LDL Direct Cholesterol

CE

Reagent for direct measurement of LDL Cholesterol concentration in human serum and plasma. For in Vitro Diagnostic Use. Do not freeze. Store at 2-8ºC .

REF: LDL-1000A / LDL-1000B

Summary:

This reagent is designed for quantitative determination of LDL Cholesterol (LDL-C) concentration in human serum and plasma.
The LDL-C particles are lipoproteins that transport cholesterol to the cells. Often called "bad cholesterol" because high levels are risk factor for coronary heart disease and are associated with obesity, diabetes and nephrosis.

Principle:

The specific detergent present in Reagent 1 solubilizes only the non-LDL lipoprotein particles (CM, HDL, VLDL). The cholesterol released will be used up by enzymatic reagent in a non-color forming reaction.
Another specific detergent present in Reagent 2 solubilizes LDL-C.
LDL Cholesterol concentration is determined by color intensity following Trinder's reaction.

Test Parameters

Method: Colorimetric
Wavelenght: Main 572-600 nm /Sub 700-750 nm
Temperature: 37 °C
Sample: Serum, plasma
Linearity: 5-600 mg/dL

Composition:

R1: Polyaniondetergent 1, Cholesterol esterase - ≤ 200.000 U/L, Cholesterol oxidase - ≤ 200.000 U/L, Peroxidase - ≤ 200.000 U/L, 4-aminoantipyrine, TOOS
R2: Detergent 2, TOOS, Tris Buffer

Testing of human serum used in the preparation of the standard is resulted as negative for the presence of antibodies anti-HIV and anti-HCV, beside for HBs antigen. Because of the possibility of being infectious, standard should be used cautiously and with GLP rules.

Reagent Stability And Storage:

Store at 2-8ºC. Reagents are stable till the expiry date stated on the label when they stored in closed vials and avoiding contamination during their usage.
There is a strong relation between on board stability and auto analysers cooling specification and carry-over values.

Precautions:

Product to be used in professional laboratories by professional operators. Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.

Preparation:

Reagents are ready to use, liquid.

Samples:

Fresh Serum or EDTA and heparinized plasma.
Note: Separate the serum or plasma as soon as possible after collection (within 3 hours). Store serum no more than 12 hours at room temperature, no more 7 days at 2-8 ºC. Serum is stable for 30 days at (-60)-(-80)°C.

Procedure:

Mix well and incubate 10 minutes at 37°C.
Read Calibrator blank tube absorbance (ABCAL) and Calibrator tube absorbance (ACAL).
Then read sample blank tube absorbance (ASB) and Sample tube absorbance (AS).
ΔA Cal = (ACAL-ABCAL) ΔA Sample = (AB-ASB)
Calibration stability: >30 days

Different incubation time gives differents absorbance values. Incubation time of sample and calibrator always have the same time duration.
Test time: 10 seconds

Calculations:

$$\frac{\Delta A \text{sample}}{\Delta A \text{CAL}} \times \text{Conc. Cal (mg/dL)} = \text{LDL Direct (mg/dL)}$$

Unit Conversion:
mmol/Lx38.61=mg/dL

Reference Intervals (Normal Values):

Optimal: <100 mg/dL (<2.59 mmol/L)
Near optimal,
Above optimal: 100 – 129mg/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 reference range.

Quality control:

All clinical laboratories should establish an Internal Quality Control program. Check instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At pre-established intervals following the Q.C. Laboratory recommandations.

Performance characteristics:

Low Linearity (LOQ):
(LOQ values are based on CV% ≤ 20%): 5 mg/dL.
High Linearity:
The test is linear up to 600 mg/dL.
Precision:
(Based on CLSI EP05A3 Doc.):

Intra-assay			Inter-assay		
Mean (mg/dL)	%CV	n	Mean (mg/dL)	%CV	n
45	4.6	20	45	4.2	25
65	3.4	20	65	3.9	25

Sensitivity (LOD):
4.5 mg/dL.
Accuracy:
No systematic differences seen in results obtained with this reagent when compared with reference reagents. It's available to get details of comparison experiments in case of requirement.
Interferences:
No interferences were observed to bilirubin T. and D. up to 15 mg/dL, hemoglobin up to 10 g/L or lipemia up to 2500 mg/dL.
A list of drugs and other interfering substances with HDL cholesterol determination has been reported by Young et. al.

Notes:

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The reagents contain sodium azide (< 0.1%) as a preservative.

References:

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