SPECTRUM

The Creative Approach to Bioscience

RHEUMATOID FACTOR (RF) Turbi Latex

REF: 561 001 100 test
R1 Buffer 2 x 20 ml
R2 Latex 1 x 10 ml

SYMBOLS IN PRODUCT LABELLING

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

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 latexcovalently bound human IgG. RF values are determined photometrically.

Reagents

Buffer
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

preparation

RF Calibrator : Reconstitute with 2 ml of distilled water : Mix gentity and bring to room temperature for about 10 minutes before use
Calibration Curve :
prepare the following RF Calibrator dilutions in NaCl 9 g/L Muttiply 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 Na Cl 9 g/L	--- 400	25 375	50 350	100 300	200 200	400 ---
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

Storage and Stability

All the compontents of the kit are stable until the expiration date on the label when stored tightly closed at (2 - 8 ºC) and contaminations prevented during their use .Do not use reagents over the expiration date .
Reagnt deterioration : presence of paticles and turbidity
Reconstituted calibrator :stable for 1 month at 2 - 8 ºC or 3 months at 20 ºC

Do not freeze: frozen Latex or Diluent couled change the functoinality of the test.

Samples

Fresh serum or plasma . stable 7 days at2 - 8 ºC or 3 months at 20 ºC the samples with presence of fibrin should be centrifuged before testing Do not use highly hemolized or lipemic samples .

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
Diluent (ml)	0.4
Latex (ml)	0.1

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 after 2 minutes (A2) 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

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.

References

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ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
561 001	100 test

Egyptian Company for Biotechnology (S.A.E)
Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.
Tel: +202 4665 1848 - Fax: +202 4665 1847
www.spectrum-diagnostics.com
E-mail:info@spectrum-diagnostics.com

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany

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ISO 13485