K-*ASSAY*®

High-Sensitive CRP Control

Lot: 1234567 (L1), 2345678 (L2), Exp. 2018-08-31

Cat. No. K80C-4M

INTENDED USE

The **K-*ASSAY*®** High-Sensitive CRP Control is intended for use as an assayed quality control material for monitoring the performance of C-Reactive Protein (CRP) immunoturbidimetric assays. FOR *IN VITRO* DIAGNOSTIC USE.

SUMMARY

The use of quality control materials to objectively monitor the precision of procedures in use in the clinical laboratory has been well established. The **K-*ASSAY*®** High-Sensitive CRP Control is provided at two levels to assist in the monitoring of analytical systems within the clinical range.

SET COMPOSITION

K80C-4M

Level 1, 2	Human serum (liquid)	2 x 1 mL each level
	Sodium azide	0.09%

High-Sensitive CRP Control Levels 1 and 2 contain pooled human serum with assigned values for 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.

Controls contain pooled human serum from CRP positive human serum. The serum has been tested and found non-reactive for the presence of HBsAg, HCV Ab, and HIV antibody by an FDA approved method. However, it is not possible to guarantee that any human source material is free of these 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 Microbiological and Biomedical Laboratories," 2nd ed., 1988, HHS Publication No. (CDC) 88-8395.

Do not mix or use controls from one test set with those from a different lot number. Do not use controls past their expiration date stated on each control container label.

Controls in this set contain sodium azide as a preservative. Sodium azide may form explosive compounds in metal drain lines. When disposing of controls 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.

Do not pipette by mouth. Avoid ingestion and contact with skin.

CONTROL PREPARATION

1. Gently invert the bottle before use.
2. The control is ready to use.
3. Replace the cap immediately after use to prevent evaporation or contamination.

STORAGE AND HANDLING

Store controls at 2-8℃. Return all controls to 2-8℃ promptly after use. Controls can be used up to the expiration date shown on the vial label and package insert.

CONTROL STABILITY

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

PROCEDURE

Materials Supplied

K80C-4M

Level 1	Human serum	2 x 1 mL (blue cap)
Level 2	Human serum	2 x 1 mL (green cap)

Materials Required But Not Supplied

K-*ASSAY*® High-Sensitive CRP Assay
K-*ASSAY*® CRP Calibrator

Two-reagent clinical chemistry analyzer

Assay Procedure:

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

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

LIMITATIONS OF PROCEDURE

Accurate and reproducible results are dependent upon properly functioning instruments, reagents, and good laboratory technique. Erroneous results can occur from improper storage, reconstitution inaccuracies, and technical errors associated with assay procedures.

This product is intended for use as an assayed control for quantitative assays of listed constituents in human serum. This product is not intended for use as a calibrator.

EXPECTED VALUES

KAMIYA BIOMEDICAL COMPANY has established the expected values. Values listed were obtained using a Hitachi 911, ***K-ASSAY*** ® hsCRP (Cat. No. KAI-160) with hsCRP Calibrator (Cat. No. KAI-161C) and ***K-ASSAY*** ® CRP (3) (Cat. No. KAI-082) with CRP (3) Calibrator E (Cat. No. KAI-084C) and CRP (3) Calibrator F (Cat. No. KAI-086C). Subsequent modifications in instrument, reagent, or procedure may invalidate these results. The assignment of mean values was derived from analysis of vials representative of the entire lot.

Values listed are specific for each lot only. Verify that the lot numbers on the vials of High-Sensitive CRP Control correspond to the lot numbers listed for the Assay Data.

Analyte values were also obtained from manufacturers of instrument specific reagents, or from reference laboratories.

The Expected Range and the Mean are provided to assist the laboratory until it has established its own mean and standard deviation. It is considered good laboratory practice for each laboratory to establish its own mean and standard deviation for its test methods. The indicated Mean and Expected Range of the Mean should serve as a guide in assessing the performance of each test method.

Recovered values may be method dependent. The variations that can occur over time and between laboratories may be attributed to differences in laboratory technique, instrumentation, reagent lot, method modifications, and other systematic errors including random errors.

ASSAY DATA

Lot : Level 1: 1234567 Level 2: 2345678

			L1 VALUES		L2 VALUES	
PROTEIN TEST	**MANUFACTURER**	**UNITS**	**MEAN**	**EXPECTED RANGE**	**MEAN**	**EXPECTED RANGE**
K-ASSAY ® hsCRP	KAMIYA BIOMEDICAL COMPANY Analyzer: Hitachi 911	mg/L	0.47	0.37 – 0.56	1.56	1.25 – 1.87
	KAMIYA BIOMEDICAL COMPANY Analyzer: Beckman CX 7	mg/L	0.53	0.42 – 0.64	1.70	1.36 – 2.04
K-ASSAY ® CRP (3) + Cal E *	KAMIYA BIOMEDICAL COMPANY Analyzer: Hitachi 911	mg/L	0.52	0.41 – 0.62	1.64	1.31 – 1.97
K-ASSAY ® CRP (3) + Cal F *	KAMIYA BIOMEDICAL COMPANY Analyzer: Hitachi 911	mg/L	0.5	0.4 – 0.6	1.7	1.4 – 2.0
NhsCRP	Dade Behring BNII	mg/L	0.54	0.43 – 0.65	1.36	1.09 – 1.63
CRPH	Beckman Coulter Immage	mg/L	0.58	0.46 – 0.70	2.19	1.75 – 2.63
CRP	Olympus AU 400/640	mg/L	0.51	0.41 – 0.61	1.70	1.36 – 2.04

* Standardized to the International Federation of Clinical Chemistry (IFCC) International Reference Preparation for Plasma Protein CRM 470.

The expected values for the ***K-ASSAY*** ® High-Sensitive CRP Control 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 appropriate control values.

LABELING SYMBOLS

LOT	Lot Number
CONTROL	Control
	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

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ORDERING / PRICING / TECHNICAL INFORMATION

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