RF (Rheumatoid Factor) (2-8°C)

(TURBIDIMETRY)

CATALOGUE NUMBER	KIT SIZE (ml)
MPRRF01	1x40ml/1x10ml/1x2ml
MPRRF02	2x40ml/2x10ml/1x2ml
MPRRF03	4x40ml/4x10ml/1x2ml

Intended Use:
For *In Vitro* Diagnostic Use Only
RF Turbidimetry is intended to be used for quantitative measurement of RF in human serum or plasma.
The product is intended for use by qualified laboratory personnel only.

Clinical Significance:
Rheumatoid Factors are a group of antibodies directed to determinants in the Fc portion of the IgG molecule. Although RF are found in a number of rheumatoid disorders, such as Systemic Lupus Erythematosus and Sjorgens syndrome, we well as in non-rheumatic conditions, its central role in clinic lies its utility as an aid in the diagnosis of Rheumatoid Arthritis. A study by the American college of Rheumatology shows that 80.4% of RA patients were RF positive.

Test 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 the patient sample that can be quantified by comparison from a calibrator known RF concentration.

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
R1 – Buffer	Tris Buffer	20 mmol/l (pH 8.2)
	Preservative	
R2 – Latex Reagent	Latex particles coated with human gamma globulin & Preservative	pH 7.4
RF Calibrator	Human serum RF	Concentration stated on vial label. (NIBSC 64/002)

Precautions:
Components of 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.

Reagent Preparation and Stability:
R1: Buffer: Ready to use
R2: Latex Reagent: Ready to use
R1 and R2 are stable to the expiry date stated when stored unopened at 2-8°C. Once opened store tightly capped without contamination at 2-8°C. Do not use the reagents after the expiry date.
Exercise the normal precautions associated with the handling of laboratory reagents and dispose of carefully according to local guidelines.
RF Calibrator:
Reconstitute with 2ml of distilled water. Mix gently and incubate at room temperature for 10 minutes before use.
Calibration Curve:

Calibrator Dilution	1	2	3	4	5	6
Calibrator RF (ul)	-	25	50	100	200	400
Normal Saline (ul)	400	375	350	300	200	-
Factor	0	0.0625	0.125	0.250	0.50	1.00

Reconstituted calibrator is stable for 1 month at 2-8°C or 3 months at -20°C.

Sample / Sample Preparation / Sample Stability:
Fresh Serum. Stable for 7 days at 2-8°C or 3 months at -20°C. Samples with presence of fibrin should be centrifuged before testing. Do not use highly lipaemic or haemolysed samples.
Assay Procedure:

WAVELENGTH	650nm (600 – 650 nm)
TEMPERATURE	37°C
CUVETTE	1cm Path Length
BLANK	Distilled Water

	Blank	Calibrator / Sample
R1 - Buffer	800 µl	800 µl
R2 – Latex Reagent	200 µl	200 µl
Mix and read the absorbance (blank reagent)		
Normal Saline	7 µl	–
RF Calibrator / Sample	-	7 µl
Mix and read the absorbance after 2 minutes of sample addition.		

Calculation:
Calculate the absorbance difference (A2-Ablank reagent) for each point of the calibration curve and plot the values obtained against the RF concentration of each calibrator dilution. RF concentration in the sample is calculated by interpolation of its (A2-Ablank reagent) in the calibration curve.

Reference values:
Normal values up to 20 IU/ml. Each laboratory should establish its own reference range.

Performance Characteristics:

Linearity limit:
Up to 6 IU/ml give non-reproducible results.

Measurement Range
6-160 IU/ml, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in normal saline and retested. The linearity limit and measurement range depends on the sample to reagent ratio as well as the analyser used. It will be higher by decreasing the sample volume, although the sensitivity of the assay will be proportionally decreased.

Prozone Limit:
No prozone effect was detected up to 800 IU/ml.

Sensitivity: Δ 3.34 mA IU/ml

Precision:
The reagent has been tested for 20 days, using three different RF concentrations in a EP5 based study.

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

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 RF were assayedand the results were as follows:
$Y = 1.2042 x + 3.1344$, $r^2 = 0.91$.
The results of the performance characteristics depend on the analyser used.

Interferences:
Haemoglobin (10g/l), Bilirubin (20 mg/dl) lipaemia (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.

Application for Automated systems:
For Applications on automated systems – contact technical department.

Quality Control and Calibration Material:
It is recommended that a laboratory uses reference control sera to verify the reagent performance. Results obtained should fall within the specified ranges. If results fall outside these ranges actions should be taken in line with the laboratory's internal quality procedures.
Prestige recommend the following controls

Specific Protein Control Level 1: **QCCSPC1**
Specific Protein Control Level 2: **QCCSPC1**
Specific Protein Control Level 3: **QCCSPC1**

References:

1. Frederick Wolfe et al. Arthritis and Rheumatism 1991; 34: 951-960.
2. Robert W Dorner et al. Clinica Chimica Acta 1987; 167: 1-21
3. Robert H Shmerling et al. The American Journal of Medicine 1991; 91: 528-534.
4. Vladimir Muie 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.

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		

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