K-*ASSAY*®

Serum FDP

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

Cat. No. KAI-320

INTENDED USE

The **K-*ASSAY*®** Serum FDP Assay is an *in vitro* research reagent for the quantitative determination of fibrin/fibrinogen degradation products in human serum. 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*®** Serum FDP Assay measures both cross-linked fibrin degradation products and non-cross-linked fibrinogen degradation products in serum 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, which is proportional to the concentration of FDP in the serum 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 12 mL
Tris Buffer

R2: Latex Suspension 1 x 5 mL
Latex suspension / Anti-human fibrinogen rabbit polyclonal antibody

WARNINGS AND PRECAUTIONS

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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.

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 < 0.1% w/v 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 Center for Disease Control, Atlanta, GA., 1976.

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 refrigerated (2-8°C). Return all reagents to 2-8°C promptly after use.

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

Collect blood into a dedicated FDP tube. Centrifuge the tube at 3,000 rpm for 10 minutes. Serum is then separated and frozen if testing cannot be performed the same day. It is recommended that specimen collection be carried out in accordance with NCCLS document M29-T2.

INSTRUMENT

Measurement of absorbance is to be made with an instrument able to accurately read absorbances. 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

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

Materials Required But Not Supplied

Calibrators: **K-*ASSAY*®** Serum FDP Calibrator,
Cat. No. KAI-321C

K-*ASSAY*® Serum FDP Calibrator Diluent for use in diluting high FDP serum samples and calibrator reconstitution / dilution (provided with **K-*ASSAY*®** Serum FDP Calibrator, Cat. No. KAI-321C).

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: glass or plastic

Assay Procedure

Note: Allow all reagents and specimens to warm to room temperature. Mix all reagents gently before using.

An example of automated application:

Sample			3 μL
↓			
•	←	R-1 (Buffer Reagent)	170 μL
↓		37°C, 4.5 min	
•	←	R-2 (Latex Suspension)	40 μL
↓		37°C, 2.4 min	

Start read: 323 seconds, 546 nm
Final read: 412 seconds, 546 nm

Automated Method

Parameters for automated analyzers are available.

CALIBRATION

A multi-point calibration curve should be made using the **K-*ASSAY*®** Serum 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 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

If FDP value is greater than the highest calibrator value, dilute sample with **K-*ASSAY*®** Serum FDP Diluent (provided with **K-*ASSAY*®** Serum FDP Calibrator, Cat. No. KAI-321C) and re-assay.

PERFORMANCE

Precision

(Within Run)
The following results were obtained on a Roche/Hitachi analyzer with pooled human serum:

	Sample I	Sample II
N	20	20
Mean	3.97 μg/mL	14.42 μg/mL
Std. Dev.	0.0979	0.1725
CV	2.47%	1.20%

Accuracy / Correlation

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

y = 0.9697x + 0.2924
r = 0.9990
n = 62
x = another company's FDP assay
y = **K-*ASSAY*®** Serum FDP Assay

Lower Limit of Detection

The lower limit of detection is 0.2 μg/mL.

Assay Range

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

INTERFERENCE

Bilirubin, Conjugated	No interference up to 20 mg/dL
Bilirubin, Unconjugated	No interference up to 20 mg/dL
Chyle (Formazine Turbidity)	No interference up to 3,000 FTU
Hemoglobin	No interference up to 500 mg/dL
Rheumatoid Factor	No interference up to 570 IU/mL

LABELING SYMBOLS

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

EU AUTHORIZED REPRESENTATIVE

CE

EC REP

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