K-*ASSAY*®

Lp(a) Control

Lot E546, Exp. 2026-10-31

Cat. No. K114C-4M

INTENDED USE

The **K-*ASSAY*®** Lipoprotein(a) [Lp(a)] Control is intended for use as an assayed quality control material for monitoring the performance of Lp(a) immunoturbidimetric assays.

FOR *IN VITRO* DIAGNOSTIC USE.

SUMMARY

The use of quality control materials to objectively monitor the precision of procedures in use in the clinical laboratory has been well established. The **K-*ASSAY*®** Lp(a) Control is provided at two levels to assist in the monitoring of analytical systems within the clinical range.

SET COMPOSITION

Level 1, 2 Human serum (lyophilized) 2 x 1 mL each level

Lp(a) Control Levels 1 and 2 contain pooled human serum with assigned values for Lp(a).

WARNINGS AND PRECAUTIONS

For *In Vitro* Diagnostic Use Only. ℞ only.

Not to be used internally in humans or animals. Normal precautions exercised in handling laboratory reagents should be followed.

Controls contain pooled human serum from Lp(a) positive human serum. The serum has been tested and found non-reactive for the presence of HBsAg, HCV Ab, and HIV antibody by an FDA approved method. However, it is not possible to guarantee that any human source material is free of these infectious agents.

Therefore, all products containing human serum should be handled in accordance with good laboratory practices using appropriate precautions as described in the CDC/NIH Manual, "Biosafety in Microbiological and Biomedical Laboratories," 2nd ed., 1988, HHS Publication No. (CDC) 88-8395.

Do not mix or use controls from one test set with those from a different lot number. Do not use controls past their expiration date stated on each control container label.

Controls in this set contain < 0.1% w/v sodium azide as a preservative. Sodium azide may form explosive compounds in metal drain lines. When disposing of controls through plumbing fixtures, flush with copious amounts of water. For further information, refer to "Decontamination of Laboratory Sink Drains to Remove Azide Salts," in the Manual Guide-Safety Management No. CDC-22 issued by the Centers for Disease Control, Atlanta, Georgia.

Do not pipette by mouth. Avoid ingestion and contact with skin.

CONTROL PREPARATION

1. Allow controls to come to room temperature. Remove cap carefully.
2. Add 1.0 mL of deionized water. Let rest for 15 minutes.
3. Invert gently until dissolved.

STORAGE AND HANDLING

Store controls at 2-8°C. Return all controls to 2-8°C promptly after use. Unopened controls can be used for up to 18 months from the date of manufacture, as indicated by the expiration date on the package and bottle labels.

CONTROL STABILITY

After reconstitution, the controls are stable for 2 weeks at 2-8°C or 2 months if aliquoted and stored at -20°C.

Discard controls if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard.

PROCEDURE

Materials Supplied

Level 1	Human serum	2 x 1 mL
Level 2	Human serum	2 x 1 mL

Materials Required But Not Supplied

K-*ASSAY*® Lp(a) Immunoturbidimetric Assay

K-*ASSAY*® Lp(a) Calibrator

Two-reagent clinical chemistry analyzer

Assay Procedure

NOTE: Allow all reagents and specimens to come to room temperature.

The **K-*ASSAY*®** Lp(a) Controls are assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the **K-*ASSAY*®** Lp(a) immunoturbidimetric assay.

LIMITATIONS OF PROCEDURE

Accurate and reproducible results are dependent upon properly functioning instruments, reagents, and good laboratory technique. Erroneous results can occur from improper storage, reconstitution inaccuracies, and technical errors associated with assay procedures.

This product is intended for use as an assayed control for quantitative assays of listed constituents in human serum. This product is not intended for use as a calibrator.

EXPECTED RESULTS

KAMIYA BIOMEDICAL COMPANY has established the expected values. Values listed were obtained using an Abbott Architect c8000 and **K-*ASSAY*®** Lp(a) immunoturbidimetric assay (Cat. No. KAI-044) with Lp(a) Calibrator (Cat. No. KAI-018C). Subsequent modifications in instrument, reagent, or procedure may invalidate these results. The assignment of mean values was derived from analysis of vials representative of the entire lot.

Values listed are specific for each lot only. Verify that the lot numbers on the vials of Lp(a) Control correspond to the lot numbers listed for the Assay Data.

The Expected Range of the Mean is provided to assist the laboratory until it has established its own mean and standard deviation. It is considered good laboratory practice for each laboratory to establish its own mean and standard deviation for its test methods. The indicated Mean and Expected Range of the Mean should serve as a guide in assessing the performance of each test method.

ASSAY DATA

	MEAN	RANGE
LEVEL 1 **Lot E546, Exp. 2026-10-31**	22.3 mg/dL	17.8 - 26.8 mg/dL
LEVEL 2 **Lot E546, Exp. 2026-10-31**	65.8 mg/dL	55.9 - 75.7 mg/dL

The expected values for the **K-*ASSAY*®** Lp(a) Control are continually being revised through ongoing quality assurance. Please refer to the package insert included with each control set for the most appropriate control values.

Recovered values may be method dependent. The variations which can occur over time and between laboratories may be attributed to differences in laboratory technique, instrumentation, reagent lot, method modifications, and other systematic errors including random errors.

LABELING SYMBOLS

REF	Catalog Number
	Expiration or “Use By” Date
LOT	Lot Number
CONTROL	Control
	Consult Package Insert for Instructions for Use
IVD	For *In Vitro* Diagnostic Use
CE	CE Mark Registered
℞	For Prescription Use Only
	Potential Human Biohazard
2°C 8°C	Temperature Limitation. Store between 2 and 8 degrees C
	Manufacturer
EC REP	Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE

CE

EC REP

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