

# Plasma FDP

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

<b>Cat. No. KAI-111</b>
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### 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      2 x 10.5 mL  
Tris Buffer

R2: Latex Suspension      1 x 6 mL  
Latex suspension / Anti-human D-monomer mouse monoclonal antibody

### 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.

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

Reagent 1 (R-1) Buffer Reagent	2 x 10.5 mL
Reagent 2 (R-2) Latex Suspension	1 x 6 mL

#### 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 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
↓	
• ←R1 (Buffer Reagent)	160 µL
↓	37 °C, 4.5 min.
• ←R2 (Latex Suspension)	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 (Example)

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 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
<b>N</b>	20	20
<b>Mean</b>	5.185 µg/mL	18.515 µg/mL
<b>Std. Dev.</b>	0.1694	0.2159
<b>CV</b>	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

	Catalog Number
	Expiration or "Use By" Date
	Lot Number
	Consult Package Insert for Instructions for Use
	CE Mark Registered
	Temperature Limitation. Store between 2 and 8 degrees C
	Manufacturer
	Authorized Representative in the European Community

## EU AUTHORIZED REPRESENTATIVE



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## ORDERING / PRICING / TECHNICAL INFORMATION



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