

K-ASSAY®

hsCRP Calibrator

Lot 1170, Exp. 2018-11-30

Cat. No. KAI-161C**INTENDED USE**

The **K-ASSAY®** hsCRP Calibrator Set is intended for use of the calibration of the C-reactive protein (CRP) method. For *in vitro* diagnostic use only.

SUMMARY

The **K-ASSAY®** High Sensitivity C-Reactive Protein (hsCRP) Calibrator Set (Cat. No. KAI-161C) is a set of four calibrator levels. These four levels and saline are to be used for a five-point calibration of the **K-ASSAY®** hsCRP Assay (Cat. No. KAI-160), which is a latex immuno-turbidimetric assay for the quantification of C-reactive protein in human serum or plasma.

KIT COMPOSITION

Reactive components

Human serum and additives

Non-reactive components

Sodium azide (NaN₃) <0.1%

The **K-ASSAY®** hsCRP Calibrator Set is a four-level set that is supplied in liquid form (4 x 1 mL). The calibrator levels are manufactured from human serum. The concentration of each calibrator is lot specific and the c-reactive protein concentrations are expressed in mg/L.

WARNINGS AND PRECAUTIONSFOR *IN VITRO* DIAGNOSTIC USE. Rx only.

Exercise the normal precautions for handling all laboratory reagents. Each donor unit of plasma used in the preparation of this Calibrator Set was tested by FDA-approved methods and found negative for the Human Immunodeficiency Virus Antibody (HIV I/II Ab), Hepatitis B Surface Antigen (HBsAg), and Hepatitis C Virus Antibody (HCV). Because no method can offer complete assurance as to the absence of infectious agents, however, this material and all patient samples should be handled as though capable of transmitting infectious disease and disposed of accordingly.

Additional safety information concerning storage and handling of this product is provided within the Material Safety Data Sheet for this product. To obtain an MSDS, please contact our diagnostics technical support department.

Avoid contact with skin and eyes.

Contains sodium azide, which may react with lead or copper plumbing to form explosive compounds. Flush drains with copious amounts of water when disposing of this reagent.

CALIBRATOR PREPARATION

The **K-ASSAY®** hsCRP Calibrator Set is supplied in liquid form. Mix carefully before each use.

STORAGE AND STABILITYStore at 2 to 8°C. **DO NOT FREEZE.***Note:* Store tightly capped when not in use.

Stability is up to the expiration date on label when stored at 2 to 8°C.

PROCEDURE**Materials Supplied**The **K-ASSAY®** hsCRP Calibrator Set consists of 4 liquid vials.

Calibrator A (White Cap)	1 x 1 mL
Calibrator B (Red Cap)	1 x 1 mL
Calibrator C (Black Cap)	1 x 1 mL
Calibrator D (Blue Cap)	1 x 1 mL

Materials Required But Not Supplied**K-ASSAY®** hsCRP assay, Cat. No. KAI-160

0.9% saline solution

General laboratory equipment

Details of Procedure

Prepare calibrator 1 through 4 as stated in the CALIBRATOR PREPARATION section. Take care to avoid the formation of bubbles. *Note:* A saline solution is required to generate a 5-point calibration.

CALIBRATOR VALUES**Lot 1170**











	<u>CRP</u>
A	0.83 mg/L
B	4.26 mg/L
C	9.71 mg/L
D	20.67 mg/L

The values for **K-ASSAY®** hsCRP 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.

REFERENCES

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2. Du Clos TW: Function of C-reactive protein, Ann Med 32: 274-278, 2000.
3. Tietz, N.W. (Ed.), Clinical Guide to Laboratory Tests, 4th Edition, Alan H. Wu, Saunders Elsevier (2006).
4. Maksimowicz-McKinnon K, Bhatt DL, and Calabrese LH: Recent advances in vascular inflammation: C-reactive protein and other inflammatory biomarkers, Curr. Opin. Rheumatol 16: 18-24, 2004.
5. Pearson TA, Mensah GA, Alexander RW, et al. Markers of inflammation and cardiovascular diseases; application to clinical and public health practice: A statement for healthcare professionals from the Centers for Disease Control and Prevention and the American Heart Association. Circulation 2003; 107: 499-511.
6. Use of anticoagulants in Diagnostic laboratory Investigations. WHO Publication WHO/DIL/LAB 99.1/Rev. 2 Jan. 2002.
7. Benitz, W.E., et al., Serial serum C-reactive protein levels in the diagnosis of neonatal infection. Pediatrics 1998;102:E41

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

EU AUTHORIZED REPRESENTATIVE



Advena Ltd.

Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013 Malta

ORDERING / PRICING / TECHNICAL INFORMATION



KAMIYA BIOMEDICAL COMPANY

12779 Gateway Drive
Seattle, WA 98168 USA
TEL: (206) 575-8068 / (800) 526-4925
FAX: (206) 575-8094

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