tests
	Do not reuse
	Keep away from sunlight
	Fragile handle with care
	Keep dry
	Forbidden to inversion