

# DIRECT LDL CHOLESTEROL (D-LDL-C)

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

Liquid. Dual reagents (Ratio: R1/R2: 3/1). Store at +2/+8°C. For in Vitro Diagnostic Use (IVD). Do not freeze.

Ref No	Pack
MH-102	80 mL

*Changes made in the instructions for use are marked as grey.*

## INTENDED USE

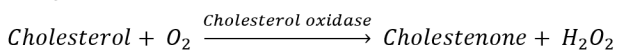
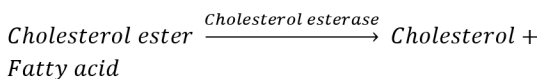
The test is applied for the quantitative determination of LDL (Low Density Lipoprotein)-cholesterol in human serum and plasma.

## TEST SUMMARY AND PROCEDURE <sup>1, 2, 3, 4, 5</sup>

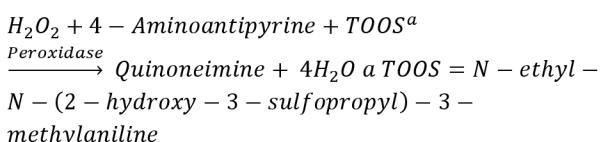
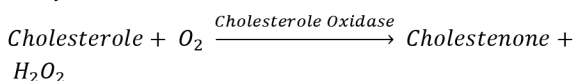
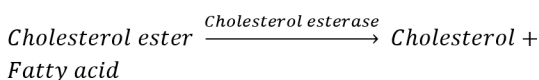
The main function of LDL is to take these molecules from the cells and tissues that produce cholesterol and triglycerides and transport them to the cells and tissues that need them. The blood level of LDL is associated with atherosclerosis, and therefore coronary artery disease, stroke and peripheral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

The assay consists of distinct reaction steps:

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



## 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

Reagents are ready for use.

## REAGENT STABILITY AND STORAGE <sup>6</sup>

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 45 days at +2/+8°C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.

Reagent stability and storage data have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

## SAMPLE

Samples are collected according to the standard procedure.

Serum or plasma should be separated as soon as possible (within 3 hours) after collection. <sup>7</sup>

Direct LDL is stable for: <sup>8</sup>  
7 days at +2/+8°C,  
12 months at -20°C.

## Unit Conversion:

mmol/L x 38.61 = mg/dL

## REFERENCE INTERVAL (NORMAL VALUES) <sup>9</sup>

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 normal range.

Reference interval has been verified by using CLSI EP28-A3c protocol.

## QUALITY CONTROL AND CALIBRATION

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

ARCON N (Level I Control) Lyophilized  
**Ref.No: VT-001**

ARCON P (Level II Control) Lyophilized  
**Ref.No: VT-002**

The assay requires the use of an Arcal Auto Calibrator / Arcal Lipids (HDL-LDL Calibrator) Lyophilized. We recommend:

Arcal Lipids (HDL-LDL Calibrator) Lyophilized  
**Ref.No: VT-004**

**Calibration Stability:** It strongly depends on the application characteristics of in-use auto analyser and capacity of cooling. 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 quality control values are acceptable. Reagent should be calibrated after lot changes.

## PERFORMANCE CHARACTERISTICS

**Limit of Detection (LoD):** The limit of the test detection is 4.5 mg/dL.

**Limit of Quantitation (LoQ)** [LoQ values are based on Coefficient of Variation Percentage (CV) ≤ 20%].<sup>10</sup> 5 mg/dL.

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

**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:<sup>11</sup>

### 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) (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 Deviation  
 CV: Variation Coefficient

±10% CV% deviations between devices can be observed

Precision Studies data have been verified by using CLSI EP05-A3 protocol.

## Interference:<sup>14, 15, 16, 17</sup>

No significant interactions were observed for hemoglobin, conjugated bilirubin, lipemia up to the interferent concentration given in the table.

Interferant 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 of the 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.

## WARNINGS AND PRECAUTIONS

IVD: For in Vitro Diagnostic use only.

Do not use expired reagents.

Reagents with two different lot numbers should not be interchanged.

For professional use.

Follow Good Laboratory Practice (GLP) guidelines.

Contains sodium azide.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

#### Danger

- EUH032 :Releases a very toxic gas if contacts with acid.
- H317 :May cause allergic skin reaction.

#### Precaution

- P280 :Use protective gloves / clothes / glasses / mask.
- P264 :Wash your hands properly after using.
- P272 :Contaminated work clothes should not be allowed to be used outside of the workplace.

#### Intervention

- P302+P352 :Wash with plenty of water and soap if it contacts with skin.
- P333+P313 :Seek medical help if it irritates your skin or develops rash.
- P362+P364 :Remove contaminated clothes and wash properly before using.

#### Disposal

- P501 :Dispose the vials and contents according to the local regulations.

#### REFERENCES

- Tietz, N.W., Fundamentals of Clinical Chemistry, p. 940, W.B. Saunders Co., Philadelphia, 1987.
- Tietz NW. Clinical Guide to Laboratory Test. 2nd ed. Philadelphia, PA: WB Saunders Company; 1995;52.
- Tietz NW. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia, PA: WB Saunders Company; 1995:88-91.
- Tietz NW, ed. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia: WB Saunders 1995:919.
- Tietz Fundamentals of Clinical Chemistry. 5th ed. Burtis CA, Ashwood ER, eds. Philadelphia, PA: WB Saunders Company; 2001:605.
- Clinical and Laboratory Standards Institute (CLSI). Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline. CLSI Document EP25-A. Wayne, PA: CLSI; 2009.
- National Committee for Clinical Laboratory Standards, National Evaluation Protocols for Interference Testing, Evaluation Protocol Number 7, Vol. 4, No. 8, June 1984.
- Jansen EHL, Beekhof PK, Schenk E. Long Term Stability of Lipid Metabolism in Frozen Human Serum: Triglycerides, Free Fatty Acids, Total-, HDL- and LDL-cholesterol, Apolipoprotein-A1 and B. J Mol Biomark Diagn 2014;5:4.
- Clinical and Laboratory Standards Institute (CLSI). Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition. CLSI Document EP28-A3c. Wayne, PA: CLSI; 2010.
- Clinical and Laboratory Standards Institute (CLSI). Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline. CLSI Document EP17-A. Wayne, PA: CLSI; Vol. 24 No. 34.
- Clinical and Laboratory Standards Institute (CLSI). Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014
- Passing-Bablok W et al. A General Regression Procedure for Method Transformation. J Clin Chem Clin Biochem 1988;26:783-79.
- Clinical and Laboratory Standards Institute (CLSI). Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition; Approved Guideline. CLSI Document EP09-A2. Wayne, PA: CLSI; Vol. 22 No. 19.
- Clinical and Laboratory Standards Institute (CLSI). Interference Testing in Clinical Chemistry; Approved Guideline. CLSI Document EP07. Wayne, PA: CLSI; 3rd Edition. CHERIAN G., SOLDIN ST. Clin. Chem. 27:5:748-752 (1981)
- Third Report of the Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), NIH Publication No. 01-3670, May 2001.
- Wieland H, Seidel D. Quantitative Lipoprotein Electrophoresis.
- Westgard, J.O., Carey, R.N., Wold, S., Criteria for judging precision and accuracy in method development and evaluation. Clinical Chemistry 1974;20:825-833.
- Tietz NW. Clinical guide to laboratory tests, 2nd ed. Saunders Co, 1991. 1988;26:783-790
- Rifai N, Warnick GR, McNamara JR, Belcher JD, Grinstead GF, Expected Values Handbook of Laboratory Medicine, Li-hua Zhu 1998.
- Frantz Jr ID. Measurement of Low-Density-Lipoprotein Cholesterol in Serum: a Status Report. Clin Chem 1992;38:150-160.
- Kannel, W.B., Castelli W.P., Gordon, T., Cholesterol in the Prediction of Artherosclerotic Disease; New Perspectives Based on the Framingham Study, Am. Intern. Med., 90:85 (1979).
- Bachoric P. Measurement of Low-Density-Lipoprotein. 245-263. In: Handbook of Lipoprotein Testing (eds. Rifai, Warnick and Dominiczak), 2nd edition, AACC press, 2000.
- National Cholesterol Education Program. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel II). NIH Publication No. 93-3095, 1995.
- Naito HK, Strong JP, Scott MG, Roheim PS, Asztalos BF, Zilversmit DB, Srinivasan SR, Berenson GS, Wilson PWF, Scanu AM, Malikow MR. Atherogenesis: current topics on etiology and risk factors. Clin Chem 1995;41:132-133 No. 1.

25. Armstrong V, Seidel D. Evaluation of a Commercial Kit for the Determination of LDL-Cholesterol in Serum Based on Precipitation of LDL with Dextran Sulfate. *Ärztl. Lab.* 1985;31:325-330.



**Archem Sağlık Sanayi ve Tic. A.Ş. . (With official contract based manufacturing agreement with Validity Sağlık Hiz.Sanayi A.Ş. Company)** Mahmutbey Mah. Halkalı Cad. No:124 Kat:4 Bağcılar/İstanbul/Türkiye  
**Tel:** + 90 212 444 08 92  
**Fax:** +90 212 629 98 89  
**info@archem.com.tr** **www.archem.com.tr**  
**info@validity.com.tr** **www.validity.com.tr**



Val

### SYMBOLS

IVD

In Vitro Diagnostic Medical Device

LOT

Lot Number

R1

Reagent 1

R2

Reagent 2

GTIN

Global Trade Item Number

REF

Reference Number

GLP

Good Laboratory Practices

FOR USE WITH

Identifies Products to Be Used Together

PRODUCT OF TURKEY

Product of Turkey



Manufacturer



Expiration Date



Temperature Limits



Consult Instructions for Use



Caution



Number of Tests