K-*ASSAY*®

Apo AI / Apo B Calibrator

Lot A123, Exp. 2024-11-30

Cat. No. KAI-008C

INTENDED USE

The **K-*ASSAY*®** Apo AI/B Calibrator is intended to be used for the calibration of the **K-*ASSAY*®** Apo AI and Apo B immunoturbidimetric assays. FOR *IN VITRO* DIAGNOSTIC USE.

SUMMARY

The calibrator in this kit is human serum tested and found negative for HBsAg and HIV Ab. It contains known quantities of apolipoprotein AI and B. 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 AI and Apo B immunoturbidimetric assays.

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.

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.

Calibrators in this kit contain sodium azide as a preservative. Sodium azide may form explosive compounds in metal drain lines. When disposing of calibrators 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. CSC-22 issued by the Centers for Disease Control, Atlanta, Georgia.

Calibrators contain pooled human serum. Each donor unit used in the preparation of this product has been tested by an FDA approved method and found non-reactive for the presence of HBsAg and HIV antibody. However, it is not possible to guarantee that they are free of hepatitis B virus (HBV), human immunodeficiency virus (HIV), or other infectious agents.

Therefore, all products that contain human serum 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. Swirl gently to dissolve.

2. Prepare 5 calibrators (B-F) using the dissolved serum and diluent according the following protocol:

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

3. A multi-point calibration curve for apolipoprotein AI or B can be made using the 5 calibrators and diluent solution (Calib. A, 0 mg/dL). Apolipoprotein AI/B 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.

INSTRUMENT

Measurement of absorbance is to be made with a clinical chemistry analyzer able to accurately read absorbance at 600 and 800 nm. Refer to the instrument manual from the manufacturer regarding the following:

a) Use or function
b) Installation procedures and requirements
c) Principles of operation
d) Performance characteristics, operating instructions

e) Calibration procedures including materials and / or equipment to be used
f) Operational precautions, limitations, and hazards
g) Service and maintenance information

PROCEDURE

Materials Supplied

Calibrator should be used as specified in the **K-*ASSAY*®** Apo AI or B assay package insert.

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

Materials Required But Not Supplied

K-*ASSAY*® Apo AI or B immunoturbidimetric assays

Purified water

Test tubes and required glassware

Two-Reagent Clinical Chemistry Analyzer:
Capable of accurate absorbance reading at 600/800 nm
Capable of accurately dispensing the required volumes
Capable of maintaining 37°C

Details of Procedure:

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

K-*ASSAY*® Apo AI/B Calibrators are assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the **K-*ASSAY*®** Apo AI/B assay.

Fresh calibrators should be used every time the instrument is calibrated.

It is recommended that the user determine calibration curve frequency as this depends on the instrument and type/number of other assays being performed.

LABELING SYMBOLS

REF	Catalog Number
	Expiration or "Use By" Date
LOT	Lot Number
	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

CALIBRATOR VALUES

Lot A123

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

Apo AI (mg/dL)*	Apo B (mg/dL)*
338.0	256.0

After reconstitution and dilution:

Calibrators A-F, values given in mg/dL						
	A	B	C	D	E	F
Apo AI	0.0	33.8	67.6	135.2	202.8	338.0
Apo B	0.0	25.6	51.2	102.4	153.6	256.0

* This calibrator has been correlated to the WHO Apo AI Reference Material, SP-01, and to the WHO Apo B Reference Material, SP3-08.

The expected values for the **K-*ASSAY*®** Apo AI/B 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.

QUALITY CONTROL

Normal and abnormal controls of known concentration should be included in each assay performed. These controls should fall within the stated values assigned to the controls. The validity of the assay is in question if the value for the controls generated by the assay's calibration curve does not fall within the stated range. Recalibrate if the value determined for the controls falls outside the stated recovery range.

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