CRP rapid test

For professional in vitro diagnostic use only.

**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, serum or plasma. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues. For professional use only. The semi-quantitative CRP test is a rapid test used to detect CRP in whole blood, serum or plasma. The sensitivity of the test is 10 mg/l CRP.

**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 pentamer 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 rate (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, immune/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 nonspecific, the value of measuring acute phase 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 immunassay. 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 30 mg/l CRP semi-quantitative reference marker, another immobilized goat-anti-mouse antibody in the control 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 (30 mg/l marker) is developed. The liquid colloidal gold conjugates continue to move to the control area (C) band 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.

**MATERIALS PROVIDED**

The CRP test kit contains the following items to perform the test:
- 10 CRP Test cassette
- 10µl micropipette (for whole-blood collection)
- Buffer solution
- Mixing tube + dropper tips
- Sample dropper within the pouch
- Instruction

**STORAGE AND STABILITY**

The CRP test kit should be stored at room temperature or 2-30°C. 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.
### 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" line).

2. The middle section of the Result Window indicates the Reference Band ("R" line).

3. The right section of the Result Window indicates the Test Band ("T" line).

#### NEGATIVE

- **CRP concentration of less than 10 mg/l:**
  - There is no visible test line (T).

#### POSITIVE

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

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

#### INVALID

If after performing the test, no color band for the reference band or the control band is visible within the Result Window (independent of the T-Line appearance), 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:

- Generally, the higher the CRP level in the specimen, the stronger the "T" band color will be. Specimen with very high CRP level specimens (>1000 mg/l) can cause reduced "T" line color intensity (Prozone Effect).

### 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.

### PERFORMANCE CHARACTERISTICS

Blood samples from 450 patients were taken from patients who had met a certain profile, namely, people over the age of 50 with no previous history of cardiovascular disease. The age range of these individuals was from 50 to 74 years, 58% were female and 42% were male. Whole blood specimens were collected from all patients in a test tube containing anti-coagulation agents, e.g. sodium heparin. The collected blood specimens were tested in a commercially available CRP test (Immunochemistry Protein Analysis System, IMMAGE 800, Beckman Coulter, USA) and the Diagnostik Nord GmbH CRP test. Each of the collected blood samples are equally divided into 4 portions with 4 sodium heparin tubes and properly identified for later data collection. The 4 portions are used to be tested with IMMAGE 800, and 3 LOTs of Diagnostik Nord GmbH CRP test. All comparison studies were conducted blindly.

### REFERENCES


### 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; Gentamic Acid, 20 mg/dl; Glucose, 2000 mg/dl; Hemoglobin, 500 mg/dl; Ketones, 40 mg/dl; Measanol, 3 mg/dl; Nitrite, 20 mg/dl; Penicillin, 40,000 U/dl; Sodium Heparin, 3 mg/dl; Lithium Heparin, 3 mg/dl.

### SYMBOLS

- **CE** — For in-vitro diagnostic use only
- **LOT** — Lot number
- **Expiry date**
- **Carefully read package insert**
- **Store at room temperature 2-30 °C**
- **Keep dry**
- **catalogue number**

### PRODUCER

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