Rheumatoid Factor (RF- Immunoturbidimetric Method)

In-vitro Diagnostic reagent/kit for quantitative determination of Rheumatoid Factor (RF) in serum/plasma sample on Photometric System.

Reagent

Reagent 1: Diluent Solution
Reagent 2: Latex Solution
Calibrator: Lyophilized Calibrator (Value on Label)

Principle

The RF-Turbilatex is a quantitative turbidimetric test for the measurement of RF in human serum or plasma. Latex particles coated with human gammaglobulin are agglutinated when mixed with samples containing RF. The agglutination causes an absorbance change, dependent upon the RF contents of sample that can be quantified by comparison from a calibrator of known RF concentration.

Summary

Rheumatoid factors are a group of antibodies directed to determinants in the Fc portion of the immunoglobulin G molecule. Although rheumatoid factors are found in a number of rheumatoid disorders, such as systemic lupus erythematosus (SLE) and Sjögren's syndrome, as well as in nonrheumatic conditions, its central role in clinic lies its utility as an aid in the diagnosis of rheumatoid arthritis (RA). A study of the "American College of Rheumatology" shows that the 80.4% of RA patients were RF positive.

Storage Instruction and Reagent Stability

The reagent and calibrator is stable until the expiration date on the label when stored tightly closed at 2^0-8^0C.
If found Particles and Turbidity means Reagent deterioration.
Do not freeze; frozen Latex or Diluent could change the functionality of the test.

Components and Concentrations

Reagent contained: Tris buffer 20 mmol/L, Latex particles coated with human gammaglobulin and Preservative.
Calibrator: Lyophilized Serum - RF Value on Label

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. Rf Calibrator is in lyophilized form and need to be reconstituted with 2.0 mL of distilled water before use. Close the vial carefully and allow the calibrator to stand for 10 minutes swirling occasionally.

Avoid foaming! Do not shake!
Calibrator after reconstitution is stable till 1 months if stored at 2° – 8°C and for 3 months at –20°C, if protected from light and contamination is avoided.

Calibrator dilution	1	2	3	4	5	6
Calibrator RF (µL)	--	25	50	100	200	400
NaCl 9 g/L (µL)	400	375	350	300	200	-
Factor	0	0.0625	0.125	0.250	0.50	1.00

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

Specimen

Serum, heparin, plasma or EDTA plasma separate at the latest 1h after blood collection from cellular contents.
7 days at 2° – 8°C
90 days at –20°C
Only freeze once! Discard contaminated specimens.

Assay Procedure

Wavelength: 630 (600-650)nm
Temperature: 37^0C
Light path: 10 mm

	Sample/ Calibrator
Reagent 1 Diluent	800 µL
Latex Reagent 2	200 µL
Sample /Calibrator	7 µL
Mix and read the absorbance immediately (A1) and after 2 minutes (A2) of the sample addition.	

CALCULATIONS:

$$RF\ (IU/mL) = \frac{(A2\text{-}A1)\ sample}{(A2\text{-}A1)\ calibrator} \times \text{Calibrator concentration}$$

Quality Controls

For internal quality control any normal and abnormal controls should be assayed with each batch of samples.
Each laboratory should establish corrective action in case of deviations in control recovery.

Warnings and Precautions

1. Keep out of reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
2. Take off immediately all contaminated clothing.
3. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow. Avoid contact with skin and mucous membranes.
4. For professional use only!

Performance Characteristics Measuring Range

The test has been developed determine RF activities within a measuring range from 5- 160 IU/mL. If such value is exceeded the sample should be diluted 1 + 4 with double distilled water and results multiplied by 5.

Interferences

No interference was observed by, Bilirubin up to 20 mg/dL and Triglycerides up to 1000 mg/dL.

Linearity/Limit of Maximum Detection

The higher limit of detection is 160 IU/mL.

Sensitivity/Limit of Detection

The lower limit of detection is 5 IU/mL.

Precision

Intra-assay n = 20	Mean (IU/mL)	SD (IU/mL)	CV (%)
Sample 1	41.95	0.74	1.77
Sample 2	76.36	1.01	1.32
Sample 3	234.92	1.29	0.55

Inter-assay n = 20	Mean (IU/mL)	SD (IU/mL)	CV (%)
Sample 1	42.41	0.37	0.87
Sample 2	77.41	0.63	0.81
Sample 3	235.76	0.80	0.34

Method Comparison

A comparison of Precision Biomed RF (y) with a commercially available test (x) using 20 samples gave following results:

$y = 1.001x + 0.247$; $r^2 = 0.999$

Reference Range

Normal value up to 20 IU/mL.

Each laboratory should check if reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Quick Reference

Parameter	RF
Mode	Fixed time
Reaction slope	Increasing
Wavelength	630(600-650) nm
Path length	10 mm
Temperature	37°C
Reagent 1 volume	800 µL
Reagent 2 volume	200 µL
Sample volume	7 µL
Delay	5 Sec
Rate	120 sec
Normal range	Up to 20 IU/mL
Linearity	160 IU/mL
Sensitivity	5 IU/mL

Pack Size

Cat No.	Configuration	Pack
RFT00050	Reagent R1 - 1 x 40mL Reagent R2 - 1 x 10mL Calibrator – 1 x 2.0mL	50mL

Literature

1. Frederick Wolfeetal. Arthritis and Rheumatism1991;34:951-960.
2. Robert W Dorneretal. Clinica Chimica Acta1987; 167:1-21
3. Robert HS hmerlingetal. The American Journal of Medicine 1991; 91:528 –534.
4. Vladimir Muiéetal. Scand JRheumatology1972; 1:181 –187.
5. Paul Retal. Clin Chem1979; 25/11:1909–1914.
6. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press,1995.

Version : RFT/00

IVD In Vitro Diagnostic Use | See Pack Insert For Procedure | Single Use only | CE

Temperature Limit | Manufacturer's Address | Manufacturing Date | Expiry Date | LOT Lot Number

Manufactured in India by :

Precision Biomed Pvt. Ltd.

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