

## RHEUMATOID FACTOR (RF)

**LATEX-ENHANCED IMMUNOTURBIDIMETRIC ASSAY FOR SERUM RHEUMATOID FACTOR RX DAYTONA PLUS**

### 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 **daytona plus**, RX series analyser.

### FOR PRESCRIPTION USE ONLY.

#### Cat. No.

RF 8345

R1. RF Assay Buffer

1 x 11.7 ml

R2. RF Latex Reagent

1 x 5.7 ml

#### GTIN:

05055273214291

### CLINICAL SIGNIFICANCE <sup>(1,2)</sup>

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.

### SPECIMEN COLLECTION AND PREPARATION

Fresh serum is recommended. The serum may be stored at +2°C to +8°C for 48 hours after collection. If the test cannot be carried out within this period of time, the serum should be frozen at -20°C. 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.

Solutions R1 and R2 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.

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) or Randox Liquid Protein Calibrators (Cat. No. IT2691).  
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 8396

### PROCEDURE NOTE

The Chemistry Parameters for Randox Dedicated RX **daytona plus** 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 bar code. 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.

### RX DAYTONA PLUS 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.

### INTERFERENCE

Physiological changes in serum or plasma analyte concentrations can be caused by a number of substances. Comprehensive discussion of possible interfering substances, their serum or plasma concentrations, and their possible physiological involvements is beyond the scope of this document. The listed reference contains specific details on known potential interfering substances (3). The user must remain vigilant to the possible effect on results of unknown interferences from medications or endogenous substances. All patient results must be evaluated in light of the total clinical status of the patient.

### NORMAL VALUES IN SERUM

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<sup>1</sup>. 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 an RX **daytona plus** analyser at +37°C.

### PROZONE EFFECTS

Antigen excess effects are not noted until levels approach 522 IU/ml.

### REPORTABLE RANGE

Linearity data demonstrates that the reportable range for Rheumatoid factor on the RX **daytona plus** is 6 to 99.4 IU/ml.

### SENSITIVITY

The limit of Quantitation (LoQ), the limit of Detection (LoD) and the limit of Blank (LoB) were determined consistent with CLSI guidelines EP17-A. LoQ is the lowest concentration that can be detected with  $\leq 20\%$  bias and  $\leq 20\%$  imprecision. LoD is the lowest concentration that can be detected to determine the presence or absence of Rheumatoid factor. LoB is the highest concentration that is likely to be observed in a blank sample.

### RX daytona plus

Limit of Blank (IU/ml)	1.14
Limit of Detection (IU/ml)	5.70
Limit of Quantitation (IU/ml)	6.00

### PRECISION

#### Within Run Precision

	Level 1	Level 2	Level 3
Mean (IU/ml)	9.42	22.9	47.5
SD	0.89	0.99	0.46
CV (%)	9.49	4.31	0.97
n	20	20	20

### 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. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Washington, DC: AACC Press; 2000.

The presence of a vertical bar in the margin indicates a Technical update from the previous revision.

EC	REP
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Randox Teoranta, Meenmore,  
Dungloe, Donegal,  
F94 TV06, Ireland

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