DIRECT LDL CHOLESTEROL (D-LDL-C)

Diagnostic reagent for determination of LDL (Low Density Lipoprotein) concentration.

Liquid. Dual Reagents. Store at +2°C /+8°C. For in Vitro Diagnostic Use(IVD). Do not freeze.

WL:578-600 nm Method: Endpoint/Sblank

	Standard Blank	Standard Tube	Sample Blank	Sample Tube
R1	900µL	900µL	900µL	900µL
Standard	10µL	10µL	0	0
Sample	0	0	10µL	10µL

➢ Mix for 3 minutes and add:

R2	0	300µL	0	300µL

Mix and incubate at 37 °C 5 minutes by stopwatch. Then read accordingly. Blank: D. water. Note: Incubation time of sample always should be the same time of incubation time of standard. Longer incubation time give high results.
Calibration stability: >30 days. Test time: 10 seconds

INTENDED USE

This test is used for quantitative determination of LDL cholesterol concentration in human serum and plasma.

TEST SUMMARY AND PROCEDURE

The main function of LDL is to take these molecules from the cells and tissues that produce cholesterol and triglycerides and transport them to the cells and tissues that need them. The blood level of LDL is associated with atherosclerosis, and therefore coronary artery disease, stroke and peripheral vascular disease.

The assay consists of distinct reaction steps:

1. LDL complexes with polyanion, detergent 1 in Reagent 1 can only dissolve in non-LDL lipoprotein particles (CM, HDL, VLDL). The released cholesterol will be consumed by the enzymatic reagent, and without the chromogenic coupler, a colorless reaction will occur.

Cholesterol ester $\xrightarrow{\text{Cholesterol esterase}}$ *> Cholesterol + Fatty acid*

Cholesterol + 0₂ $\xrightarrow{\text{Cholesterol oxidase}}$ *> Cholestenone + H_2O_2*

2. Cholesterol released from D-LDL reacts with the chromogenic coupler through detergent 2 in Reagent 2 and forms color.

Cholesterol ester $\xrightarrow{\text{Cholesterol esterase}}$ *> Cholesterol + Fatty acid*

Cholesterole + 0₂ $\xrightarrow{\text{Cholesterole Oxidase}}$ *> Cholestenone + H202*

H202 + 4 — Aminoantipyrine + TOOSα $\xrightarrow{\text{Peroxidase}}$ *Quinoneimine + 4H_2O α TOOS = N — ethyl — N — (2 — hydroxy — 3 — sulfopropyl) — 3 — methylaniline*

TEST PARAMETERS

Method : Colorimetric
Wavelength: Main: 572 - 600 nm/Sub 700-750 nm
Linearity : 600 mg/dL

REAGENT COMPONENTS

Reagent 1:

Polyanion Detergent 1		
Cholesterol Esterase	:	≤ 200.000 U/L
Cholesterol Oxidase	:	≤ 200.000 U/L
Peroxidase	:	≤ 200.000 U/L
4-Aminoantipyrine		
TOOS		

Reagent 2:
Detergent 2
TOOS
Tris Buffer

REAGENT PREPARATION

Reagent are ready to use.

REAGENT STABILITY AND STORAGE

Reagents are stable at +2/+8°C till the expiration date stated on the label which is only for closed vials.

Once opened vials are stable for 30 days at +2/+8°C in optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Sample are collected according to the standard procedure.

Serum and plasma should be separated as soon as possible (within 3 hours) after collection.

Direct LDL is stable for:

7 days at +2/+8 °C,

12 months at -20 °C..

Unit Conversion:
mmol/L x 38.67 = mg/dL

REFERENCE INTERVAL (NORMAL VALUES)

Optimal	: <100 mg/dL (<2.59 mmol/L)
Near Optimal, Above Optimal	: 100 – 129 mg/dL (2.59 – 3.34 mmol/L)
Borderline High	: 130 – 159 mg/dL (3.37 – 4.12 mmol/L)
High	: 160 – 189 mg/dL (4.14 – 4.89 mmol/L)
Very High	: ≥ 190 mg/dL (≥ 4.92 mmol/L)

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

QUALITY CONTROL AND CALIBRATION:

Commercially available control material with established values determined by this method may be used.

We recommend:

Assayed Control Serum Normal

Assayed Control Serum Abnormal

The assay requires the use of a Lipids (HDL-LDL Calibrator) Lyophilized.

Calibration Stability: It is strongly depending of application to auto analyzers and auto analyzers specification. Calibration stability is 30 days.

If controls are not within acceptable limits, calibration is required and each laboratory should establish its own Quality Control diagrams and corrective and preventive action procedures.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD): The limit of detection of the test is 4.5 mg/dL
Limit of Quantitation (LoQ) [values are based on Coefficient of Variation Percentage (CV) %≤20]: 5 mg/dL

High Linearity: The method is linear up to 600 mg/dL.

For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.

Linearity may considerably vary depending on the instrument used.

Precision Studies:
Repeatability (Within Run) (Within-Run)

Mean Concentration	SD*	CV%	n
41.51 mg/dL	0.92	2.22	40
109.37 mg/dL	1.87	1.71	40

Repeatability (Day-to-Day Run)

Mean Concentration	SD*	CV%	n
40.81 mg/dL	1.25	3.06	84
101.61 mg/dL	3.52	3.46	84

*SD: Standard Derivation
*CV: Variation Coefficient

Deviations of +10% CV% between devices may be observed.

Interference:

No significant interference was observed for hemoglobin, conjugated bilirubin and lipemia up to the interferent concentration given in the table.

Interferent and Concentration	LDL Target (mg/dL)	N	%Observed Recovery
Hemoglobin 900 mg/dL	112	3	93
Bilirubin 22.5 mg/dL	119.4	3	90
Lipemia 702 mg/dL	78.4	3	110

The acceptable interference limit is set 10% below the highest interference concentration within ±10% recovery ofthe target.

Interferences may affect the results due to medication or endogenous substances

These performance characteristics have been obtained by using an analyzer. Results may vary if a different instrument or a manual procedure is used.

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