HDL CHOLESTEROL SL

Direct Enzymatic method without precipitating

Liquid Reagents ready to use

CE IVD

REF. 0021 **1x80 ml**
REF. 0026 **1x120 ml**

Azienda certificata DNV

GIESSE DIAGNOSTICS

INTENDED USE

Quantitative determination of HDL Cholesterol in serum and plasma.

PRINCIPLE

Specific polianions 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 = 60/90 ml	Good Buffer Polianions 4-AAP	100 mmol/l 1 mmol/l 4 mmol/l
Reagent (B) Volume = 20/30 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 freeze. Once opened reagents are stable for 2 months at 2-8°C if contamination is avoided.

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.

Volumes can be proportionally modified.

This method describes the manual procedure to use the kit.

For automated procedure, ask for specific applications.

RESULTS CALCULATION

HDL (mg/dl) = (Ax – Abx)/ (Ac – Abc) x Calibrator Value

mg/dl x 0.02586 = mmol/l

For the calculation of LDL cholesterol use the following formula:

LDL (mg/dl) = Cholesterol – (HDL+ Triglycerides)

EXPECTED VALUES

HDL:

Women:	42 - 88	mg/dl
Men:	35 - 80	mg/dl

LDL:

Adults:	66 - 178	mg/dl

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 **calibrator (REF.6010)** and **controls (REF.6011).**

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
DS	0.3	0.7
CV %	0.8	0.7

Precision inter-assay:

	Level 1	Level 2
Mean (mg/dl)	32.8	100.1
DS	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).

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