K-*ASSAY*®

Apo AII / CII / CIII / E Control

Lot A123/B456, Exp. 2024-03-31

CAT. NO. K315C-4M

INTENDED USE

The **K-*ASSAY*®** Apo AII / CII / CIII / E Control is intended for use as a consistent test sample of known concentration for monitoring assay conditions for the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

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*®** Apo AII / CII / CIII / E Control is provided at two levels.

SET COMPOSITION

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

Apo AII / CII / CIII / E Control Levels 1 and 2 contain pooled human serum with assigned values for the listed constituents.

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.

Controls contain pooled human serum from Apolipoprotein positive human serum. The serum has been tested and found non-reactive for the presence of HBsAg, HCV Ab, and HIV antibody by an FDA approved method. However, it is not possible to guarantee that any human source material is free of these infectious agents.

Therefore, all products containing human serum should be handled in accordance with good laboratory practices using appropriate precautions as described in the CDC/NIH Manual, "Biosafety in Microbiological and Biomedical Laboratories," 2nd ed., 1988, HHS Publication No. (CDC) 88-8395.

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

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

Do not use controls past their expiration date stated on each control container label.

Controls in this set contain < 0.1% w/v sodium azide as a preservative. Sodium azide may form explosive compounds in metal drain lines. When disposing of controls 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. CDC-22 issued by the Centers for Disease Control, Atlanta, GA.

CONTROL PREPARATION

1. Allow controls to come to room temperature. Remove cap carefully.
2. Add 1.0 mL of deionized water. Let rest for 15 minutes.
3. Invert gently until dissolved.

STORAGE AND HANDLING

Store controls at 2-8°C. Return all controls to 2-8°C promptly after use. Unopened controls 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.

CONTROL STABILITY

After reconstitution, the controls' Apo AII, Apo CII, and Apo CIII values are stable for 2 weeks at 2-8°C or 2 months if aliquoted and stored at -20°C.

After reconstitution, the controls' Apo E values are stable for 3 days at 2-8°C or 2 months if aliquoted and stored at -20°C.

Discard controls if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard.

PROCEDURE

Materials Supplied

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

Materials Required But Not Supplied

K-*ASSAY*® Apo AII, Apo CII, Apo CIII and/or Apo E Assay kits.

K-*ASSAY*® Apo AII / CII / CIII Calibrator or Apo E Calibrator.

Two-reagent clinical chemistry analyzer

Assay Procedure

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

The **K-*ASSAY*®** Apo AII / CII / CIII / E Controls are assayed using the same procedure as the samples run in the test procedure. See package insert from the corresponding **K-*ASSAY*®** Apo AII, Apo CII, Apo CIII, or Apo E 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 the listed constituents in human serum. This product is not intended for use as a calibrator.

EXPECTED VALUES

KAMIYA BIOMEDICAL COMPANY has established the expected values. Values listed were obtained using an Abbott Architect c8000 and **K-*ASSAY*®** reagents and calibrators. Subsequent modifications in instrument, reagent, or procedure may invalidate these results. 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 **K-*ASSAY*®** Apo AII / CII / CIII / E 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

All values listed are for research use only in the U.S. Not for use in diagnostic procedures in the U.S.

ASSAY	LEVEL 1 LOT A123, EXP. 2024-03-31		LEVEL 2 LOT B456, EXP. 2024-03-31	
	MEAN (mg/dL)	RANGE (mg/dL)	MEAN (mg/dL)	RANGE (mg/dL)
Apolipoprotein AII	27	22 – 32	42	36 – 48
Apolipoprotein CII	2.7	2.2 – 3.2	5.1	4.3 – 5.9
Apolipoprotein CIII	8.5	6.8 – 10.2	14.6	12.4 – 16.8
Apolipoprotein E	3.1	2.5 – 3.7	5.3	4.5 – 6.1

The expected values for the **K-*ASSAY*®** Apo AII / CII / CIII / E 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
CE	CE Mark Registered
	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

EU AUTHORIZED REPRESENTATIVE

CE

EC REP

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Printed September 2022