WAALER ROSE TEST

For *in Vitro* **diagnostic use**

Rapid agglutination slide test for the qualitative and semiquantitative determination of rheumatoid factor (RF)

I. INTRODUCTION AND INTENDED USE

The Waaler Rose test is a semiquantitative method that permit to evidence the presence of rheumatoid factor in the human serum sample tested; this factor is present during the rheumatoid arthritis; RA is a chronic, systemic inflammatory disorder that may affect many tissues and organs, but principally attacks flexible joints. Once the rheumatoid factor appeared in the serum no longer disappears, even in the early stages of disease remission. The Waaler Rose Test is a hemagglutination test on sensitized red blood cells for the qualitative and semiquantitative determination of rheumatoid factor (RF).

II. PRINCIPLE OF THE TEST

Stabilized sensitized red blood cells with IgG are agglutinated when mixed with samples containing RF.

III. REAGENTS AND MATERIALS

Suspension:	suspension of red blood cells, coated with sensibilized IgG; preservative.
Positive Control:	control, ready for use, containing enough RF to gice a distinct agglutination.
Negative Control:	control, ready for use, non-reactive with the Waaler-Rose reagent.

IV. STORAGE AND STABILITY

Store the reagents and the controls at temperature between *+2°C and +8°C*. Do not freeze.

V. SAMPLES

Fresh serum. Stable *7 days* at +2-8°C or *3 months* at –20°C.

VI. PROCEDURE

Bring all reagents and serum samples to room temperature. Mix gently red cells suspension before use.

Qualitative test

Distribute in the different areas on the slide:

	Sample	Positive Control	Negative Control
Sample	1 drop	--	--
Positive Control	--	1 drop	--
Negative Control	--	--	1 drop
Suspension	1 drop	1 drop	1 drop
Mix with the sticks and spread the fluid over the entire area of the cell. Shake slowly the slide by hand or by revolving stirrer for 1 min. Let the slide stand for 2 minutes better if lightly tilted. Observe under artificial light.			

Semi-Quantitative test

Dilute the sample with saline solution as indicated in the following table:

Serum diution	1:2	1:4	1:6	1:16	1:32	1:64
Serum RF (IU/mL)	16	32	64	128	256	512

Follow the method of qualitative test.

VII. INTERPRETATION OF RESULTS

Qualitative test

A positive result of at least 8 I.U./l is given by a distinct agglutination. In this case the semiquantitative analysis is recommended.

Semi-Quantitative test

The titre is given by the last dilution with visible agglutination.

VIII. CHARACTERISTICS

Sensitivity

The reagent shows a sensitivity of about 8 I.U./ml.

Diagnostic meaning

RF determination allows to differentiate between rheumatoid arthritis, in which the positive results are about 80% of the examined cases, and rheumatic fever in which the positiveness is practically absent. Sometimes RF test is positive in the serum of patients with polyarthritis nodosa, systemic lupus erythematosus, hepatitis.

IX. NOTES

- Results obtained on sample should always be compared with results obtained on control.
- The positive control shows agglutination within 2 min.
- The negative control may show a light granulation without any agglutination within 3 min.
- Lipemic or contaminated sera may cause false positive results.
- Reaction times longer than 2 minutes may produce false positive results.
- The latex reagent, control sera and buffer contain sodium azide as preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- All reagents of human source have been tested for HBsAg and HIV antibody and found to be negative. However the material should still be regarded as potentially hazardous.
- Sometimes the results obtained with W.R. reagent are different from those obtained with R.F. latex. The differences are due to the different substrate sensitisation. Nevertheless both are useful to determine R.F. factors.
- If the test area of the slide proves repellent clean it with alcohol.
- **As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.**

- **The components of this I.v.D. are tested always each other without verify the compatibility with components produced by others manufacturers. Is not excluded that these components can be used with components of same chemical composition but produced by others manufacturers, but there is not an experimental evidence of this compatibility.**
- The kit must be used by clinical test trained personnel only.
- **ATTENTION:** Slides are made of plastic, so that they can be washed with normal water.

X. BIBLIOGRAPHY

1. Rose H.M. – Proc. Soc. Exp. Biol. Med. **68**, 1-14 (1948)
2. Waaler E. – Acta Path. Microb. Scand. **17**, 172-179 (1940)
3. Waaler M. e coll. – Arth. Rheum. **4**, 47-54 (1961)
4. Janeff J. – Arth. Theum. **13**, 193-200 (1970)
5. Jones e coll. – Amer. J. Clin. Path. **60**, 603-610 (1973)

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (DXXX)		Fabbricante
	Consult Instructions for Use		Use By (year/month)	REF	Catalogue number		Do not reuse
	Keep dry		Fragile, handle with care	NON STERILE	Non-sterile		Keep away from heat

CONTENT

REF.	**UA80250 62 tests**	***UA80255 62 tests***	***UD80252 Controls***
Suspension (white cap)	1 x 2,5 mL	*1 x 2,5 mL*	
Positive Control (red cap)	1 x 0,5 mL	*1 x 0,5 mL*	*1 x 0,5 mL*
Negative Control (green cap)	1 x 0,5 mL	*1 x 0,5 mL*	*1 x 0,5 mL*
Slide with 6 test areas	2 items	*10* items	
Sticks (1X25 items)	3 (75 items)	3 (75 items)	
Instruction for use	1 item	1 item	*1 item*
EDMA Code	**12 11 01 90 00**	**12 11 01 90 00**	**12 50 01 13 00**

CE IVD