LDL-c direct FS

Reliable atherosclerotic risk assessment

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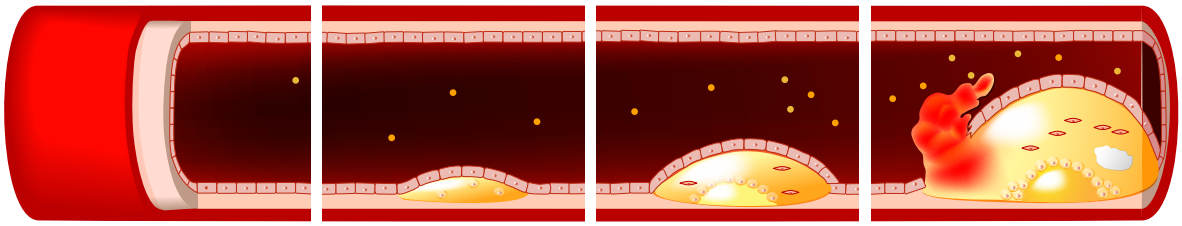
Clinical relevance

Atherosclerotic cardiovascular disease (ASCVD) and its clinical manifestations, such as stroke and myocardial infarction (MI) represent the leading global mortality cause. The key events to initiate ASCVD are the retention and accumulation of cholesterol-rich apoB-containing lipoproteins (LDL-C) within the arterial intima. If the concentration of LDL-C rises above a certain level, the probability of intimal retention of LDL leads to the initiation and progressive development of atherosclerotic plaque [1].

It has been shown that LDL-C-lowering therapy reduces atherosclerotic cardiovascular disease risk in patients with and without ASCVD. According to national and international guidelines for the management of dyslipidemia, determination of LDL-C is the primary basis for treatment; most guidelines have established target LDL-C levels to guide the selection and dosing of lipid-lowering therapy [2]. Furthermore, guidelines recommend to assess LDL-C concentration for patient risk classification.



Plaque starts to build up during adolescence caused by a combination of genetic and lifestyle factors. Often no symptoms appear until plaque shows ruptures and the blood flow becomes restricted.

LDL-C direct vs. Friedewald

Ultracentrifugation is the gold standard of LDL-C measurement in clinical laboratories, but is being replaced by alternative methods due to time requirement and costs. A common approach to determine LDL-C is the Friedewald calculation, which estimates LDL-C from measurements of total cholesterol (TC), triglycerides (TG), and high-density lipoprotein cholesterol (HDL-C) but the method only approximates LDL-C.

Originally developed for research purposes, the Friedewald equation has been widely adopted in clinical practice for several decades and, therefore, represents a valuable alternative to the gold standard. However, extensive evaluation has shown that this equation tends to underestimate LDL-C levels in the setting of high triglyceride levels where especially low LDL-C levels might result in undertreatment of high-risk patients [3].

For this reason, direct measurement of LDL-C shows clear advantages, in particular better precision due to a single measurement. Furthermore, neither non-fasting blood specimens nor the presence of elevated triglyceride concentrations considerably affects direct LDL-C determination.

New DiaSys method

LDL-c direct FS is a homogeneous method without centrifugation steps for direct measurement of LDL-cholesterol. Block polymer detergents protect HDL, VLDL and chylomicrons in the extent that only LDL-cholesterol is selectively determined by enzymatic cholesterol measurement.

$$\text{LDL-cholesterol ester} \xrightarrow{\text{CHE \& CHO}} \Delta^4\text{-Cholestenon + free fatty acids + } H_2O_2$$

$$H_2O_2 + \text{4-Aminoantipyrine + H-DAOS} \xrightarrow{\text{POD}} \text{Blue dye + } H_2O$$

Benefits of LDL-c direct FS at a glance

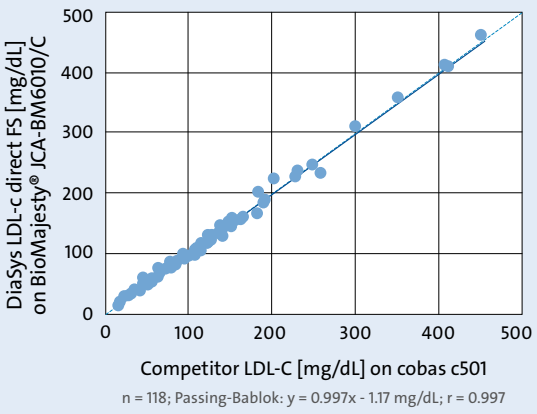
- Direct homogeneous method without sample pre-treatment
- Wide measuring range up to 500 mg/dL to comfortably detect levels outside the healthy range
- No significant interference from triglycerides and other endogenous substances
- Excellent precision over the entire measuring range
- Good comparability to competitor assays
- Superior stability for calibration and on board
- Standardized to international reference material NIST-SRM®-1951c level 2

Performance data

Precision

Within run (n=20)	Mean [mg/dL]	CV [%]
Sample 1	90.8	0.912
Sample 2	149	0.909
Sample 3	433	0.582
Between day (n=20)	**Mean [mg/dL]**	**CV [%]**
Sample 1	89.1	1.68
Sample 2	143	0.971
Sample 3	419	1.17

Method comparison



n = 118; Passing-Bablok: y = 0.997x - 1.17 mg/dL; r = 0.997

Leading technology in fluid-stable reagents from DiaSys

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DiaSys offers reagent kits for manual and automated use.
Detailed information about LDL-c direct FS is available on our website:
www.diasys-diagnostics.com/ldl-c-direct-fs and in the product catalog.

References

[1] Ference BA, Ginsberg HN et al. Low-density lipoproteins cause atherosclerotic cardiovascular disease. 1. Evidence from genetic, epidemiologic, and clinical studies. A consensus statement from the European Atherosclerosis Society Consensus Panel. Eur Heart J 2017; 38: 2459–2472.

[2] Grundy SM, Stone NJ, Bailey AL, Beam C, Birtcher KK, Blumenthal RS, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ ACPM/ADA/AGS/APhA/ASPC/NLA/ PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2018; 73(24):e285-e350.

[3] Nauck M, Warnwick GR, Rifai N. Methods for measurement of LDL-cholesterol: a critical assessment of direct measurement by homogeneous assays versus calculation. Clin Chem 2002; 48: 236-54.

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