Bioway Chemistry Reagent Series
Rheumatoid Factor Reagent Kit

Detection of Rheumatoid Factor in Human Serum on Chemistry Analyzers

Cat. No. R049K11 ***Rheumatoid Factor Reagent Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

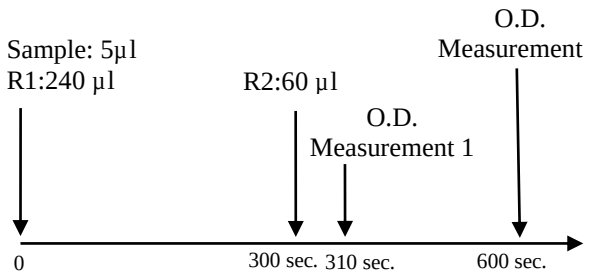

Table 1: Instrument Parameters*

Calibration method	6 point non-linear	Slope of reaction	increase
Wavelength	700nm	Sample volume	5 µl
Test method	2 point end	R1 volume	240 µl
Reaction temperature	37℃	R2 volume	60 µl

*Refer to Figure 1 and the package insert for detail

INTENDED USE

Bioway Chemistry Reagent Series **Rheumatoid Factor Reagent Kit** (the Kit) is a latex-enhanced immunoturbidimetric assay intended for *in vitro* quantitative detection of rheumatoid factor in human blood on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Rheumatoid Factors (RF) are heterogeneous group of high molecular weight auto-antibodies of immunoglobulin isotypes IgM, IgA, IgG, and IgE. They are produced by plasma cells present at sites of issue injury, and may play a role in the regulation of humoral and cellular immunity and protection against invading microorganisms though the exact function of RF remains unclear. Studies have shown that both environmental and genetic factors can affect the synthesis of RF. RF levels are often elevated in patients with rheumatoid arthritis and Sjogren's syndrome, and could also rise in scleroderma, dematomyositis, Waldenstrom's disease, sarcoidosis, and systemic lupus erythematosus.

TEST PRINCIPLES

The Kit utilizes latex-enhanced immunoturbidimetry to measure the RF level in human serum or plasma. During the test, RF in the sample binds with the specific human anti-RF gamma-globulin that is coated on latex particles to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry analyzer. The change in absorbance is proportional to the level of RF in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

MATERIALS PROVIDED

Reagents:

R1	Buffer solution, sodium azide < 0.1%
R2	latex particles coated with human gamma-globulin, sodium azide < 0.1%

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer.
2. RF calibrator set (available for purchase) and control set (commercially available).

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8℃. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. R1 and R2 reagents are stable for 1 month at 2-8℃ after opening.

PRECAUTIONS

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
5. Reagents contain less than 0.1% sodium azide as preservative; avoid contact with skin and eyes, flush with copious amounts of water when disposing.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect serum samples.
It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at 2- 4° C for up to 3 days or at -20° C for up to 1 months. Avoid repeated freezing and thawing.

TEST PROCEDURE (see Figure 1)

No pretreatment required for reagents and samples.

Calibration: 6 level calibrator set available for purchase. Recommend using Bioway calibrators for optimal results. Use multi-point non-linear calibration method.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 5 µl of sample and 240 µl of R1; mix well and incubate at 37℃ for 300 seconds.
2. Add 60 µl of R2, mix well and incubate at 37℃ for 10 seconds.
3. Take optical density measurement OD 1.
4. Take optical density measurement OD 2 at 600 seconds.
5. Calculate ΔOD = OD 2 – OD 1

RESULT

The RF value can be obtained by using the calculated ΔOD to find the corresponding value on a calibration curve prepared with known values.

EXPECTED VALUES

<30 IU/mL, as determined by previous studies.
It is recommended for each laboratory to establish its own expected values. RF levels can be influenced by hereditary factors and vary with ethnic population.

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QUALITY CONTROL

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. Hemolysis samples may cause inconsistent results.
3. The test result from the Kit should not be used as the only basis for definite diagnosis.

PERFORMANCE CHARACTERISTICS

Linearity: 6 – 160 IU/mL (R≥0.990)

Precision: Within Run: CV≤6%;
Run-to-Run: CV≤10%

Interference: no interference detected for: Bilirubin (60 mg/dL), and hemoglobin (1000 mg/dL).

Reagent Blank Absorbance: at 700nm wavelength and 10 mm optical diameter, O.D. ≤ 1.60.

REFERENCES

1. Ritchie, RF (ed). Serum Proteins in Clinical Medicine, Volume 1 Laboratory Section. Scarborough, ME: Foundation for Blood Research; 11.06.02-1; 1996.
2. Ritchie, RF (ed). Serum Proteins in Clinical Medicine, Volume 1 Laboratory Section. Scarborough, ME: Foundation forBlood Research; 11.06.02-2; 1996.
3. Tietz NW, Pruden E, McPherson RA, Fuhrman, SA (eds). Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia, PA:WB Saunders Co; 544-545; 1995.

Not Intended for Sale in the United States.

Pointe Biotech (Nanjing) Co., Ltd.

No.85,Xingmin South Road, Jiang Ning District, Nanjing,P.R.China 211100
Tel:86-25-52425019,
Fax:86-25-52424836
info@biowaydx.com