DZ560A

sdLDL ASSAY

The Small Dense Low-Density Lipoprotein Cholesterol (sdLDL) Assay is a homogeneous enzymatic assay for use in the quantitative determination of sdLDL in human serum. LDL-cholesterol is a critical risk factor for developing coronary heart disease (CHD). Studies found that small, dense LDL, compared to the normal LDL, is more strongly associated with the development of CHD. Determination of sdLDL by ultracentrifugation, electrophoresis-based, or nuclear magnetic resonance methods are laborious and time-consuming.[1-2]

Diazyme's sdLDL test is a homogenous, direct assay for the fast and easy quantification of sdLDL cholesterol. It facilitates the fully-automated measurement of sdLDL.

DIAZYME sdLDL ASSAY ADVANTAGES

- Homogenous enzymatic assay
- Low limit of quantitation: 2.2 mg/dL
- Improves laboratory efficiency and workflow
- Fast test results (10 minutes) for a rapid turnaround time
- Liquid stable format requires no reagent preparation
- Wide range of instrument parameters available for simplifying implementation

REGULATORY STATUS

USA: For Research Use Only

DIAZYME
Innovations in Clinical Diagnostics

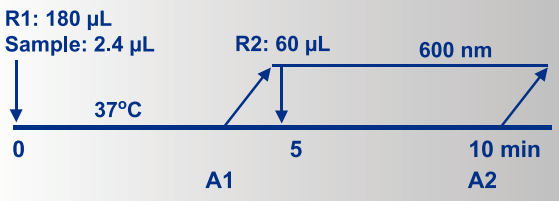
sdLDL ASSAY

Dual Vial
Liquid Stable

ASSAY SPECIFICATIONS

Method	Homogeneous Enzymatic Assay
Sample Type & Volume	Serum Sample Volume 2.4 µL
Method Correlation	N = 40 y-intercept = 1.07 Slope = 1.07 R^2 = 0.94 Sample Range: 10 to 70 mg/dL
LOD **LOQ**	1.6 mg/dL 2.2 mg/dL
Calibration Levels	2-Point Calibration

sdLDL Assay Procedure*



***Analyzer Dependent**

For a list of validated parameters please contact Diazyme technical support at 858-455-4768 or email support@diazyme.com

1. Koba S, Hirano T, Ito Y, Tsunoda R, Yokota Y, Ban Y, Iso Y, Suzuki H, Katagiri T. Significance of small dense low-density lipoprotein-cholesterol concentrations in relation to the severity of coronary heart disease. Atherosclerosis 2006; 189:206-214.

2. Hirano T, Ito Y, Saegusa H, Yoshino G. A novel and simple method for quantification of small, dense LDL. J Lipid Res 2003; 44:2193-2201.

ASSAY PRECISION

In the study, two serum samples containing 6.8 and 46.5 mg/dL sdLDL respectively, were tested on hitachi 917 in one run with 20 replicates. Within-Run Precision is listed in the table below:

	Level 1	Level 2
N	20	20
Mean (mg/dL)	6.8	46.5
SD (mg/dL)	0.26	1.53
CV (%)	3.76	3.30

ASSAY INTERFERENCE

To determine the level of interference from the substances present in serum, the Diazyme sdLDL Assay was used to test two serum samples with 8 mg/dL and 40 mg/dL sdLDL spiked with various concentrations of substances following the CLSI EP7-A2. The following substances do not interfere with this assay at the levels tested (less than 10% bias).

Interferent	Concentration
Bilirubin	40 mg/dL
Bilirubin Conjugated	40 mg/dL
Hemoglobin	250 mg/dL
Ascorbic acid	10 mM
Triglycerides	1000 mg/dL

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