SPECTRUM

The Creative Approach to Bioscience

RHEUMATOID FACTOR (RF) ImmunoTurbidimetry 3rd Generation

(Aggregated human IgG method)

REF: 598 001 100 test

R1 Buffer	2 x 20 ml
R2 Reagent 2	1 x 8.2 ml
Standard	1 x 0.2 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		Manufactured by
REF	Catalogue Number		(Xi) - Irritant
	Consult instructions for use		
	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. The RF is a term used to describe a variety of antibodies (in most cases of the IgM type) that will react with modified human IgG (e.g. IgG in circulating immune complexes, IgG adsorbed to latex, etc.) and IgG of animal origin.RF is highly associated with rheumatoid arthritis, as high as 90 % of patients with RA have RF titers of more than 20 IU/mL.

Test Principle

This RF test is based upon the RF antigen-antibody reaction

Reagents

R1 Buffer
50 mmol/L Good's buffer (pH7.4).
Sodium azide (0.95 g/L).

R2 reagent 2
Heat-aggregated human IgG(<0.5 mg/ml).
Sodium azide (0.95 g/L)

Standard
RF concentration is stated on the vial label.

Materials required but not provided with the kit

Controls

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. Disposal of all waste material should be in accordance with local guidelines.
As with other diagnostic tests, results should be interpreted considering all other test results and the clinical situation of the patient.

Reagent Preparation, Storage and Stability

All reagents are supplied ready to use.
Reagents in the original vial are stable to the expiration date on the vial label when capped and stored at (2 - 8 ºC).

RF Standard:
The Standard is stable to the expiration date on the vial label when capped and stored at (2 - 8 ºC).
Once opened the Standard is stable for 6 weeks if stored tightly closed at 2 - 8 ºC after use.

Specimen collection and preparation

Fresh serum . stable 2 days at 2 - 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	340 nm
Temperature	37ºC
Cuvette	1cm light path

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

	Standard	Sample
Reagent (R1)	400 µl	400 µl
Standard	25µl	---
Sample	---	25µl
Mix and incubate for 2 minutes,read absorbance (A1)		
Reagent (R2)	80 µl	80µl

After addition of **R2,** incubate and after 5 minutes record 2nd reading (A2)

Calculation

Generate a reference curve by successive 1 : 2 dilutions of standard in saline (At Least 4 points are recommended). Use Saline as zero point. Determine Δ absorbance of the sample and each standard as following:
Δ absorbance of sample = (A2 - A1) sample
Δ absorbance of each standard = (A2 - A1) for each standard
Plot the calibration curve and obtain the result..

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

3 IU/ml

Precision

	CV (%)	
	Intra-Run	Inter-Run
Low	3.65	3.57
Medium	2.69	1.34
High	1.54	1.91

Interferences

Bilirubin (50 mg/dL)
Ascorbic acid (50 mg/dL)
Haemoglobin (500 mg/dL)
Intrafat (3 %) had no effect on the RF assay

Senstivity

3 IU /mL.

Linearity

500 IU /mL.

Specimens showing higher concentration should be diluted 1+4 using physiological saline and repeat the assay (result×5).

Expected Values

0-20 IU/mL.
Each laboratory should establish an expected range for the geographical area in which it is located.

Waste Disposal

Disposal of all waste materials should be done in accordance to local guide lines.

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-Bandilla,K.I. and MC DUffie,F.C,Arthritis Rheum,12,74(1969).

3-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.

4-Muller,W,The Serology of Rheumatoid Arthritis.Berlin- Gottingen-Heidelberg 97(1962).

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

6-Waaler,e,Acta Path.Microb.scan,17 (1940).

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
598 001	100 test

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