Intended Use
System reagent for the quantitative determination of α-1-Antitrypsin (α-1-AT) in human serum on Beckman Coulter AU analyzers.

Summary
α-1-Antitrypsin is an acute phase reactant. This term refers to proteins whose serum concentrations rise significantly during acute inflammation due to causes including surgery, myocardial infarction, infections and tumors. α-1-Antitrypsin has anti-protease activity. An inherited deficiency in this protein is associated with lung and liver disease and is used in the diagnosis of cirrhosis of the liver. Low levels of α-1-Antitrypsin are found in neonatal respiratory distress syndrome, in severe protein losing disorders, and in congenital deficiency.¹

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 AU400/400e/480, AU600/640/640e/680 and AU2700/5400/AU5800 Beckman Coulter Analyzers.

Reagents
Final concentration of reactive ingredients:
Tris buffer 99 mmol/L
Goat anti-human α-1-Antitrypsin antisera
Tween-20
Polyethylene Glycol 6000
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 α-1-Antitrypsin 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 or precipitate, or any change in reagent color may indicate degradation and warrant discontinuance 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.²

Sample Storage and Stability
Serum Samples are stable up to 1 week when stored 2 - 8°C.³ These samples can be stored frozen (-20°C) for up to 2 months.

Interfering Substances
Results of studies conducted show that the following substances may interfere with this α-1-Antitrypsin 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 1000 mg/dL Intralipid*¹

* Intralipid, manufactured by Kabi/Vitrum 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 for a compilation of reported interferences with this test.⁴

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

Materials Provided
α-1-Antitrypsin Reagent

Materials required but not provided
Serum Protein Multi-Calibrator 2 (Cat # ODR3023)
α-1-Antitrypsin

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 α-1-Antitrypsin procedure is every 90 days. Calibration of this α1-AT procedure is accomplished by use of the Serum Protein Multi-Calibrator 2 (Cat # ODR3023), 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 appropriate α-1-Antitrypsin 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.

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

Dynamic Range
The α1-AT turbidimetric procedure is linear from 30 – 500 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 | 84 – 218 mg/dL |

This reference range was determined from healthy blood donors (data on file). 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 α-1-Antitrypsin reagent on Beckman Coulter chemistry analyzers according to established procedures. Results obtained in individual laboratories may differ.

Precision

<table>
<thead>
<tr>
<th>N = 100</th>
<th>Within run</th>
<th>Total</th>
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<tbody>
<tr>
<td>Mean, mg/dL</td>
<td>SD</td>
<td>CV%</td>
</tr>
<tr>
<td>80.7</td>
<td>0.89</td>
<td>1.1</td>
</tr>
<tr>
<td>153.8</td>
<td>1.41</td>
<td>0.9</td>
</tr>
<tr>
<td>225.1</td>
<td>2.11</td>
<td>0.9</td>
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</table>

Method Comparison

Patient samples were used to compare this α-1-Antitrypsin Reagent. The table below demonstrates representative performance on AU analyzers.

<table>
<thead>
<tr>
<th>Method</th>
<th>AU640</th>
<th>AU600</th>
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<tbody>
<tr>
<td>Y Method</td>
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<td>2.8</td>
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<tr>
<td>X Method</td>
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</tr>
<tr>
<td>No. of Samples (n)</td>
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</tr>
<tr>
<td>Range (mg/dL)</td>
<td>54-274</td>
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</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