Finecare™ CRP (C-reactive protein) Rapid Quantitative Test

Catalog No. W201

INTENDED USE

The Finecare™ CRP (C-reactive protein) Rapid Quantitative Test along with Finecare™ FIA Meter is intended for vitro quantitative determination of C- reactive protein (CRP) in human whole blood, serum or plasma.
-Fluorescence immunoassay
-Predict future cardiovascular diseases (CVD)
-Diagnosis for infection and inflammation

For in vitro diagnostic use only.For professional use only.

SUMMARY

The C - reactive protein (CRP) is synthesized by the liver in response to interleukin-6 and well known as one of the classical acute-phase reactants and as a marker of inflammation. The serum CRP level may rise from a normal level of <5 mg/L to 500 mg/L during the body's general, non-specific response to infectious and other acute inflammatory events. high-sensitivity CRP (hsCRP) is also emerging as the strongest and most independent predictive risk factor for atherosclerosis and cardiovascular diseases (CVD).

For people the diagnosis of inflammatory disease and CVD assessment cutoffs have been recommended as follows:

Concentrations	Clinical Reference
＜1.0 mg/L	Low CVD risk (No Inflammation Situation)
1.0～3.0 mg/L	Moderate CVD risk (No Inflammation Situation)
＞3.0 mg/L	High CVD risk (No Inflammation Situation)
＞10 mg/L	There may be other infections (bacterial infections or viral infections)
10～20 mg/L	Generally indicates viral infections or mild bacterial infection
20～50 mg/L	Generally indicates moderate bacterial infection
＞50 mg/L	Generally indicates serious bacterial infection

PRINCIPLE

The Finecare™ CRP Rapid Quantitative Test is based on fluorescence immunoassay technology. The Finecare™ CRP Rapid Quantitative Test uses a sandwich immunodetection method, when sample is added to the sample well of the Test Cartridge, the fluorescence-labeled detector CRP antibody binds to CRP antigen in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and CRP are captured to CRP antibody that has been immobilized on test strip. Thus the more CRP antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of CRP captured and Finecare™ FIA Meter shows CRP concentrations in blood specimen. The default results unit of Finecare™ CRP Rapid Quantitative Test is displayed as XXXmg/L from Finecare™ FIA Meter. The working range and the detection limit of the CRP Test system are 0.5～200 mg/L and 0.5mg/L.

PRECAUTIONS

1. This kit is for in vitro diagnostic use only.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Do not use Test Cartridge if its lot # does not match with ID Chip # that is inserted onto the equipment.
5. The Finecare™ CRP Rapid Quantitative Test kit is only operational in the Finecare™ FIA Meter.
6. Do not use the Test Cartridge if the pouch is punctured or not well sealed.
7. TheTest Cartridge and Meter should be used away from vibration and magnetic field. During normal usage, the Meter itself may cause vibration, which should be regarded as normal.
8. Use separate clean pipette tips and detector buffer vials for different specimens.
9. Blood specimens, used Test Cartridges, pipette tips and detector buffer vials should be handled and disposed in accordance with standard procedures and relevant regulations of microbiological hazard materials.
10. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

MATERIAL

Material Provided

Test Cartridge	25
Test Cartridge ID Chip	1
Detector buffer	25
Whole blood sampler	25
Leaflet of instruction	
Instruction of whole blood sampler	

Material Required But Not Provided

1. Finecare™ FIA Meter
2. Transfer Pipette Set (10μL, 100μL size)
3. Specimen Collection Containers
4. Sterile Lancets(for Fingerstick Whole Blood only)
5. Alcohol Pads
6. Centrifuge (for Plasma/Serum only)
7. Timer

STORAGE AND STABILITY

1. Store the detector buffer at 4～30℃. The buffer is stable up to 24 months.
2. Store Finecare™ CRP Rapid Quantitative Test Cartridge at 4～30℃, shelf life is up to 24 months.
3. Test Cartridge should be used within 1 hour after opening the pack.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with serum or plasma or whole blood.

For Whole Blood Collected by Fingerstick: Please refer to the instruction of whole blood sampler.

For Whole Blood Collected by Venipuncture:
1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant (EDTA recommended)
2. It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged periods. If the specimens are not tested immediately, they may be stored at 2℃～8℃.
3. It's not suitable to test the whole blood samples storing at 2℃～8℃ for more than 2 days.

For Serum and Plasma:
1. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
2. Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2℃～8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.

TEST PROCEDURE

Refer to Finecare™ FIA Meter Operation Manual for the complete instructions on use of the Test. The test should be operated in room temperature.

Step1: Preparation

Check/insert ID Chip into the equipment.

Step2: Sampling

Draw 8.5 μL of whole blood or 5 μL of serum/plasma with a transfer pipette and add it to the buffer tube.

Step3: Mixing

Mix well the specimen with buffer for 1 minute by tapping or inverting the tube.

Step4:Loading

Take 75μL of sample mixture and load it onto the sample well of the Test Cartridge.

Step5:Testing

1. Finecare™ FIA meter:

Standard test: Insert the Test Cartridge onto the Test Cartridge Holder and click "Test". 3 minutes later, the result will show in the display and print out when click "Print".

Quick test: Put the Test Cartridge on the operation platform.3 minutes later, insert the Test Cartridge onto the Test Cartridge Holder and click "Test". The result will show in the display and print out when click "Print".

2. Finecare™ multi-channel FIA meter:
Insert the Test Cartridge onto the Test Cartridge Holder. 3 minutes later, the result will show in the display and print out when click “Print”.

Please refer to the **Operationin** user manual of Finecare™ FIA Meter for details.

QUALITY CONTROL

Each Finecare™ CRP Rapid Quantitative Test Cartridge contains internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the Test Cartridge was inserted and read properly by Finecare™ FIA Meter. An invalid result from the internal control causes an error message on Finecare™ FIA Meter indicating that the test should be repeated.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human whole blood, serum and plasma specimen.
2. The results of Finecare™ CRP Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If hsCRP test results do not agree with the clinical evaluation, additional tests should be performed.
3. The false positive results may come from cross-reactions with some similar antibodies in blood; and similar epitopes from non-specific components in blood capturing fluorescent labeled antibodies.
4. EDTA other than anticoagulants (e.g. heparin or citrate) is suggested to use for plasma.
5. Other factors may interfere with Finecare™ CRP Rapid Quantitative Test and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison study has been performed using 146 human blood samples, CRP concentrations ranging from 0.56mg/L to 120.8mg/L, demonstrated good correlation with a commercially available kit.
Comparison between the Finecare™ CRP Rapid Quantitative Test and the DADE BEHRING BN ProSpec was conducted for 146 clinical samples, the Correlation Coefficient is 0.984.

Assay Range and Detection Limit

- Assay Range: 0.5～200 mg/L
- Detection Limit : 0.5 mg/L

Linearity

A serial concentration of CRP controls of 0.5mg/L, 5.0mg/L, 10.0mg/L, 20.0mg/L, 50.0mg/L, 100.0mg/L were each tested for three times, the Correlation Coefficient (R) is ≥ 0.995.

Precision

Intra-Run
Within-run precision has been determined by using 10 replicates of four specimens containing 1.0 mg/L, 5.0 mg/L, 10.0 mg/L and 20.0 mg/L CRP. C.V. is ≤ 15%.

Inter-Run
Between-run precision has been determined by using 10 replicates for each of three lots using CRP specimen levels at 1.0 mg/L, 5.0 mg/L, 10.0 mg/L and 20.0 mg/L. C.V. is ≤ 15%.

BIBLIOGRAPHY OF SUGGESTED READING

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2. Volanakis JE. Human C-reactive protein: expression, structure, and function. Mol Immunol 2001;38:189-197.
3. Koenig W, Sund M, Frohlich M, et al. C-reactive protein, a sensitive marker of inflammation, predicts future risk of coronary heart disease in initially healthy middle-aged men. Circulation 1999;99:237-242.
4. Rifai N, Ridker PM. Proposed Cardilvascular Risk Assessment Algorithm Using High-Sensitivity C - reactive protein and Lipid Screening. ClinChem 2001;47:28-30.

IVD	In Vitro Diagnostic Use		See Instruction for Use		Expiry Date
Σ	Tests per Kit		Manufacturing Date		Keep Dry
LOT	Batch Number	EC REP	Authorized Representative		Keep away from Sunlight
4℃ 30℃	Store between 4～30℃				

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