NEO LATEX
RHEUMATOID FACTOR (RF)
(LATEX AGGLUTINATION TEST)

NEOGENIX
DIAGNOSTICS PVT LTD

KIT NAME	KIT SIZE	KIT SIZE
NEO LATEX - RF	25Test	100 Test

INTRODUCTION
Measurement of rheumatoid factor is used for differentiating rheumatoid arthritis from other chronic inflammatory arthritis and is impotant in the progress and therapeutic management of the disease. Rheumatoid factor has been associated with some bacterial and viral infections (ex.Hepatities, infectious, Mononucleosis) some chronic infections (ex.Tuberculosis, parasitic disease, sub acute Bacterial Endocardities) and cancer.

METHOD PRINCIPLE
The latex reagent coated with the Human gammaglobulin (gG). The test specimen serum is mixed with RF latex reagent and allowed to react. If RF is present within detectable levels then a visible agglutination is observed. If RF is absent below detectable levels then no agglutination is observed.

REAGENTS

Reagent Name	25 TEST	100 TEST
R1 RF Latex	1 ml	4 ml
R2 Positive Control	0.5 ml	0.9 ml
R3 Negative Control	0.5 ml	0.9 ml

WORKING REAGENT PREPARATION AND STABILITY
1. Store the reagent at 2-8°C. DO NOT FREEZE.
2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial labels.

SPECIMEN
Only serum should be used to testing. If any delay in testing , store the samples at 2-8°C. Samples can be stored for upto a week. Do not use hemolysed serum.

MATERIAL PROVIDED WITH THE KIT
Accessories : Glass Slide, Plastic Droppers, Mixing sticks.

ADDITIONAL MATERIAL REQUIRED
Stop watch.

NOTES:
1. In vitro diagnostic reagent for laboratory and professional use only Not for medicinal use.
2. All the reagents derived form human source have been tested for HBsAg and Anti HIV antibodies and are found to be non-reactive. However handle the material as if infectious.
3. Reagent contains 0.1% sodium Azide as a preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. The reagent can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the performance of the reagent be verified with the positive and negative controls supplied with the kit.
5. Shake the RF latex reagent well before use to disperse the latex particles uniformly and improve test readability.
6. Only a clean and dry glass slide must be used. Clean the slide with distilled water and wipe dry.
7. Accessories provided with the kit only must be used for optimum results.

PROCEDURE
Bring reagent and samples to room temperature before use.

Qualitative Method
1. Pipette one drop of serum onto the glass slide using the disposable plastic droppers provided with kit.
2. Add one drop of RF latex reagent to the drop of test specimen on the slide. Do not let the dropper tip touch the liquid on the slide.
3. Using a mixing stick, mix the serum and RF latex reagent uniformly over the entire circle.
4. Immediately start a stop watch. Rock the slide gently, back and forth observing for agglutination macroscopically at two minutes.

Semi Quantitative Method:
1. Using normal saline prepare serial dilutions of the Serum sample positive in the qualitative method 1:2, 1:4 1:8,1:16,1:32,1:64 and so on.
2. Pipette each dilution of the serum sample onto separate reaction circles.
3. Add one drop of RF latex reagent to each drop of the diluted serum sample on the slide. Do not let the dropper tip touch the liquid on the slide.
4. Using a mixing stick, mix the sample and the latex reagent uniformly over the entire circle.
5. Immediately start a stop watch. Rock the slide gently, back and forth, observing for agglutination macroscopically at two minutes.

INTERPRETATION OF TEST RESULTS
Qualitative Method
Agglutination is a positive test result and indicates the presence of detectable levels of RF in the test specimen.

No agglutination is a negative test result and indicates the absence of detectable levels of RF in the test specimen.

Semi Quantitative method
Agglutination in the highest serum dilution corresponds to the amount of RF in IU/ml present in the test specimen.

Calculation
RF (IU/ml) = S x D

Where S = Sensitivity of the reagent ie., 20 IU/ml
D = Highest dilution of serum showing agglutination.

REMARKS:

1. Marked lipemic, hemolysed and contaminated serum samples could produce non-specific results.
2. Use of plasma rather than serum can lead to false positive results.
3. Do not read results beyond two minutes.
4. Rheumatoid factors are not exclusive found in rheumatoid arthritis but sometimes in syphilis, systemic lupus erythematosus, hepatitis, hepergammaglobulinemia also.
5. It is recommended that results of the test should be correlated with clinical findings to arrive at the final diagnosis.
6. RF regent is sensitive to the presence of IgM RF with heterogeneous specificity.

LITERATURE

1. Heller G.,Jacobson S.A., Koloday MH, Kammerer M.H., J. Immunol, 72:66 (1954).
2. Singer J.M, bull Rheum, Dis, 24: 762 (1974).