RF

(Turbilatex Method)

INTENDED USE

Diagnostic reagent for quantitative measurement of RF. Only for in vitro use in clinicallaboratory (IVD)..

CLINICAL SIGNIFICANCE

Rheumatoid factors are a group of antibodies directed to determinants in the Fc portion of the immunoglobulin G molecule. Although rhematiod factors are found in a number of rheumatoid disorders , such as systemic lupus erythematosus (SLE) and Sjogren's syndrome ,as well as in nonreheumatic conditions , its central role in clinic lies its utility as an aid in the diagnosis of rheumatoid rethritis (RF)

PRINCIPLE

The RF-Turbilatex is a quantitative turbidimetric test for measurement 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 calibrator of known RF concentration.

SAMPLE COLLECTION AND PRESERVATION

Fresh serum.Stable for 7 days at 2 - 8°C or 3 months at -20°C. The samples with particles or fibrin should be centrifuged to eliminate them. Do not use haemolized orlipemic samples.

REAGENTS COMPOSITION

1.Diluent (R1)
2.Latex (R2)
3.Calibrator (R3)

The assay is calibrated to the Reference Material NIBSC 64/2 (Rheumatoid Arthritis Serum) WHO.

REAGENT PREPARATION AND STABILITY

Shake gently the latex vial gently before use. Prepare the necessary amount as follow: 1 mL Latex Reagent + 4 mL Diluent

The reagent kit should be stored at 2 - 8°C and is stable till the expiry date indicated on the label. Working Reagent: Stable for 1 month at 2 - 8º C. But it is recommended to prepare afresh Working Reagent based on its workload.

Calibrator is Stable till expiry at 2 - 8º C.

Particles and turbidity indicates contamination or reagents deterioration.All the reagents of the kit are stable upto the end of the indicated month of the expiry.Do not use reagents over the expiration date.Do not freeze; Frozen reagents could change the functionally of the test

Multipoint Calibration:

1. Calculation of sample concentration is against interpolation of theabsorbance (A2-A1) in the calibration curve.
2. Calibration curves are prepare by RF calibrator dilutions in NaCI 9 g/L

Multiply the concentration of the RF calibrator by the corresponding factor stated in table below to obtained the RF concentration of each dilution.

Calibrator Dilution	1	2	3	4	5	6
Calibrator RF (µl)	-- 400	25 375	50 350	100 300	200 200	400 -
Factor	0	0.0625	0.125	0.25	0.5	1.0

ASSAY PROCEDURE

Pre warm at 37ºC the required amount of working solution before use.

PIPETTE INTO TEST TUBES

	Calibrator	Test
Reagent (R_1)	800 µl	800 µl
Calibrator	10µl	----
Reagent (R_2)	200 µl	200 µl
Sample	---	10 µl

Mix and read the absorbance immediately at 10 Seconds (A1) and at 120 Seconds minutes (A2) of the sample addition.

SYSTEM PARAMETERS

Pre warm at 37ºC the required amount of working solution before use.

Reaction Type	Two Point Kinetic
Wavelength Main / sub	650 nm (600 – 650)
Reaction Slope	Increase Slope
Blank –Zero Setting	Against Distilled Water
Reaction Temp.	37ºC
Cuvette Path	1 cm length path
Delay or LagTime	10 second
Interval Time or Measuring Time	120 second
Sample Volume	10µl
Reagent volume	R_1 800 µl + R_2 200 µl
Calibrator Concentration	As mention on Calib.
Low Normal at 37ºC	6.0 IU/mL
High Normal at 37ºC	20.0 IU/mL
Linearity at 37ºC	160 IU/mL

CALCULATION

One point Calibration: Serun RF IU/mL

$$= \frac{\Delta \text{ Abs of Sample (A2- A1)}}{\Delta \text{ Abs of Calibrator (A2 - A1)}} \text{ X Calibrator concentration}$$

REFERENCE NORMAL RANGE at 37ºC

Serum : 6 to 20 IU/mL at 37ºC

It is suggested that each laboratory establish its own reference range .The results of the performance characteristics depend on the used analyzer.

LINEARITY

Linearity limit: Up to 160 IU/mL

1. Linearity limit: Up to 160 (Calibration curve) .
2. Prozone effect: No prozone effect was detected upon 800 IU/mL.
3. Detection limit: Values less than 6 IU/mL give non-reproducible results.
4. Sensitivity: Ä 3.34 mA.IU/mL.

QUALITY CONTROL

Serum controls are recommended for internal quality control. Each laboratory shouldestablish its own Quality Control Scheme and corrective actions if controls do not meet the acceptable tolerance.

INTERFERENCE

Do not interference in Bilirubin (20 mg/dL),Lipemia (10 g/L), Hemoglobin (10 g/L),Other substances may interfere Notes:

Samples with higher concentrations should be diluted 1/5 in NaCl 9 g/L and retestedagain. The linearity limit depends on the sample reagent ratio. It will be higher bydecreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

PRECAUTIONS

Components from human origin have been tested and found to be negative for the presence of HBsAg and HCV, and of antibody to HIV(1/2). However, handle cautiously as potentially infectious. Good laboratory safety practices should be followed when handling laboratory reagents or human samples.

Ref References

1. Frederick Wolfe et al. Arthritis and Rheumatisim 1991; IU/mL. 34: 951-960.
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3. Robert H Shmerling et al. The American Journal of Medicine 1991; 91: 528-534.
4. Vladimir Muie et al. Scand J Rheumatology 1972; 1:181-187.
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6. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

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