Turbilife™ Rheumatoid Factor (Immunoturbidimetry)

CLINICAL SIGNIFICANCE

Rheumatoid factors are a heterogeneous group of autoantibodies directed against the antigenic determinants on the Fc-region of IgG molecules. They are important in the diagnosis of rheumatoid arthritis, but can also be found in other inflammatory-rheumatic diseases and in various non-rheumatic diseases. They are also found in clinically healthy persons over 60 years of age. Despite these restrictions, the detection of rheumatoid factors is a diagnostic criterion of the American College of Rheumatology for classifying rheumatoid arthritis. These autoantibodies occur in all the immunoglobulin classes, although the usual analytical methods are limited to the detection of rheumatoid factors of the IgM type.

The classic procedure for the quantitation of rheumatoid factors is by agglutination with IgG-sensitized sheep erythrocytes or latex particles. Particular problems of these semi-quantitative methods are the poor between-laboratory precision and reproducibility, together with standardization difficulties. For these reasons, new assay methods such as nephelometry, turbidimetry, enzyme-immunoassays and radioimmunoassay have been developed. This kit is based on the immunological agglutination principle with enhancement of the reaction by latex particles.

TEST PRINCIPLE

Latex bound heat inactivated IgG (antigen) reacts with the RF antibodies in the sample to form antigen-antibody complexes, following agglutination and is measured turbidimetrically.

NORMAL RANGE

<30 IU / ml

It is recommended that laboratories should establish their own normal range.

KIT CONTENTS

	Code No. KRFT1 25T	Code No. KRFT2 50T
Reagent 1. Buffer solution	20ml	40ml
Reagent 2. Latex reagent	5ml	10ml
Reagent 3. Calibrator	1 vial	1 vial

SPECIMEN

Serum

WORKING REAGENT PREPARATION

All the reagents are ready to use

CALIBRATION

A six point calibration is recommended making serial dilutions of the calibrator, with normal saline. Multiply the concentration of the calibrator by the corresponding factor indicated in the table below to obtain the RF concentration of each point of the curve.

Dilution	1	2	3	4	5	6
Calibrator (µl)	--	10	20	40	60	80
Saline (µl)	80	70	60	40	20	--
Factor	0.0	0.125	0.25	0.5	0.75	1.0

PROCEDURE

Pipette into test tubes as follows:

	Blank	Test
Specimen	7µl (D.water)	7µl
R1 Buffer	800 µl	800 µl
R2 Latex	200 µl	200 µl

Read absorbance A1 after 10 seconds and A2 after 120 seconds at 620nm (600-650) for blank and test.

CALCULATIONS

$$\Delta A = [(A) \text{ sample or calibrator}] - [(A) \text{ blank}]$$

The concentration of RF in patient sera has to be calculated from ΔA using mathematical function as log it / log or can be read from a graph using values of 6 levels of standards in the concentration of 0 to 160 IU / ml RF. For zero value is recommended to use saline solution (0.9%).

QUALITY CONTROL

It is recommended to include Immunology Quality Control Serum (Level 1 & II) with each assay batch to verify the performance of the procedure. Failure to obtain the proper range of values in the assay of control sera may indicate reagent deterioration, instrument malfunction or procedural errors.

SYSTEM PARAMETERS

Mode	:	Fixed Time Kinetic
Wave length	:	620nm (600-650)
Delay time	:	10 seconds
Measuring time	:	120 seconds
Flow Cell Temp	:	37^0C
Reagent volume	:	R1: 800 µl + R2: 200 µl
Sample volume	:	7µl
Low normal	:	0
High normal	:	30
Calb. Conc.	:	Refer calibrator vial
Units	:	IU / ml
Blank	:	Reagent

NOTES

Haemolyzed or Lipeamic samples are not suitable for testing.
Centrifuge samples containing precipitate before performing.
No interference for hemoglobin – 1000 mg / dl, sodium citrate – 1000 mg / dl, Heparin – 50 mg / dl, Bilirubin – 20 mg / dl, Triglycerides – 2500 mg / dl.

LINEARITY

Linearity of the kit is 2 - 160 IU / ml.

BIBLIOGRAPHY

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