RF TURBILATEX

Code	Product Name	Pack Size
SE029A	RF Turbilatex	50 ml

BEACON

Intended Use
For the quantitative determination of C-reactive protein in human serum.

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 Sjdgren'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

Reagent 1: Diluent	Tris buffer 20 mmol/L, Preservative.
Reagent 2: Latex Antigen	Latex particles coated with gammaglobulin, Preservative.
Regent 3: RF Calibrator	Calibrator The RF concentration is stated on the vial label.

Precautions
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.

Calibration
Use RF Calibrator Provided with kit. The sensitivity of the assay and the target value of the calibrator have been standardized against the International Reference Standard from NIBSC 64/002. Recalibrate when control results are out of specified tolerances, when using different lot of reagent and when the instrument is adjusted.

Preparation
RF Calibrator: Ready to use.

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 dulution	1	2	3	4	5	6
Calibrator RF (µL)	-	25	50	100	200	400
NaCL 9 g/L (µL)	400	375	350	300	200	-
Factor	0	0,0625	0,125	0,25	0,5	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-+8°C and contaminations prevented during their use. Do not use reagents over the expiration date.

Reagent Deterioration: Presence of particles and turbidity.
Do not freeze; frozen Latex or Diluent could change the functionality of the test.

Additional Equipment
- Thermostatic bath at +37°C.
- Spectrophotometer or photometer thermostatable at +37°C with a 650 nm filter.

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

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

Addition Sequence	Blank
Diluent R1	900 µL
Latex R2	100 µL

5. Mix and read the absorbance (Blank reagent).
6. Add the sample/ calibrator.

BEACON DIAGNOSTICS PVT. LTD. *424, NEW GIDC, KABILPORE, NAVSARI - 396 424. INDIA*

	Blank	Calibrator / Sample
NaCl 9 g/L (µL)	7	-
Calibrator or sample (µL)	-	7

7. Mix and read the absorbance after 2 minutes (A_2) of the sample addition.

Calculations

Calculate the absorbance difference (A_2-$A_{blank\ reagent}$) of each point of the calibration curve 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 (A_2-$A_{blank\ \ reagent}$) 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

Normal values up to 20 IU/mL.

Each laboratory should establish its own reference range.

Performance Characteristics

1. **Limit detection:** Values less than 6 IU/mL give non-reproducible results.
2. **Measurement range:** 6-160 IU/mL, 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.
3. **Prozone effect:** No prozone effect was detected upon 800 IU/mL.
4. **Sensitivity:** Δ3.34 mA. IU/mL.
5. **Precision:**

Intra-assay precision Within run (n=20)	Mean (IU/mL)	SD (IU/mL)	CV (%)
Sample 1	53.017	1.26	2.37
Sample 2	25.298	0.36	1.44

Inter-assay precision Run to run (n=20)	Mean (IU/mL)	SD (IU/mL)	CV (%)
Sample 1	89.72	1.79	2.00

6. **Accuracy:** Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similer characteristics. 86 samples ranging from 1 to 160 IU/mL of RF were assayed. The correclation coefficient(r) was 0.999 and the regression equation y =0.999x+0.968 IU/mL.

The results of the perfomance characteristics depend on the analyzer used.

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.
5. Paul R et al. Clin Chem 1979; 25/11: 1909 — 1914.
6. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

Symbols Used On Labels

REF	Catalogue Number		Manufacturer
	See Instruction for Use	LOT	Lot Number
CONT	Content		Storage Temperature
	Expiry Date	IVD	In Vitro Diagnostics

BEA/24/RFT/SE/IFU Ver-02
21/09/2025