RF (Rheumatoid Factor) Kit
CliniQuant
Latex Turbidimetry

Meril Diagnostics

IVD For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF RHFLIT-01	R1 RF Reagent	R2 RF Reagent	R3 RF Calibrator
Pack size	1 x 40 ml	1 x 10 ml	1 x 1 ml

INTENDED USE
This reagent is intended for quantitative determination of Rheumatoid Factor concentration in serum by latex turbidimetry .

CLINICAL SIGNIFICANCE
Rheumatoid factor is the auto-antibody directed to determinants in the Fc portion of the immunoglobulin G molecule. The presence of rheumatoid factor in serum can also indicate the occurrence of suspected autoimmune activity unrelated to rheumatoid arthritis, such as that associated with tissue or organ rejection, in such instances, RF may serve as one of several serological markers for autoimmunity.

PRINCIPLE OF THE METHOD
Latex particles coated with human gamma globulin are agglutination when mixed with samples containing RF. The agglutination causes an absorbance change, dependent upon the RF contents of the patient sample that can be quantified by comparison from a calibrator of known RF concentration.

KIT COMPONENTS
R1 - RF Reagent
R2 - RF Reagent
R3 - RF Calibrator

MATERIALS REQUIRED BUT NOT PROVIDED
Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath, controls, saline.

REAGENT PREPARATION , STORAGE & STABILITY
Reagent is ready to use. Mix reagent R2 well before processing.
Mix reagent 1 & reagent 2 in ratio of 4:1. Keep away from direct light sources.
Stability : up to expiration date on labels at 2-8°C. Do not freeze the reagent.

WARNINGS AND PRECAUTIONS
1. For *in vitro* use only.
2. This pack insert must be completely understood prior to operation. Do not modify the test procedure or substitute reagents from other manufacturers or other lots unless the reagent is stipulated as interchangeable. It is recommended to handle carefully by entitled and professionally educated person.
3. Do not pipette by mouth. Use disposable gloves while performing the assay. Wash hands thoroughly when finished.
4. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
5. Do not use reagents beyond the expiry date.
6. In case of skin contact with any of the reagents, wash thoroughly with running water.

Fresh serum : Stable for 7 days at 2 - 8°C. Do not use hemolysed or lipemic sample.

Programme Parameter for MERILYZER CliniQuant

Reading Mode	Fixed Time
Standard Conc.	lot specific
Filter - 1 (nm)	620 nm
Temperature	37 ° C
Volume (µl)	500
Delay Time (Sec)	10
Read Time (Sec)	120
Reaction Direction	Increase
Reference Low	0
Reference High	20
Linearity Limit	100

TEST PROCEDURE

Dispense	Blank	Standard	Sample
Working reagent	1ml	1ml	1ml
Distilled water	20 µl	-	-
Standard	-	20 µl	-
Sample	-	-	20 µl

Mix, incubate 10 seconds at 37°C, then record absorbance as A1. After exactly 120 seconds, record again absorbance as A2.

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RESULT CALCULATION

Serum :

RF IU/ml =A2-A1(Sample)/A2-A1(Standard) x Concentration of Standard

EXPECTED VALUES

Up to 20 IU/ml.

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal and assayed abnormal to confirm the validity of the test and assure the accuracy of patient result.

Using the recommended Calibrator or the Standard included, calibrate the assay:

a. When using a new reagent or lot
b. When QC values are out of range

PERFORMANCE CHARACTERISTICS

1.Linearity

The linearity up to 100 IU/ml.

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 2.38 IU/ml.

The limit of quantification is 7.23 IU/ml.

3. Interferences

No interference has been observed for the following

Bilirubin up to 20 mg/dl

Hemoglobin up to 500 mg/dl

Triglycerides up to 500 mg/dl

4. Precision

Intra-assay precision

	Mean	SD	CV
n = 20	IU/ml	IU/ml	%
Control L1	27.10	0.69	2.53
Control L3	71.31	1.16	1.63

Inter-assay precision

	Mean	SD	CV
n = 20	IU/ml	IU/ml	%
Control L1	26.23	1.20	4.57
Control L3	70.33	2.86	4.06

5. Methods Comparison

Comparison was done between RF Reagent (y) & reference RF Kit (x) using 20 samples gave following results:

y = 1.0463x - 0.5014 r2 = 0.9837

LIMITATIONS

Samples with values above 100IU/ml should be diluted with 0.9% saline, re-run and multiply results by dilution factor.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1.Fredrick Woffe et al. Arthritis and rheumatism 1991;34:528-534.

2. Robert W Dorner et al. Clinica Chemica Acta 1987;167;1-21.

3. Robert H Shmerling et al The American Journal of medicine 1991;

4. Vladimir Mule at al Scand J Rheumatalogy 1972;1;181-187.

5. Data on file: Meril Diagnostics.

IFU/RHFLIT01/02

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Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged