

K-ASSAY®

Urine FDP Calibrator

Lot 1234AB/YZ1234, Exp. 2024-10-31

Cat. No. KAI-326C

INTENDED USE

The **K-ASSAY®** Urine FDP Calibrator is intended to be used for the multi-point calibration of the **K-ASSAY®** Urine FDP Assay for urine samples. FOR RESEARCH USE ONLY IN THE U.S. NOT FOR USE IN DIAGNOSTIC PROCEDURES IN THE U.S.

SUMMARY

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

KIT COMPOSITION

| | |
|---|-----------|
| Lyophilized Human Urine FDP Calibrator FDP from human plasma | 5 x 2 mL |
| Urine FDP Calibrator Diluent Tris-HCl buffer (pH 8-9) | 1 x 40 mL |

WARNINGS AND PRECAUTIONS

FOR RESEARCH USE ONLY IN THE U.S. NOT FOR USE IN DIAGNOSTIC PROCEDURES 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 contain FDP from human plasma that was tested and found negative for HBsAg and for antibodies against HCV and HIV 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 contains < 0.1% w/v 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, GA.

K-ASSAY® Urine FDP Calibrator

PREPARATION OF CALIBRATORS

- Calibrators are lyophilized and require reconstitution. Diluent is ready to use. Add exactly 2 mL of **K-ASSAY®** Urine FDP Calibrator Diluent to one vial containing the lyophilized FDP to dissolve it and allow to sit for 30 minutes. Swirl gently to dissolve. The concentration of the dissolved FDP is indicated on the vial label and may change from lot to lot.
- Prepare 6 calibrators (A-F) using the calibrator stock solution and Urine FDP Calibrator Diluent according to the following protocol:

| | A | B | C | D | E | F |
|-----------------------|-----|------|-----|-----|-----|-----|
| Dilution | 0 | 1/16 | 1/8 | 1/4 | 1/2 | 1 |
| Calibrator 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 urine FDP can be made using these 6 prepared calibrators. Urine FDP 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 calibrators can be used for 6 hours if stored at 2-8°C.

Diluted calibrators can be used for 2 hours if stored at 2-8°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**® Urine FDP assay package insert.

Urine FDP Calibrator 5 x 2 mL
Urine FDP Calibrator Diluent 1 x 40 mL

Materials Required But Not Supplied

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

CALIBRATOR VALUES











Lot 1234AB/YZ1234, Exp. 2023-02-28

| | |
|---|-------------------|
| Value after reconstitution with 2 mL of K-ASSAY ® Urine FDP Calibrator Diluent | 4.00 µg/mL |
|---|-------------------|

| Calibrators A-F, After Reconstitution and Dilution (µg/mL) (See PREPARATION OF CALIBRATORS) | | | | | |
|--|-------------|-------------|-------------|-------------|-------------|
| A | B | C | D | E | F |
| 0.00 | 0.25 | 0.50 | 1.00 | 2.00 | 4.00 |

The expected value for the **K-ASSAY**® Urine FDP 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 |
|  | Calibrator |
|  | Reagent |
|  | 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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