

LDL Cholesterol Direct



Order Information

Cat. No. **OAR1124**
 Kit Configuration
 Reagent 1: 2 x 15 mL
 Reagent 2: 1 x 10 mL
 Calibrator: 1 x 1 mL

Summary

Low Density Lipoproteins (LDL) are molecules that transports cholesterol to the cells. Since LDLs provides cholesterol to the cells, LDL is also called as “bad cholesterol” because high levels are associated with heart diseases, diabetes, obesity and coronary artery disease.

Method

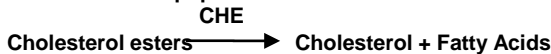
Photometric test using Enzymatic Cholesterol.

Principle

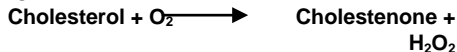
This assay helps direct determination of Low Density Lipoprotein Cholesterol (LDLc) concentrations in the serum without the need of any pre-treatment or centrifugation of the sample.

The detergent present in the reagent dissolves the lipoprotein and releases the Cholesterol which reacts with the enzymes and chromogens to produce colored complex. The intensity of color formed is directly proportional to the LDLc concentration present in the sample.

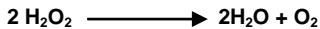
Dissolution of Lipoprotein:



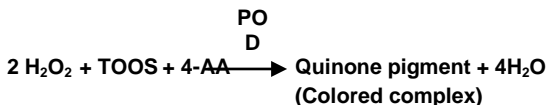
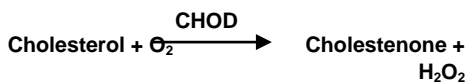
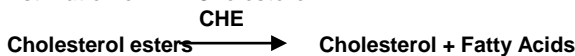
CHOD



Catalase



Estimation of LDL Cholesterol:



Reagents

Storage Instructions and Reagent Stability

Reagent and Calibrator are stable up to the end of the indicated month of expiry, if stored at 2° – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

Reagent 1: Enzyme
 Solution Reagent 2:
 Substrate Solution
 Calibrator: LDL Calibrator (Separate Pack)

Composition

Reagent: Buffer Detergent 1 < 1.0%, Cholesterol esterase <

1500u/l, Cholesterol oxidase <1500 u/l, Peroxidase < 1300 u/l, 4- Aminoantipyrine < 0.1%, Ascorbic oxidase < 3000 u/l, N,N-bis (4- sulfobutyl) -m-toluidine, disodium (DSBmT) < 1.0mm, Preservative. Calibrator – Lyophilized Serum - LDL Cholesterol value on Label.

Warnings and Precautions

Please take the necessary precautions for the use of laboratory reagents.

For diagnostic purposes, the results should always be assessed with the patient’s medical history, clinical examinations and other findings Avoid direct contact with skin and do not swallow.

In very rare cases, samples of patients with gammopathy might give falsified results.

For professional use only!

Waste Management

Please refer to local regulatory requirements.

Reagent Preparation

The reagents are ready to use.

Materials required but not provided

NaCl solution 9 g/L
 General laboratory equipment

Specimen

Serum, heparin, plasma or EDTA plasma separate at the latest 1h after blood collection from cellular contents.

7 days at 2–8°C

30 days at –20°C

Only freeze once! Discard contaminated specimens.

Assay Procedure

Wavelength 600 to 700 nm

Optical Path 10 mm

Temperature 37°C

	Blank	Sample or Calibrator
Sample or Calibrator	--	3 µL
Reagent 1	300 µL	300 µL
Mix incubate for 5 min. and read absorbance A1		
Reagent 2	100 µL	100 µL
Mix incubate for 5 min. and read absorbance A2		

(Note: For Semi-Auto Analyzers: R1: 450 µL, R2: 150 µL and Sample volume: 4 µL)

ΔA = (A1-A2) sample or Calibrator

Calculation

With

Calibrator ΔA Sample

$$\text{LDL-C (mg/dL)} = \frac{\Delta A \text{ Sample}}{\Delta A \text{ Calibrator}} \times \text{Conc. Calibrator (mg/dL)}$$

Conversion Factor

$$\text{LDL-C (mg/dL)} \times 0.02586 = \text{LDL-C (mmol/L)}$$

Quality Controls

For internal quality control any normal and abnormal controls should be assayed with each batch of samples. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics measuring range

The test has been developed to determine the quantity of LDL Cholesterol within a measuring range from 10-1000 mg/dL. When values exceed this range samples should be diluted 1 + 4 with NaCl solution (9 g/L) and the result multiplied by 5.

Specificity/Interferences

No interference was observed by, Ascorbic Acid upto 50 mg/dL, Bilirubin upto 30 mg/dL and triglycerides upto 1200 mg/dL.

Sensitivity/Limit of Detection

The lower limit of detection is 10 mg/dL.

Linearity

The higher limit of detection is 1000 mg/dL.

Precision

Intra-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	93.75	1.13	1.21
Sample 2	146.71	1.28	0.88

Inter-assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	85.50	1.09	1.28
Sample 2	135.81	1.27	0.93

Method Comparison

A comparison of Nucleus Diagnosys LDL Cholesterol (y) with a commercially available test (x) using 15 samples gave following results:

$$y = 0.997x + 1.066; r^2 = 0.988$$

Reference Range

Normal	<100 mg/dL
Low Risk	100-129 mg/dL
Borderline Risk	130-160 mg/dL
High Risk	>160 mg/dL

Each laboratory should check if the references range are transferable to its own patient population and determine own reference ranges if necessary.

Literature

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