RHEUMATOID FACTOR (RF)

Qualitative and semiquantitative determination of rheumatoid factor by agglutination to latex

TEST SUMMARY

Rheumatoid factors, contained in the serum, produce agglutination of latex particles coated with IgG.

SAMPLES

Fresh serum. Stability 7 days at 2-8°C. For longer periods of time it is recommended to freeze samples at –20°C. Frozen samples must be totally unfrozen and brought to room temperature before using. Samples in which turbidity is observed must be cleared by centrifugation before being analysed.

REAGENTS

Latex
Latex particles coated with IgG; conservative and stabilizer.

Positive control
Human base stabilized solution of rheumatoid factors with a titre that gives a clear agglutination.

Negative control
Proteic solution not reactive with latex.

All reagents contain 0.095% of sodium azide.

REAGENTS PREPARATION AND STORAGE

Reagents are ready for the use.
The latex suspension must be resuspended with much care. When the suspension becomes homogeneous by sweet inversion, it is necessary to fill and to empty the dosage's pipette many times.
Stability: the components of this kit will remain stable until the expiration date stated on the label, when stored at 2-8°C. Do not freeze.

MATERIAL REQUIRED BUT NOT SUPPLIED

Physiologic solution.
COD. AK00210 Slide and disposable stirrers.

PRECAUTIONS

Reagent may contain not reactive and conservative components. It is opportune to avoid contacts with the skin and do not swallow.
Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

QUALITATIVE PROCEDURE

Reagents	Sample	Positive control	Negative control
Sample	50 µl (1 gt)	--	--
Control +	--	50 µl (1 gt)	--
Control -	--	--	50 µl (1 gt)
Latex	50 µl (1 gt)	50 µl (1 gt)	50 µl (1 gt)

Mix using disposable stirrers and spreading homogeneously the mixture on the slide, then, shake slide for 2 minutes by a sweet rotating motion or by a stirrer at 100 r.p.m., and observe eventual agglutination using artificial light.

RESULTS INTERPRETATION

POSITIVE: A clear agglutination within 2 minutes.
NEGATIVE: No agglutination within 2 minutes.
In case of positivity it is opportune to titre semi quantitatively the serum.

SEMIQUANTITATIVE PROCEDURE

Prearrange serial dilution of the serum, pipetting in six slide areas, 50 µl of physiologic solution and 50 µl of sample in the first area. Using the same pipette (inspiring and discharging many times) mix carefully contents of first area and transfer 50 µl in the following area etc. Discharge 50 µl from last area. Dispense latex suspension, shake, and after 3 minutes observe agglutination. The titre is given by last clear agglutination. Procedure is summarized in the scheme below .

Reagents	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6
Physiologic	50 µl	50 µl	50 µl	50 µl	50 µl	50 µl
Sample	50 µl	50 µl from 1	50 µl from 2	50 µl from 3	50 µl from 4	50 µl from 5
Reject 50 µl from last area						
Latex	50 µl	50 µl	50 µl	50 µl	50 µl	50 µl
Titre	16 UI/ml	32 UI/ml	64 UI/ml	128 UI/ml	256 UI/ml	512 UI/ml

EXPECTED VALUES

Approximately 70-80% of patients with a clinical diagnosis of rheumatoid arthritis are seropositive for rheumatoid factor. Positive results were shown for nearly all patients with variants of rheumatoid arthritis such as Felty's or Sjogren's syndrome. A positive result can be expected in less than 5% of healthy individuals, while in the population aged 60 years and older, 30% may be seropositive using latex tests for the detection of rheumatoid factor.

CLINICAL SIGNIFICANCE

Rheumatoid factors found in the sera of most patients with rheumatoid arthritis as well as in a variety of other diseases, are a group of antibodies most belonging to the IgM class directed against determinants on the Fc fragment of the patients' IgG immunoglobulin.

NOTE

- If reaction's times are bigger than 2 minutes, they may cause a supervalutation of samples concentrations.
- Human sera used in controls have been found negative in the reaction with HIV and HBsAg. However, they should be handled with care.
- If the results are incompatible with clinical presentation, they have to be evaluated within a total clinical study.

CALIBRATION

Positive and Negative control sera should be always used to distinguish an eventual background's agglutination of reactive.

TEST PERFORMANCE

Interferences
Any interferences are produced with :

Haemoglobin	≤ 1000 mg/dl
Bilirrubin	≤ 20 mg/dl
Lipids	≤ 1000 mg/dl

Lipemic or turbid samples may give false positivity.

Sensitivity
Test gives positive results as from concentrations of 8 UI/ml.

Not happened phenomenon of prozone in RF concentrations studied until 800 UI/ml.

Specificity
A comparison with an available commercial method gave following results on 118 samples compared, giving a specificity = 98%.

		LTA srl +	LTA srl -	TOT.
COMPETITORS	+	48	1	49
		98%	2%	
	-	2	67	69
		3%	97%	
	TOT.	50	68	118

WASTE DISPOSAL

Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

PACKAGING

CODE AK00210	**(100 TESTS)**
Latex	1 x 5 ml

CODE AK00211	**(100 TESTS)**
Latex	1 x 5 ml
Positive control	1 x 0.5 ml
Negative control	1 x 0.5 ml
Slide black spot	3
Stirrers	50

CODE AK00235	**(RF Controls)**
Positive control	1 x 0.5 ml
Negative control	1 x 0.5 ml

REFERENCES

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SYMBOLS

IVD	Only for IVD use
LOT	Lot of manufacturing
REF	Code number
	Storage temperature interval
	Expiration date
	Warning, read enclosed documents
	Read the directions
	Biological risk

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