K-*ASSAY*®

Factor XIII

For the Quantitative Determination of Coagulation Factor XIII in Plasma

REF KAI-105

INTENDED USE

The **K-*ASSAY*®** Factor XIII Assay is an *in vitro* reagent for the quantitative determination of Coagulation Factor XIII in human plasma. FOR *IN VITRO* DIAGNOSTIC USE.

INTRODUCTION AND SUMMARY

Coagulation Factor XIII is a transglutaminase that plays an important role in hemostasis since it participates in the final stages of the coagulation cascade. It is an enzyme of the blood coagulation system that cross-links and stabilizes fibrin. By polymerizing fibrin monomers, it enables the formation of a firm blood clot.

PRINCIPLE OF TEST

Latex particles coated with antibody specific to human Factor XIII form immune complexes in the presence of Factor XIII from the sample. The immune complexes cause an increase in light scattering, which is proportional to the concentration of Factor XIII in the plasma sample. The light scattering is measured by reading turbidity at 500 to 600 nm. The sample Factor XIII concentration is determined versus dilutions of a Factor XIII calibrator of known concentration.

KIT COMPOSITION

Reagents (Liquid Stable)

R1: Buffer Reagent 2 x 9.5 mL
Tris Buffer

R2: Latex Suspension 1 x 6 mL
Latex suspension / Anti-human Factor XIII rabbit polyclonal antibody

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.

Do not mix or use reagents from one test kit with those from a different lot number.

Do not use reagents past their expiration date stated on each reagent container label.

Do not pipette by mouth. Avoid ingestion and contact with skin. The buffer solution is weakly alkaline (pH = 8.3). Avoid direct contact to skin and eyes. If contact occurs, flush with copious amounts of water and seek medical attention if necessary.

Reagents in this kit contain < 0.1% w/v sodium azide as a preservative. Sodium azide may form explosive compounds in metal drain lines. When disposing of reagents 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.

REAGENT PREPARATION

Reagents are ready to use and do not require reconstitution. Before use, gently invert Reagent 2 at least once a week.

STORAGE AND HANDLING

All reagents should be stored at 2-8°C.

REAGENT STABILITY

Unopened reagents can be used until the expiration date shown on the package and bottle labels if stored at 2-8°C. Once the reagent vial has been opened, store tightly capped at 2-8°C and use within 1 month. Discard reagents if they become contaminated. Evidence of obvious precipitation in reagent 2 (R-2) solution is cause to discard.

SPECIMEN COLLECTION AND PREPARATION

Plasma
Whole blood is collected in a tube containing 3.2% buffered sodium citrate (blue-top). After collection, immediately mix the sample with the anticoagulant by gently inverting the tube at least six times. Centrifuge and carefully remove the plasma. Plasma samples should be assayed within 24 hours, or stored frozen until they can be tested.

AUTOMATED ANALYZER APPLICATION

Suitable for two-reagent analyzers that can measure a rate reaction at an absorbance of 500 to 600 nm.

PROCEDURE

Materials Supplied

Reagent 1 (R-1) Buffer Reagent 2 x 9.5 mL
Reagent 2 (R-2) Latex Suspension 1 x 6 mL

Materials Required But Not Supplied

Calibrators: **K-*ASSAY*®** Factor XIII Calibrator, REF KAI-106C

K-*ASSAY*® Factor XIII Calibrator Diluent for use in high sample dilution and calibrator reconstitution/dilution (provided with **K-*ASSAY*®** Factor XIII Calibrator, REF KAI-106C).

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

Pipettes: capable of accurately dispensing the required volumes

Test Tubes: plastic

Assay Procedure

An example of standard protocol automated application:

Sample			3 µL
↓			
•	←	R-1 (Buffer Reagent)	150 µL
↓		37°C, 4.5 min	
•	←	R-2 (Latex Suspension)	50 µL
↓		37°C, 3.8 min	

Start read: 358 seconds, 546 nm, Final read: 498 seconds, 546 nm

Note: Allow all reagents and specimens to warm to room temperature (18-25°C). Mix all reagents gently before using.

Automated Method

Parameters for automated analyzers are available.

CALIBRATION

A multi-point calibration curve should be made using the **K-*ASSAY*®** Factor XIII Calibrator. It is recommended that the user determine calibration curve frequency as this depends on the instrument and type/number of other assays being performed. Initially, calibration should be performed each day.

QUALITY CONTROL

A quality control program is recommended for all clinical testing laboratories. It is recommended that at least two levels of control (with known concentrations of Factor XIII) be included in all assay runs.

Two levels of quality control material of known values should be run according to state, federal, and accreditation requirements or whenever there are questionable results or instrument performance, after analyzer maintenance or manufacturer's service, with each new lot of reagent, and at a minimum of every 30 days for opened vials to check storage conditions.

The values obtained for controls should ideally fall within the manufacturer's specified range. However, due to differences in assays and analyzers used to assay a control by the control manufacturer, a laboratory may establish its own control ranges by assaying the controls a sufficient number of times to generate a valid mean and acceptable range.

CALCULATIONS

Factor XIII levels are determined by the analyzer using the prepared calibration curve.

LIMITATIONS OF PROCEDURE

If Factor XIII value is greater than the highest calibrator value, dilute sample with **K-*ASSAY*®** Factor XIII Calibrator Diluent (provided with **K-*ASSAY*®** Factor XIII Calibrator, REF KAI-106C) and re-assay.

PERFORMANCE

Precision Assay

(Within Run)
The following results were obtained on a Stago STA-R Max analyzer with pooled human plasma:

	Sample I	Sample II
N	40	40
Mean	43.00 %	88.45 %
Std. Dev.	1.049	2.646
CV	2.44 %	2.99 %

Accuracy / Correlation

A comparison of the **K-*ASSAY*®** Factor XIII and another company's latex Factor XIII reagent was performed with the following results:

y = 1.1264x - 0.8644
r = 0.9714
n = 56
x = another company's latex Factor XIII
y = **K-*ASSAY*®** Factor XIII

Assay Range

4.3 % to 129 % (or value of highest calibrator)

EXPECTED VALUES

The expected value as reported in the scientific literature is between 53 and 221 %.[1] Due to population differences, each laboratory should establish its own expected values using this kit.

INTERFERENCE

Bilirubin F	No interference up to 19.7 mg/dL
Bilirubin C	No interference up to 22.0 mg/dL
Hemoglobin	No interference up to 450 mg/dL
Chyle (Formazine Turbidity)	No interference up to 2400 FTU
Rheumatoid Factor	No interference up to 570 IU/mL

REFERENCES

1. Bolton-Maggs PH, Perry DJ, Chalmers EA, et al. The rare coagulation disorders--review with guidelines for management from the United Kingdom Haemophilia Centre Doctors' Organisation. Haemophilia. 2004;10(5):593–628. doi:10.1111 / j.1365-2516.2004.00944.x PMID: 15357789.

LABELING SYMBOLS

REF	Catalog Number
	Expiration or "Use By" Date
LOT	Lot Number
	Consult Package Insert for Instructions for Use
IVD	For *In Vitro* Diagnostic Use
CE	CE Mark Registered
℞	For Prescription Use Only
2°C 8°C	Temperature Limitation. Store between 2 and 8 degrees C
	Manufacturer
EC REP	Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE

CE

EC REP

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