

**K-ASSAY**<sup>®</sup>

# Apo All / CII / CIII Calibrator

Lot A123, Exp. 2017-02-28

Cat. No. KAI-041C

**INTENDED USE**

The **K-ASSAY**<sup>®</sup> Apo All/CII/CIII Calibrator is intended to be used for the multi-point calibration of the **K-ASSAY**<sup>®</sup> 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**<sup>®</sup> 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. Not For Use in Diagnostic Procedures in the U.S.

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 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  |
|  | Reagent   |
|  | Calibrator  |
|  | 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           |

## ORDERING / PRICING / TECHNICAL INFORMATION



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Printed September 2015