DZ-LITE OxPL LIPOPROTEIN ASSAY

Diazyme DZ-Lite OxPL Lipoprotein Assay measures oxidized lipoproteins in human serum. DZ-Lite OxPL lipoprotein (oxPL-apoB) Assay is intended to be used for the in vitro quantitative measurement of oxidized phospholipid of low-density lipoproteins such as LDL and Lp(a) in human serum. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. DZ-Lite OxPL Lipoprotein (OxPL-apoB) Assay is FDA 510(k) exempt (see Code of Federal Regulations Title 21, Volume 8: 21CFR862.1475).

Lipoproteins such as Low-density lipoprotein (LDL) and lipoprotein (a) or Lp(a) can be oxidized in the circulation as well as in any of the cells within the artery, including the endothelial cells, macrophages, smooth muscle cells and T lymphocytes. Studies have shown that oxidized lipoproteins are more prone to be taken up by macrophages and to cause formation of foam-cells which lead to plaque formation in blood vessels[1] (see schematic diagram of plaque formation in Figure 1). The oxidation process modifies both lysine amino acids and phospholipids such as phosphocholine on the apoB subunit of LDL and Lp(a) lipoproteins. In the literatures, oxidation of lysine residues on apoB is referred as oxLDL, and oxidation on the phospholipids of apoB is referred as oxPL lipoprotein or oxPL-apoB. Diazyme provides both oxLDL assay and oxPL lipoprotein assay. The sum of oxLDL and oxPL lipoprotein may represent the status of the total level of oxidation of lipoproteins in the blood circulation.

Studies have shown that OxPL lipoprotein is associated with increased risk of atherosclerotic lesion formations, particularly in pathologically defined vulnerable and disrupted plaques (Figure 1). OxPL lipoproteins are key mediators in the initiation and progression of atherosclerosis and the development of cardiovascular disease (CVD) and clinical events, such as myocardial infarction, acute coronary syndromes, stroke, angiographically determined coronary, carotid and peripheral arterial disease, and calcific aortic valve stenosis.[2-5]

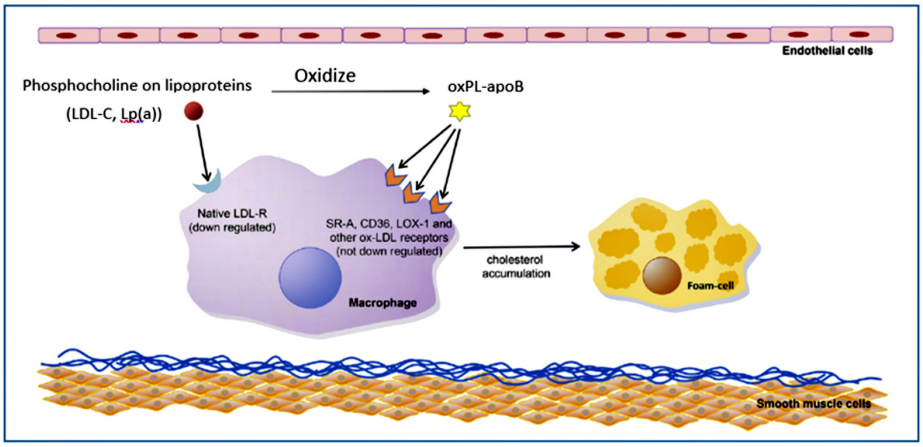


Figure 1

DZ-LITE OxPL LIPOPROTEIN ASSAY

ASSAY SPECIFICATIONS

Method	Chemiluminescent Immunoassay (CLIA)
Instrument	DZ-Lite 3000 Plus
Sample Type	Serum or Plasma
Accuracy	R^2 = 0.75 in comparison study with ELISA from Dr. Tsimikas lab at UCSD using 40 fresh serum samples
Linearity	Up to 50.0 nM
LOQ	0.57 nM
Measuring Range	0.57 to 50 nM
Throughput	DZ-Lite 3000 Plus: >200 tests/hr
Correlation to LDL-C	No

For Diazyme Sales inquiries please contact sales@diazyme.com

For Diazyme Technical Support please call 858.455.4768 or email support@diazyme.com

1. *S. Gao, J. Liu, Association between circulating oxidized lowdensity lipoprotein and atherosclerotic cardiovascular disease, Chronic Diseases and Translational Medicine 3 (2017) 89e94*
2. *Tsimikas S, Brilakis ES, Miller ER, McConnell JP, Lennon RJ, Kornman KS, Witztum JL, Berger PB. Oxidized phospholipids, Lp(a) lipoprotein, and coronary artery disease. N Engl J Med. 2005;353:46-57.*
3. *Tsimikas S, Mallat Z, Talmud PJ, Kastelein JJ, Wareham NJ, Sandhu MS, Miller ER, Benessiano J, Tedgui A, Witztum JL, Khaw KT, Boekholdt SM. Oxidation-specific biomarkers, lipoprotein(a), and risk of fatal and nonfatal coronary events. J Am Coll Cardiol. 2010;56:946-955.*
4. *Leibundgut G, Scipione C, Yin H, Schneider M, Boffa MB, Green S, Yang X, Dennis EA, Witztum JL, Koschinsky ML, Tsimikas S. Determinants of binding of oxidized phospholipids on apolipoprotein(a) and lipoprotein(a). J Lipid Res. 2013;54:2815-2830.*
5. *Bertoia ML, Pai JK, Lee JH, Taleb A, Joosten MM, Mittleman MA, Yang X, Witztum JL, Rimm EB, Tsimikas S, Mukamal KJ. Oxidation-specific biomarkers and risk of peripheral artery disease. J Am Coll Cardiol. 2013;61:2169-2179. lipoprotein(a). J Am Coll Cardiol. 2014;63:1724-1734.*

ASSAY ADVANTAGES

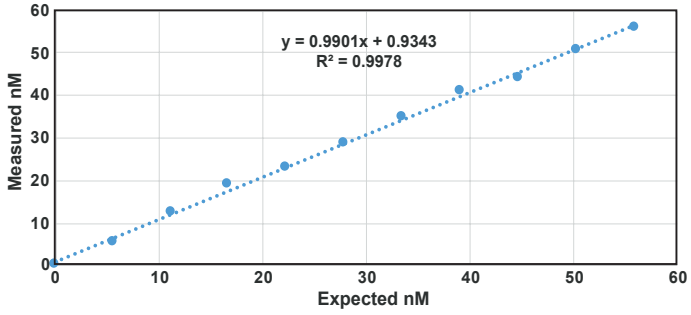
- Specific for oxidized phosphocholines on apoB-100 containing lipoproteins
- Assay is fully automated
- No manual sample pre-dilution required
- A substantial amount of clinical data strongly supports the link between OxPL-apoB level and risks of CVD

ASSAY PRECISION

Performance studies were conducted using the DZ-Lite 3000 Plus automated chemiluminescent immunoassay analyzer. In the study, samples spiked with calibrator were tested in one run with 12 replicates.

	Level 1	Level 2
N	12	12
Mean (nM)	6.0	40.0
SD (nM)	0.33	1.21
CV (%)	5.6%	3.0%

ASSAY LINEARITY



REGULATORY STATUS

510(k) Exempt

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