RF LATEX SLIDE TEST

INTENDED USE
BIOLINE RF LATEX SLIDE TEST reagent is for the Qualitative determination of RF in human 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 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

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

REAGENT COMPOSITION
Latex Reagent: *Latex particles coated with human gamma-globulin, pH 8,2. Preservative*
Positive control: Human serum with an RF concentration > 30 IU/mL.
Negative control : Animal serum. Preservative

WARNINGS AND PRECAUTIONS
1. For *in vitro* diagnostic use.
2. 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.

REAGENT PREPARATION
Reagent and controls (Positive and Negative) are ready to use.

REAGENT 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 2-8ºC and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.
--Mix reagents gently before use.

REAGENT DETERIORATION
Presence of particles and turbidity.

SPECIMEN COLLECTION AND STABILITY
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 hemolyzed or lipemic samples

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

MANUAL 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 (Approx 50 µL) 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 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 an 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.

EXPECTED VALUES
Up to 8 IU/mL. Each laboratory should establish its own reference range

PERFORMANCE CHARACTERISTICS
1.Analytical sensitivity: 8 -16 IU/mL, under the described assay conditions
Prozone effect: No prozone effect was detected up to 1500 IU/mL.
1. Diagnostic sensitivity: 100 %.
2. Diagnostic specificity: 100 %.

LIMITATIONS OF THE 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.

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.