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Turbi-Latex Rheumatoid Factor (RF)

Quantitative Determination of RF.
Turbidimetric Immunoassay.

For professional in vitro diagnostic use only.

INTENDED USE

Quantitative determination of Rheumatoid Factor in Serum. Turbidimetric Immunoassay.

GENERALITIES

Rheumatoid Factor (RF) is an auto-antibody which reacts with fragment Fc of human IgG and is present, in particular, in patients affected by rheumatoid arthritis (RA), and can be considered as an indication of the inflammatory process. High RF concentrations often indicate a marked degeneration of the disease. The classical test methods are based on the agglutination of erythrocytes or latex particles coated with human IgG. These methods are suitable for qualitative or semiquantitative evaluations, while the turbidimetric immunoassay technique adopted in the present test allows the reproducible, quantitative determination of the rheumatoid factor concentration. Determination of the RF is therefore of clinical importance to establish the diagnosis and prognosis, and to monitor therapeutic efficacy in rheumatoid arthritis.

TEST PRINCIPLE

Turbidimetric immunoassay method. Latex particles are activated with human, denatured IgG, by means of a covalent bond to increase sensitivity and stability of the reagent. The suspension of coated particles agglutinates in the presence of RF, causing a degree of turbidity which can be detected photometrically and is proportional to the RF concentration in the sample. The quantitative analysis is obtained by interpolation of this photometric value with those found by testing known concentrations of RF.

REAGENT COMPOSITION

R1: Buffer	
Sodium phosphate	30 mmol/L
EDTA	10 mmol/L
Sodium azide	< 0.1 %
R2: Anti-RF	
Denaturated Human IgG	
Glycine buffer	20 mmol/L
Sodium azide	< 0.1 %
Cal	
RF	value on label

STORAGE, PREPARATION AND SHELFLIFE

Liquid and ready to use reagents, stable until the expiry date shown, if stored as indicated on the label and avoid contamination, evaporation and prolonged exposure to direct light. Do not freeze the reagents. Discard the reagent if signs of deterioration appear, such as the presence of particles and turbidity or failure to recover the values of certified control sera. After opening the bottles, it is advisable to withdraw the necessary volume, to immediately close the bottles and store them in the fridge to avoid contamination, degradation from direct light and evaporation.

SAMPLE COLLECTION AND PREPARATION

Fresh serum, Specimen without lipemia or hemolysis are preferred.
Stability: RF in serum is stable for 1 day at 2-8ºC. Freeze for longer storage at -20°C.

TEST PROCEDURE

Wavelength	: 578 nm
Light path	: 1 cm
Temperature	: 37 °C
Measurement:	: against Reagent Blank
Assay type	: Fixed Time

Assay:

	Blank	Assay
Buffer	**800 µL**	**800 µL**
Anti-RF	**200 µL**	**200 µL**
Sample/ Cal	**/**	**10 µL**

-Mix and incubate and Read Absorbance (Abs1).
- After exactly further 120 seconds read Absorbance (Abs2).
- Calculate ΔAbs (Abs2 – Abs1).

CALCULATION

Calibration:

It is recommended to use the RF Calibrators for calibration. Dilute to 6 calibrators as follows:

Dilution	1	2	3	4	5	6
Ratio	1	1/2	1/4	1/8	1/16	0
Cal/H_2O (µL)	200/0	100/100	50/150	50/350	25/375	0/200

Generate the calibration curve with the ΔAbs values and concentration of the calibrators.
Calculate the analytical result expressed in "U/mL", from the calibration curve. All samples with a RF concentration higher than the highest calibration point and/or giving a signal denoting an excess of antigen must be diluted and retested. It is advisable to use doubling dilutions in saline.
The calibration curve is valid for at least one month. However, its validity should be checked periodically.

Serum:

Calculate ΔAbs (Abs2 – Abs1).
Read the concentration of controls and samples on the graph.

QUALITY CONTROL

Normal and abnormal control sera of known concentration should be analyzed routinely with each group of unknown samples.

EXPECTED VALUES

Serum: The typical reference range is **≤ 8 U/mL.**
Each laboratory should establish a range of expected values based on its patient population and, if necessary, determine its own reference interval. For diagnostic purposes, results should always be assessed together with the patient's medical history, clinical examination and other results.

PERFORMANCE

PRECISION:

Low Level: Samples= 20; Average = 35.8; S.D. = 0.66; CV = 3.3%.
High Level: Samples = 20; Average = 78.05; S.D. = 0.52; CV = 2.6%.

ACCURACY:

A comparison between this method (x) and a certified method of trade (y) gave the following correlation:

y=1.2042 x + 3.134 r = 0.954

SENSITIVITY: 2.00 mg/L.
LINEARITY: 260 mg/dL.

PRECAUTIONS

The kit reagents are not classified as dangerous. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. After contact with skin, wash immediately with plenty of water. Wear suitable protective clothing, gloves and eye/face protection.

INTERFERENCES

No interference was observed by Bilirubin up to 50 mg/dL, Hemoglobin up to 500 mg/dL and lipemia up to 3000 mg/dL Triglycerides, Ascorbic acid up to 50 mg/dL.

LITERATURE

- Tietz N.W. Textbook of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p.493, p.481.
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- Klauss K., Bandilla M. D., and Mc Duffie M. D., Arthritis and Rheumatism, vol.12, n°2, p.74-81 (1969).
- Young D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-511 to 3-512

USED SYMBOLS

IVD	In Vitro Diagnostic Medical Device
	Manufacturer
	Date of Manufacture
REF	Catalogue Number
LOT	Batch Code
	Use by YYYY-MM (MM = end of month)
	Operator's Manual; Operating Instructions
	Keep away from Sunlight
	Keep away from Rain
	Temperature Limit
	Caution
	Do not use if Package is Damaged
	Do Not Re-Use
	Contains Sufficient for <N> Tests