CORALYZER
System Pack

LDL-D CHOLESTEROL KIT

(Direct Enzymatic Method)

For the determination of LDL Cholesterol in serum.
(For Invitro Diagnostic Use Only)

Summary

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 nephrosis. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

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. First by the elimination of lipoprotein non - LDL Cholesterol and then the measurement of LDLc. The intensity of the color formed is proportional to the LDLc concentration in the sample.

Elimination of non-LDL Cholesterol

Cholesterol Esterase

Cholesterol esters + H_2O ⟶ Cholesterol + Fatty acids

Cholesterol Oxidase

Cholesterol + O_2 ⟶ 4-Cholestenone + H_2O_2

Peroxidase

$2H_2O_2$ + 4-Aminoantipyrine ⟶ Colourless End Product

Measurement of LDL Cholesterol

Cholesterol Esterase

Cholesterol esters ⟶ Cholesterol + Fatty acids

Cholesterol Oxidase

Cholesterol + O_2 ⟶ 4-Cholestenone + H_2O_2

Peroxidase

2 H_2O_2 + TOOS + 4-Aminoantipyrine ⟶ Quinonimine + $4H_2O$

Normal reference values

Low Risk : < 100 mg/dl
Normal Risk : 139 - 160 mg/dl
High Risk : > 160 mg/dl

It is recommended that each laboratory establish its own normal range representing its patient population.

Contents

Coralyzer 100 System Packs	**40 ml**	**100 ml**
L1 : LDL-D Reagent 1	30 ml	3 x 25 ml
L2 : LDL-D Reagent 2	10 ml	25 ml
Coralyzer 200 System Packs	**40 ml**	**100 ml**
L1 : LDL-D Reagent 1	30 ml	2 x 37.5 ml
L2 : LDL-D Reagent 2	10 ml	2 x 12.5 ml

Storage / stability

Contents are stable at 2-8°C till the expiry mentioned on the labels.

Reagent preparation

Reagents are ready to use.

Sample material

Serum or Heparinized plasma. LDL is reported to be stable in the sample for 1 week when stored at 2-8°C.

Calibration

Calibrator is recommended for calibration of this assay.

Linearity

This procedure is linear upto 1000 mg/dl.

Note

Components from human origin in the calibrator 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.
Do not use the reagents if there are particles or turbidity.
Control sera are recommended to monitor the performance of assay procedures. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

References

Kaplan A et al. Lipoprotein. Clin Chem The C.V. Mosby Co. St Louis.
Okada M. et al. Low-density lipoprotein cholesterol can be chemically measured J. Lab. Clin. Mad., 1998; 132, 195-201.
Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.
Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

Programming on	**CORALYZER 100/200**
Item	LDL
Full Name	LDL DIRECT
Test Method	End Point
Base Information	
Unit	mg/dl
Filter	546 nm
Sub. Filter	670 nm
Decimal	xx.xx
High pollute	No
Reagent Blank	
Blank Medium	Reagent
Blank Value	0
Blank Low	0
Blank High	2
Sample	
Sample Volume	3
Dilution Times	1
Range Setup	
Reagent	
Rgt. 1 Volume	225
Rgt. 2 Volume	75
Linearity	1000
Read data for check	
Assistant Start	14
Assistant End	14
Range Low	0
Range High	2
Test Point Start	31
Test Point End	32
Standard	
Number of standard	1
Factor	1
Correct Factor	1
Standard Cup	User Defined
Conc.	See Calibrator

Manufactured by :
Coral Clinical Systems
A Division of Tulip Diagnostics (P) Ltd.
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