K-*ASSAY*®

Plasma Control

Level 1: Lot A123, Exp. 2018-02-28
Level 2: Lot A456, Exp. 2018-02-28

Cat. No. K81C-6M

INTENDED USE

The **K-*ASSAY*®** Plasma Control is intended to be used as a consistent test sample of known concentration for monitoring the performance of D-Dimer and Plasminogen assays. FOR *IN VITRO* DIAGNOSTIC USE. Values for AT-III, α2PI, and FDP are for research use only in the U.S. Not for use in diagnostic procedures in the U.S.

SUMMARY

The controls in this kit are human plasma tested and found negative for HBsAg, HCV Ab, and HIV Ab. They contain known concentrations of D-Dimer (antigen), AT-III (antigen), α2PI (activity), FDP (antigen), and Plasminogen (activity). They are to be used as controls with the **K-*ASSAY*®** D-Dimer and other assays.

SET COMPOSITION

K81C-6M, Levels 1 and 2	
Human plasma (lyophilized)	3 x 0.5 mL each level
Sodium azide	0.09%

Plasma Control Levels 1 and 2 contain pooled human plasma with assigned values for D-Dimer and other analytes.

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.

Controls contain pooled human plasma. The plasma 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 plasma/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. Reconstitute Plasma Control with 0.5 mL of distilled water.
2. Gently invert vial until dissolution is complete (do not shake).
3. Allow the vial to sit at room temperature (18-26℃) for 25 minutes prior to use.
4. Replace the cap immediately after use to prevent evaporation or contamination.
5. Return the vial to 2-8℃ promptly after use.

STORAGE AND HANDLING

Store controls at 2-8℃. Return all controls to 2-8℃ promptly after use. Reconstituted controls can be used up to a week if kept at 2-8℃ and a month at -20℃ (with 1 time thawing only).

CONTROL STABILITY

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

PROCEDURE

Materials Supplied

K81C-6M		
Level 1	Human plasma	3 x 0.5 mL
Level 2	Human plasma	3 x 0.5 mL

Materials Required But Not Supplied

K-*ASSAY*® D-Dimer assay and calibrators, or other assays

Two-reagent clinical chemistry analyzer

Assay Procedure

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

K-*ASSAY*® Plasma Controls are assayed using the same procedure as the patient test samples. See package insert from the **K-*ASSAY*®** D-Dimer or other assays.

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 plasma. This product is not intended for use as a calibrator.

EXPECTED VALUES

KAMIYA BIOMEDICAL COMPANY has established the expected values. 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 Plasma Control correspond to the lot numbers listed for the Assay Data.

The Expected Range of the Mean is 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.

ASSAY DATA

ASSAY	UNIT	LEVEL 1 LOT A123, EXP. 2018-02-28		LEVEL 2 LOT A456, EXP. 2018-02-28	
		MEAN	RANGE	MEAN	RANGE
K-*ASSAY*® D-Dimer (KAI-090)	µg/mL	1.43	1.14 – 1.71	13.52	10.81 – 16.22
AT-III (Antigen)*	mg/dL	30.4	25.0 – 35.8	14.8	12.6 – 17.0
α2PI (Activity)*	%	95.6	77.4 – 113.8	46.4	34.8 – 58.0
FDP (Antigen)*	µg/mL	6.3	5.2 – 7.4	30.8	24.7 – 36.9
Plasminogen (Activity)	%	94.1	83.1 – 105.1	48.3	38.7 – 57.9

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The expected values for the **K-*ASSAY*®** Plasma Control are continually being revised through ongoing quality assurance. Please refer to the package insert included with each control set for the most appropriate control values. Recovered values may be method dependent. The variations which 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.

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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