



Rapid Latex agglutination slide test for the qualitative and semi quantitative in-vitro determination of Rheumatoid Factor in sample for Rheumatoid Arthritis.

Presentation

Pack size	RF latex reagent (R1)	RF positive control (R2)	RF negative control (R3)
25T	0.9ml	0.3ml	0.3ml
50T + 10T	2x1.1ml	0.3ml	0.3ml

Summary

The Clinical significance of RF test is in differentiating between Rheumatoid Arthritis & other inflammatory and autoimmune conditions. In Rheumatoid Arthritis the presence of RF has been demonstrated in approximately 80% of cases examined, whereas, in Rheumatic Fever for example, RF is nearly always absent. Positive results may occur occasionally in various pathological diseases including systemic lupus erythematous hepatitis, Cirrhosis, lymphomas, sarcoidosis and certain other diseases.

Principle

RF test is based on latex agglutination test. Specially selected polystyrene particles are coated with purified human globulin (IgG). When a serum sample, positive for Rheumatoid Factor is mixed with the latex reagent, a positive reaction is indicated by a distinctly visible agglutination of the latex particles in the test cell of the slide. In serum sample, negative for Rheumatoid Factor, the latex remains as a smooth suspension in the test cell.

Contents, reagents and material provided

1. RF latex reagent. Mix gently before use. Suspension of polystyrene latex particles, coated with purified human Globulin (IgG).
2. Positive control, reactive with RF latex reagent.
3. Negative control, non reactive with RF latex reagent.
4. 1 glass slide
5. Disposable plastic droppers with rubber teat.
6. Disposable mixing sticks.

Storage & Stability

Latex reagent & control sera are stable up to the expiry date printed on the labels when stored at 2-8°C. Do not freeze.

Specimen

Use fresh serum specimen. However the same may be stored at 2-8°C up to 24 Hrs. and at -20°C up to 4 weeks. Plasma should not be used because fibrinogen may cause non specific agglutination of the latex particles.

Precautions & Notes

1. Kit reagents are for in-vitro diagnostic use only.
2. Strictly follow the instructions mentioned in the product insert.
3. Bring specimens & reagents to room temperature before use.
4. Mix latex reagent gently before use.
5. Interpret results exactly at 2 minutes.
6. Accessories provided with the kit only must be used for optimum results.
7. The reagents contain Sodium azide as a preservative. Do not swallow. Avoid contact with skin & mucous membrane.
8. All reagents of human source have been tested negative for HbsAg & anti-HIV antibodies and found to be non-reactive.
9. RF reagent is sensitive to the presence of IgM RF with heterogenous specificity.
10. It is recommended that results of the test should be correlated with clinical findings to arrive at the final Diagnosis.

Procedure

A. Qualitative analysis

Bring latex reagent, controls and serum specimens to room temperature
Mix the latex reagent thoroughly prior to use.

Drop on to separate cells of the slide, using disposable plastic droppers provided with the kit:

Serum specimen	1 drop
Positive control	1 drop
Negative control	1 drop
RF latex reagent, on to all the sample & control cells of the slide in use.	1 drop each

Do not let the dropper tip touch the liquid on the slide. Mix with separate mixing sticks and spread the fluid over the entire area of the particular cell. Tilt the slide back & forth for 2 minutes so that the mixture rotates slowly inside the cells or place the slide on an automated rotator at 100 rpm. Observe for agglutination at the end of 2 minutes.

Interpretation of results

Observation	Conclusion
Agglutination within 2 minutes	RF Positive
Smooth Suspension/ No agglutination	RF Negative

B. Semi Quantitative analysis

Prepare 0.9% saline solution. Then dilute specimen with saline solution as under until the last dilution giving distinct agglutination.

Dilution	RF (IU/ml in undiluted specimen)
1+1 (1:2)	24
1+3 (1:4)	48
1+7 (1:8)	96
1+15 (1:16)	192
1+31 (1:32)	384

Continue test as described in Qualitative analysis

Interpretation of results

Titre is the highest dilution giving visible agglutination.

Sensitivity

The reagent is standardised to detect RF concentrations greater than 12 IU/ml

Quality Control

The positive and negative control serum may be used for routine performance check.

References

1. Waaler E, Acta Path. Microb. Scand., 17(1940) 1&2
2. Muller W., The Serology of Rheumatoid Arthritis, Berberlin Gottingen-Heidelberg(1962)97
3. Singer J.M, Bull Rheum. Dis, 24 762 (1974)

