



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 (20°C)	50.0 mmol/L
	Cholesterol esterase (CHE)	380 U/L
	Cholesterol oxidase (CHOD)	380 U/L
	Peroxidase (POD)	400 U/mL
	(TOOS)	0.45 mmol/L
	4 – Aminoantipyrine (4-AA)	1.00 mmol/L
Reagent (R2)	TRIS	50 mmol/L
	N-(2-hydroxy-3-sulfopropyl)-3,5-dimethoxyaniline (TOOS)	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 2-8°C and contaminations are prevented during their use.

Do not freeze the reagents.

LDLc CAL: Once reconstitute

- Stable for 1 week at 2-8°C or 5 weeks at -20°C.

- 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 inhale. 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			
	Authorized Representative		Expiration date
	For in-vitro diagnostic use		CAUTION, consult instructions for use
	Catalogue number		Manufactured by
	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 (37°C).

	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 $\Delta A = A2 - A1$.

CALCULATIONS

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

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

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

REFERENCE VALUES

Levels of the risk

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

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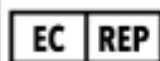
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