# DIRECT LDL-CHOLESTEROL

Test for the quantitative determination of LDL-cholesterol in human serum and plasma.
Liquid. Dual reagents. Store at 2°C - 8°C. Do not freeze. For in Vitro Diagnostic Use.

| Ref No | Pack | Ref No | Pack | Ref No | Pack | Ref No | Pack |
|---|---|---|---|---|---|---|---|
| LD2600 | 4X100 ML | DML20 | 720 Tests | BY2600 | 6234 Tests | MLD20 | 2545 Tests |
| LD2601 | 4X50 ML | RLD20 | 1818 Tests | BY2601 | 4675 Tests | MLD21 | 1273 Tests |
| LD2602 | 4X25 ML | RLD21 | 600 Tests | NLD20 | 577 Tests | LLD20 | 2700 Tests |
| LD2603 | 4X10 ML | SLD20 | 2077 Tests | NLD21 | 393 Tests | LLD21 | 1800 Tests |
| TLD20 | 3318 Tests | SLD21 | 1292 Tests | KLD20 | 3122 Tests | | |
| TLD21 | 1636 Tests | SLD22 | 738 Tests | KLD21 | 2341 Tests | | |

## INTENDED USE

The test is applied for the quantitative determination of LDL (Low Densitiy Lipoprotein)-cholesterol in human serum and plasma.

## TEST PRINCIPLE

The assay consists of distinct reaction steps:

1. The LDL complexes with polyanion. The detergent 1 in Reagent 1 is soluble only in the non-LDL lipoprotein particles (CM, HDL, VLDL). The cholesterol released will be used up by enzymatic reagent and be in a non-color forming reaction without the chromogenic coupler.
2. The cholesterol released from LDL-C by detergent 2 in Reagent 2 reacts with chromogenic coupler for the colour formation.

## TEST PARAMETERS

Method :
Wavelenght : 572- 700 nm
Temperature : 2-8°C
Sample : Serum, plasma
Linearity : 20-300 mg/dL

## REAGENT COMPOSITION

**Reagent 1:**
Polyanion detergent 1
Cholesterol esterase : ≥800U/L
Cholesterol oxidase : ≥400U/L
Peroxidase : ≥5000U/L
4-aminoantipyrine
TOOS

**Reagent 2:**
Detergent 2
TOOS

Human serum used in the preparation of the standard has been tested and found to be negative for the presence of antibodies anti-HIV and anti-HCV, as well as for HBs antigen. However, the standard should be handled cautiously as potentially infectious.

## REAGENT PREPARATION

Working reagents are stable at 2-8ºC in case of closed vials and avoiding contamination after preparation.

For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

## REAGENT STABILITY AND STORAGE

Store at 2-8ºC. Reagents are stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.

On board stability is strongly related to auto analysers cooling specification and carry-over values.

## SAMPLE

**Samples:** Fresh Serum or EDTA and heparinized plasma on an empty stomach are the recommended specimens.
**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 5 days at 2-8 ºC.

## TEST PROCEDURE

**Sample Start**
There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

**Substrate Start**

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

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## CALCULATIONS

The LDL-Direct concentration in the sample is calculated using the following general formula:

$$\text{Cholesterol (mg/dl)} = \frac{A_{calibrator}}{A_{sample}} \text{ xConc.of Std./Cal (mg/dl)}$$

LDL=Cholesterol-(HDL + Triglyserid/5)

**Unit Conversion**

mmol/Lx38.61=mg/dL

## REFERENCE INTERVALS (NORMAL VALUES) (Based On Rules CLSI C28-P Document)*

Normal value : < 3.12mmol/L
Bordering high values : 3.15-3.61mmol/L (121-139mg/dL)
High risk values : > 3.64mmol/L ( > 140mg/dL)
*It is recommended that each laboratory establish its own reference range.

## QUALITY CONTROL AND CALIBRATION

It is recommended to use the Archem Serum level I and Level II to verify the performance of the measurement procedure. Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.
Calibrator:
We recommend: ARCHEM Calibrator Set (Standard)
*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

## PERFORMANCE CHARACTERISTICS

**Low Linearity:** 20 mg/dL

**High Linearity:** The test is linear up to 10.4mmol/L (400mg/dL).

**Precision Studies (Based on CLSI EP5 Doc.):**

**Repeatability (within run)(intra-assay):**

| Mean concentration | CV | n |
|---|---|---|
| 45 mg/L | 4.6 % | 20 |
| 65.0 mg/L | 3.4 % | 20 |

**Reproducibility (run to run) (inter-assay):**

| Mean concentration | CV | n |
|---|---|---|
| 45 mg/L | 4.2 % | 25 |
| 65 mg/L | 3.9 % | 25 |

**Sensitivity (LOD) (Based on CLSI EP17 document):** 10 mg/dl

**Trueness:** Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

**Interferences:**

Criterion: Recovery within ±10% of initial values at LDL cholesterol levels of 4.0 mmol/L (154 mg/dL).

Icterus: No significant interference up to an I index of 60 (approximate conjugated and unconjugated bilirubin concentration: 1026 µmol/L (60 mg/dL)).

Hemolysis: No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L (1000 mg/dL)).

Lipemia (Intralipid): No significant interference up to an L index of 200.

There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration. No significant interference from LDL (≤75 mg/dL), VLDL (≤140 mg/dL), or chylomicrons (≤2000 mg/dL triglycerides).

## 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. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles can not 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 linearity limit depends on the sample to reagent ratio.

## PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general “Good Laboratory Practice” (GLP) guidelines.

R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

## ABBREVIATIONS

CV% : Coefficient of Variation Percentage
GLP : Good Laboratory Practice
IU : International Unit
LDL : Low Density Lipoprotein
mA : miliabsorbance
mL : mililiter
QC : Quality Control

## REFERENCES


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8. Wieland H, Seidel D. Quantitative Lipoprotein Electrophoresis.


## SYMBOLS

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|---|---|
| IVD | Only for invitro diagnostic use |
| LOT | Lot of manufacturing |
| R1 | Reagent 1 |
| R2 | Reagent 2 |
| CONC | Concentration |
| INGRED | Reagent Ingredients |
| SN | Serial Number |
| REF | Reference Number (Catalog No) |
| | Expiration date |
| | Storage temperature interval |
| | Read the directions |
| | Biological risk |

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