

K-ASSAY®

Total IgE Calibrator

Lot K037, Exp. 2018-08-09

Cat. No. KAI-093C

INTENDED USE

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

SUMMARY

The calibrator in this kit is human serum containing known quantities of IgE. 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®** Total IgE (KAI-092) assay.

KIT COMPOSITION

Human Serum	5 x 1 mL
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WARNINGS AND PRECAUTIONS

FOR *IN VITRO* DIAGNOSTIC USE. Rx only.

Calibrators contain human serum that 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

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 by the expiration date on the package and bottle labels. The opened calibrators are stable for one month 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 one month if stored at 2-8°C.

PROCEDURE**Materials Supplied**

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

Human Serum	5 x 1 mL
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Materials Required But Not Supplied

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

CALIBRATOR VALUES











LOT K037

Calibrator 1	0 IU/mL
Calibrator 2	204 IU/mL
Calibrator 3	518 IU/mL
Calibrator 4	990 IU/mL
Calibrator 5	2,032 IU/mL

The expected values for the **K-ASSAY**® Total IgE 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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Printed August 2017