CHRONOLAB

CE

IVD

RF- Latex

Slide agglutination

Qualitative determination of Rheumatoid Factors (RF)

PACKAGING

Ref.: 101-0247	Cont.: 50 tests
Ref.: 101-0218	Cont.: 100 tests
Ref.: 101-0191	Cont.: 100 tests

Store at 2 - 8º C.

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.

PRINCIPLE OF THE METHOD

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

REAGENTS

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

Toxic (T): R61: May cause harm to the unborn child.

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.

CALIBRATION

The RF-latex sensitivity is calibrated against the RF International Calibrator from WHO (WHO 64/2 Rheumatoid Arthritis Serum).

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 2-8º C and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.

Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.

Reagents deterioration: Presence of particles and turbidity.

ADDITIONAL EQUIPMENT

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

SAMPLES

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

Samples with presence of fibrin should be centrifuged before testing. Do not use highly haemolized or lipemic samples.

PROCEDURE

Note:

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 rheumatoid factors.

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 rigorously or on a vortex mixer before using and add one drop (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 a RF concentration equal or greater than 8 IU/mL (Note 1).

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 test procedure, as well as a comparative pattern for a better results interpretation.

All result different from the negative control result, will be considered as a positive.

REFERENCE VALUES

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

PERFORMANCE CHARACTERISTICS

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 118 samples compared with the same method of a competitor.

INTERFERENCES

Bilirubin (20 mg/dL), hemoglobin (10 g/L), and lipids (10 g/L), do not interfere. Other substances may interfere[6].

LIMITATIONS OF 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.

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