

K-ASSAY®

High-Sensitive D-Dimer Calibrator

Lot 1234AB/YZ5678, Exp. 2019-01-31

Cat. No. KAI-103C

INTENDED USE

The **K-ASSAY®** High-Sensitive D-Dimer Calibrator is intended to be used for the multi-point calibration of the **K-ASSAY®** High-Sensitive D-Dimer Assay. NOT FOR USE IN THE U.S.

SUMMARY

The calibrators in this kit contain known quantities of D-Dimer. The calibrators are to be used for calibrating the **K-ASSAY®** High-Sensitive D-Dimer assay.

KIT COMPOSITION

Lyophilized Human D-Dimer Calibrator 5 x 2.6 mL

***** Please note the reconstituted volume can change for different lots. *****

High-Sensitive D-Dimer Calibrator Diluent 1 x 40 mL

Tris-HCl buffer (pH 8-9), sodium azide 0.05%

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.

Calibrators are prepared from purified human fibrinogen that was isolated from human plasma which had been tested and found negative for HBsAg and HIV antibodies by an FDA approved method. However, it is not possible to guarantee that they are free of hepatitis B virus (HBV), human immunodeficiency virus (HIV), or other infectious agents. Therefore, 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.

The diluent in this kit contain sodium azide as a preservative. Sodium azide may form explosive compounds in metal 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 Management No. CSC-22 issued by the Centers for Disease Control, Atlanta, Georgia.

PREPARATION OF CALIBRATORS

- Calibrators are lyophilized and require reconstitution. Diluent is ready to use. Add **exactly 2.6 mL of diluent** to one vial containing the lyophilized D-Dimer to dissolve it and allow to sit for 30 minutes. Swirl gently to dissolve. The concentration of the dissolved D-Dimer is indicated on the vial label and may change from lot to lot.
- Prepare 6 calibrators (A-F) using the dissolved stock and diluent according to the following protocol:

	A	B	C	D	E	F
Dilution	0	1/16	1/8	1/4	1/2	1
Dissolved Stock (µL)	0	50	100	200	400	800
Diluent (µL)	800	750	700	600	400	0
Total (µL)	800	800	800	800	800	800

- A multi-point calibration curve for high-sensitive D-Dimer can be made using these 6 prepared calibrators. High-sensitive D-Dimer calibrator values are obtained by multiplying the dilution by the appropriate calibrator value of the reconstituted stock.

STORAGE AND HANDLING

All stock calibrators and diluent should be stored refrigerated (2-8°C). Return all calibrators to 2-8°C promptly after use.

Unopened calibrators can be used for 2 years from the date of manufacturing as indicated by the expiration date on the package and bottle labels.

Reconstituted and diluted calibrators can be used for 6 hours if stored at room temperature (18-25°C).

Reconstituted stock calibrators (not diluted) can be frozen one time and stored at -20°C for up to 1 month. Do not refreeze a second time.

Unopened diluent can be used for 2 years from the date of manufacturing as indicated by the expiration date on the package and bottle labels. Opened diluent can be used up to the expiration date provided that the cap is tightly closed to prevent evaporation and the solution is not contaminated.

CALIBRATOR STABILITY

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

PROCEDURE

Materials Supplied

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

Lyophilized High-Sensitive D-Dimer Calibrators 5 x **2.6 mL**
High-Sensitive D-Dimer Calibrator Diluent 1 x 40 mL

Materials Required But Not Supplied

K-ASSAY® High-Sensitive D-Dimer Assay

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

Test Tubes: glass or plastic

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

CALIBRATOR VALUES

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

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Stock Value after reconstitution with 2.6 mL of K-ASSAY ® High-Sensitive D-Dimer Calibrator Diluent	8,000 ng/mL DDU or 8.0 µg/mL DDU
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***** Please note the reconstituted volume can change for different lots. *****

Calibrators A-F, After Reconstitution and Dilution						
	A	B	C	D	E	F
ng/mL DDU	0	500	1,000	2,000	4,000	8,000
µg/mL DDU	0.0	0.5	1.0	2.0	4.0	8.0

The expected value for the **K-ASSAY**® High-Sensitive D-Dimer Calibrator is 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
	Reagent
	Calibrator
	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
	Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE



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