ALBUMIN

OSR6102	**4 x 29 mL**	**R1**
OSR6202	**4 x 54 mL**	**R1**
OSR6602*	**4 x 165 mL**	**R1**

Intended Use
System reagent for the quantitative determination of Albumin in human serum on Beckman Coulter Clinical Chemistry AU analyzers.
*Albumin reagent OSR6602 for use on the AU2700/5400 system only.

Summary
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 (600/800nm) and is proportional to the albumin concentration in the sample.

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

System Information
For AU400/400^e/480, AU600/640/640^e/680 and AU2700/5400 Beckman Coulter Analyzers**.**

Reagents
Final concentration of reactive ingredients:

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

Also contains preservatives.

Precautions
1. For in vitro diagnostic use.
2. **WARNING! Irritant!** May cause sensitization by skin contact. Avoid contact with skin. In case of external contact, rinse affected areas with plenty of water.

Preparation of Reagents
For OSR6102 and OSR6202, the Albumin reagents are ready for use. No preparation is required. For OSR6602, insert the pipe supplied into the 180mL reagent vial before use on the analyzer. Care must be taken when handling the pipe to avoid contamination. The pipe is for single use only. Do not remove the large cap.

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.

Specimen Collection and Preparation
Serum, heparinized or EDTA plasma samples, free from hemolysis are the recommended specimens. Separate from blood cells as soon as possible.

Sample 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]

Interfering Substances
Results of studies[5] 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.

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. For further information on interfering substances, refer to Young[6] for a compilation of reported interferences with this test.

Procedure
A complete list of test parameters and operational procedure can be found in the User's Guide appropriate to the analyzer.

Albumin

Materials Provided
Albumin Reagent
Pipe (one per each 180 mL vial)

Materials Required But Not Provided
Chemistry Calibrator (Cat # DR0070)

Stability of Final Reaction Mixture
The Beckman Coulter AU analyzer automatically computes every determination at the same time interval.

Calibration
The frequency of calibration is every 30 days. Calibration of this albumin procedure is accomplished by use of the Chemistry Calibrator (Cat # DR0070), which is traceable to the College of American Pathology (CAP) Reference Preparation for Serum Protein # 4.

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 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 User's Guide. Quality control testing should be performed in accordance with regulatory requirements and each laboratory's standard procedure.

Results
Automatically printed out for each sample in g/dL at 37°C. For SI units (g/L) the result must be multiplied by 10.

Dynamic 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.

Expected Values

New Born:[4]	2.8 - 4.2 g/dL
Recumbent Adult:[4]	3.5 - 5.0 g/dL
Ambulatory Female:[4]	3.7 - 5.3 g/dL
Ambulatory Male:[4]	4.2 - 5.5 g/dL
Beckman Coulter Determined Reference Range:[7]	3.5 - 5.7 g/dL

Expected values may vary with age, sex, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practice.

Specific Performance Characteristics
The following data was obtained using the Albumin Reagent on Beckman Coulter AU analyzers according to established procedures. Results obtained in individual laboratories may differ.

Precision[9]
Estimates of precision, based on CLSI recommendations,[8] 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 = 100	Within run		Total	
Mean, g/dL	**SD**	**CV%**	**SD**	**CV%**
2.9	0.02	0.8	0.04	1.5
5.35	0.04	0.8	0.07	1.3

Method Comparison[9]
Patient samples were used to compare this Albumin Reagent. The table below demonstrates representative performance on AU analyzers.

Y Method	AU640
X Method	AU600
Slope	0.982
Intercept	- 0.02
Correlation Coeff. (r)	0.9988
No. of Samples (n)	182
Range (g/dL)	1.5-5.4

Sensitivity
Typical change in absorbance for 1 g/dL of Albumin is 138 mAbsorbance.

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. CLSI/NCCLS, Interference Testing in Clinical Chemistry, EP7-P, 1986.
6. Young, D.S., Effects of Drugs on Clinical Laboratory Tests, 5th Edition, AACC Press, 2000.
7. Beckman Coulter Inc. data on samples collected from 200 blood donors in North Texas.
8. CLSI/NCCLS, Guideline EP5-T2, 1992.
9. Data is on file for specific AU analyzers.

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