

K-ASSAY[®]

Prealbumin Calibrator

Lot A123, Exp. 2017-02-28

Cat. No. KAI-054C

INTENDED USE

The **K-ASSAY**[®] Prealbumin Calibrator is intended to be used for the calibration of the **K-ASSAY**[®] Prealbumin immunoturbidimetric assay for quantifying prealbumin in serum specimens. FOR *IN VITRO* DIAGNOSTIC USE.

SUMMARY

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

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

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

WARNINGS AND PRECAUTIONS**FOR *IN VITRO* DIAGNOSTIC USE.**

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

Prealbumin was isolated from pooled human serum which 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**[®] Prealbumin assay 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® Prealbumin 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® Prealbumin Calibrators are assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the **K-ASSAY**® Prealbumin assay.

CALIBRATOR VALUES

Lot A123

	<u>Prealbumin (mg/dL)</u>
A	0
B	5
C	15
D	30
E	45
F	60











The Prealbumin Calibrators have been standardized against the IRMM ERM-DA470 reference material.

The values for **K-ASSAY**® Prealbumin Calibrator are continually being revised through on going 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.

INTERFERENCE

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

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

ORDERING / PRICING / TECHNICAL INFORMATION



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