RF-TURBILATEX

Latex Turbidimetry

IVD CE

PRODUCTCODE

TL003

INTENDED USE

The RF-Turbilatex is a quantitative turbidimetric test for the measurement of RF in human serum or plasma.

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 Sjögren'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.

PRINCIPLE

Latex particles coated with human gamma globulin 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

REAGENTS

Diluent (R1)	Tris buffer 20 mmol/L, pH 8.2, Preservative
Latex (R2)	Latex particles coated with human gamma globulin, pH 7.4, Preservative
RF-CAL	Calibrator. Human serum. The RF concentration is stated on the viallabel.

PREPARATION

RF Calibrator: Reconstitute with 2.0 mL of distilled water. Mix gently and bring to room temperature for about 10 minutes before 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 below to obtain the RF concentration of each dilution.

Calibrator dilution	1	2	3	4	5	6
Calibrator RF (µL) NaCl 9 g/L (µL)	-- 400	25 375	50 350	100 300	200 200	400 --
Factor	0	0.0625	0.125	0.25	0.5	1.0

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.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Reagents should not be left inside the analyzer after use; they must be stored refrigerated at 2-8ºC. Latex may sediment. Mix reagents gently before use. Do not use reagents over the expiration date.

Do not freeze; frozen latex and diluent could change the functionality of the test.

Reagent deterioration: Presence of particles and turbidity.

Reconstituted calibrator: Stable for 1 month at 2-8ºC or 3 months at –20ºC.

SPECIMEN AND SAMPLE PREPARATION

Fresh serum or plasma, Stable 7 days at 2-8ºC or 3 months at –20ºC.

The samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.

PROCEDURES

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

Diluent R1	800 µL
Latex R2	200 µL

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

	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 before and after testing samples 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.

NORMAL RANGE

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 depend 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 3.34 mA. IU/mL
5. **Precision:** The reagent has been tested for 20 days, using three different FR concentrations in a EP5-based study.

EP5	CV (%)		
	35.8 IU/mL	78.05 IU/mL	123.26 IU/mL
Total	4.5%	4.1%	5.9%
Within Run	3.3%	2.6%	3.2%
Between Run	1.7%	2.3%	3.4%
Between Day	2.5%	2.1%	3.6%

6. **Accuracy:** Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 41 samples of different concentrations of FR were assayed. The correlation coefficient $(r)^2$ was 0,91 and the regression equation y = 1,2042x +3,1344.

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

INTERFERENCES

Hemoglobin (10 g/L), Bilirubin (20 mg/dL) and lipemia (10 g/L), do not interfere. Other substances may interfere[6].

NOTES

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

SYMBOL ON LABELS

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

BIBLIOGRAPHY

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