K-*ASSAY*®

Fibrinogen Control

Level 1: Lot 137347, Exp. 2020-04-30
Level 2: Lot 159604, Exp. 2020-03-31

Cat. No. K63C-10M

INTENDED USE

The **K-*ASSAY*®** Fibrinogen Control is intended for use in the quality control of fibrinogen assays.

SUMMARY

The use of controls is a valuable tool for assuring quality in coagulation testing. Fibrinogen Controls contain a known amount of fibrinogen in the low and high abnormal range. These controls provide reliable markers for monitoring the accuracy of abnormal fibrinogen results and can be used to verify the extent of the reportable range.

PRODUCT DESCRIPTION

FOR *IN VITRO* DIAGNOSTIC USE. Rx only.

Composition: K-*ASSAY*® Fibrinogen Controls are processed from human plasma collected with sodium citrate anticoagulant (4% w/v). The plasmas are adjusted to yield fibrinogen values in the low as well as high abnormal range. <1.0% stabilizers and buffers are added prior to lyophilization.

Store unopened vials at 2-8°C. Reconstitute with 1.0 mL of distilled water. Swirl gently and let stand undisturbed for 15 minutes at room temperature. Do not invert vial or mix vigorously. After proper reconstitution, Level 2 Fibrinogen Control is stable for 8 hours when stored in capped vial at 2-8°C and Level 1 Fibrinogen Control is stable for 16 hours when stored in capped vial at 2-8°C[4]. A precipitate may form when refrigerated. Gently warm the plasma to 37°C to minimize any precipitate.

Erratic values, product color variations, or lack of vacuum in the vials could indicate product deterioration. However, poor control performance could also be due to other factors within the test system.

Caution: Each unit of source material used in the preparation of these products has been tested by an FDA licensed method and found non-reactive for HbsAg and negative for antibodies to HIV and HCV. However, no known test method can offer complete assurance that products derived from human blood will not transmit hepatitis, AIDS, or other infectious diseases. These products, like all materials of human origin, should be handled as potentially infectious biological material.

PROCEDURE

Materials Provided:

Level 1 Fibrinogen Control Plasma, 5 x 1 mL
Level 2 Fibrinogen Control Plasma, 5 x 1 mL

Materials Required But Not Provided:

Distilled water
Pipette capable of accurately delivering 1.0 mL

Assay Procedure

Test Level 1 and Level 2 Fibrinogen Controls following protocols established for patient samples. (If using **K-*ASSAY*®** Fibrinogen assay, a 1:21 dilution is performed on all samples and controls.) Actual results depend on many factors, including lot number, reagent, and instrument used. Ranges must be determined in each laboratory with changes of lot number, reagent, or instrument. Normal and abnormal controls should be run at the initiation of testing each day and at least once each shift, or with each group of assays. Controls should also be tested with each reagent change or major instrument adjustment. In laboratories where there is a heavy workload of PTs and/or APTTs, test a normal and an abnormal control at a minimum of every 40 samples[1]. Follow instructions provided by instrument and reagent manufacturers.

RESULTS

Results depend on reagents, instruments, and individual laboratory protocols. However, Level 1 Fibrinogen and Level 2 Fibrinogen Controls are formulated to have fibrinogen values below and above the normal range, respectively. Each laboratory should establish ranges with their instruments and reagents. Follow troubleshooting procedures when results fall outside the established range.

LIMITATIONS OF PROCEDURE

All controls are subject to the limitations of the test system. Variables such as temperature, reagent stability, instrument performance, and individual technique can influence final results. Always follow instrument and reagent manufacturer's guidelines.

EXPECTED VALUES

Values were assigned using the **K-*ASSAY*®** Fibrinogen assay and also a thrombin clotting time (Clauss[2]) methodology. Actual values recovered depend on the instrument and reagent used.

PERFORMANCE CHARACTERISTICS

Level 1 Fibrinogen Control is formulated to have a value of approximately 70 to 120 mg/dL (thrombin clotting time). Level 2 Control is formulated to have a value of approximately 500 to 650 mg/dL (thrombin clotting time). Fibrinogen controls have been used in a quality control program covering multiple runs over a period of time. The coefficient of variation was less than 10%[5].

		Level 1 Lot No. 137347		Level 2 Lot No. 159604	
Method	**Units**	**Mean**	**Expected Range**	**Mean**	**Expected Range**
K-*ASSAY*® Fibrinogen	mg/dL	164	131 – 196	561	449 – 673
Clauss Fibrinogen	mg/dL	95	N/A	591	N/A

REFERENCES

1. NCCLS: One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline. NCCLS document H47-A. NCCLS, Wayne, PA, 1996.
2. Clauss, A., Rapid physiological coagulation method for the determination of fibrinogen, Acta Haemat. 17:237-246. 1957.
3. NCCLS: Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays. 3rd edition. Approved guideline. NCCLS Document H21-A3. Wayne, PA, 1998.
4. Stability data found in DHF.
5. Data found in 510(k) file.

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
IVD	For *In Vitro* Diagnostic Use
	Consult Package Insert for Instructions for Use

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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