K-*ASSAY*®

Total IgE Control

Lot A123, Exp. 2023-07-06

CAT. NO. K94C-4M

INTENDED USE

The **K-*ASSAY*®** Total IgE Control is intended for use as a consistent test sample of known concentration for monitoring the performance of the **K-*ASSAY*®** Total IgE 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*®** Total IgE Control is provided at two levels.

SET COMPOSITION

Level 1, 2 Human Serum 2 x 1 mL each level

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.

Controls contain Total IgE from human blood material that was tested and found negative for HBs antigen, HCV antibodies, 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 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.

Controls in this set contain < 0.1% w/v sodium azide as a preservative. Sodium azide may form explosive compounds in metal drain lines. When disposing of controls 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.

CONTROL PREPARATION

Controls are liquid and ready to use.

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 1 year from the date of manufacture, as indicated by the expiration date on the package and bottle labels.

CONTROL STABILITY

Opened controls can be used for 1 month if 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	Human Serum	2 x 1 mL
Level 2	Human Serum	2 x 1 mL

Materials Required But Not Supplied

K-*ASSAY*® Total IgE immunoturbidimetric assay

K-*ASSAY*® Total IgE Calibrator

Two Reagent Clinical Chemistry Analyzer Capable of:
- Accurate absorbance readings at approx. 570 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*®** Total IgE Controls are assayed using the same procedure as the samples run in the test procedure. See package insert from the **K-*ASSAY*®** Total IgE immuno-turbidimetric 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 Total IgE 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 Total IgE 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*® Total IgE	**IU / mL**	175	150 – 200	350	315 – 385

The expected values for the **K-*ASSAY*®** Total IgE 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
	Potential Human Biohazard
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

Advena Ltd.
Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013 Malta

ORDERING / PRICING / TECHNICAL INFORMATION

KAMIYA BIOMEDICAL COMPANY
12779 Gateway Drive
Seattle, WA 98168 USA
TEL: (206) 575-8068 / (800) 526-4925
FAX: (206) 575-8094

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