

## LDL CHOLESTEROL

### Direct Enzymatic Colorimetric Method

**IVD** For in -vitro diagnostic use only.

2°C 8°C  
Store at 2-8°C

#### INTENDED USE

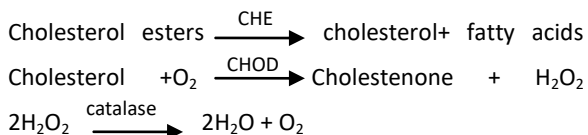
For the measurement of cholesterol concentration in human serum or heparinized plasma or EDTA plasma.

#### PRINCIPLE

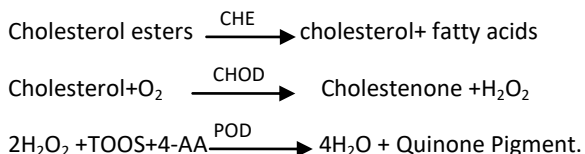
Direct determination of serum LDLc (low-density lipoprotein cholesterol) levels without the need for any pre-treatment or centrifugation steps.

The assay takes place in two steps.

#### 1. Elimination of lipoprotein no –LDL:



#### 2. Measurement of LDLc



The intensity of the color formed is proportional to the LDLc concentration in the sample.

#### CLINICAL SIGNIFICANCE

The LDLc particles are 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.

#### PRECAUTIONS

**LDLc CAL:** components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2) .however handle cautiously as potentially infectious.

#### REAGENTS

<b>R1</b> Enzymes	PIPES PH 7.0 Cholesterol esterase (CHE) Cholesterol oxidase ( CHOD) Catalase TOOS	50mmol/L ≥600U/L ≥500 U/L ≥600 KU/L 2mmol/L
<b>R2</b> Enzymes	PIPES BUFFER PH 7.0 4-Aminoantipyrine (4-AA) Peroxidase (POD)	50mmol/L 4mmol/L ≥4KU/L
<b>LDL CAL.</b>	Calibrator .Lyophilized human serum	

#### ADDITIONAL EQUIPMENT

- Spectrophotometer or colorimeter measuring at 600 nm.
- Matched cuvettes 1.0 cm light path.
- General laboratory equipment.

#### PREPARATION

- R1 and R2: are ready to use.
- Calibrator:  
Dissolve the contents in 1 mL of distilled water then cap the vial and mix gently to dissolve contents.

#### STORAGE AND STABILITY

- 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.
- Signs of reagent deterioration:
  - Presence of particles and turbidity.
- R1 AND R2 : Once opened is stable 4 weeks at 2-8 °C.

- LDLc cal: once reconstitute 30 hours at 20-25°C, 2 weeks at 2-8 °C or 3 months -20 °C.

#### SAMPLE

- Serum ,heparinized plasma or EDTA plasma.
- If any sample show precipitates, centrifuge before using.
- Stability of the serum: 6 days at 2-8°C.
- Do not freeze the samples.

#### PROCEDURE

1. Assay conditions  
Wavelength.....600 (590-700) nm.  
Cuvette.....1cm.light path  
Temperature .....37°C.
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette

	Blank	Standard	Sample
<b>R1(μL)</b>	300	300	300
<b>Standard(μL)</b>	--	4	--
<b>Sample(μL)</b>	--	--	4

4. Mix and incubate for 5 minutes at 37°C.
5. Add:

<b>R2(μL)</b>	100	100	100
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6. Mix and incubate for 5 minutes at 37°C.
7. Read the absorbance (A), against the blank.

#### CALCULATIONS

$$\begin{aligned} \text{(A) Sample} - \text{(A) Blank} &\times \text{Calibrator .conc} \\ \text{(A) Calibrator} - \text{(A) Blank} &= \text{mg/dL of LDLc in the sample} \end{aligned}$$

Conversion factor: mg/dL x 0.0259 = mmol/L

#### QUALITY CONTROL

- If controls values are found outside the defined range, check the instrument, reagents and procedure for problems.
- Each laboratory should establish its own Quality Control scheme and

corrective actions if controls do not meet the acceptable tolerances.

**REFERENCE VALUES**

<b>RISK</b>	LDL-Cholesterol level
<b>Optimal</b>	< 100 mg/dl
<b>Near or above optimal</b>	100-129 mg/dl
<b>Borderline high</b>	130-160 mg/dl
<b>High</b>	>160 mg/dl

These values are for orientation purpose, each laboratory should establish its own reference range.

**PERFORMANCE CHARACTERISTICS**

**Measuring range:**

From detection limit of 10 mg/dl to linearity limit of 976 mg/dl. If the results obtained were greater than linearity limit, dilute the sample ½ with NaCl 9 g/L and multiply the result by 2.

**Precision:**

	Intra-assay (n=20)		Inter-assay (n=20)	
<b>Media (mg/dL)</b>	31.4	67.8	32.1	68.1
<b>SD</b>	0.42	1.11	0.92	2.02
<b>CV (%)</b>	1.35	1.64	2.87	2.97

**Sensibility:** 1 mg/dL = 0.001784 (A).

**Accuracy:**

Results obtained using ATLAS reagents (y) did not show systematic differences when compared with other commercial reagents (x).

The results obtained using 50 samples were the following:

Correlation coefficient (r)<sup>2</sup>: 0.99123.

Regression equation: y= 0.914x + 1.58283.

The results of the performance characteristics depend on the analyzer used.

**INTERFERENCES**

No interferences were observed with ascorbic acid up to 50 mg/dl, hemoglobin up to 0.5 g/dl , bilirubin

up to 30 mg/dl, rheumatoid factors up to 1000 IU/ml of lipaemic samples up to 1200 mg/dl. Lipaemic samples with a triglyceride concentration > 1200 mg/dl should be diluted 1/10 with NaCl 9 g/L and multiply the result by 10.

















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	Catalogue Number		Temperature limit
	In Vitro diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry