

K-ASSAY®

CRP (3) Calibrator E

[For CRP(3) Assay - Wide Range]

Lot 123456, Exp. 2017-08-31

Cat. No. KAI-084C**INTENDED USE**

The **K-ASSAY®** CRP (3) Calibrator E is intended to be used for the calibration of the **K-ASSAY®** CRP (3) immunoturbidimetric assay for quantifying C-Reactive Protein (CRP) in serum and plasma (sodium EDTA or lithium heparin) samples. 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. These are to be used as calibrators for the **K-ASSAY®** CRP (3) immunoturbidimetric assay.

KIT COMPOSITION**Calibrators (Liquid Stable)****MATERIALS PROVIDED**

| | | |
|----------------|-----------|----------|
| Calibrator 1-5 | Human CRP | 5 x 2 mL |
|----------------|-----------|----------|

Contain pooled human serum with assigned values for the specific serum protein CRP.

WARNINGS AND PRECAUTIONSFOR *IN VITRO* DIAGNOSTIC USE.

Only use application parameters specific for **K-ASSAY®** CRP (3) Calibrator E with the **K-ASSAY®** CRP (3) Reagents. There are two other calibrator sets that may be used with the **K-ASSAY®** CRP (3) Reagents. Failure to use application parameters specific for **K-ASSAY®** CRP (3) Calibrator E may produce erroneous values.

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 lead drain lines. When disposing of calibrators through plumbing fixtures, flush with copious amounts of water. For

K-ASSAY® CRP (3) Calibrator E

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.

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 that 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 two years from the date of manufacturing as indicated on the expiration date on the package and bottle labels. Opened bottles of calibrators can be used for 1 month if stored at 2-8°C.

CALIBRATOR STABILITY

Discard calibrators if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard.

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

Calibrators should be used as specified in the **K-ASSAY**® CRP (3) immunoturbidimetric assay package insert.

Materials Supplied

| | |
|---------------------------------|----------|
| Calibrator 1 (Yellow Cap) | 1 x 2 mL |
| Calibrator 2 (Light Yellow Cap) | 1 x 2 mL |
| Calibrator 3 (Light Green Cap) | 1 x 2 mL |
| Calibrator 4 (Pink Cap) | 1 x 2 mL |
| Calibrator 5 (Maroon Cap) | 1 x 2 mL |

Materials Required But Not Supplied

K-ASSAY® CRP (3) immunoturbidimetric assay

Clinical chemistry analyzer: capable of accurate absorbance readings at 570 nm with appropriate cuvettes and calculating rate reactions, capable of accurately dispensing the required volumes, and capable of maintaining 37°C.

Saline solution (0 mg/L calibrator)

Details of Procedure

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

K-ASSAY® CRP (3) Calibrator E is assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the **K-ASSAY**® CRP (3) immunoturbidimetric assay.

Use **K-ASSAY® CRP (3) Calibrator E only with CRP (3) Assay with Calibrator E protocol.**

CALIBRATOR VALUES

Lot 123456











| Calibrator | CRP* | | |
|------------|-------|-------|--------|
| | mg/dL | mg/L | µg/dL |
| 1 | 0.25 | 2.5 | 250 |
| 2 | 1.00 | 10.0 | 1,000 |
| 3 | 2.00 | 20.0 | 2,000 |
| 4 | 8.00 | 80.0 | 8,000 |
| 5 | 16.00 | 160.0 | 16,000 |

* Traceable to IFCC CRM470.

Use saline solution as the 0 mg/L calibrator.

The values for the **K-ASSAY**® CRP (3) Calibrator E 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

| | |
|---|---|
|  | 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 |

ORDERING / PRICING / TECHNICAL INFORMATION



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Printed September 2015