

**K-ASSAY®**

# Fibrinogen Calibrator

Lot A123, Exp. 2022-03-31

**Cat. No. KAI-089C and KAI-136C****INTENDED USE**

The **K-ASSAY®** Fibrinogen Calibrator is intended to be used for the calibration of the **K-ASSAY®** Fibrinogen immunoturbidimetric assay. FOR *IN VITRO* DIAGNOSTIC USE.

**SUMMARY**

The stock calibrator contains known quantities of fibrinogen. It is to be used to prepare 4 levels of calibrator for use with the **K-ASSAY®** Fibrinogen immunoturbidimetric assay.

**KIT COMPOSITION**

<u>KAI-089C</u> Fibrinogen Calibrator (L)	6 x 1 mL, lyophilized
<u>KAI-136C</u> Fibrinogen Calibrator	1 x 1 mL, lyophilized

**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 container label.

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

**Potential biohazard material.** Human source material. Treat as potentially infectious. All blood products are tested and found non-reactive for hepatitis B surface antigen (HBsAG) and HIV antibody when tested by FDA-accepted third generation methods. No known methods for HBsAG and HIV can offer total assurance that products derived from human blood will not transmit these diseases. Therefore, products derived from human blood and patient samples should be considered potentially hazardous and handled as if capable of transmitting infectious agents.

**CALIBRATOR PREPARATION**Preparation of Calibrator Stock Solution:

Add 1 mL of purified water to lyophilized calibrator to make calibrator stock solution. (Swirl gently to avoid foaming)

NOTE: Some analyzers can be programmed to automatically dilute the calibrators so the below manual dilution steps should not be performed for such an analyzer. Check your instrument application sheet before proceeding with manual dilutions.

Preparation of Calibrators:

1. Calibrator D: Dilute calibrator stock solution 3/21 in saline (ex. 300 µL calibrator stock solution + 1800 µL saline)
2. Calibrator C: Dilute a portion of Calibrator D 1/2 in saline (ex. 500 µL Calibrator D + 500 µL saline)
3. Calibrator B: Dilute a portion of Calibrator D 1/4 in saline (ex. 500 µL Calibrator D + 1500 µL saline)
4. Calibrator A: Use saline only.

**Calibrator Preparation Summary Table:**

The following table summarizes how to make the 4 calibrators.

	Calibrator Stock	Cal D	Saline
Cal. D ( 3 / 21 )	300 µL		1800 µL
Cal. C ( 1.5 / 21 )		500 µL	500 µL
Cal. B ( 0.75 / 21 )		500 µL	1500 µL
Cal. A ( 0 )			1000 µL

Use Calibrator A, B, C, and D for calibration curve.

Calibrator values input into the analyzer must take into consideration the 1/21 dilution of the sample in order to calculate the actual fibrinogen concentration in the original samples. The following formula should be used for this:

Calibrator Input Value = Calibrator stock solution concentration x dilution ratio x 21 (for sample dilution)

Examples:

Calibrator D = Calibrator stock concentration x 3 / 21 x 21  
 Calibrator C = Calibrator stock concentration x 1.5 / 21 x 21  
 Calibrator B = Calibrator stock concentration x 0.75 / 21 x 21  
 Calibrator A = 0

Calibration Input Values should be input into the chemistry analyzer for Calibrator A, B, C, D. Please see section CALIBRATOR VALUES on the reverse side of this package insert for the concentrations of each level for this particular lot. For adjustment to NIBSC standardized values, please see the section titled INTERNATIONAL STANDARDIZATION.

**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 until the expiration date on the package and bottle labels.

## CALIBRATOR STABILITY

Reconstituted fibrinogen calibrator and the diluted calibrator solutions can be used for 1 week if stored at 2-8°C. However, calibrators should not be used if fibrin crystals are observed to have formed.

## INSTRUMENT

Measurements of absorbance are to be made with a clinical chemistry analyzer able to accurately read absorbance at 340 and 700 nm. Refer to the instrument manual from the manufacturer regarding the following:

- Use or function
- Installation procedures and requirements
- Principles of operation
- Performance characteristics, operating instructions
- Calibration procedures including materials and / or equipment to be used
- Operational precautions, limitations, and hazards
- Service and maintenance information

## PROCEDURE

Calibrators should be used as specified in the **K-ASSAY**® Fibrinogen package insert.

### Materials Supplied

Fibrinogen Stock Calibrator (Used to prepare levels A-D): 1 mL

KAI-089C	Fibrinogen Calibrator (L)	6 vials
KAI-136C	Fibrinogen Calibrator	1 vial

### Materials Required But Not Supplied

**K-ASSAY**® Fibrinogen immunoturbidimetric assay

Two-Reagent Clinical Chemistry Analyzer:

- Capable of accurate absorbance reading at 340/700 nm
- Capable of accurately dispensing the required volumes
- Capable of maintaining 37°C

For reconstitution and preparation of calibrators:

- Purified water
- Saline
- Pipette capable of dispensing the required volumes
- Test tubes or appropriate vials for storage of diluted calibrator

### Details of Procedure:

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

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

## CALIBRATOR VALUES

(Lot A123)

Concentration of stock calibrator, reconstituted with 1 mL of purified water (undiluted):

Fibrinogen (mg/dL)
340.0

After reconstitution, dilution, and conversion to the 21 factor:

Calibrators A-D, values given in mg/dL				
	A	B	C	D
Fibrinogen	0.0	255.0	510.0	1020.0

The expected values for the **K-ASSAY**® Fibrinogen 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.











## INTERNATIONAL STANDARDIZATION

If the user wishes to calculate or report results consistent with the National Institute for Biological Standards and Control (NIBSC) international standards for plasma fibrinogen (89/644, 98/612, 09/264) the **K-ASSAY**® Fibrinogen Calibrator values for prepared calibrators A, B, C, and D should be multiplied by 0.81 before entering these values into the analyzer.

Alternatively, if the calibrator values have not been changed, final fibrinogen assay results can be multiplied by 0.81.

Example: If the calibrator values have not been changed, a fibrinogen result of 300 mg/dL would be reported as 243 mg/dL standardized to NIBSC plasma fibrinogen standard. (300 mg/dL x 0.81 = 243 mg/dL)

## 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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