

K-ASSAY®

Insulin Calibrator

Lot QD170, Exp. 2018-11-09

Cat. No. KAI-072C

INTENDED USE

The **K-ASSAY®** Insulin Calibrator is a reagent for the calibration of the **K-ASSAY®** Insulin Assay. *FOR IN VITRO* DIAGNOSTIC USE.

SUMMARY

The calibrator in this kit is human serum containing known quantities of insulin. The serum has been tested and found negative for HBsAb and HIV Ab. This is only to be used as a calibrator for the **K-ASSAY®** Insulin assay (KAI-040) or **K-ASSAY®** Insulin (L) assay (KAI-071).

KIT COMPOSITION

Human Serum 5 x 0.5 mL, lyophilized

WARNINGS AND PRECAUTIONS

FOR IN VITRO DIAGNOSTIC USE. Rx only.

Calibrators contain human serum, which was tested and found negative for HBsAg and HIV 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.

CALIBRATOR PREPARATION

1. Calibrators are lyophilized and require reconstitution. Add exactly 0.5 mL of purified water to each vial containing the lyophilized serum to dissolve it. Swirl gently to dissolve. The concentration of the dissolved serum is indicated on the vial label and may change from lot to lot.
2. Allow the vial to sit at room temperature (18-26°C) for 15 min. prior to use.
3. Mix before using by gently inverting the bottles.
4. Use the 5 reconstituted calibrators without dilution and purified water for the zero calibrator (0 µIU/mL) to make a calibration curve. Load the 6 calibrators from lowest to highest concentration on the analyzer.

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 18 months from the date of manufacturing as indicated by the expiration date on the package and bottle labels. The opened calibrators are stable for two weeks when 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. Opened calibrators are stable for two weeks if stored at 2-8°C.

PROCEDURE**Materials Supplied**

Calibrator should be used as specified in the **K-ASSAY®** Insulin assay package insert.

Human Serum 5 x 0.5 mL, lyophilized

Materials Required But Not Supplied

K-ASSAY® Insulin assay, Cat. No. KAI-040 or
K-ASSAY® Insulin (L) assay, Cat. No. KAI-071
 Pipette
 Purified water

Details of Procedure

Note: Allow all reagents and specimens to come to room temperature (18-25°C). Mix all reagents gently before using.

K-ASSAY® Insulin Calibrators are assayed using the same procedure as the samples run in the test procedure. See package insert from the **K-ASSAY®** Insulin assay.











CALIBRATOR VALUES

Lot: QD170

Calibrator 1	4.0 µIU/mL
Calibrator 2	9.5 µIU/mL
Calibrator 3	23.2 µIU/mL
Calibrator 4	48.4 µIU/mL
Calibrator 5	100.3 µIU/mL

The expected values for the **K-ASSAY**® Insulin 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. Values are traceable to the Human Insulin for Immunoassay International Reference Preparation, NIBSC Code 66/304.

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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