RF

Turbilatex Method

Intended Use:
RF (Rheumatoid Factor) Test reagent/kit is a medical device intended for the screening of Rheumatoid Factor (RF) in human specimen. It is intended for *in vitro* diagnostics use by trained healthcare professionals in IVD laboratory only and not near patients.

Clinical Significance
Measurement of rheumatoid factor is used for differentiating rheumatoid arthritis from other chronic inflammatory arthritis and is important in the progress and therapeutic management of the disease. Rheumatoid factor has been associated with some bacterial and viral infections (ex. Hepatitis, infectious, Mononucleosis) some chronic infections (ex. Tuberculosis, parasitic disease. Subacute Bacterial Endocarditis) and cancer.

Principle
TheRF-Turbi latex is a quantitative turbidimetric test for the measurement of RF in human serum or plasma.
Latex particles coated with human gamma globulin are agglutinated when mixed with samples containing RF. The agglutination causesan absorbance change, dependent up on the RF contents of sample that can be quantified by comparison from a calibrator of known RF concentration.

Reagent Composition

R1 Diluent	Tris buffer 20 mmol/L, pH 8.2.
R2 Latex	Latex particles coated with human gamma globulin,pH8.2
RF Calibrator	Human serum RF concentration is stated on vial label. and it is traceable to the "Rheumatoid Arthritis Serum" 64/002 from WHO (NIBSC)

Precaution

Componentsfromhumanoriginhavebeentestedandfoundtobene gativeforthe presenceof HBsAg,HCV, and antibodytoHIV (1/2).However handlecautiouslyas potentiallyinfectious.

Calibration
Use RF Calibrator ONLY.
The sensitivity of the assay and the target value of the calibrator have been
Standardized against the International Reference Standard from NIBSC64/002. Recalibrate when control results are out of specified tolerances, when using differentlot of reagentand when the instrument is adjusted.

Preparation
RF Calibrator: Ready to use.

CalibrationCurve: Prepare the following RF calibrator dilutionsin NaCl9g/L. Multiply the concentration of the RF calibrator by the corresponding factor stated in tablebel low to obtain the RF concentration feach dilution.

Calibratordilution	1	2	3	4	5	6
CalibratorRF(µL)	--	10	20	40	60	80
NaCl9g/L(µL)	80	70	60	40	20	--
Factor	0	0.125	0.25	0.5	0.75	1.0

Working Reagent:
Swirl the latex vial before use. Mix Latex and Diluent in a 1:4 ratio (i.e 2 ml R2 + 8 ml R1) prior to use.
Working Reagent is stable during 20 days at 2-8^{0}C

Stability and Storage
All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C and contaminations are prevented during their use. Do not use reagents over the expiration date.
Reagent deterioration: Presence of particles and turbidity.

Additional Equipment
- Thermostatic bath at 37°C.
- Spectrophotometer or photometer thermostatable at 37°C with a 540 nm filter.

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

Assay Parameters

Mode	Two Point / Fixed Time
Reaction	Ascending
Wavelength	650 nm (600-650)
Blank With	Distilled Water
Sample Volume	5 µl
Reagent Volume	400 µl : 100 µl
Delay Time	10 (Sec)
Read Time	120 (Sec)
Calibrator Conc.	See Vial Label
Linearity Limit	Up to 100 IU/ml
Unit	IU/ml

Procedure
1. Bring the reagents and the photometer (cuvette holder) to 37°C.
2. Assay conditions:
   Wavelength: 650 nm (600-650)
   Temperature: 37°C
   Cuvette light path: 1 cm
3. Adjust the instrument to zero with distilled water.
4. Pipette into a cuvette

Addition Sequence	**Test**
R1 Diluent	400 µl
R2 Latex	100 µl
Calibrator or Sample	5 µl

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

Calculation

$$RF\ (IU/ml) = \frac{Abs\ (A2\text{-}A1)\ sample}{Abs\ (A2\text{-}A1)\ calibrator} \times Calibrator\ conc.$$

OR

Calculate the absorbance difference

(A2-Ablank reagent) of each point of the calibration curve and plot the values obtaine dagainst the RF conc. Of each calibrator dilution.
Rheumatoid Factor concentration in the sample is calculated by interpolation of its (A2-A1 blank reagent) in the calibration curve.

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

Normalvaluesupto30IU/mL.

Each laboratory should establish its own reference range.

Performance Characteristics

1. Limit detection:Values less than5IU/ml give non-reproducible results.
2. Measurement range:6-100IU/ml,under the described assay conditions. Samples with higher concentrations should be diluted1/5in NaCl9g/L and retested again.
3. The linearity limit and measurement range depends on thes ampleto 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.
4. Prozone effect: No prozone effect was detected upon 800IU/ml.
5. Sensitivity:3.0mA.IU/ml.
6. Precision:The reagent has been tested for20days,using three different RF concentrations in a study.

Notes

1. Clinical diagnosis should not be madeon findings of a single test result, but should integrate both clinical and laboratory data.

References

1. Frederick Wolfe et al.Arthritis andRheumatism1991;34: 951- 960.
2. Robert W Dorneret al.ClinicaChimicaActa1987; 167: 1-21.
3. Robert HShmerlingetal.TheAmerican Journalof Medicine1991; 91: 528– 534.
4. VladimirMuié et al.ScandJRheumatology 1972;1: 181– 187.
5. PaulR et al.Clin Chem 1979; 25/11: 1909– 1914.
6. YoungDS. Effectsof drugson clinical laboratorytest, 4thed.AACCPress,1995

Packaging

R1. Diluent: 1 x 40ml

R2. Latex : 1 x 10ml

RF-CAL:1 x 2ml

For *in vitro* Diagnostic Use Only