K-*ASSAY*®

RLP-C Control

Lot 503ABG, Exp. 2023-07-31

CAT. NO. K262C-6M

INTENDED USE

The **K-*ASSAY*®** RLP-C Control is intended for use as a consistent test sample of known concentration for monitoring the performance 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 use of quality control materials to objectively monitor the precision of procedures has been well established. The **K-*ASSAY*®** RLP-C Control is provided at two levels.

SET COMPOSITION

Level 1, 2 Human serum (lyophilized) 3 x 1 mL each level

Control Levels 1 and 2 contain pooled human serum with assigned values for RLP-C.

WARNINGS AND PRECAUTIONS

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

Do not mix or use controls from one test kit with those from a different lot number.

Do not use controls past their 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.

These controls are 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.

CONTROL PREPARATION

1. Allow control vials 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 each vial to dissolve the lyophilized serum.
3. Replace the rubber stopper and gently invert each vial to mix material, taking care to avoid formation of bubbles. Do not shake.
4. Allow the vials to sit at room temperature for a minimum of one hour. Visually inspect the vials to insure all material has fully dissolved before use.

STORAGE AND HANDLING

All controls should be stored refrigerated (2-8°C) in the dark. Return all controls to 2-8°C and the dark promptly after use. Unopened controls can be used for up to 12 months from the date of manufacture, as indicated by the expiration date on the package and bottle labels.

CONTROL STABILITY

Opened and reconstituted controls can be used for 2 days if stored at 2-8°C, tightly capped, and kept in the dark. Discard the controls if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard.

PROCEDURE

Materials Supplied

Level 1	Human serum	3 x 1 mL
Level 2	Human serum	3 x 1 mL

Materials Required But Not Supplied

K-*ASSAY*® RLP-C assay

K-*ASSAY*® RLP-C Calibrator

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

Purified water

Assay Procedure

NOTE: Allow all reagents and specimens to come to room temperature.

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

LIMITATIONS OF PROCEDURE

Accurate and reproducible results are dependent upon properly functioning instruments, reagents, and good laboratory technique. Erroneous results can occur from improper storage, reconstitution inaccuracies, and technical errors associated with assay procedures.

This product is intended for use as an assayed control for quantitative assays of RLP-C in human serum. This product is not intended for use as a calibrator.

EXPECTED VALUES

KAMIYA BIOMEDICAL COMPANY has established the expected values. The assignment of mean values was derived from analysis of vials representative of the entire lot.

Values listed are specific for each lot only. Verify that the lot numbers on the vials of RLP-C Control correspond to the lot numbers listed for the Assay Data.

The Expected Range of the Mean is provided to assist the laboratory until it has established its own mean and standard deviation. It is considered good laboratory practice for each laboratory to establish its own mean and standard deviation for its test methods. The indicated Mean and Expected Range of the Mean should serve as a guide in assessing the performance of each test method.

ASSAY DATA

ASSAY	UNIT	LEVEL 1 LOT 503ABG, EXP. 2023-07-31		LEVEL 2 LOT 503ABG, EXP. 2023-07-31	
		MEAN	RANGE	MEAN	RANGE
K-ASSAY ® RLP-C	mg / dL	4.7	3.3 - 6.1	14.1	10.3 - 17.9
	mmol / L	0.12	0.09 - 0.16	0.36	0.27 - 0.46

The expected values for the ***K-ASSAY*** ® RLP-C Control are continually being revised through ongoing quality assurance. Please refer to the package insert included with each control set for the most appropriate control values. Recovered values may be method dependent. The variations which can occur over time and between laboratories may be attributed to differences in laboratory technique, instrumentation, reagent lot, method modifications, and other systematic errors including random errors.

LABELING SYMBOLS

REF	Catalog Number
	Expiration or “Use By” Date
LOT	Lot Number
CONTROL	Control
	Consult Package Insert for Instructions for Use
	Potential Human Biohazard
2°C 8°C	Temperature Limitation. Store between 2 and 8 degrees C
	Manufacturer

ORDERING / PRICING / TECHNICAL INFORMATION

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