DIAZYME OxLDL TURBIDIMETRIC ASSAY

The Diazyme OxLDL Turbidimetric Assay is for the quantitative determination of OxLDL in serum and plasma by latex enhanced immunoturbidimetric method. OxLDL Assay is intended to be used for the in vitro quantitative measurement of oxidized low-density lipoproteins in human serum or plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. OxLDL Assay is FDA 510k exempt (see Code of Federal Regulations Title 21, Volume 8: 21CFR862.1475).

DIAZYME OxLDL TURBIDIMETRIC ASSAY PRINCIPLE

Diazyme OxLDL Assay is a latex enhanced immunoassay. Latex particles are coated separately with a monoclonal antibody specific for oxidized lysine amino acids on apoB and a monoclonal antibody specific for apoB. In the presence of oxLDL, the latex particles form agglutination that results in optical change of the reaction mixture. The absorbance change at 600nm is proportional to the amount of oxLDL in the sample. The assay is run on fully automated clinical chemistry analyzers.

DIAZYME OxLDL TURBIDIMETRIC ASSAY ADVANTAGES

- Specific for oxidized lysine residues on apoB100 of LDL-C
- Provides fast, automated, and cost-effective alternative to ELISA, making OxLDL testing more accessible for cardiovascular and metabolic disease evaluation
- Meets CLSI EP6-A standards for consistent and reproducible results
- Overcomes the issue of ELISA based OxLDL assays with direct correlations to LDL-C levels
- Proportional to the amount of oxidized lysine residues on apoB100 of LDL-C
- Liquid stable reagents
- Available on clinical chemistry analyzers

DIAZYME OxLDL TURBIDIMETRIC ASSAY

ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidimetric (600 nm wavelength)
Sample Type	Serum and Plasma
Precision (%CV)	≤ 10%
LOQ	7.6 U/L
Measuring Range	13 - 115 U/L
Throughput	AU680: >400 tests/hr

For Diazyme Sales inquiries please contact *sales@diazyme.com*

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

1. *Yicong Zhanga et al. Treatment of atherosclerotic plaque: perspectives on Theranostics. Journal of Pharmacy and Pharmacology, 71 (2019), pp. 1029–1043*
2. *Holvoet P et al. Association between circulating oxidized low-density lipoprotein and incidence of the metabolic syndrome. JAMA. 2008; 299: 2287-2293.*
3. *Holvoet P et al. Circulating oxidized LDL is a useful marker for identifying patients with coronary artery disease. Arterioscler Thromb Vasc Biol. 2001; 21: 844-848.*
4. *Nishi K et al. Oxidized LDL in carotid plaques and plasma associates with plaque instability. Ateriosclerosis Thromb Vasc Biol. 2002; 22: 1649-1654.*
5. *Tsimikas S et al. Oxidized phospholipids, Lp(a) lipoprotein, and coronary artery disease. N Engl J Med. 2005; 353: 46-57.*
6. *Meisinger C et al. Plasma oxidized low-density lipoprotein, a strong predictor for acute coronary heart disease events in apparently healthy, middle-aged men from the general population. Circulation.2005; 112: 651-657.*
7. *Pfützner A A, Efstrathios K, Löbig M, Armbruster FP, Hanefeld M, Forst T. Differences in the results and interpretation of oxidized LDL Cholesterol by two ELISA assays--an evaluation with samples from the PIOstat Study. Clin Lab. 2009;55(7-8):275-281. PubMed 19894406*

ASSAY BACKGROUND

Diazyme OxLDL Turbidimetric Assay measures oxidized lipoproteins in human serum or plasma. Lipoproteins such as Low-density lipoprotein (LDL) 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 Figure 1 of plaque formation). The oxidation process modifies both lysine amino acids and phospholipids on the apoB subunit of LDL cholesterol. In the literature, 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 (OxPL-apoB). The sum of OxLDL and OxPL lipoprotein may represent the status of the total level of oxidation of lipoproteins in the blood circulation.

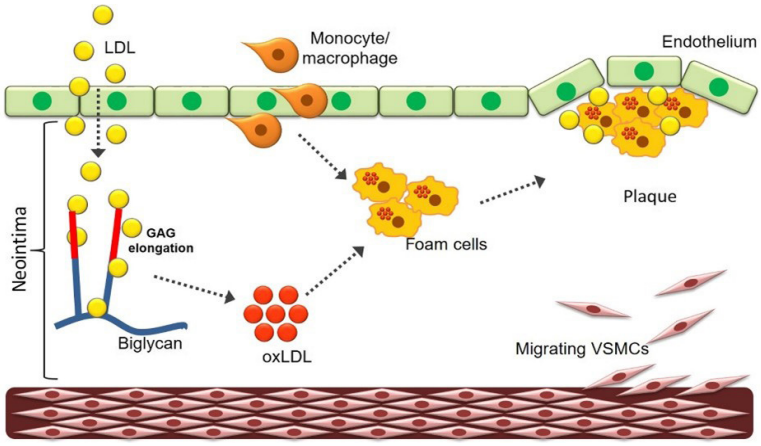

Figure 1

In the recent scientific reports, both oxLDL and oxPL lipoprotein assays were cited to be key factors in the biological process that initiates and accelerates the development of the early atherosclerotic lesion, the fatty streak2-6. Studies report that plasma level of OxLDL was cited as a sensitive biomarker of atherosclerosis. Elevated levels of OxLDL were reported to be associated with accelerated atherogenesis, CAD, acute myocardial infarction, and stable and unstable angina, as well as with metabolic syndrome[2-6]. OxLDL measurement has been used to test the efficacy of CVD drugs (eg, statins) to reduce oxidative stress.[7]

REGULATORY STATUS

510(k) Exempt

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