D-Dimer Assay Kit (D-D)

Method: Latex Enhanced IT

Cat. No.	Size	Instrument
GB9600M	R1: 1×60 ml R2: 1×20 ml	For Hitachi 717 & Shimadzu CL7200/8000
GS9601M	R1: 1×60 ml R2: 1×20 ml	For Hitachi917 & OlympusAU640/400/600

INTENDED USE

For the *in vitro* quantitative determination of D-Dimer in serum or plasma.

CLINICAL SIGNIFICANCE

D-Dimer containing moieties are formed by plasmin degradation of factor XIIIa cross linked fibrin. Elevated levels of D-Dimer are found in clinical conditions such as deep vein thrombosis (DVT), pulmonary embolism (PE) and disseminated intravascular coagulation (DIC). D-Dimer levels rise during pregnancy and high levels are associated with complications.

ASSAY PRINCIPLE

D-Dimer in serum or plasma reacts with antibody specific for human D-Dimer,which is coated with latex partical.The formation of antibody-antigen complex results in a increase of absorbance at 540nm.

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Tris	100mmol/L
Reagent 2 (R2)	
Latex coated with anti D-dimer monoclonal antibody	0.15%

SAMPLE COLLECTION AND PREPARATION

Use fresh patient serum or plasma samples.

Serum samples are stable for 7 days at 2-8℃, or 4 weeks at -20℃ (A single freeze-thaw cycle does not affect the assay response.) Serum separated by centrifugation as soon as possible after collection with collecting tube dedicated to FDP containing thrombin and aprotinin may have stability similar to that of citrated plasma.

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.

Stable up to the expiry date when stored at 2-8℃.

Once opened the reagent is stable for 1 month on-board the analyser at 2-8℃.

ASSAY PROCEDURE

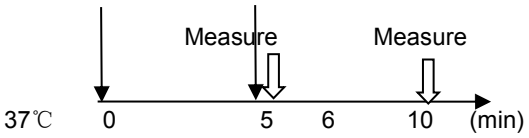
Test Procedure for Analyzers (Hitachi 7180)

Assay Mode: 2 Point End 18-27

Wave length (sub/main): 800/546nm

Sample 8 µl

R1: 150µl R2: 50 µl



CALIBRATION

Gcell D-Dimer calibrator (Cat. No: GC-D-D).

CALCULATIONS OF RESULTS

Plot calibrator concentrations against the corresponding ΔA values using graph paper. The concentration of D-Dimer in the sample is obtained by reading of a value from the calibration curve. Do not attempt to extrapolate above or below the range of the calibrators.

QUALITY CONTROL

Gcell D-Dimer Control (Cat.No: CQ-D-D).

The control intervals and limits should be adapted to each laboratory's individual requirement. Values obtained should fall within specified limits. If the control values fall outside these ranges and repetition excludes technical 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.

NORMAL RANGES

Serum/Plasma: < 1.0 µg/ml

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CE version 2014

It is recommended that each laboratory should establish its own normal range to reflect the age, sex, diet and geographical location of the population.

MAIN PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 40 μg/ml. If the concentration in sample is above this concentration, please dilute the sample with 0.9% NaCl and assay the sample repeatly. Multiply the result by the dilution fator.

PRECISION

The CV of the test should be ≤ 10%.

Intar assay precision		
N=20	level 1	level 2
Mean(μg/ml)	1.19	14.36
SD	0.04	0.04
CV(%)	3.69	0.29

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(μg/ml)	1.26	1.26	1.24
$\bar{x}$	1.25		
(Xmax-Xmin)/$\bar{x}$	(1.26-1.24)/1.25*100=1.12%		

INTERFERENCE

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

Bilirubin up to 20 mg/dl

Triglycerides up to 1000 mg/dl

Hemoglobin up to 500 mg/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

Shisou, K, Fujimaki, M: Fibrin/Fibrinogen degradation products (FDP) , Japanese Society of Laboratory Medicine (598): 892, 1989

Rylatt D.B.,et al: An immunoassay for human D dimer using monoclonal antibodies. Thromb. Res., 31(6):767,1983.

Shisou, K, Fujimaki, M: Assay of Stabilized FDP, Japan Society on Thrombosis and Homeostasis, 2(1): 82, 1991

INDEX OF SYMBOLS

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

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