Spectrum For Diagnostic Industries

RHEUMATOID FACTOR (RF)
Turbi Latex

IVD

REF.	Pack size
380 02 020	100 test R1 Buffer 2 X 20 ml R2 Latex 1 X 10 ml Calibrator 1 vial

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 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: 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-A_{blank}) 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.

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

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.

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