

# Lp(a) 21 FS\*

**Diagnostic reagent for quantitative in vitro determination of lipoprotein (a) [Lp(a)] in serum or plasma on photometric systems**

## Order Information

Cat. No.	Kit size
1 7139 99 10 930	R1 2 x 20 mL + R2 2 x 10 mL
1 7139 99 10 931	R1 3 x 20 mL + R2 3 x 10 mL
1 7140 99 10 059	5 x 1 mL TruCal Lp(a) 21: Calibrator set with 5 different levels

## Summary [1,2]

Lipoprotein (a) [Lp(a)] is a particle consisting of a LDL molecule (LDL: low density lipoprotein) bound to apolipoprotein (a) which can have different sizes depending on the isoforms. It seems that apolipoprotein (a) can inhibit fibrinolysis competing with plasminogen due to a considerable structural homology, an effect which cannot be observed with LDL free of apolipoprotein (a). Lp(a) is considered an atherogenic risk factor which is independent of other lipid parameters and exogenous factors such as diet. Increased Lp(a) levels have a high predictive value for coronary heart disease, especially in combination with elevated LDL-cholesterol. While the determination of total cholesterol and triglycerides is used for coronary risk screening, measurement of Lp(a), beside LDL-cholesterol, HDL-cholesterol, apolipoprotein A1 and apolipoprotein B, is a valuable tool for differential diagnosis of coronary heart disease.

## Method

Particle enhanced immunoturbidimetric test

## Principle

Determination of the Lp(a) concentration by photometric measurement of antigen-antibody-reaction between antibodies against Lp(a) bound to particles and Lp(a) present in the sample.

## Reagents

### Components and Concentrations

<b>R1:</b>	Glycine-buffer	pH 8.3	< 1.5%
<b>R2:</b>	Glycine-buffer	pH 8.2	< 1.5%
	Latex particles coated with anti-human lipoprotein (a) antibody (rabbit)		

### Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagents!

### Warnings and Precautions

1. The reagents contain sodium azide (0.9 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
2. The reagents contain biological material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [6].
4. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
5. For professional use only!

## Waste Management

Please refer to local legal requirements.

## Reagent Preparation

The reagents are ready to use.

## Materials required but not provided

NaCl solution 9 g/L  
General laboratory equipment

## Specimen

Serum, heparin plasma or EDTA plasma

Stability [3]:

2 days	at	20 – 25°C
2 weeks	at	4 – 8°C
3 months	at	-20°C

Only freeze once!

Discard contaminated specimens.

## Assay Procedure for Analyzers

**Application sheets for automated systems are available on request.**

Wavelength	700 nm
Optical path	1 cm
Temperature	37°C
Measurement	Against reagent blank

	Blank	Sample/calibrator
<b>Sample/calibrator</b>	-	15 µL
<b>Dist. water</b>	15 µL	-
<b>Reagent 1</b>	600 µL	600 µL
Mix, incubate for 3 – 5 min., then add:		
<b>Reagent 2</b>	300 µL	300 µL
Mix, read absorbance (A1) within 30 sec., incubate for 5 min., then read absorbance (A2).		

$$\Delta A = (A2 - A1) \text{ sample/calibrator}$$

## Calculation

The Lp(a) concentration of unknown samples is derived from a calibration curve using an appropriate mathematical model such as spline. The calibration curve is obtained with 5 calibrators at different levels and NaCl solution (9 g/L) for determination of the zero value.

Stability of calibration: 4 weeks

## Calibrators and Controls

For the calibration of automated photometric systems, use DiaSys TruCal Lp(a) 21 calibrator set. TruCal Lp(a) 21 calibrator values with the unit mg/dL have been made traceable to a reference preparation. TruCal Lp(a) 21 calibrator values with the unit nmol/L have been made traceable to the WHO/IFCC reference material SRM 2B (PRM IFCC Standard). For internal quality control, a DiaSys TruLab Lp(a) control should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruLab Lp(a) Level 1	5 9830 99 10 046	3 x 1 mL
TruLab Lp(a) Level 2	5 9840 99 10 046	3 x 1 mL

## Performance Characteristics

### Measuring Range

The test has been developed to determine Lp(a) concentrations within a measuring range from 3 – 110 mg/dL or 6 – 260 nmol/L, at least up to the concentration of the highest calibrator. If values exceed this range samples should be diluted 1+1 with NaCl solution (9 g/L) and the result multiplied by 2.

### Prozone Limit

No prozone effect was observed up to a Lp(a) value of 400 mg/dL or 800 nmol/L.

### Specificity/Interferences

Due to its antibodies, DiaSys Lp(a) 21 FS is a specific immunoassay for human Lp(a). No interference was observed by bilirubin up to 40 mg/dL, hemoglobin up to 500 mg/dL, lipemia up to 2,000 mg/dL triglycerides and rheumatoid factor up to 500 IU/mL. No cross reactions with plasminogen and apolipoprotein B were seen under test conditions. For further information on interfering substances refer to Young DS [4].

### Sensitivity/Limit of Detection

The lower limit of detection is 3 mg/dL or 6 nmol/L.

### Precision (n= 20)

Intra-assay precision	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	26.9	0.540	2.00
Sample 2	32.9	0.557	1.69
Sample 3	52.3	0.528	1.01

Inter-assay precision (single calibration)	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	26.2	0.803	3.06
Sample 2	32.2	0.720	2.24
Sample 3	52.2	1.08	2.06

### Method Comparison

A comparison of DiaSys Lp(a) 21 FS (x) with a commercially available reagent (y) with 36 samples gave following results:  
 $y = 0.952 x + 2.58$  mg/dL;  $r = 0.990$ .

A comparison of DiaSys Lp(a) 21 FS (x) with a commercially available reagent (y) with 36 samples gave following results:  
 $y = 1.01 x + 1.89$  mg/dL;  $r = 0.980$ .

A method comparison of DiaSys Lp(a) 21 FS to the NWLRL\* assay system with 20 samples gave the following results:  
 $y = 0.94 x + 5.50$  nmol/L;  $r = 0.997$ .

\*Northwest Lipid Research Laboratories

## Reference Range [5]

Not elevated:	< 30 mg/dL (< 75 nmol/L)
Borderline:	30-50 mg/dL (75-125 nmol/L)
Elevated:	> 50 mg/dL (> 125 nmol/L)

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

## Literature

1. Rifai N, Bachorik PS, Albers JJ. Lipids, lipoproteins and apolipoproteins. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3<sup>rd</sup> ed. Philadelphia: W.B Saunders Company; 1999. p. 809-61.
2. Marcovina SM, Koschinsky ML. Lipoprotein (a): Structure, measurement and clinical significance. In: Rifai N, Warnick GR, Dominiczak MH, eds. Handbook of lipoprotein testing. Washington: AACC Press; 1997. p. 283–313.
3. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 36–37.
4. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
5. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2025 [cited 2026 Jan 27]. Available from: <https://www.clinical-laboratory-diagnostics.com/>
6. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240–1243.

## Manufacturer



DiaSys Diagnostic Systems GmbH  
Alte Strasse 9 65558 Holzheim Germany