**Intended Use**
System reagent for the quantitative determination of Prealbumin (PALB) in human serum on Beckman Coulter AU analyzers.

**Summary**
Prealbumin is a transport protein. It plays a significant role in the metabolism of vitamin A by complexing with retinol-binding protein which in turn complexes with Vitamin A transporting it through the body. This protein is an acute phase reactant whose levels fall in inflammation, malignancy, cirrhosis of the liver and protein wasting diseases of the gut or kidneys. Decreases are associated with liver disease and malnutrition. Levels of Prealbumin increase in Hodgkins disease.\(^1\,^2\)

**Methodology**
Immune complexes formed in solution scatter light in proportion to their size, shape and concentration. Turbidimeters measure the reduction of incident light due to reflection, absorption, or scatter.

In the procedure, the measurement of the decrease in light transmitted (increase in absorbance) through particles suspended in solution as a result of complexes formed during the antigen-antibody reaction, is the basis of this assay.

**System Information**
For AU400/440/480, AU600/640/680, AU2700/5400 Beckman Coulter Analyzers.

**Reagents**
Final concentration of reactive ingredients:
- Solution of Polymers in Phosphate Buffered Saline (pH 7.1 – 7.3)
- Rabbit anti-human Prealbumin antiserum
Also contains preservatives.

**Precautions**
1. For *in vitro* diagnostic use.
2. Do not ingest. Harmful if swallowed.
3. Contains sodium azide as a preservative which may react with lead joints in copper plumbing to form explosive compounds. Even though the reagent contains minute quantities of sodium azide, drains should be well flushed with water when discarding the reagent.

**Preparation of reagents**
The Prealbumin reagent is 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 - 8°C.
2. Opened bottles of reagent are stable for 90 days when stored in the refrigerated compartment of the analyzer.

**Indications of Deterioration**
Visible signs of microbial growth, turbidity, precipitate, or change in color in the Prealbumin reagents may indicate degradation and warrant discontinuation of use.

**Specimen Collection and Preparation**
Fasting serum specimen, free from hemolysis, is the recommended specimen. Avoid highly lipemic samples, which may produce excessively high scatter signals.\(^3\)

**Sample Storage and Stability**
Serum samples are stable 7 days when stored 2 - 8°C. These samples can be stored frozen (≤-20°C) for up to 2 months.

**Interfering Substances**
Results of studies conducted\(^4\) show that the following substances may interfere with this Prealbumin procedure:
- Ascorbate: No significant interference up to 20 mg/dL Ascorbate
- Bilirubin: No significant interference up to 40 mg/dL Bilirubin
- Hemolysis: No significant interference up to 500 mg/dL Hemolysate
- Lipemia: No significant interference up to 500 mg/dL Intralipid*

* Intralipid, manufactured by KabiVitrum 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\(^5\) 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**
Prealbumin Reagent

**Materials required but not provided**
Prealbumin Calibrator (Cat # ODR3029)
Prealbumin

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

Calibration
The frequency of calibration for the Prealbumin turbidimetric procedure is every 90 days. Calibration of this Prealbumin procedure is accomplished by use of the Prealbumin Calibrator (Cat # ODR3029), which is traceable to IFCC International Reference Preparation CRM470 (RPPHS).

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 immunology control material should be tested a minimum of once a day. In addition, these 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.

Please note that recovery of Non-Beckman Coulter controls may vary with reagent lots of immunoassay products, due to the use of non-human materials in the controls.

Results:
Automatically printed out for each sample in mg/dL at 37°C.

Dynamic Range
The Prealbumin turbidimetric procedure is linear from 3 - 80 mg/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
Adults: 17 – 34 mg/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 Prealbumin 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, are consistent with typical performance. The within run precision is less than 5% CV and total precision is less than 10% CV. Assays of serum pools and control sera were performed and the data reduced following CLSI guidelines above.

<table>
<thead>
<tr>
<th>N = 100</th>
<th>Within run</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean, mg/dL</td>
<td>SD</td>
<td>CV%</td>
</tr>
<tr>
<td>14.1</td>
<td>0.09</td>
<td>0.6</td>
</tr>
<tr>
<td>25.3</td>
<td>0.14</td>
<td>0.6</td>
</tr>
<tr>
<td>35.5</td>
<td>0.35</td>
<td>1.0</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Y Method</th>
<th>AU640</th>
</tr>
</thead>
<tbody>
<tr>
<td>X Method</td>
<td>AU600</td>
</tr>
<tr>
<td>Slope</td>
<td>1.028</td>
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<tr>
<td>Intercept</td>
<td>-0.66</td>
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<tr>
<td>Correlation Coeff. (r)</td>
<td>0.999</td>
</tr>
<tr>
<td>No. of Samples (n)</td>
<td>158</td>
</tr>
<tr>
<td>Range (mg/dL)</td>
<td>5-75</td>
</tr>
</tbody>
</table>

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

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