AGD TurbiPak RF

(Turbilatex Method)

Code: AGD-RF50

Pack size:R1- 40ml ;R2-10ml

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.

REAGENTS IN THE PACK / KIT

R1 - RF Buffer	1 x 40 ml
R2 - RF Latex	1 x 10 ml
RF Calibrator	1 vial

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 REAGENT

Prepare working reagent by mixing 4 parts R1-RF &1 Part of R2-RF.

Stability of working reagent is:10 days at 2-8°C

REAGENTS

Ready to use, Two Reagents system.

SHELF LIFE

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 PARAMETERS

Reaction Type	Two point
Blank/Zero Setting	NA
Wavelength	630nm
Reaction Slope	Increasing
Light Path	1 cm
Reaction Temperature	37°C
Unit	IU/ml
Reagent Volume	1000µl
Sample Volume	10µl
Delay time (sec)	10 sec
Read Time (sec)	120 sec
Linearity	200 IU/ml
Calibrator Concentration	Refer concentration on vial
Calibration Type	Spline (5 points)

*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

PROCEDURE

Assay can be performed with use of separate R1-RF & R2-RF Reagents.

Working Reagent	1000µl
Bring up the reagent at room temperature.	
Sample	10µl

CALCULATIONS

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

Note: When result is displayed as ** please check calibration table.

- **When sample OD is higher than the highest calibrator OD dilute the sample.**
- **When the sample OD is lower than lowest calibrator OD then result for sample should consider as zero.**

PERFORMANCE CHARACTERISTIC

- **LINEARITY :**

Reagent is linear up to 200 IU/ml.
For Higher values,dilute sample with normal saline & 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.

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. Please note that the quality control material is used to check the function of reagents and the machine together.

LIMITATIONS PRECAUTIONS

- Storage conditions as mentioned on the kit to be adhered.
- Do not freeze or expose the reagents to higher temperature as it may affect the performance of the kit.
- 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.

REFERENCES

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. (1984).Ann. Rheum. Dis., 42,679-685.

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