

LIPOPROTEIN (a) MOLARITY ASSAY



Cardiovascular Biomarker



DIAZYME

Innovations in Clinical Diagnostics

LIPOPROTEIN (a) MOLARITY ASSAY



Lipoprotein(a) [Lp(a)] is an independent, genetically determined risk factor for atherosclerotic cardiovascular disease (ASCVD) and aortic valve stenosis. Current clinical guidelines recommend Lp(a) measurement at least once in every adult's lifetime . For individuals with FH, premature ASCVD, or high Lp(a), cascade testing of first-degree family members for high Lp(a) concentration is recommended to identify those at increased ASCVD risk . The new ACC/AHA guideline (March 2026) also recommends that clinical laboratories employing Lp(a) assays that are insensitive to apolipoprotein(a)[apo(a)] isoforms and traceable to official reference standard materials.¹

DIAZYME LIPOPROTEIN (a) MOLARITY ASSAY ADVANTAGES

- FDA 510(k) Cleared
- Results reported in nmol/L
- Align with ACC/AHA guideline recommendation
- Reagent, Calibrator and Control are all liquid stable
- Provide results in < 10min with ready-to-use reagents
- Lp(a) isoform insensitive
- Results traceable to CDC reference materials and IFCC Reference Measurement Procedure (RMP)
- Fully automated applications available for a wide range of analyzers
- Cost effective, enables broader adoption of standardized Lp(a) testing

REGULATORY STATUS

FDA 510k Cleared

 Marked under IVDR
2797

LIPOPROTEIN (a) MOLARITY ASSAY

ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidimetric Assay
Sample Type & Volume	Serum or K2EDTA/K3EDTA Plasma or Li-Heparin Plasma
Method Correlation	N = 209 Slope = 1.012 y-intercept = -0.149 Correlation coefficient r = 0.992 Sample Range: 7.8 to 223.3 nmol/L
LOB/ LOD / LOQ	LOB: 0.49 nmol/L LOD: 1.50 nmol/L LOQ: 4.85 nmol/L (20% CV)
Linearity	Measuring Range: 4.85 to 240 nmol/L
Calibration Levels	6-Point Calibration

ASSAY PRECISION

The precision of the Lipoprotein (a) Assay was evaluated according to Clinical and Laboratory Standards Institute EP5-A3 guideline. In the study, two levels of controls and five levels of serum specimens containing Lipoprotein (a) covering assay measuring range were tested with 2 runs per day with duplicates over 20 working days on Beckman Coulter AU680. The results of the within-run, between-run, between-day, and total CV% are listed in the following table (N=252):

Sample	Mean (mg/dL)	Within-Run	Between-Run	Between-Day	Between-Lot	Total
	(N=252)	CV%	CV%	CV%	CV%	CV%
Control 1	34.24	1.70%	1.18%	1.50%	0.32%	2.09%
Control 2	94.21	0.66%	0.48%	0.57%	0.19%	0.82%
Sample 1	34.57	1.76%	1.28%	1.13%	0.63%	1.97%
Sample 2	74.59	0.83%	0.57%	0.75%	0.14%	1.03%
Sample 3	115.55	0.60%	0.48%	0.42%	0.13%	0.69%
Sample 4	148.85	0.96%	0.64%	0.56%	0.12%	0.99%
Sample 5	198.84	0.91%	0.64%	0.53%	0.22%	0.96%

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SCIENTIFIC STATEMENTS ON USE OF LP(a)

The table below shows NLA recommended Lp(a) thresholds, alongside Lp(a) attributable ASCVD risk.²

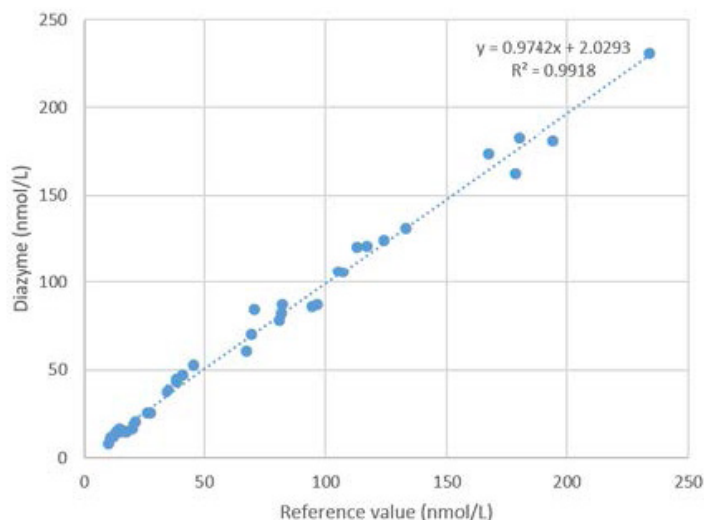
	Lp(a)-attributable ASCVD risk
< 75 nmol/L	Low Lp(a)-attributable ASCVD risk.
75 - < 125 nmol/L	Intermediate Lp(a) attributable ASCVD risk.
≥ 125 nmol/L	High Lp(a)-attributable ASCVD risk, with increasing risk with higher Lp(a) values.

1. 2026 ACC /AHA /AACVPR /ABC /ACPM/ ADA/ AGS / APhA /ASPC/NLA /PCNA Guideline on the Management of Dyslipidemia JACC. V O L . 8 7 , N O . 1 9 , 2 0 2 6

2. Koschinsky ML, Bajaj A, Boffa MB, et al. A focused update to the 2019 NLA scientific statement on use of lipoprotein(a) in clinical practice. J Clin Lipidol. 2024;18(3):e308-e319.

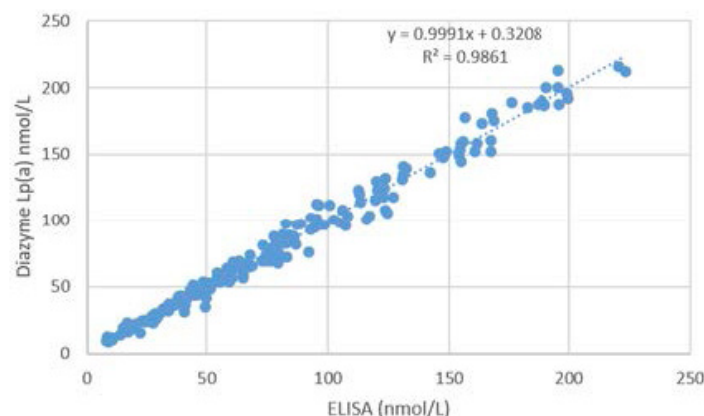
TRACEABILITY TO CDC REFERENCE MATERIALS

Traceability to CDC reference materials (example shown for reagent lot LT0008925).



METHOD COMPARISON

Method comparison of Diazyme's molarity Lp(a) assay with an isoform-independent Lp(a) ELISA assay. The graph shown is an example using data from a single reagent lot test.



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