K-*ASSAY*®

Serum FDP Control

Lot 4111N/4111P, Exp. 2021-11-30

Cat. No. K322C-10M

INTENDED USE

The **K-*ASSAY*®** Serum FDP Control is intended to be used as a consistent test sample of known concentration for monitoring the performance of the **K-*ASSAY*®** Serum FDP assay. FOR RESEARCH USE ONLY IN THE U.S. NOT FOR USE IN DIAGNOSTIC PROCEDURES IN THE U.S.

SUMMARY

The controls in this set are human plasma tested and found negative for HBsAg, HCV Ab, and HIV Ab. They contain known concentrations of the listed constituents. They are to be used as controls with the **K-*ASSAY*®** Serum FDP assay.

SET COMPOSITION

K322C-10M, Levels 1 and 2

Human Plasma (Lyophilized) 5 x 0.5 mL (each level)

Serum FDP Control Levels 1 and 2 contain pooled human plasma with assigned values for the listed constituents.

WARNINGS AND PRECAUTIONS

FOR RESEARCH USE ONLY IN THE U.S. NOT FOR USE IN DIAGNOSTIC PROCEDURES IN THE U.S.

Not to be used internally in humans or animals. Normal precautions exercised in handling laboratory reagents should be followed.

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.

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

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 FDA approved methods. However, it is not possible to guarantee that any human source material is free of these infectious agents.

Therefore, all products containing human plasma 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.

CONTROL PREPARATION

1. Reconstitute 1 vial of each Serum FDP Control level with 0.5 mL of purified water and allow to sit for 30 minutes.
2. Gently swirl vial until dissolution is complete and the solution is homogenous (do not shake).
3. Replace the cap immediately after use to prevent evaporation or contamination.
4. Return the vial to 2-8°C promptly after use.

STORAGE AND HANDLING

Store lyophilized and reconstituted controls at 2-8°C. Return all controls to 2-8°C promptly after use. Unopened controls can be used until the expiration date shown on the package and bottle labels.

Reconstituted controls can be used for up to 7 days if stored at 2-8°C.

Reconstituted controls can be frozen one time and stored at -20°C for up to 5 weeks. **Do not refreeze a second time.**

CONTROL STABILITY

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

PROCEDURE

Materials Supplied

Level 1	Lyophilized Human Plasma	5 x 0.5 mL
Level 2	Lyophilized Human Plasma	5 x 0.5 mL

Materials Required But Not Supplied

K-*ASSAY*® Serum FDP assay and calibrator

Two-Reagent Clinical Chemistry Analyzer:
Capable of accurate absorbance reading at 500 - 600 nm
Capable of accurately dispensing the required volumes
Capable of maintaining 37°C

Pipettes: capable of accurately dispensing the required volumes

Purified Water

Assay Procedure

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

K-*ASSAY*® Serum FDP Control is assayed using the same procedure as the samples run in the test procedure. See the package insert from the **K-*ASSAY*®** Serum FDP 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 plasma. This product is not intended for use as a calibrator.

EXPECTED RESULTS

KAMIYA BIOMEDICAL COMPANY has established the expected values. Values listed were obtained using a Hitachi 902 and **K-*ASSAY*®** Serum FDP assay and calibrator. 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 **K-*ASSAY*®** Serum FDP 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.

LABELING SYMBOLS

LOT	Lot Number
CONTROL	Control
	Expiration or "Use By" Date
REF	Catalog Number
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

EU AUTHORIZED REPRESENTATIVE

CE

EC REP

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ASSAY DATA

ASSAY	LEVEL 1 LOT 4111N, Exp. 2021-11-30		LEVEL 2 LOT 4111P, Exp. 2021-11-30		Units
	Mean	Range	Mean	Range	
Serum FDP	6.00	4.50 – 7.50	22.80	17.10 – 28.50	µg/mL

The expected values for the **K-*ASSAY*®** Serum FDP 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.

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