



Store at: +2+8°C.

Presentation:
Cod. SE009 50 Test.
Cod. SE010 100 Test.

Procedure

Diagnostic reagent for qualitative measurement of RF (Rheumatoid Factors).

Only for *in vitro* use in clinical laboratory (IVD)

TEST SUMMARY

The RF-latex is a slide agglutination test for the qualitative and semi-quantitative detection of rheumatoid factors in human serum. Latex particles coated with human gamma globulin are agglutinated when mixed with samples containing RF.

REAGENTS COMPOSITION

Latex	Latex particles coated with human gamma globulin, pH, 8.2. Preservative.
Control (+) Red cap	Human serum with a RF concentration > 30 IU/mL. Preservative.
Control (-) Blue cap	Animal serum. Preservative.

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.

Good laboratory safety practices should be followed when handling laboratory reagents or human samples.

REAGENT PREPARATION AND STABILITY

All the kit components are ready to use. Mix reagents gently before use.

Do not freeze; frozen reagents could change the functionality of the test.

Reagents deterioration:

- Presence of particles and turbidity.

All the kit components 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 use reagents over the expiration date.

CALIBRATION

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

SPECIMEN

Fresh serum. Stable 7 days at 2-8° C or 3 months at -20°C.

The samples with particles or fibrin should be centrifuged to eliminate them. Do not use haemolysed or lipemic samples.

Discard contaminated specimen.

MATERIAL REQUIRED BUT NOT PROVIDED

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

General laboratory equipment

TEST PROCEDURE

Qualitative method

1. Allow the reagents and sample 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 control into separate circles on the slide test.
3. Mix the RF-latex reagent rigorously or on a vortex mixer before using and add one drop (50 µL) next to the sample to be tested.
4. Mix both drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Rotate the slide with 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:

$$8 \times \text{RF Titer} = \text{IU/mL}$$

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.

Serum controls RF are recommended for internal quality control. Each laboratory should establish its own Quality Control scheme and corrective actions.

REFERENCE VALUES

Up to 8 IU/mL.

It is suggested that each laboratory establish its own reference range.

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 no rheumatic conditions, its central role in clinic lies its utility as an aid in the diagnosis of rheumatoid arthritis (RA). A study of the "American College of Rheumatology" shows that the 80.4% of RA patients were RF positive.

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENT PERFORMANCE

- Analytical sensitivity:
8 (6-16) IU/mL, under the described assay conditions
- Prozone effect:
No prozone effect was detected up to 1500 IU/mL.
- Diagnostic sensitivity: 100 %
- Diagnostic specificity: 100 %

The diagnostic sensitivity and specificity have been obtained using 139 samples compared with the same method of a competitor.

INTERFERING SUBSTANCES

Interferences:

- Do not interfere: Hemoglobin (10 g/L), bilirubin (20 mg/dL), lipemia (10 g/L).
- Other substances may interfere⁶.

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 RF.

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

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