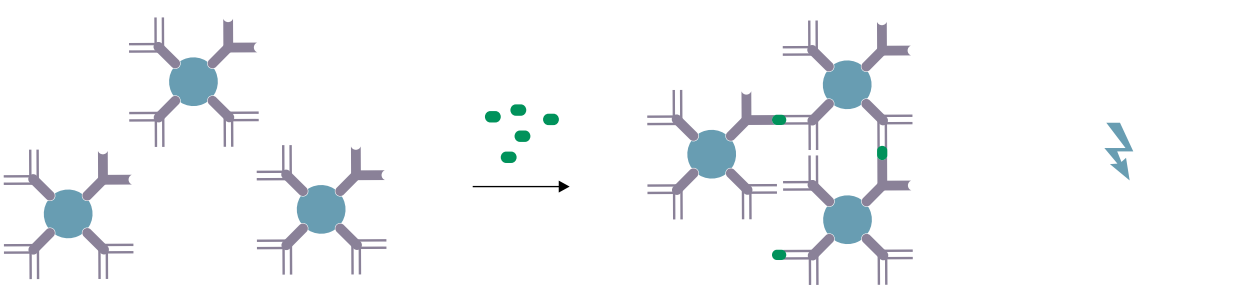
Tina-quant® Lipoprotein (a) Gen. 2

Turbidimetric in vitro test for the quantitative determination of lipoprotein (a) in human serum and plasma

Indication

High lipoprotein (a) (Lp(a)) concentrations in serum correlate with premature manifestation of atherosclerosis and strokes. When Lp(a) concentrations exceed 75 nmol/L, the coronary risk is approximately doubled. In combination with elevated LDL-cholesterol concentrations, the risk increases approximately six-fold. An elevated Lp(a) level is considered to be the most sensitive parameter for the development of coronary heart disease, irrespective of other plasma lipoproteins. Lp(a) should be determined together with total cholesterol, HDL-cholesterol and LDL-cholesterol as well as triglycerides when assessing the total arteriosclerotic risk. According to the European Arthrosclerosis Society Lp(a) measurement should be recommended in selected cases at high risk and in subjects with a family history of premature cardio vascular disease.[1]

Test principle: Particle-enhanced turbidimetric immunoassay (PETIA)



Latex particles coated with anti-Lp(a)

Sample Lp(a)

Antigen-antibody complex

Turbidimetric measurement of antigen-antibody complex

Mixing and incubating of antibody reagent and sample

The latex enhanced particles coated with anti-Lp(a) antibodies in the reagent agglutinate with the human Lp(a) in the sample. During the incubation phase an antigen-antibody complex is formed.

Measurement of the antigen-antibody complex

The degree of the turbidity caused by the aggregate can be determined turbidimetrically at 800/660 nm and is proportional to the amount of Lp(a) in the sample: the higher the Lp(a) concentration, the higher the turbidity.

Turbidimetry technology

Turbidimetry is Roche's technology for homogeneous immunoassay detection. Continuous development of turbidimetric technology over the past years – both in detection methods as well as in assay design – have made turbidimetry a highly precise and sensitive detection method. The use of bichromatic wavelengths in spectrophotometry in conjunction with the measurement of a sample blank minimizes interference effects.

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Tina-quant® Lipoprotein (a) Gen. 2 test characteristics

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Analyzer compatibility	**cobas c** 311 analyzer **cobas c** 501/502 module COBAS INTEGRA® ***400 plus***/800	**cobas c** 701/702 module	Roche/Hitachi **MODULAR®** *ANALYTICS* <P>
Sample material	Serum, Plasma	Serum, Plasma	Serum, Plasma
Reaction time	10 minutes	10 minutes	10 minutes
On-board stability	6 weeks	6 weeks	6 weeks
Calibration frequency	Each reagent lot	Each reagent lot	Each reagent lot
Traceability	This method has been standardized against the IFCC reference material SRM2B for nmol/L.		
Measuring range	7 – 240 nmol/L	7 – 240 nmol/L	7 – 240 nmol/L
Expected values	The European Atherosclerosis Society recommends screening for elevated Lp(a) in those at intermediate or high CVD/CHD risk.[2] Based on the evaluation of Framingham data values above 75 nmol/L are regarded as a cut-off value for the presence of an increased risk.[3] Elevated Lp(a) levels can be found in most racial/ethnicity groups, with the prevalence being lowest in whites and Asians. The median Lp(a) levels in black subjects and in Asian Indians from southern locations are 2- to 4-fold higher compared with whites, and up to 68 % of blacks have Lp(a) levels >75 nmol/L, whereas levels above this threshold are present in around 25 % of whites.[4] Therefore reference ranges have not been established for this assay for different ethnic populations or disease states. Since Lp(a) levels are largely influenced by hereditary factors and vary with ethnic populations it is recommended that each laboratory establish own expected values.		
Repeatability	**cobas c** 501 module 18.2 nmol/L = 5.6 % 88.7 nmol/L = 2.5 % 226 nmol/L = 0.8 %	**cobas c** 701 module 24.6 nmol/L = 1.7 % 66.4 nmol/L = 2.4 % 233 nmol/L = 0.6 %	Roche/Hitachi **MODULAR®** *ANALYTICS* <P> 25.9 nmol/L = 1.5 % 67.9 nmol/L = 1.8 % 230 nmol/L = 0.5 %
Intermediate precision	**cobas c** 501 module 18.2 nmol/L = 8.0 % 88.7 nmol/L = 3.0 % 226 nmol/L = 1.1 % Results for intermediate precision were obtained on the master system **cobas c** 501.		

References

1 Reiner, Ž., Catapano, A.L., De Backer, G. et al. (2011). ESC/EAS Guidelines for the Management of Dyslipidaemias. *Eur Heart J,* 32, 1769-1818.

2 Nordestgaard, B.G., Chapman, M.J., Ray, K. et al. (2010). Lipoprotein (a) as a cardiovascular risk factor: current status. *Eur Heart J Dec, 31*(23), 2844-2853.

3 Marcovina, S.M., Koschinsky, M.L., Albers, J.J. et al. (2003). Report of the National Heart, Lung, and Blood Institute Workshop on Lipoprotein (a) and Cardiovascular Disease: Recent Advances and Future Directions. *Clin Chem Nov, 49*(11), 1785-1796.

4 Tsimikas, S., Clopton, P., Brilakis, E.S. et al. (2009). Relationship of Oxidized Phospholipids on Apolipoprotein B-100 Particles to Race/Ethnicity, Apolipoprotein (a) Isoform Size, and Cardiovascular Risk Factors: *Results From the Dallas Heart Study, Circulation Apr, 119*(13), 1711-1719.

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Order information

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Tina-quant® Lipoprotein (a) Gen. 2 **cobas c** 701/702	200 tests	05 852 633 190
Tina-quant® Lipoprotein (a) Gen. 2 **MODULAR®** P small	R1: 2 x 8 mL R2: 2 x 3mL (100 tests)	05 852 528 190
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