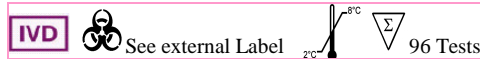


**AccuDiag™
Lp(a)
ELISA Kit**

Cat# 1740-9



Test	Lp (a) ELISA
Method	Enzyme Linked Immunosorbent Assay
Principle	ELISA- Solid Phase, Sandwich ELISA
Detection Range	3 µg/dL - 405 µg/dL
Sample	5 µL serum
Total Time	~ 150 min.
Shelf Life	12- 18 Months from the manufacturing date
Specificity	90 %
Sensitivity	3 µg /dL

INTENDED USE

To quantify total human lipoprotein A (Lp(a)).

TEST PRINCIPLE

Solid phase capture sandwich ELISA assay using a microwell format.

MATERIALS AND COMPONENTS

Materials provided with the test kits

- Goat Anti-Human Lp(a) coated microwell strips 12x8 with plastic frame
- Lp(a)N Conjugate – 12mL
- Lp(a) standard (diluted 1:400) – 1 mL **Store at -20 ° C**
- TMB/peroxide substrate color developer –12mL
- Lp(a) specimen diluent – 60mL
- Sulfuric acid termination reagent (0.5N) –12mL
- 15 X Wash buffer concentrate – 60mL

Patient and Standard Dilutions

Dilute each serum or plasma specimen to be tested 1:400 with the Lp(a) specimen diluent provided. (Serum specimens with high Lp(a) levels should be diluted more than 1:400 for accurate Lp(a) determination.)

***Note: A pre-dilution using PBS (phosphate buffer) may be done followed by a final dilution in specimen diluents to bring the serum or plasma final dilution to 1:400.**

Construct a standard curve as follows:

- Perform a series of at least four, twofold dilutions of the 1:400 standard. Use the specimen diluent alone as a blank or zero control.
- Use the declared value on the vial of Lp(a) standard to calculate the values on the standard curve.

ASSAY PROCEDURE

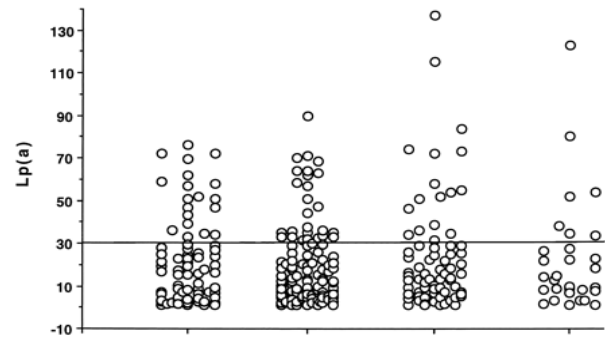
***Caution: All human fluids should be treated as infectious agents that could carry HIV.**

*Allow each reagent to reach room temperature before use.

- Add 100uL of *diluted* specimen or standard to each microwell.
- Incubate at room temperature for 60 minutes.
- Decant and wash each microwell five times with wash buffer (dilute buffer 1:15 with reagent grade water).
- Add 100uL of anti-human Apo B-100 conjugate to each well.
- Incubate at room temperature for 60 minutes.
- Decant and wash as in step 3.
- Add 100uL of TMB/peroxide substrate and incubate at room temperature for 30 minutes.
- Terminate the reaction with 100uL of 0.5N sulfuric acid.
- Zero the microwell reader at 450nm using the specimen diluent zero control well.
- Determine the optical density (O.D.) of the remaining wells.
- Construct a standard curve using the O.D. values obtained for each of the standards.
- Interpolate the unknowns from the standard curve.

*** Interpolated concentrations greater than 400 µg/dL should be sub diluted 1:4 and re-assayed then corrected mathematically.**

Table 1. Lp(a) levels (mg/dl) in centenarians and controls



	Centenarians (n=75)	<65 years, randomly selected (n=114)	>65 years, randomly selected (n=73)	>60 years, healthy selected (n=30)
Age range (in years)	100–106	8–64	65–98	61–80
Age mean	100.9 ± 1.4	35.8 ± 11.8	83.5 ± 7.6	71.4 ± 5.5
Lp(a) average	22.4	19.3	23.8	23.0
Lp(a) median	17.2	12.5	15.2	14.2
Lp(a) range	1–76	1–90	1–137	1–123
Log Lp(a) (x̄±SD)	1.11 ± 0.52	1.06 ± 0.48	1.13 ± 0.51	1.12 ± 0.51
% subjects with Lp(a) >30 mg/dl	25.3	22.8	23.3	23.3
% subjects with Lp(a) <30 mg/dl	74.7	77.2	76.7	76.7

Table is from “Lipoprotein(a) and lipoprotein profile in healthy centenarians: a reappraisal of vascular risk factors” in the Faseb Journal 1998; 12:433-437

LIMITATIONS OF PROCEDURE

No single assay should be used as the only basis for arriving at a diagnostic conclusion. For research use only.

Dynamic Range:

3 µg/dL – 405 µg/dL


Reproducibility:

C.V. 4%-8% depending upon the region of the standard curve.

PRECAUTIONS

STORAGE

The expiration date for the package and each component is stated on the label(s). Store all components at 2-8°C with the exception of the standard, which should be stored frozen.

<p>ISO 13485 ISO 9001</p>  <p>Diagnostic Automation/ Cortez Diagnostics, Inc. 23961 Craftsman Road, Suite E/F, Calabasas, California 91302 USA</p>			
Date Adopted	Cat # 1740-9		
2008-04-28	AccuDiag™- Lp(a) ELISA -2013		
<table border="1" style="display: inline-table;"> <tr> <td>EC</td> <td>REP</td> </tr> </table>	EC	REP	<p>CEpartner4U, Esdoornlaan 13, 3951DB Maarn. The Netherlands. www.cepartner4u.eu</p>
EC	REP		
Revision B Date: 09-19-2013			