SPECTRUM

The Creative Approach to Bioscience

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

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

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 microparticules 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 ºC) and .**Do not freeze.**
Open vial is stable for 3 months at the specifeid 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 ºC or 3 months at -20 ºC

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
NaCl 9 g/L	400	375	350	300	200	---
Calibrator RF	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 ºC or 3 months at -20 ºC.

Procedure

1 - Bring the reagents and the photometer to 37ºC
2 - Assay conditions:

Wavelength	650 nm (600 -650 nm)
Temperature	37ºC
Cuvette	1cm light path

3 - Adjust the instrument to zero with distilled water .
4 - Pipette into a cuvette :

	blank
Buffer Reagent	0.4 ml
Latex Reagent	0.1 ml

5 - Mix and read the absorbance (blank reagent)
6 - Add the sample / Calibrator

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

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

Calculation

Calculate the absorbance difference
(A_2-A blank) of each point of the calibrator dilution and plot the values obtained against the RF concentration of each calibrator dilution . Rheumatiod factor concentration in the sample is calculated by interpolation of its (A_2-Ablank) in the calibration curve.

Quality Control

Control sera are recommended to monitor the perfomance 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

Performance characteristics

Detection limit

Values less than 6 IU/mL give non-reproducible results.

Prozone effect

No prozone effect was detected upon 800 IU/mL.

Precision

The reagent has been tested for 20 days, using three different RF concentrations in a EP5-based study.

EP5	CV (%)		
	35.8 IU/mL	78.05 IU/mL	123.26 IU/mL
Total	4.5 %	4.1 %	5.9 %
Within Run	3.3 %	2.6 %	3.2 %
Between Run	1.7 %	2.3 %	3.4 %
Between Day	2.5%	2.1 %	3.6%

Accuracy

Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 41 samples
of different concentrations of RF were assayed. The correlation coefficient (r)2
was 0.91 and the regression equation y = 1,2042x +3,1344. The results of the performance characteristics depend on the analyzer used.

Expected Values

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

Senstivity

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) , bilirrubin (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.

2- Bartfield H. Distribution of rheumatoid factor activity in non rheumatoid states. Ann NY Acad Sci 1969; 168:30-40. Singer JM, Plotz CM. The latex fixation test. Am J Med 1956; 21:888-92.

3- Moore TL, Dorner RN. Rheumatoid factors. Clin Biochem 1993; 26:75- 84.

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.

7- Sonderdruck aus DG Klinische Chemie Mitteilungen 1995; 26: 207 – 224

ORDERING INFORMATION	
CATALOG NO.	QUANTITY
561 001	100 test

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