**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 test sample. The light scattering is measured by reading turbidity at 500 to 600 nm. The sample Factor XIII concentration is determined after dilution of an external standard of a Factor XIII standard curve.

**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**

- 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 lot 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 = 9.3). 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.

**STORAGE AND HANDLING**

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

**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: White 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 automated analyzers that can measure a rate reaction at an absorbance of 500 to 600 nm. Refer to the instrument manufacturer's protocol for details on the following:

- Use of function
- Calibration procedures and requirements
- Principles of operation
- Performance characteristics, operating instructions
- Calibration procedures including materials and/or equipment to be used
- Calibration procedures, imitations, and hazards
- Service and maintenance information

**PROCEDURE**

**Materials Supplied**

**K-ASSAY®** Factor XIII Calibrator, EXPIRED

- REAGENT KAI-105
  - Reagent 1 (R-1) Buffer Reagent 2 x 9.5 mL
  - Reagent 2 (R-2) Antibody Reagent 1 x 6 mL

**Materials Required But Not Supplied**

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

**ASSAY PROCEDURE**

- A two-reagent calibration curve should be made using the **K-ASSAY®** Factor XIII Calibrator. It is recommended that the user determine calibration curve factors as this depends on the instrument 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.

**CALCULATIONS**

- Factor XIII levels 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, KAI-106C) and re-assay.

**INTERFERENCE**

- Bilirubin
  - No interference up to 19.7 mg/dL
  - No interference up to 22.5 mg/dL
- Hemoglobin
  - No interference up to 450 mg/dL
  - No interference up to 2400 FTU
- Rheumatoid Factor
  - No interference up to 570 fU/mL

**EXPECTED VALUES**

- 71 - 140% based on a study involving 79 normal samples (using a 90% confidence interval). Each laboratory should establish its own normal range.

**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>Sample II</th>
<th>Sample III</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>10</td>
<td>16</td>
</tr>
<tr>
<td>Mean</td>
<td>96.72</td>
<td>54.77</td>
</tr>
<tr>
<td>Std. Dev.</td>
<td>0.6408</td>
<td>0.5945</td>
</tr>
<tr>
<td>CV</td>
<td>6.66</td>
<td>1.99</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 - 0.295
- r = 0.9946
- n = 50
- x = another company's latex Factor XIII
- y = **K-ASSAY** Factor XIII

**Lower Limit of Detection**

The lower limit of detection is 2.3 %

**ASSAY RANGE**

- 2.3 % to 140 % (or value of highest calibrator)

**LABELING SYMBOLS**

Lot Number
Principle of Operation
Expiration or "Use By" Date
Catalog Number
For In Vitro Diagnostic Use
Temperature Limitation: Store between 2 and 8 degrees C
Potential Human Biohazard
Manufacturer
Consult Package Insert for Instructions for Use Authorized Representative in the European Community

**ORDERING / PRICING / TECHNICAL INFORMATION**

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