CRP

IMMUNOTURBIDIMETRIC ASSAY FOR CRP
RX SERIES

INTENDED USE

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

Cat. No.

CP 3826	R1. Assay Buffer	6 x 20 ml
	R2. Antibody Reagent	3 x 9 ml

GTIN: 05055273201765

CLINICAL SIGNIFICANCE [1, 2]

CRP is one of the proteins commonly referred to as acute phase reactants. CRP is distinguished by its rapid response to trauma or infection. The rise in concentration of CRP occurs much earlier (in four to six hours) than for other acute phase reactants which usually take more than 24 hours to produce a detectable signal in serum. In addition CRP levels return to normal quickly at the end of the acute episode. Measurement of CRP aids in evaluation of the amount of injury to body tissues.
Testing for CRP is indicated in the following clinical situations: monitoring recovery from surgery; myocardial infarction; transplantation; inflammatory bowel disease; rheumatic diseases, and infectious diseases

PRINCIPLE

Sample is reacted with specific antiserum to form a precipitate which is measured turbidimetrically at 340 nm. By constructing a standard curve from the absorbances of standards, the CRP concentration of sample can be determined.

SAMPLE COLLECTION AND PREPARATION

Serum is used undiluted. CRP remains stable in serum for at least 3 days at +15°C to +25°C, 6 days at +2°C to +8°C or 6 months at –20°C. Frozen samples should be thawed at room temperature and mixed thoroughly before use. Refreezing thawed samples is not recommended. Do not use plasma.

REAGENT COMPOSITION

Contents	Initial Concentrations in the Test
R1. Assay Buffer	
Polyethylene Glycol	maximum 4 %
Tris/HCl buffer	20 mmol/l, pH 7.4
Sodium Chloride	150 mmol/l
Sodium Azide	0.09%
R2. Antibody Reagent	
Anti (human) 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.

Solution R1 contains 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.

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 expiry date when stored at +2°C to +8°C.

R2. Antibody Reagent
Supplied ready for use. Stable up to expiry date when stored at +2°C to +8°C.

MATERIALS PROVIDED

Assay Buffer
Antibody Reagent

MATERIALS REQUIRED BUT NOT PROVIDED.

Randox Liquid Specific Protein Calibrator, Cat No IT 2691.
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 NOTES

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 **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 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.

CALIBRATION
0.9% NaCl as zero calibrator and Randox Liquid Assayed Specific Protein Calibrator are recommended for calibration.

QUALITY CONTROL
Randox Liquid Assayed Specific Protein Controls Levels 1, 2 and 3 are recommended for daily quality control to monitor accuracy and precision. 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
The antiserum is monospecific for human CRP and has not been shown to cross-react with other serum proteins under the conditions of the assay. Lipaemia interferes with the assay. Extremely haemolytic samples and high levels of ionic detergents may interfere in the assay.

Analytes other than CRP were added to a normal sample spiked with CRP. The following analytes were tested up to the following levels and found not to interfere:

Haemoglobin	1000 mg/dl
Free Bilirubin	25 mg/dl
Conjugate Bilirubin	25 mg/dl
Triglycerides	250 mg/dl
Intralipid®	200 mg/dl

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 [4, 5]
0 - 5 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.

SPECIFIC PERFORMANCE CHARACTERISTICS
The following performance characteristics were obtained using an RX **daytona** analyser.

LINEARITY
The linearity of this assay is approximately 220 mg/l (22.0 mg/dl) depending on the lot specific values of the calibrators in use. In the event of a rerun, the linearity is extended to 1100 mg/l (110 mg/dl).

SENSITIVITY
The minimum detectable concentration of CRP with an acceptable level of precision was determined as 2.88 mg/l.

PROZONE EFFECTS
Antigen excess effects are not noted at levels up to 2000 mg/l.

PRECISION

Intra Assay Precision

	Level 1	Level 2	Level 3
Mean (mg/l)	5.91	73.9	154
SD	0.349	2.61	2.58
CV (%)	5.90	3.53	1.68
n	20	20	20

Inter Assay Precision

	Level 1	Level 2	Level 3
Mean (mg/l)	5.94	72.2	156
SD	0.591	2.43	4.67
CV (%)	9.95	3.37	2.98
n	20	20	20

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

Y = 0.98 X + 0.96 and a correlation coefficient of r = 0.99

42 patient samples were analyzed spanning the range 2.49 to 139 mg/l.

REFERENCES
1. Claus, D.R., Osmaud, A.P., Gewurz, H; J. Lab. Clin. Med **87**, 120-128 (1976).
2. Shire, B., de Beer, F.C., Pepys, M.B.; Clin. Chim. Acta **117,** 13-23 (1981).
3. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Washington, DC: AACC Press; 2000.
4. Dati, F., Johnson, A.M., Whicher, J.T. The existing Interim Consensus Reference Ranges and the Future Approach. Clin. Chem. Lab. Med. **39** (11): 1134-1136 (2001).
5. Türkay, C., Aydogan, T., Karanfil, A., Erkmen Uyar, M., Selcoki, Y., Kanbay, M. T- Wave Depletion and Bradycardia Possibly Secondary to Acute Pancreatitis: Review of the Literature. Turk. J. Gasteroenterol. 2009: **20**(4): 295-297.

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

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