

LDL CHOLESTEROL

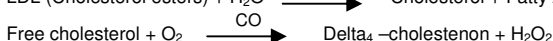
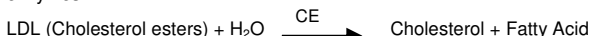
(Homogenous Direct Method)

Intended Use

LDL Cholesterol is a reagent kit used for the determination of LDL-cholesterol based on enzymatic homogenous method.

Principle

The LDL cholesterol reagent is produced using a combination of detergents and phosphorus compounds which specifically bind HDL, VLDL and CM (chilomicrons) but not LDL. This combination impedes HDL, VLDL and CM from reacting with CO (cholesterol oxidase) and CE (cholesterol esterase), while LDL-cholesterol is able to react with both enzymes.



The compound (Quinone dye) which forms is read at λ 546 nm, develops a color, the intensity of which is proportional to the LDL concentration in the test sample.

Reagent provided

1. Reagent – R1
2. Reagent – R2
3. Calibrator (Con. As on vial)

Reagent storage and stability

The kit should be stored at $2^\circ - 8^\circ\text{C}$ and is stable till the expiry date indicated on the label. DO NOT FREEZE THE REAGENT.

Reagent Preparation

Liquid reagents ready for use. After opening the reagents of R1 and R2 are stable for 60 days if closed, stored at $2^\circ - 8^\circ\text{C}$, and protect from direct light. Do not mix different batches.

Specimen collection and preservation

Serum or heparinized plasma samples should be used. Samples can be stored for 7 days at $4-8^\circ\text{C}$ and 30 days at -20°C .

Assay guidelines for Analyzers

Reaction Type	End Point (2 step)
Reaction time	5 + 5 mins
Wave length	578 nm.
Flow cell temperature	37°C
Blank	Reagent
Sample volume	10 μl (0.01 ml)
Reagent Volume	0.750 ml + 0.250 ml
Linearity	Up to 450 mg/dl

Perform the assay as given below:

	Blank	Calibrator	Sample
	-	10 μl (0.01 ml)	10 μl (0.01 ml)
R1	0.750 ml	0.750 ml	0.750 ml
Mix and incubate for 5 minutes at 37°C .			
R2	0.250 ml	0.250 ml	0.250 ml
Mix and incubate for 5 minutes at 37°C . Measure the absorbance at 578 nm.			

Calculation

$$\text{LDL-Cholesterol (mg/dl)} = \frac{\text{Abs. of Sample}}{\text{Abs. of Calibrator}} \times \text{Conc. of Calibrator}$$

Normal range

Serum/Plasma.

Men and Women:

- Normal values (no risk): <130 mg/dl (<3.37 mmol/L)
- Borderline (moderate risk): 130-159 mg/dl (3.37 - 4.12 mmol/L)
- High value (high risk): >160 mg/dl (>4.13 mmol/L)

Note: Expected range varies from population to population and each laboratory should establish its own normal range.

Limitation

Reaction is linear up to 450 mg/dl. If the LDL cholesterol value exceeds 450 mg/dl, then dilute the specimen with normal saline and repeat the assay. In such case the results obtained should be multiplied by dilution factor to obtain correct LDL cholesterol value.

Quality Control

To ensure adequate quality control measures, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware, Wavelength setting and Expiration date of reagents.

Accuracy-Recovery

The recovery of LDL Cholesterol from samples at known concentrations showed an accuracy of 100%.

Interference

The high dilution of the sample with the reagent reduces to a minimum the interference by lipids. Bilirubin below 40 mg/dl does not interfere in the reaction. Haemoglobin interferes at concentrations above 500 mg/dl and Ascorbic Acid in concentrations over 100 mg/dl does not cause interference.

Sensitivity

At 546 nm a concentration of 3.45mg/dl of LDL Cholesterol can estimate.

References

1. Butris, CA and Ashwood, E.R (ed), Tietz Fundamentals of Clinical Chemistry , 4th edition, W B Saunders Company, Philadelphia, 1996, pp. 382.
2. Thomas, L. (ed.), Clinical Laboratory Diagnostics: Use and Assessment of Clinical Laboratory Results, 1st edition, TH-Books Verlagsgesellschaft mbH, Frankfurt/Main, Germany 1998, pp. 172.
3. Bachorik, Paul S. and Ross, John W., National Cholesterol Education Program Recommendations for Measurement of Low- Density Lipoprotein Cholesterol: Executive Summary Clin Chem. 1995;41;1714-1420.
4. Rifai, N. et al., Measurement. of Low-Density Lipoprotein Cholesterol in Serum: a Status report, Clin Chem. 1992;38.
5. Aufenanger, J. and Zawta, B., pre-analytical Aspects of Lipoprotein Measurement., Clin Lab 1999:45.

Symbols

 IVD	In Vitro Diagnostics.	 Caution.	 Keep away from sun light.	 Date of Manufacture.
 LOT	Batch No.	 Read Instructions.	 Fragile.	 Product Expiry Date.
 CONT	Content.	 Storage Temperature.	 Keep Dry.	 Manufactured By.
 REF	Catalogue No.			



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NEW DELHI-110028.

W. www.keediagnostics.com.

E. info@keediagnostics.com T. 011 43136000.



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