TruLab Lp(a)

Assayed quality control material for monitoring assay performance of quantitative in vitro determination of Lp(a)

Order Information

5 9840 99 10 046 Level 2 3 x 1 mL

Description

TruLab Lp(a) is a lyophilized control material for Lp(a) based on human blood material (serum). The Lp(a) concentration in TruLab Lp(a) Level 2 is within the elevated range.

Storage

The vials of TruLab Lp(a) 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 production of TruLab Lp(a) 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 control 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 lyophilisate 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 control to stand for 30 minutes swirling occasionally. Avoid foaming! Do not shake!

Procedure

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

Assay Values

Assay values may vary with different reagents and methodologies used. The assay values listed below are specific for this lot number of control only.

Literature

1. Röhle G, Siekmann L. Quality assurance of quantitative determination. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1393-1401.
2. Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395).

Waste Management

Please refer to local legal requirements.

Manufacturer

DiaSys Diagnostic Systems GmbH
Alte Strasse 9
65558 Holzheim
Germany

IVD CE

Assay value according to new standardization [mg/dL]

	Reagent	Lot No.	Expiry Date	Assay Value New Standardization	Range
TruLab Lp(a) Level 2	**Lp(a) 21 FS**	39021	2028-05-31	53.3 mg/dL	42.6 – 64.0 mg/dL
				533 mg/L	426 – 640 mg/L

Assay value according to IFCC (SRM 2B) standardization

	Reagent	Lot No.	Expiry Date	Assay Value	Range
TruLab Lp(a) Level 2	**Lp(a) 21 FS**	39021	2028-05-31	109 nmol/L	87.2 – 131 nmol/L