

HDL CHOLESTEROL SL

Direct Enzymatic method without precipitating
Liquid Reagents ready to use

REF 12300160 R1 8X20mL
REF 12310040 R2 8X5mL

IVD

PRODUCT CODE: HDL-4D28



Company with
Quality System
ISO 9001 – ISO 13485
Certified by LMS

INTENDED USE

Quantitative determination of HDL Cholesterol in serum and plasma.

PRINCIPLE

Specific polyanions in the first phase block the interfering lipoproteins (LDL, VLDL and chylomicrons) and a specific surface-active agent inhibits the coloration of VLDL, LDL and chylomicrons in the second phase. The intensity of color produced is directly proportional to the HDL cholesterol in the sample.

SAMPLE

Fresh serum, plasma. Centrifuge and collect serum as soon as possible. Avoid samples with high concentrations of ascorbic acid. HDL in the sample is stable 3 days at 2-8°C and one month at -20°C.

KIT COMPONENTS

Reagent (A) Volume = 90 ml	Good Buffer Polianions 4-AAP	100 mmol/l 1 mmol/l 4 mmol/l
Reagent (B) Volume = 30 ml	Cholesterol esterase Cholesterol oxidase Peroxidase HDAOS Detergent	800 U/l 500 U/l 1500 U/l 1 mmol/l 4 mmol/l

The reagents are stable until the expiration date indicated on the label if stored at 2-8°C and protected from light. Do not use over expiry date. Once opened reagents are stable for 2 months at 2-8°C if contamination is avoided. Do not freeze. Keep bottles closed when not in use.

REAGENTS PREPARATION

Liquid Reagents, bring to room temperature (15-25°C) before use.

PRECAUTIONS AND WARNINGS

Reagents may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow. Use the normal precautions required in the laboratory. Dispose of waste according to local laws.

PROCEDURE

Wavelength:	600 nm		
Lightpath:	1 cm		
Temperature:	37°C		
Reading:	against blank reagent		
Method:	Increasing End Point		
pipette:	blank	Sample	calibrator
Reagent (A)	300 µl	300 µl	300 µl
water	4 µl		
sample		4 µl	
calibrator			4 µl
Mix, incubate at 37°C for 5 minutes, read the absorbance of blank sample (Abx) against blank reagent, then add:			
Reagent (B)	100 µl	100 µl	100 µl
Mix, incubate at 37°C for 5 minutes and read the absorbance of the sample (Ax) and the calibrator (Ac) against blank reagent.			

RESULTS CALCULATION

$$\text{HDL (mg/dl)} = (Ax - Abx) / (Ac - Abc) \times \text{Calibrator Value}$$

For the calculation of LDL Cholesterol use the following formula:

$$\text{LDL (mg/dl)} = \text{Total Cholesterol} - \text{HDL} - (\text{Triglycerides}/5)$$

This formula will be valid if the value of triglycerides is less than 400 mg/dl and the patient does not have a type III hyperlipoproteinemia.

Conversion factor: mg/dl x 0.02586 = mmol/l

EXPECTED VALUES

HDL:

Women: 42 - 88 mg/dl (1.09 - 2.28 mmol/l)

Men: 35 - 80 mg/dl (0.90 - 2.07 mmol/l)

LDL:

Adults: 66 - 178 mg/dl (1.71 - 4.60 mmol/l)

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL

You must perform the controls at each kit's use and verify that the values obtained are within the reference range reported in the operating instructions. For this purpose we recommend the use of Sicurobio control sera: ACUTROL 1 (REF. SB-8334) and ACUTROL 2 (REF. SB-8335).

PERFORMANCE

Sensitivity: the sensitivity of the method is: 2 mg/dl.

Linearity: the method is linear up to 200 mg/dl. For higher values, dilute the sample 1:5 and multiply the result by 5.

Precision intra-assay:

	Level 1	Level 2
Mean (mg/dl)	32.9	101.4
SD	0.3	0.7
CV %	0.8	0.7

Precision inter-assay:

	Level 1	Level 2
Mean (mg/dl)	32.8	100.1
SD	0.4	1.1
CV %	1.3	1.1

Interferences: bilirubin does not interfere up to 20 mg/dl. Hemoglobin does not interfere up to 500 mg/dl. Triglycerides do not interfere up to 800 mg/dl.

Correlation against a reference method: $Y = 0.99x + 2.81$ $r = 0.996$

REFERENCES

1. Trinder P., Ann. Clin. Biochem. 6, 24 (1969)
2. Kaplan LA, Pesce AJ, Clinical Chemistry, Mosby Ed. 1989
3. Vassault A. et al., Ann. Biol. Clin., 44, 686 (1986).
4. Friedewald W.F., et al., Clin. Chem. 18: 449-502, 1972.