Ana-Chek® RF - TURBILATEX

METHOD – IMMUNOTURBIDIMETRY
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 Ana-Chek® RF-Turbilatex is a quantitative turbidimetric test for the measurement of RF in human serum or plasma. Latex particles coated with human gamma globulin 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.

KIT COMPONENTS

Diluent (R1)	1 x 40 ml.
Latex Reagent (R2)	1 x 10 ml.
RF Calibrator	1 vial

REAGENT 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. Swirl the latex reagent gently before use. Do not shake vigorously. Working reagent is stable for 1 month at 2-8 ^{0}C. Do not freeze the reagent, Frozen latex and diluent could change the functionality of the test. 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	Two point Kinetic	Sample Volume	10 µl
Wavelength Primary	650 nm	Incubation Temp.	37 °C
Flow Cell Temp.	37 °C	Delay Time	10 sec.
Blank setting	Distilled Water	Read Time	120 sec.
Linearity	160 IU/mL	Calibrator Conc.	On Vial

PRECAUTIONS & HANDELING

For in vitro diagnostic use only. DO NOT pipette by mouth. Avoid contact with skin and eyes. If spilt, thoroughly, wash affected areas with water. For further information, consult the RF Turbilatex Reagent Material Safety Data Sheet. Reagent contains Sodium Azide as a preservative. This may react with copper or lead plumbing to form explosive metal azides. Upon disposal, flush with large amounts of water to prevent azide build up. The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. Don't freeze the reagent. Do not shake the reagent vigorously. Do not use the reagent after the expiration date printed on the kit. Handle the calibrator cautiously as potentially infectious material.

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls.

SPECIMEN COLLECTION & PRESERVATION

Fresh serum 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 hemolyzed or lipemic samples.

ASSAY PROCEDURE

	Calibrator	Test
Reagent	1000 µl	1000 µl
Calibrator	10 µl	NA
Sample	NA	10 µl
Aspirate the reaction mixture into the flow cell and record the absorbance at 10th and 130th sec.		

CALCULATION

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

REFERENCE VALUES FOR NORMAL PEOPLE

Adults: Upto 20 IU/mL.

Note: We recommend each laboratory to establish their own reference range.

PERFORMANCE CHARACTERISTICS

1. Linearity limit is upto 160 IU/mL, under the described assay conditions. Samples with higher concentrations should be diluted 1/5th in normal saline and retested. 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.
2. No prozone effect was detected up to 800 IU/mL.
3. Sensitivity: 6 IU/mL.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry 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.

BIBLIOGRAPHY

1. Vladimir Muié et al. Scand J Rheumatology 1972; 1: 181 – 187.
2. Frederick Wolfe et al. Arthritis and Rheumatism 1991; 34: 951-960.
3. Robert H Shmerling et al. The American Journal of Medicine 1991; 91: 528 – 534.
4. Robert W Dorner et al. Clinica Chimica Acta 1987; 167: 1- 21.
5. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995
6. Paul R et al. Clin Chem 1979; 25/11: 1909 – 1914.

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485: 2016
GMP
CE