

Plasma FDP

For the Quantitative Determination of Fibrin/Fibrinogen Degradation Products in Plasma

Cat. No. KAI-111

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%

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.

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.

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 manual from the manufacturer regarding the following:

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

PROCEDURE**Materials Supplied**

KAI-111	
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

Materials Required But Not Supplied

Calibrators: **K-ASSAY**® Plasma FDP Calibrator,
Cat. No. KAI-112C

K-ASSAY® Plasma FDP Calibrator Diluent for use in high sample dilution and calibrator reconstitution/dilution (provided with **K-ASSAY**® Plasma FDP Calibrator, Cat. No. KAI-112C).

Purified water.

Two Reagent Clinical Chemistry 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		4 µL
↓		
• ← R-1 (Buffer Reagent)		160 µL
↓		
• ← R-2 (Antibody Reagent)		50 µL
↓		
		37°C, 4.4 min

Start read: 323 seconds, 546 nm
Final read: 534 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**® Plasma 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.

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 Plasma 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

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:

	Sample I	Sample II
N	20	20
Mean	5.185 µg/mL	18.515 µg/mL
Std. Dev.	0.1694	0.2159
CV	3.27 %	1.17 %

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 = another company's Plasma FDP assay

y = **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





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