CORMAY LIPOPROTEIN (a)

DIAGNOSTIC KIT FOR DETERMINATION OF LIPOPROTEIN (a) CONCENTRATION

Kit name	Kit size	Cat. No
CORMAY LIPOPROTEIN (a)	1 x 64 ml	6-302

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

The lipoprotein Lp(a) present in a sample form with the specific anti-Lp(a) antibody an immunological complex. The increase of turbidity after the addition of antiserum measured spectrophotometrically is proportional to Lp(a) concentration in the sample.

REAGENTS

Package

1-Reagent	1 x 54.5 ml
2-Reagent	1 x 9.5 ml

The reagents are stable up to the expiry date printed on the package when stored at 2-8°C. The reagents are stable for 4 weeks on board the analyser at 2-10°C. Do not freeze the reagents. Protect from light and contamination!

Concentrations in the test

1-Reagent	
glycine buffer (pH 9.0) with protein stabilizers	0.1 M
preservative	
2-Reagent	
glycine buffer (pH 8.2)	0.1 M
sodium chloride	0.15 M
bovine serum albumin (BSA)	0.5%
Anti Lp(a) antibody	
preservative	

Warnings and notes

- Products for in vitro diagnostic use only.
- The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Do not use after expiry date.
- Do not interchange caps.
- Reagent should be mixed before use by gentle inverting the bottle several times.
- The appearance of turbidity or control sera values outside the manufacturer's acceptable range may indicate of reagent instability.
- Products contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

ADDITIONAL EQUIPMENT

- automated clinical chemistry analyser capable of accommodating two-reagent assays;
- general laboratory equipment;

SPECIMEN

Serum or plasma.
Sample can be stored one day at 4°C. If the test cannot be done immediately, the sample should be placed in a tightly sealable container and stored at -70°C. Repeated freezing and thawing should be avoided.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

The reagents are ready to use.
These reagents may be used in automatic analysers according to their user manual.
Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

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. **Calibrator and 0.9% NaCl** should be used for calibration.
The calibration curve should be prepared every 4 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analysers Hitachi 912 and Hitachi 911. Results may vary if a different instrument is used.

- **Sensitivity:** 0.75 mg/dl.
- **Linearity:** up to 80 mg/dl.
- **Specificity / Interferences**
  Haemoglobin up to 10 g/l, bilirubin up to 440 µmol/l and intralipid up to 0.5% do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	21.47	0.62	2.87
level 2	63.05	0.62	0.98

Reproducibility (day to day) n = 10	Mean [g/l]	CV [%]
level 1	17.60	4.99

- **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 50 samples gave following results:
y = 1.2037 x - 3.253 mg/dl;
R = 0.9675 (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. Marcovina S. M., Koschinsky M. L., Report of the National Heart, Lung, and Blood Institute Workshop on Lipoprotein(a) and Cardiovascular Disease: Recent Advances and Future Directions, Clin Chem 49: 1785-1796, 2003.
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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