

K-ASSAY®

D-Dimer Control

Lot 123K, Exp. 2023-09-30

CAT. NO. K92C-4M

INTENDED USE

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

SET COMPOSITION

Level 1, 2 Lyophilized Human D-Dimer 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 D-Dimer from human plasma 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.

CONTROL PREPARATION

1. Allow controls to come to room temperature. Remove cap carefully.
2. Add 1.0 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 1 year from the date of manufacture, as indicated by the expiration date on the package and bottle labels.

CONTROL STABILITY

The opened, reconstituted controls are stable for one month 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	D-Dimer Control	2 x 1 mL
Level 2	D-Dimer Control	2 x 1 mL

Materials Required But Not Supplied

K-ASSAY® D-Dimer immunoturbidimetric assay

K-ASSAY® D-Dimer 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®** D-Dimer Controls are assayed using the same procedure as the samples run in the test procedure. See package insert from the **K-ASSAY®** D-Dimer immunoturbidimetric 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 D-Dimer 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 D-Dimer 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

Lot 123K, Exp. 2023-09-30


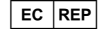
ASSAY	UNIT	LEVEL 1		LEVEL 2	
		MEAN	RANGE	MEAN	RANGE
K-ASSAY® D-Dimer	µg / mL	3.00	2.55 – 3.45	11.00	9.35 – 12.65

The expected values for the K-ASSAY® 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.

LABELING SYMBOLS

	Catalog Number
	Expiration or "Use By" Date
	Lot Number
	Control
	Consult Package Insert for Instructions for Use
	For <i>In Vitro</i> Diagnostic Use
	CE Mark Registered
	For Prescription Use Only
	Potential Human Biohazard
	Temperature Limitation. Store between 2 and 8 degrees C
	Manufacturer
	Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE



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