

K-ASSAY[®]

Beta-2 Microglobulin Urine Control

Lot 123456, Exp. 2023-06-30

CAT. NO. K284C-2M

INTENDED USE

The **K-ASSAY**[®] Beta-2 Microglobulin Urine Control is intended for use as a consistent test sample of known concentration for monitoring the performance of the **K-ASSAY**[®] Beta-2 Microglobulin immunoturbidimetric assay with urine samples.

FOR *IN VITRO* DIAGNOSTIC USE.**SUMMARY**

The use of quality control materials to objectively monitor the precision of procedures has been well established. The **K-ASSAY**[®] Beta-2 Microglobulin Urine Control is provided at two levels.

SET COMPOSITION

Level 1, 2 Human Beta-2 Microglobulin in Good's Buffer
1 x 2 mL each level

WARNINGS AND PRECAUTIONS

For *In Vitro* Diagnostic Use Only. R only.

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

Controls contain Beta-2 Microglobulin extracted from human serum that was tested and found negative for HBs antigen, HCV antibodies, and HIV antibodies by an FDA approved method. 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 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.

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

The controls are ready to use. They do not require reconstitution.

STORAGE AND HANDLING

Store controls at 2-8°C. Return all controls to 2-8°C promptly after use. Unopened controls can be used until the expiration date on the package and bottle labels.

CONTROL STABILITY

After opening, controls can be used for 10 weeks if re-capped and stored at 2-8°C.

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

PROCEDURE**Materials Supplied**

Level 1 Beta-2 Microglobulin Urine Control, 1 x 2 mL
Level 2 Beta-2 Microglobulin Urine Control, 1 x 2 mL

Materials Required But Not Supplied

K-ASSAY[®] Beta-2 Microglobulin immunoturbidimetric assay

K-ASSAY[®] Beta-2 Microglobulin Urine Calibrator

Two Reagent Clinical Chemistry Analyzer Capable of:
Accurate absorbance readings at approx. 570 nm
Accurately dispensing the required volumes
Maintaining 37°C

Assay Procedure

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

The **K-ASSAY**[®] Beta-2 Microglobulin Urine Controls are assayed using the same procedure as the samples run in the test procedure. See package insert from the **K-ASSAY**[®] Beta-2 Microglobulin immunoturbidimetric 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 Beta-2 Microglobulin in human urine. 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 Beta-2 Microglobulin Urine 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

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ASSAY	SAMPLE TYPE	UNIT	LEVEL 1		LEVEL 2	
			MEAN	RANGE	MEAN	RANGE
K-ASSAY® Beta-2 Microglobulin	Urine	µg / L	164	148 - 180	2,076	1,868 - 2,284

The expected values for the **K-ASSAY® Beta-2 Microglobulin Urine 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

	Catalog Number
	Expiration or "Use By" Date
	Lot Number
	Control
	Consult Package Insert for Instructions for Use
	For <i>In Vitro</i> Diagnostic Use
	CE Mark Registered
	For Prescription Use Only
	Potential Human Biohazard
	Temperature Limitation. Store between 2 and 8 degrees C
	Manufacturer
	Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE



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