

K-ASSAY®

Fibrinogen Calibrator

Lot C702, Exp. 2018-08-31

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.

Calibrators 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 Guide Management No. CDC-22 issued by the Center for Disease Control, Atlanta, GA. 1976.

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 PREPARATIONPreparation 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:

$$\begin{aligned} \text{Calibrator D} &= \text{Calibrator stock concentration} \times \frac{3}{21} \times 21 \\ \text{Calibrator C} &= \text{Calibrator stock concentration} \times \frac{1.5}{21} \times 21 \\ \text{Calibrator B} &= \text{Calibrator stock concentration} \times \frac{0.75}{21} \times 21 \\ \text{Calibrator A} &= 0 \end{aligned}$$

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 for up to 18 months from the date of manufacture, as indicated by 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 C702)

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

| |
|--------------------|
| Fibrinogen (mg/dL) |
| 318.0 |

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

| Calibrators A-D, values given in mg/dL | | | | |
|--|-----|-------|-------|-------|
| | A | B | C | D |
| Fibrinogen | 0.0 | 238.5 | 477.0 | 954.0 |

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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Printed July 2017