

K-ASSAY®

Microalbumin Calibrator

Lot G711, Exp. 2018-12-31

Cat. No. KAI-020C

INTENDED USE

The **K-ASSAY®** Microalbumin Calibrator is for the calibration of the **K-ASSAY®** Microalbumin assay for quantifying albumin in urine specimens. FOR *IN VITRO* DIAGNOSTIC USE.

SUMMARY

The calibrators in this kit are human albumin calibrators containing known quantities of human albumin. There is also a calibrator containing only diluent (150 mM sodium chloride). These calibrators are to be used with the **K-ASSAY®** Microalbumin assay.

KIT COMPOSITION**Calibrators (Liquid Stable)**

Calibrator A:	150 mM Sodium Chloride	1 x 1 mL
Calibrator B-F:	Human Albumin 150 mM Sodium Chloride	5 x 1 mL

WARNINGS AND PRECAUTIONS

FOR *IN VITRO* DIAGNOSTIC USE. Rx only.

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

Albumin was isolated from pooled human serum that was tested and found negative for HBsAg, HCV, and HIV-1 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 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.

CALIBRATOR PREPARATION

The calibrators are ready to use and 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 up to 18 months from the date of manufacture, as indicated by the expiration date on package and bottle labels.

CALIBRATOR STABILITY

Opened bottles of calibrators can be used for 1 month if stored at 2-8°C. Discard calibrators if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard.

Calibrator transferred to the instrument sample cup may concentrate over time. Therefore, calibrators should be capped and stored at 2-8°C when not in use. Otherwise, fresh calibrators should be used for each calibration.

INSTRUMENT

Measurements of absorbance are to be made with a clinical chemistry analyzer able to accurately read absorbance at 340 and 700 nm. Refer to the instrument manual from the manufacturer regarding the following:

- Use or function
- Installation procedures and requirements
- Principles of operation
- Performance characteristics, operating instructions
- Calibration procedures including materials and / or equipment to be used
- Operational precautions, limitations, and hazards
- Service and maintenance information

PROCEDURE**Materials Supplied**

Calibrators should be used as specified in the **K-ASSAY®** Microalbumin package insert.

Calibrator A	1 x 1 mL
Calibrator B	1 x 1 mL
Calibrator C	1 x 1 mL
Calibrator D	1 x 1 mL
Calibrator E	1 x 1 mL
Calibrator F	1 x 1 mL

Materials Required But Not Supplied

K-ASSAY[®] Microalbumin immunoturbidimetric assay

Two-Reagent Clinical Chemistry Analyzer:

Capable of accurate absorbance reading at 340/700 nm

Capable of accurately dispensing the required volumes

Capable of maintaining 37°C

Test Tubes: glass or plastic

Details of Procedure

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

K-ASSAY[®] Microalbumin Calibrators are assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the

K-ASSAY[®] Microalbumin assay.

INTERFERENCE

Dust particles or other particulates in the reaction may result in extraneous light-scattering resulting in variable results.

CALIBRATOR VALUES

Lot G711

Albumin (mg/dL)

A	0.0
B	0.5
C	1.0
D	5.0
E	10.0
F	30.0

The values for **K-ASSAY**[®] Microalbumin Calibrator Set 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

Lot Number

 STD

Calibrator



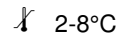
Expiration or "Use By" Date

 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

EU AUTHORIZED REPRESENTATIVE



 EC REP

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