K-*ASSAY*®

Microalbumin Urine Control

Lot 54321/2, Exp. 2026-09-30

Cat. No. K37C-4M

PRODUCT DESCRIPTION

The **K-*ASSAY*®** Microalbumin Urine Controls are supplied in two levels. They are ready to use, liquid, requiring no reconstitution or dilution. They are prepared from human urine, fortified to target levels with human albumin and creatinine. Preservatives including sodium azide have been added to inhibit microbial growth.

INTENDED USE

The **K-*ASSAY*®** Microalbumin Urine Controls are intended as a means of monitoring various microalbumin assay methods to validate quantitation of patient samples. Control materials having known component concentrations are an integral part of diagnostic procedures. Daily monitoring of control values establishes intra-laboratory parameters for accuracy and precision of the test method. FOR *IN VITRO* DIAGNOSTIC USE.

SET COMPOSITION

Level 1	2 x 7 mL
Level 2	2 x 7 mL

WARNINGS AND PRECAUTIONS

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

POTENTIAL BIOHAZARD MATERIAL. All blood donor units comprising the source plasma used in the manufacture of the albumin have been tested and found non-reactive for Hepatitis B Surface Antigen and HIV antibody when tested by FDA accepted methods. No known test method can assure that a product derived from human blood does not contain Hepatitis or HIV virus. Such samples should be handled at the Center for Disease Control's Bio-Safety Level 2 recommendations.

DISPOSE OF CAREFULLY. Sodium azide may accumulate in plumbing traps and pose a threat of explosion.

STORAGE AND STABILITY

1. The controls should be stored at 2-8°C. When stored at 2-8°C, the controls are stable until the expiration date stated on the label.
2. When stored at 2-8°C between each use, the controls are stable for six months after opening.
3. When using the control with the Micral Test Strips, the control will remain stable for six months after opening, until after 10 uses, or until the expiration date, whichever occurs first.
4. Discard the controls if turbid or if there is any evidence of microbial contamination.

PROCEDURE

1. Remove controls from the refrigerator and allow to come to room temperature (20-25°C), about 15-30 minutes.
2. Invert gently to assure homogeneity of the contents. Avoid foaming. Treat the control as you would a patient sample in accordance with instructions in the **K-*ASSAY*®** Microalbumin assay package insert.
3. Immediately recap the controls and return to 2-8°C when not in use.

LIMITATIONS

The expected mean and ranges were established using reagents available at the time of the assay. Any future changes made by the manufacturer of a test method may give different values from those previously recovered. Use of methods other than the ones used to establish the expected values may give different values from the ones indicated. Limitations of the test method are included in the package insert for the reagent or instrument being used.

Depending on the instrument and the reagents used to measure Creatinine, the mean Creatinine values listed may decrease up to 10% over the entire shelf life of the control.

Note: When using Vitros Slides for Creatinine with this control, dilute the control 1:41 instead of the normal 1:21. Run as usual and correct for the dilution.

EXPECTED VALUES

The expected values have been established and tested by KAMIYA BIOMEDICAL COMPANY and other laboratories. Individual laboratory means should fall within the ranges listed. These values should be used as a guide in evaluating the performance of the test methods. Each laboratory should establish its own precision parameters for the methods used to measure each analyte. Actual values recovered depend on the instrument and reagent used.

ASSAY DATA

REAGENT	LEVEL 1 Lot No. 54321, Exp. 2026-09-30		LEVEL 2 Lot No. 54322, Exp. 2026-09-30	
	Mean (mg/dL)	Range (mg/dL)	Mean (mg/dL)	Range (mg/dL)
K-*ASSAY*® Microalbumin	0.92	0.74 – 1.10	6.32	5.06 – 7.58
Siemens/Dade Creatinine using Siemens/Dade Dimension	27.98	22.38 – 33.57	222.93	178.35 – 267.52

LABELING SYMBOLS

REF	Catalog Number
	Expiration or "Use By" Date
LOT	Lot Number
CONTROL	Control
	Consult Package Insert for Instructions for Use
IVD	For *In Vitro* Diagnostic Use
CE	CE Mark Registered
Rx	For Prescription Use Only
	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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