

K-ASSAY®

D-Dimer Calibrator

Lot 666W, Exp. 2024-05-03

Cat. No. KAI-091C

INTENDED USE

The **K-ASSAY®** D-Dimer Assay is an *in vitro* diagnostic reagent for the quantitative determination of cross-linked fibrin degradation products containing D-Dimer in human plasma or serum by immunoturbidimetric assay. The **K-ASSAY®** D-Dimer Calibrator is intended to be used for the multi-point calibration of the **K-ASSAY®** D-Dimer Assay. FOR *IN VITRO* DIAGNOSTIC USE.

SUMMARY

The calibrators in this kit contain known quantities of purified D-Dimer from human plasma. The plasma has been tested and found negative for HBsAb and HIV Ab by an FDA-approved method. This is to be used as a calibrator for the **K-ASSAY®** D-Dimer assay (KAI-090).

KIT COMPOSITION

Lyophilized Human D-Dimer 6 x 1 mL

WARNINGS AND PRECAUTIONS

FOR *IN VITRO* DIAGNOSTIC USE. Rx only.

Calibrators contain D-Dimer from human plasma that was tested and found negative for HBsAg 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 calibrators from one test kit with those from a different lot number.

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

PREPARATION OF CALIBRATORS

1. Calibrators are lyophilized and require reconstitution. Add exactly 1.0 mL of purified water to each vial containing the lyophilized D-Dimer to dissolve it. Swirl gently to dissolve. The concentration of the dissolved D-Dimer is indicated on the vial label and may change from lot to lot.
2. Mix before using by gently inverting the bottles.
3. Use the six reconstituted calibrators without dilution to make a calibration curve. Load the 6 calibrators, in order of lowest to highest concentration, on the analyzer.

STORAGE AND HANDLING

All calibrators should be stored refrigerated (2-8°C). Return all calibrators to 2-8°C promptly after use. Unopened calibrators can be used for one year from the date of manufacturing as indicated by the expiration date on the package and bottle labels. The reconstituted calibrators are stable for one month at 2-8°C.

Calibrator Stability

Discard calibrators if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard. Reconstituted calibrators can be used for one month if stored at 2-8°C.

PROCEDURE

Materials Supplied

Calibrator should be used as specified in the **K-ASSAY®** D-Dimer assay package insert.

Human D-Dimer 6 x 1 mL

Materials Required But Not Supplied

K-ASSAY® D-Dimer assay, KAI-090

Pipettes

Purified water

Details of Procedure

Note: Allow all reagents and specimens to come to room temperature (18-25°C). Mix all reagents gently before using.

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

CALIBRATOR VALUES












The assigned values for the **K-ASSAY**® D-Dimer Calibrator is provided in D-Dimer Units (DDU).

Lot 666W

Calibrator 1	0.00 µg/mL DDU
Calibrator 2	2.17 µg/mL DDU
Calibrator 3	4.35 µg/mL DDU
Calibrator 4	7.78 µg/mL DDU
Calibrator 5	14.87 µg/mL DDU
Calibrator 6	31.83 µg/mL DDU

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

	Catalog Number
	Expiration or "Use By" Date
	Lot Number
	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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