

Institution _____ Procedure No. _____

Procedure	Rheumajet RF- NCCLS
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Prepared by	Date Adopted	Supersedes Procedure #

Review Date	Revision Date	Signature

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PRINCIPLE:

The **Rheumajet RF** latex reagent is a suspension of polystyrene latex particles of uniform size coated with human immunoglobulin. Latex particles allow visual observation of the antigen-antibody reaction. When a serum containing rheumatoid factor is mixed with the Rheumajet RF latex, the uniform appearance of the latex suspension will convert to a clear agglutination. This change occurs because the rheumatoid factor present in the serum reacts with the IgG coated latex particles forming a web between them.

Note: When **Rheumajet RF** latex is mixed with neat serum, if the serum contains 10 IU/mL or greater of rheumatoid factor, a clear agglutination will appear. Results are expressed in International Units per mL based on the International Reference Preparation of Rheumatoid Arthritis Serum (World Health Organization).

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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° and 8° C for no longer than 8 days after collection. For longer periods the samples must be frozen (-20°C). As in all serological tests, hemolytic or contaminated serum must not be used.

EQUIPMENT AND MATERIALS

Materials Required:

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

Materials Provided:

- Rheumajet RF 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 disposable slide.
5. Place a 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 for two minutes manually or on a rotary shaker set at 80 - 100 rpm.
8. Look for the presence or absence of agglutination after the two minute time period.

PROCEDURE - SEMI-QUANTITATIVE (Stepwise)

1. Allow reagents and samples 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 pipette, 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 well mixed.
5. Take 0.05mL of the mixture made on section 2 and transfer to section 3.

Section	1	2	3	4	5	6	
Saline uL	-	50	50	50	50	50	
Serum uL	50	50	-	-	-	-	
Mix and Transfer			50→	50→	50→	50→	50→ Discard
Dilution	1:1	1:2	1:4	1:8	1:16	1:32	
I.U./mL	10	20	40	80	160	320	

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.
7. Gently shake the vial of latex reagent, placing a drop on sections 1 through 6 of the slide containing the different serum solutions.
8. Mix both drops with a stirrer covering the whole surface of the slide section.
9. Gently rotate the slide two minutes manually or on a rotary shaker set at 80-100 rpm.
10. Look for the presence or absence of agglutination after two minutes.

REPORTING RESULTS:

Qualitative - The presence of agglutination indicates a titer of rheumatoid factor greater than or equal to 10 IU/mL. The absence of agglutination indicates a titer of rheumatoid factor less than 10 IU/mL.

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

Limitations: Results should be read two minutes after the mixing of the reagents on the slide. A reading obtained after this period of time may be incorrect. Existence of prozone at high titers has not been encountered.

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EXPECTED VALUES:

The diagnosis of rheumatoid factor is based largely on clinical examination, but laboratory tests are useful to support the clinical diagnosis and to evaluate the severity and course of the disease in the individual patient. One of the most useful clinical markers for the rheumatoid arthritis is rheumatoid factor in serum. Rheumatoid factor is a term used to describe a variety of antibodies or immune complexes, or both, that occur within rheumatoid arthritis, as well as in a variety of other diseases.

Since increased levels of rheumatoid factor may accompany certain immune responses such as infectious mononucleosis, certain diseases such as sarcoidosis, systemic lupus erythematosus and Sjogren's Syndrome and may also be found in a considerable percentage of elderly individuals, the interpretation of the clinical significance of a positive test result must be made with caution. Extremely high titers usually present no problem in interpretation, but low titers may be found in early rheumatoid arthritis as well as in the situations mentioned above. Less commonly, a positive test may result in situations where chronic inflammatory disease is suspected, such as bacterial endocarditis, tuberculosis, leprosy, etc.