Diagnostic Kit for C-reactive Protein

A test for the diagnosis of inflammatory condition and ACS by measuring CRP/hs-CRP in whole blood, serum or plasma with the use of Immunofluorescence Analyzer.

English

- For *in-vitro* diagnostic use

PACKING SPECIFICATION
25 Tests/ Kit (07CRP5025)

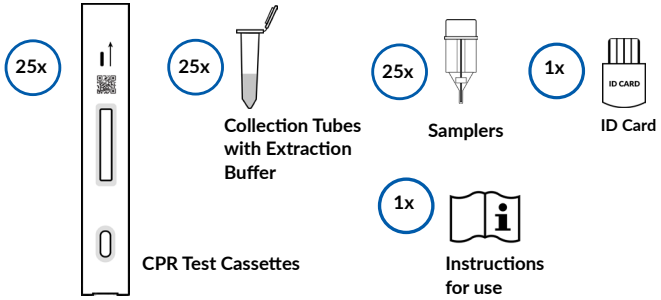
INTENDED USE
The CRP Test Cassette (Whole Blood/Serum/Plasma) is based on Fluorescence Immunoassay for the quantitative determination of C-reactive protein (CRP) in human serum, plasma or whole blood as an aid in the evaluation of infection, tissue injury and inflammatory disorders along with measurement of high sensitivity CRP (hs-CRP) for evaluation of acute coronary syndromes (ACS). The test is intended for healthcare professionals use.

SUMMARY
CPR is an acute-phase reactant that precipitated with Pneumococcal C-polysaccharide, and is a non-specific immune response component. CRP has wide distribution in our body, and is an acute-phase protein produced in the liver in response to microbial infection or tissue injury, it measures general levels of inflammation in the body, and the hs-CRP can be used to detect lower concentrations of CRP in serum or plasma. Studies revealed hs-CRP levels seem to be correlated with Atherosclerosis and Acute Myocardial Infarction. And the hs-CRP is an inflammation "marker" for ACS patient and is helpful for primary prevention and risk assessment of cardiovascular disease. Its combination with the ratio of total cholesterol to HDL-C is more accurate than other risk factors in predicting cardiovascular disease.
The American Heart Association and US Centers for Disease Control and Prevention have advocated hs-CRP as a predictor of cardiovascular disease (CVD) to define risk groups: less than 1.0 mg/L indicates low risk, 1.0 to 3.0 mg/L means moderate risk, and the amount above 3.0 mg/L (lower than 10 mg/L) strongly suggests a high risk of CVD. Moreover, higher CRP levels are found in late pregnant women, mild inflammation and viral infections (10~40 mg/L), active inflammation, bacterial infection (40~200 mg/L), severe bacterial infections and burns (>200 mg/L).

PRINCIPLE
The CRP Test Cassette is detects CRP based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains CRP, it attaches to the fluorescent microspheres-conjugated anti-CRP antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of CRP in the sample correlates linearly with the fluorescence signal intensity captured on the Test line.
According to the fluorescence intensity of the test and standard curve, the concentration of CRP in the sample can be calculated by the Immunofluorescence Analyzer.

REAGENTS
The test include anti-CRP antibody coated fluorophore and anti-CRP antibody coated on the membrane.

MATERIALS PROVIDED



MATERIALS REQUIRED BUT NOT PROVIDED
- Immunofluorescence Analyzer MPQuanti® (07IMA001)
- Pipette
- Specimen Collection Containers
- Centrifuge (for serum/plasma specimen only)
- Timer

PRECAUTIONS
1. For professional *in-vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The CRP Test Cassette should only be used with the Analyzer by approved medical professionals.

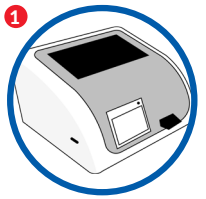
STORAGE AND STABILITY
1. The test should be stored at 4 - 30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the test from contamination.
5. Do not use if there is evidence of microbial contamination or precipitation Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SAMPLE COLLECTION AND PREPARATION

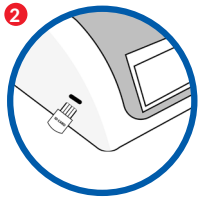
Blood Sample Taking
1. Collect the specimen according to standard procedures.
2. To collect Fingerstick Whole Blood specimens:
   - Wash the patient's hand with soap and warm water or clean with an alcohol pad. Allow to dry.
   - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
   - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
   - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
   - Add the Fingerstick Whole Blood specimen to the buffer tube by using the sampler or a pipette.
3. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
4. Do not leave specimens at room temperature for prolonged periods. Serum and Plasma specimens may be stored at 2 - 8 °C for up to 3 days, for long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2 - 8 °C if the test is to be used within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens. Only clear, non-hemolyzed specimens can be used.
6. EDTA, Heparin sodium, can be used as the anticoagulant tube for collecting the blood specimen.

Sample Dilution / Sample Stability
1. Administer the blood-filled end-to-end capillary into the plastic tube with buffer. Alternatively, the specimen (5 µL of serum or plasma / 7.5 µL of whole blood) can be added directly with the micro pipette into the buffer.
2. Close the tube and shake the sample by hand vigorously for approximately **10 seconds** to mix the sample and dilution buffer.
3. Let the diluted sample homegenize for approximately 1 minute.
4. The diluted sample can then be used immediately or stored for up to 8 hours.

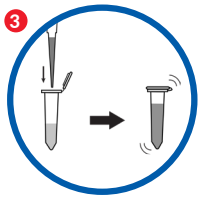
TEST PROCEDURE
Refer to Immunofluorescence Analyzer User Manual for the complete instructions for use of the Test. The test should be in room temperature.
Allow the test cassette, specimen and buffer to reach room temperature (15 - 30 °C) prior to testing.



Turn on the Analyzer power.

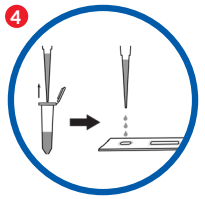


Take out the ID Card and insert it into the Analyzer ID Card Slot. Choose test mode and/or sample type according to needs.



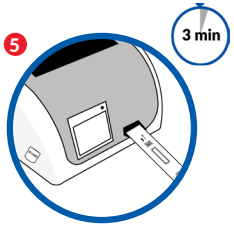
Serum or plasma: Pipette **5 µL of serum or plasma** into the buffer tube, mix the specimen and the buffer well.

Whole blood: Transfer **7.5 µL of whole blood** into the buffer tube with sampler provided or pipette; mix the specimen and the buffer well.



Add diluted specimen with a Pipette: Pipette **75 µL of diluted specimen** into the sample well of the cassette. Start the timer at the same time.

Add specimen with sampler provided: Discard the first 2 drops, then **add 2 drops of diluted specimen** into the sample well of the cassette. Start the timer at the same time.



Test results should be interpreted at **3 minutes** with the use of Immunofluorescence Analyzer.

Caution: There are different test modes of the Immunofluorescence Analyzer. The difference between them is incubation of the test cassette is outside or inside the analyzer. Choose test mode accordingly and confirm sample type.
Consult the user manual of the analyzer for detailed operation information.
Operator must consult the Immunofluorescence Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.

INTERPRETATION OF TEST RESULTS

Results read by Immunofluorescence Analyzer.
The result of tests for C-reactive Protein is calculated by Immunofluorescence Analyzer and display the result on the screen. For additional information, please refer to the user manual of Immunofluorescence Analyzer.
Assay range of CRP is 0.5 - 200 mg/L.

QUALITY CONTROL

Each CRP Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test cassette was tested and read properly by Immunofluorescence Analyzer. An invalid result from the internal control causes an "N/A" message on Immunofluorescence Analyzer and indicates that the test should be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The CRP Test Cassette (Whole Blood/Serum/Plasma) is for professional *in-vitro* diagnostic use, and should only be used for the quantitative detection of C-reactive protein.
2. The CRP Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of CRP antigen in the specimen and should not be used as the sole criterion for evaluating inflammatory conditions.
3. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. High concentrations of CRP may produce a dose hook effect, resulting in incorrect interpretation of CRP levels. High dose hook effect has not been observed with this test up to 200 mg/L of CRP.
5. The test assay range of this test kit is 0.5 - 200 mg/L. When the concentration of the sample exceeds the upper limit of the test, the high-concentration sample should be diluted with calf serum or negative samples, and the maximum dilution factor should not exceed 4 times.
6. The results of CRP Tests are based on measuring the levels of CRP in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED VALUES

Concentrations	Clinical Reference
<1.0 mg/L	Low CVD risk
1.0 ~ 3.0 mg/L	Moderate CVD risk (No Inflammation)
>3.0 mg/L	High CVD risk (No Inflammation)

Concentrations	Clinical Reference
>10 mg/L	Probable 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

PERFORMANCE CHARACTERISTICS

1. Accuracy
The test deviation ≤±15%

2. Assay Range and Detection Limit

- Assay Range: 0.5 – 200 mg/L
- Minimum Detection Limit (Analytical Sensitivity): 0.5 mg/L

3. Linear range
0.5 – 100 ng/mL, R≥0.990

4. Precision
Intra-lot precision
Within-run precision has been determined by using 10 replicates of 2 specimens containing 1.0 mg/L, 10.0 mg/L of CRP. C.V. is ≤ 15%.
Inter-lot precision
Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 1.0 mg/L, 10.0 mg/L of CRP. C.V. is ≤15%.

5. Method comparison
The assay was compared with CRP test of Maccura Biotechnology Co.,Ltd with 110 samples. The correlation coefficient(r) is 0.994.

BIBLIOGRAPHY

1. Morley JJ, Kushner (1982) Serum C-reactive protein levels in disease. In: Kushner I, Volanakis JE, Gewurz H,eds. C-reactive protein and the plasma protein response to tissue injury. Ann. NY Acad. Sci. 389: 406-417.
2. Peltola HO (1982) C-reactive protein for rapid monitoring of infections of the central nervous system. Lancet:980-983.
3. Macy EM, Hayes TE and Tracy RP (1997) Variability in the measurement of C-reactive protein in healthy subjects: implications for reference intervals and epidemiological applications. Clin. Chem. 43, 52-58.

SYMBOLS

	Consult Instructions For Use	REF	Catalogue Number
IVD	For *In-vitro* Diagnostic use	EC REP	Authorized Representative
4°C 30 °C	Store at 4 °C ~ 30 °C		Do Not Reuse
	Keep away from Sunlight		Do Not Use if Package is Damaged
LOT	Lot Number	CE	European Conformity
	Manufacturer		Date of Manufacture
	Expiration Date	Σ	Tests per Kit
UDI	Unique Device Identifier		

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Rev: 07CRP5025-011-03-42-EN
Effective date: 20.03.2024