

K-ASSAY[®]

KL-6 Calibrator

Lot A123, Exp. 2024-08-31

Cat. No. KAI-251C

INTENDED USE

The **K-ASSAY**[®] KL-6 Calibrator is intended to be used for the multi-point calibration of the **K-ASSAY**[®] KL-6 (Krebs von den Lungen-6) immunoturbidimetric assay. FOR RESEARCH USE ONLY IN THE U.S. NOT FOR USE IN DIAGNOSTIC PROCEDURES IN THE U.S.

SUMMARY

The calibrators in this kit contain a known quantity of KL-6. The KL-6 calibrator is to be used to make a 5 point calibration for the **K-ASSAY**[®] KL-6 immunoturbidimetric assay.

KIT COMPOSITION

Calibrator 1: 150 mM NaCl 1 x 1 mL

Calibrator 2-5: Human KL-6 in 150 mM NaCl 4 x 1 mL

WARNINGS AND PRECAUTIONS

For Research Use Only in the U.S. Not For Use in Diagnostic Procedures in the U.S.

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

Do not mix or use calibrator from one test kit with those from a different lot number.

Do not use the calibrator past the expiration date stated on each container label.

Do not pipette by mouth. Avoid ingestion and contact with skin.

The calibrators in this kit do not contain human blood components. However, no assay can be completely free of risk from infection. As such, the material should be handled as potentially infectious 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.

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 reagents 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 Centers for Disease Control, Atlanta, GA.

K-ASSAY[®] KL-6 Calibrator**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 up to 12 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.

PROCEDURE

Calibrators should be used as specified in the **K-ASSAY**[®] KL-6 immunoturbidimetric assay package insert.

Materials Supplied

KL-6 Calibrators, 5 levels 5 x 1 mL

Materials Required But Not Supplied

K-ASSAY[®] KL-6 immunoturbidimetric assay

Two Reagent Clinical Chemistry Analyzer Capable of:
 Accurate absorbance readings at approx. 570 nm
 Accurately dispensing the required volumes
 Maintaining 37°C

Details of Procedure

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

The **K-ASSAY**[®] KL-6 Calibrator is assayed using the same procedure as the samples run in the test procedure. See package insert from the **K-ASSAY**[®] KL-6 immunoturbidimetric assay.










CALIBRATOR VALUES

Lot A123

Calibrator 1	0	U/mL
Calibrator 2	1,250	U/mL
Calibrator 3	2,500	U/mL
Calibrator 4	5,000	U/mL
Calibrator 5	10,000	U/mL

The expected values for the **K-ASSAY**® KL-6 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 value.

LABELING SYMBOLS

	Catalog Number
	Expiration or "Use By" Date
	Lot Number
	Consult Package Insert for Instructions for Use
	CE Mark Registered
	Potential Human Biohazard
	Temperature Limitation. Store between 2 and 8 degrees C
	Manufacturer
	Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE



EC REP

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Printed August 2023