BECKMAN COULTER CE

AU

Instructions For Use

HDL
HDL-CHOLESTEROL

REF OSR6187 4 x 27 mL R1, 4 x 9 mL R2
OSR6287 4 x 51.3 mL R1, 4 x 17.1 mL R2
OSR6687 4 x 138 mL R1, 4 x 55 mL R2

For *in vitro* diagnostic use only.

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE

INTENDED USE

Enzymatic colour test for the quantitative determination of HDL-cholesterol in human serum and plasma on Beckman Coulter analysers.

OSR6687 for use on the AU5800, AU2700 and AU5400 systems only.

SUMMARY AND EXPLANATION

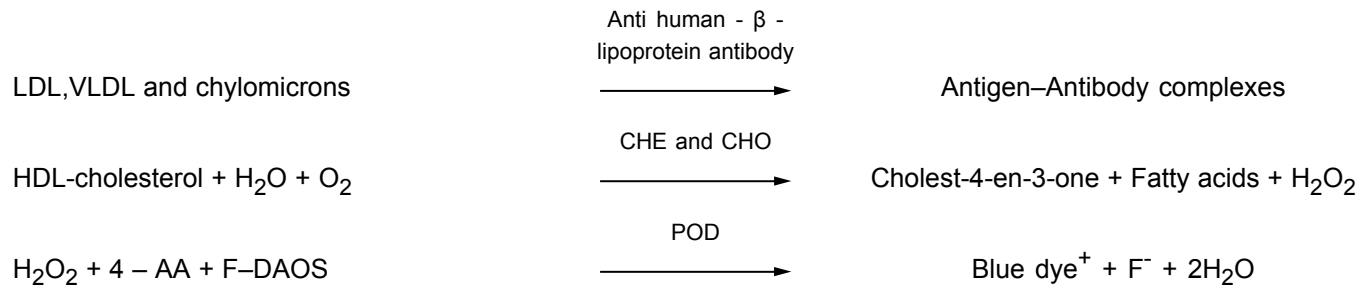
Reference[1]

Approximately 25% of total serum cholesterol is transported in the HDL fraction. Numerous clinical and epidemiological studies have demonstrated a strong inverse association between HDL-cholesterol and the incidence of coronary heart disease. It has been proposed that the uptake and transport of cholesterol from peripheral tissue to the liver acts as a protective factor against the development of atherosclerotic plaques. Determination of HDL-cholesterol is therefore essential for the interpretation of individual cholesterol determinations. Low HDL-cholesterol is a risk factor independent of total cholesterol concentration and is highly predictive of the risk of coronary heart disease. Measurement of HDL-cholesterol is used in the early recognition of atherosclerosis risk, and may also be used in the monitoring of individuals during treatment with lipid lowering drugs.

METHODOLOGY

Anti human-β-lipoprotein antibody in R1 binds to lipoproteins other than HDL (LDL, VLDL and chylomicrons). The antigen-antibody complexes formed block enzyme reactions when R2 is added. HDL-cholesterol is quantified by the presence of an enzyme chromogen system.

CHEMICAL REACTION SCHEME



SPECIMEN

TYPE OF SPECIMEN

Serum and heparinised plasma (fasting and non-fasting): Stable for 7 days when stored at 2…8°C and 2 days when stored at 15…25°C.[2]

Specimen storage and stability information provides guidance to the laboratory. Based on specific needs, each laboratory may establish alternative storage and stability information according to good laboratory practice or from alternative reference documentation.

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:

Anti human-β-lipoprotein antibody	Variable
Cholesterol esterase (CHE)	0.8 IU/mL
Cholesterol oxidase (CHO)	4.4 IU/mL
Peroxidase (POD)	1.7 IU/mL
Ascorbate Oxidase	2.0 IU/mL
Good's buffer (ph 7.0)	30 mmol/L
N-Ethyl – N - (2-hydroxy-3-sulfopropyl) - 3.5– dimethoxy – 4 fluoroaniline (F–DAOS)	0.20 mmol/L
4-Aminoantipyrine	0.67 mmol/L
Preservative	
Detergent	

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.

GHS HAZARD CLASSIFICATION

HDL Cholesterol R1	WARNING	
		
		
	H317	May cause an allergic skin reaction.
	H411	Toxic to aquatic life with long lasting effects.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
	P391	Collect spillage.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

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

REAGENT PREPARATION

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

STORAGE AND STABILITY

The reagents are stable, protected from light, unopened, up to the stated expiry date when stored at 2…8°C. Once open, reagents stored on board the instrument are stable for 30 days.

The colour of R2 may turn to light green when stored on board the analyser. This does not affect the performance of the reagent.

CALIBRATION

CALIBRATOR REQUIRED

HDL-Cholesterol Calibrator ODC0011.

The calibrator is traceable to the US CDC (Centre for Disease Control) HDL-cholesterol reference method.

Recalibrate the assay every 30 days and perform reagent blank every 7 days, or when the following occur:

Change in reagent bottle or significant shift in control values;

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

QUALITY CONTROL

HDL/LDL-Cholesterol Control Serum ODC0005 or other control materials with values determined by this method 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.

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 analysers automatically compute the HDL-cholesterol concentration of each sample.

REPORTING RESULTS

REFERENCE INTERVALS

National Cholesterol Education Program (NCEP) guidelines[3]

< 1.03 mmol/L (< 40 mg/dL)	Low HDL-cholesterol (major risk factor for coronary heart disease)
≥ 1.55 mmol/L (≥ 60 mg/dL)	High HDL-cholesterol (“negative” risk factor for coronary heart disease)

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

When triglyceride in a sample exceeds 11.3 mmol/L (1,000 mg/dL), dilute the sample with a saline solution, repeat assay and multiply result by dilution factor.

INTERFERENCES

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

Ascorbate :	Interference less than 3% up to 20 mg/dL ascorbate
Bilirubin:	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

*No significant interference was observed from samples containing native triglycerides up to 11.3 mmol/L (1,000 mg/dL), however there is poor correlation between lipemia and triglyceride concentration – see limitations section.

Venipuncture immediately after or during the administration of Metamizole (Dipyrone) may lead to falsely low results for HDL Cholesterol. Venipuncture should be performed prior to the administration of Metamizole.

N-acetyl-p-benzoquinone imine (metabolite of Paracetamol) will generate erroneously low results in samples for patients that have taken toxic doses of paracetamol.

Refer to Young[4] 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 0.05 - 4.65 mmol/L (2 -180 mg/dL).

SENSITIVITY

The lowest detectable level on an AU640 analyser was calculated as 0.002 mmol/L.

The lowest detectable level represents the lowest measurable level of HDL-cholesterol 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 HDL-Cholesterol OSR6187 assay on the AU640 against another commercially available HDL-cholesterol assay. Results of linear regression analysis were as follows:

y = 1.212x + 0.080	r = 0.993	n = 200	Sample range = 0.31 – 2.54 mmol/L

PRECISION

The following data was obtained on an AU640 using 3 serum pools analysed over 10 days.

n = 60	**Within-run**		**Total**	
Mean mmol/L	**SD**	**CV%**	**SD**	**CV%**
0.69	0.006	0.85	0.013	1.92
1.09	0.007	0.62	0.018	1.69
2.08	0.013	0.61	0.027	1.32

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
HDL1N	HDL-Cholesterol (Serum)

Setting Sheet Footnotes

User defined

† HDL Cholesterol Calibrator Cat. No.: ODC0011

* Values set for working in SI units (mmol/L). To work in mg/dL multiply by 38.7.

‡ Perform reagent blank every 7 days

REVISION HISTORY

Revised GHS section

Preceding version revision history

IFU updated to add Vietnamese language.

REFERENCES

1. Riesen WF. Lipid metabolism. In: Thomas L, ed. Clinical laboratory diagnostics. Use and assessment of clinical laboratory results. Frankfurt/Main: TH-Books Verlagsgesellschaft, 1998:171-173.

2. 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.2:26pp.

3. National Cholesterol Education Program Expert Panel. Executive summary of the third report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). JAMA 2001;285: 2486-2497.

4. Young DS. Effects of Drugs on Clinical Laboratory Tests, AACC, 5th ed. AACC Press, 2000.

Beckman Coulter Ireland Inc., Lismeehan, O'Callaghan's Mills Co. Clare, Ireland (001) 703-527-3887
www.beckmancoulter.com