CORMAY RF WAALER

HAEMAGGLUTINATION TEST FOR DETECTION OF RHEUMATOID FACTOR (WAALER ROSE)

Kit name	Kit size	Cat. No
CORMAY RF WAALER 100	100 tests	6-253

INTRODUCTION
Rheumatoid factor (RF) is an autoantibody against the Fc portion of the IgG molecule, commonly seen in sera at a high concentration in some conditions, particularly in patients with rheumatoid arthritis. The measurement of RF value is useful in evaluating the diagnosis, effects of therapy and prognosis of RA, systemic lupus erythematosus, chronic hepatopathy, etc.

METHOD PRINCIPLE
Stabilized sheep erythrocytes sensitized with rabbit IgG anti-sheep erythrocyte are agglutinated when mixed with samples containing RF.

REAGENTS
Package

	CORMAY RF WAALER 100
WR-Reagent	1 x 5 ml
WR-Control (+) (red cap)	1 x 1 ml
WR-Control (-) (blue cap)	1 x 1 ml
Stirrers	2 x 25 pcs.
Slides (6 circles each)	2 x 8 pcs.

Reagent preparation and stability
The reagents are ready to use.
The reagents when stored at 2-8°C are stable up to expiry date printed on the package. Do not freeze.

Concentrations in the test

stabilized sheep erythrocytes sensitized with rabbit IgG anti-sheep erythrocyte	400 mmol/l
human serum solution	150 mmol/l
animal serum solution	150 mmol/l
sodium azide	< 0.1 %

Warnings and notes
- Product for in vitro diagnostic use only.
- The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- 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.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.
- Individuals suffering from infectious mononucleosis, hepatitis, syphilis as well as elderly people may give positive results.
- Results obtained with a RF-Latex method do not compare with those obtained with Waaler Rose test. Differences in the results between methods do not reflect differences in the ability to detect rheumatoid factors.
- Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

ADDITIONAL EQUIPMENT
- general laboratory equipment.

SPECIMEN
Serum. Stable 7 days at 2-8ºC or 3 months at –20ºC.
Samples with presence of fibrin should be centrifuged.
Do not use highly hemolized or lipemic samples.
It is recommended to perform the assay with freshly collected samples.

PROCEDURE
The test is recommended for the qualitative and semi-quantitative manual assays.

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 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 45º from the horizontal and let the slide again to stay on a flat surface for 1 minute more.
7. Read the test.

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 U/ml.

Semi-quantitative method
1. Make serial two fold dilutions of the sample in 0.9% NaCl solution.
2. Proceed for each dilution as in the qualitative method.

Reading and interpretation
The result (titer), in the semi-quantitative method, is defined as the highest dilution showing a positive result.
The approximate RF concentration in the patient sample is calculated as follows:

RF concentration (U/ml) = 8 x the highest dilution

REFERENCE VALUES

adults	< 8 U/ml

It is recommended for each laboratory to establish its own reference ranges for local population.

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.

PERFORMANCE CHARACTERISTICS
- **Analytical sensitivity:** 8 (6-16) U/ml.
- **Prozone effect:** no prozone effect up to 800 U/ml.
- **Diagnostic sensitivity:** 100%.
- **Diagnostic specificity:** 93.6 %
- **Interferences:**
  Haemoglobin up to 10 g/l, bilirubin up to 20 mg/dl, triglycerides up to 10 g/l do not interfere with the test.

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

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

Date of issue: 01. 2008.

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01/08/01/08