**INTENDED USE**
Qualitative determination of Rheumatoid Factors (RF)

**PRINCIPLE**
WAALER ROSE is a slide agglutination test for the qualitative and semi-quantitative 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
- Control (+) WR
  - Volume = 0.5 ml
- Control (-) WR
  - Volume = 0.5 ml
- Animal serum
- Preservative

**PRECAUTIONS AND WARNINGS**
- **Biological risk for Control (+)**
  - Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully, 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**
- 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.

**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.

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

**EXPECTED VALUES**
- Up to: 8 U/ml

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

**CALCULATIONS**
The approximate RF concentration in the sample is calculated as follow:

\[ 8 \times \text{RF Titer} = \text{U/ml} \]

**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**