DELTA
RF-Turbilatex
Latex turbidimetry

ORDER INFORMATION

CODE : DL3501: R1-1x40 ML + R2-1x10ML

Quantitative determination of Rheumatoid Factors (RF). IVD.
Store 2-8ºC.

PRINCIPLE OF THE METHOD :
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.

CLINICAL 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 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.

REAGENTS :

Diluent (R1)	Tris buffer 20 mmol/L, pH 8.2. Sodium azide 0.90 g/L. Merthiolate 0.05 g/L.
Latex (R2)	Latex particles coated with human gammaglobulin, pH 7.4. Sodium azide 0.90 g/L. Merthiolate 0.05 g/L.
RF - CAL	RF Calibrator. RF concentration is stated on the vial label.

PREPARATION :
Working reagent: Swirl the latex vial gently before use. Prepare the necessary amount as follow:
- 1 mL Latex Reagent + 4 mL Diluent

RF Calibrator: Ready to use. Value mentioned on the vial in IU/ml.

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 bellow 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

STORAGE AND STABILITY :
All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not use reagents over the expiration date.

Working reagent: Stable for 30 days at 2-8ºC.

Reagent deterioration: Presence of particles and turbidity.

RF calibrator: Ready to use. Stable till expiry at 2-8ºC. Do not freeze.

Do not freeze. Frozen latex and diluent could change the functionality of the test.

ADDITIONAL EQUIPMENT
- Thermostatic bath at 37ºC.
- Spectrophotometer or photometer thermostatable at 37ºC with a 650 nm filter (600 – 650 nm).

SAMPLES
Fresh serum or plasma. Stable 7 days at 2-8ºC or 3 months at –20ºC.
The samples with presence of fibrin should be centrifuged before testing.
Do not use highly hemolized or lipemic samples.

GENERAL SYSTEM PARAMETERS :

Reaction Type	Fixed Time
Wave length	650nm (600-650 nm)
Light Path	1 Cm
Reaction Temperature	37ºC
Blank / Zero Setting	Distilled Water
Reagent Volume	1 ml
Sample Volume	10 µl
Delay / Lag Time	10 sec
Read Time	120 sec
Read Interval	120 Sec
Calibrator Concentration	Stated on Vial Label
Normal Value	Upto 20 IU/ml
Linearity (One Point Calibration)	80 IU/ml
Linearity (Multi Point Calibration)	160 IU/ml

PROCEDURE :
1. Bring the reagents and the photometer (cuvette holder) to 37ºC.

2. Assay conditions: Wavelength : 650 nm (600-650 nm)
Temperature : 37 ºC
Cuvette ligth path : 1cm
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette:

Working Reagent (ml)	1.0 ml
Calibrator or Sample (µl)	10 µl

5. Mix and read the absorbance after 10 sec. (A1) and after 2 minutes (A2) of the sample addition.

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

$$RF\ (IU/mL) = \frac{(A_2\text{-}A_1)_{sample}}{(A_2\text{-}A_1)_{calibrator}} \times \text{Calibrator concentration}$$

QUALITY CONTROL :
Control Sera are recommended to monitor the performance 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.

REFERENCE VALUES :
Normal values up to 20 IU/mL. Each laboratory should establish its own reference range.

LINEARITY :

1. **Limit detection:** Values less than 6 IU/mL give non-reproducible results.

2. **Measurement range**: 6 - 160 IU/mL (Multi Point Calibration)
6 - 80 IU/mL (One Point Calibration) under the described assay conditions.

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 to 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.

INTERFERENCES :
Hemoglobin (10 g/L), Bilirrubin (20 mg/dL) and Lipemia (10 g/L), do not interfere. Other substances may interfere.

NOTES :
Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

BIBLIOGRAPHY :

1. Frederick Wolfe et al. Arthritis and Rheumatism 1991; 34: 951- 960.
2. Robert W Dorner et al. Clinica Chimica Acta 1987; 167: 1-21.
3. Robert H Shmerling et al. The American Journal of Medicine 1991; 91: 528 – 534.
4. Vladimir Muié et al. Scand J Rheumatology 1972; 1: 181 – 187.

DELTA LAB
1116, Bhadrakali Compound, Off Mumbai - Goa Highway, At Post Zarap,
Tal. : Kudal, Dist. Sindhudurg, Maharashtra - 416 510, INDIA
Tel / Fax : 0 23 62 - 23 20 30, Email : delta@deltalab.in, Web : www.deltalab.in