RF TURBILATEX SYSTEM PACK

(Latex Turbidimetry Method)

B Auto 200, Unicorn 230, Unicorn 120 , Bonavera Chem 200 , Beaconic chem 200,Beaconic B200,Beaconic analyzer 120 & Bonavera chem 100(Fully Auto Biochemistry Analyzer)

BEACON

Code	Product Name	Pack Size
BA228	RF Turbilatex System Pack	1x20 + 1x5 ml

INTENDED USE

Quantitative determination of Rheumatoid factor in 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 Sjogren's syndrome, as well as in nonrheumatic conditions, its central role in clinic lies its utility as an aid in the diagnosis of the 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, pH 8.2. Preservative.
Reagent 2 Latex Reagent	Latex particles coated with human gammaglobulin, pH 7.4. Preservative.
Reagent 3 Calibarator	The RF Calibarator 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.

PREPARATION

RF Calibrator : Redy 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 dilution	1	2	3	4	5	6
Calibrator RF (µL)	–	25	50	100	200	100
NaCl 9 g/L (µL)	100	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 are prevented during their use. Do not use reagents over the expiration date.

On board stability: Min 30 days if refrigerated (+8 - +14°C) and not contaminated.

Reagent deterioration: Presence of particles and turbidity.

SAMPLES

Fresh serum or plasma. Stable 7 days at +2 - +8°C . The samples with presence of fibrin should be centrifuged before testing.

Do not use highly hemolized or lipemic samples.

QUALITY CONTROL

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: Δ 3.34mA.IU/ml

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5.Precision:

Intra-assay precision Within run (n=20)	Mean (IU/mL)	SD (IU/mL)	CV (%)
Sample 1	56.99	1.59	2.79
Sample 2	25.21	0.82	3.25

Inter-assay precision Run to run (n=20)	Mean (IU/mL)	SD (IU/mL)	CV (%)
Sample 1	15.97	0.61	3.83

7. Accuracy : Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 86 samples ranging from 1 to 160 IU/mL of RF were assayed. The correlation coefficient (r) was 0.999 and the regression equation y =1.0194x - 0.6184 IU/mL

The results of the performance characteristics depend on the analyzer used.[6]

INTERFERENCES

Hemoglobin (10 g/L), bilirubin (20 mg/dL) and lipemia (10 g/L), do not interfere. Other substances may interfere.

WARNING AND PRECAUTIONS

MSDS will be provided on request.

Parameter For B Auto 200, Unicorn 230, Unicorn 120 , Bonavera Chem200 , Beaconic chem 200,Beaconic B200,Beaconic analyzer 120&Bonavera chem 100

Test Name	RF TURBILATEX
Full Name	RF TURBILATEX
PRI Wave	630 nm
SEC Wave	-
Assay/Point	FIXED TIME
Start	18
End	25
Decimal	2
Unit	IU/ML
Linearity Range Low	6
Linearity Range High	160
Sample Volume	2 µl
Reagent 1 (R1) Volume	160 µl
Reagent 1 (R2) Volume	40 µl
Substrate Depleted/Abs.limit	-
Linearity	160 IU/ML
Out Of Linearity Range	-
Calibration Type	Spline
Points	6
Blank Type	Reagent
Concentration Blank	0.00
Concentration Std	Refer calibrator value sheet

NOTES

The program is made as per the in house testing, it can be modified as per requirements.

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 Domer et al. Clinica Chimica Acta 1987, 167: 1-21.
3. Robert H Shmerling e al. The American Journal of Medicine 1991; 91: 528 - 534.
4. Viadimir 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/SB/IFU Ver-05
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