RF – Turbilatex
Letex Turbidimetry

INTENDED USE
Genixx RF Turbilatex test kit is intended to use for the quantitative, in-vitro determination of rheumatoid factors in human serum.

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 non-rheumatic conditions, its central role in clinic lies in the utility as an aid in the diagnosis of rheumatoid arthritis (RA).

METHOD
Turbidimetry

PRINCIPLE
RF Turbilatex test for rheumatoid factor is a quantitative turbidimetric test for the measurement of RF in human serum. 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

Activation buffer (R1)	Tris buffer 20 mmol/L, pH 8.2. Preservative
Latex reagent (R2)	Latex particles coated with human gamma globulin, pH 7.4. Preservative
RF calibrator	RF concentration is stated on the vial label

ADDITIONAL EQUIPMENT
Semi-automatic biochemistry analyzer thermostable at 37°C with 630 nm filter (600 – 650 nm), 0.9% saline

STORAGE AND STABILITY
All the kit components are ready to use, and are stable up to the expiry date printed onthe label, when stored tightly closed at 2-8°C
Do not freeze the reagents, frozen reagents could change the functionality of the test. Always keep vials in vertical position, if the position is changed gently mix to dissolve the aggregates that may be present.
Reagents deterioration: Presence of particles and turbidity

PRECAUTIONS
Components from human origin have been tested and found to be negative for thepresence of HbsAg, HCV and HIV. However, handle cautiously as potentially infectious.

SAMPLES
Recommended to use fresh serum samples. However, the sample stored at 2-8°C can be tested up to 7 days or the sample stored at -20° C can be tested up to 3 months. Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.

PREPARATION
Working reagent: Swirl the latex reagent vial gently before use. Prepare the necessary amount as: 0.4 ml of activation buffer (R1) + 0.1 ml of latex reagent (R2)
RF calibrator: Ready to use. Stable up to mentioned expiry date
Calibration curve: Prepare the RF calibrator conc. in 0.9% saline by serial dilution as per the conc. stated on the calibrator vial
For example:

Std calibrator dilution	5	4	3	2	1
0.9% saline (µl)	-	200	200	200	200
RF calibrator (µl)	200	200	200	200	200
Total volume (µl)	500	200	200	200	400
Diluted calibrator curve conc.	146	73	36.5	18.25	9.125

Note: Prepare the dilution as per the volume required and conc. Stated on the vial label

SYSTEM PARAMETER

Method	Multi-standard/Fixed time
Filter	630 nm
Temperature	37 °C
Unit	IU/ml
No. of std.	5
	1) 9.125 2) 18.25 3) 36.5 4) 73 5) 146 — Diluted calibrator curve conc.
Delay time	5 secs
Read time	120 secs
Activation buffer (R1) vol	400 µl
Latex reagent (R2) vol	100 µl
Calibrator/sample vol	7 µl
Aspirate vol	400 µl
Linearity	160 IU/ml

PROCEDURE
1. Allow the reagents and samples to reach room temperature before use.
2. **Assay condition**
   Wavelength: 630 nm
   Temperature: 37 °C
   Cuvette light path: 1 cm
3. Adjust the instrument to zero with distilled water.
4. Pipette into cuvette:

Working reagent (µl)	500 (µl)
Calibrator or sample (µl	7 (µl)

5. Mix and read the absorbance after 2 mins (120 secs)

CALCULATIONS
Calculate the absorbance difference (A_2 – $A_{\text{blank reagent}}$) of each point of 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 – $A_{\text{blank reagent}}$) in the calibration curve.

REFERENCE VALUES
Normal values up to 20 IU/ml. Each laboratory should establish its own reference value

PERFORMANCE CHARACTERISTICS
1. Detection limit: Values less than 6 IU/ml may give non- reproducible results.
2. Linearity limit: Up to 160 IU/ml under described assay conditions.
3. Samples with higher concentration should be diluted 1/5 in 0.9% saline and retested again.
4. Prozone effect: No prozone effect was detected up to 800 IU/ml.

INTERFERENCES
Bilirubin (20mg/dL), hemoglobin (10g/L), lipids (10g/L), do not interfere. Other substances may interfere

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

BIBLIOGRAPHY

1. Robert W Dorner et al. Clinica Chiminca Acta 1987;167:1-21
2. Frederick Wolfe et al. Arthritis and Rheumatism 1991;34:951-960
3. Young DS. Effects of drugs on clinical laboratory test, 4th ed.AACC Press,1995.
4. Robert H Shmerling et al. The American Journal of Medicine 1991;91:528-534

PACKAGING & ORDERING INFORMATION

Catalogue No. (Product Code)	GB00080	GB00058
Pack Sizes in Tests	25	50
Activation buffer (R1) in ml	20	40
Latex reagent (R2) in ml	05	10
Calibrator in ml	0.5	0.5
IFU (Product insert) in Nos.	01	01

	Keep dry		**Store between**
IVD	**For *in vitro* Diagnostic use only**		**Consult Instruction for Use**
	Protect from sunlight		**Do not use if package is damaged**
	Caution		**Fragile**
Σ	**Pack size**	LOT	**Lot Number**
	Date of manufacturing		**Expiry**

MANUFACTURED BY:

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