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<b>Procedure</b>	<b>Rheumajet CRP - NCCLS</b>
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<b>Prepared by</b>	<b>Date Adopted</b>	<b>Supersedes Procedure #</b>

<b>Review Date</b>	<b>Revision Date</b>	<b>Signature</b>

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**PRINCIPLE:** The Rheumajet **CRP** latex reagent is a suspension of polystyrene latex particles of uniform size coated with the IgG fraction of anti-human CRP specific serum. Latex particles allow visual observation of the antigen-antibody reaction. When a serum containing Greactive protein is mixed with the Sure-View CRP latex reagent, the uniform appearance of the latex suspension will convert to a clear agglutination. This change occurs because the C-reactive protein present in the serum reacts with the IgG coated latex particles, forming a web between them.

**Note:** When Rheumajet CRP latex is mixed with neat serum, and if the serum contains

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6 mg/L or greater of C-reactive protein, a clear agglutination will occur.

## **SPECIMEN**

**Type:** Use fresh serum. **DO NOT USE PLASMA**

**Handling Conditions:** If the test cannot be performed on the same day of sample collection, the serum may be stored between 2-8° C for no longer than 8 days. For longer periods the sample must be frozen. It is not necessary to inactivate the serum. As with all serological tests, hemolytic or contaminated serum must not be used.

## **EQUIPMENT AND MATERIALS**

### **Materials Required:**

- Normal saline (0.9% NaCl) for semi-quantitative procedure
- Rotator
- Serological or automatic pipettes
- Timer
- Stirrers

### **Materials Provided:**

- Rheumajet CRP latex reagent
- Positive control - pre-diluted
- Negative Control - pre-diluted
- Disposable Slides

**Storage Requirements:** Reagents and controls should be stored at 2-8° C.

**DO NOT FREEZE.**

### **QUALITY CONTROL**

1. Prior to each set of determinations, the latex reagents should be tested with each run using the positive and negative controls provided in the kit.
2. Both controls should be used following steps 4 through 8 of the Qualitative procedure. Do not dilute the controls prior to use.
3. The reaction between the positive control and the reagent should show clear agglutination, different from the uniform appearance of the negative control. If no agglutination takes place, the test should be repeated; if there is still no agglutination the kit should be discarded.

### **PROCEDURE - QUALITATIVE (Stepwise)**

1. Allow reagents and controls to reach room temperature (20 - 30° C).
2. Gently shake the reagent vial to disperse and suspend the latex particles. Vigorous shaking should be avoided.
3. Use neat serum.
4. Place 0.05 mL of neat serum in one section of a disposable slide.
5. Place 1-drop of reagent next to the drop of serum.
6. Mix both drops together using a stirrer covering the entire surface of the slide section.
7. Gently rotate the slide manually for 2-minutes or on a rotary shaker set at 80-100 rpm.
8. Look for the presence of agglutination after the 2-minute time period.

**PROCEDURE - SEMI-QUANTITATIVE (Stepwise)**

1. Allow reagents to reach room temperature (20-30° C).
2. Place 0.05 mL of normal saline on slide sections 2 through 6.
3. Using an automatic pipet, place 0.05 mL of neat serum on slide sections 1 and 2.
4. Using the same pipette, take in and release the serum and the normal saline in section 2 several times until they are well mixed.
5. Take 0.05 mL of the mixture made on section 2 and transfer to section 3.
6. Repeat steps 4 and 5 to obtain a thorough mixing of reagents, transferring 0.05 mL from section 3 to section 4 and so on in succession, through section 6, discarding the last 0.05 mL.

<b>Section</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>
<b>Saline uL</b>	-	50	50	50	50	50
<b>Serum uL</b>	50	50	-	-	-	-
<b>Mix and Transfer</b>			50→	50→	50→	50→ Discard
<b>Dilution</b>	1:1	1:2	1:4	1:8	1:16	1:32
<b>mg/1</b>	6	12	24	48	96	192

7. Gently shake the vial of latex reagent; place 1 drop of the latex reagent on sections 1 through 6 of the slide containing the different serum dilutions.
8. Mix both drops together with a stirrer covering the entire surface of the slide section.
9. Gently rotate the slide manually for 2-minutes or on a rotary shaker set at 80-100 rpm.

10. Look for the presence or absence of agglutination after 2-minutes.

### **REPORTING RESULTS**

**Qualitative:** The presence of agglutination indicates a titer of C-reactive protein greater than 6 mg/L. The absence of agglutination indicates a titer of C-reactive protein of less than 6 mg/L.

**Semi-quantitative:** The approximate titer corresponds to the highest serum dilution that still presents a clearly visible agglutination.

**Reference Ranges:** The presence of C-reactive protein in human serum or plasma has long been used as a sensitivity indicator of an inflammatory or necrotic process. Levels of C-reactive protein increase in a variety of diseases; pulmonary and acute respiratory disease, acute abdominal disease, disease of the kidney and urinary tracts, rheumatic fever and rheumatoid arthritis, cardio-vascular diseases, diseases of the digestive system, metabolic and endocrine disturbances, diseases of the blood, malignant and benign tumors and a few diseases of the skin.

C-reactive protein in concentrations of 0.02-13.5 mg/L have been regularly demonstrated in serum obtained from apparently healthy children and adults of both sexes. C-reactive protein must, therefore, be considered a normal constituent of serum.

A weak positive correlation was found between C-reactive protein concentration and age. No significant difference in C-reactive protein concentration is demonstrated between men and non-pregnant women. The mean value of C-reactive protein in adults is 0.47 mg/L.

**\*Further information regarding this test such as limitations of the procedure and performance characteristics, can be found in the package insert for the product.**