RF
(Rheumatoid Factor)
Immunoturbidity Method

INTENDED USE:

The RF - Immunoturbidity method is a turbidimetric test for the quantitative determination of RF in human serum or plasma.

INTRODUCTION:

Rheumatoid Factor (RF) intended for *in-vitro* quantitative determination of Rheumatoid Factor in human serum or plasma. Rheumatoid Factors (RF) are heterogenous group of high molecular weight auto - antibodies of immunoglobulin isotypes lgM, lgA, lgG and lgE. They are produced by plasma cells present at sites of issue injury, and may play a role in the regulation of humoral and cellular Immunity and protection against invading microorganisms though the exact functional RF remains unclear. Studies have shown that both environmental and genetic factors can affect the synthesis of RF. RF levels are often elevated in patients with rheumatoid arthritis and Sjogren's syndrome and could also rise in scleroderma, dermatomyositis, waldenstrom's disease.

PRINCIPLE:

The reagent consists of a suspension of latex particles of homogeneous size sensitized with anti-RF, capable of aggregation in the presence of RF. This aggregation process produces an increase in the size of the latex particles which in turn produces an increase in the absorbance of the system.

KIT CONTENTS:

Reagent 1 : RF Buffer.

Reagent 2 : RF Latex.

Reagent 3 : RF Calibrator.

Product Insert

PREPARATION OF WORKING REAGENT:

Working reagent preparation mix gently 4 part of Reagent-1 (RF Buffer) with 1 Part of Reagent-2 (RF Latex) and avoid foaming.

Stability of working reagent is 4 days at 2-8°C.

STORAGE AND STABILITY:

The reagents when stored at 2-8°C are stable up to expiry date mentioned on the label. The reagent is stable for 10 days onboard the analyser at 2-10°C. Protect from light and avoid contamination.

SPECIMEN COLLECTION AND STORAGE:

Fresh sera stored at 2-8°C for no longer than 48 hours. It is necessary to freeze the sample when the assay is to be carried out after that period of the time. Discard contaminated or haemolyzed sera.

PRECAUTIONS:

1. Storage conditions as mentioned on the kit to be adhered.
2. Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
3. Before the assay bring all the regents to room temperature.
4. After use store the kit contents immediately at 2- 8°C.
5. Avoid contamination of the reagent during assay process.
6. Use clean glassware free from dust or debris.

PLOTTING OF MULTI-POINT CURVE:

The Immunoturbidity RF is based on Non-Liner Reactions, hence, it is strongly recommended to run multi-standard mode to plot the multi-curve to have better accuracy and precise result.

Serial Dilution step

Tube	1st	2nd	3rd	4th	5th
Calibrator	100 µl	50 µl from 1st Tube	50 µl from 2st Tube	50 µl from 3rd Tube	50 µl from 4th Tube
Normal Saline	0	50 µl	50 µl	50 µl	50 µl
Ratio of Dillution	Neat	1/2	1/4	1/8	1/16

PROCEDURE (Automated):

Refer to specific instrument application instructions.

TEST PROCEDURE (Manual):

Wavelength : 630 nm

Temperature : 37°C

Cuvette : 1 cm

Pipette into clean dry test tubes labelled Calibrator (C) and Test (T) as follows:

Reagent	Calibrator (C)	Test (T)
Working Reagent	1000 µl	1000 µl
Calibrator	10 µl	—
Sample	—	10 µl

Mix well, after about 10 sec. (37°C) read the absorbance A1 of the test (T) and calibrator (C) against air or water. After exactly 120 secs. read the absorbance A2 of the test (T) and Calibrator (C). Calculate ΔA/min. (A2- A1) for the test and calibrator.

CALCULATION:

RF concentration (IU/ml) = ΔA(T) / ΔA (C) x calibrator concentration

NORMAL VALUES:

Upto 20 IU/ml

**It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL:

To ensure adequate quality control, each run should include assayed normal and abnormal controls. If commercial controls are not available it is recommended that known value samples be aliquoted, frozen and used as controls.

PERFORMANCE CHARACTERISTICS:

1. **Sensitivity / Limit of Quantitation:** 2 IU/ml
2. **Linearity :** up to 150 IU/ml.
   Samples that give higher concentration should be diluted in saline Nacl 0.9% (1-4) and the final result have to be multiplied by 5.
3. **Specificity /Interferences**
   No interference was observed by Bilirubin (260 umol/l), Haemoglobin (10 g/L). Triglycerides (50 g/L). ASO (400 Ul/ml). Haparin (12mg/dl). CRP (70mg/L). Other drugs and substances may interfere in the test.

REFERENCE:

1.) Anderson, B. Antigens associated with Rheumatoid Artritis, in Natelson, S. Pesce, A.J., Dietz, A.A. eds. Current Topics in Clinical Chemistry, V3: Clinical Immunochemistry. (1979) AA.CC. 176-190.

2.) Johnson, P. M., Faulk, W.P., (1976). Clin. Immunol. Immunopathol., 6,414-440 Taborn, J.D., Walker, S.E., (1979) Lab. Med., 10,392-395.

3.) Witherigton, R.H., Teitsson, I., Valdimarsson, H., Seifert, M.H.(1994). Ann. Rheum. Dis., 42.679-685

4.) Winkles, J.W., Lunec, J. Gray, L. (1989). Clin Chem. 35 (2), 303-307 ed. AACC Press, 2000.

APPLICATIONS:

Input parameter for semiauto/auto analyzers are given below:-

Method	Fixed Time (2-Point)
Wavelenght	630 nm
Zero Setting	Distilled Water
Temperature Setting	37°C
Incubation Temperature	37°C
Incubation Time	—
Delay Time	10 secs
Read Time	120 secs
No. of Reading	2
Interval Time	—
Sample Volume	10 µl
Reagent Volume	1000 µl
Concentration	Refer Calibrator vial
Units	IU/ml
Factor	—
Reaction Slope	Increasing
Linearity	150 IU/ml

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