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.

**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 OPERATION**

Latex particles coated with antibody specific to human Factor XIII form immune complexes when incubated with plasma. The light scattering is measured by reading turbidity at 500 to 600 nm. Immune complexes cause an increase in light scattering, which is proportional to the concentration of Factor XIII in the plasma sample.

**KIT COMPOSITION**

- Reagents (Liquid Stable)
  - R1: Buffer Reagent
  - R2: Antibody Reagent
  - Latex suspension / Anti-human Factor XIII rabbit polyclonal antibody, Sodium Azide 0.05 %

**WARNINGS AND PRECAUTIONS**

- **FOR IN VITRO DIAGNOSTIC USE.** Rx 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 pipeette 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 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.

**SPECIMEN COLLECTION AND PREPARATION**

**Plasma**

White blood cells are centrifuged at 2,000 rpm for 15 minutes in a refrigerated centrifuge. After centrifugation, the separate plasma supernatant is used. The stored plasma can be used for up to 8 hours, or stored frozen if it can be tested.

**AUTOMATED ANALYZER APPLICATION**

Suitable for two-reagent automated analyzers that can measure a rate reaction at an absorbance of 550 to 600 nm. Use the instrument manufacturer's instructions for the instrument model used. It is recommended that at least two levels of control (with known concentrations of Factor XIII) be included in all assay runs.

**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.

**CALIBRATION**

The upper limit of detection is 200 IU/mL and the lower limit of detection is 2.3 IU/mL.

**INTERFERENCE**

No interference up to 19.7 mg/dL.

No interference up to 22.0 mg/dL. Bilirubin F

Hemoglobin

Chole (Formazine Turbidity)

Lysis

Pneumatob Factor

No interference up to 570 IU/mL.

**EXPECTED VALUES**

- **Factor XIII**
  - Mean: 100.0 IU/mL
  - 90% CI: 90.0 - 110.0 IU/mL

- **Calibrator Diluent**
  - Mean: 10.0 IU/mL
  - 90% CI: 9.0 - 11.0 IU/mL

**PERFORMANCE**

Precision Assay

Within Run

The following results were obtained on a Roche/Hitachi analyzer with pooled human plasma:

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean (%)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>100.0</td>
<td>0.9</td>
</tr>
<tr>
<td>2</td>
<td>100.0</td>
<td>0.9</td>
</tr>
<tr>
<td>3</td>
<td>100.0</td>
<td>0.9</td>
</tr>
</tbody>
</table>

**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 = 0.9602x - 0.035

r = 0.9946

n = 50

A calibration curve was used to evaluate the precision of the test.

**ORDERING / PRICING / TECHNICAL INFORMATION**

**KAWMIR BIOMEDICAL COMPANY**

12779 Gateway Darren, Seattle, WA 98168 USA

TEL: (206) 575-8068 / (800) 526-4025

FAX: (206) 575-8094

**EU AUTHORIZED REPRESENTATIVE**

Advena Ltd.

Tower Business Centre, 2nd Flr.,

Tower Street, Swatar, BKR 4013 Malta

**ORDERING / PRICE / TECHNICAL INFORMATION**

**KAWMIR BIOMEDICAL COMPANY**

12779 Gateway Darren, Seattle, WA 98168 USA

TEL: (206) 575-8068 / (800) 526-4025

FAX: (206) 575-8094

**K-ASSAY® Factor XIII**

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

Two Reagent Clinical Chemistry Analyzer:

- Capable of accurate absorbance readings at 500-600 nm
- Capable of accurately dispensing the required volumes

**K-ASSAY® Factor XIII Calibrator Diluent (provided with K-ASSAY® Factor XIII Calibrator, KAI-106C) and re-assay.**

**K-ASSAY® Factor XIII Calibrator Diluent (provided with K-ASSAY® Factor XIII Calibrator, KAI-106C).**

Pipetted: 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
- ● R-2 (Antibody Reagent) 50 µL

**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) and gently vortex 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 every day.

**LIMITATIONS OF PROCEDURE**

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