CHRONOLAB

CE

IVD

WAALER ROSE
Slide hemaglutination

Quantitative determination of Rheumatoid Factors (RF).

PACKAGING

Ref: 101-0219	*Cont.: 100 tests* 5 ml of Waaler Rose 1 ml Control +, 1 ml Control – 16 x 6 disposable slides
Ref: 101-0628	*Cont.: 1 L.*

Store at +2 to +8ºC

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 lays 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

The Waaler Rose test is a slide hemaglutination method for the qualitative and semi-quantitative detection of RF in human serum.
Stabilized sheep erythrocytes sensitized with rabbit IgG anti-sheep erythrocyte are agglutinated when mixed with samples containing RF.

REAGENTS

1. **Waller Rose**
   Stabilized sheep erythrocytes sensitized with rabbit IgG anti-sheep erythrocyte, pH, 8.2. Preservative.
2. **Control + (**Red cap)
   Human serum with a RF concentration $\geq$ 30 IU/mL. Preservative
3. **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.

CALIBRATION

The Waller Rose sensitivity is calibrated against the International RF Reference WHO 64/1 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 to +8ºC 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 agregates that may be present.
Reagents deterioration: Presence of particles and turbidity.

ADDITIONAL EQUIPMENT

- Vortex mixer.
- Pippetes 50 µL

SAMPLE

Fresh serum. Stable 8 days at +2 to +8ºC or 3 months at –20ºC.
Samples with the presence of fibrin should be centrifuged before testing.
Do not use highly hemolized or lipemic samples.

NOTES

1. Results obtained with a Waaler Rose method do not compare with those obtained with RF- Latex method. Differences in the results between methods do not reflect differences in the ability to detect rheumatoid factors.

PROCEDURE

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 WR reagent vigorously or on a vortex mixer before using and add one drop (50 µL) next to the samples 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. Let the slide undisturbed on a flat surface for 2 minutes
6. After this time, twist very carefully the slide once to about 45º from the horizontal and let the slide again to stay on a flat surface for 1 minute more.

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 avoiding any movement or lifting the slide during the observation. The presence of visible 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.

CALCULATION

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 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

REFERENCE VALUES

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

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: 100 %.
4. Diagnostic specificity: 93.6 %.

INTERFERENCES

Hemoglobin (10 g/L), bilirubin (20 mg/dL) and triglycerides (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 Waaler Rose method but also should be complemented with a RF-Latex test along with the clinical examination.

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