Cat. No 7-428

BS-400
Chemistry Analyzer

CE CORMAY

A-400 LIPOPROTEIN (a)

DIAGNOSTIC KIT FOR DETERMINATION OF LIPOPROTEIN (a) CONCENTRATION

INTRODUCTION

Lipoprotein(a) is a complex, cholesterol-carrying particle in the blood related to LDL wchich, when present at high levels, may be associated with the development of atherosclerosis and coronary heart disease, independent of LDL cholesterol and apoB. The structural component of Lp(a) distinguishing it from LDL is apolipoprotein(a), a large protein attached by disulfide bonding to the apoB-100 component of LDL. The similarity of the apo(a) sequence to those of plasminogen and hepatocyte growth factor suggests that the role of lipoprotein(a) in promoting the development of atherosclerosis may come from its capability to:

1) interfere in the breakdown of blood clots,
2) stimulate atherosclerotic cell proliferation.

Lp(a) levels is largely due to hereditary factors and considered to be useful in assessment of atherosclerosis risks.

METHOD PRINCIPLE

When an antigen-antibody reaction occurs between Lp(a) in a sample and anti-Lp(a) antibody which has been sensitized to latex particles, agglutination results. This agglutination is detected as an absorbance change (700 nm), with the magnitude of the change being proportional to the quantity of Lp(a) in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of know concentration.

REAGENTS

Package

1-Reagent	1 x 36 ml
2-Reagent	1 x 18 ml

The reagents when stored at 2-10°C are stable up to expiry date printed on the package. Protect from light and avoid contamination!

Concentrations in the test

suspension of latex particles sensitized with anti-Lp(a) antibodies (rabbit) (pH 7.3) glycine buffer solution (pH 9.0)	0.4 w/v%

Warnings and notes

- Product for in vitro diagnostic use only.
- Reagent bottles should be shaken before use by gently inverting several times.
- After measurements are taken, reagent bottles should capped and kept at 2-10°C. Care should be taken not to interchange the caps of reagent bottles.
- Reagents with different lot numbers should not be interchanged or mixed.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN

Serum or plasma (Na-EDTA, K-EDTA, Na-Heparin, Li-Heparin).
If the test cannot be done immediately, the sample should be placed in a tightly sealable container and stored at -20°C. Repeated freezing and thawing should be avoided.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

These reagents may be used in automatic analyser BS-400.
1-Reagent and 2-Reagent are ready to use.
For reagent blank 0.9% NaCl is recommended.

APPLICATION

BASIC

Test information		Reagent volume	
No.	40	R1	180
Test	Lp(a)	R2	90
Full Name	Lipoprotein (a)	R3	
Std. No.	40	R4	

Sample volume

Standard	6	15	10
Increased	12	15	10
Decreased	3	15	10

Reaction Parameters

Reac. Type	Endpoint	Direction	Increase
Pri. Wave	700	Rgt. Blank	44 45
Sec. Wave		Reac. Time	76 77

Result Setup

Decimal	0.1	Slope	1
Unit	mg/dl	Inter	0

Judgment Criteria

Absorbance	0	0	Lin. Range
Incre. Test	0		Lin. Limit
Decre. Test	0		Subs. Limit

□ Prozone ○ Rate ○ Antigen

Q1	0	Q2	0	Q3	0	Q4	0
PC	0			ABS	0		

CALIBRATION

Calibration

Rule	Spline
Replicate	1
K	

Judgment Criteria

Sensitivity	Blank Abs.
Factor Diff.	Error Limit
SD	Corr. Coeff.

REFERENCE VALUES [4]

serum, plasma	< 30 mg/dl

It is recommended for each laboratory to establish its own reference ranges for local population. Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY Lp(a) CONTROL N (Cat. No 4-492) and CORMAY Lp(a) CONTROL P (Cat. No 4-493) with each batch of samples.
For the calibration of automatic analysers systems the CORMAY Lp(a) CALIBRATORS kit (Cat. No 4-281) is recommended. A calibration curve should be drawn each time the test performed.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using an automatic analyser TBA-30R. Results may vary if a different instrument is used.

- **Analytical range:** 0.5 – 80 mg/dl.
  For higher concentration dilute the sample with 0.9% NaCl and repeat the assay. Multiply the result by dilution factor.

- **Specificity / Interferences**
  Haemoglobin up to 0.5 g/dl, bilirubin up to 30 mg/dl, triglycerides up to 6000 mg/dl, intralipid up to 500 mg/dl, RF up to 500 IU/ml do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	20.9	0.1	0.33
level 2	43.5	0.3	0.74

- **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 66 serum samples gave following results:
y = 1.108 x – 1.44 mg/dl;
R = 0.989 (R – correlation coefficient)

A comparison between CORMAY reagent (y) and commercially available assay (x) using 57 plasma samples gave following results:
y = 1.079 x – 0.16 mg/dl;
R = 0.990 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

1. Utermann G. et al.: Lp(a) Glycoprotein Phenotypes. Inheritance and relation to Lp(a)-lipoprotein concentrations in plasma., J. Clin. Invest., 80, 458 (1987).
2. McLaren J. W. et al.; cDNA sequence of human apolipoprotein(a) is homologus to plasminogen., Nature, 300, 132 (1987).
3. Neumeister B., Besenthal I., Liebich H.: Diagnostyka laboratoryjna., Urban & Partner, 126-127, (2001).
4. Alan H.B. Wu, ed.: Tietz Clinical Guide to Laboratory Tests, 4th ed. W.B. Saunders Company., 678, (2006).

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