

WAALER ROSE ema kit

Qualitative and semiquantitative determination
by erythrocytes agglutination on slide
of Rheumatoid Factors in serum

100 tests

REF 6003

PRINCIPLE

The rheumatoid disease is a systemic morbid disease associated with a chronic inflammatory process. From a diagnostic perspective it is characterized by VES, α -2 gamma globulins and CRP increase and by the presence of rheumatoid factors.

Rheumatoid factors, if present in the serum, agglutinate with rabbit erythrocytes sensitized with rabbit immunoglobulins to form an easily visible agglomerate (Waaler-Rose method).

REAGENTS

Kits components:

REF 6003

REAGENT 1 (liquid, white cap) 1 x 5 ml

Ram erythrocytes sensitized with rabbit immunoglobulins ram anti-erythrocytes, ready to use.

REAGENT 2 (liquid, red cap) 1 x 1 ml

Positive control, ready to use.

REAGENT 3 (liquid, blue cap) 1 x 1 ml

Negative control, ready to use.

WARNING: the reagents contain sodium azide (< 0.1%) as preservative. Handle with caution and avoid ingestion and contact with skin.

SLIDE 17 pieces

STIRRER 100 pieces

STABILITY: sealed and stored at 2-8°C, reagents are stable up to the expiration date printed on the label.

SAMPLE

Serum.

STABILITY: 2 days at 2-8°C, 1 month at -20°C.

PREPARATION OF THE REAGENTS

Let the reagents reach the test temperature before use. Shake the Reagent 1 accurately before use. Make sure all erythrocytes are in suspension and not deposited on the bottom of the vial.

MANUAL PROCEDURE OF THE QUALITATIVE TEST

Pour the reagents in the proper areas of the slide, as the following table:

	Sample	Pos. Control	Neg. Control
Sample	50 μ l		
Reagent 2		1 drop	
Reagent 3			1 drop
Reagent 1	1 drop	1 drop	1 drop

Mix to spread the liquid on the whole area of the slide. Shake the slide gently (round movement) for 2 minutes and then evaluate the results.

READING OF THE RESULTS

The presence of any agglutination in the sample shows the rheumatoid factor concentrations of at least 6 IU/ml. On positive sera, it is recommended to perform the title with the semiquantitative test as further on described.

MANUAL PROCEDURE WITH THE SEMIQUANTITATIVE TEST

Dilute the sample with saline solution as follows:

Dilution	1:2	1:4	1:8	1:16	1:32
Sensitivity equal to UI/ml	12	24	48	96	192

Proceed on each dilution as for the qualitative test.

RESULTS

The last dilution which shows any agglutination corresponds to the title of the sample.

REFERENCE VALUES

RF is usually not found in serum.

NOTES








1. Longer reaction times may give false positive results.
2. Always compare the results with the controls.
3. All reagents have been deactivated and tested for HIV, HBsAg and HCV antibodies. However, they should be treated as potentially infectious.

REFERENCES

Waaler E. Acta Path. Microb. Scand. 17,1-2, (1940)

Muller W. "The Serology of Rheumatoid Arthritis" Gottingen 97 (1962)

KEY SYMBOLS

	In Vitro diagnostic medical device
	batch number
	catalog number
	temperature limits
	use by
	caution
	read instructions for use

IVD

CE

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MANUFACTURER



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