Pariksha Biotech
A game changer in IVD

LDL Cholesterol Estimation Kit

High-Q LDL Cholesterol - Direct

(4th Generation/Homogenous/Direct)

HIGH
Command on Quality

Intended Use:

Kit for the quantitative determination of LDL-Cholesterol concentration in human serum and plasma by direct method

Summary

Plasma lipoproteins are spherical particles containing varying amounts of cholesterol, triglycerides, phospholipids and proteins. The phospholipid, free cholesterol and protein constitute the outer surface of the lipoprotein particle, while the inner core contains mostly esterified cholesterol and triglycerides. These particles serve to solubilize and transport cholesterol and triglycerides in the

bloodstream. The relative proportions of protein and lipid determine the density of these lipoproteins and provide a basis on which to begin their classification. These classes are: chylomicrons, very-low density lipoprotein (VLDL), lowdensity lipoprotein (LDL) and high density lipoprotein (HDL). Numerous clinical studies have shown that the different lipoprotein classes have very distinct and varied effects on coronary heart disease risk. The studies all point to LDL cholesterol as the key factor in the pathogenesis of atherosclerosis and coronary artery disease (CAD) , while HDL cholesterol has been observed to have a protective effect. Even within the normal range of total cholesterol concentrations, an increase in LDL cholesterol can occur with an associated increased risk for CAD.

Principle

The High-Q LDL-C assay is a homogenous method for directly measuring LDL-C concentrations in serum or plasma, without the need for any off-line pretreatment or centrifugation steps. The method is in a two reagent format and depends on the properties of a unique detergent. This detergent (Reagent1) solubilizes only the non LDL lipoprotein particles(HDL, VLDL,CM). The cholesterol released is consumed by cholesterol esteraseand cholesterol oxidase in a non color forming reaction. Asecond detergent (Reagent 2) solubilizes the remaining LDL particles and a chromogenic coupler allows for color formation. The enzyme reaction with LDL-C in the presence of the coupler produces color that is proportional to the amount of LDL cholesterol present in the sample.

Reagent Presentation:

Reagent-1 and Reagent-2 are Liquid Stable and Ready to use. Calibrator needs to be reconstituted in distilled water.

Storage and Stability

All unopened reagents are stable until the expiration date on the label when stored at 2-8°C.

Specimen Collection and Preparation

Patients are not required to fast prior to blood collection.Serum, EDTA-treated or heparinized plasma are the recommended specimens. Anticoagulants containing citrates should not be used because of the possible assay errors due to citrates.If not analyzed immediately, specimens may be stored at 2-8°C for up to 8 days. If specimens need to be stored for longer than 8 days, they may be stored frozen at -20°C for 30 days.

Assay Procedure:

High-Q LDL-Cholesterol reagent is intended for measurement of serum LDL-Cholesterol using a clinical chemistry analyzer. Below is the best suited test procedure for many of the major analyzers. This procedure can be adapted and modified for use with other analyzers also.

System Parameters:

Reaction Type (Mode)	End Point
Reaction Direction	Increasing
Wave Length	546 nm
Flow Cell Temp.	37°C
Blank	Reagent Blank
Reagent Volume	600 µl (R1) + 200 µl (R2)
Sample	8 µl
Calibrator Concentration	— (On the Vials Lot Specific)
Linearity	500 mg/dl

Reagent	Blank	Calibrator	Test
LDL R1	600 µl	600 µl	600 µl
Calibrator	----	8 µl	----
Sample	----	----	8 µl
Mix and Incubate for 5 Minutes at 37 °C			
LDL R2	200 µl	200 µl	200 µl

Mix well incubate for 5 minutes at 37°C

Read absorbance of Calibrator (C) and Test (T) against Reagent Blank (B) at 546 nm

Calculations:

$$\text{LDL Concentration in mg/dl} = \frac{\text{Abs. of Test}}{\text{Abs. of Calibrator}} \times \text{LDL Calibrator Concentration (Lot Specific)}$$

Calibration

1) The High-Q LDL Cholesterol Calibrator is required for the calibration of this assay.
2) Other commercially available LDL calibrators have not been tested with this assay.
3) The value of the High-Q LDL Cholesterol Calibrator was assigned by procedures traceable to National Reference System for Cholesterol (NRS/CHOL).
4) Since different methods of LDL-estimation Reagents are available now a days, the concentration of High-Q LDL-C calibrator must not be cross compared with other commercially available calibrators as all the calibrator manufacturers' fix the calibrator concentration depending upon the type of LDL-Cholesterol Assay they are using for calibration of calibrators at their end.

Calibration Frequency :

Recalibration is recommanded.

- Whenever the reagent lot is changed
- as per the requirement of QC procedures.

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Performance Characteristics:

1. Reagent Blank : < 0.200 Abs.
2. Specificity : 90 - 110 % of expected values
3. Reproducibility : Coefficient of variation < 5 %
   (Within run and in between runs)

Expected Values:

The following NCEP cutpoints for patient classification are used for the prevention and management of coronary heart disease

It is recommended that each laboratory should verify the reference interval for its patient population.

LDL Cholesterol	Classification
<100 mg/dL	Optimal
100-129 mg/dL	Near Optimal/Above Optimal
<130 mg/dL	Desirable
130-159 mg/dL	Borderline High Risk
≥160-189 mg/dL	High Risk
≥190 mg/dL	Very High Risk

Measuring Range : From detection limit of 6.7 mg/dl to linearity limit of 500 mg/dl If the result obtained is greater than linearity limit, dilute the sample 1/2 with NaCl (9 g/L) and multiply the result by 2.

Reagents

Component	Ingredients	Concentration
Reagent 1	Pipes Buffer (pH 7.3) Detergent 1 Cholesterol esterase Cholesterol oxidase Peroxidase 4-Aminoantipyrine	100 mMol/L <4.5% >2000 U/L >450 U/L >5000 U/L <0.123%
Reagent 2	Preservative Buffer (pH 7.3) Detergent 2 N,N-bis (4-sulfobutyl) -m-toluidine, disodium (DSBmT) Preservative	0.1% 50 mMol/L >1.0% <1.0 mM 0.1%

Linearity

3.7 - 500 mg/dl

Precision:

	Intra -assay			Inter -assay		
Mean (mg/dl)	63.2	107	49.0	65.2	112	253
SD	0.64	1.89	0.79	0.3	0.7	1.7
CV	1.01	1.76	1.61	0.45	0.60	0.65

Accuracy :

Results obtained using High-Q LDL reagents (y) did not show systematic difference when compared with another commercial reagents (x).The results obtained using 92 samples were the following :

Correlation coefficient ®: 0.998.

Regression equation: y=4.6 + 0.940 (x)

The results of the performance characteristics depend on the analyzer used.

Quality Control:

Reliability of test results should be routinely monitored with quality-control materials or serum that reasonably represent performance with patient specimens. Controls or serum pools should be run with each assay to ensure that the reagents are functioning properly. An acceptable range for each lot of control material should be established by the laboratory.

Results:

To convert from conventional units to S.I. units, multiply the conventional units by 0.02586.

mg/dL x 0.02586 = mMol/L LDL-cholesterol

Limitations / Interfering Substances:

All interference studies were conducted .

Substance Tested	Concentration with no significant (±10%) interference
Ascorbic Acid	40 mg/dL
Hemoglobin	500 mg/dL
Bilirubin	30 mg/dL
Gamma-Globulins	6000 mg/dL
Lipemia as Triglycerides	1500 mg/dL

References:

1. Gotto AM, Lipoprotein metabolism and the etiology of hyperlipidemia, Hospital Practice, 23: Suppl.1, 4 (1988).

Ordering information:

Ref./Cat. No.	Pack Size	Presentation
P-LDL-40	40 ml	30 ml (R1) + 10 ml (R2)
P-LDL-80	80 ml	2 x 30 ml (R1) + 2 x 10 ml (R2)
P-LDL-160	160 ml	2 x 60 ml (R1) + 2 x 20 ml (R2)
P-LDL-320	320 ml	4 x 60 ml (R1) + 4 x 20 ml (R2)

Product Features

- **Liquid Stable, Ready to use, Two Reagents (3 Parts R1+ 1 Part R2), 10 Minutes Assay**
- **Linearity: 500 mg/dl**
- **Correlation with gold standard Beta quantification & Immuno separation.**
- **Overcomes critical limitations of Friedewald formula. Meets NCEP guidelines.**
- **Works well with Fasting & Non fasting patient samples.**
- **Precision with high triglyceride samples.**
- **Measuring Wavelength 546 nm (Monochrmatic),**
- **Lyophilized Calibrator provided**
- **Serum / Heparinized or EDTA Plasma as Specimens**

Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

eIFU Indicator

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SCAN TO EXPLORE MORE

Manufactured in India by :
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