LiquiMAX LDL Cholesterol - Direct

(4th Generation/Homogenous/Direct)

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
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AVLDL2-20	20 ml	15 ml (R1)+ 5 ml (R2)
AVLDL2 - 40	40 ml	30 ml (R1) + 10 ml (R2)
AVLDL2 - 80	80 ml	2 x 30 ml (R1) + 2 x 10 ml (R2)
AVLDL2 - 160	160 ml	2 x 60 ml (R1) + 2 x 20 ml (R2)
AVLDL2 - 320	320 ml	4 x 60 ml (R1) + 4 x 20 ml (R2)

INTENDED USE:

LiquiMAX LDL Cholesterol - Direct is an in-vitro diagnostic kit is use for the quantitative determination of LDL-Cholesterol concentration in human serum and plasma by direct method.

PRODUCT FEATURES

1. Liquid Stable, Ready to use, Two Reagents (3 Parts R1+ 1 Part R2), 10 Minutes Assay
2. Linearity 1000 mg/dl
3. Correlation with gold standard Beta quantification & Immuno separation.
4. Overcomes critical limitations of Friedewald formula. Meets NCEP guidelines.
5. Works well with Fasting & Non fasting patient samples.
6. Precision with high triglyceride samples.
7. Measuring Wavelength 546 nm (Monochrmatic), 660/546 (Bichromatic)
8. Lyophilized Calibrator provided
9. Serum / Heparinized or EDTA Plasma as Specimens

CLINICAL SIGNIFICANCE :

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 LiquiMAX 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.

STORAGE AND STABILITY

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

KIT COMPONENTS

1. LDL Cholesterol Reagent R1
2. LDL Cholesterol Reagent R2
3. LDL Cholesterol Calibrator : Concentration as stated on the label

COMPOSITION:

Reagent 1. MES buffer (pH 6.5), TODB N,N-Bis(4-sulfobutyl)-3-methylaniline, polyvinyl sulfonic acid, polyethylene-glycol-methyl ether, MgCl2, detergent, EDTA.

Reagent 2. MES buffer (pH 6.5), cholesterol esterase, cholesterol oxidase, peroxidase, 4-aminoantipyrine, detergent.

HDL C Calibrator: Concentration value is traceable to NIST SRM1951b

REAGENT RECONSTITUTION & STABILITY

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

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard any turbid reagent if blank reagent absorbance exceeds 0.2 at 546 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN COLLECTION & STORAGE

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.

SYSTEM PARAMETERS:

Reaction Type	:	End Point
Wave Length	:	546 nm
Flow Cell rpm	:	37°C
Reagent Volume	:	R1-600 µl + R2 200 µl
Sample Volume	:	8 µl
Blanking with	:	Reagent
Calibrator Conc.	:	Printed on vial
Unit	:	mg/dl
Low Normal	:	0
High Normal	:	130
Linearity	:	1000 mg/dL

TEST PROCEDURE

Reagent	Calibrator	Test
Reagent R1	600 µl	600 µl
Calibrator	8 µl	-
Sample	-	8 µl
Mix and incubate for 5 minutes at 37° C		
Reagent R2	200 µl	200 µl

Mix Well and incubate for 5 minutes at 37° C, read abs. at 546 nm

CALCULATION:

$$\text{LDL Conc. In Serum or Plasma} = \frac{\text{Abs. of Test}}{\text{Abs. of Calibrator}} \times \text{Calibrator Conc.}$$

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

Conversion

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

QUALITY CONTROL & CALIBRATION

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.

Calibration Frequency:

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

PERFORMANCE CHARACTERISTICS

1. Linearity

Linearity : 1000 mg/dl

2. Sensitivity/ Limit of Detection (LOD)

The lower limit of detection is 6.7 mg/dl

3. Interferences

No significant interference was observed from Ascorbic Acid 40 mg/dL, Hemoglobin 500 mg/dL, Bilirubin 30 mg/dL, Gamma-Globulins 6000 mg/dL, Lipemia as Triglycerides 1500 mg/dL

4. Precision:

Intra-Assay

N=20	Mean (mg/dl)	SD (mg/dl)	CV%
Control serum 1	63.2	0.64	1.01
Control serum 2	107	1.89	1.76
Control serum 3	49	0.79	1.61

Inter-Assay

N=20	Mean (mg/dl)	SD (mg/dl)	CV%
Control serum 1	65	0.3	0.45
Control serum 2	112	0.7	0.60
Control serum 3	253	1.7	0.65

5. Method Comparison:

Results obtained using LiquiMAX 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 R: 0.998.
Regression equation: y=4.6 + 0.940 (x)
The results of the performance characteristics depend on the analyzer used.

LIMITATIONS

From detection limit of 6.7 mg/dl to linearity limit of 1000 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.

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

REFERENCES:

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

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		

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ISO 13485 Certified Company
GMP 5th Schedule MDR 2017

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