INTENDED USE

The K-ASSAY® Serum/Urine FDP Assay is an in vitro research reagent for the quantitative determination of fibrin/fibrinogen degradation products in human serum and urine. 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 fibrin degradation products (FDP) are produced.

The K-ASSAY® Serum/Urine FDP Assay measures both cross-linked fibrin degradation products and non-cross-linked fibrinogen degradation products in serum and urine with a polyclonal antibody against human fibrinogen.

PRINCIPLE OF TEST

Latex particles coated with antibody specific to human fibrinogen form immune complexes in the presence of FDP from the sample. The immune complexes cause an increase in light scattering. 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 fibrinogen rabbit polyclonal antibody, Sodium Azide 0.05%

WARNINGS AND PRECAUTIONS

FOR RESEARCH USE ONLY IN THE U.S. Not for use in diagnostic procedures in the U.S.

False high FDP values may result if all the fibrinogen in the serum sample has not been completely converted to fibrin. Therefore, a dedicated FDP collection tube is recommended.

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.

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 STABILITY

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.

Pipettes: capable of accurately dispensing the required volumes

Test Tubes: glass or plastic

Two Reagent Clinical Chemistry Analyzer:

Capable of accurate absorbance readings at 500-600 nm

Capable of accurately dispensing the required volumes

Capsule of maintaining 37°C

ASSAY

Suitable for two-reagent automated analyzers that can measure a rate reaction at an absorbance of 500 to 600 nm. Refer to the instrument manual from the manufacturer regarding the following:

a) Use or function

b) Installation procedures and requirements

c) Principles of operation

d) Performance characteristics, operating instructions

e) Calibration procedures including materials and / or equipment to be used

f) Operational precautions, limitations, and hazards

g) Service and maintenance information

PROCEDURE

Materials Supplied

KAI-107

Reagent 1 (R-1) Buffer Reagent 2 x 12 mL
Reagent 2 (R-2) Antibody Reagent 1 x 5 mL

Materials Required But Not Supplied

Calibrators: K-ASSAY® Serum/Urine FDP Calibrator, Cat. No. KAI-108C

K-ASSAY® Serum/Urine FDP Calibrator Diluent for use in diluting high FDP serum samples and calibrator reconstitution / dilution (provided with K-ASSAY® Serum/Urine FDP Calibrator, Cat. No. KAI-108C).

K-ASSAY® Urine FDP Sample Diluent (only for use in diluting high FDP urine samples - Cat. No. KAI-109D).

Purified water.

ASSAY

An example of standard protocol automated application for testing serum samples:

Sample 3

↓

• R-1 (Buffer Reagent) 170 µL

↓

37°C, 4.5 min

• R-2 (Antibody Reagent) 40 µL

↓

37°C, 2.4 min

Start read: 323 seconds, 546 nm

Final read: 412 seconds, 546 nm

An example of standard protocol automated application for testing urine samples:

Sample 3

↓

• R-1 (Buffer Reagent) 135 µL

↓

37°C, 4.5 min

• R-2 (Antibody Reagent) 36 µL

↓

37°C, 4.1 min

Start read: 341 seconds, 546 nm

Final read: 516 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® Serum/Urine FDP 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.

Different calibration curves are prepared for serum and urine samples. Please refer to the K-ASSAY® Serum/Urine FDP Calibrator package insert and instrument applications.
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 FDP) 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

FDP levels are determined by the analyzer using the prepared calibration curve.

LIMITATIONS OF PROCEDURE

Serum
If FDP value is greater than the highest calibrator value, dilute sample with K-ASSAY® Serum/Urine FDP Diluent (provided with K-ASSAY® Serum/Urine FDP Calibrator, Cat. No. KAI-108C) and re-assay.

Urine
If FDP value is greater than the highest calibrator value, dilute sample with K-ASSAY® Urine FDP Sample Diluent (Cat. No. KAI-109D) and re-assay.

PERFORMANCE

Precision Assay
The following results were obtained on a Roche/Hitachi analyzer with pooled human serum or urine:

Accuracy / Correlation

Serum
A comparison of the K-ASSAY® Serum/Urine FDP reagent and another company’s Serum FDP reagent was performed with the following results on serum samples:

\[
\begin{align*}
    y &= 0.9697x + 0.2924 \\
    r &= 0.9990 \\
    n &= 62 \\
    x &= \text{another company’s FDP assay} \\
    y &= \text{K-ASSAY® Serum/Urine FDP Assay}
\end{align*}
\]

Urine
A comparison of the K-ASSAY® Serum/Urine FDP reagent and another company’s Urine FDP reagent was performed with the following results on urine samples:

\[
\begin{align*}
    y &= 0.9503x + 0.0448 \\
    r &= 0.9866 \\
    n &= 36 \\
    x &= \text{another company’s Urine FDP assay} \\
    y &= \text{K-ASSAY® Serum/Urine FDP Assay}
\end{align*}
\]

Lower Limit of Detection

Serum
The lower limit of detection is 0.2 µg/mL.

Urine
The lower limit of detection is 0.02 µg/mL.

Assay Range

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

Urine
0.02 µg/mL to 3.2 µg/mL (or value of highest calibrator)

INTERFERENCE

Serum and Urine

- Bilirubin F: No interference up to 20 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 3,000 FTU
- Rheumatoid Factor: No interference up to 570 kU/mL

LABELING SYMBOLS

- Lot Number
- 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

HAMIYA BIOMEDICAL COMPANY
12779 Gateway Drive
Seattle, WA 98188 USA
TEL: (206) 575-8068 / (800) 526-4925
FAX: (206) 575-8094