

K-ASSAY®

High-Sensitive D-Dimer Control

Lot 12A34N/12A34P, Exp. 2019-01-31

Cat. No. K115C-10M**INTENDED USE**

The **K-ASSAY®** High-Sensitive D-Dimer Control is intended to be used as a consistent test sample of known concentration for monitoring the performance of the **K-ASSAY®** High-Sensitive D-Dimer assay.

NOT FOR USE IN THE U.S.

SUMMARY

The controls in this set are human plasma tested and found negative for HBsAg, HCV Ab, and HIV Ab. They contain known concentrations of D-dimer. They are to be used as controls with the **K-ASSAY®** High-Sensitive D-Dimer assay.

SET COMPOSITION

K115C-10M, Levels 1 and 2
Human Plasma (Lyophilized) 5 x 0.5 mL (each level)

Control Levels 1 and 2 contain pooled human plasma with assigned values for D-dimer.

WARNINGS AND PRECAUTIONS

NOT FOR USE 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 pipette by mouth. Avoid ingestion and contact with skin.

Controls contain pooled human plasma. The plasma has been tested and found non-reactive for the presence of HBsAg, HCV Ab, and HIV antibody by an FDA approved method. However, it is not possible to guarantee that any human source material is free of these infectious agents.

Therefore, all products containing human plasma should be handled in accordance with good laboratory practices using appropriate precautions as described in the CDC/NIH Manual, "Biosafety in Microbiological and Biomedical Laboratories," 2nd ed., 1988, HHS Publication No. (CDC) 88-8395.

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

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

CONTROL PREPARATION

1. Reconstitute 1 vial of each control level with 0.5 mL of purified water and allow to sit for 30 minutes.
2. Gently swirl vial until dissolution is complete and the solution is homogenous (do not shake).
3. Replace the cap immediately after use to prevent evaporation or contamination.
4. Return the vial to 2-8°C promptly after use.

STORAGE AND HANDLING

Store lyophilized and reconstituted controls at 2-8°C. Return all controls to 2-8°C promptly after use. Unopened controls can be used for 2 years from the date of manufacturing as indicated by the expiration date on the package and bottle labels.

Reconstituted controls can be used for up to 7 days if stored at 2-8°C.

Reconstituted controls can be frozen one time and stored at -20°C for up to 5 weeks. Do not refreeze a second time.

CONTROL STABILITY

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

PROCEDURE**Materials Supplied**K115C-10M

Level 1	Lyophilized Human Plasma	5 x 0.5 mL
Level 2	Lyophilized Human Plasma	5 x 0.5 mL

Materials Required But Not Supplied

K-ASSAY® High-Sensitive D-Dimer assay and calibrator(s)

Two-Reagent Clinical Chemistry Analyzer:

Capable of accurate absorbance reading at 500 - 600 nm

Capable of accurately dispensing the required volumes

Capable of maintaining 37°C

Pipettes: capable of accurately dispensing the required volumes

Purified Water

Assay Procedure

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

K-ASSAY® High-Sensitive D-Dimer Control is assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the **K-ASSAY**® High-Sensitive D-Dimer assay.

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 listed constituents in human plasma. This product is not intended for use as a calibrator.

EXPECTED RESULTS









KAMIYA BIOMEDICAL COMPANY has established the expected values. Values listed were obtained using a Hitachi 902 and the **K-ASSAY**® High-Sensitive D-Dimer assay 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.

Values listed are specific for each lot only. Verify that the lot numbers on the vials of **K-ASSAY**® High-Sensitive D-Dimer 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.

LABELING SYMBOLS

	Lot Number
	Control
	Expiration or "Use By" Date
	Catalog Number
	2-8°C Temperature Limitation. Store between 2 and 8 degrees C
	Potential Human Biohazard
	Manufacturer
	Consult Package Insert for Instructions for Use

EU AUTHORIZED REPRESENTATIVE



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ASSAY DATA

ASSAY	LEVEL 1		LEVEL 2		Units
	LOT 12A34N, Exp. 2019-01-31		LOT 12A34P, Exp. 2019-01-31		
	Mean	Range	Mean	Range	
K-ASSAY ® High-Sensitive D-Dimer	826	661 – 991	2207	1766 – 2648	ng/mL (DDU)
	0.826	0.661 – 0.991	2.207	1.766 – 2.648	µg/mL (DDU)

The expected values for the **K-ASSAY**® High-Sensitive D-Dimer 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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