LDL CHOLESTEROL DIRECT

IVD CE

PRODUCT CODE
CZ010

INTENDED USE
The reagent kit is intended for the ***In vitro*** quantitative determination direct LDL Cholesterol in Serum / Plasma.

CLINICAL SIGNIFICANCE
The LDL 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 nephritis. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE

The reagent is based on the following reactions:

1. Elimination of non LDL-Cholesterol $\xrightarrow{\text{Cholesterol esterase}}$ Cholesterol + fatty acids

Addition sequence	B	C	T
Reagent R1	375 µl	375 µl	375 µl

$$\text{Cholesterol} + O_2 \xrightarrow{\text{Cholesterol oxidase}} \text{Cholestenone} + H_2O_2$$

$$H_2O_2 \xrightarrow{\text{Catalase}} O_2 + H_2O$$

2. Specific measurement of LDL-Cholesterol after release of LDL-Cholesterol by detergents in Reagent 2.

$$\text{Cholesterol ester} + H_2O \xrightarrow{\text{Cholesterol esterase}} \text{Cholesterol} + \text{fatty acid}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{Cholesterol oxidase}} \text{Cholestenone} + H_2O_2$$

$$H_2O_2 + \text{4- AA} + \text{TOOS} \xrightarrow{\text{Peroxidase}} \text{Quinone} + H_2O$$

The intensity of the quinone pigment produced is proportional to the cholesterol concentration when measured at 578 nm.

CONTENTS:
Reagent 1
Reagent 2
Reagent 3: Direct LDL Calibrator

MATERIALS REQUIRED BUT NOT PROVIDED:-
- Clean & Dry Glassware.
- Laboratory Glass Pipettes or Micropipettes & Tips.
- Bio-Chemistry Analyzer.

SAMPLES:
Fresh serum (free of hemolysis), EDTA Plasma.

PREPARATION OF REAGENT & STABILITY:
The **Reagent 1** & **Reagent 2** are ready to use.
Calibrator: Reconstitute with 1 ml distilled water. Let it stand for 30 min at room temperature. Dissolve the content of the vial by swirling gently to avoid the formation of foam.
Stability: Reconstituted calibrator is stable for 7 days at 2°- 8°C.

GENERAL SYSTEM PARAMETERS:

Reaction Type	: End Point
Wave Length	: 578 nm (578-620 nm)
Cuvette Temp	: 37°C
Reagent Volume	: R1 375 µl + R2 125 µl Sample
Volume	: 5 µl
Calibrator Conc.	: As mentioned on vial label Zero Setting : Reagent Blank
Light Path	: 1 cm
Incubation	: 5 mints + 3 mints

PROCEDURE
Pipette into clean dry test tubes labeled as Blank (B), Calibrator (C) and Test (T):

Reagent 1			
Calibrator	-	5 µl	-
Sample	-	-	5 µl
Mix well and incubate for 5 mints at 37°C.			
Reagent 2	125 µl	125 µl	125 µl

Mix and incubate for 3 min. at 37°C. Measure the absorbance of calibrator & Test against reagent blank at 578nm.

CALCULATION:

$$\text{LDL-D Concentration} = \frac{\text{Abs. Of Test}}{\text{Abs. of calibrator}} \times \text{Calibrator concentration}$$

NORMAL VALUE

< 130 mg/dl Desirable
130 - 159 mg/dL Border line high risk for CHD
> 160 mg/dL High risk for CHD.
Each Laboratory should establish its own normal range representing its patient population.

LINEARITY
This procedure is linear up to 1000 mg/dl. If values exceed This limit dilute the serum with normal saline (NaCl 0.9%) And repeat the assay, multiply result by dilution factor.

QUALITY CONTROL
It is recommended to use LDL Cholesterol control sera of the known value.

INTERFERENCES
No interference was observed by the presence of: Hemoglobin : Up to 500 mg/dl
Bilirubin (free) : Up to 40 mg/dl Bilirubin (conjugated) : Up to 40 mg/dl Ascorbic Acid : Up to 50 mg/dL
Triglyceride's : Up to 1000 mg/dl

SYMBOL ON LABELS

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

BIBLIOGRAPHY
1. Crouse J.R *et al.*, Studies of Low density Lipoprotein molecular weight in human being with coronary artery disease. J.Lipid Res 26:5666 (1985)

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3. Gordon, *et al* High Density Lipoprotein as a protective Factor Against Coronary heart disease. Am J Med 1977;62:707.

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