PATHOZYME DIAGNOSTICS

RF TURBILATEX

(TURBIDIMETRY METHOD)

CAT NO.: RFT

Reagent kit for quantitative estimation of Rheumatoid Factors (RF) in Serum or Plasma.

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

PRINCIPLE:

The latex particles coated with human gamma globulins are agglutinated when they react with samples that contain rheumatoid factors (RF). The latex particles agglutination is proportional to the concentration of the RF in the sample and can be measured by turbidimetry.

SPECIMEN COLLECTION:

Fresh serum or plasma. Stable for 7 days at 2-8°C or 3 months at –20°C. Samples with presence of fibrin should be centrifuged before testing. Hemolyzed or contaminated samples are not suitable for testing.

KIT PRESENTATION:

Pack Size	1 X 25 ml	1 X 50 ml
R1 - RF (Buffer Reagent)	1 X 22.5 ml	1 X 45 ml
R2 - RF (Latex Reagent)	1 X 2.5 ml	1 X 05 ml
RF Calibrator	1 Vial	1 Vial

WORKING REAGENT PREPARATION:

R1 – RF (Buffer Reagent) & R2 – RF (Latex Reagent) are Ready To Use.

REAGENT STORAGE AND STABILITY:

All reagents are stable at 2-8°C until the expiry date stated on the label.

CALIBRATION CURVE:

Prepare dilutions of the Calibrator using Normal Saline (0.9gm% NaCl) as diluent. Multiply the concentration of the Calibrator by the corresponding factor indicated in the table below to obtain the RF concentration of each point of the curve.

	A	B	C	D	E
Dilution Factor	1	2	4	8	16	Blank
Saline (µl)	---	50	50	50	50	--
Calibrator (µl)	100	50	50	50	50	--
Factor	0	0.500	0.250	0.125	0.0625	--

For Dilution factor 1: calibrator as it is (A)
For Dilution factor 2: 50 µl of (A) and 50 µl (B)
For Dilution factor 4: 50 µl of (B) and 50 µl (C)
For Dilution factor 8: 50 µl of (C) and 50 µl (D)
For Dilution factor 16: 50 µl of (A) and 50 µl (E)
Normal Saline = 0.9gm% NaCl

ONE POINT CALIBRATION (linear range up to 100 IU/ mL):

Prepare a RF calibrator dilution: 33µl RF Calibrator + 66µl Normal Saline (0.9 gm% NaCl). Calculate the standard Concentration.

Conc. of diluted Calibrator = Conc. of Calibrator /3

ASSAY PARAMETERS:

Reaction	: Fix Time	Sample Volume	: 20 µl
Wavelength	: 630nm	R1 + R2 Volume	: 900 µl + 100 µl
Flow Cell Temp.	: 37°C	Calibrator Conc.	: As On Vial
Initial Delay	: 5 Sec	Reaction Slope	: Increasing
Interval Time	: 120 Sec	Zero Setting	: Dist. Water
Read Time	: 120 Sec	Linearity	: 120
No. of Reading	: 01	Unit	: IU/ml

PROCEDURE:

Pipette into TT	Calibrator	Test
R1 - RF (Buffer Reagent)	900 µl	900 µl
RF Calibrator	20 µl	--
Sample (Test)	--	20 µl
R2 - RF (Latex Reagent)	100 µl	100 µl

Mix & aspirate immediately and read difference in absorbance between 5 seconds (AT_1) and 120 seconds (AT_2) for Calibrator and Test at 630 nm.

CALCULATION:

$$\text{RF (IU/ml)} = \frac{\Delta\text{Abs of Test X Calibrator Conc.}}{\Delta\text{Abs of Calibrator}}$$

Where $\Delta Abs = (AT_1) - (AT_2)$

The absorbance 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 absorbance in the calibration curve.

NORMAL VALUES:

Up to 18 IU/ml
Each laboratory should establish its own reference range.

LINEARITY:

This method is linear up to **120 IU/ml**. For values above 120 IU/ml, dilute the sample suitably with 0.9 % saline, and repeat the assay. Apply correction due to dilution to arrive at a final result.

Detection limit: Values less than 5 IU/ml give non reproducible results.
Analytical Sensitivity: 3.0 mA / IU/ml
Prozone Effect: No Prozone effect up to 800 IU/ml.

IFU No.: 065/91 | Rev. No.: 00/120723

Expiry Date | IVD In-Vitro Diagnostics Use | Storage | Mfg. Date | LOT Batch Number | REF Catalogue Number | See Package Insert

PATHOZYME DIAGNOSTICS
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Precision:

Intra – Assay

The realization of 20 determinations of the same sample at the same day showed a Coefficient of Variation (CV) of 4.12%.

Intrer – Assay

The realization of 10 determinations of the same sample at different days showed a Coefficient of Variation (CV) of 1.18%.

Accuracy: Results obtained using this reagent (y) was compared to those obtained using a commercial reagent (x) with similar characteristics. 56 samples of different concentrations of RF were assayed. The correction coefficient (r) was 0.93 and the regression equation y = 1.1982x + 3.1284.

The results of the performance characteristics depend on the analyzer and different commercial reagent.

INTERFERENCES:

Bilirubin (20 mg/dL), Hemoglobin (40 g/L) and Lipemia (10 g/L) do not interfere. Other substances may interfere.

NOTES:

1. Multipoint calibration gives more accurate result than one point calibration.
2. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.
3. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meet the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact to the distributor for any question on the application method.
4. The linearity limit 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.

REFERENCES:

1. Sager D, Wernick RM, Davey MP. *Laboratory Medicine* 23: 15 (1992).
2. Moore TL, Dorner RW. *Clinical Biochem* 26: 75 (1993).
3. Price CP, Spencer K, Whicher J. *Ann Clin Biochem* 20: 1 (1983).

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