

K-ASSAY®

Ferritin / IgE / Insulin Control

L1: Lot LIA17031, Exp. 2017-03-31**L2: Lot LIA17032, Exp. 2017-03-31****L3: Lot LIA17033, Exp. 2017-03-31****Cat. No. K59C-3M, K59C-L1, K59C-L2, K59C-L3****INTENDED USE**

The **K-ASSAY®** Ferritin / IgE / Insulin Control is intended for use in the clinical laboratory as a consistent test sample of known concentration for monitoring assay conditions in many immunological determinations. Include **K-ASSAY®** Ferritin / IgE / Insulin Control with patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument. **FOR IN VITRO DIAGNOSTIC USE.**

PRODUCT DESCRIPTION

The **K-ASSAY®** Ferritin / IgE / Insulin Controls are liquid stable control material prepared from human serum. Analyte levels are adjusted with various pure chemicals and preparations from human tissue or body fluids. Preservatives and stabilizers are added to maintain product integrity.

CAUTION: **K-ASSAY®** Ferritin / IgE / Insulin Control is prepared from human source material. Components of the control that are derived from human source material have been tested using FDA accepted methods and found to be non-reactive for Hepatitis B surface antigen (HBsAg), Hepatitis C (HCV), HIV-1 and HIV-2. However, no test method can offer complete assurance that products derived from human source material are free from infectious agents. This control must be handled in accordance with recommendations from Centers for Disease Control/National Institutes of Health manual, "Biosafety in Microbiological and Biomedical Laboratories," 1996.

CAUTION: The packaging of this product contains dry natural rubber.

SET COMPOSITION:K59C-3M

Level 1 1 x 5 mL
Level 2 1 x 5 mL
Level 3 1 x 5 mL

K59C-L1

Level 1 2 x 5 mL

K59C-L2

Level 2 2 x 5 mL

K59C-L3

Level 3 2 x 5 mL

CONTROL RANGES

Control ranges are provided as guidelines until the laboratory has established its own statistical limits. The printed values are based upon replicate assays of representative samples by participating laboratories in accordance with established protocol and/or by direct correlation with another specific analytical system. The correlation factors used for each constituent have been derived from a comprehensive inter-laboratory Quality Assurance Program. All values directly assayed have been assigned with instrument and instrument manufacturer's reagents available at the time of assay. Subsequent instrument or reagent modifications may invalidate these assigned values. Expected values may vary slightly with different reagent and/or methodologies used. Refer to the included table for values obtained for specific systems. Values listed are specific for this lot of control only. Good laboratory practice suggests that each laboratory establish its own parameters.

STORAGE AND STABILITY

Unopened vials of **K-ASSAY®** Ferritin / IgE / Insulin Control are stable for 90 days from receipt when stored at 2-8°C. Once opened, vials of **K-ASSAY®** Ferritin / IgE / Insulin Controls are stable for 30 days when stored tightly capped at 2-8°C. **K-ASSAY®** Ferritin / IgE / Insulin Control maintained at -20°C is stable until the expiration date on the box.

Supplies of **K-ASSAY®** Ferritin / IgE / Insulin Controls may be shipped on dry ice and received frozen. Since laboratory receiving and storage capabilities vary considerably, the following directions for receipt, storage and handling of the frozen product must be followed:

1. Request that controls be shipped by "Next Day Air" on dry ice.
2. Alert receiving department to immediately notify the laboratory when product is received.
3. Verify that product is frozen solid on receipt.
4. Immediately transfer the product to freezer maintained at -20°C. **Self-defrosting freezers are not suitable.**
5. Thaw at room temperature on a rocker or with periodic gentle inversion.
6. Once thawed, immediately store at 2-8°C. **ONCE THAWED, DO NOT REFREEZE THE CONTROL.**

K-ASSAY® Ferritin / IgE / Insulin Control users must schedule shipments to comply with the recommended storage instructions.

Bacterial contamination produces an increase in turbidity and/or a characteristic odor. Discard vial if evidence of microbial contamination is observed.

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

PROCEDURE

Thoroughly mix the contents of the vial before each use by gently inverting for several minutes. Open the vial and transfer the required quantity of control into a clean sample cup. Replace the cap immediately and store the opened vial at 2-8°C. Assay controls in accordance with the reagent and/ or instrument manufacturer’s instructions for unknown specimens.










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.

DO NOT use a syringe needle to withdraw sample through the control bottle cap.

LABELING SYMBOLS

LIMITATIONS OF PROCEDURE

Compatibility of the **K-ASSAY**® Ferritin / IgE / Insulin Controls has been demonstrated only with the methods shown in this insert. Caution should be employed when using these controls with methods for which values have not been printed. The specificity of antibodies used in immunoassay procedures may vary between lots. As with patient specimens, cross-reactivities between certain constituents in this control serum may occur with some reagents.

-  Lot Number
-  Control
-  Expiration or “Use By” Date
-  Catalog Number
-  For *In Vitro* 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

Consult reagent manufacturer’s package insert regarding possible interferences.

ORDERING / PRICING / TECHNICAL INFORMATION

Accurate and reproducible results are dependent upon properly functioning instruments, reagents, and good laboratory technique.


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

EXPECTED RESULTS

KAMIYA BIOMEDICAL COMPANY has established the expected values. Values listed were obtained using a Hitachi 911 and **K-ASSAY**® reagents and calibrators. Subsequent modifications in instrument, reagent, or procedure may invalidate these results. The assignment of mean values was derived from analysis of vials representative of the entire lot.

ASSAY DATA

PROTEIN TEST	REAGENT MANUFACTURER	UNITS	L1 VALUES Lot: LIA17031		L2 VALUES Lot: LIA17032		L3 VALUES Lot: LIA17033	
			MEAN	EXPECTED RANGE	MEAN	EXPECTED RANGE	MEAN	EXPECTED RANGE
Ferritin	KAMIYA BIOMEDICAL COMPANY Analyzer: Hitachi 911	ng/mL	16	13 – 19	143	114 – 172	272	218 – 326
Total IgE	KAMIYA BIOMEDICAL COMPANY Analyzer: Hitachi 911	IU/mL	35	28 – 41	160	128 – 192	286	229 – 344
Insulin	KAMIYA BIOMEDICAL COMPANY Analyzer: Hitachi 911	µIU/mL	6.5	5.2 – 7.8	56.0	44.8 – 67.3	104.7	83.8 – 125.7

The expected values for the **K-ASSAY**® Ferritin / IgE / 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.

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