Instruction for High Sensitive C-Reactive Protein (hs-CRP) Test Kit (Immunofluorescence)

1. Product Name

Generic name: High Sensitive C-Reactive Protein (hs-CRP) Test Kit (Immunofluorescence)

Trade name: hs-CRP.

2. Package

Specification	Kit Capacity	REF
25T/kit	Sample diluent: 25*1mL Test card: 25* 1 T	52026010
50T/kit	Sample diluent: 50*1mL Test card: 50* 1 T	52027010

3. Intended Use & Indication

For *in vitro* quantitative determination of High Sensitive C-Reactive Protein content in human serum, plasma or whole blood.

It is mainly used as an aid in the screening and monitoring of infection and inflammation.

Products for professional use only.

4. Test Principle

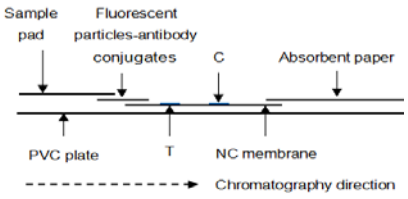
When the test sample is added to the sample port on the test card, CRP in the sample combines with mouse anti-CRP monoclonal antibody which is coupled to fluorescent particles to form fluorescent particles - antibody - antigen complexes. This immune complex reaches to the test area (T) along the nitrocellulose membrane and combines with the pre-coated mouse anti-CRP monoclonal antibody, its fluorescence intensity is proportional to the CRP content in the sample, the remaining antibody coupled with fluorescent particles reaches to the quality control area (C) and combines with pre-coated goat anti-mouse IgG. If the sample does not contain CRP, the test area (T) will not appear fluorescence.

5. Main components & Additional Required Equipment

The test kit consists of test card, magcard, sample diluent and the instruction.

(1) The test card consists of the card housing and test strip. Test strip contains a sample pad, glass fiber (coated with fluorescent particles-CRP antibody conjugates), nitrocellulose (NC) membrane (test area (T) is coated with CRP monoclonal antibody, quality control area (C) is coated with goat anti-mouse IgG), absorbent paper and PVC plate.

Diagram is as follows:



Schematic diagram of test strip

(2) Magcard: load calibration curve information for reagents with this batch.

(3) Sample diluent: the main component is phosphate buffer (PBS), containing surfactant and preservative.

(4) Other materials required for the test: sample collection set.

(5) Equipment: applicable to FA50/FA120 Quantitative Immunoassay Analyzer manufactured by Genrui Biotech Inc.

6. Accessories Required But Not Provided

(1) Pipettes and pipette tips: 100 μL.

(2) Timer.

7. Special Storage & Transport Conditions

(1) The test kit is kept in sealed aluminum foil bag and can be stored at 2-30℃. The unopened pack is valid for 18 months from the date of manufactured. Once opened, it is valid for 1 hour.

(2) Transport at 2-30℃.

8. Sample Requirements

(1) The optimal sample is fresh non-hemolyzed serum, plasma or whole blood. Recommended to use venous blood, results of other body fluids and samples may not be accurate.

(2) Complete the sample test within 24h at room temperature after the sample is collected. Keep serum and plasma refrigerated at 2-8℃ for not more than 7 days and frozen below -18℃ for not more than 1 month. Whole blood sample should not be frozen, or stored at 2-8℃ for more than 7 days.

(3) Bring the samples to room temperature before the test. Frozen samples need to be melted completely, re-warmed and mixed before use, avoid repeated freezing and thawing.

(4) Human serum or plasma is recommended to be used for testing. EDTA is recommended to be used as coagulant.

9. Test Procedure

Carefully read the instruction before using the test kit and strictly follow the instruction to ensure reliable results. Bring all reagents to room temperature (18-25℃) before use.

(1) Startup: Click “STD Mode” in the main menu to enter the measurement interface, click “Item” to select the desired test item and click “Type” to select the sample type.

(2) Click “Lot No.” to enter the card swiping interface, place magcard of the corresponding item to the magnetic induction zone, when hearing a “di” sound, the magcard is swiped successfully. Make sure the magcard and the test card are from the same batch (Note: reagents are precalibrated and specific calibration curve parameters for each batch of reagents have been stored in the magcard.).

(3) Sampling: Insert the sample collection capillary into the centrifuge tube, leave the capillary tip below the sample surface until enough sample has been collected in the capillary. Puncture the top of the sample collection tube by the sample collection top, insert the capillary tip into the tube that pre-filled with sample diluent. Pinch the tube for 5-10 times to wash off all the sample. Shake the assembled sample collection tube up and down for between 30 seconds and 1 minute. Leave 2 drops of diluted sample onto the sampling window of the testing kit and start timing at the same time.

(4) Insert the test kit into the analyzer’s test slot (the sample port end toward the inside). Click “Measure”, the instrument will automatically detect and print out the results after 3 minutes (If using “Fast Mode”, keep it for 3 minutes and quickly insert it into the analyzer’s test slot).

10. Reference Interval

Reference range: CRP<10 mg/L,

hs-CRP<1.0 mg/L.

11. Explanation for Test Results

(1) When fluorescent strips the control area (C) appears on, the analyzer will automatically detect the fluorescence and analyze the test card, and then provide quantitative results.

(2) When the control area (C) does not appear fluorescent strips, the analyzer cannot detect the fluorescence and alarm automatically, indicating that the operation is incorrect or the test card is damaged, in this case, carefully read the instructions again and re-test with a new test card. If the problem still exists, immediately stop using products of this batch and contact your supplier.

(3) When the sample test results are greater than 200mg/L, the instrument displays > 200mg/L, when the test results are less than 0.5mg/L, the instrument displays < 0.5mg/L. The former can be diluted with saline water by an integer multiple before testing, multiply the result by the dilution ratio.

(4) This test kit does not produce Hook Effect within 500mg/L.

12. Detection limit

(1) This test kit is for *in vitro* diagnostic use only.

(2) Diagnosis and treatment can not only rely on this test result, it should be taken into account the patients' clinical history and other laboratory test results. Each laboratory is recommended to establish its own reference range based on the detected patient population.

13. Interfering Substance

Hemoglobin, bilirubin, cholesterol, triglycerides, HAMA antibody and rheumatoid factor in samples can interfere with the test results, the maximum allowable concentrations of hemoglobin is 5 g/L, bilirubin is 2 mg/mL, cholesterol is 15 mg/mL, triglycerides is 30 mg/mL, HAMA antibody is 40 ng/mL, rheumatoid factor is 525 IU/mL.

14. Product Performance Indicators

(1) Analysis sensitivity: ≤ 0.5mg/L.

(2) Linearity range: 0.5-200mg/L (Linear correlation coefficient: r ≥ 0.990).

(3) Measurement precision: Repeatability: CV ≤ 15%

Inter-batch relative deviation: CV ≤ 15%.

(4) Accuracy: -15%≤ Bias% ≤ +15%.

(5) The Interference test result: -15% ≤ Bias% ≤ +15%.

15. Precautions

(1) Once opened, use the test cards as soon as possible, otherwise it may cause moisture. Do not re-use the test cards.

(2) Components in test kit of different batches cannot be used interchangeably.

(3) For substances containing sources of infection or suspected of containing sources of infection, there should be proper bio-safety assurance procedures. Pay attention to the following matters:

a) Wear gloves when handling sample or reagent for disinfection.

b) Disinfect spilled sample or reagent with disinfectant.

c) Disinfect or handle potential contamination sources of all samples or reagents in accordance with local regulations.

16. Explanation of graphic symbol

	Consult Instructions for use		Temperature Limitation
LOT	Lot No.		Expiry Date
IVD	*In Vitro* Diagnostic Reagent	CE	CONFORMITE EUROPEENNE
	Production Date		Biohazard
	Manufacturer		Volume
Σ	Contains sufficient for < n>tests		Keep away from sunlight
	Do not re-use		Dark dry preservation
EC REP	Authorized representative in the European community	REF	Catalogue number

17. Reference

Ultrarapid, Ultrasensitive One-Step kinetic Immunoassay for C-Reactive Protein (CRP) in Whole Blood Samples: Measurement of the Entire CRP Concentration Range With a Single Sample Dilution Clin, Chem, Feb 2002, 48: 269-277.

18. Metrological Traceability

The kit was traced to Randox QC material.

19. Help information

If you need help please contact after sales.

20. Manufacturer

Genrui Biotech Inc.

Address: 4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China.

21. Instruments & Applications

Genrui's Immunofluorescence products, designed to work in automated lab environment, which are compatible with the FA50/FA120 Quantitative Immunoassay Analyzer. There may or may not be an application developed for you particular instrument, please visit the instrument section of our website.

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