DIAZYME LIPOPROTEIN (a) ASSAY

The Diazyme's Lipoprotein (a) (Lp(a)) Assay is an in vitro diagnostic test intended for the quantitative determination of Lp(a) concentrations in human serum and plasma. The assay is used in clinical laboratories to aid in the evaluation of Lp(a) as an independent risk factor for cardiovascular diseases, such as coronary heart disease (CHD) and stroke. Designed for use on fully automated clinical chemistry analyzers, the Diazyme Lp(a) Assay offers a precise and reliable method for measuring Lp(a) levels, using a latex-enhanced immunoturbidimetric principle. With its ready-to-use liquid-stable reagents and broad measuring range, the assay provides fast and accurate results to support cardiovascular risk assessment.[1-8]

DIAZYME LIPOPROTEIN (a) ASSAY ADVANTAGES

- Independent of the size of apo (a) protein.
- Supports early identification of CHD, stroke, and restenosis risks through quantitative Lp(a) measurement.[1-8]
- Reagent, Calibrator and Control are all liquid stable.
- Fully automated applications available for a wide range of analyzers.
- Shows excellent agreement with leading commercial assays.
- Provides results in under 10 minutes with ready-to-use reagents for efficient lab workflows.

REGULATORY STATUS

510(k) Cleared; EU: CE IVD;
Health Canada Registered

Coming Soon: Inquire about our nmol/L Lipoprotein (a) Solutions

DIAZYME
Innovations in Clinical Diagnostics

LIPOPROTEIN (a) ASSAY

Dual Vial
Liquid Stable

ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidimetric Assay
Sample Type & Volume	Serum or Plasma Sample Volume 4 µL
Method Correlation	N = 99 y-intercept = 1.0033 Slope = 0.9828 R^2 = 0.9868 Sample Range: 61 to 93.2 mg/dL
LOD **LOQ**	1.3 mg/dL 3.2 mg/dL
Linearity	Range up to 100 mg/dL
Calibration Levels	6-Point Calibration

Lipoprotein (a) Assay Procedure*

***Analyzer Dependent**

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

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4. Stubbs P, Seed M, Lane D, Collinson P, Kendall F, Noble M. Lipoprotein (a) as a risk predictor for cardiac mortality in patients with acute coronary syndromes. Eur Heart J. 1998; 19:1355-1364.
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7. Desmarais RL, Sarembock IJ, Ayers CR, Vernon SM, Powers ER, Gimple LW. Elevated serum lipoprotein (a) is a risk factor for clinical recurrence after coronary balloon angioplasty. Circulation. 1995; 91:1403-1409.
8. Miyata M, Biro S, Arima S, et al. High serum concentration of lipoprotein (a) is a risk factor for restenosis after percutaneous transluminal coronary angioplasty in Japanese patients with single-vessel disease. Am Heart J. 1996; 132:269-273.

ASSAY PRECISION

The precision of the Diazyme Lipoprotein (a) Assay was evaluated according to Clinical and Laboratory Standards Institute EP5-A2 guideline. In the study, five levels of serum specimens containing Lipoprotein (a) covering assay AMR were tested with 2 runs per day with duplicates over 20 working days on Beckman Coulter AU400 using three lots of the reagents. The results of the withinrun, between-run, between-day, and total CV% for three lots of the reagent combined are listed in the following table (N=240):

Sample	Mean (mg/dL)	Within-Run SD CV%	Between-Run SD CV%	Between-Day SD CV%	Total SD CV%
Serum 1	7.9	0.29 3.7%	0.18 2.3%	0.72 9.2%	0.80 10.1%
Serum 2	14.6	0.43 2.9%	0.00 0.0%	0.83 5.7%	0.93 6.4%
Serum 3	20.1	0.63 3.1%	0.00 0.0%	1.03 5.1%	1.21 6.0%
Serum 4	57.6	0.85 1.5%	0.0000 0.0%	1.49 2.6%	1.71 3.0%
Serum 5	95.9	0.75 0.8%	0.51 0.5%	1.12 1.2%	1.44 1.5%

ASSAY INTERFERENCE

Interference studies were conducted according to the CLSI EP7-A2 guidelines. The acceptance criterion was set at 10% or less deviation between the spiked sample and the control. The assay's results were not significantly affected by the following substances:

Interferent	Concentration
Bilirubin	40 mg/dL
Bilirubin Conjugated	40 mg/dL
Hemoglobin	1000 mg/dL
Ascorbic acid	176 mg/dL
Triglycerides	1000 mg/dL

DIAZYME LABORATORIES, INC.
12889 Gregg Court, Poway, CA 92064 USA
PO Box 85608, San Diego, CA 92186 USA
Tel: +1-858-455-4768 +1-888-DIAZYME
www.diazyme.com sales@diazyme.com

DIAZYME EUROPE GMBH
Zum Windkanal 21, 01109 Dresden, Germany
Tel: +49-351-886-3300 Fax: +49-351-886-3366
sales@diazyme.de

SHANGHAI DIAZYME CO., LTD.
Building 8, 3879 Dongchuan Road
Minhang District, Shanghai, 200245
Tel: +86-21-54843802 Fax: +86-21-51320663
www.lanyuanbio.com service@lanyuanbio.com