RF-Latex CE

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For *in vitro* diagnostic use only			

RF-Latex

Determination of rheumatoid factors

SLIDE TEST

PRINCIPLE

RF-Latex Test is a rapid agglutination procedure, based on modification of the Singer method[1], developed for the direct detection and the semi-quantitation on a slide of rheumatoid factors (RF) in serum.
The assay is performed by testing a suspension of latex particles coated with human gamma globulin against unknown serums. The presence or absence of a visible agglutination, indicates the presence or absence of RF in the samples tested.

REAGENT COMPOSITION

R — **RF-Latex Reagent**. Suspension of polystyrene latex particles coated with human gamma globulin in a buffered saline solution. Contains 0.95 g/L of sodium azide.

CONTROL + — Human serum with an activity equivalent to appr. 25 IU/mL. Contains 0.95 g/L of sodium azide.

CONTROL - — Animal serum with an activity < 5 IU/mL. Contains 0.95 g/L of sodium azide.

Precautions: Components of different human origin have been tested and found to be negative for the presence of antibodies anti-HIV 1+2 and anti-HCV, as well as for HBsAg. However, the controls should be handled cautiously as potentially infectious.
Warning: The reagents in this kit contain sodium azide. Do not allow to contact with skin or mucous membranes.

PACKAGING CONTENTS

REF — 2355005, kit 50 tests.
1 vial RF-Latex Reagent, 1x1 mL Positive control, 1x1 mL Negative control, 3 Test cards and 1x50 disposable stirrers.

REF — 2355010, kit 100 tests.
2 vials mL RF-Latex Reagent, 1x1 mL Positive control, 1x1 mL Negative control, 3 Test cards and 2x50 disposable stirrers.

STORAGE AND STABILITY

Store at 2-8ºC. Do not freeze. Frozen reagents could change the functionality of the test.
Reagent and Controls are stable until the expiry date stated on the label.

REAGENT PREPARATION

Reagent and Controls are ready to use.

SAMPLES

Fresh, clear serum.
After the clear serum has been separated it may be stored at 2-8ºC for upto one week or longer periods at –20ºC.

MATERIAL REQUIRED

- Automatic pipettes.
- Saline solution (0.9% NaCl, only for semi-quantitation procedure).
- Mechanical rotator, adjustable at 100 r.p.m.
- Laboratory alarm clock.

PROCEDURE

I. Qualitative Test

1. Bring the test reagents and samples to room temperature (Note 1).
2. Mix the Reagent vial gently. Aspirate dropper several times to obtain a thorough mixing.
3. Place 1 drop (50 µL) of the serum under test into one of the circles on the card. Dispense 1 drop of positive control serum and 1 drop of negative control into two additional circles.
4. Add 1 drop of RF-Latex Reagent to each circle next to the sample to be tested.
5. Mix the contents of each circle with a disposable stirrer while spreading over the entire area enclosed by the ring. Use separate stirrers for each mixture.
6. Rotate the slide by means of a mechanical rotator (100 r.p.m.) for a period of **2 minutes** (Note 2).
7. Observe immediately under a suitable light source for any degree of agglutination.

Reading
Nonreactive: Smooth suspension with no visible agglutination, as shown by negative control.

Reactive: Any degree of agglutination visible macroscopically.

II. Semi-quantitative Test

1. Dilute sample with ClNa 9 g/L following the 2-fold dilutions procedure as follow:

Dilution	1/2	1/4	1/8	1/16	1/32
Sample (µL)	100				
ClNa 9 g/L (µL)	100	100	100	100	100
Transfer (µL)		100	100	100	100
RF (IU/mL) non-diluted sample	16	32	64	128	256

2. Test each dilution as described in Qualitative Test.

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Reading
Same as in Qualitative Test. The titer of the specimen is reported as the highest dilution that shows reactivity. The next higher dilution should be negative (Note 3).
If the highest dilution tested is reactive repeat the test starting with a preliminary 1:32 dilution. Use a 1:50 dilution of negative control in ClNa 9 g/L to the replace the ClNa 9 g/L solution in the new 2-fold dilution series.
The approximate RF level (IU/mL) present in the sample may be obtained multiplying the titer of the last positive dilution by the minimum detectable unit (analytical sensitivity).

e.g. titer 1/16
RF concentration = 8 x 16 = 128 IU/mL

QUALITY CONTROL

Positive and negative controls should be run daily following the steps outlined in the Qualitative Test, in order to check the optimal reactivity of the antigen.
The positive control should produce clear agglutination. If the expected result is not obtained, do not use the kit.

EXPECTED VALUES[2-4]

Of those patients with a clinical diagnosis of rheumatoid arthritis approximately 70-80% are seropositive for rheumatoid factor. Positive results were shown for nearly all patients with variants of rheumatoid arthritis such as Felty's or Sjogren's syndrome.
A positive result can be expected in less than 5% of healthy individuals, while in the population aged 60 years and older as many as 30% may be seropositive using latex tests for the detection of rheumatoid factor.

CLINICAL SIGNIFICANCE[5-7]

Rheumatoid factors found in the sera of most patients with rheumatoid arthritis as well as in a variety of other diseases, are a group of antibodies most belonging to the IgM class directed against determinants on the Fc fragment of the patients'IgG immunoglobulin.
Rheumatoid factors testing has a high diagnostic value on a tentative diagnosis made on the basis of case history and clinical findings.

ANALYTICAL PERFORMANCE

- The minimum detectable unit (analytical sensitivity) is of approximately 8 IU/mL (6-16 IU/mL), tested against a RF standard traceable to WHO Reference Material 64/1.
- Diagnostic specificity: 98.8%.
- Prozone effect: No prozone effect was detected up to 800 IU/mL.
- Results obtained with this reagent did not show significant differences when compared with reference reagents. Details of the comparison experiments are available on request.
- Hemoglobin (<10 g/L), bilirubin (<20 mg/dL) and lipemia (<10 g/L) do not interfere. Other substances may interfere[8].

LIMITATIONS OF THE PROCEDURE

- Positive reactions do occur in conditions other than rheumatoid arthritis such as mononucleosis, hepatitis, syphilis, various other infections and in elderly patients. When tested by the quantitative test, however, most of these specimens give very low results.
- False negative results may be given by patients in the early or in sub-clinical chronic phases of the disease.

NOTES

1. The sensitivity of the test may be reduced at low temperatures. The best results are achieved at 15-25ºC.
2. The delays in reading the results may generate in over-estimation of the antibody present.
3. Titers obtained with the latex do not compare with titers obtained with the Waaler-Rose test. Differences in titer do not reflect a difference between methods in the ability to detect rheumatoid factors.

SOURCES OF ERROR

- Bacterial contamination of controls and specimens as well as freezing and thawing of the RF-Latex Reagent may lead to false positive results.
- Traces of detergent in the test cards may give false positive results. Wash used cards first under tap water until all reactants are removed and then with distilled water. Allow to air dry, avoiding the use of organic solvents as they may impair the special finish on the slide.
- The RF-Latex Reagent must not be used beyond its expiry date because a prolonged storage can affect the sensitivity of the suspension.

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QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

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