# TruCal Lp(a) 21

**Calibrator set for use in tests for quantitative in vitro determination of lipoprotein (a) [Lp(a)] on photometric systems**

## Order Information

1 7140 99 10 059 5 x 1 mL

## Description

TruCal Lp(a) 21 is a set of lyophilized calibrators with five different levels based on human blood material (serum) for determination of Lp(a) with the DiaSys reagent Lp(a) 21 FS.

## Storage

The calibrators both reconstituted and unopened must be stored at 2 – 8°C protected from light.

## Stability

Unopened: Until the end of the indicated month of expiry.
Reconstituted: At least 14 days

Proper storage and handling of this product must be observed.

## Warnings and Precautions

1. Each individual blood donation used for the production of TruCal Lp(a) 21 was found to be non-reactive when tested with approved methods for HBsAg, anti-HIV 1+2 and anti-HCV. As there is no possibility to exclude definitely that products derived from human blood transmit infectious agents, it is recommended to handle the calibrators with the same precautions used for patient specimens.
2. Contains sodium azide (0.9 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
3. Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
4. For professional use only!

## Preparation

The lyophilizate is vacuum-sealed; therefore, the vial should be opened very carefully to avoid loss of dried material. For reconstitution add exactly 1.0 mL of distilled water. Close the vial carefully and allow the calibrator to stand for 30 minutes swirling occasionally. Avoid foaming! Do not shake!

## Procedure

Please refer to the reagent package insert for instructions for use.

## Calibrator Values [4]

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).

Values listed below are specific for this lot number of calibrator only.

## Literature


1. Stenman UH. Standardization of immunoassays. In: Price CP, Newman DJ, editors. Principles and practice of immunoassay. New York: Stockton Press; 1997.p.243-68.
2. Dati F. Reference materials and guidelines for standardization of methods in laboratory medicine. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1402–1426.
3. Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395).
4. Dati F, Marcovina SM et al. First WHO/IFCC international reference reagent for lipoprotein(a) for immunoassay-Lp(a) SRM 2B. Eur J Clin Chem Lab Med 2004; 42(6):670–676.


## Waste Management

Please refer to local legal requirements.

IVD CE


## Manufacturer

DiaSys Diagnostic Systems GmbH
Alte Strasse 9
65558 Holzheim Germany


| | Lot no. | Expiry date | Calibrator value new standardization | Calibrator value |
|---|---|---|---|---|
| **TruCal Lp(a) 21 Level 1** | 37959 | 2026-12-31 | 6.10 mg/dL<br>61.0 mg/L | 12.2 nmol/L |
| **TruCal Lp(a) 21 Level 2** | 37960 | 2026-12-31 | 13.4 mg/dL<br>134 mg/L | 26.7 nmol/L |
| **TruCal Lp(a) 21 Level 3** | 37961 | 2026-12-31 | 36.2 mg/dL<br>362 mg/L | 68.1 nmol/L |
| **TruCal Lp(a) 21 Level 4** | 37962 | 2026-12-31 | 69.7 mg/dL<br>697 mg/L | 152 nmol/L |
| **TruCal Lp(a) 21 Level 5** | 37963 | 2026-12-31 | 92.8 mg/dL<br>928 mg/L | 200 nmol/L |