RF LATEX

Slide Agglutination

IVD CE

PRODUCT CODE
SL003

INTENDED USE
This reagent is intended for *in vitro* qualitative & semi quantitative determination of Rheumatoid factor (RF) in serum.

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 non-rheumatic conditions, its central role in clinic lies its utility as an aid in the diagnosis of rheumatoid arthritis (RA). A study of the "American College of Rheumatology" shows that the 80.4% of RA patients were RF positive.

PRINCIPLE
The RF-latex is a slide agglutination test for the qualitative and semi-quantitative detection of RF in human serum. Latex particles coated with human gamma globulin are agglutinated when mixed with samples containing RF.

REAGENTS

Latex	Latex particles coated with human gamma-globulin, pH, 8.2. Preservative. Contains N, N-dimethylformamide
Control (+) Red Cap	Human serum with a RF concentration > 30 IU/ml, preservative
Control (–) Green Cap	Animal serum, preservative

ACCESSORIES
Reaction slide, mixing sticks

ADDITIONAL REQUIREMENTS
Mechanical rotator with adjustable speed at 80-100 rpm

STORAGE AND STABILITY
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 2-8°C and contaminations are prevented during their use.
Do not freeze: frozen reagents could change the functionality of the test.
Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.
Reagent's deterioration: Presence of particles and turbidity.

PRECAUTIONS
Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However, handle cautiously as potentially infectious.

SPECIMEN AND SAMPLE PREPARATION
Fresh, clear serum. After the clear serum has been separated it may be stored at 2-8ºC for up to one week or longer periods at –20ºC with presence of fibrin should be centrifuged.
Do not use highly hemolyzed or lipemic samples.

PROCEDURES
Qualitative Method
1- Allow the reagents and samples to reach room temperature. The Sensitivity of the test may be reduced at low temperatures.
2- Place (40 ul) of the sample and one drop of each Positive and Negative control into separate circles on the slide test.
3- Swirl the RF Latex reagent rigorously before using and add one drop (40 ul) next to the sample to be tested.
4- Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5- Place the slide on a mechanical rotator at 80 - 100 rpm for 2 minutes. False positive results could appear if the test is read later than 2 minutes.

Semi-Quantitative Method
1- Make serial two-fold dilutions of the sample in 9 g/L saline solution.
2- Proceed for each dilution as in the qualitative method.

INTERPRETATION OF RESULT
Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator. The presence of agglutination indicates a RF concentration equal or greater than 10 IU/mL (Note1)
The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

CALCULATIONS
The approximate RF concentration in the patient sample is calculated as follows:
10 X RF Titer = IU/mL

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.

REFERENCE VALUES
Up to 10 IU/mL, each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS
1. *Analytical sensitivity*: 10 IU/mL, under the described assay conditions
2. *Prozone effect*: No prozone effect was detected up to 800 IU/mL.
3. *Diagnostic sensitivity:* 100 %.
4. *Diagnostic specificity:* 100 %.

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

NOTES
1- The incidence of false positive results is about 3-5%. Individuals suffering from infectious mononuclear hepatitis, syphilis as well as elderly people may give positive results.
2- Diagnosis should not be solely based on the results of latex method, but also should be complemented with a Waaler Rose test along with clinical examination.

SYMBOL ON LABELS

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

REFERENCES

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. Schubart 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.

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