K-*ASSAY*®

Cystatin C Control

Lot: A123, Exp. 2017-02-28

Cat. No. K100C-2M and K100C-4M

INTENDED USE

The **K-*ASSAY*®** Cystatin C Control is intended for use as an assayed quality control material for monitoring the performance of cystatin C assays.

FOR *IN VITRO* DIAGNOSTIC USE.

SUMMARY

The use of quality control materials to objectively monitor the precision of procedures in use in the clinical laboratory has been well established. The **K-*ASSAY*®** Cystatin C Control is provided at two levels to assist in the monitoring of analytical systems within the clinical range.

SET COMPOSITION

K100C-2M
Level 1, 2 1 x 1 mL each level, liquid
Human Cystatin C
150 mM Sodium Chloride
25 mM HEPES
Sodium azide < 0.1 w/v %

K100C-4M
Level 1, 2 2 x 1 mL each level, liquid
Human Cystatin C
150 mM Sodium Chloride
25 mM HEPES
Sodium azide < 0.1 w/v %

Cystatin C Control Levels 1 and 2 contain human cystatin C solutions with assigned values for cystatin C.

WARNINGS AND PRECAUTIONS

For *In Vitro* Diagnostic Use Only.

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

Cystatin C was isolated from human urine that was tested and found negative for HIV I & II antibodies, Hepatitis B surface antigen, and Hepatitis C antibodies by FDA approved methods. However, all products that 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 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 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, Georgia.

CONTROL PREPARATION

Controls are liquid and ready to use.

STORAGE AND HANDLING

Store controls at 2-8℃. Return all controls to 2-8℃ 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

Opened controls can be used for 1 month if stored at 2-8℃.

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

PROCEDURE

Materials Supplied

K100C-2M

Level 1	Human Cystatin C	1 x 1 mL
Level 2	Human Cystatin C	1 x 1 mL

K100C-4M

Level 1	Human Cystatin C	2 x 1 mL
Level 2	Human Cystatin C	2 x 1 mL

Materials Required But Not Supplied

K-*ASSAY*® Cystatin C Assay, Cat. No. KAI-073 or KAI-074

K-*ASSAY*® Cystatin C Calibrator, Cat. No. KAI-099C

Two-reagent clinical chemistry analyzer

Assay Procedure

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

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

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 listed constituents. This product is not intended for use as a calibrator.

EXPECTED RESULTS

KAMIYA BIOMEDICAL COMPANY has established the expected values. Values listed were obtained using an Abbott Architect c8000 and **K-*ASSAY*®** Cystatin C assay (Cat. No. KAI-073 / KAI-074) with Cystatin C Calibrator (Cat. No. KAI-099C). 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 Cystatin 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.

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.

ASSAY DATA

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			L1	VALUES	L2	VALUES
ASSAY	**MANUFACTURER**	**UNITS**	**MEAN**	**EXPECTED RANGE**	**MEAN**	**EXPECTED RANGE**
Cystatin C	KAMIYA BIOMEDICAL COMPANY	mg/L	0.8	0.6 – 1.0	1.6	1.4 – 1.8
Standardized* Cystatin C	KAMIYA BIOMEDICAL COMPANY	mg/L	0.7	0.5 – 0.9	1.4	1.2 – 1.6

* Standardized against ERM-DA471 / IFCC Reference Material.

The expected values for the **K-*ASSAY*®** Cystatin C Control 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 appropriate control values.

LABELING SYMBOLS

LOT	Lot Number
CONTROL	Control
	Expiration or "Use By" Date
REF	Catalog Number
IVD	For *In Vitro* Diagnostic Use
2-8°C	Temperature Limitation. Store between 2 and 8 degrees C
	Potential Human Biohazard
	Manufacturer
	Consult Package Insert for Instructions for Use
EC REP	Authorized Representative in the European Community

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ORDERING / PRICING / TECHNICAL INFORMATION

KAMIYA BIOMEDICAL COMPANY
12779 Gateway Drive
Seattle, WA 98168 USA
TEL: (206) 575-8068 / (800) 526-4925
FAX: (206) 575-8094

CE

EC REP

Medical Device & QA Services Ltd (MDQAS)
Spring Court, Spring Road, HALE.
Cheshire. WA14 2UQ. United Kingdom.
Tel: +44 (0) 845 527 5078 Fax: +44 (0) 161 903 9787
E-mail: info@mdqas.com www.mdqas.com