

RHEUMATOID FACTOR (RF) LATEX KIT

latex slide test for the qualitative and semi-quantitative measurement of RF in human serum.

INTENDED USE

A latex slide test for the qualitative and semi-quantitative measurement of RF in human serum.

INTRODUCTION

Rheumatoid factors (RF) are antibodies directed against antigenic sites in the Fc fragment of human and animal IgG. Their frequent occurrence in rheumatoid arthritis makes them useful for diagnosis and monitoring of the disease. One method used for rheumatoid factor detection is based on the ability of rheumatoid arthritis sera to agglutinate sensitized sheep red cells, as observed by Waaler and Rose. A more sensitive reagent consisting of biologically inert latex beads coated with human gamma globulin was later described by Singer and Plotz. The RF kit is based on the principle of the latex agglutination assay of Singer and Plotz. The major advantage of this method is rapid performance (2 minute reaction time) and lack of heterophile antibody interference.

PRINCIPLE

The RF reagent is based on an immunological reaction between human IgG bound to biologically inert latex particles and rheumatoid factors in the test specimen. When serum containing rheumatoid factors is mixed with the latex reagent, visible agglutination occurs.

MATERIALS PROVIDED

- RF Latex Reagent: A suspension of uniform polystyrene particles coated with IgG (human) in glycine buffer.
- RF Positive Control Serum: A stabilized, prediluted human serum contains > 30 IU/ml of RF.
- RF Negative Control Serum: A stabilized, prediluted human serum not reactive with the RF latex.
- Reaction Slide
- Stirring sticks
- Glycine Buffer (20x): add one part to nineteen parts of distilled water before use.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Test Tubes (for dilution)
- Serological pipettes (for sample addition and for dilution)
- Rotator (optional)

PRECAUTIONS

- All reagents contain 0.1 % (w/v) sodium azide as a preservative.
- Reagents containing sodium azide may combine with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide buildup.
- For In Vitro diagnostic use.
- Positive and negative controls prepared using human sera found negative for hepatitis B surface antigen (HBsAg) by FDA required test; however, handle controls as if potentially infectious.
- Accuracy of the test depends on the drop size of the

latex reagent (40µl). Use only the dropper supplied with latex and hold it perpendicularly when dispensing.

- Use a clean pipette tip and stirring stick for each specimen, and glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- Check reactivity of the reagent using the controls provided.

STORAGE AND STABILITY

- Reagents are stable until stated expiration date on bottle label when stored refrigerated (2-8°C).
- Do not freeze.
- The RF latex reagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal.
- Do not use the latex reagent or controls if they become contaminated.

SPECIMEN COLLECTION AND STORAGE

- Use fresh serum collected by centrifuging clotted blood.
- If the test cannot be carried out on the same day, store the specimen for 7 days at 2-8°C and for 3 months at -20°C.
- As in all serological tests, hemolytic or contaminated serum must not be used.
- Do not use PLASMA.

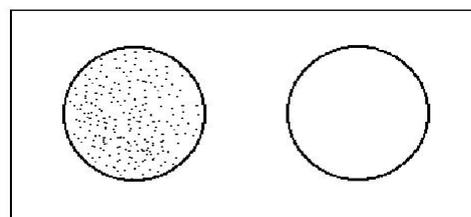
PROCEDURE

A. FOR QUALITATIVE TEST

1. Bring reagents and specimens to room temperature before use. Shake the RF-latex reagent gently to obtain uniform suspension.
2. Place one drop (40 µl) of the RF Positive Control on field #1 of the reaction slide. Place one drop (40 µl) of the RF Negative Control on field #2. The remaining fields are used for test specimens. Using a serological pipette, place 40 µl of the undiluted specimens on successive fields. Use different tip for each sample.
3. Add one drop of RF latex reagent to each test field. Using the stirring sticks, mix and spread reaction mixture over entire test field.
4. Rotate the slide for 2 minutes either by hand or with a rotator (80-100rpm) and read immediately under indirect oblique light.

INTERPRETATION OF QUALITATIVE RESULTS

A negative reaction is indicated by a uniform milky suspension with no agglutination as observed with the RF Negative Control. A positive reaction is indicated by any observable agglutination in the reaction mixture. A weakly reactive serum produces a very fine granulation or a partial clumping. The specimen reaction should be compared to the RF Controls.



Positive

Negative

Clear agglutination indicates an RF concentration equal or more than 8 IU/ml in the non-diluted serum specimen. Sera that are positive in the qualitative test should be re-tested in the semi-quantitative test to verify borderline results.

B. FOR SEMI-QUANTITATIVE TEST

1. Set up at least five test tubes: 1:2, 1:4, 1:8, 1:16, 1:32, etc..
2. Dilute sample according to dilution factor on each test tube with glycine saline solution.
3. Place one drop of each of positive and negative controls on to the slide ring. Place 40 µl of each serum dilution on successive fields of the reaction slides.
4. Gently re-suspend the RF Latex Reagent and add one drop to each test field.
5. Mix well with the provided stirring sticks. Gently rock the slide for two minutes and read immediately under indirect light.

INTERPRETATION OF SEMI-QUANTITATIVE RESULTS

The titer of the test is equal to the highest dilution, which shows a visible agglutination. To determine the mg/L, multiply the titer with the conversion factor (8):

Dilution	1:2	1:4	1:8	1:16	Etc.
Mg/L	16	32	64	128	Etc.

INTERFERENCES NON INTERFERING SUBSTANCES:

- Hemoglobin (10g/dl)
- Bilirubin(20mg/dl)
- Lipemia(10g/dl)

Other substances may interfere.

QUALITY CONTROL

1. RF Positive and Negative Control should be included in each test batch.
2. Acceptable performance is indicated when a uniform milky suspension with no agglutination is observed with the RF Negative Control and agglutination with large aggregates is observed with the RF Positive Control

PERFORMANCE CHARACTERISTICS

Analytical sensitivity

8(6-16) IU/ml, under the described assay conditions.

PROZONE EFFECT

No prozone effect was detected up to 1500 IU/ml.

DIAGNOSTIC SENSITIVITY

98%.

DIAGNOSTIC SPECIFICITY

97%.

The diagnostic sensitivity and specificity have been obtained using 118 samples compared with the same method of a computer.

LIMITATIONS

- Reaction time is critical. If reaction time exceeds 2 minutes, drying of the reaction mixture may cause false positive result.
- Freezing the RF Latex Reagent will result in spontaneous agglutination.
- Intensity of agglutination is not necessarily indicative of relative RF concentration; therefore, screening reactions should not be graded.
- Increased levels of RF may be found in some diseases other than rheumatoid arthritis such as infectious mononucleosis, sarcoidosis, lupus erythematosus, Sjogren's syndrome.^{6,7}

- Certain patients with rheumatoid arthritis will not have the RF present in their serum.⁶

EXPECTED VALUE

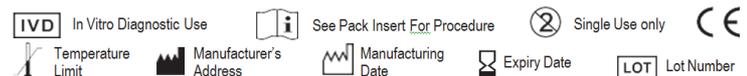
1. The diagnosis of rheumatoid is based largely on clinical examination, but laboratory tests are useful to support the clinical diagnosis and to evaluate the severity and course of the disease in the individual patient. One of the most useful clinical markers for rheumatoid arthritis is rheumatoid factor in serum. Rheumatoid factor is a term used to describe a variety of antibodies or immune complexes or both, that occur with rheumatoid arthritis as well as in a variety of other diseases.
2. Different studies have shown positive serological reactions for rheumatoid factor in as high 90% of patients with rheumatoid arthritis compared with less than 5% in control groups.

REFERENCES

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4. Rose.H.M., et al., *Proc.Soc.Exp.Biol.Med* 68:1(1943).
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6. Wincheester.R. *Am.Soc.for Micro* 665 (1976).
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Pack Size

Cat No.	Configuration	TEST
RF000025	1.Latex Reagent - 1 x 1ML 2.Positive and Negative Control-2X0.3ML	25
RF000100	1.Latex Reagent - 1 x 4ML 2.Positive and Negative Control-2X0.3ML	100



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