LIQUIZYME

DIRECT LDL CHOLESTEROL

(Detergent Method)

BEACON

Code	Product Name	Pack Size
LS022A	Liquizyme Direct LDL Cholesterol	40 ml
LS022B	Liquizyme Direct LDL Cholesterol	160 ml
LS022C	Liquizyme Direct LDL Cholesterol	80 ml
LS022D	Liquizyme Direct LDL Cholesterol	320 ml

Intended Use

Diagnostic reagent for quantitative in vitro determination of LDL Cholesterol in human serum and plasma.

Clinical Significance

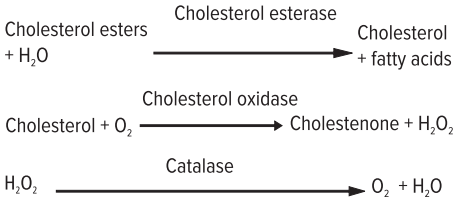
Low Density Lipoproteins (LDL) are synthesized in the liver by the action of various lipolytic enzymes on triglyceride-rich Very Low Density Lipoproteins (VLDLs). Specific LDL receptors exist to facilitate the elimination of LDL from plasma by liver parenchymal cells. It has been shown that most of the cholesterol stored in atherosclerotic plaques originates from LDL. For this reason the LDL Cholesterol concentration is considered to be the most important clinical predictor of all single parameters, with respect to coronary atherosclerosis.

Accurate measurement of LDL Cholesterol is of vital importance in therapies which focus on lipid reduction to prevent atherosclerosis or reduce its progress and to avoid plaque rupture. Can be applied on automated analyzers.

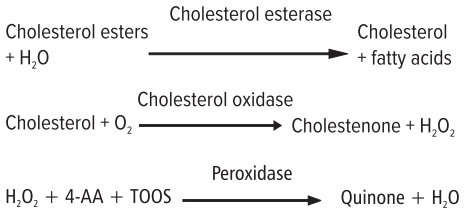
Principle

The reagent is based on the following reactions:

1. Elimination of non LDL-Cholesterol



2. Specific measurement of LDL-Cholecterol 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.

Reagent Composition

Reagent 1 : LDL R1 Reagent

Tris buffer	:	>80 mmol/L
4-AAP	:	>0.5 mmol/L
Detetgent	:	Q.S
Cholesterol Esterase	:	>3000 U/L
Cholesterol Oxidase	:	>900 U/L

Reagent 2 : LDL R2 Reagent

Peroxidase	:	>1000 U/L

Reagent 3: Direct LDL Calibrator

Refer vial label for concentration

Reagent Preparation

Reagents R1 and R2 are liquid, ready to use.

Material Required But Not Provided

- Clean & Dry container.
- Laboratory Glass Pipettes or Micropipettes & Tips.
- Colorimeter or Bio-Chemistry Analyzer.

Stability And Storage

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at +2–+8°C. Reagents are light-sensitive. Do not let bottles remain open. Keep containers tightly closed.

Specimen Collection And Handling

Use serum or hepairin plasma.

It is recommended to follow NCCLS procedures (or similar standardized conditions).

Stability In Serum / Plasma :

12 hours	:	at +20 – +25°C
10 days	:	at +4 – +8°C

Discard contaminated specimens.

Calibration

Calibration with LDL Direct calibrator provided in the kit is recommended.

Quality Control

It's recommended to run normal and abnormal control sera to validate reagent performance.

Unit Conversion

mg/dl = 0.026 mmol/L

BEACON DIAGNOSTICS PVT. LTD. *424, NEW GIDC, KABILPORE, NAVSARI - 396 424. INDIA*

Normal Value

< 130 mg/dl	:	Desirable
130 - 159 mg/dL	:	Border line high risk for CHD
> 160 mg/dL	:	High risk for CHD

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

Performance Data

Data contained within this section is representative of performance on Beacon system.
Data obtained in your laboratory may differ from these values.

Limit of quantification	:	2.60 mg/dl
Linearity	:	1000 mg/dl
Measuring range	:	2.60 – 1000 mg/dl

Precision

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	76.01	2.75	3.62
Sample 2	123.69	2.19	1.77

Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	45.67	2.21	4.85

Comparison

A comparison between Liquizyme Direct LDL Cholesterol (y) and a commercially available test (x) using 20 samples gave following results :

y = 0.988 x + 3.267 mg/dl
r = 0.999

Interferences

Following substances do not interfere :
haemoglobin up to 10 g/l, bilirubin up to 40 mg/dl, triglycerides up to 2000 mg/dl.

Warning And Precautions

For in vitro diagnostic use. To be handled by entitled and professionally educated person.
Reagent of the kit are not classified like dangerous.

Waste Management

Please refer to local legal requirements.

Assay Procedure

Wavelength	:	578 nm
Cuvette	:	1 cm

Addition Sequence	Reagent Blank	Sample / Calibrator
Reagent 1	375 µl	375 µl
D. D. Water	5 µl	-
Sample / Calibrator	-	5 µl
Mix and incubate 5 min. At +37°C. Then add		
Reagent 2	125 µl	125 µl

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

Calculation

$$\text{LDL-D (mg/dl)} = \frac{\text{Abs. of T}}{\text{Abs. of C}} \times \text{Concentration of Calibrator}$$

Applications for automatic analysers are available on request.

Assay Parameters For Photometers

Mode	End point
Wavelength 1 (nm)	578
Wavelength 2 (nm)	-
Sample Volume (µl)	5
Reagent Volume (µl)	375+125
Incubation time (min.)	5+3
Incubation temp. (°C)	37
Normal Low (mg/dl)	-
Normal High (mg/dl)	130
Linearity Low (mg/dl)	2.60
Linearity High (mg/dl)	1000
Blank with	Reagent
Unit	mg/dl

References

1. Executive Summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult tretment Panel III)", JAMA, 285:2486 (2001).

Symbols Used On Labels

REF	Catalogue Number		Manufacturer
	See Instruction for Use	LOT	Lot Number
CONT	Content		Storage Temperature
	Expiry Date	IVD	In Vitro Diagnostics

BEA/24/LDL/LS/IFU Ver-03
21/09/2025

JAS-ANZ BSCIC ISO 9001 : 2015 BSCIC ISO 13485:2016