

**Instructions For Use**

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**ALB  
ALBUMIN****REF**OSR6102 4 x 29 mL R1  
OSR6202 4 x 54 mL R1  
OSR6602 4 x 173 mL R1*For in vitro diagnostic use only.***ANNUAL REVIEW**

Reviewed by	Date	Reviewed by	Date

**PRINCIPLE****INTENDED USE**

Photometric colour test for the quantitative determination of albumin in human serum and plasma on Beckman Coulter analysers.

OSR6602 for use on the AU5800, AU2700 and AU5400 systems only.

**SUMMARY AND EXPLANATION**

Reference<sup>1,2</sup>

Albumin is the most abundant protein in human plasma, representing 55-65% of the total protein. Its primary biological functions are to transport and store a wide variety of ligands, to maintain the plasma oncotic pressure and to serve as a source of endogenous amino acids. Albumin binds and solubilises non-polar compounds such as plasma bilirubin and long-chain fatty acids as well as binding numerous pharmaceuticals.

Hyperalbuminemia is infrequent and is caused by severe dehydration and excessive venous stasis. Hypoalbuminemia may be caused by impaired synthesis e.g. in liver disease or in protein deficient diets; increased catabolism as a result of tissue damage and inflammation; reduced absorption of amino acids caused by malabsorption syndromes or malnutrition; protein loss to the exterior as observed in nephrotic syndrome, enteropathy or burns; and altered distribution e.g. in ascites. Severe hypoalbuminemia results in a serious imbalance of intravascular oncotic pressure causing the development of edema.

Measurements of albumin concentrations are vital to the understanding and interpretation of calcium and magnesium levels because these ions are bound to albumin, and so decreases of albumin are also directly responsible for depression of their concentrations.

**METHODOLOGY**

Reference<sup>3</sup>

A coloured complex is formed when bromocresol green reacts with albumin. The absorbance of the albumin-BCG complex is measured bichromatically (600/800nm) and is proportional to the albumin concentration in the sample.

## CHEMICAL REACTION SCHEME



## SPECIMEN

### TYPE OF SPECIMEN

Serum and EDTA or heparinised plasma.

Separated plasma and serum is stable at 2...8°C for 30 days and at 15...25°C for 7 days.<sup>4</sup>

## REAGENTS

### WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents.

Dispose of all waste material in accordance with local guidelines.

### REACTIVE INGREDIENTS

Final concentration of reactive ingredients:

Succinate buffer (pH 4.2)	100 mmol/L
Bromocresol green	0.2 mmol/L
Preservative	

The concentrations of the reactive components of the reagents shown on the kit label are the actual concentrations in the individual R1/R2 vials. The reagent composition which is shown in the Instructions For Use is the final concentration of these components in the reaction cuvette after addition of R1, Sample, and R2.

### GHS HAZARD CLASSIFICATION

Albumin

DANGER



H316	Causes mild skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H412	Harmful to aquatic life with long lasting effects.
P273	Avoid release to the environment.
P280	Wear protective gloves, protective clothing and eye/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor/physician.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before use.
	Ethoxylated lauryl alcohol 0.1 - < 1%
	Succinic Acid 3 - 8%
	reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

SDS

Safety Data Sheet is available at [techdocs.beckmancoulter.com](http://techdocs.beckmancoulter.com)

## REAGENT PREPARATION

The reagent is ready for use and can be placed directly on board the instrument.

## STORAGE AND STABILITY

The reagent is stable, unopened, up to the stated expiry date when stored at 2...25°C. Once open, reagent stored on board the instrument is stable for 90 days.

## CALIBRATION

### CALIBRATOR REQUIRED

System Calibrator Cat. No. 66300.

The calibrator albumin value is traceable to IFCC (International Federation of Clinical Chemistry) standard CRM 470. Recalibrate the assay when the following occur:

Change in reagent lot number or significant shift in control values;

Major preventative maintenance was performed on the analyser or a critical part was replaced.

## QUALITY CONTROL

Controls Cat. No. ODC0003 and ODC0004 or other control materials with values determined by this Beckman Coulter system may be used.

Each laboratory should establish its own control frequency however good laboratory practice suggests that controls be tested each day patient samples are tested and each time calibration/blanking is performed.

The results obtained by any individual laboratory may vary from the given mean value. It is therefore recommended that each laboratory generates analyte specific control target values and intervals based on multiple runs according to their requirements. These target values should fall within the corresponding acceptable ranges given in the relevant product literature.

If any trends or sudden shifts in values are detected, review all operating parameters.

Each laboratory should establish guidelines for corrective action to be taken if controls do not recover within the specified limits.

## TESTING PROCEDURE(S)

Refer to the appropriate Beckman Coulter AU analyser User Guide/Instructions For Use (IFU) for analyser-specific assay instructions for the sample type as listed in the Intended Use statement. The paediatric application is suitable for use with small volume serum/plasma samples.

## CALCULATIONS

The Beckman Coulter analysers automatically compute the albumin concentration of each sample.

## REPORTING RESULTS

### REFERENCE INTERVALS

Reference<sup>5,6</sup>

Serum (Adults)

35 – 52 g/L (3.5 – 5.2 g/dL)

Serum (Newborn 0 – 4 day)

28 – 44 g/L (2.8 – 4.4 g/dL)

Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should verify the transferability of the expected values to its own population, and if necessary determine its own reference interval according to good laboratory practice. For diagnostic purposes, results should always be assessed in conjunction with the patient's medical history, clinical examinations and other findings.

## PROCEDURAL NOTES

### INTERFERENCES

Results of studies conducted to evaluate the susceptibility of the method to interference were as follows:

Icterus: Interference less than 10% up to 40 mg/dL or 684 µmol/L bilirubin

Haemolysis: Interference less than 10% up to 4.5 g/L haemoglobin

Lipemia: Interference less than 10% up to 800 mg/dL Intralipid

In very rare cases Gammopathy, especially monoclonal IgM (Waldenström's macroglobinemia), may cause unreliable results

Refer to Young<sup>7</sup> for further information on interfering substances.

## PERFORMANCE CHARACTERISTICS

### PERFORMANCE CHARACTERISTICS

Data contained within this section is representative of performance on Beckman Coulter systems. Data obtained in your laboratory may differ from these values.

#### LINEARITY

The test is linear within a concentration range of 15 – 60 g/L (1.5 – 6.0 g/dL)

#### SENSITIVITY

The lowest detectable level in serum on a DxC 700 AU analyser was estimated at 0.15 g/L.

The lowest detectable level represents the lowest measurable level of albumin that can be distinguished from zero. It is calculated as the absolute mean plus three standard deviations of 20 replicates of an analyte free sample.

#### METHODS COMPARISON

Patient serum samples were used to compare this Albumin OSR6102 assay on the AU600 against another commercially available albumin assay. Results of linear regression analysis were as follows:

$y = 0.982x - 3.860$	$r = 0.994$	$n = 121$	Sample range = 11.70 – 50.85 g/L
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#### PRECISION

The following data was obtained on a DxC 700 AU using 3 serum pools analysed over 20 days.

n = 80 Mean g/L	Within-run		Total	
	SD	CV%	SD	CV%
23.1	0.13	0.58	0.23	0.99
47.2	0.25	0.52	0.38	0.81
55.8	0.18	0.31	0.27	0.48

## ADDITIONAL INFORMATION

DxC 700 AU requires that each reagent application has a standard format of abbreviated Closed Test Name. This Closed Test Name is required to allow automated loading of the calibrator information for each application as part of the DxC 700 AU Closed System. Refer to the table below for the Closed Test Name assigned to each application for this assay.

Test Name	Description
ALB1N	Albumin (Serum)
ALB1NP	Albumin (Serum Paediatric)

### Setting Sheet Footnotes

# User defined

† System Calibrator Cat. No.: 66300

\* Values set for working in SI units (g/L). To work in g/dL divide by 10.

### REVISION HISTORY

Revised GHS section

### Preceding version revision history

IFU updated to add Vietnamese language.

## REFERENCES

1. Grant GH, Silverman LM, Christenson RH. Amino acids and proteins. In: Tietz NW, ed. Fundamentals of clinical chemistry. Philadelphia:WB Saunders Company, 1987:328-329.
2. McPherson RA. Specific proteins. In: Henry JB, ed. Clinical diagnosis and management by laboratory methods. Philadelphia:WB Saunders Company, 1996:244-245.
3. Dumas BT, Watson WA, Biggs HG. Albumin standards and the measurement of serum albumin with bromcresol green. Clin Chim Acta 1971;31:87-96.
4. Young DS, ed. Effects of preanalytical variables on clinical laboratory tests, 2nd ed. Washington:AACC Press, 1997:3-15-3-16.
5. Baudner S, Dati F. Standardization of the measurement of 14 proteins in human serum based on the new IFCC/BCR/CAP international reference material CRM 470. J Lab Med 1996;20:145-152.
6. Painter PC, Cope JY, Smith JL. Reference information for the clinical laboratory. In: Burtis CA, Ashwood ER, eds. Tietz textbook of clinical chemistry. Philadelphia:WB Saunders Company, 1999; 1800pp.
7. Young DS. Effects of drugs on clinical laboratory tests, 5<sup>th</sup> ed. AACC Press, 2000.

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