



ATLAS WAALER ROSE SLIDE HEAGLUTINATION KIT

For the qualitative and semi-quantitative determination of Rheumatoid Factors (RF) in human serum.

For *In-Vitro* and professional use only
Store at 2-8°C

INTRODUCTION

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 Sjogren's syndrome, as well as in non-rheumatic conditions, its central role in clinic lays its utility as an aid in the diagnosis of rheumatoid arthritis (RA). Most patients of RA shows positive RF result.

PRINCIPLE

The Waaler Rose test is a slide hemagglutination 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. Waaler Rose Reagent: Stabilized sheep erythrocytes sensitized with rabbit IgG anti-sheep erythrocyte, pH 8.2, sodium azide 0.95g/L.
2. Waaler Rose positive control: Human serum with RF concentration \geq 30IU/ml. Sodium azide 0.95g/L.
3. Waaler Rose negative control: Animal serum. Sodium Azide 0.95g/L

Store the reagent kit at 2 - 8°C. **DO NOT FREEZE.**

PRECAUTIONS

1. Reagents containing sodium azide may combine with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide buildup.
2. For *In Vitro* diagnostic use.
3. Components from human origin have been tested and found negative for the presence of HbsAg, HCV and antibodies to HIV (1/2). However, handle controls as if potentially infectious.

REAGENT 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 2-8°C 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.

SPECIMEN COLLECTION AND STORAGE

1. Use fresh serum collected by centrifuging clotted blood.
2. If the test cannot be carried out on the same day, the serum may be stored between 2 - 8°C for no longer than 72 hours after collection. Samples are stable for 7 days at 2-8°C or 3 months at -20°C.
3. Do not use highly hemolyzed or lipemic samples.
4. Do not use plasma.

MATERIALS PROVIDED

1. Waaler Rose Reagent
2. Positive Control.
3. Negative Control.
4. White Glass Slide.
5. Stirring Sticks.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer.
2. Test Tubes.
3. Test Tube Rack.
4. Serological pipettes.
5. Glycine saline buffer.

PROCEDURE

Qualitative Test:

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.

2. Place 40µl of the sample and one drop of each positive and negative control into separate circles on the slide test.
3. Swirl the Waaler Rose reagent gently before use and add one drop (40µl) 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. Let the slide undisturbed on a flat surface for 2 minutes.
6. After this time, twist very carefully the slide once to about 45° horizontally and let the slide again to stay on a flat surface for 1 minute more.

Semi-Quantitative Test:

1. Set up at least five test tubes: 1:2, 1:4, 1:8, 1:16, 1:32, etc..
2. Dilute sample according to dilution factor on each test tube with saline solution.
3. Proceed for each dilution as in the qualitative method.

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.

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 8IU/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:

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

LIMITATIONS

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 RF Latex test along with the clinical examination.

PERFORMANCE

1. Analytical Sensitivity: 8 (6-16) IU/ml, under the described assay conditions.
2. Prozone effect: No prozone effect was detected up to 800IU/ml.
3. Diagnostic sensitivity: 100%
4. Diagnostic Specificity: 93.6%

INTERFERENCES

Hemoglobin (10g/L), bilirubin (20mg/dL) and lipemia (10g/L) do not interfere. Other substances may interfere.

REFERENCES

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