

K-ASSAY[®]

Ferritin Calibrator

Lot 217071, Exp. 2019-08-31

Cat. No. KAI-094C**INTENDED USE**

The **K-ASSAY**[®] Ferritin Calibrator is an *in vitro* diagnostic reagent for calibration of the **K-ASSAY**[®] Ferritin Assay. FOR *IN VITRO* DIAGNOSTIC USE.

SUMMARY

The calibrators in this kit are human serum tested and found negative for HBsAg and HIV Ab. They contain known quantities of human ferritin. These are to be used as calibrators for the **K-ASSAY**[®] Ferritin assay.

KIT COMPOSITION**Calibrators (Liquid Stable)****MATERIALS PROVIDED**

Calibrator 1-4 Human Ferritin 4 x 1 mL
Contains pooled human serum with assigned values for ferritin.

WARNINGS AND PRECAUTIONS

FOR *IN VITRO* DIAGNOSTIC USE. Rx 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 calibrators from one test kit with those from a different lot number.

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

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

Calibrators in this kit contain <0.1 w/v% sodium azide as a preservative. Sodium azide may form explosive compounds in lead drain lines. When disposing of calibrators 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 Guide Management No. CDC-22 issued by the Center for Disease Control, Atlanta, GA. 1976.

Calibrators contain purified human serum. Each donor unit used in the preparation of this product has been tested by an FDA approved method and found non-reactive for HbsAg, HCV antibody and HIV antibodies. However, it is not possible to guarantee that they are free of hepatitis B virus (HB), hepatitis C virus, human immunodeficiency virus (HIV), or other infectious agents. Therefore, all products containing human serum should be handled in accordance with good laboratory practices using appropriate precautions as described in the CDC/NIH Manual, "Biosafety in Microbiology and Biomedical Laboratories," 2nd ed., 1988, HHS Publication No. (CDC) 88-8395.

CALIBRATOR PREPARATION

The calibrators are ready to use.

STORAGE AND HANDLING

All calibrators should be stored refrigerated (2-8°C) and protected from light. Return all calibrators to 2-8°C promptly after use. Unopened calibrators can be used for 24 months from the date of manufacturing as indicated on the expiration date on the package and bottle labels. Opened bottles of calibrators can be used for 2 months if tightly capped and 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.

INSTRUMENT

Measurements of absorbance are to be made with a clinical chemistry analyzer able to accurately read absorbance at 570 and 800 nm. Refer to the instrument manual from the manufacturer regarding the following:

- a) Use or function
- b) Installation procedures and requirements
- c) Principles of operation
- d) Performance characteristics, operating instructions
- e) Calibration procedures including materials and / or equipment to be used
- f) Operational precautions, limitations, and hazards
- g) Service and maintenance information

PROCEDURE

Calibrators should be used as specified in the **K-ASSAY**® Ferritin assay package inserts.

Materials Supplied

Calibrator 1	1 x 1 mL
Calibrator 2	1 x 1 mL
Calibrator 3	1 x 1 mL
Calibrator 4	1 x 1 mL

Materials Required But Not Supplied

K-ASSAY® Ferritin assay

Saline (0.9% NaCl) as 0 ng/mL (blank) calibrator.

Clinical chemistry analyzer: capable of accurate absorbance readings at 570 and 800 nm with appropriate cuvettes, capable of accurately dispensing the required volumes, and capable of 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**® Ferritin Calibrator is assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the **K-ASSAY**® Ferritin assay.

CALIBRATOR VALUES

Lot 217081

	1 st IS Values	3 rd IS Values
Saline (Not Included)	0 ng/mL	0 ng/mL
Calibrator 1	100 ng/mL	119 ng/mL
Calibrator 2	200 ng/mL	238 ng/mL
Calibrator 3	500 ng/mL	595 ng/mL
Calibrator 4	1,000 ng/mL	1,190 ng/mL

Notes:

An additional saline blank (0 ng/mL ferritin) is required for best results.

Please note there are two sets of values which can be used with our Ferritin assay. Please choose one.











The “1st IS Values” are traceable to the World Health Organization 1st International Standards for Ferritin, lot 80/602 (NIBSC). These are the values that have traditionally been used for our assay. Use of these calibrator values will ensure values for newly tested samples are aligned with sample values previously obtained.

The “3rd IS Values” are traceable to the World Health Organization 3rd International Standard for Ferritin, lot 94/572 (NIBSC). This is the current international standard. Use of these values will help ensure good correlation with other Ferritin assays that are using this standardization.

The needs of individual labs can differ. However, if possible, we would suggest use of the “3rd IS Values” to ensure best correlation to the current international standards.

The values for the **K-ASSAY**® Ferritin 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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