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WAALER ROSE

Diagnostic reagent set **(Slide latex tests)** for the in-vitro qualitative screening and semi-quantitative determination of Rheumatoid Factors present in infected human serum manually.

REF: BS.1/RFR1.050.0050	50 test	REF: BS.1/RFR1.100.0100	100 test

CLINICAL SIGNIFICANCE

Test the Waaler-Rose test is the indirect hemagglutination.
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 nonrheumatic conditions, its central role in clinic lays 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.

METHOD PRINCIPLE [2]

BioScien Waaler Rose is a slide hemaglutination 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.

REAGENT COMPOSITION

Reagents:	Composition
WR Reagent	Stabilized sheep erythrocytes sensitized with rabbit IgG anti-sheep erythrocyte, pH, 8.2. Preservative
Positive Control	Human serum with a RF concentration ≥ 30 IU/ml.Preservative
Negative Control	Animal serum. Preservative

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person. Do not ingest or inhale as reagent contains sodium azide which is classified as dangerous substance for environment.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
  S56: dispose of this material and its container at hazardous or special waste collection point.
  S57: use appropriate container to avoid environmental contamination.
  S61: avoid release in environment.

For further information, refer to the Waaler Rose reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

BioScien Waaler Rose reagent is ready-to-use and is stable until expiration date stated on label when properly stored in an upright position and refrigerated at 2-8°C (do not freeze).

Deterioration
The ***BioScien*** Waaler Rose reagent can be damaged due to microbial contamination. Don't use Waaler Rose in presence of particles and turbidity.

SPECIMEN COLLECTION AND PRESERVATION [2]

Fresh serum. Stable 8 days at 2-8ºC or 3 months at –20ºC.
Samples with the presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples.

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes
- Centrifuge
- Stop watch
- Variable Micropipettes
- Vortex mixer

ASSAY PROCEDURE

Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures. Shake and mix antigens well before dispensing

Qualitative procedure
1. Identify each reaction circle of the slide test to make one positive control, one negative control and the desired number of samples respectively.
2. Place one drop of positive control reagents, one drop of negative control and one drop of patient's serum (50 µL) to be tested onto each reaction circles.
3. Mix the WR Reagent vigorously or on a vortex mixer before using and add one drop (50 µL) to the reaction circles containing positive controls, negative control and patient's serum.
4. Mix contents of each circle uniformly over the entire circle with separate mixing sticks.
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. Serum to be titrated is serially diluted (1:2, 1:4, 1:8 etc.) in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method.

READING AND INTERPRETATION

Qualitative procedure	
Positive	Agglutination indicates a RF concentration equal or greater than 8 IU/mL.
Negative	No agglutination as indication for the RF level in the patient's serum within the normal range.
Semi-Quantitative procedure	
Titer	The titer is defined as the highest dilution showing a positive result.

RF Titer (IU/ml) = Highest dilution with positive reaction x Reagent sensitivity (8 IU/ml).
e.g., if the agglutination is present up to a titer 1:8, the approximate serum RF level is 8 x 8 = 80 IU/ml.

QUALITY CONTROL

The positive controls have been included with the test kit to monitor the performance of the reagent. Good physiological saline may be used as a negative control, if the expected results have not been observed; the reagent should not be used. For more information, please contact ***BioScien*** technical support.

PERFORMANCE CHARACTERISTICS

Precision (reproducibility and repeatability): Precision of WR suspensions is 100% (+/- one double dilution).

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 %.

LIMITATIONS OF PROCEDURE

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 a RF-Latex test along with the clinical examination.
3. 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.

INTERFERING SUBSTANCES

Bilirubin (20 mg/dL) and lipaemia (10 g/L) and Hemoglobin (10 g/L) do not interfere. Other substances may interfere.

EXPECTED VALUES

Up to 8 IU/ml
Each laboratory should establish its own reference range.

REFERENCES

1. Robert H Shmerling et al. The American Journal of Medicine 1991; 91: 528 – 534.
2. Robert W Dorner et al. Clinica Chimica Acta 1987; 167: 1 – 21.
3. Koritz T N et al. Journal of Inmmunological Methods. 1980; 32; 1 – 9.
4. Assameh S N et al. Journal of Immunological Methods 1980; 34: 205 – 215.
5. Frederick Wolfe et al. Arthritis and Rheumatism 1991; 34: 951- 960.
6. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

SYMBOLS IN PRODUCT LABELLING

IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number		Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		

EC REP

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