GENESIS

Instructions For Use

RF Turbilatex (4+1) (Turbidimetric Method)

Cat no.	Size
6103 101	50 Test
6103 102	100 Test
6103 103	200 Test

INTENDED USE
RF Turbi Latex Reagent is intended for the in vitro Quantitative diagnostic determination of rheumatoid factor (RF) in human serum or plasma.

PRINCIPLE OF THE METHOD
The RF-Turbilatex is a quantitative turbidmetric 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 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 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.

REAGENTS

Reagent (R1)	Tris buffer 20 mmol/L, pH 8.2. Sodium azide 0.95 g/L.
Reagent (R2)	Latex particles coated with human gammaglobulin, pH 7.4. Sodium azide 0.95 g/L.
Calibrator	Calibrator. Human serum. The RF concentration is stated on the vial label.

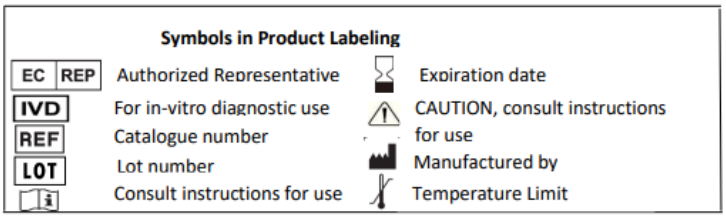
PRECAUTIONS AND WARNINGS
Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.

CALIBRATION
The sensitivity of the assay and the target value of the calibrator have been standardized against the International Reference NIBSC 64/2 (Rheumatoid Arthritis Serum) WHO. It is not recommended the use of other commercially available RF calibrators.

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 (range from 20 to 160 IU/mL): Prepare the following RF calibrator dilutions in physiological saline. 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)	-	10	25	50	75	100
NaCl 9 g/L (µL)	100	90	75	50	25	-
Factor	0	0.1	0.25	0.5	0.75	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 2-8ºC and contaminations are prevented during their use. Do not use reagents over the expiration date.
Reagent deterioration: Presence of particles and turbidity.
Reconstituted calibrator: Stable for 1 month at 2-8ºC or 3 months at - 20ºC.
Do not freeze; frozen latex and diluent could change the functionality of the test.



ADDITIONAL EQUIPMENT
-Thermostatic bath at 37ºC.
-Spectrophotometer or photometer thermostat able at 37ºC with a 650 nm filter (600 – 650 nm).

SAMPLES
1. Fresh serum or plasma. Stable 7 days at 2-8ºC or 3 months at –20ºC.
2. The samples with presence of fibrin should be centrifuged before testing.
3. Do not use highly hemolysis or lipemic samples

PROCEDURE
1.Bring the reagents and the photometer (cuvette holder) to 37ºC.
2.Assay conditions:

Mode:	fixed time
Wavelength:	650 nm (600-650 nm)
Temperature:	37 ºC
Cuvette light path:	1cm
Delay time:	5 sec
Measuring time:	120 sec

3.Adjust the instrument to zero with distilled water.
4.Pipette into a cuvette:

	Cal / Sample
Calibrator or sample (µL)	4.0
R1 Diluent (mL)	0.4
R2 Latex (mL)	0.1

5.Mix and read the absorbance (A1) after **5 sec** and after **2 minutes** read the absorbance (A2) .

CALCULATIONS
Calculate the absorbance difference
(A2-A1) 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 (A2-A1) in the calibration curve.

QUALITY CONTROL
Control Sera are recommended to monitor the performance of manual and automated assay procedures. Control Sera ASO/CRP/RF is available with Level (Low) and Level (High).
Each laboratory should establish its own quality control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE 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.***Linearity limit:*** 6-160 IU/mL, under the described assay conditions. Samples with higher concentrations should be diluted in **1/5** physiological saline and retested again. The linearity limit and measurement range depends on the sample/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:*** 3.34 mA. IU/mL.

5. Precision:

	Intra-assay (n=20)		Inter-assay (n=20)	
Mean (IU/mL)	15.0	45.0	15.0	45.0
SD	0.83	1.24	0.98	2.35
CV	5.5	2.7	6.5	5.2

6. 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 0.95 and the regression equation
y = 0.797x -1.075.

The results of the performance 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

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