

K-ASSAY®

Apo All / CII / CIII Calibrator

Lot A123, Exp. 2022-04-30

Cat. No. KAI-041C

INTENDED USE

The **K-ASSAY®** Apo All/CII/CIII Calibrator is intended to be used for the multi-point calibration of the **K-ASSAY®** Apo All, Apo CII, and Apo CIII immunoturbidimetric assays. FOR RESEARCH USE ONLY IN THE U.S. NOT FOR USE IN DIAGNOSTIC PROCEDURES IN THE U.S.

SUMMARY

The calibrators in this kit are human serum containing known quantities of apolipoproteins All, CII, and CIII. 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®** Apo All, Apo CII, and Apo CIII immunoturbidimetric assays.

KIT COMPOSITION

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

WARNINGS AND PRECAUTIONS

FOR RESEARCH USE ONLY IN THE U.S. Not for use in diagnostic procedures in the U.S.

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

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.

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

The calibrator and diluent contain < 0.1% w/v sodium azide as a preservative. Sodium azide may form explosive compounds in metal drain lines. When disposing of calibrator or diluent 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 Center for Disease Control, Atlanta, GA.

Calibrator contains human serum that was tested and found negative for HBsAg and HIV antibodies by an FDA approved method. However, all products that 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.

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 apolipoproteins All, CII, and CIII can be made using the 5 calibrators (Calibrators B-F) and saline (Calibrator A, 0 mg/dL). Apolipoprotein All, CII, and CIII 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**® Apo All, Apo CII, or Apo CIII immunoturbidimetric assay package insert.

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

Materials Required But Not Supplied

K-ASSAY® Apo All, Apo CII, or Apo CIII 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**® Apo All/CII/CIII Calibrators are assayed using the same procedure as the samples run in the test procedure. See package insert from the **K-ASSAY**® Apo All, Apo CII, or Apo CIII immunoturbidimetric assay.











CALIBRATOR VALUES (Lot A123)

Concentration of lyophilized serum, reconstituted with 1 mL of purified water (undiluted):

Apo All (mg/dL)	Apo CII (mg/dL)	Apo CIII (mg/dL)
94	12.2	32.3

The expected values for the **K-ASSAY**® Apo All/CII/CIII Calibrator are 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 values.

LABELING SYMBOLS

	Lot Number
	Calibrator
	Reagent
	Expiration or "Use By" Date
	Catalog Number
	2-8°C Temperature Limitation. Store between 2 and 8 degrees C
	Potential Human Biohazard
	Manufacturer
	Consult Package Insert for Instructions for Use
	Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE





Advena Ltd.

Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013 Malta

ORDERING / PRICING / TECHNICAL INFORMATION



KAMIYA BIOMEDICAL COMPANY

12779 Gateway Drive
Seattle, WA 98168 USA
TEL: (206) 575-8068 / (800) 526-4925
FAX: (206) 575-8094

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