Reactivos GPL
Barcelona, España

CE

- RF WAALER -

Waaler Rose
Slide haemoagglutination

Store at: +2+8ºC.

Presentatión:
Cod. SE015 50 Test.
Cod. SE016 100 Test.

Procedure

Diagnostic reagent for qualitative measurement of Rheumatoid factors.

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

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

REAGENTS COMPOSITION

Waaler Rose	Suspension of stabilized sheep erythrocytes sensitized with rabbit IgG anti-sheep erythrocyte, pH, 8.2. Sodium azide 0.95 g/L.
Control (+)	Human serum with a RF concentration ≥ 30 IU/mL. Sodium azide 0.95 g/L.
Control (-)	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 and HCV, and of 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 components are ready to use.
Do not use reagents over the expiration date.
Do not freeze; frozen reagents could change the functionality of the test.
If appear particles and turbidity do not use.

All the reagents of the kit are stable up to the end of the indicated month and year of expiry. Store tightly closed at 2-8ºC,. Do not use reagents over the expiration date.

CALIBRATION
The RF-WR sensitivity is calibrated against the WHO 64/1 Rheumatoid Arthritis Serum.

SPECIMEN
Fresh serum. Stable 7 days at 2-8ºC or 3 months at –20ºC.
The samples with particles or fibrin should be centrifuged to eliminate them.
Do not use haemolized or lipemic samples.

Discard contaminated specimen.

MATERIAL REQUIRED BUT NOT PROVIDED

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. Shake the RF-WR reagent gently before using and add a drop (50 µL) of this reagent 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. 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.

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 the procedure, as well as a comparative pattern for a better result interpretation.

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 non-rheumatic 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.

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 800 IU/mL.
- *Diagnostic sensitivity*: 100 %
- *Diagnostic specificity*: 93.6 %

INTERFERING SUBSTANCES
Interferences:
- Hemoglobin (10 g/L), bilirubin (20 mg/dL), lipemia (10 g/L), do not interfere.
- Other substances may interfere[6].

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.

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 Waaler Rose method but also should be complemented with a RF-Latex test along with the clinical examination.

BIBLIOGRAPHY

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