APOLIPOPROTEIN B

OSR6143	**4 x 13 mL**	**R1**
	4 x 7 mL	**R2**

Intended Use
System reagent for the quantitative determination of Apolipoprotein B in human serum on Beckman Coulter AU analyzers.

Summary
Lipids are transported throughout the body by complex structures called lipoproteins. Lipoproteins are classified into five major density classes: chylomicrons, very low density lipoprotein (VLDL), intermediate density lipoprotein (IDL), low density lipoprotein (LDL) and high density lipoprotein (HDL). Over the past several decades, decreased serum levels of high density lipoprotein (HDL) and increased levels of low density lipoprotein (LDL) have been associated with increased risk of coronary artery disease.

Associated with these lipoproteins, at least five major apolipoproteins have been described and have been labeled A through E. Apolipoprotein B (Apo B) is the major protein component of VLDL and LDL, and therefore plays an essential role in lipid transport and metabolism.

Methodology
Immune complexes formed in solution scatter light in proportion to their size, shape and concentration. Turbidimeters measure the reduction of incidence light due to reflection, absorption or scatter.
In this procedure, the decrease in intensity of light transmitted (increase in absorbance) through particles suspended in solution is the result of complexes formed during the antigen-antibody reaction.

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

Reagents
Final concentration of reactive ingredients:

TRIS buffer pH 7.4	15 mmol/L
Polyethylene glycol 6000	4 w/v
Goat Anti-Apolipoprotein B antiserum	≈ 1.93 g/L

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 Apolipoprotein B 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 Apolipoprotein B 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.[1]

Sample Storage and Stability
Apolipoprotein B specimens are stable for 1 year when stored at ≤ -20°C.[2]

Interfering Substances
Results of studies[3] show that the following substances may interfere with this Apolipoprotein B 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 500 mg/dL Hemolysate
Lipemia: No significant interference up to 200 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 time 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[4] for a compilation of reported interferences with this test.

Apolipoprotein B

Procedure

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

Materials Provided
Apolipoprotein B Reagent

Materials Required But Not Provided
Apolipoprotein A1 and B Calibrator (Cat # ODR3022)

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

Calibration
The frequency of calibration for the Apolipoprotein B procedure is every 7 days. Calibration of this Apolipoprotein B procedure is accomplished by use of the Apolipoprotein A1 and B calibrator, which is traceable to WHO-IFCC International reference reagents for Apolipoprotein A1 and B (SP1-01 and SP3-07) according to IFCC protocols.

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, 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 Apolipoprotein B turbidimetric assay is linear from 40 to 200 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:[5] 50 - 155 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 Apolipoprotein B Reagent on Beckman Coulter AU analyzers according to established procedures. Results obtained in individual laboratories may differ.

Precision[7]
Estimates of precision, based on CLSI recommendations,[6] are consistent with typical performance. The within run precision is less than 5% CV and the total precision is less than 10% CV. Assays of serum pools and control sera were performed and the data reduced following CLSI guidelines above.

N= 100	Within run		Total	
Mean, mg/dL	SD	CV%	SD	CV%
35.2	0.4	1.1	0.6	1.7
57.2	0.5	0.9	0.8	1.3

Method Comparison[7]
Patient samples were used to compare this Apolipoprotein B Reagent. The table below demonstrates representative performance on AU analyzers.

Y Method	AU640
X Method	AU600
Slope	1.049
Intercept	- 2.1
Correlation Coeff. (r)	0.9984
No. of Samples (n)	135
Range (mg/dL)	41-163

References

1. Rose, N.R., Friedman, H, and Fahey, J.L, Manual of Clinical Laboratory Immunology, Third Edition, American Society for Microbiology,Washington, DC, 1986.
2. Pesce, A.J. and Kaplan, L.A,. Methods in Clinical Chemistry, C.V. Mosby Company, 1987.
3. CLSI/NCCLS, Interference Testing in Clinical Chemistry, EP7-P, 1986.
4. Young, D.S., Effects of Drugs on Clinical Laboratory Tests, 5th Edition, AACC Press, 2000.
5. Beckman Coulter Inc., data on samples collected from 200 blood donors in North Texas.
6. CLSI/NCCLS Evaluation Protocol EP5-T2, 1992.
7. Data is on file for specific AU analyzers.

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

CE