SEROCON®

RF LATEX

(Slide Agglutination Method)

BEACON

Code	Product Name	Pack Size
SE023A	RF Latex(Slide Agglutination Method)	25 T
SE023B	RF Latex(Slide Agglutination Method)	50 T
SE023C	RF Latex(Slide Agglutination Method)	100 T
SE023D	RF Latex(Slide Agglutination Method)	250 T

Intended Use

For the qualitative determination of Rheumatoid factor in human serum.

Principle Of The Method

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.

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 Sjogren's syndrome, as well as in nonrheumatic conditions, its central role in clinic lays 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.

Reagents

Reagent 1: RF Latex Antigen	Latex particles coated with human gamma-globulin Preservative.
Reagent 2: Positive Control	Positive control with preservative.
Reagent 3:Negative Control	Negative control with preservative.

Accessories :

Disposable Plastic Droppers, Disposable Applicator Sticks, Rubber Teat, Glass Slides.

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.

Calibration

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

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.
Reagents deterioration: Presence of particles and turbidity.

Additional Equipment

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.
- Pipettes 50 µL.

Samples

Fresh serum. Stable 7 days at +2-+8ºC.
Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples.

Procedure

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 50 µL of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Mix the RF-latex reagent vigorously or on a vortex mixer before using and add one drop (50 µL) next to the sample to be tested.
4. Mix the drops using a Disposable Applicator Sticks, spreading them over the entire surface of the circle. Use different Disposable Applicator Sticks for each sample.
5. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two 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.

Reading And Interpretation

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 8 IU/mL.
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:
8 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 8 IU/mL. Each laboratory should establish its own reference range.

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
Bilirubin (20 mg/dL), hemoglobin (10 g/L), and lipids (10 g/L), do not interfere. Other substances may interfere.

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

Notes
1. Results obtained with a latex method do not compare with those obtained with Waaler Rose test. Differences in the results between methods do not reflect differences in the ability to detect rheumatoid factors.

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.

Symbols Used On Labels

REF	Catalogue Number		Manufacturer
	See Instruction for Use	LOT	Lot Number
CONT	Content		Storage Temperature
	Expiry Date	IVD	In Vitro Diagnostics

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