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

$$\text{Cholesterol esters} + H_2O \xrightarrow{\text{Cholesterol esterase}} \text{Cholesterol} + \text{fatty acids}$$

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

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

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

$$\text{Cholesterol esters} + H_2O \xrightarrow{\text{Cholesterol esterase}} \text{Cholesterol} + \text{fatty acids}$$

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

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

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

**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 Pippetes or Micropippetes & 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 |
| 12 weeks | : | at -20°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

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**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 | 131 | 2.56 | 1.96 |
| Sample 2 | 47 | 0.91 | 1.94 |

| Inter-assay precision Run to run (n=20) | Mean (mg/dl) | SD (mg/dl) | CV (%) |
|---|---|---|---|
| Sample 1 | 66 | 0.90 | 1.36 |

**Comparison**

A comparison between Liquizyme Direct LDL Cholesterol (y) and a commercially available test (x) using 20 samples gave following results :
y = 0.960 x + 0.462 mg/dl
r = 0.994

**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.**

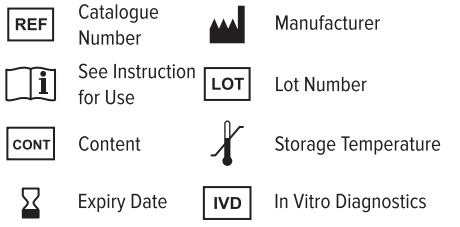
**Assay Parameters For Photometers**

| 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**





BEA/24/LDL/LS/IFU-02 18/05/2022