

IVD  
Store at 2 - 8°C.

Ref. 22112 RF Kit  
100 t 5 ml  
pos control 1 ml  
neg control 1 ml  
Glass slide



RF-LATEX

**RF- Latex**  
Slide agglutination

*A rapid slide test for the Qualitative determination of Rheumatoid Factor in human serum*

**PRINCIPLE OF THE METHOD**

The RF reagent is a suspension of polystyrene latex particles sensitized with specially prepared human IgG in order to avoid unspecific agglutination. The RF latex reagent sensitivity has been adjusted to detect a minimum of 8 IU/ml of rheumatoid factors according with the WHO International Standard without previous sample dilution.

**REAGENTS**

Latex : Latex particles coated with human gamma-globulin, pH, 8.2. Sodium azide 0.95 g/L.  
Control + : Human serum with a RF concentration > 30 IU/mL. Sodium azide 0.95 g/L.  
Control - : Animal serum. Sodium azide 0.95 g/L.

**PRECAUTIONS**

Reagents containing sodium azide may combine with copper and lead plumbing to form highly explosive metal azides. Dispose of reagent by flushing with large amounts of water to prevent aside build up. The positive and negative controls were prepared from human sera, which have been tested and found to be non-reactive for the presence of HbsAg, HCV and HIV(1/2) antibodies. However, no test method can offer complete assurance that infectious agents are absent. Therefore all human specimens should be considered potentially infectious. Toxic (T): R61: May cause harm to the unborn child.

**CALIBRATION**

The RF-latex sensitivity is calibrated against the WHO 64/2 Rheumatoid Arthritis serum.

**STORAGE AND STABILITY:**

The reagent and control sera are stable up to the expiry date when stored tightly closed, protected from light and contaminations prevented during their use. Do not freeze !

**SAMPLES**

Use fresh clear serum specimens. Plasma, lipemic serum or microbial contamination may cause erroneous results. If the test cannot be performed immediately, store the specimen at +2 to +8°C for up to 8 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 reagents and specimens to room temperature before use.
2. Place one drop (50 µl) of the positive control on field #1 of the reaction slide.  
Place one drop (50 µl) of the negative control on field #2.  
Using a pipette, place one drop (50 µl) of each undiluted test specimen on successive fields.
3. Gently resuspend the Latex Reagent and add one drop (50 µl) to each test field. Use stick to spread reaction mixture over entire test field.
4. Rotate the slide (80-100 r.p.m.) for 2 minutes and read *immediately* under direct light.

Semi-quantitative method

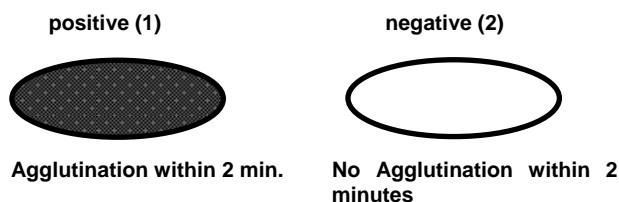
1. Bring reagents and specimens to room temperature before use.
2. Make serial two fold dilutions of the sample in saline (NaCl 9 g/l).
3. Proceed for each dilution as in the qualitative method.

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 (2). A positive reaction is indicated by any observable agglutination in the reaction mixture. The specimen reaction should be compared with the positive control (1).

Interpretation :



The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

Concentration will be reciprocal of positive reading dilution x 8:  
8 x n° of dilution    8 x 2    8 x 4    8 x 8  
IU/ml                    16        32        64

Normal Levels : Adults < 8 IU/ml

**LIMITATIONS**

The rheumatoid factors are immunoglobulins (most of the IgM) with antibody activity. These factors are present in most patients suffering Rheumatoid Arthritis. There are different rheumatoid factors and does not exist any test 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. We recommend the use of WR test, 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 elderly people may give positive results

**QUALITY CONTROL**

Positive and Negative controls are recommended to monitor the performance of test procedure, as well as a comparative pattern for a better results interpretation.

**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 800 IU/mL.
3. Diagnostic sensitivity: 98 %.
4. Diagnostic specificity: 97 %.

**INTERFERENCES**

Hemoglobin (10 g/L), bilirubin (20 mg/dL) and lipemia (10 g/L), do not interfere. Other substances may interfere.

**NOTES**

Contaminated sera and a longer reaction time than 3 minutes may cause false positive agglutination. As with all diagnostic methods, the final diagnosis should not be made on the results of a single test, but should be based on a correlation of test results with other clinical findings.

Langdorp, 03.2011