WAALER ROSE

Slide hemaglutination

Quantitative determination of Rheumatoid Factors (RF). IVD

Store at +2 to +8ºC

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.

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.

REAGENTS

1. **Waller Rose**
   Stabilized sheep erythrocytes sensitized with rabbit IgG anti-sheep erythrocyte, pH, 8.2. Sodium azide 0.95 g/L.
2. **Control + (**Red cap)
   Human serum with a RF concentration ≥ 30 IU/mL. Sodium azide 0.95 g/L.
3. **Control – (**Blue cap)
   Animal serum. Sodium azide, 0.95 g/L.

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.
Reagents deterioration: Presence of particles and turbidity.

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 hemolyzed or lipemic samples.

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. Swirl the WR reagent gently 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.

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.

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.

NOTES

1. 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.
2. 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.
3. 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.

REFERENCES

1. Robert W Dorner et al. Clinica Chimica Acta 1987; 167: 1–21.
2. Frederick Wolfe et al. Arthritis and Rheumatism 1991; 34: 951-960.
3. Robert H Shmerling et al. The American Journal of Medicine 1991; 91: 528–534.
4. Koritz T N et al. Journal of Inmmunological Methods. 1980; 32; 1–9.
5. Assameh S N et al. Journal of Immunological Methods 1980; 34: 205 – 215.
6. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995

PACKAGING

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