ACCUCARE

RF-Turbilatex

Latex Turbidimetry.

Quantitative determination of RF in serum
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	CONT
TRF 25	1 x 25 ML
TRF 50	1 x 50 ML

CLINICAL SIGNIFICANCE

Rheumatoid Factor is 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 Sjogrens syndrome as well as in nonrheumatic conditions its central role in clinic lies its utility as an aid in the diagnosis of rheumatoid arthritis.As the study of the American college of Rheumatology shows that the 80.4% of RA patients were RF positive.

PRINCIPLE

RF turbilatex is a quantitative turbidimetric test for the measurement of RF in human serum. 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 samples that can be quantified by comparison from a calibrator of known RF concentration.

REAGENT COMPOSITION

Reagent I : Tris buffer 20 mmol/l,pH 8.2, Sodium Azide 0.95 g/L
Reagent II : Latex particles coated with human gamma-globulin.
RF – CAL : Concentration is stated on the vial label.

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only.
2. DO NOT pipette by mouth. Avoid contact with skin and eyes. If spilt, thoroughly, wash affected areas with water. For further information, consult the RF Reagent Material Safety Data Sheet.
3. Reagent contains Sodium Azide as a preservative. This may react with copper or lead plumbing to form explosive metal azides. Upon disposal, flush with large amounts of water to prevent azide build up.
4. Do not use the reagent after the expiration date printed on the kit.
5. 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 the calibrator cautiously as potentially infectious material.

SAMPLE COLLECTION AND PRESERVATION

Fresh serum: Stable for 7 days at 2-8℃ or 3 months at -20℃.
Samples with presence of fibrin should be centrifuged before testing.
Do not use highly hemolysed or lipemic sample.

REAGENT PREPARATION

Working reagent: swirl the latex vial gently before use. Prepare the necessary amount as follows.
8 ml Diluent + 2 ml Latex reagent (800µl+200µl)

RF calibrator: Ready to use value mention on vial in IU/ml.

ONE POINT CALIBRATION (LINEAR RANGE UP TO 120 IU/ML)

RF Calibrator is ready to use.

MULTI POINT CALIBRATION (LINEAR RANGE UP TO 160 IU/ML)

Multi Point calibrator Available on request (Optional)
Prepare the following RF calibrator dilutions in NaCl 9 g/dL, Multiply the concentration of the RF calibrator by the corresponding factor stated in the 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/dL (µl)	100	90	75	50	25	_
Factor	0	0.1	0.25	0.50	0.75	1.0

REAGENT STABILITY

All the component of the kit are stable until the expiry date on the label when stored tightly closed at 2-8℃ and contaminants prevented during there use, Do not use expired reagents.
Working reagent : stable for 30 days at 2-8℃.
RF Calibrator : stable till expiry at 2-8℃. Do not freeze.

AUTOMATED PARAMETERS	
Wavelength	650 (600-650) nm
Cuvette	1 cm light path
Reaction Temperature	37 ℃
Measurement	Against Distilled water
Reaction	2 point kinetics
Reaction Direction	Increasing
Sample / Reagent Ratio	1 : 100
Linearity	160 IU/mL

ASSAY PROCEDURE

PIPETTE INTO TEST TUBES

	CAL	SAMPLE
Sample	-	10 µl
Standard	10 µl	-
Reagent	1000 µl	1000 µl

Mix well, and read the absorbance after 10 sec A1 and after 2 minutes A2 of the sample addition.

CALCULATION

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

LINEARITY

The method is linear to a concentration of 6-160 IU/ml.
If the concentration exceeds this value, the sample should be diluted 1:5 with 0.9% saline solution and re-assayed.

REFERENCE INTERVAL

Serum plasma	upto 20 IU/ML.

QUALITY CONTROL

To ensure adequate quality control, Normal and abnormal control with assayed values should be run as unknown samples.

INTERFERENCES

Hemoglobin 10 g/dL, Bilirubin 20 mg/dL and Lipemia 10 g/dL do not interfere. Other substances may interfere.

BIBLIOGRAPHY

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4. Vladimir Mule at al Scand J Rheumatalogy 1972;1;181-187.

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