BECKMAN COULTER

AU/DxC AU US

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.

For Rx use only

PRINCIPLE

INTENDED USE

System reagent for the quantitative determination of Albumin in human serum on Beckman Coulter Clinical Chemistry AU/DxC AU analyzers.

SUMMARY AND EXPLANATION

Serum albumin measurements are used in the diagnosis of numerous diseases. Elevated serum albumin levels are usually the result of dehydration. Decreased serum albumin levels are found in a number of conditions including kidney disease, liver disease, infections, severe burns and cancer.[1]

METHODOLOGY

In 1965, Rodkey[2] introduced a convenient, direct method for determining albumin concentrations in serum utilizing a neutral buffered solution of bromocresol green (BCG) as the dye binding indicator. In 1971, Doumas et al.[3] increased the sensitivity of the reaction by adding a nonionic surfactant to the reagent to prevent turbidity and improve linearity. This Albumin method is a modification of the Doumas and Rodkey procedures utilizing a different buffering system.

At pH 4.2, bromocresol green reacts with albumin to form an intense green complex. The absorbance of the albumin-BCG complex is measured bichromatically (600/800 nm) and is proportional to the albumin concentration in the sample.

$$\text{Albumin} + \text{Bromocresol} \xrightarrow{\text{pH 4.2}} \text{Green Complex}$$

SPECIMEN

SPECIMEN STORAGE AND STABILITY

Albumin is stable in serum for one week at room temperature (15 - 25°C) and for one month refrigerated (2 - 8°C).[4]

Specimen storage and stability information provides guidance to the laboratory. Based on specific needs, each laboratory may establish alternative storage and stability information according to good laboratory practice or from alternative reference documentation.

Additional handling conditions as designated by this laboratory:

SPECIMEN COLLECTION AND PREPARATION

Serum, Li/Na Heparinized or K2/K3 EDTA plasma samples, free from hemolysis are the recommended specimens. Separate from blood cells as soon as possible.

Additional instructions for patient sample preparation as designated by this laboratory:

Additional type conditions as designated by this laboratory:

REAGENTS

CONTENTS

Albumin Reagent

Reagent storage location in this laboratory:

WARNING AND PRECAUTIONS

1. Exercise the normal precautions required for handling all laboratory reagents.
2. 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
Also contains preservatives.	

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 beckmancoulter.com/techdocs

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

Chemistry Calibrator (Cat # DR0070)

Storage location of the Calibrator in this laboratory:

EQUIPMENT AND MATERIALS

For use on the AU480, AU680, AU5800, DxC 500 AU, DxC 500i and DxC 700 AU Beckman Coulter Analyzers.

OSR6602 for use on the AU5800 system only.

Storage location of test tubes or sample cups in this laboratory:

REAGENT PREPARATION

The Albumin reagents are ready for use. No preparation is required.

STORAGE AND STABILITY

1. The unopened reagents are stable until the expiration date printed on the label when stored at 2 - 25°C.
2. Opened reagents are stable for 90 days when stored in the refrigerated compartment of the analyzer.
3. Contamination after opening must be avoided.

INDICATIONS OF DETERIORATION

Visible signs of microbial growth, gross turbidity, precipitate, or change in color in the Albumin reagent may indicate degradation and warrant discontinuance of use.

Additional storage requirements as designated by this laboratory:

STABILITY OF FINAL REACTION MIXTURE

The Beckman Coulter AU/DxC AU analyzer automatically computes every determination at the same time interval.

CALIBRATION

CALIBRATION INFORMATION

The frequency of calibration is every 30 days. Calibration of this albumin procedure is accomplished by use of the Chemistry Calibrator (Cat # DR0070). For traceability information refer to the calibrator instructions for use.

Recalibration of this test is required when any of these conditions exist:

1. A reagent lot number has changed or there is an observed shift in control values.
2. Major preventative maintenance was performed on the analyzer.
3. A critical part was replaced.

QUALITY CONTROL

During operation of the Beckman Coulter AU/DxC AU analyzer, at least two levels of an appropriate quality control material should be tested a minimum of once a day. In addition, controls should be performed after calibration with each new lot of reagent, and after specific maintenance or troubleshooting steps described in the appropriate Beckman Coulter AU/DxC AU analyzer Instructions For Use (IFU) and Reference Manual. Quality control testing should be performed in accordance with regulatory requirements and each laboratory's standard procedure.

Location of controls used at this laboratory.

CONTROL NAME	SAMPLE TYPE	STORAGE

TESTING PROCEDURE(S)

A complete list of test parameters and operational procedures are provided in the relevant AU/DxC AU analyzer IFU and Reference Manual.

RESULTS INTERPRETATION

The default unit of measure is g/dL, for conversion to SI units (g/L) the result is multiplied by 10.

REPORTING RESULTS

EXPECTED RESULTS

New Born:[4]	2.8 - 4.2 g/dL
Adults:[5]	3.5 - 5.2 g/dL

Reference Intervals shown above were taken from the literature. 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.

Expected reference ranges in this laboratory:

INTERVALS	SAMPLE TYPE	UNITS

Additional reporting information as designated by this laboratory:

PROCEDURAL NOTES

INTERFERENCES

Results of studies[6] show that the following substances interfere with this albumin procedure.

The criteria for no significant interference is recovery within 10% of the initial value.

Bilirubin:	No significant interference up to 40 mg/dL Bilirubin
Hemolysis:	No significant interference up to 450 mg/dL Hemolysate
Lipemia:	No significant interference up to 800 mg/dL Intralipid*

*Intralipid, manufactured by KabiVitrium Inc., is a 20% IV fat emulsion used to emulate extremely turbid samples.

In very rare cases, gammopathy, especially monoclonal IgM (Waldenström's macroglobulinemia) may cause unreliable results.

The information presented is based on results from Beckman Coulter studies and is current at the date of publication. Beckman Coulter Inc., makes no representation about the completeness or accuracy of results generated by future studies. Further information on interfering substances is available.[7]

Laboratory specific procedure notes:

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.

DYNAMIC RANGE / ANALYTICAL MEASURING RANGE

The Albumin procedure is linear from 1.5 to 6.0 g/dL. Samples exceeding the upper limit of linearity should be diluted and repeated. The sample may be diluted, repeated and multiplied by the dilution factor automatically utilizing the AUTO REPEAT RUN.

SENSITIVITY

Reference [8]

The table below is data from DxC 500 AU analyzer.

Sample Type	LoD	LoQ
Serum	0.0103 g/dL	0.0217 g/dL

LoD is defined as the lowest concentration that can be detected with a probability of 95%.

LoQ is the lowest level of measurand which can be quantitatively determined with a within-laboratory CV of ≤ 20%, established as per EP17-A2.

METHODS COMPARISON

Reference[9]

Patient serum samples were evaluated in method comparison studies.

Results of Deming regression analysis were as follows:

Y Method	DxC 700 AU
X Method	AU5800
Slope	0.989
Intercept	0.055
Correlation Coeff. (r)	0.997
No. of Samples (n)	126
Range (g/dL)	1.7 - 5.5

PRECISION

Reference[9]

Estimates of precision, based on CLSI recommendations,[10] are consistent with typical performance. The within run precision is less than 3% CV and total precision is less than 3% CV. Assays of control sera were carried out and data reduced following CLSI guidelines above.

N = 80	Within-run		Total	
Mean, g/dL	SD	CV%	SD	CV%
3.57	0.02	0.4	0.03	0.9
4.45	0.02	0.4	0.04	0.9
5.25	0.02	0.5	0.04	0.8

ADDITIONAL INFORMATION

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

Test Name	Description
ALB1U	Albumin (Serum)

Refer to the Beckman Coulter Chemistry Systems Reagent Guide (BAGUIDE) for specific chemistry information for the AU/DxC AU clinical chemistry systems and guidance on symbols used on all AU/DxC AU product labelling.

Setting Sheet Footnotes

User defined

Lot or Lot + Bottle

† Beckman Coulter System Calibrator Cat No.: DR0070

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

REVISION HISTORY

Updated Specimen Section

Updated REPORTING RESULTS section

Updated PROCEDURAL NOTES section

Updated Performance Characteristics section

Updated References section

Preceding version revision history

Add DxC 500i instrument to IFU

REFERENCES

1. Friedman, R.B. and Young, D.S., Effects of Disease on Clinical Laboratory Tests, 3rd Edition, AACC Press, 1997.
2. Rodkey, F.L., Clin Chem, 2: 478; 1965.
3. Doumas, B.T., Watson, W.A. and Biggs, H.G., Clin Chem Acta 31: 87-96, 1971.
4. Tietz, N.W., Clinical Guide to Laboratory Tests, 2nd Edition, W.B.Saunders, 1990.
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. CLSI. Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition. CLSI document EP07-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2005.
7. AACC Effects on Clinical Laboratory Tests: Drugs, Disease, Herbs and Natural Products https://clinfx.wiley.com/aaccweb/aacc/
8. Clinical and Laboratory Standards Institute. Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition. CLSI document EP17-A2, Wayne PA 2012.
9. Data is on file for specific AU/DxC AU analyzers.
10. CLSI. Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition. CLSI document EP05-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.

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