The Rheumatoid Factor Turbidimetric Immunoassay Kit

Catalogue number: 51B010

For the quantitative determination of Rheumatoid Factor in human serum and plasma

This package insert must be read in its entirety before using this product
Use only the current version of product data sheet enclosed with the kit

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FOR RESEARCH USE ONLY
NOT FOR USE IN DIAGNOSTIC PROCEDURES

Version: 1.1

TABLE OF CONTENT

PACKING SPECIFICATION

Cat. No.	Size	Approximately tests
51B010-05	R1: 15ml, R2: 5ml	100
51B010-10	R1: 30ml, R2: 10ml	200
51B010-20	R1: 60ml, R2: 20ml	400
51B010-50	R1: 150ml, R2: 50ml	1000
51B010-100	R1: 300ml, R2: 100ml	2000

INTRODUCTION

Rheumatoid Factor (RF) is an abnormal antibody made by human immune system which can bind to other healthy antibodies and destroy the function of patients' normal immune system. High levels of rheumatoid factor in the plasma are most often related to autoimmune diseases, such as rheumatoid arthritis and Sjogren's syndrome. Therefore, RF is a more accurate and sensitive biomarker for diagnosing autoimmune diseases. In clinical research, the increase in serum secretion of RF has not be only indicated rheumatoid arthritis and Sjogren's syndrome, but also associated with a number of other diseases, e.g. Cancer, Chronic infections, Inflammatory lung diseases, Mixed connective tissue disease, Systemic lupus erythematosus. Thus, monitoring RF levels has a great clinic significance for general health screening, especially in older age group. The reference value of the RF in plasma is < 14 IU/ml.

PRINCIPLE OF THE ASSAY

This assay is a turbidimetric immunoassay for the quantitative measurement of rheumatoid factor in human serum and plasma. A standard or sample is added into a cuvette and mixed with the reaction buffer R1. After a short incubation, the test reagent R2, which is a suspension of microparticles coated with normal human IgG antibodies, of which Fc portion can be highly specific recognized by rheumatoid factor, is added into the cuvette and mixed. The presence of rheumatoid factor in the standard or sample causes the immune-particles to aggregate. The extent to which the microparticles aggregate is quantified by the amount of light scattering measured as absorbance by a chemistry analyzer. The concentration of rheumatoid factor in unknown samples can be interpolated from a reference curve using the standards provided.

REAGENTS SUPPLIED

R1 – Reaction buffer, a ready-to-use buffer solution containing salt, polyether compound and preservative

R2 – Test reagent, a ready-to-use suspension of polymer microparticles coated with normal human IgG polyclonal antibodies in storage buffer

OTHER MATERIALS REQUIRED

1. Clinical chemistry analyzer
2. rheumatoid factor Calibrator (provided separately, Cat. #51B010-S1)
3. rheumatoid factor Control (optional, provided separately, Cat. #51B010-C1)
4. Deionized water
5. Analyzer-specific reagent containers for R1 and R2

STORAGE

The kit should be stored at 2-8°C upon receipt. Once opened, the reagents may be stored at 2-8°C for up to 4 weeks.

SAMLE HANDLING

This kit can be used to determine rheumatoid factor in human serum and plasma samples. Blood specimens should be collected aseptically into appropriate tubes. Plasma should be prepared by standard techniques for laboratory testing. The prepared specimens should be stored in closed vessels. If the assay cannot be performed within 24 hours or specimens are to be shipped, the specimens should be frozen at −20°C or below. For long- term storage of specimens, −70°C or below is recommended. To avoid freeze-thaw cycles, specimens should be aliquoted. Do not use hemolyzed, hyperlipemic, heat-treated or contaminated specimens. No dilution of the sample is required in this assay.

ASSAY PROCEDURE

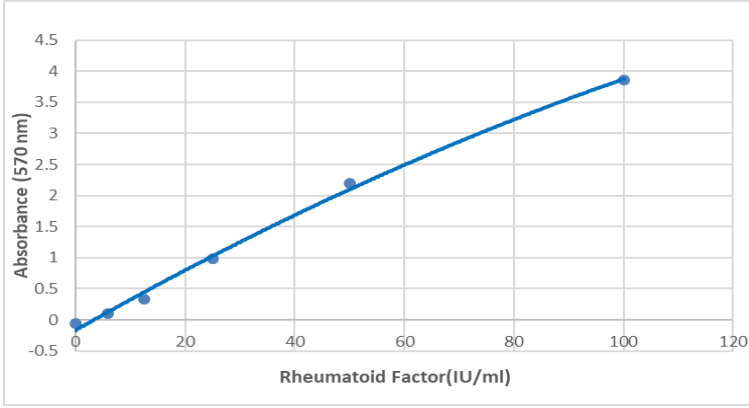
Assay procedures may vary depending on the automated chemistry analyzer to be used. A general example of assay procedures is stated as follow:

1. Dispense 150µl of R1 into a clean cuvette
2. Add 3µl of serum or plasma sample or rheumatoid factor calibrator and incubate at 37˚C for 5 minutes
3. Further add 50µl of R2
4. Read change of absorbance at 570 nm for 8 minutes after the addition of R2
5. Calculate the concentration of Rheumatoid factor in unknown sample by interpolation from a reference curve using the standards provided

TYPICAL STANDARD CURVE

The following standard curve is provided for demonstration only. A standard curve should be generated for each assay.

Rheumatoid factor (IU/ml)	Absorbance (570 nm)
0	-0.052
6	0.105
12.5	0.326
25	0.977
50	2.191
100	3.856



CALCULATION

1. Subtract the absorbance of the blank from that of standards and samples.
2. Generate a standard curve by plotting the absorbance obtained (y- axis) against rheumatoid factor concentrations (x-axis). The best fit line can be generated with any curve-fitting software by regression analysis. 4-parameter curve fitting can be used for calculation.
3. Determine rheumatoid factor concentration of samples from standard curve.

ASSAY CHARACTERISTICS

A. Sensitivity

The sensitivity is defined as the lower limit of detection and is estimated as the mean of the blank sample plus three times the SD obtained from the blank sample. The sensitivity of rheumatoid factor assay is 1 IU/ml.

B. Precision

The precision of the rheumatoid factor assay is <5% CV. two samples consisting of two different levels of international standard controls were assayed 20 times separately.

Sample	Mean Rheumatoid factor (IU/ml)	SD (IU/ml)	CV
ISC 1	49.98	1.81	3.63%
ISC 2	8.85	0.157	1.78%

C. Linearity

The rheumatoid factor assay is linear between 1 IU/ml to 100 IU/ml.

D. Interference

No interference was detected with hemoglobin up to 5g/L, conjugated bilirubin up to 300 mg/L, free bilirubin up to 300 mg/L, and up to 5g/L lipid emulsion.