RF-TURBILATEX

(Latex Turbidimetric Test)

IMMUNOPAK

Last update 09-2020

Ref. IM-RFT.083, 1x50 ml

INTENDED USE

Quantitative determination of Rheumatoid Factors (RF) in serum.

DIAGNOSTIC SIGNIFICANCE

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 Sjogren'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).

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 the patient sample that can be quantified by comparison from a calibrator of known RF concentration.

PRESENTATION

All the reagents to be stored at 2-8^{0}C	No. of Bottles / Vials
	1x50 ml
• R1 Diluent	1x45 ml
• R2 Latex	1x5 ml
• RF Calibrator	1

*Value may vary from lot to lot.

PRECAUTION

Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.

PREPARATION OF WORKING REAGENT

Mix 0.9 ml of Diluent (R1) with 0.1 ml of latex (R2).

PREPARATION OF WORKING CALIBRATOR

Reconstitute with 2.0 ml of distilled water. Mix gently and incubate at room temperature for 10 minutes before use.

REAGENT STORAGE AND STABILITY

All reagents are stable at 2-8° C till the expiry date mentioned on the label.

Do not freeze, frozen Latex or diluent could change the functionality of the test.

Reagent deterioration: Presence of particles and turbidity.

Working reagent is stable for 30 days at 2-8°C.

RF Calibrator is stable for 1 month at 2-8°C or 3 months at -20°C.

SPECIMEN COLLECTION

Fresh serum is stable for 7 days at 2-8°C or 3 months at -20°C. Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or Lipemic samples.

(A) FOR MULTIPOINT CALIBRATION

Calibration curve (range from 20 to150 IU/mL)

Prepare the following RF calibrator dilutions in NaCl 9 gm/L. Multiply the concentration of 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(µl)	-	10	25	50	75	100
NaCl 9 g/L (µl)	100	90	75	50	25	-
Factor	0	0.1	0.25	0.5	0.75	1.0
Concentration of diluted Calibrator (IU/ml)	0	15.3	38.3	76.5	114.8	153

(B) FOR ONE POINT CALIBRATION (LINEAR RANGE UP TO 100 IU/ ml)

Prepare a RF calibrator dilution

30 µl RF Calibrator +70 µl NaCl 9 g/L

Multiply the RF calibrator concentration by 0.3 to obtain the RF concentration of the diluted working calibrator which is equal to 45.9 IU/ml.

REACTION PARAMETERS

- Type of Reaction : End point / Multi Standard
- Wavelength : 650 nm (600-650)
- Flow cell temperature : 37°C
- Sample/Calibrator Volume : 7 µl
- Reagent Volume : 1 ml
- Zero setting with : Reagent Blank
- Light Path : 1 cm
- Incubation : 2 min
- Delay Time : 5 Sec

TEST PROCEDURE

Pipette In Test Tube	BLANK	CALIBRATOR / SAMPLE
NaCl 9 g/L (µl)	7	-
Calibrator or sample (µl)	-	7
Working Reagent (ml)	1.0	1.0

Mix and read the absorbance of blank (A1) and serum / calibrator (A2) after 2 minutes.

1. For Multipoint Calibration: Use all the 6 dilution of Calibrator as stated above.
2. For Single point calibration: Use diluted Calibrator as stated above.

TEST RESULT

(A) BY MULTIPOINT CALIBRATION

Calibration curve: Calculate the absorbance difference (A2-A1) of each point of the calibration curve and point the values obtained against the RF concentration of each calibrator dilution. Rheumatoid factor concentration in the sample is calculated by interpolation of its (A2-A1) in the calibration curve.

(B) BY ONE POINT CALIBRATION

$$\text{RF IU/ml} = \frac{\text{(A2-A1) Sample}}{\text{(A2-A1) Calibrator}} \times \text{Diluted working calibrator concentration}$$

QUALITY CONTROL

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

LIMITATIONS FOR INTERFERENCES
Bilirubin (20 mg/dl), hemoglobin (10 g/L) and lipemia (10 g/L) do not interfere. Other substances may interfere.

NORMAL VALUE
Up to 20 IU/ml.
Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS
A. Linearity: Up to 100 IU/ml for single point calibration & up to 150 for multipoint calibration under the described assay conditions.
B. Detection limit: Value less than 3 IU/ml give non-reproducible results.
C. Measurement range (calibration curve): 20-150 IU/ml under thedescribed assay condition. Samples with higher concentrations, should be diluted 1/5 in NaCl 9 g/L and retested again. The linearity limit and measurement range depends on the sample / reagent ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
D. Sensitivity: Δ 3.34mAIU/ml

NOTE
1. Multipoint calibration gives more accurate result than one point calibration.
2. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

REFERENCES
1. Frederick Wolfe et al. Arthritis and Rheumatism 1991; 34:951-960.
2. Robert W Dorner et al. ClinicaChimcaActa 1987;167:1-21.