FULL RANGE CRP (frCRP)

IMMUNOTURBIDIMETRIC ASSAY
RX DAYTONA PLUS

INTENDED USE

A CRP test system is a device intended for the quantitative *in vitro* determination of C-reactive protein (CRP) concentration in serum. This product is suitable for use on the RX **daytona plus**, RX **series** analyser.

Cat. No.		
CP 8315	R1. Assay Buffer	4 x 10 mL
	R2. Antibody-latex Reagent	4 x 10 mL

GTIN: 05055273208597

CLINICAL SIGNIFICANCE [1-4]

C-reactive protein is present in serum of normal individuals at levels between 0 - 5 mg/L. Elevated levels outside the normal range are associated with acute phase response and measurements may be useful for the detection of infection, tissue injury, inflammatory disorders and associated diseases.
Research has indicated that CRP levels, which are within the normal range, can be used in a variety of different population subgroups for the assessment of cardiovascular risk for developing a fatal myocardial infarction. CRP levels within the normal range have been associated with coronary heart disease mortality in high-risk individuals. Elevated serum cholesterol levels, elevated diastolic blood pressure and cigarette smoking indicate high-risk.
A complete clinical history is required for accurate interpretation of CRP levels. CRP levels within the normal range may be affected by a number of different factors and should always be compared to previous values.

PRINCIPLE

Sample is reacted with a buffer and anti-CRP coated latex. The formation of the antibody-antigen complex during the reaction results in an increase in turbidity, the extent of which is measured as the amount of light absorbed at 570 nm. By constructing a standard curve from the absorbance of the standards, CRP concentration of sample can be determined.

SAMPLE COLLECTION AND STORAGE [5]

Fresh serum is recommended. Stable for 11 days at +15°C to +25°C or 2 months at +2°C to +8°C. Sample can be frozen once at -15°C to -25°C for a maximum of 3 years (do not refreeze).

REAGENT COMPOSITION

Contents	Initial Concentration of Solutions
R1. Assay buffer	
Glycine	170 mM
Sodium chloride	100 mM
Sodium EDTA disodium salt dihydrate	50 mM
Bovine serum albumin	1%
R2. Antibody-Latex Reagent	
Latex particles coated with antibody to CRP	

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

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

Reagent 1 = Assay Buffer
Reagent 2 = Antibody - Latex Reagent

MATERIALS PROVIDED

Assay Buffer
Antibody-Latex Reagent

MATERIALS REQUIRED BUT NOT PROVIDED

RX **series** Saline, (Cat. No. SA 8396)
Randox CRP Calibrator Series:
Cat. No. CP 2499
Randox High Sensitivity CRP Control Level 1:
Cat. No. CP 2476
Randox High Sensitivity CRP Control Level 2:
Cat. No. CP 2477
Randox Liquid Assayed Specific Protein Controls:

Level 1	Cat. No. PS 2682
Level 2	Cat. No. PS 2683
Level 3	Cat. No. PS 2684

PROCEDURE NOTES

This assay can be used to measure CRP levels within (high sensitivity) and above the normal range.

To avoid the potential for reagent carryover, it is recommended that the testing order of the reagents is confirmed. Please consult the reagent carryover document available on www.randox.com under support and documentation - Reagent product inserts or by contacting Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

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 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

The use of Randox CRP Calibrator Series is recommended for calibration. Enter lot specific values based on those given in the Randox CRP calibrator insert.

QUALITY CONTROL

We recommend a range of CRP controls for daily quality control to monitor accuracy and precision. The choice of controls will depend on which end of the normal range is being investigated. Randox High Sensitivity CRP Control Level 1, Randox High Sensitivity CRP Control level 2 and Randox Liquid Assayed Specific Protein Controls are available. 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.

EXPECTED VALUES [6-9]

Adults	0 - 5 mg/L
Newborns, cord blood	<0.6 mg/L
Infants from 4th day of life to 1 month	<1.6 mg/L

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

PERFORMANCE CHARACTERISTICS

The following performance characteristics were obtained using an RX **daytona plus** analyser.

LIMITATIONS AND INTERFERENCES

The analytes below were tested up to the following levels and were found not to interfere at CRP concentrations of 1.25 mg/L and 80 mg/L.

	1.25 mg/L	80 mg/L
Haemoglobin	1000 mg/dL	1000 mg/dL
Free Bilirubin	60 mg/dL	60 mg/dL
Conjugate Bilirubin	60 mg/dL	60 mg/dL
Triglycerides	2000 mg/dL	2000 mg/dL
Intralipid®	1500 mg/dL	2000 mg/dL

Increases in CRP values are non-specific for a wide range of disease processes and should not be interpreted without a complete clinical evaluation.

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 [10]. 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.

REPORTABLE RANGE

Linearity data demonstrates that the reportable range for CRP on the RX **daytona plus** is to 153 mg/L.

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 ≤40% Total error. LoD is the lowest concentration that can be detected to determine the presence or absence of CRP. LoB is the highest concentration that is likely to be observed in a blank sample.

RX daytona plus

Limit of Blank (mg/L)	0.11
Limit of Detection (mg/L)	0.252
Limit of Quantitation (mg/L)	0.5

PROZONE

CRP sample values greater than 1026 mg/L are likely to exhibit antigen excess (prozone) and should be diluted as for elevated samples.

PRECISION

Intra Assay Precision

	Level 1	Level 2	Level 3
Mean (mg/L)	3.86	54.5	85.9
SD	0.069	1.04	1.17
CV (%)	1.79	1.91	1.36
n	79	80	79

Inter Assay Precision

	Level 1	Level 2	Level 3
Mean (mg/L)	3.86	54.5	85.9
SD	0.081	1.61	1.56
CV (%)	2.11	2.96	1.81
n	79	80	79

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
Y = 1.02 X - 0.05
and a correlation coefficient of r = 1.00

42 patient samples were analysed spanning the range 0.485 to 161.46 mg/L.

REFERENCES

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

EC REP

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