Fibrin Degradation Products Assay Kit (FDP)

Method: Latex Enhanced IT

Cat.NO.	Size	Instrument
GB8610M	R1:1×60ml R2:1×22ml	For Hitachi 7060/7150 & Shimadzu CL7200/8000
GS8611M	R1:1×60ml R2:1×22ml	For Hitachi 7170 & Olympus AU640/400/600
GX8611M	R1:1×60ml R2:1×22ml	For SYNCHRON CX5/7/9/LX20
GT8611M	R1:1×48ml R2:1×18ml	For TOSHIBA

INTENDED USE

For the quantitative in vitro determination of fibrin degradation products in serum or plasma.

CLINICAL SIGNIFICANCE

Fibrin degradation products reflects the fibrinolysis function. The level increases obviously in the following disease:

1. Primary fibrinolysis hyperfunction
2. Secondary fibrinolysis hyoerfunction:kidney disease, organ transplantation rejection,thrombolytic therapy and so on.
3. Vascular embolism disease: pulmonary embolism, myocardial infaraction, deep venous thrombosis.
4. Leukemia chemotherapy after the induction period, Hemorrhagic disease of grow in quantity of platelets,uremia,liver disease etc.

ASSAY PRINCIPLE

Latex particles coated anti-human FDP antibody reactes with FDP in the sample.The formation of immune complexes can be detected by changes in the turbidity at 600nm, and the FDP level is proportional to the degree of change in the sample.

REAGENT COMPOSITON

Contents	Concentration of Solutions
Reagent 1 (R1)	
Tris buffer	50 mmol/L
Reagent 2 (R2)	
latex particles of FDP antibody	0.1w/v%

SAMPLE COLLECTION AND PREPARATION

1. Fresh plasma (EDTA potassium,citric acid or heparin),or fresh serum in blood collection tube with antiplasmin and coagulant. Centrifuge the blood immediately after collection blood. Test the samples in a day. If not, store them at 4-8℃ for 1 day, at -80℃ for 1 month.
2. If the sample contains insolubles, please centrifuge or filter it before assay it.

STABILITY AND PREPARATION OF REAGENTS

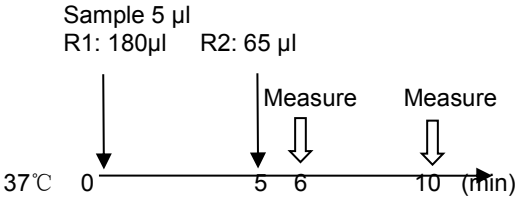
Stable up to the expiry date when stored at 2-8℃,protected from light and contamination is avoided. Do not freeze the reagents.

ASSAY PROCEDURE

Test Procedure for Analyzers (Hitachi7180)

Assay Mode: 2 Point End 19-28

Wave length (sub/main): 600nm



CALIBRATION

We recommend that this assay should be calibrated using Gcell calibrator GC-FDP.

CALCULATION OF RESULTS

FDP (µg/ml) = $\Delta A_{Sample}/\Delta A_{Std}$ x $Conc._{Std}$ (µg/ml)

QUALITY CONTROL

For quality control, use Gcell FDP Control as daily quality control sera and can be purchased separately. Values should fall within a specific range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

REFERENCE RANGE

≤ 5 µg/ml

It is recommended that each laboratory should assign its own normal range as this is dependent upon geographical location.

PERFORMANCE CHARACTERISTICS

LINEARITY

In the range of 2.5~ 80 µg/ml, the linear correlation coefficient r ≥ 0.990. In the range of 2.5 ~ 15 µg/ml (containing 15 µg/ml), linearity deviation shall not exceed ± 1.5 µg/ml. Between 15 ~ 80 µg/ml, the linear deviation should not exceed ± 10%.

PRECISION

The CV of the test should be ≤10%.

Intar assay precision		
N=20	level 1	level 2
Mean(µg/ml)	6.93	12.40
SD	0.32	0.42
CV(%)	4.62	3.39

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(µg/ml)	12.31	11.94	12.54

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$\bar{x}$	12.26
(Xmax-Xmin)/$\bar{x}$	(12.54-11.94)/12.26*100=4.89%

INTERFERENCE

The following analytes were tested up to levels indicated ang found not to interfere:

Bilirubin: up to 20mg/dl
Intralipid: up to 600mg/dl
Hemoglobin: up to 500mg/dl

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

1. R S Schifreen, G S Cembrowski, D C Campbell, etc. Clinical Chemistry. 31:1468-1473(1985).
2. J J Hoffmann and,M A Verhappen. Clinical Chemistry. 34:2135-2140(1988).

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

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