

RHEUMATOID FACTOR (RF)

Turbi Latex

REF: 561 001 **100 test**

Buffer Reagent 2 x 20 ml
 Latex Reagent 1 x 10 ml
 Calibrator 1 x 2 ml

Intended Use

In vitro diagnostic reagents for the quantitative determination of Rheumatoid Factor (RF) in human serum by means of particle-enhanced turbidimetric immunoassay.

Background

The most consistent serological feature of rheumatoid arthritis is the increased concentration of autoantibodies directed against antigenic sites in the Fc region of human and animal IgG, namely rheumatoid factors (RFs) in the blood and joint fluid. The potential role of these factors in the pathogenesis of this disease has been studied extensively, with the finding that both environmental and genetic factors affect production of RF. RF determinations are clinically important for the diagnosis, prognosis, and assessment of therapeutic efficacy of rheumatoid arthritis. Although RFs may be found in all immunoglobulin classes, the RF most frequently detected in the laboratory is IgM type, present in about 75 - 80 % of adult patients with rheumatoid arthritis but in about 10 % of children with juvenile rheumatoid arthritis.

Test Principle

This RF test is based upon the reactions between IgM-anti-IgG (RF) in patient's sample and latex covalently bound human IgG. RF values are determined photometrically.

Reagents

Buffer Reagent

Phosphate buffer (0,05 M) pH: 8,0 containing NaCl (0,15M), detergent and polyethyleneglycol.
 Preservative : sodium azide < 1g/L

Latex Reagent

A suspension of latex microparticles covalently bound human IgG in a glycin buffer (0,1 M, pH: 8,2), containing NaCl (0,15 M) and bovine serum albumin (0,5%).
 Preservative: Sodium azide 0,075%

Calibrator

Human-based reference fluid. Preservative: sodium azide, 0,075 %.

All raw materials of human origin used in the manufacture of this product showed no reactivity when tested for HBsAg, anti-HIV-1/2 and HCV with commercially available test methods. However, this product should be handled as though capable of transmitting infectious diseases

Precautions and Warnings











For in vitro diagnostic use only. Do not pipette by mouth. Reagents containing sodium azide must be handled with precaution. Sodium azide can form explosive azides with lead and copper plumbing. Since absence of infectious agents cannot be proven, all specimens and reagents obtained from human blood should always be handled with precaution using established good laboratory practices.

Reagent Preparation , Storage and Stability

All the reagents are stable until the expiration date stated on the label when stored tightly closed at (2 - 8 °C) and **Do not freeze**. Open vial is stable for 3 months at the specified temperature.

RF Calibrator : Reconstitute with 2 ml distilled water, mix gently and bring to room temperature for about 10 minutes before use.

Reconstituted calibrator is stable for 1 month at 2 - 8 °C or 3 months at -20 °C

SYMBOLS IN PRODUCT LABELLING	
 Authorised Representative	 Use by/Expiration Date
 For in-vitro diagnostic use	 CAUTION. Consult instructions for use
 Batch Code/Lot number	 Manufactured by
 Catalogue Number	 (Xi) - Irritant
 Consult instructions for use	 Temperature Limitation

Calibration Curve

Prepare the following RF Calibrator dilutions in NaCl 9 g/L. Multiply the concentration of the RF Calibrator by the corresponding factor stated in table below to obtain the RF concentration of each dilution.

Calibrator dilution	1	2	3	4	5	6
Calibrator RF	---	25	50	100	200	400
Na Cl 9 g/L	400	375	350	300	200	---
Factor	0	0.0625	0.125	0.25	0.5	1
Concentration(IU/ml) (for example: the undiluted C = 200 IU/ml)	0	12.5	25	50	100	200

Deterioration

The RF latex reagent should have a white, turbid appearance free of granular particulate. Visible agglutination or precipitation may be a sign of deterioration, and the reagent should be discarded. The RF diluent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarded.

Sample Preparation and Storage

Use fresh serum or plasma. Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples .

Stability: 7 days at 2 - 8 °C or 3 months at -20 °C.

Procedure

- Bring the reagents and the photometer to 37°C
- Assay conditions:
 Wavelength 650 nm (600 -650 nm)
 Temperature 37°C
 Cuvette 1cm light path
- Adjust the instrument to zero with distilled water .
- Pipette into a cuvette :

	blank
Buffer Reagent	0.4 ml
Latex Reagent	0.1 ml

- Mix and read the absorbance (blank reagent)
- add the sample / Calibrator

	Blank	Sample / Calibrator
NaCl 9 g/L	4 µl	---
Sample / Calibrator	---	4 µl

- Mix and read the absorbance (A₂) after 2 minutes of the sample addition.

Calculation

Calculate the absorbance difference (A₂-A blank) of each point of the calibrator dilution and plot the values obtained against the RF concentration of each calibrator dilution . Rheumatoid factor concentration in the sample is calculated by interpolation of its (A₂-Ablank) in the calibration curve.

Quality Control

Control sera are recommended to monitor the performance of manual and automated assay procedures .
Each laboratory should establish its own Quality Control Scheme and corrective actions if controls do not meet the acceptable tolerances

Expected Values

Up to 20 IU/mL.
Each laboratory should establish its own reference range.

Sensitivity

6 IU /mL.

Linearity

160 IU /mL.
specimens showing higher concentration should be diluted 1+4 using physiological saline and repeat the assay (result×5).

Interferences

Hemoglobin (10 g/L) , bilirubin (20 mg/dL) and lipemia (10 g/L) , do not interfere. Other substances may interfere⁶.

Waste Disposal

Disposal of all waste material should be in accordance with local guidelines.

References

- 1- Arnet FC, Edworthy SM, Bloch DA, McShane DJ, et al. The American Rheumatism Association 1987. Revised criteria for the classification of rheumatoid arthritis. Arthritis Rheum 1988; 31:315-24.
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- 4- Young DS. Effects of Drugs on Clinical Laboratory Test. 5th Edition, AACC Press, 2000.
- 5- Passing H, Bablok W. A new biometrical procedure for testing the equality of measurements from two analytical methods.
- 6- Application of linear regression procedures for method comparison studies. Part I. J Clin Chem Clin Biochem 1983; 21:709-20.
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ORDERING INFORMATION	
CATALOG NO.	QUANTITY
561 001	100 test



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