WAALER ROSE slide
Slide Hemagglutination.
Kit with controls and accessories.

Packaging
Code 8040141  100 test

INTENDED USE
Qualitative determination of Rheumatoid Factors (RF)

PRINCIPLE
WAALER ROSE is a slide agglutination test for the qualitative and semiquantitative detection of Rheumatoid Factor (RF) in human serum. Stabilized sheep erythrocytes sensitized with rabbit IgG anti-sheep erythrocyte are agglutinated when mixed with samples containing RF.

SAMPLE
Fresh Serum. Stable 8 days at 2-8°C or 3 months at -20°C. Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples.

KIT COMPONENTS
Reagent (A) WR
Liquid Volume = 5.0 ml
Stabilized sheep erythrocytes sensitized with rabbit IgG anti-sheep erythrocyte. pH 8.2 Preservative.

Control (+) WR
Volume = 0.5 ml
Human serum with a RF concentration ≥ 30 U/ml Preservative.

Control (-) WR
Volume = 0.5 ml
Animal serum Preservative.

Stirrers 2 pz 

Reaction Slide 2 pz

The Reagents are stable until the expiration date printed on the label, when stored tightly closed at 2-8°C. Once opened, the reagents are stable one month at 2-8°C if contamination is avoided. Do not freeze. Keep bottles closed when not in use.

REAGENT PREPARATION
All the kit components are ready to use.

PRECAUTIONS AND WARNINGS
Biological risk for Control (+) 
Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow. Use the normal precautions required in the laboratory. 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. Dispose of waste according to local laws.

PROCEDURE
Qualitative Method:
Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures. Gently mix the reagent WR to obtain a homogeneous suspension. Dispense 50 μl of serum upon a selected spot of the reaction slide, add one drop of WR reagent and accurately mix with a stirrer paying attention to uniformly distribute the liquid on the selected spot. Rotate the slide 2 or 3 times. Leave the slide in horizontal position for 2 minutes. After this time, twist the slide once to about 45° from the horizontal and let the slide again to stay on a flat surface for 1 minute more, and observe the possible agglutination.

Semi-quantitative method:
Make serial two fold dilutions of the sample in saline solution. Proceed for each dilution as in the quantitative method.

READING AND INTERPRETATION
Examine the presence or absence of visible agglutination. The presence of agglutination indicates a RF concentration equal or greater than 8 U/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 sample is calculated as follow:

8 x RF Titer = U/ml

EXPECTED VALUES
Up to: 8 U/ml

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL
Positive and Negative Controls are recommended to monitor the performance of the reagent and to have a better results interpretation.

PERFORMANCE
Sensitivity: 8 (6-16) U/ml
Prozone Effect: No prozone effect up to 800 U/ml.
Diagnostic sensitivity: 100 %
Diagnostic specificity: 93.6 %
Interferences: bilirubin does not interfere up to 20 mg/dl. Hemoglobin and lipemia do not interfere up to 10 g/l.

METHOD LIMITATIONS
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 Slide but also should be complemented with a RF-latex test along with the clinical examination.

NOTE
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