RHEUMATOID FACTOR (RF)

LATEX-ENHANCED IMMUNOTURBIDIMETRIC ASSAY FOR SERUM RHEUMATOID FACTOR
RX SERIES

INTENDED USE

A RF test system is a device intended for the quantitative *in vitro* determination of Rheumatoid Factors (RF) concentration in serum. This product is suitable for use on the RX **series** instruments which includes the RX **daytona** and RX **imola**.

Cat. No.		
RF 3836	R1. RF Assay Buffer	2 x 20 ml
	R2. RF Latex Reagent	2 x 8 ml

GTIN: 05055273205060

CLINICAL SIGNIFICANCE [1, 2]

This test system is intended to be used as an aid in the diagnosis of rheumatoid arthritis.
The agglutination reaction between antibody coated red blood cells and Rheumatoid Arthritis (RA) sera was first demonstrated by Waaler and Rose in 1940. The reaction has since been shown to be caused by certain factors in the RA sera. These Rheumatoid Factors (RF) are a heterogeneous group of high molecular weight auto antibodies directed against the body's own immunoglobulins. They are produced by plasma cells present at sites of tissue injury. The initiating antigen is thought to be one or more viruses or viral antigens that persist in the joint tissues. Research has shown that both environmental and genetic factors can affect the production of RF with various biological properties. RF have also been observed in the serum of patients with lupus erythematosus, hepatitis, liver cirrhosis, syphilis and various other conditions but the RF titre is much lower than in RA. Between 60 and 80% of patients with active Rheumatoid Arthritis (RA) possess this abnormal protein in their blood and joint fluid, and its detection is therefore of value in the diagnosis and monitoring of the disease.

PRINCIPLE

Rheumatoid factors are antibodies directed against the Fc portion of IgG. The majority of rheumatoid factors are IgM antibodies, but may be IgG or IgA. Conditions giving rise to such factors include rheumatic conditions and chronic inflammatory processes. The Randox RF latex reagent is a suspension of polystyrene latex particles of uniform size coated with human IgG. When serum containing rheumatoid factor is mixed with the RF latex reagent an increase in turbidity can be measured at 550 nm. By constructing a standard curve from the absorbance of standards, the rheumatoid factor concentration can be determined.

SAMPLE COLLECTION AND STORAGE [3]

Fresh serum is recommended. Serum may be stored at +15°C to +25°C for 24 hours or at +2°C to +8°C for 3 days after collection.
If the test cannot be carried out within this period of time, the serum can be frozen once at –15°C to –25°C for 4 weeks.
Lipaemic or haemolytic samples and high levels of detergents may interfere in this assay.

REAGENT COMPOSITION

Contents

R1.	**RF Assay Buffer**	
	Glycine Buffer	pH 8.3, 170 mmol/l
	Sodium Chloride	100 mmol/l
	Bovine serum albumin	3 % w/v
	Sodium Azide	0.09 % w/v
R2.	**RF Latex Reagent**	
	Glycine Buffer	pH 7.3, 170 mmol/l
	Sodium Chloride	100 mmol/l
	Latex particle adsorbed human IgG	0.17 % w/v
	Sodium Azide	0.09 % w/v

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

All reagents contain Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

Health and Safety Data Sheets are available on request.

Please dispose of all biological and chemical materials according to local guidelines.

The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

STABILITY AND PREPARATION OF REAGENTS

R1. RF Assay Buffer
Supplied ready for use. Stable up to expiry date when stored at +2°C to +8°C.

R2. RF Latex Reagent
Supplied ready for use. Stable up to expiry date when stored at +2°C to +8°C. Invert several times before use, avoiding the formation of foam.

R1 = RF Assay Buffer
R2 = RF Latex Reagent

MATERIALS PROVIDED

RF Latex Reagent
RF Assay Buffer

MATERIALS REQUIRED BUT NOT PROVIDED

Randox RF Calibrator Series (Cat. No. RF 2301)
Randox Liquid Assayed Specific Protein Controls: -
Level 1 Cat. No. PS 2682
Level 2 Cat. No. PS 2683
Level 3 Cat. No. PS 2684
RX **series** Saline (Cat. No. SA 3854)

PROCEDURE NOTE

The Chemistry Parameters for Randox Dedicated RX **series.** Assays are predefined on the hard drive of the analyser PC. The required programs should be downloaded to the analyser software. Please note that the predefined chemistry parameters use SI units. If the alternative units are required, these can be edited by the user. In this case, the technical range should be edited in accordance with the users selected units. All necessary instructions are encoded on the barcode. If the barcode cannot be read by the analyser, enter manually the series of numbers given beneath the barcode. If problems continue, contact Randox Laboratories Technical Services, Northern Ireland + 44 (0) 28 9445 1070.

CALIBRATION

0.9% NaCl solution as zero calibrator and Randox RF Calibrator Series are recommended for calibration.

QUALITY CONTROL

Randox Liquid Assayed Specific Protein Controls Level 1, Level 2 and Level 3 are recommended for Quality Control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check cleanliness of all equipment in use.
3. Check water. Contaminants i.e. bacterial growth may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents.
6. Contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

Quality control requirements should be determined in conformance with government regulations or accreditation requirements.

SPECIFICITY / INTERFERENCES

The analytes below were tested up to the following levels and were found not to interfere:

Haemoglobin	1000 mg/dl
Intralipid	2%
Bilirubin	250 µmol/l
Triglycerides	26 mmol/l

NORMAL VALUES

The cut off value which constitutes the upper limit of normal is subject to dispute. However, values less than 10 IU/ml are considered to be within the normal range. The World Health Organisation has suggested a level approaching 12.5 IU/ml as being the upper limit of normal[1].

It is recommended that each laboratory should establish an expected range to reflect the geographical location and the age, sex and diet of the population.

INTERPRETATION OF RESULTS

Rheumatoid factors as detected by serological techniques are not necessarily specific for rheumatoid arthritis. A high result should always be confirmed by performing parallel tests. Increased levels of rheumatoid factor may be observed in infectious mononucleosis and in patients suffering from systemic lupus erythematosus, sarcoidosis and various other conditions. The clinical significance of a positive result should be interpreted cautiously. However, a large rheumatoid factor concentration is associated with rheumatoid arthritis rather than rheumatic fever.

SPECIFIC PERFORMANCE CHARACTERISTICS

The following performance data was obtained using a RX **daytona** analyser at +37°C.

ASSAY RANGE

The range of this assay is approximately 6.72 to 104 IU/ml.
In the event of a rerun, the upper limit of the assay range is increased to 2155 IU/ml.

PROZONE EFFECTS

Antigen excess effects are not noted until levels approach 723 IU/ml.

LINEARITY

The method is linear up to a RF concentration of 104 IU/ml.

SENSITIVITY

The minimum detectable concentration of RF with an acceptable level of precision was determined as 6.72 IU/ml.

PRECISION

Intra Assay

	Level 1	Level 2	Level 3
Mean (IU/ml)	8.85	25.5	48.5
SD	0.849	1.47	1.86
CV (%)	9.60	5.78	3.83
n	20	20	20

Inter Assay

	Level 1	Level 2	Level 3
Mean (IU/ml)	15.3	27.5	57.4
SD	0.951	1.26	1.01
CV (%)	6.22	4.58	1.76
n	20	20	20

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y = 0.95 X - 0.62
and a correlation coefficient of r = 0.99

33 patient samples were analysed spanning the range 6.73 to 42.3 IU/ml.

REFERENCES

1. Anderson, S.G., Bentzon, M.W., Houba, V. and Krag, P. Bull. Wld. Hlth. Org. **42**: 311-318 (1970).
2. Galvin, J.P. *et al*., Clin. Lab. Assays **4**: 73-95 (1983).
3. Guder WG, Narayanan S, Wisser H, *et al*. The Quality of Diagnostic Samples. Brochure in Samples: From the Patient to the Laboratory. 2nd Edition, Darmstadt: GIT- Verlag, 2001.

EC REP

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