Semi Quantitative CRP Test Cassette
For Serum, Plasma or Whole Blood Specimens
(Revised 9-06-2019)

Intended Use

A C-reactive protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the C-reactive protein in whole blood. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues. For professional use only.

Summary

CRP is a member of the pentraxin family of proteins, which are nonspecific, acute-phase reactant proteins composed of 5 identical 23-kDa polypeptide subunits arranged in a cyclic pentameter shape.] Each of these subunits contains one binding site for a phosphocholine molecule and 2 binding sites for calcium. C-reactive protein (CRP) and erythrocyte sedimentation rare (ESR) are known as acute phase proteins, which reflect a measure of the acute-phase response. The term "acute phase" refers to local and systemic events that accompany inflammation. Local responses include vasodilation, platelet aggregation, neutrophil chemotaxis, and release of lysosomal enzymes. Systemic responses include fever, leukocytosis, and a change in the hepatic synthesis of acute phase proteins (a hepatic protein, which by definition, increases or decreases in serum concentration by at least 25%). Stimuli to the acute phase include many different forms of tissue injury, such as infection, immuno/allergic reaction, thermal injury, hypoxic injury, trauma, surgery, and malignancy.The clinical use of acute phase protein is as an aid to diagnosis. Because the acute phase response is relatively non-specific, the value of measuring acutephase protein concentrations is to assess the extent of inflammation reflecting momentary disease activity. Similar to tumor markers, acute-phase proteins may monitor the course of disease in response to therapeutic intervention.

Principle

The CRP test is a sandwich immunoassay. The test contains a nitrocellulose membrane strip with an immobilized Mouse anti-CRP antibody in the test line region (T), an immobilized goat anti-rabbit antibody in the reference line region (R) as 30mg/l CRP semi-quantitative reference marker, another immobilized goat-anti-mouse antibody in the control line region (C) and a mouse anti-CRP antibody as well as a rabbit antibody which are coupled with colloidal gold on the conjugate pad.

During the assay the analyte (i.e. CRP antigen) in the blood reacts with the colloidal gold coupled CRP antibody on the Conjugate Pad thus forming an antibody – antigen – colloidal gold complex while the liquid is moving along the membrane all complexes and conjugates are transported along the membrane. When the complexes reach the respective immobilized Mouse anti-CRP antibody on the membrane, they are trapped and will form a sandwich complex consisting of: immobilized antibody – antigen (analyte) – antibody – Colloidal Gold. Only when the applied blood sample contains a certain concentration of CRP, the formation of this sandwich complex will result in a visible purple T-line. The liquid colloidal gold conjugates also migrate to the reference line and a fixed visible intensity of R (30mg/l marker) is developed. The liquid colloidal gold conjugates continue to move to the control area (C) line on the membrane. There, this conjugate will form a complex with the immobilized anti mouse antibody resulting in the formation of a purple colored control (C) line. This indicates that the test has been performed correctly. The test line (T) intensity is used to semi-quantitatively determine CRP concentration in the blood sample. The C/R/T lines may not line up perfectly with the C/R/T markings on the cassette. The gap distances (C to R and R to T) are approximately the same between the cassette C/R/T markings and C/R/T lines.

The semi quantitative CRP test is a rapid test used to detect CRP in whole blood. The sensitivity of the test is 10 mg/L CRP.

Materials Provided

The CRP test kit contains the following items to perform the test:

1. CRP Test Cassette
2. 10µl Micropipette (for whole-blood collection)
3. Buffer Solution
4. Mixing Tube
5. Sample Dropper
6. Instructions.

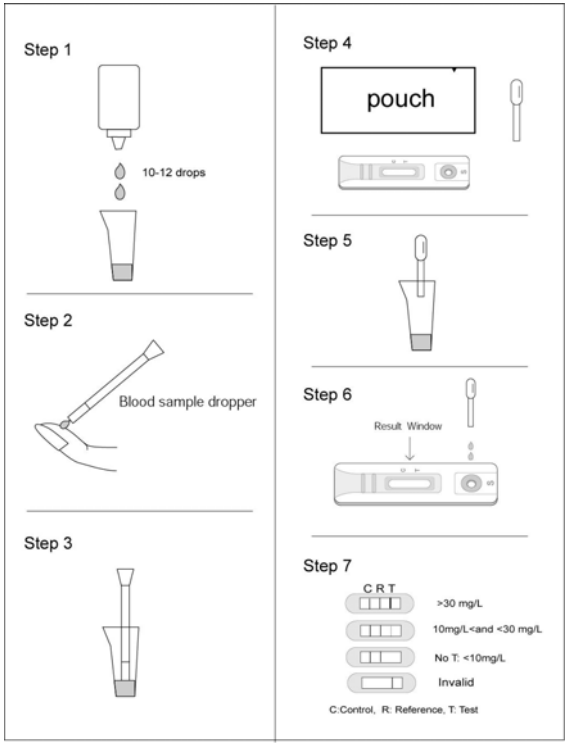
Precautions

The CRP test kit should be stored at room temperature or 4-30ºC (40-86ºF). If test kit is refrigerated, it should be brought to room temperature before use. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

Procedure of the Test

1. Open the buffer bottle and hold it upside down. Make sure holding the bottle vertically (Note: drops may contain air-bubbles if not holding the buffer bottle vertically), slowly add 10 to 12 hanging drops to the mixing tube.
2. Collect 10µl of whole-blood (up to the blue line on the 10µl Micropipette) or 3.5µl (collection pipette not provided) of serum/plasma into the mixing tube already containing the buffer, mix well. If finger pricking is used for blood specimen collection, Do NOT squeeze finger tip for specimen, as it may result in higher CRP reading due to local injury.
3. Remove the sample dropper and test cassette from the foil pouch. Place the test cassette on a flat, dry surface. Obtain specimen from the mixing tube using the sample dropper, and holding the sample dropper above the test cassette and add 4 to 6 drops into the Sample Well.
4. As the test begins to work, you will see purple color dyes move across the Result Window in the center of the test cassette.
5. Interpret test results at 5 minutes.

Caution: The above interpretation time is based on reading the test results at room temperature of 15 to 30 degrees C. If your room temperature is significantly lower than 15 degrees C, then the interpretation time should be properly increased.



Interpretation of the Test:

1. A color band will appear at the left section of the Result Window to show that the test is working properly. This band is the Control Band ("C" band).
2. The middle section of the Result Window indicates the Reference Band ("R" band).
3. The right section of the Result Window indicates the Test Band ("T" band).

CRP concentration of less than 10mg/L: there is no visible test line (T).

CRP concentration of 10mg/L or less than 30mg/L: The intensity of the test line (T) is weaker than reference line (R) indicating that CRP level is 10mg/L to less than 30mg/L.

CRP concentration of 30mg/L: The intensity of the test line (T) is similar to the reference line (R) indicating that CRP level is 30mg/L.

CRP concentration higher than 30mg/L: The intensity of the test line (T) is darker than the reference line (R) indicating that CRP level is higher than 30mg/L.

Note: Generally, the higher the CRP level in the specimen, the stronger the "T" band color will be. Specimen with very high CRP level

specimens (>1000mg/L) can cause reduced “T” line color intensity (Prozone Effect).

Invalid: If after performing the test, no color band for the reference band or the control band is visible within the Result Window, the result is considered invalid. Some causes of invalid results are not following the directions correctly, such as insufficient amount of sample or buffer added or the test may have deteriorated beyond the expiration date.

Note: A positive result will not change once it has been established at 7 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after 7 minutes. Interpreting test results after 7 minutes, the sensitivity of the test will be higher than 10mg/l. Some specimens with a high rheumatoid factor concentration may yield a nonspecific positive result

Limitations of the Test

Although the CRP Test is very accurate in detecting CRP, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained.

As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

Warnings

1. The same lancet needle (not provided with the test) should be used for one person only and should not be shared with another person, because the used needle is a biohazard.
2. Decontaminate and dispose of all specimens, reaction kits, lancet needles and potentially contaminated materials, as if they were infectious wastes, in a biohazard container.
3. Do not use the kit after the expiration date.
4. For in vitro diagnostic use only.

Interference Study

The following substances at the specified concentrations have not shown to interfere with the CRP test.
Acetaminophen, 20 mg/dl; Acetyl salicylic Acid, 20 mg/dl; Ascorbic Acid, 20 mg/dl; Atropine, 20 mg/dl; Bilirubin, 60 mg/dl; Caffeine, 20 mg/dl; Creatinine, 20 mg/dl; Gentisic Acid, 20 mg/dl; Glucose, 2000 mg/dl; Hemoglobin, 500 mg/dl; Ketones, 40 mg/dl; Mestranol, 3 mg/dl; Nitrite, 20 mg/dl; Penicillin, 40,000 U/dl; Sodium Heparin, 3 mg/dl; Lithium Heparin, 3 mg/dl.

References:

1. Caswell M. Effect of patient age on tests of the acute-phase response. Arch Pathol Lab Med 1993;117:906–909.
2. Anderson R , Hugander A , Ghazi S , Ravan H , Offenbartl S, Nystron P et al. Diagnostic value of disease history, clinical presentation and inflammatory parameters of appendicitis. World J Surg 1999;23(2):133-40.