K-*ASSAY*®

CRP Calibrator

Lot A123, Exp. 2024-04-30

Cat. No. KAI-012C

INTENDED USE

The **K-*ASSAY*®** CRP Calibrator is intended to be used for the calibration of the **K-*ASSAY*®** CRP immunoturbidimetric assay for quantifying serum levels of C-Reactive Protein (CRP). FOR *IN VITRO* DIAGNOSTIC USE.

SUMMARY

The calibrators in this kit are human serum tested and found negative for HBsAg and HIV Ab. They contain known quantities of human C-Reactive Protein. There is also a calibrator containing only diluent (150 mM sodium chloride). These calibrators are to be used with the **K-*ASSAY*®** CRP immunoturbidimetric assay.

KIT COMPOSITION

Calibrators (Liquid Stable)

MATERIALS PROVIDED

Calibrator A	150 mM Sodium Chloride	1 x 1 mL
Calibrator B-F	Human CRP	5 x 1 mL

Calibrators B-F contain pooled human serum with assigned values for the specific serum protein CRP.

WARNINGS AND PRECAUTIONS

FOR *IN VITRO* DIAGNOSTIC USE. ℞ 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 < 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 Center for Disease Control, Atlanta, GA.

Calibrators contain purified human serum. Each donor unit used in the preparation of this product has been tested by an FDA approved method and found non-reactive for HBsAg and HIV antibodies. However, it is not possible to guarantee they are free of hepatitis B virus (HB), human immunodeficiency virus (HIV), or other infectious agents. Therefore, all products containing human serum should be handled in accordance with good laboratory practices using appropriate precautions as described in the CDC/NIH Manual, "Biosafety in Microbiology and Biomedical Laboratories," 2nd ed., 1988, HHS Publication No. (CDC) 88-8395.

CALIBRATOR PREPARATION

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

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

Opened bottles of calibrators can be used for 1 month if stored at 2-8°C. 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°C 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 340 and 700 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

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

Materials Supplied

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*® CRP immunoturbidimetric assay

Clinical chemistry analyzer: capable of accurate absorbance readings at 340 and 700 nm with appropriate cuvettes, capable of accurately dispensing the required volumes, and capable of maintaining 37°C.

Details of Procedure

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

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

CALIBRATOR VALUES
Lot A123*

	CRP (mg/dL)
A	0.0
B	0.9
C	4.1
D	8.0
E	12.2
F	23.9

* Standardized against CAP/BCR/IFCC Reference Preparation for Proteins in Human Serum (RPPHS), lot 91/0619.

The values for the **K-*ASSAY*®** CRP 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.

LABELING SYMBOLS

REF	Catalog Number
	Expiration or “Use By” Date
LOT	Lot Number
	Consult Package Insert for Instructions for Use
IVD	For *In Vitro* Diagnostic Use
CE	CE Mark Registered
℞	For Prescription Use Only
	Potential Human Biohazard
2°C 8°C	Temperature Limitation. Store between 2 and 8 degrees C
	Manufacturer
EC REP	Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE

CE

EC REP

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