AGD

CliniPak

RF (Turbilatex Method)

Code	Pack Size
AGDSP-RF20	R1- 1X16ml; R2-1X4ml

INTENDED USE

RF is a reagent for in vitro quantitative determination of Rheumatoid Factor concentration In Human Serum.

CLINICAL SIGNIFICANCE

Rheumatoid factors (RF) are heterogenous group of high molecular weight auto antibodies of immunoglobulin isotypes IgM,IgA,IgG, IgE.They are produced by plasma cells present at sites of tissue injury, and may play a role in regulation of humoral and cellular immunity and protection against evading micro organisms.

Increased Levels: are observed in Rheumatoid Arthritis and Sjogren's syndrome, scleroderma, dematomyositis Waldenstrom's disease, sarcoidosis & systemic lupus erythematosus.

PRINCIPLE

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

REAGENT COMPOSITION

R1-Buffer	Glycine buffer,pH 8.1,Sodium Azide 0.9g/L
R2 - Latex Reagent	Suspension of Latex particles sensitized with anti-human RF,Sodium Azide 0.9g/L

WORKING REAGENTS

Ready to use, Two Reagents system.

REAGENT STORAGE AND STABILITY

All reagents are supplied ready to use and stable until expiration date stated on label when stored in refrigerator at 2-8°C.

SAMPLE

Recommended Sample: Fresh sera or stored at 2-8°C for no longer than 48 hours.It is necessary to freeze the sample if the assay is to be carried out after that notice of period.

BASIC PARAMETER

SHORT NAME	RF
NAME	RF
ASSAY	Two point
MAIN WAVE	630nm
SUB WAVE	0
DECIMAL	2
UNIT	IU/ml
R1 VOLUME	240µl
INCUBATION	60 secs
R2 VOLUME	60 µl
SAMPLE VOLUME	6.0µl
INCUBATION	0 secs
REACTION TIME (DELAY)	10 sec
CHECK TIME (READ)	120 sec
LINEAR RANGE	150 IU/ml
SUBSTRATE SHORTAGE	>2.0
ABSORBANCE RANGE	2.5
LINEARITY LIMIT	40
DILUTION RATIO	6
SAMPLE VOLUME	50
CALIBRATION	Spline (5 point)

*Enter calibrator value as per the lot of calibrator and method.

CALIBRATION

Calibration type : Spline (5 points)
Prepare the dilutions of calibrators in given below manner for calibration.
Serial dilution step :

	1st	2nd	3rd	4th	5th
Calibrator	100 µl	50µl from 1st tube	50µl from 2nd tube	50µl from 3rd tube	50µl from 4th tube
Normal Saline	0	50µl	50µl	50µl	50µl
Ratio Of Dilution	Neat	1/2	1/4	1/8	1/16

PERFORMANCE CHARACTERISTIC

SENSITIVITY: 2 IU/mL

LINEARITY : Reagent is linear up to 150 IU/ml. For Higher values,dilute sample with DI water & multiply result by dilution factor.

INTERFERENCES: No Interferences up to Hemoglobin (10 g/L), Triglyceride (50g/L), ASO (IU/ml), Heparin (12 mg/dl), CRP (70 mg/L) was observed. Other drugs and substances may interfere In the tests.

CALCULATIONS

RF concentration = Δ A (T) / Δ A(C)* Calibrator concentration

REFERENCE NORMAL VALUE

Serum- Up to 20 IU/ml

QUALITY CONTROL

To ensure adequate quality control,it is recommended that the laboratory should use a normal and abnormal commercial reference control serum.The quality control material is used to check the function of reagents and the machine together.

LIMITATIONS & PRECAUTIONS

- Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
- Storage condition as mentioned on the kit to be adhered.
- Before the assay bring all the reagents to the room temperature.
- Avoid contamination of the reagent during assay process.
- Use clean glassware free from dust and debris.
- Reagent to sample ratio as mentioned above must be strictly adhered, as any changes it affects the factor and result.
- In case reagent comes in contact with eyes,immediately rinse with plenty of water and seek medical advice.

REFERENCES

1. Anderson, B., Antigens associated with Rheumatoid Artritis, in Natelson, S., Peace, 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. (1984).Ann. Rheum. Dis., 42,679-685.

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EU REP

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