**INTENDED USE**
The K-ASSAY® Plasma FDP Assay is an in vitro research reagent for the quantitative determination of fibrin/fibrinogen degradation products in human plasma. FOR RESEARCH USE ONLY IN THE U.S. Not for use in diagnostic procedures in the U.S.

**INTRODUCTION AND SUMMARY**
During fibrinolysis and fibrinogenolysis, plasmin breaks down fibrin and fibrinogen. When insoluble fibrin is degraded, a variety of cross-linked fibrin degradation products (FDP) are produced. When fibrinogen is degraded, non-cross-linked fibrinogen degradation products (FDP) are produced.

The K-ASSAY® Plasma FDP Assay measures both cross-linked fibrin degradation products and non-cross-linked fibrinogen degradation products in plasma with monoclonal antibody against D-monomer. It does not measure fibrinogen nor fragment E.

**PRINCIPLE OF TEST**
Latex particles coated with an antibody specific to human D-monomer form immune complexes in the presence of fibrin/fibrinogen degradation products from the sample. The immune complexes cause an increase in light scattering, which is proportional to the concentration of FDP in the plasma sample. The light scattering is measured by reading turbidity at 500 to 600 nm. The sample FDP concentration is determined versus dilutions of a FDP calibrator of known concentration.

**KIT COMPOSITION**
Reagents (Liquid Stable)
- R1: Buffer Reagent
- Tris Buffer, Sodium Azide 0.05%
- R2: Antibody Reagent
- Latex suspension / Anti-human D-monomer mouse monoclonal antibody, Sodium Azide 0.05%

**PROCEDURE**
Materials Supplied
- KAI-112 Calibrator
- Reagent 1 (R-1) Buffer Reagent 2 x 10.5 mL
- Reagent 2 (R-2) Antibody Reagent 1 x 6 mL
- Latex suspension / Anti-D-monomer mouse monoclonal antibody

**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 for 18 months from the date of manufacture as indicated on the expiration date 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. In the U.S., follow NCCLS guideline H3-A2. Plasma samples should be assayed within 24 hours, or stored frozen until they can be tested.

**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 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 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.

**CALCULATIONS**
- Plasma FDP levels are determined by the analyzer using the prepared calibration curve.

**LIMITATIONS OF PROCEDURE**
If Plasma FDP value is greater than the highest calibrator value, dilute sample with K-ASSAY® Plasma FDP Calibrator Diluent (provided with K-ASSAY® Plasma FDP Calibrator, Cat. No. KAI-112C) and re-assay.
### 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 I</th>
<th>Sample II</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Mean</td>
<td>5.185 µg/mL</td>
<td>18.515 µg/mL</td>
</tr>
<tr>
<td>Std. Dev.</td>
<td>0.1684</td>
<td>0.2159</td>
</tr>
<tr>
<td>CV</td>
<td>3.27 %</td>
<td>1.17 %</td>
</tr>
</tbody>
</table>

**Accuracy / Correlation**

A comparison of the K-ASSAY® Plasma FDP reagent and another company's Plasma FDP reagent was performed with the following results:

\[
y = 1.0025x - 0.7291 \\
r = 0.9795 \\
n = 52 \\
x = \text{another company's Plasma FDP assay} \\
y = \text{K-ASSAY® Plasma FDP Assay}
\]

**Lower Limit of Detection**

The lower limit of detection is 2 µg/mL.

**Assay Range**

2 µg/mL to 80 µg/mL (or value of highest calibrator)

### INTERFERENCE

- Bilirubin F: No interference up to 18 mg/dL
- Bilirubin C: No interference up to 20 mg/dL
- Hemoglobin: No interference up to 500 mg/dL
- Chyle (Formazine Turbidity): No interference up to 2,400 FTU
- Rheumatoid Factor: No interference up to 500 IU/mL

### LABELING SYMBOLS

- Lot Number
- Reagent Expiration or "Use By" Date
- Catalog Number
- 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

### EU AUTHORIZED REPRESENTATIVE

Advena Ltd.
Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013 Malta

### ORDERING / PRICING / TECHNICAL INFORMATION

KAMIVA BIOMEDICAL COMPANY
12779 Gateway Drive
Seattle, WA 98168 USA
TEL: (206) 575-8068 / (800) 526-4925
FAX: (206) 575-8094