RF-Latex

INTENDED USE

The RF-latex is a slide agglutination test for the qualitative and semiquantitative detection of rheumatoid factors in human serum.

METHOD

Latex Slide test

CLINICAL SIGNIFICANCE

Rheumatoid factors are a group of antibodies directed to determinants in the Fc portion of the immunoglobulin G molecule. Although rheumatoid factors are found in a number of rheumatoid disorders, such as systemic lupus erythematosus (SLE) and Sjögren's syndrome, as well as in nonrheumatic conditions, its central role in clinic lies its utility as an aid in the diagnosis of rheumatoid arthritis (RA). An study of the "American College of Rheumatology" shows that the 80.4% of RA patients were RF positive. Sometimes autoantibodies are produced by the human body against self antigens. The precise role that this aberrant immunity plays in the pathogenesis of certain rheumatic diseases is unknown. However the presence of these autoantibodies serves as credible marker of the disease.

In rheumatoid arthritis, diagnostically useful autoantibodies termed as "Rheumatoid factors" (RF) can be detected which are immunoglobulins of the class IgM, IgG, IgA and IgE. Practically, IgM class RF with specificity to human IgG (Fc) is the most useful prognostic marker of RA. The clinical significance of RF determinations consists in differentiation between rheumatoid arthritis, in which RF of modified IgM class have been demonstrated in the serum of approximately 80% of the cases examined and rheumatic fever, in which RF are almost always absent. The agglutination test is most frequently used because of its greater sensitivity and simplicity.

Vitro RF is a latex agglutination slide test for detection of rheumatoid factors of the IgM class.

ASSAY PRINCIPLE

Vitro latex particles coated with human gammaglobulin are agglutinated when mixed with samples containing RF. If RF is present within detectable levels then a visible agglutination is observed. If RF is absent below detectable levels then no agglutination is observed.

REAGENTS

RF Latex	A uniform suspension of polystyrene latex particles coated with suitably modified Fc faction of IgG. The reagent is standardized to detect 10 IU/ml of RF or more.
Positive control	reactive with the Vitro RF reagent.
Negative control	non-reactive with the Vitro RF reagent.

Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance.

REAGENT STORAGE AND STABILITY

Store the reagents at 2-8°C. DO NOT FREEZE.

All the kit components are ready to use, and will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test. Mix reagents gently before use. Reagents deterioration: Presence of particles and turbidity.

SPECIMEN

Fresh serum. Stable 7 days at 2-8ºC or 3 months at –20ºC. Samples with presence of fibrin should be centrifuged. Do not use highly hemolized or lipemic samples.

No special preparation of the patient is required prior to specimen collection by approved techniques. Do not use hemolyzed serum.

PROCEDURE

Bring reagent and samples to room temperature before use.

Qualitative Method

1. Pipette one drop of serum onto the glass slide using the disposable pipette provided with kit.
2. Add one drop (50µl) of Vitro RF latex reagent to the drop (50µl) of test specimen on the slide. Do not let the dropper tip touch the liquid on the slide.
3. Using a mixing stick, mix the serum and Vitro RF latex reagent uniformly over the entire circle.
4. Immediately start a stopwatch. Rock the slide gently, back and forth or place the slide on a mechanical rotator at 80-100 r.p.m observing for agglutination macroscopically at **two minutes**.

Semi Quantitative Method

Using isotonic saline prepare serial dilutions of the serum sample positive in the qualitative method 1:2, 1:4, 1:8, 1:16, 1:32, 1:64 and so on.

Pipette each dilution of the serum sample onto separate reaction circles. Start with the 1:2 diluted test specimen.

1. Add one drop of Vitro RF latex reagent to each drop of the diluted serum sample on the slide. Do not let the dropper tip touch the liquid on the slide.
2. Using a mixing stick, mix the sample and the latex reagent uniformly over the entire circle.
3. Immediately start a stopwatch. Rock the slide gently, back and forth or place the slide on a mechanical rotator at 80-100 r.p.m observing for agglutination macroscopically at **two minutes**.

INTERPRETATION OF RESULTS

Qualitative Method

Agglutination is a positive test result and indicates the presence of RF in the test specimen.

No agglutination is a negative test result and indicates the absence of detectable levels of RF in the test specimen.

Semi Quantitative Method

Agglutination in the highest serum dilution corresponds to the RF in IU/ml.

The concentration of RF can be calculated as follows:

$$RF\ (IU/ml) = S \times D$$

where

S = Sensitivity of the reagent i.e., 10 IU/ml.

D = Highest dilution of serum showing agglutination.

QUALITY CONTROL

Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation. All result different from the negative control result, will be considered as a positive.

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EXPECTED VALUES

Up to 8 IU/mL(adults). Each laboratory should establish its own reference range.

PERFORMANCE EVALUATION

1. Analytical sensitivity: 8 (6 - 16) IU/mL, under the described assay conditions.
2. Prozone effect: No prozone effect was detected up to 1500 IU/mL.
3. Diagnostic sensitivity: 98 %.
4. Diagnostic specificity: 97 %.

REMARKS

1. Markedly lipemic, hemolysed and contaminated serum samples could produce non-specific results.
2. Serum samples having markedly higher protein content may produce non-specific reagent aggregation.
3. Use of plasma rather than serum can lead to false positive results.
4. Do not read results beyond two minutes.
5. It is recommended that all positive test results should be further tested with methods enabling quantitation of RF titers.
6. It is recommended that results of the tests should be correlated with clinical findings to arrive at the final diagnosis.
7. Since RF production is a non specific response to tissue injury, it is recommended that results of the test should be correlated with clinical findings to arrive at the final diagnosis.
8. In cases where an increase in RF levels is suspected, but the screening test shows a negative result, semi-quantitation should be done to rule out prozone effect.

INTERFERING SUBSTANCES

Bilirubin (20 mg/dL), hemoglobin (10 g/L), lipids (10 g/L), rheumatoid factors (300 IU/mL) do not interfere. Other substances may interfere[7]

NOTES

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. All the reagents derived from human source have been tested for HBsAg and Anti HIV antibodies and are found to be non-reactive. However handle the material as if infectious.
3. Reagent contains 0.1% Sodium Azide as a preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. The reagent can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the performance of the reagent be verified with the positive and negative controls supplied with the kit.
5. Shake the Vitro RF latex reagent well before use to disperse the latex particles uniformly and improve test readability.
6. Only a clean and dry glass slide must be used. Clean the slide with distilled water and wipe dry.
7. Accessories provided with the kit only must be used for optimum results.

BIBLIOGRAPHY

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SYMBOL DECLARATION

	Manufacturer
	Consult instructions for use
LOT	Batch code (Lot #)
REF	Catalog number
	Temperature limitation
IVD	In vitro diagnostic medical device
	Use by
	Caution. Consult instructions
	Keep away from light

ORDERING INFORMATION

REF Complete Kit	SIZE	REF Latex Only
40301	100 tests	40303
40302	50 tests	40304

*All kit sizes are available with or without accessories which include:

- Positive Control.
- Negative Control.
- Slide.
- Mixing Straws.

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