

K-ASSAY®

Beta-2 Microglobulin Urine Calibrator

Cat. No. KAI-282C

INTENDED USE

The **K-ASSAY**® Beta-2 Microglobulin Urine Calibrator is intended to be used for the calibration of the **K-ASSAY**® Beta-2 Microglobulin assay for the quantitative analysis of Beta-2 Microglobulin (β 2MG) in urine samples. FOR *IN VITRO* DIAGNOSTIC USE.

SUMMARY

These are to be used as calibrators for the **K-ASSAY**® Beta-2 Microglobulin assay, **with urine samples only**. (Use Cat. No. KAI-281C Beta-2 Microglobulin Serum / Plasma Calibrator for serum or plasma samples).

KIT COMPOSITION

Calibrators (Liquid Stable)

Calibrator 1-5, Human Beta-2 Microglobulin, 5 x 2 mL

Contain pooled human urine with assigned values for β 2MG.

WARNINGS AND PRECAUTIONS

FOR *IN VITRO* DIAGNOSTIC USE. Rx only.

Only use application parameters specific for **K-ASSAY**® Beta-2 Microglobulin Urine Calibrator with the **K-ASSAY**® Beta-2 Microglobulin assay on urine samples. When using serum or plasma samples, use **K-ASSAY**® Beta-2 Microglobulin Serum / Plasma Calibrator (Cat. No. KAI-281C). Failure to use application parameters specific for the Beta-2 Microglobulin Urine Calibrator 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 metal 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 Management No. CDC-22 issued by the Center for Disease Control, Atlanta, GA.

Calibrators contain Beta-2 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 HBs antigen and HCV and HIV-1/HIV-2 antibodies. However, it is not possible to guarantee that they are free of hepatitis B virus (HBV), hepatitis C virus (HCV), human immuno-deficiency 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 until 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 STABILITY

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 570 nm. 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 **K-ASSAY**® Beta-2 Microglobulin assay package insert.

Materials Supplied

Calibrator 1 (Cream Cap)	1 x 2 mL
Calibrator 2 (Yellow Cap)	1 x 2 mL
Calibrator 3 (White Cap)	1 x 2 mL
Calibrator 4 (Blue Cap)	1 x 2 mL
Calibrator 5 (Pink Cap)	1 x 2 mL

Materials Required But Not Supplied

K-ASSAY® Beta-2 Microglobulin assay, Catalog Number KAI-280

Clinical chemistry analyzer: capable of accurate absorbance readings at 570 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 Procedure

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

K-ASSAY® Beta-2 Microglobulin Urine Calibrator is assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the **K-ASSAY**® Beta-2 Microglobulin immunoturbidimetric assay.

Use K-ASSAY® Beta-2 Microglobulin Urine Calibrator only with the urine instrument protocols .

CALIBRATOR VALUES

Beta-2 Microglobulin

Calibrator 1	250 µg/L
Calibrator 2	500 µg/L
Calibrator 3	1,500 µg/L
Calibrator 4	5,000 µg/L
Calibrator 5	8,000 µg/L

Use saline solution as the 0 µg/L calibrator.

Values are standardized against the WHO (World Health Organization) 1st international standard material for Beta-2 Microglobulin.

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