BECKMAN COULTER CE

AU

Instructions For Use

APO A1
APO A1

REF OSR6142 4 x 13 mL R1, 4 x 13 mL R2

For *in vitro* diagnostic use only.

PRINCIPLE

INTENDED USE

Immuno-turbidimetric test for the quantitative determination of Apo A1 (Apolipoprotein A1) in human serum on Beckman Coulter analysers.

SUMMARY AND EXPLANATION

Reference[1,2,3]

Lipids are transported throughout the body by complex structures called lipoproteins. Lipoproteins are classified into five (5) 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 labelled A through E. The principle apolipoproteins of HDL are the A apolipoproteins, constituting nearly 90% of the protein mass. Apo A1 has a role in the removal of excess cholesterol from the tissues and reduced levels of Apo A1 have been observed in patients with coronary heart disease. Apo A1 measurements are frequently used in characterising patients with genetic disorders that lead to low HDL cholesterol concentrations. Apo B plays an essential role in the delivery of cholesterol to the tissues, the most abundant form of Apo B, Apo B_{100} is present in all atherogenic lipoprotein fractions VLDL, IDL and LDL. Elevated levels of Apo B_{100} are associated with an increased risk of coronary artery disease.

METHODOLOGY

When a sample is mixed with R1 buffer and R2 antiserum solution, Apo A1 reacts specifically with anti-human Apo A1 antibodies to yield insoluble aggregates. The absorbance of these aggregates is proportional to the Apo A1 concentration in the sample.

SPECIMEN

SPECIMEN STORAGE AND STABILITY

Reference[4]

Serum: Stable for 8 days when stored at 2...8°C and 1 day when stored at 15...25°C.

REAGENTS

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents.

Dispose of all waste material in accordance with local guidelines.

This product contains material of animal origin. The product should be considered as potentially capable of transmitting infectious diseases.

REACTIVE INGREDIENTS

Final concentration of reactive ingredients

TRIS buffer (pH 7.4)	18 mmol/L
Sodium chloride	106 mmol/L
Polyethylene glycol 6000	3.5% w/v
Goat anti-Apo A1 antibodies	≈ 0.14 g/L
Preservative	

The concentrations of the reactive components of the reagents shown on the kit label are the actual concentrations in the individual R1/R2 vials. The reagent composition which is shown in the Instructions For Use is the final concentration of these components in the reaction cuvette after addition of R1, Sample, and R2.

⚠ CAUTION

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

GHS HAZARD CLASSIFICATION

Not classified as hazardous

SDS	Safety Data Sheet is available at beckmancoulter.com/techdocs

REAGENT PREPARATION

The reagents are ready for use and can be placed directly on board the instrument

REAGENT STORAGE AND STABILITY

The reagents are stable, unopened, up to the stated expiry date when stored at 2…8°C. Once open, reagents stored on board the instrument are stable for 90 days.

CALIBRATION

CALIBRATION INFORMATION

Apo A1 & B Calibrators Cat. No. ODR3022.

The calibrator Apo A1 values are traceable to the WHO International Reference Material, SP1-01.

Recalibrate the assay every 90 days or when the following occur:

Change in reagent lot or significant shift in control values;

Major preventative maintenance was performed on the analyser or a critical part was replaced.

Following calibration, the resulting curve should be visually reviewed, on the Beckman Coulter analyser, for acceptability using the software options - Routine, Calibration Monitor, Calibration Curve. Quality control procedures should be undertaken immediately following calibration in accordance with good laboratory practice.

QUALITY CONTROL

Controls Cat. No. ODC0003 and ODC0004 or other control materials with values determined by this Beckman Coulter system may be used.

Each laboratory should establish its own control frequency however good laboratory practice suggests that controls be tested each day patient samples are tested and each time calibration/blanking is performed.

The results obtained by any individual laboratory may vary from the given mean value. It is therefore recommended that each laboratory generates analyte specific control target values and intervals based on multiple runs according to their requirements. These target values should fall within the corresponding acceptable ranges given in the relevant product literature.

Due to variations in antisera material, quality control targets and ranges should be reassessed when switching between reagent lots.

If any trends or sudden shifts in values are detected, review all operating parameters.

Each laboratory should establish guidelines for corrective action to be taken if controls do not recover within the specified limits.

TESTING PROCEDURE(S)

Refer to the appropriate Beckman Coulter AU analyser User Guide/Instructions For Use (IFU) for analyser-specific assay instructions for the sample type as listed in the Intended Use statement.

CALCULATIONS

The Beckman Coulter analyzers automatically compute the Apo A1 concentration of each sample.

REPORTING RESULTS

REFERENCE INTERVALS

Reference[2]

Male	1.05 – 1.75 g/L (105 – 175 mg/dL)
Female	1.05 – 2.05 g/L (105 – 205 mg/dL)

Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should verify the transferability of the expected values to its own population, and if necessary determine its own reference interval according to good laboratory practice. For diagnostic purposes, results should always be assessed in conjunction with the patient's medical history, clinical examinations and other findings.

PROCEDURAL NOTES

LIMITATIONS

Samples with extremely abnormal optical characteristics, especially turbidity, may produce atypical results.

INTERFERENCES

Results of studies conducted to evaluate the susceptibility of the method to interference were as follows:

Icterus:	Interference less than 3% up to 40 mg/dL or 684 µmol/L bilirubin
Haemolysis:	Interference less than 3% up to 5 g/L haemoglobin
Lipemia:	Interference less than 10% up to 900 mg/dL Intralipid

Refer to Young[5] for further information on interfering substances.

PERFORMANCE CHARACTERISTICS

PERFORMANCE CHARACTERISTICS

Data contained within this section is representative of performance on Beckman Coulter systems. Data obtained in your laboratory may differ from these values.

LINEARITY

The test is linear within a concentration range of 0.40 – 2.50 g/L (40 – 250 mg/dL).

SENSITIVITY

The lowest detectable level in serum on a DxC 700 AU analyser was estimated at 0.005 g/L.

The lowest detectable level represents the lowest measurable level of Apo A1 that can be distinguished from zero. It is calculated as the absolute mean plus three standard deviations of 20 replicates of an analyte free sample.

METHODS COMPARISON

Patient serum samples were used to compare this Apo A1 OSR6142 assay on the AU600 against another commercially available Apo A1 assay. Results of linear regression analysis were as follows:

y = 0.887x – 0.081	r = 0.990	n = 80	Sample range = 0.591 – 2.319 g/L

PRECISION

The following data was obtained on a DxC 700 AU using 3 serum pools analysed over 20 days.

n=80	Within-run		Total	
Mean g/L	**SD**	**CV%**	**SD**	**CV%**
1.10	0.01	0.71	0.01	0.98
1.63	0.01	0.75	0.02	1.20
2.18	0.02	0.73	0.02	1.03

ADDITIONAL INFORMATION

DxC 700 AU requires that each reagent application has a standard format of abbreviated Closed Test Name. This Closed Test Name is required to allow automated loading of the calibrator information for each application as part of the DxC 700 AU Closed System. Refer to the table below for the Closed Test Name assigned to each application for this assay.

Test Name	Description
APA1G	APO A1 (Serum)

Setting Sheet Footnotes
User defined

† Apo A1 & B Calibrator Cat. No. ODR3022

* Values set for working in SI units (g/L). To work in mg/dL multiply by 100.

REVISION HISTORY

Added new languages

Preceding version revision history

Updated Calibration section

Removed reference to obsolete calibrator.

Updated Additional Information section

REFERENCES

1. Stein EA. Lipids, lipoproteins, and apolipoproteins. In: Tietz NW, ed. Fundamentals of clinical chemistry. Philadelphia:WB Saunders Company, 1987:454-456.

2. Riesen WF. Lipid metabolism. In: Thomas L, ed. Clinical laboratory diagnostics. Use and assessment of clinical laboratory results. Frankfurt/Main: TH-Books Verlagsgesellschaft, 1998:172-173.

3. Bhatnagar D, Durrington PN. Measurement and clinical significance of apolipoproteins A-1 and B. In: Rifai N, Warnick GR, Dominiczak MH, eds. Handbook of lipoprotein testing. Washington: AACC Press, 1997:177-198.

4. Ehret W, Heil W, Schmitt Y, Töpfer G, Wisser H, Zawta B, et al. Use of anticoagulants in diagnostic laboratory investigations and stability of blood, plasma and serum samples. WHO/DIL/LAB/99.1 Rev.2:23pp.

5. Young DS. Effects of drugs on clinical laboratory tests, 5thed. AACC Press, 2000.

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