# ALBUMIN (ALB)

**Bromocresol Green**
**RX DAYTONA PLUS**

## INTENDED USE

An Albumin test system is a device intended for the quantitative *in vitro* determination of Albumin concentration in serum. This product is suitable for use on the RX **series** analyser the RX **daytona plus**.

**Cat. No.**

| | | |
|---|---|---|
| AB 8301 | R1. Bromocresol Green | 4 x 20 ml |

**GTIN:** 05055273208115

## 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. 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.

Safety Data Sheets are available on request.

Please dispose of all biological and chemical material 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. 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 8396)

## 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 **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

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 9445 1070.

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

## 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 an RX **daytona plus** analyser.

## INTERFERENCE

The following analytes were tested up to the levels indicated at Albumin concentrations of 35.0 g/l and 55.0 g/l and found not to interfere:

| | **35.0 g/l** | **55.0 g/l** |
|---|---|---|
| Haemoglobin | 500 mg/dl | 1000 mg/dl |
| Total Bilirubin | 60 mg/dl | 60 mg/dl |
| Conjugate Bilirubin | 60 mg/dl | 60 mg/dl |
| Triglycerides | 2000 mg/dl | 2000 mg/dl |
| Intralipid® | 1000 mg/dl | 2000 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.

## REPORTABLE RANGE

Linearity data demonstrates that the reportable range for Albumin on the RX **daytona plus** is 2.5 to 66.4 g/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 ≤20% bias and ≤20% imprecision. LoD is the lowest concentration that can be detected to determine the presence or absence of Albumin. LoB is the highest concentration.

**RX daytona plus**

| | |
|---|---|
| Limit of Blank (g/l) | 0.000 |
| Limit of Detection (g/l) | 0.083 |
| Limit of Quantitation (g/l) | 2.50 |

## PRECISION

### Within Run Precision

| | **Level 1** | **Level 2** | **Level 3** |
|---|---|---|---|
| Mean (g/l) | 16.9 | 29.4 | 62.9 |
| SD | 0.333 | 0.452 | 0.844 |
| CV (%) | 1.97 | 1.53 | 1.34 |
| n | 79 | 80 | 80 |

### Total Precision

| | **Level 1** | **Level 2** | **Level 3** |
|---|---|---|---|
| Mean (g/l) | 16.9 | 29.4 | 62.9 |
| SD | 0.359 | 0.518 | 1.01 |
| CV(%) | 2.12 | 1.76 | 1.60 |
| n | 79 | 80 | 80 |

## CORRELATION

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

Y = 1.051X – 1.372
and a correlation coefficient of r = 0.999

60 patient samples were analysed spanning the range 9.09 to 55.94 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.

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

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