

IMMAGE® Immunochemistry System

New Lp(a) Reagent Completes Cardiovascular Disease Test Panel

Chemistry
Lab Automation
Information Systems
Molecular Diagnostics
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Primary Care

Assay Information

Coronary heart disease is the leading cause of death in the U.S. and many other Western industrialized countries. Most cases of heart disease are caused by a fundamental malady: atherosclerosis, the accumulation of fatty deposits in artery walls. Some causes of atherosclerosis and heart disease are now clear. High blood pressure, diabetes, smoking and other factors seem to increase the likelihood of heart disease. Diets rich in cholesterol and saturated fats contribute to the elevation of lipid (fat) levels in the blood and to the progression of atherosclerosis.

Lipoproteins, used to transport cholesterol, are also another important risk factor. Discovered by Berg in 1963, Lipoprotein(a) plays a major role in this pathology.¹ The measurement of Lp(a), in conjunction with other lipoprotein tests, is of diagnostic significance when assessing atherosclerotic cardiovascular disease in specific populations.

Lp(a) is comprised of two proteins, Apo(a) [Apolipoprotein (a)] and Apo B-100, which are linked by a disulfide bond. Apo(a) is a heavily glycosylated protein unique to Lp(a); Apo B-100 is found in other lipoproteins, including LDL.

Although Lp(a)'s lipid composition² is very similar to LDL, Lp(a) concentration level is independent from dietary or pharmacological effects.

<u>Property</u>	<u>Lp(a)</u>	<u>LDL</u>
Diameter (nm)	25-30 nm	19-23 nm
Molecular weight (daltons)	2.9-3.7 x 10 ⁶	2.75 x 10 ⁶
Electrophoretic mobility	Pre-beta	Beta
Density (g/mL)	1.040 – 1.130	1.019 – 1.063
Lipid-protein ratio	75:25-64:36	80:20
Major lipids	Apo B-100, Apo(a)	Apo B-100

Numerous epidemiological studies have all found a positive association of plasma Lp(a) concentration with premature myocardial infarction.³ It is also suggested that the serum level of Lp(a) could be associated with genetic factors, because the level of variance by ethnic group parallels total cholesterol levels.⁴

1. Berg, K. A New Serum Type System in Man: Lp System, *Acta Pathol Microbiol Scand.*, 1963; 59: 369-382.

2. Tietz Textbook of Clinical Chemistry, 3rd edition; 1999:section V; p. 820.

3. Danesh, J. Lipoprotein(a) and Coronary Heart Disease, Meta-Analysis of Prospective Studies. *Circulation*, 2000; 102: 1082.

4. Brown, S. Plasma lipid, lipoprotein cholesterol, and apoprotein distributions in selected U.S. communities. The atherosclerosis Risk in Communities (ARIC) Study, *Arteriosclerosis Thromb.* 1993; 13: 1139.

Product Information

Beckman Coulter Lipoprotein (a) Reagent (LPAX) is intended for the quantitative determination of human Lipoprotein (a) in serum or plasma samples on the fully automated IMMAGE® Immunochemistry System. The IMMAGE utilizes proven rate nephelometry methodology to provide specific, reproducible, quantitative Lp(a) results. Beckman Coulter's LPAX test is a unique, particle-enhanced reagent that increases sensitivity and eliminates the need for sample preparation. Offline dilutions and centrifugation are not necessary, saving time and labor in the laboratory. The IMMAGE test offers:

- Liquid, ready-to-use reagents
- Single-point calibration verification
- 30-day calibration stability
- Up to 24-month open-bottle stability when properly stored

Principle

Rate nephelometry

Sensitivity

2.0 mg/dL

Measuring Range

2.0-640 mg/dL (20-6400 mg/L)

Sample Type

Serum or plasma

Precision

<5% within run

<6.5% total

Stability

24 months if stored at 2 to 8°C

Calibration Stability

30 days

Sample Volume

86.5 µL (minimum)

Interference

The reaction is not affected by the turbidity samples containing ≤500 mg/dL (4+) Lipids.* Absence of cross reactivity with plasminogen.

Reference Interval^a

The LPAX reference interval values for human serum Lp(a) were established using the IMMAGE and Array® 360 systems, for a population of African-American males (ages 20-63) and females (ages 20-81), and Caucasian males (ages 25-81) and females (ages 24-85) from the U.S.A., having a normal lipid profile as defined by the National Institute of Health,¹ National Cholesterol Education Program,² with total cholesterol levels of <239 mg/dL.

Lp(a) Concentration (mg/dL)^b

	N	Median	Range
Males			
African-American	258	38.6	21.8 to 72.3
Caucasian	312	13.9	5.6 to 33.8
Females			
African-American	260	46.9	21.7 to 74.3
Caucasian	344	12.5	5.7 to 31.2

^a Because of the variability associated with population characteristics each laboratory should establish its own limits of normal.

^b Expressed as anti-log transformed concentration defined as the 25th to the 75th percentile.

Method Comparison

APO-Tek Lp(a)TM Elisa Method

n = 400

Slope = 0.810

Ordering Information

447450	LPAX Reagent (150 tests)
465365	LPA Calibrator (2 x 1 mL)
447660	Diluent 2 (4 x 120 mL)
447650	Buffer 1 (4 x 120 mL)

*Intralipid is a registered trademark of Kabivitrum, Inc.

1. National Institutes of Health, Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (*Adult Treatment Panel II*), NIH Publication No. 93-3095 (1993).

2. Summary of the Second Report of the National Cholesterol Education Program (NCEP) on the *Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel II)*. JAMA, June 16, 1993, Volume 269m, No. 23, page 3015



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