ISE S.r.l. CUSTOMISED SOLUTIONS FOR YOUR LABORATORY	EN	Lipoprotein (a)			Instruction For Use	CE IVD	Rev.E - 15-11-22
	REF	R3330000047	R1: 1x 18.0 mL	R2: 1x 3.5 mL			
		A-R1100002901	R1: 1x 50.0 mL	R2: 1x 6.0 mL			

Intended Use
Quantitative determination of Lipoprotein (a) [LP(a)] in human serum by turbidimetric immunoassay
For professional in vitro diagnostic use only.

Diagnostics 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
The same reagents are supplied in different volume formats depending on the I.S.E. S.r.l. analysers utilised and installed reagent support.

Supplied Volumes

	Product Code	
	R3330000047	*A-R1100002901*
Vial size	*18 / 18 mL*	*50 / 20 mL*
Reagent 1	1 x 18.0 mL	1x 50.0 mL
Reagent 2	1x 3.5 mL	1x 6.0 mL

Reagent format

Reagent	*Format*	*Code*
Reagent 1 – Buffer (liquid)	Ready to Use	
Reagent 2 – Latex (liquid)	Ready to Use	

Reagent Contents

Reagent 1:	*Conc.*	*U.M.*
Sodium chloride	9	g/L
Detergent	0.01	%
Sodium azide	0.95	g/L
Reagent 2:		
Glycine buffer (pH 7.43)	-	-
Rabbit anti human LP (a) antibody sensitized latex	0.5	%
Sodium azide	0.95	g/L

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
1. Saline (9 g/L NaCl)
2. Calibrators and Controls

Key Reference	*Description*
R1300001701	Lipoprotein A Calibrator High, 1 mL
R1400000501	Lipoprotein A Control Low, 1 mL
R1400000601	Lipoprotein A Control High, 1 mL

A dilution of delipidated and defibrinated human serum with phosphate buffered sodium chloride. Contains sodium azide (0.95 g/L). Value is stated in the insert.

Sample collection and storage
Use fresh serum. If the test cannot 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.

General Assay Procedure
Application sheets are available upon request for use with I.S.E. S.r.l. automated systems. All applications not explicitly approved by I.S.E. S.r.l. cannot be guaranteed in terms of performance and must therefore be established by the operator.
Wavelength λ=578nm.

Sample/Control/Standard: ready for use.
Reference curve: generate a reference curve by diluting the standard high level Ref. *R1300001701* 1:1, 1:2, 1:4, 1:8 in saline 9 g/L. Use saline 9 g/L as zero point.

Quality control
It is necessary, each time the kit is used, to perform the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.
If erratic results occur, please contact an authorised ISE representative.

Normal Ranges
0 - 30 mg/dL.
Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

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

Measuring range: 0 – 80 mg/dL
Detection Limit: 1.25 mg/dL
Hookeffect: No risk
Sensitivity: 0.0147 ABS units/concentration unit

Precision of the method

Condition	*U.M.*	*Low*	*Medium*	*High*
Intra-Run	CV%	2.58	2.19	2.16
Inter-Run	CV%	3.85	3.70	3.48

Accuracy of the method

Control	*U.M.*	*Assigned*	*Measured*
Bio-Rad 1	mg/dL	43 (37 - 49)	40.7
Bio-Rad 2	mg/dL	6.6 (5.3 - 7.9)	6.2

Specificity: Monospecific.
Interferences: No interference for: Apolipoprotein B (200 mg/dL), Plasminogen (200 mg/dL), Haemoglobin (500 mg/dL), Bilirubin (30 mg/dL), Rheumatoid Factor (500 IU/mL).
Limitations: None
Comparison with ELISA method: y = 0.910x - 1.973 *r = 0.989*
Stability at 4°C: at least 3 years after production

Precautions and Warnings
1. In vitro diagnostic use only.
2. Refer to the safety data sheets (SDS) and take the necessary precautions for the use of laboratory reagents.
3. Do not use after expiry date and do not interchange reagents from different lots.
4. Replace caps on reagents immediately after use. Do not switch caps.
5. Do not pipet by mouth. Do not smoke, eat, drink or use cosmetics during the use of the reagent. Do not swallow.
6. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains whit water thoroughly after disposing of fluids containing sodium azide.
7. Each donor unit used in the preparation of the reagents, standards 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. However, the material must be considered potentially hazardous and handled with the same care as samples taken from patients.
8. Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing.
9. Take care to avoid self-inoculation, splashing of mucous membranes or generation of aerosols. Laboratory gloves should be worn while handling patients' samples or disposing of solid or liquid wastes.
10. In addition to the eventual risk indications regarding the active components, the reagents contain inactive components such as preservatives (e.g. sodium azide or others) and detergents. The total concentrations of these components are lower than the limits reported by the current directive sand following modification and amendments. However, it is recommended to handle reagents carefully, to avoid ingestion and contact with eyes, skin and mucus membranes and to use laboratory reagents according to good laboratory practice.
11. All human samples must be handled and disposed of as potentially infectious materials.

Disposal of reagent
Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

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Reporting of serious incidents

The user must report (through the distributor) any serious accident occurring in relation to the device to both the manufacturer and the competent authority of the European Union Member State in which the user and / or patient is established. For other jurisdictions, reports of serious incidents must be produced in accordance with regulatory requirements.

Symbols on labels and packaging

IVD	In vitro diagnostic medical device
REF	Catalog Number
LOT	Lot number
	Manufacturer
	Expiry date
	Temperature limitation
	Consult Instructions for use
Rn	Reagent “n”

References

1. 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 - 108

Revision history		
Rev.E	15-11-2022	Revision of the document