GENESIS

Instructions For Use

LDL Direct (Enzymatic Method)

Cat no.	size
1111 101	1*40
1111 102	2*40

Intended use
LDL Direct Reagent is intended for the in vitro Quantitative diagnostic determination of LDL Cholesterol in human serum and plasma.

DIAGNOSTIC CHARACTERISTICS
The LDLc particle is lipoproteins that transport cholesterol to the cells. Often called "bad cholesterol" because high levels are risk factor for coronary heart disease and are associated with obesity, diabetes and nephrosis .
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE OF THE METHOD
The assay consists of distinct reaction steps:
1. The LDL complexes with poly anion. The detergent 1 in Reagent 1 is soluble only in the non-LDL lipoprotein particles (CM, HDL, VLDL). The cholesterol released will be used up by enzymatic reagent and be in a non-color forming reaction without the chromogenic coupler.
2. The cholesterol released from LDL-C by detergent 2 in Reagent 2 reacts with chromogenic coupler for the colour formation.

COMPOSITION

Reagent (R1)	GOOD pH 7.0 (20ºC) Cholesterol esterase (CHE) Cholesterol oxidase (CHOD) Peroxidase (POD) (TOOS) 4 – Aminoantipyrine (4-AA)	50.0 mmol/L 380 U/L 380 U/L 400 U/mL 0.45 mmol/L 1.00 mmol/L
Reagent (R2)	TRIS N-(2-hydroxy-3-sulfopropyl)-3,5-dimethoxyaniline (TOOS)	50 mmol/L 0.45 mmol/L
Calibrator	Lyophilized human serum	83.8 mg/dL

STORAGE
All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations are prevented during their use.
Do not freeze the reagents.
LDLc CAL: Once reconstitute
-Stable for 1 week at 2-8ºC or 5 weeks at –20ºC.
- Do not use reagents over the expiration date.

REAGENT PREPARATION
- R 1 and R 2: Are ready to use.
- LDLc CAL: Dissolve the contents with 1 mL of distilled water.

ADDITIONAL EQUIPMENT
- Analyzer, spectrophotometer able to read at (578) nm.
- General laboratory equipment.

SPECIMEN AND STABILITY
Serum: After sampling, the test should be performed without delay.
Repeated freezing and thawing should be avoided.

Precautions and Warnings
Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Symbols in Product Labeling

EC REP	Authorized Representative		Expiration date
IVD	For in-vitro diagnostic use		CAUTION, consult instructions for use
REF	Catalogue number		Manufactured by
LOT	Lot number		Temperature Limit
	Consult instructions for use		

PROCEDURE
1. Assay Parameters:
Mode:……fixed time
Wavelength……..578 nm
Cuvette:……...1 cm light path
2. Pipette into labeled test tubes:

	Blank	Standard	Sample
REAGENT (R1)	300 µL	300 µL	300 µL
STANDARD (S)	---	4 µL	---
SAMPLE	---	---	4 µL

3. Mix thoroughly and incubate the tubes for 5 minutes at (37ºC).

	Blank	Standard	Sample
REAGENT (R2)	100 µL	100 µL	100 µL

Mix and Read immediately the absorbance (A1) of the samples and calibrator.
After 5 minutes, read the absorbance (A2) of the samples and calibrator.
Calculate the increase of the absorbance ΔA= A2 – A1.

CALCULATIONS
HDL Cholesterol concentration in the sample is calculated using the following general formula:

$$\frac{\text{A Sample}}{\text{A Calibrator}} \times \text{CAL conc.} = \text{mg/dL LDL}$$

$$\text{x } 0.0259 = \text{mmol/l LDL}$$

REFERENCE VALUES
Levels of the risk

Desirable	< 100 mg/dL	Medium	130-160 mg/dL	High	> 160 mg/dL

QUALITY CONTROL
It is recommended to use the Control Serum level I and II to verify the performance of the measurement procedure.
Each laboratory should establish its own internal Quality Control.

METROLOGICAL CHARACTERISTICS
Measuring range :(10.0 mg/dL - 400 mg/dL).
If the results obtained were greater than linearity limit, dilute the sample 1/2 with NaCl 9 g/L and multiply the result by 2.

Precision:

	Intra-assay		Inter-assay	
Mean (mg/dL)	45.0	65.0	45.0	65.0
SD	0.64	0.79	0.7	1.7
CV (%)	3.4	4.6	4.2	3.9

Sensitivity: 1 mg/dL = 0.0008A
Accuracy: Results obtained using our reagents (y) did not show systematic differences when compared with other commercial reagents(x).
The results obtained using 92 samples were the following:
Correlation coefficient (r): 0.998.
Regression equation: y= 4.6 + 0.940 x.

INTERFERENCES
No interferences were observed with:
ascorbic acid up to 50 mg/dL,
hemoglobin up to 500 mg/dL or
bilirubin up to 30 mg/dL.
Drugs and substances may interfere.

BIBLIOGRAPHY
1. Kaplan A et al. Lipoprotein. Clin Chem The C.V. Mosby Co. St Louis.
2. Okada M. et al. Low-density lipoprotein cholesterol can be chemically measured J. Lab. Clin. Mad., 1998; 132, 195-201.
3. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press,1995.

GENESIS LAB FOR DIAGNOSTIC REAGENTS
1st industrial area, Obour City, Cairo, Egypt
(+202) 44891632 Fax : (+202) 44891632
www.genesis-egy.com
info@genesis-egy.com

IFU-LDL-01
Rev. (2) 17/09/2023

ISO 13485:2016 Medical Devices

CE

EC REP CMC Medical device, C/ Horacio Lengo n18 C.P 29006, Málaga-Spain