RF Latex kit

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

100 tests **REF 6002**

Also available:
2 x 5 ml RF latex (without controls) **REF 6102**

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.
In this test the rheumatoid factors, if present in the serum, agglutinate with latex particles sensitized with human immunoglobulins to form an easily visible agglomerate.

REAGENTS

Kits components: **REF 6002**
REAGENT 1 (liquid, white cap) **1 x 5 ml**
Latex polystyrene particles in suspension sensitized with human immunoglobulins, 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 latex particles 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 Positive control Negative control	50 µl	1 drop	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 8 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 UI/ml	16	32	64	128	256

Proceed on each dilution same as for the qualitative test.

RESULTS

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

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

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

IVD CE

Ed. 02 - Mar 2015 MS

MANUFACTURER

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