K-*ASSAY*®

Lp(a) Calibrator

Lot A123, Exp. 2018-12-31

Cat. No. KAI-018C

INTENDED USE

The **K-*ASSAY*®** Lp(a) Calibrator is intended to be used for the multi-point calibration of the **K-*ASSAY*®** Lp(a) immunoturbidimetric assay. FOR *IN VITRO* DIAGNOSTIC USE.

SUMMARY

The calibrator in this kit is human serum containing known quantities of Lp(a). There is also a diluent solution (saline solution) for making a series of dilutions. These are to be used to make a multi-point calibration curve for the **K-*ASSAY*®** Lp(a) immunoturbidimetric assay.

KIT COMPOSITION

Lyophilized Human Serum	1 x 1 mL
Diluent (saline solution)	2 x 2 mL

WARNINGS AND PRECAUTIONS

FOR *IN VITRO* DIAGNOSTIC USE. Rx only.

Calibrators contain human serum which was tested and found negative for HBsAg and HIV antibodies by an FDA approved method. However, all products which contain human source material should be handled in accordance with good laboratory practices and appropriate control. See the National Institute of Health Manual, "Biosafety in Microbiology and Biomedical Laboratories," 2nd ed., 1988.

Do not mix or use calibrators from one test kit with those from a different lot number.

Do not use calibrators past their expiration date stated on each container label.

CALIBRATOR PREPARATION

1. Add exactly 1 mL of purified water to the vial containing the lyophilized serum to dissolve it.

2. Prepare 5 calibrators using the dissolved serum and diluent according the following protocol:

	B	C	D	E	F
Dilution	1/10	2/10	4/10	6/10	1
Dissolved serum (µL)	50	100	200	300	350
Diluent (µL)	450	400	300	200	0
Total (µL)	500	500	500	500	350

3. A multi-point calibration curve for Lp(a) can be made using the 5 calibrators and diluent solution (0 mg/dL). Lp(a) calibrator values are obtained by multiplying the dilution by the appropriate calibrator value of the reconstituted serum.

STORAGE AND HANDLING

All calibrators should be stored refrigerated (2-8°C). Return all calibrators to 2-8°C promptly after use. Unopened calibrators 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.

CALIBRATOR STABILITY

Opened, reconstituted, and diluted calibrators can be used for 2 weeks if stored at 2-8°C and tightly capped. Discard calibrators if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard.

Calibrator transferred to the instrument sample cup may concentrate over time. Therefore, calibrators should be capped and stored at 2-8°C when not in use. Otherwise, fresh calibrators should be used for each calibration.

PROCEDURE

Materials Supplied

Calibrators should be used as specified in the ***K-ASSAY*** ® Lp(a) immunoturbidimetric assay package insert.

Lyophilized Human Serum	1 x 1 mL
Diluent	2 x 2 mL

Materials Required But Not Supplied

K-ASSAY ® Lp(a) immunoturbidimetric assay

Purified water

Details of Procedure

Note: Allow all reagents and specimens to come to room temperature. Mix all reagents gently before using.

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

CALIBRATOR VALUES
(Lot A123)

After reconstitution of the vial of lyophilized human serum with 1 mL of purified water, the Lp(a) concentration indicated on the vial label will be obtained.

Lp(a) (mg/dL)
156

After reconstitution and dilution:

Calibrators A-F, values given in mg/dL						
	A	B	C	D	E	F
Lp(a)	0.0	15.6	31.2	62.4	93.6	156.0

The expected value for the ***K-ASSAY*** ® Lp(a) Calibrator is continually being revised through ongoing quality assurance. As a result, the expected values may change from lot to lot. Please refer to the package insert for each lot for the exact calibrator value.

LABELING SYMBOLS

LOT	Lot Number
RGT	Reagent
STD	Calibrator
	Expiration or "Use By" Date
REF	Catalog Number
IVD	For *In Vitro* Diagnostic Use
2-8°C	Temperature Limitation. Store between 2 and 8 degrees C
	Potential Human Biohazard
	Manufacturer
	Consult Package Insert for Instructions for Use
EC REP	Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE

CE

EC REP

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