

K-ASSAY®

Apo AI / Apo B Calibrator

Lot E782, Exp. 2018-10-31

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:

	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 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

