

K-ASSAY®

Urine Alpha-1 Microglobulin Calibrator

Lot 123456, Exp. 2018-01-31

Cat. No. KAI-067C**INTENDED USE**

The **K-ASSAY®** Urine Alpha-1 Microglobulin Calibrator is intended to be used for the calibration of the **K-ASSAY®** Alpha-1 Microglobulin assay for the quantitative analysis of alpha-1 microglobulin in urine samples. *FOR IN VITRO* DIAGNOSTIC USE.

SUMMARY

These are to be used as calibrators for the **K-ASSAY®** Alpha-1 Microglobulin assay, **with urine samples only**. (Use Cat. No. KAI-068C Serum Alpha-1 Microglobulin Calibrator for serum or plasma samples).

KIT COMPOSITION**Calibrators (Liquid Stable)****MATERIALS PROVIDED**

Calibrator 1-4 Human Alpha-1 Microglobulin 4 x 1 mL

Contains pooled human urine with assigned values for the protein Alpha-1 Microglobulin.

WARNINGS AND PRECAUTIONS

FOR IN VITRO DIAGNOSTIC USE. Rx only.

Only use application parameters specific for **K-ASSAY®** Urine Alpha-1 Microglobulin with the **K-ASSAY®** Alpha-1 Microglobulin assay on urine samples. When using serum or plasma samples, use **K-ASSAY®** Serum Alpha-1 Microglobulin Calibrator (Cat. No. KAI-068C). Failure to use application parameters specific for Urine Alpha-1 Microglobulin may produce erroneous values.

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

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

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

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

Calibrators in this kit contain < 0.1 w/v% sodium azide as a preservative. Sodium azide may form explosive compounds in lead drain lines. When disposing of calibrators 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 Guide Management No. CDC-22 issued by the Center for Disease Control, Atlanta, GA. 1976.

Calibrators contain alpha-1 microglobulin extracted from human serum. Each donor unit used in the preparation of this product has been tested by an FDA approved method and found non-reactive for HBsAg and HIV antibodies. However, it is not possible to guarantee that they are free of hepatitis B virus (HB), human immunodeficiency virus (HIV), or other 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 Microbiology and Biomedical Laboratories," 2nd ed., 1988, HHS Publication No. (CDC) 88-8395.

CALIBRATOR PREPARATION

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

STORAGE AND HANDLING

All calibrators should be stored refrigerated (2-8°C). Return all calibrators to 2-8°C promptly after use. Unopened calibrators can be used for one year from the date of manufacturing as indicated on the expiration date on the package and bottle labels. Opened bottles of calibrators can be used for 1 month if stored at 2-8°C.

Calibrator Deterioration

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

INSTRUMENT

Measurements of absorbance are to be made with a clinical chemistry analyzer able to accurately read absorbance at 560 nm and 800 nm (primary/sub). Refer to the instrument manual from the manufacturer regarding the following:

- a) Use or function
- b) Installation procedures and requirements
- c) Principles of operation
- d) Performance characteristics, operating instructions
- e) Calibration procedures including materials and / or equipment to be used
- f) Operational precautions, limitations, and hazards
- g) Service and maintenance information

PROCEDURE

Calibrators should be used as specified in the Alpha-1 Microglobulin immunoturbidimetric assay package insert.

Materials Supplied

Calibrator 1 (Gray Cap)	1 x 1 mL
Calibrator 2 (White Cap)	1 x 1 mL
Calibrator 3 (Blue Cap)	1 x 1 mL
Calibrator 4 (Green Cap)	1 x 1 mL

Materials Required But Not Supplied

K-ASSAY[®] Alpha-1 Microglobulin assay

Clinical chemistry analyzer: capable of accurate absorbance readings at 560 nm and 800 nm with appropriate cuvettes and calculating rate reactions, capable of accurately dispensing the required volumes, and capable of maintaining 37°C.

Saline solution (0 mg/L calibrator)

Details of Assay Procedure:

NOTE: Allow all reagents and specimens to come to room temperature. Mix all reagents gently before using.

K-ASSAY[®] Urine Alpha-1 Microglobulin is assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the **K-ASSAY**[®] Alpha-1 Microglobulin immunoturbidimetric assay. **Use saline solution as the 0 mg/L calibrator.**

Use **K-ASSAY[®] Urine Alpha-1 Microglobulin only with Urine Alpha-1 Microglobulin instrument protocols.**

CALIBRATOR VALUES











Lot 123456

Alpha-1 Microglobulin

Calibrator 1	3.4 mg/L
Calibrator 2	6.9 mg/L
Calibrator 3	17.1 mg/L
Calibrator 4	34.3 mg/L

The values for the Urine Alpha-1 Microglobulin Calibrator 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 exact calibrator values.

LABELING SYMBOLS

	Lot Number
	Calibrator
	Expiration or "Use By" Date
	Catalog Number
	For <i>In Vitro</i> 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
	Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE



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