K-*ASSAY*®

Cystatin C Calibrator

Lot A123, Exp. 2017-02-28

Cat. No. KAI-099C

INTENDED USE

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

SUMMARY

The calibrators in this kit contain known quantities of human cystatin C. There is also a calibrator containing only diluent (150 mM sodium chloride). These calibrators are to be used with the **K-*ASSAY*®** Cystatin C assay.

KIT COMPOSITION

Calibrators (Liquid Stable)

Calibrator A:	150 mM Sodium Chloride 25 mM HEPES Sodium azide ≤ 0.1 w/v %	1 x 1 mL
Calibrator B-F:	Human Cystatin C 150 mM Sodium Chloride 25 mM HEPES Sodium azide ≤ 0.1 w/v %	5 x 1 mL

WARNINGS AND PRECAUTIONS

FOR *IN VITRO* DIAGNOSTIC USE.

Not to be used internally in humans or animals. Normal precautions exercised in handling laboratory reagents should be followed.

Cystatin C was isolated from human urine that was tested and found negative for HIV I & II antibodies, Hepatitis B surface antigen, and Hepatitis C antibodies by FDA approved methods. However, 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 pipette by mouth. Avoid ingestion and contact with skin.

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.

Calibrators in this kit contain ≤ 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. CDC-22 issued by the Centers for Disease Control, Atlanta, Georgia.

CALIBRATOR PREPARATION

The calibrators are ready to use and do not require reconstitution.

STORAGE AND HANDLING

All calibrators should be stored refrigerated (2-8℃). Return all calibrators to 2-8℃ 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 package and bottle labels.

CALIBRATOR STABILITY

Opened bottles of calibrators can be used for 1 month if stored at 2-8℃. Discard calibrators if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard.

Calibrator transferred to the instrument sample cup may concentrate over time. Therefore, calibrators should be capped and stored at 2-8℃ when not in use. Otherwise, fresh calibrators should be used for each calibration.

INSTRUMENT

Measurements of absorbance are to be made with a clinical chemistry analyzer able to accurately read absorbance at 570 nm. Refer to the instrument manual from the manufacturer regarding the following:

a) Use or function
b) Installation procedures and requirements
c) Principles of operation
d) Performance characteristics, operating instructions
e) Calibration procedures including materials and / or equipment to be used
f) Operational precautions, limitations, and hazards
g) Service and maintenance information

PROCEDURE

Materials Supplied

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

Calibrator A	1 x 1 mL
Calibrator B	1 x 1 mL
Calibrator C	1 x 1 mL
Calibrator D	1 x 1 mL
Calibrator E	1 x 1 mL
Calibrator F	1 x 1 mL

Materials Required But Not Supplied

K-*ASSAY*® Cystatin C assay, Cat. No. KAI-073 or KAI-074

Two-Reagent Clinical Chemistry Analyzer:
- Capable of accurate absorbance reading at 570 nm
- Capable of accurately dispensing the required volumes
- Capable of maintaining 37°C

Details of Procedure

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

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

INTERFERENCE

Dust particles or other particulates in the reaction may result in extraneous light-scattering resulting in variable results.

CALIBRATOR VALUES

Lot A123

	Cystatin C	Standardized * Cystatin C
A	0.0 mg/L	0.00 mg/L
B	0.5 mg/L	0.43 mg/L
C	1.0 mg/L	0.85 mg/L
D	2.0 mg/L	1.70 mg/L
E	5.0 mg/L	4.25 mg/L
F	10.0 mg/L	8.50 mg/L

* Standardized against ERM-DA471 / IFCC Reference Material.

The values for **K-*ASSAY*®** Cystatin C Calibrator Set are continually being revised through on going 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	Lot Number
STD	Calibrator
	Expiration or "Use By" Date
REF	Catalog Number
IVD	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
EC REP	Authorized Representative in the European Community

ORDERING / PRICING / TECHNICAL INFORMATION

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