ALBUMIN (ALB)

Bromocresol Green
RX SERIES

INTENDED USE

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

Cat. No.		
AB 3800	R1. Bromocresol Green	9 x 51 ml
GTIN:	05055273200058	

CLINICAL SIGNIFICANCE[1]

Albumin is the most abundant serum protein representing 55-65% of the total protein. It is synthesised in the liver and has a half-life of 2 to 3 weeks.
The main biological functions of albumin are to maintain the water balance in serum and plasma and to transport and store a wide variety of ligands e.g. fatty acids, calcium, bilirubin and hormones such as thyroxine. Albumin also provides an endogenous source of amino acids.
Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

PRINCIPLE[2]

The measurement of serum albumin is based on its quantitative binding to the indicator 3,3',5,5'-tetrabromo-m cresol sulphonphthalein (bromocresol green). The albumin-BCG-complex absorbs maximally at 578 nm.

SAMPLE COLLECTION AND PREPARATION[3,4]

Serum, heparinised plasma or EDTA plasma. Normal procedures for collecting and storing serum may be used for samples to be analysed by this method. Serum is stable for 3 days at + 2 to +8°C, or 6 months at -20°C.

REAGENT COMPOSITION

Contents		Concentrations in the Test
R1.	**Bromocresol Green**	
	Succinate buffer	75 mmol/l; pH 4.2
	Bromocresol green	0.2 mmol/l
	Brij 35	
	Preservative	

SAFETY PRECAUTIONS AND WARNINGS

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

Health and 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. Bromocresol Green
Contents supplied ready for use. Stable up to the expiry date when stored at +15 to +25°C.

MATERIALS PROVIDED

Albumin Bromocresol Green Reagent

MATERIALS REQUIRED BUT NOT PROVIDED

Randox Assayed Multisera Level 2 (Cat. No. HN 1530) and Level 3 (Cat. No. HE 1532)
Randox Calibration Serum Level 3 (Cat. No. CAL 2351)
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 94451070.

CALIBRATION

0.9% NaCl as zero calibrator and Randox Calibration Serum Level 3 are recommended for calibration. A 2 point calibration is recommended.

STANDARDISATION

Randox Calibration Serum Level 3 is traceable to Albumin reference material DA470 (IFCC).

QUALITY CONTROL

Randox Assayed Multisera, Level 2 and Level 3 are recommended for daily 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 94451070.

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

INTERFERENCE

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

Haemoglobin	500 mg/dl
Free Bilirubin	25 mg/dl
Conjugate Bilirubin	25 mg/dl
Triglycerides	1000 mg/dl
Intralipid®	800 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 [5]. 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[2]

Adults	38 - 44 g/l (3.8 - 4.4 g/dl)
Neonates	38 - 42 g/l (3.8 - 4.2 g/dl)

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 a RX **daytona** analyser.

LINEARITY

This method is linear to 50.6 g/l (5.06 g/dl). In the event of a rerun the upper limit of the assay range is increased to 300 g/l (30.0 g/dl).

SENSITIVITY

The minimum detectable concentration of Albumin with an acceptable level of precision was determined as 3.20 g/l.

PRECISION

Within Run Precision

	Level 1	Level 2	Level 3
Mean (g/l)	14.6	35.6	43.1
SD	0.24	0.43	0.53
CV%	1.62	1.20	1.23
N	20	19	20

Between Run Precision

	Level 1	Level 2	Level 3
Mean (g/l)	14.0	30.6	45.4
SD	0.49	0.67	0.79
CV%	3.48	2.19	1.74
N	20	20	20

CORRELATION

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

Y = 1.00 X - 0.39
and a correlation coefficient of r = 0.97

40 patient samples were analysed spanning the range 19.9 to 52.3 g/l.

REFERENCES

1. Grant G.H., *et al* Amino Acids and Proteins; Fundamentals of Clinical Chemistry, Tietz N.W. Editor, Third Edition, WB Saunders Company Philadelphia USA, 328-329, 1987.
2. Doumas, B.T., Watson, W.A., Biggs, H.G. Clin. Chim. Acta. 1971; **31**: 87.
3. Tietz, NW, Textbook of Clinical Chemistry, W.B. Saunders, Co., Philadelphia, P.A. 1986 pp 478-497 (specimen collection and storage recommendations).
4. Tietz, NW, Clinical Guide to Laboratory Tests (Second Edition), W.B. Saunders Co., Philadelphia, P.A. 1990 p.26.
5. 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.

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