

**PRODUCT CODE**
**CZ010**
**INTENDED USE**

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

**CLINICAL SIGNIFICANCE**

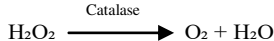
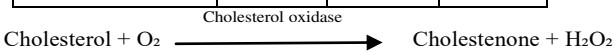
The LDL particles are lipoproteins that transport cholesterol to the cells. Often called "bad cholesterol" because high levels are risk factor for coronary heart disease and are associated with obesity, diabetes and nephritis. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

**PRINCIPLE**

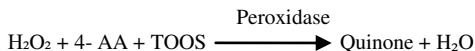
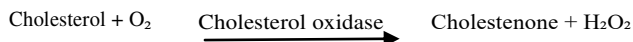
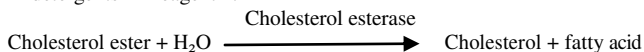
The reagent is based on the following reactions:

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



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



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  
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
	Catalogue Number		Pack Size
	Expiry Date		Volume
	Storage Condition		Lot Number
	Instruction for Use		In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests		For Single Use Only
	EC Representative		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)



- 
2. Barr, T. *et al.* Protein-Lipid Relationships in Human Plasma. *Am J Med* 1951;11:480
  3. Gordon, *et al* High Density Lipoprotein as a protective Factor Against Coronary heart disease. *Am J Med* 1977;62:707.



**Bio Research For Medical Diagnostics**

Muslim Al Attar Street,P.O.Box:1235,  
Amman-11953,Jordan  
Tel:+962 64892525, Fax: +962 64892526,  
[www.bioresearch.com.jo](http://www.bioresearch.com.jo)



**MDSS GmbH**

Schiffgraben 41  
30175 Hannover, Germany

Doc.No.: IFU-CH-035  
Rev.: 02  
Page 2 of 2