Intended Use
System reagent for the quantitative determination of Albumin in human serum on Beckman Coulter Clinical Chemistry AU analyzers. OSR6602 for use on the AU5800, AU2700 and AU5400 systems 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.

Methodology
In 1965, Rodkey 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. 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.

System Information
For AU400/400/480, AU600/640/640 and AU2700/5400/AU5800 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! Irritating to eyes. 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
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.

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).

Interfering Substances
Results of studies 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 KabiVitrum Inc., is a 20% IV fat emulsion used to emulate extremely turbid samples.

In very rare cases, gammapathy, 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. For further information on interfering substances, refer to Young 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.

Materials Provided
Albumin Reagent
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

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<tbody>
<tr>
<td>Mean, g/dL</td>
<td>2.8 - 4.2 g/dL</td>
<td>3.5 - 5.0 g/dL</td>
<td>3.7 - 5.3 g/dL</td>
<td>4.2 - 5.5 g/dL</td>
<td>3.5 - 5.7 g/dL</td>
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</table>

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
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.

<table>
<thead>
<tr>
<th></th>
<th>Mean, g/dL</th>
<th>SD</th>
<th>CV%</th>
<th>SD</th>
<th>CV%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within run</td>
<td>2.9</td>
<td>0.02</td>
<td>0.8</td>
<td>0.04</td>
<td>1.5</td>
</tr>
<tr>
<td>Total</td>
<td>5.35</td>
<td>0.04</td>
<td>0.8</td>
<td>0.07</td>
<td>1.3</td>
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Method Comparison9
Patient samples were used to compare this Albumin Reagent. The table below demonstrates representative performance on AU analyzers.

<table>
<thead>
<tr>
<th></th>
<th>Y Method</th>
<th>X Method</th>
<th>Slope</th>
<th>Intercept</th>
<th>Correlation Coeff. (r)</th>
<th>No. of Samples (n)</th>
<th>Range (g/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AU640</td>
<td>AU600</td>
<td>0.982</td>
<td>-0.02</td>
<td>0.9988</td>
<td>182</td>
<td>1.5-5.4</td>
<td></td>
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</tbody>
</table>

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

References
7. Beckman Coulter Inc. data on samples collected from 200 blood donors in North Texas.
9. Data is on file for specific AU analyzers.

Manufactured by: Beckman Coulter, Inc., 250 S. Kraemer Blvd. Brea, CA 92821, USA