K-*ASSAY*®

Insulin Control

Lot AB123, Exp. 2024-03-30

CAT. NO. K73C-4M

INTENDED USE

The **K-*ASSAY*®** Insulin Control is intended for use as a consistent test sample of known concentration for monitoring the performance of the **K-*ASSAY*®** Insulin immunoturbidimetric assay.

FOR *IN VITRO* DIAGNOSTIC USE.

SUMMARY

The use of quality control materials to objectively monitor the precision of procedures has been well established. The **K-*ASSAY*®** Insulin Control is provided at two levels.

SET COMPOSITION

Level 1, 2 2 x 0.5 mL each level, lyophilized

WARNINGS AND PRECAUTIONS

For *In Vitro* Diagnostic Use Only. ℞ only.

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

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

Do not use controls past their expiration date stated on each container label.

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

CONTROL PREPARATION

1. Allow controls to come to room temperature. Remove cap carefully.
2. Add 0.5 mL of deionized water. Let rest for 15 minutes.
3. Invert gently until fully dissolved.

STORAGE AND HANDLING

Store controls at 2-8°C. Return all controls to 2-8°C promptly after use. Unopened controls can be used for up to 18 months from the date of manufacture, as indicated by the expiration date on the package and bottle labels.

CONTROL STABILITY

Opened, reconstituted controls are stable for 2 weeks if tightly capped and stored at 2-8°C.

Discard controls if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard.

PROCEDURE

Materials Supplied

Level 1 2 x 0.5 mL, lyophilized
Level 2 2 x 0.5 mL, lyophilized

Materials Required But Not Supplied

K-*ASSAY*® Insulin assay

K-*ASSAY*® Insulin Calibrator

Two Reagent Clinical Chemistry Analyzer Capable of:
- Accurate absorbance readings at approx. 600 nm
- Accurately dispensing the required volumes
- Maintaining 37°C

Assay Procedure

NOTE: Allow all reagents and specimens to come to room temperature.

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

LIMITATIONS OF PROCEDURE

Accurate and reproducible results are dependent upon properly functioning instruments, reagents, and good laboratory technique. Erroneous results can occur from improper storage, reconstitution inaccuracies, and technical errors associated with assay procedures.

This product is intended for use as an assayed control for quantitative assays of Insulin in human serum and plasma. This product is not intended for use as a calibrator.

EXPECTED VALUES

KAMIYA BIOMEDICAL COMPANY has established the expected values. The assignment of mean values was derived from analysis of vials representative of the entire lot.

Values listed are specific for each lot only. Verify that the lot numbers on the vials of Insulin Control correspond to the lot numbers listed for the Assay Data.

The Expected Range of the Mean is provided to assist the laboratory until it has established its own mean and standard deviation. It is considered good laboratory practice for each laboratory to establish its own mean and standard deviation for its test methods. The indicated Mean and Expected Range of the Mean should serve as a guide in assessing the performance of each test method.

ASSAY DATA

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ASSAY	UNIT	LEVEL 1		LEVEL 2	
		MEAN	RANGE	MEAN	RANGE
K-*ASSAY*® Insulin	**µIU / mL**	25	20 – 30	50	40 – 60

The expected values for the **K-*ASSAY*®** Insulin Control are continually being revised through ongoing quality assurance. Please refer to the package insert included with each control set for the most appropriate control values. Recovered values may be method dependent. The variations which can occur over time and between laboratories may be attributed to differences in laboratory technique, instrumentation, reagent lot, method modifications, and other systematic errors including random errors.

LABELING SYMBOLS

REF	Catalog Number
	Expiration or “Use By” Date
LOT	Lot Number
CONTROL	Control
	Consult Package Insert for Instructions for Use
IVD	For *In Vitro* Diagnostic Use
CE	CE Mark Registered
℞	For Prescription Use Only
2°C 8°C	Temperature Limitation. Store between 2 and 8 degrees C
	Manufacturer
EC REP	Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE

CE

EC REP

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Printed September 2022