

RLP-C Calibrator

Lot A123, Exp. 2018-12-31

Cat. No. KAI-261C

INTENDED USE

The **K-ASSAY®** RLP-C Calibrator is intended to be used for the calibration of the **K-ASSAY®** RLP-C (Remnant Lipoprotein Cholesterol) assay. FOR RESEARCH USE ONLY IN THE U.S. NOT FOR USE IN DIAGNOSTIC PROCEDURES IN THE U.S.

SUMMARY

The calibrator in this kit is human serum containing a known quantity of RLP-C. Using saline as the first point, the RLP-C calibrator is to be used to make a 2 point calibration for the **K-ASSAY®** RLP-C assay.

KIT COMPOSITION

Lyophilized Human Serum 1 x 1 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 calibrator from one test kit with those from a different lot number.

Do not use the calibrator past the expiration date stated on each container label.

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

Use care when opening the vial's aluminum cap to prevent injury.

This calibrator is manufactured from human serum which was tested and found negative for HBsAg, HCV, and HIV antibodies by an FDA approved method. However, all products which contain human source material should be handled as potentially infectious 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. Allow the calibrator vial to come to room temperature before use.
2. Carefully remove the vial cap and rubber stopper and add exactly 1 mL of room temperature purified water to the vial to dissolve the lyophilized serum.
3. Replace the rubber stopper and gently invert the vial to mix material, taking care to avoid formation of bubbles. Do not shake.
4. Allow the vial to sit at room temperature for a minimum of one hour. Visually inspect the vial to insure all material has fully dissolved before use.

STORAGE AND HANDLING

The calibrator should be stored refrigerated (2-8°C) in the dark. Return the calibrator to 2-8°C and the dark promptly after use. An unopened calibrator can be used for up to 12 months from the date of manufacture, as indicated by the expiration date on the package and bottle label.

CALIBRATOR STABILITY

Opened and reconstituted calibrator can be used for 2 days if stored at 2-8°C, tightly capped, and kept in the dark. Discard the calibrator if it becomes 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, the calibrator should be capped and stored at 2-8°C when not in use. Otherwise, fresh calibrator should be used for each calibration.

PROCEDURE

The calibrator should be used as specified in the **K-ASSAY®** RLP-C assay package insert.

Materials Supplied

Lyophilized Human Serum 1 x 1 mL

Materials Required But Not Supplied

K-ASSAY® RLP-C assay

Two Reagent Clinical Chemistry Analyzer Capable of:
Accurate absorbance readings at approx. 600 nm
Accurately dispensing the required volumes
Maintaining 37°C

Purified water (for reconstitution of RLP-C Calibrator)

Saline solution (to be used as 0 mg/dL calibrator)

Details of Procedure

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

The **K-ASSAY**® RLP-C Calibrator is assayed using the same procedure as the samples run in the test procedure. See package insert from the **K-ASSAY**® RLP-C assay.









CALIBRATOR VALUES

After reconstitution of the calibrator vial with 1 mL of purified water, the RLP-C concentration will be as follows.

Lot A123
26.8 mg / dL or 0.69 mmol / L

The expected value for the **K-ASSAY**® RLP-C 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 Number
	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

ORDERING / PRICING / TECHNICAL INFORMATION



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