

K-ASSAY®

Factor XIII Calibrator

Lot NS009FX/FK1053, Exp. 2019-01-31

REF KAI-106C

INTENDED USE

The **K-ASSAY®** Factor XIII Calibrator is intended to be used for the multi-point calibration of the **K-ASSAY®** Factor XIII Assay. FOR *IN VITRO* DIAGNOSTIC USE.

SUMMARY

The calibrators in this kit contain known quantities of purified coagulation factor XIII from human plasma. The calibrators are to be used for calibrating the **K-ASSAY®** Factor XIII assay.

KIT COMPOSITION

Lyophilized Human Factor XIII Calibrator De-fibrinogenated human plasma	5 x 1 mL
Factor XIII Calibrator Diluent Tris-HCl buffer (pH 8-9), sodium azide 0.05 %	1 x 40 mL

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 pipette by mouth. Avoid ingestion and contact with skin.

Calibrators contain Factor XIII from human plasma that was tested and found negative for HBsAg and for antibodies against HCV and HIV by approved methods. 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 contains 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 1 mL of **K-ASSAY®** Factor XIII Calibrator Diluent to one vial containing the lyophilized Factor XIII to dissolve it and allow to sit for 30 minutes. Swirl gently to dissolve. The concentration of the dissolved Factor XIII is indicated on the vial label and may change from lot to lot.
- Prepare 6 calibrators (A-F) using the dissolved stock and Factor XIII Calibrator Diluent according the following protocol:

	A	B	C	D	E	F
Dilution	0	1/16	1/8	1/4	1/2	1
Dissolved Stock (µL)	0	25	50	100	200	400
Diluent (µL)	400	375	350	300	200	0
Total (µL)	400	400	400	400	400	400

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

STORAGE AND HANDLING

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

Unopened calibrators and diluent can be used until the expiration date shown on the package and bottle labels if stored at 2-8°C.

Reconstituted calibrators (undiluted) can be used for 7 days if stored at 2-8°C.

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

Diluted calibrators can be used for 2 hours if stored at 2-8°C.

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**® Factor XIII assay package insert.

Lyophilized Human Factor XIII Calibrator 5 x 1 mL
 Factor XIII Calibrator Diluent 1 x 40 mL

Materials Required But Not Supplied

K-ASSAY® Factor XIII 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: 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® Factor XIII Calibrators are assayed using the same procedure as the samples run in the test procedure. See package insert from the **K-ASSAY**® Factor XIII Assay.

CALIBRATOR VALUES












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Stock Value after reconstitution with 1 mL of K-ASSAY ® Factor XIII Calibrator Diluent	132 %
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Calibrators A-F, After Reconstitution and Dilution					
A	B	C	D	E	F
0.0 %	8.3 %	16.5 %	33.0 %	66.0 %	132.0 %

The expected value for the **K-ASSAY**® Factor XIII 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
-  For *In Vitro* 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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