IVD
Store at 2 - 8°C

REF. 22112 - RF Latex – 100 tests
1 x 5 ml RF latex
1 x 1 ml pos control
1 x 1 ml neg control
18 x 6-well disposable slides

CE

RF-Latex

Slide agglutination

Intended use
The RF latex test is a slide agglutination test, intended for the qualitative and semi-quantitative determination of Rheumatoid factor (RF) in human serum.
For *in vitro* diagnostic use only.
For professional use only.

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 in its utility as an aid in the diagnosis of rheumatoid arthritis (RA). A study of the "American College of Rheumatology" shows that 80,4% of RA patients were RF positive.

Principle
The RF reagent is a suspension of polystyrene latex particles coated with human gamma-globulin. The RF latex will agglutinate when they are mixed with samples containing RF. The latex sensitivity has been adjusted to detect a minimum concentration of 8 IU/ml of RF.

Reagent composition
Latex: Latex particles coated with human gamma-globulin, pH 8,2. Preservative.
Control +: Human serum with a RF concentration > 30 IU/ml. Preservative.
Control - : Animal serum. Preservative.

Precautions
Components of human origin have been tested and found to be non-reactive for HBsAg, HCV and antibodies against HIV (1/2). However, no test method can offer complete assurance that infectious agents are absent. Therefore all human components should be handled as potentially infectious.

Calibration
The RF latex sensitivity is calibrated against the RF International Standard from NIBSC 64/002.

Preparation
The latex and controls are ready to use.

Storage and stability
The latex and control sera are stable at 2 to 8°C up to the expiry date when stored tightly closed, protected from light and contaminations prevented during their use. Do not freeze!
Always keep the latex vials in vertical position. If the position is changed visible aggregates may be present in the vial. In this case, shake the vial vigorously or on a vortex mixer to dissolve the aggregates.
The latex, once shaken, must be uniform without visible clumping. The controls should be clear, without the presence of precipitation or turbidimetry.

Additional material required but not provided
- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Pipettes 50 µL
- Plastic stirrers
- Vortex mixer

Samples
Use fresh clear serum samples. Lipemic or highly hemolyzed samples or microbial contamination may cause erroneous results. If the test cannot be performed immediately, store the sample at 2 to 8°C for up to 7 days. For longer storage, up to 3 months, freeze the serum at –20°C. Samples with presence of fibrin should be centrifuged.

Procedure
Qualitative method
1. Bring the latex, controls and samples to room temperature before use.
2. Place one drop (50 µl) of the positive control on field 1 of the test slide.
   Place one drop (50 µl) of the negative control on field 2.
   Using a pipette, place 50 µl of each undiluted test sample on successive fields.
3. Mix the latex reagent vigorously or on a vortex mixer and add one drop (50 µl) to each test field, next to the samples to be tested. Use a stirrer to spread reaction mixture over entire test field. Use different stirrers for each sample to avoid contamination.
4. Rotate the slide (80-100 r.p.m.) for 2 minutes and read immediately under direct light. False positive results could appear if the test is read later than two minutes.

Semi-quantitative method
1. Bring the latex, controls and samples to room temperature before use.
2. Make serial two fold dilutions of the sample in saline (NaCl 9 g/l).
3. Proceed for each dilution as in the qualitative method.

Dilutions	1/2	1/4	1/8	…
Sample serum	100µl			
Saline	100µl	100µl	100µl	…
	↳	100µl		
		↳	100µl	…
Volume of the sample	50 µl	50 µl	50µl	…

Reading and interpretation
A negative reaction is indicated by a uniform milky suspension with no agglutination as observed with the negative control.
A positive reaction is indicated by any observable agglutination in the reaction mixture different from that of the negative control.
The presence of an agglutination indicates a RF concentration equal or greater than 8 IU/ml.
The titer, in the semi-quantitative method, is the reciprocal of the highest dilution displaying a positive result.

The concentration is given by the reciprocal of the dilution x 8:

8 x 1/dilution	8 x 2	8 x 4	8 x 8
IU/ml	16	32	64

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

Reference intervals
Normal levels: up to 8 IU/ml.
Each laboratory should establish its own reference range.

Limitations of the test
- The rheumatoid factors are immunoglobulins (mainly IgM) present in most patients suffering from Rheumatoid Arthritis. There are different rheumatoid factors and no test is capable to detect all of them, due to the fact that some of them act against human IgG, other against animal IgG, and other against both IgG. Therefore, the use of Waaler-Rose test is recommended as a complementary test specific for detection of rheumatoid factors against animal IgG.
- The incidence of false positive results is about 3-5%. Individuals suffering from infectious mononucleosis, hepatitis, syphilis as well as eldery people may give positive results
- Clinical diagnosis should not be made on a single test result. It should integrate clinical and other laboratory data.

Performance characteristics
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: 100 %.
4. Diagnostic specificity: 100%.

The diagnostic sensitivity and specificity have been obtained using 139 samples compared with the same method of a competitor.

Interferences
Hemoglobin (10 g/l), bilirubin (20 mg/dl) and lipids (10 g/l), do not interfere. Other substances may interfere[6].

Bibliography

1. Robert W Dorner et al. Clinica Chimica Acta 1987; 167: 1 – 21.
2. Frederick Wolfe et al. Arthritis and Rheumatism 1991; 34: 951- 960.
3. Robert H Shmerling et al. The American Journal of Medicine 1991; 91: 528 – 534.
4. Adalbert F S et al. The New England Journal of Medicine 1959; 261: 363 – 368.
5. Charles M. Plotz 1956; American Journal of Medicine; 21:893 – 896.
6. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995

10.2019, Rev. 14.1

Cypress Diagnostics: Nijverheidsstraat 8 • 2235 Hulshout • Belgium • www.diagnostics.be • Tel: ++ 32 15 67 67 68 • e-mail: cypress@diagnostics.be