LIPOPROTEIN (a)

Quantitative determination of Lipoprotein (a) in human serum by turbidimetric immunoassay.

Cat. No.	Pack name	Packaging (Content)
BLT20029	Lp (a)	2 x 25 ml Lp(a) Buffer 1 x 5 ml Lp (a) Latex 1 x 1 ml Lp (a) Calibrator

EN CE IVD

Diagnostic Implications

Lipoprotein (a) is a human serum protein whose structure is close to that of LDL. Its density lies between those of LDL and HDL.
The Lipoprotein (a) concentration in blood varies from almost undetectable levels to more than 100 mg/dl. The wide differences in LP(a) levels are largely due to hereditary factors and cannot be controlled by dietary or lifestyle changes.
The presence of high Lipoprotein (a) levels in serum is a significant marker of increased risk for atherosclerosis and coronary heart disease.
Epidemiological studies have shown, that people with normal serum cholesterol and a serum Lipoprotein (a) level over 30 mg/dl have a double risk of coronary heart disease. The risk is 8 times higher when LDL and Lipoprotein (a) levels are simultaneously elevated.

Method

Measurement of antigen-antibody reaction by the end-point method.

Reagents Provided

Buffer
Sodium chloride (9 g/l).
Detergent (0.01%).
Sodium azide (0.95 g/l).

Latex
Glycine buffer (pH 7.3).
Rabbit anti human LP (a) antibody sensitized latex (0.5%).
Sodium azide (0.95 g/l).

Calibrator
Defibrinated and delipidated human plasma, liquid stabilized and with 0.09% sodium azide as preservative.
Concentration: see bottle label

Preparation and Stability of Reagents

Reagent Preparation
Liquid reagents, ready for use.
Stability and Storage
The reagents are stable until expiry date when kept at 2-8°C. Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

Reagents required but not supplied

Saline (9 g/l NaCl)

Sample collection

Use fresh serum. If the test can not be carried out on the same day, the serum may be stored at 2-8°C for 48 hours. If stored for a longer period, the sample should be frozen.

Automation

Application procedures on clinical chemistry analyzers are available upon request.

Manual Procedure

Sample/Control: dilute 1:10 in saline (9 g/l NaCl).
Reference curve: generate a reference curve by diluting the calibrator 1:10, 1:20, 1:40 and 1:80 in sodium chloride (9 g/l). Use saline as zero point.

Test: Mix 30 µl diluted samples, calibrators and control(s) with 900 µl buffer. Read optical density (OD1) of samples, calibrators and control(s) at 600 nm. Add 80 µl of latex. Mix and incubate for 5 minutes at room temperature. Read optical density (OD2) of samples, calibrators and control(s) at 600 nm.

Calculate ΔOD's, plot a calibrator curve and read the concentration of controls and samples.

Reference Values

Normal values: 0 - 30 mg/dl .
This range is given for orientation only. Each laboratory should establish its own reference value.

Performances

The performance characteristics for the Lipoprotein (a) reagents were measured on a clinical chemistry analyzer (Cobas Mira).

Measuring Range: 0 - 80 mg/dl

Detection Limit: 1.25 mg/dl

Hook effect: No risk

Sensitivity: 0.0147 ABS units / concentration unit

Precision: [%CV]

	Low	Medium	High
Intra-Run	2.58	2.19	2.16
Inter-Run	3.85	3.70	3.48

Accuracy : [mg/dl]

Control	Assigned	Measured
APTEC	43 (37 – 49)	40.7
BIORAD1	6.6 (5.3 – 7.9)	6.2

Specificity : Monospecific

Interferences : No interference for : Apolipoprotein B (200 mg/dl), Plasminogen (200 mg/dl), Hemoglobin (500 mg/dl), Bilirubin (30 mg/dl), Rheumatoid factor (500 IU/ml)

Limitations : None

Comparison with BIOPOOL ELISA method:
y = 0.910x – 1.973;
r = 0.989

Precautions and warnings

1.*In vitro* diagnostic use only.

2.Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.

3.Each donor unit used in the preparation of the calibrators and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA.

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, CZ
e-mail: diagnostics@erbamannheim.com, www.erbamannheim.com
N/107/17/B/INT *Date of Revision:31.1. 2017*

References

Poulik, M. D., and Weiss, M. L., in F. W. Putman, Editor, "The Plasma Proteins", vol. 2 second Edition, Academic Press, New York, pp. 52 - 1108.

USED SYMBOLS:

REF	Catalogue Number	CE	CE Mark - Device comply with the Directive 98/79/EC
LOT	Batch Code	IVD	In Vitro Diagnostics
	Expiry date		Consult Instructions for Use
	Manufacturer		Storage temperature
CONT	Content		

Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, CZ
e-mail: diagnostics@erbamannheim.com, www.erbamannheim.com
N/107/17/B/INT *Date of Revision:31.1. 2017*