LPALX

cobas®

Tina-quant Lipoprotein (a) (Latex)

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
03001881 322	Tina-quant Lipoprotein (a) (Latex) 100 tests	System-ID 07 6629 1	Roche/Hitachi **cobas c** 311, **cobas c** 501/502
03001318 122	C.f.a.s. Lp(a) (3 x 1 mL)	Code 730	
11660993 216	Lp(a) Control Set		
	Level I (2 x 1 mL)	Code 204	
	Level II (2 x 1 mL)	Code 205	
04489357 190	Diluent NaCl 9 % (50 mL)	System-ID 07 6869 3	

English

System information

For **cobas c** 311/501 analyzers:

LPALX: ACN 045

For **cobas c** 502 analyzer:

LPALX: ACN 8045

Intended use

In vitro test for the quantitative immunological determination of human lipoprotein (a) in serum and plasma on Roche/Hitachi **cobas c** systems.

Summary[1,2,3,4,5,6,7,8,9,10]

Lipoprotein (a) is composed of an LDL-like particle to which the lipoprotein (a)-specific apolipoprotein (a) is bonded by a disulfide bridge. Apolipoprotein (a) is highly homologous to plasminogen. Lipoprotein (a) is a cholesterol-rich lipoprotein which is synthesized in the liver independently of triglycerides and is not subject to the influence of age or diet.

Lipoprotein (a) can act atherogenically and has been found in artery walls. Because of its structural similarity to plasminogen, it can also inhibit fibrinolysis and hence acts thrombogenically. High lipoprotein (a) concentrations in serum correlate with premature manifestation of atherosclerosis and strokes. When lipoprotein (a) concentrations exceed 0.30 g/L, the coronary risk is approximately doubled. In combination with elevated LDL-cholesterol concentrations, the risk increases approximately six-fold. An elevated lipoprotein (a) level is considered to be the most sensitive parameter for the development of coronary heart disease, irrespective of other plasma lipoproteins. Lipoprotein (a) should be determined together with total cholesterol, HDL-cholesterol and LDL-cholesterol as well as triglycerides when assessing the total arteriosclerotic risk. Lipoprotein (a) levels should be determined in patients suffering from dyslipoproteinemia, diabetes mellitus, renal failure, and cardiovascular or cerebrovascular disorders, as well as in premature onset of arteriosclerosis.

Determination of lipoprotein (a) is performed using immunoassays (RIA, ELISA), electroimmunodiffusion (EID), radial immunodiffusion, nephelometry or turbidimetry.

Test principle[9]

Particle enhanced immunoturbidimetric assay.

Human lipoprotein (a) agglutinates with latex particles coated with anti-Lp(a) antibodies. The precipitate is determined turbidimetrically at 450 nm.

Reagents - working solutions

R1 Phosphate buffer: 60 mmol/L, pH 7.5; NaCl: 100 mmol/L; polyethylene glycol (PEG): 30 g/L; preservative

R3 Latex particles coated with polyclonal anti-human Lp(a) antibodies (rabbit); glycine buffer: 25 mmol/L, pH 9.6; preservative

R1 is in position A, R3 is in position B and position C is empty.

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.

Reagent handling

Ready for use

Mix **cobas c** pack well before placing on the analyzer.

Carefully invert reagent container several times prior to use to ensure that the reagent components are mixed.

Storage and stability

LPALX

Shelf life at 2-8 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	12 weeks

Diluent NaCl 9 %

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On-board in use and refrigerated on the analyzer:	12 weeks

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.
Serum.
Plasma: Li-heparin and K_2-EDTA plasma

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Centrifuge samples containing precipitates before performing the assay.

Stability:[11]	2 days at 15-25 °C
	2 weeks at 2-8 °C
	3 months at (-15)-(-25) °C

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

- See "Order information" section

General laboratory equipment

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

The performance of applications not validated by Roche is not warranted and must be defined by the user.

Application for serum and plasma

cobas c 311 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 25-57
Wavelength (sub/main)	800/450 nm
Reaction direction	Increase
Unit	g/L (mg/dL, mg/L)

LPALX

Tina-quant Lipoprotein (a) (Latex)

Reagent pipetting		Diluent (H_2O)
R1	102 µL	–
R3	30 µL	–

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	13 µL	9 µL	180 µL
Decreased	12.5 µL	3 µL	179 µL
Increased	13 µL	9 µL	180 µL

cobas c 501 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 37-70
Wavelength (sub/main)	800/450 nm
Reaction direction	Increase
Unit	g/L (mg/dL, mg/L)

Reagent pipetting		Diluent (H_2O)
R1	102 µL	–
R3	30 µL	–

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	13 µL	9 µL	180 µL
Decreased	12.5 µL	3 µL	179 µL
Increased	13 µL	9 µL	180 µL

cobas c 502 **test definition**

Assay type	2-Point End
Reaction time / Assay points	10 / 37-70
Wavelength (sub/main)	800/450 nm
Reaction direction	Increase
Unit	g/L (mg/dL, mg/L)

Reagent pipetting		Diluent (H_2O)
R1	102 µL	–
R3	30 µL	–

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	13 µL	9 µL	180 µL
Decreased	12.5 µL	3 µL	179 µL
Increased	13.5 µL	15 µL	148 µL

Calibration

Calibrators	S1: H_2O S2-S6: C.f.a.s. Lp(a) Multiply the lot-specific C.f.a.s. Lp(a) value by the factors below to determine the standard concentrations for the 6-point calibration curve: S2: 0.396 S5: 3.500 S3: 1.053 S6: 5.405 S4: 2.100
Calibration mode	RCM2
Calibration frequency	Full calibration • after 90 days during shelf life • after reagent lot change • as required following quality control procedures

Traceability: This method has been standardized against a highly purified Lp(a) preparation which is used as an in-house master calibrator.

Quality control

For quality control, use control materials as listed in the "Order information" section.

In addition, other suitable control material can be used.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Calculation

Roche/Hitachi **cobas c** systems automatically calculate the analyte concentration of each sample.

Conversion factors:	g/L × 100 = mg/dL
	g/L × 1000 = mg/L

Limitations – interference

Criterion: Recovery within ± 10 % of initial value at an Lp(a) concentration of 0.3 g/L (30 mg/dL).

Icterus:[12] No significant interference up to an I index of 60 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 1026 µmol/L or 60 mg/dL).

Hemolysis:[12] No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL).

Lipemia (Intralipid):[12] No significant interference up to an L index of 2000. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Rheumatoid factors: No significant interference up to a level of 90 IU/mL.

Drugs: No interference was found at therapeutic concentrations using common drug panels.[13,14]

High dose hook-effect: No false result occurs up to a lipoprotein (a) concentration of 5 g/L.

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[15]

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on Roche/Hitachi **cobas c** systems. The latest version of the carry-over evasion list can be found with the NaOHD/SMS/Multiclean/SCCS or the NaOHD/SMS/SmpCln1+2/SCCS Method Sheets. For further instructions refer to the operator's manual. **cobas c** 502 analyzer: All special wash programming necessary for avoiding carry-over is available via the **cobas** link, manual input is not required.

Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.

Limits and ranges

Measuring range

0.03-1.80 g/L (3-180 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:3 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 3.

Lower limits of measurement

Lower detection limit of the test

0.03 g/L (3 mg/dL)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying three standard deviations above that of the lowest standard (standard 1 + 3 SD, repeatability, n = 21).

Expected values

Lp(a) serum concentrations in healthy persons exhibit an asymmetrical distribution and may exceed 1.00 g/L (100 mg/dL).

In a reference value study utilizing sera from 341 apparently healthy Caucasian Europeans, the following median values were found:[16]

Males (n = 154):	0.09 g/L	(9 mg/dL)
Females (n = 187):	0.11 g/L	(11 mg/dL)

Values above approx. 0.3 g/L (30 mg/dL) are associated with a higher risk of atherosclerosis.[17,18]

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Specific performance data

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

Precision

Precision was determined using human samples and controls in an internal protocol with repeatability (n = 21) and intermediate precision (3 aliquots per run, 1 run per day, 21 days). The following results were obtained:

Repeatability	*Mean*	*SD*	*CV*
	g/L (mg/dL)	*g/L (mg/dL)*	*%*
Lp (a) Control level 1	0.188 (18.8)	0.003 (0.3)	1.7
Lp (a) Control level 2	0.999 (99.9)	0.009 (0.9)	0.9
Human serum 1	0.476 (47.6)	0.004 (0.4)	0.8
Human serum 2	0.760 (76.0)	0.009 (0.9)	1.1

Intermediate precision	*Mean*	*SD*	*CV*
	g/L (mg/dL)	*g/L (mg/dL)*	*%*
Lp (a) Control level 1	0.182 (18.2)	0.004 (0.4)	2.2
Lp (a) Control level 2	0.980 (98.0)	0.014 (1.4)	1.4
Human serum 3	0.483 (48.3)	0.006 (0.6)	1.3
Human serum 4	0.761 (76.1)	0.009 (0.9)	1.2

Method comparison

Lipoprotein (a) values for human serum and plasma samples obtained on a Roche/Hitachi **cobas c** 501 analyzer (y) were compared with those determined using the corresponding reagent on COBAS INTEGRA 700 and COBAS INTEGRA 800 analyzers (x).

Sample size (n) = 218

Passing/Bablok[19]	Linear regression
y = 1.000x - 0.002 g/L	y = 1.003x + 0.005 g/L
τ = 0.936	r = 0.993

The sample concentrations were between 0.090 and 1.65 g/L (9.00 and 165 mg/dL).

References

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A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

CONTENT	Contents of kit
→	Volume after reconstitution or mixing

CE

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www.roche.com