RF - TURBILATEX

METHOD – LATEX - TURBIDIMETRY
PRODUCT CODE – LR01

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for quantitative determination of Rheumatoid Factors by using Latex Turbidimetric method.

CLINICAL 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). A study of the 'American College of Rheumatology', shows that the 80.4% RA patients were RF positive.

PRINCIPLE

The RF-Turbilatex is a quantitative turbidimetric test for the measurement of RF in human serum or plasma. Latex particles coated with human gammaglobulin are agglutinated when mixed with samples containing RF. The agglutination causes an absorbance change, dependent upon the RF contents of sample that can be quantified by comparison from a calibrator of known RF concentration.

REAGENTS

Diluent (R1) - 1 x 40 ml.
Latex Reagent (R2) - 1 x 10 ml.
RF-CAL - 1 vial. (Lyophilized. Add DW as per vial label before use).

PREPARATION, STORAGE & STABILITY

Mix the reagent R1 and R2 in the ratio of 4:1 respectively to prepare the desired volume of working reagent prior to use. Do not shake vigorously. Working reagent is stable for 1 month at 2-8 ^{0}C. Do not freeze. Frozen latex and diluent could change the functionality of the test. RF calibrator is stable for 1 month at 2-8 ^{0}C or 3 months at -20 ^{0}C after reconstitution. The reagent kit should be stored at 2-8 ^{0}C and is stable till the expiry date indicated on the label.

TEST PARAMETERS

Name	RF Turbi	Reagent Volume	1000 µl
Reaction Type	Kinetic (↑)	Sample Volume	7 µl
Wavelength Primary	650 nm	Incubation Temp.	37 °C
Flow Cell Temp.	37 °C	Delay Time	10 sec.
Blank setting	D/W	Read Time	120 sec.
Blank Abs Limit	-	Factor	-
Linearity	160 IU/ml	Calibrator Conc.	On Vial

ASSAY PROCEDURE

	Test
Reagent	1000 µl
Serum / Plasma	7 µl
Mix the reagent and sample in the above mentioned ratio	
Aspirate the reaction mixture into the flowcell and record the absorbance at 10th and 130th sec.	

CALCULATION

$$\text{RF (IU/mL)} = \frac{\Delta \text{ Abs. of sample x Conc. of calibrator.}}{\Delta \text{ Abs. of calibrator.}}$$

SPECIMEN COLLECTION & PRESERVATION

Fresh serum or plasma should be used for testing. Serum/plasma is stable for 7 days at 2-8 ^{0}C or 3 months at -20 ^{0}C. Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipaemic samples.

REFERENCE VALUES FOR NORMAL PEOPLE

Adults: Upto 20 IU/ml.

PERFORMANCE CHARACTERISTICS

Values less than 6 IU/mL give non-reproducible results.
Measurement range is from 6-160 IU/mL, under the described assay conditions. Samples with higher concentrations should be diluted 1/5th in normal saline and retested again. The linearity limit and measurement range depends on the sample to 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.
No prozone effect was detected up to 800 IU/mL.
Sensitivity: Δ 3.34 mA. IU/mL.

QUALITY CONTROL

Inclusion of a normal value and abnormal value control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for RF. We recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

INTERFERENCES

Bilirubin (20 mg/dl), hemoglobin (10 g/L), lipaemia (10 g/L), do not interfere. Other substances may interfere.

SYMBOLS: Read Instruction for use | IVD In Vitro Diagnostic Use Only | Manufactured by | Expiry Date | Storage Temperature

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