TECO DIAGNOSTICS
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D-DIMER REAGENT

TC MATRIX-240/480

INTENDED USE
The test is applied for the quantitative determination of D-Dimer concentration.

SUMMARY AND PRINCIPLE[1, 2, 3, 4, 5]
Thrombin converts fibrinogen to soluble fibrin by cleaving the fibrinopeptides A and B. The fibrin monomers polymerize spontaneously. Active factor XIII links two D- domains and generates a solid fibrin clot. A new plasmin- resistant antigenic determinant ("D-Dimer") is produced. Fragments containing D-Dimer are accordingly formed during the degradation of a fibrin clot by plasmin.

A large proportion of the fibrin degradation products consist of high molecular weight X-oligomers.

D-Dimer has a strong affinity for these high molecular weight degradation products. Only during in vitro or lysis therapy does complete degradation of D-Dimer molecules occur.

Fractions containing D-Dimer are formed by plasmin degradation of fibrin cross-linked to factor XIII. 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.

D-Dimer in plasma reacts with antibody specific for human D-Dimer, which is coated with latex partical. The formation of antibody-antigen complex results in an increase of absorbance at 600nm.

REAGENTS
Each kit contains:

Reagent 1:

Tris buffer	100 mmol/L

Reagent 2:

Latex coated with anti D-dimer monoclonal antibody	0.15%

REAGENT PREPARATION
Reagents are ready for use.

PRECAUTIONS
IVD: For in Vitro Diagnostic use only.
Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines. Contains sodium azide.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

REAGENT STORAGE AND STABILITY[6]
Reagents are stable at 2-8°C until the expiration date stated on the label which is only for closed vials.

Once opened vials are stable for 30 days at 2-8°C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.
Reagent stability and storage have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

MATERIAL REQUIRED BUT NOT PROVIDED
1. At least two levels of control materials

SPECIMEN STORAGE
Use plasma samples.

Plasma specimens are stable for:
8 hours at 20-25°C,
4 hours at 2-8°C,
6 months at -20°C

A single freeze-thaw cycle does not affect the assay response.
Plasma is separated by centrifugation separated collector tube as soon as possible after collection, and thrombin and aprotinin containing FDP can have the same stability as citrated plasma.

PROCEDURE

Test Name:	D-DIMER	R1:	117
Full Name:	D-DIMER	R2:	32
Pri. Wave:	630 nm	SAMPLE VOLUME:	3.1
Sec. Wave:	/	Calibration Type:	Multilinear
Assay/ Point:	Fix-time	K Value:	/
Start - End:	18 - 32	Point:	3
Decimal place:	1	Blank Type:	Reagent
Unit:	ug FEU/mL	Point 0 (Blank) Con.:	0.0
Linearity Range:	0.01 - 12	Point 1 (CAL) Con.:	
Correlation Factor:	1.0000 - 0.0000	Point 2 (CAL) Con.:	

QUALITY CONTROL
Commercially available control material with established values determined by this method may be used.

CALIBRATION
The assay requires the use of a D-Dimer Calibrator set.

Calibration Stability: It strongly depends on the application characteristics of in-use auto analyzer and capacity of cooling. Calibration stability is 30 days.

Each laboratory should establish its own internal quality control scheme and procedures for corrective and preventive action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

REFERENCE INTERVAL (NORMAL VALUES)
Plasma < 0.5 ug FEU/mL

It is recommended that each laboratory establish its own normal range.

Reference interval has been verified by using Clinical and Laboratory Standards Institute (CLSI) EP28-A3c protocol.

PERFORMANCE CHARACTERISTICS
Limit of Detection (LoD): The limit of detection is 0.08 ug FEU/mL.

Limit of Quantitation [LoQ values are based on Coefficient of Variation Percentage (CV) % 20]:[8] 0.15 ug FEU/mL.

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

Comparison[10, 11]: Correlation with a comparative method is: r= 0.993 (Aralik 0.16 ug FEU/mL ile 8.55 ug FEU/mL)
According to Passing-Bablok equation:
Slope: 0.99
Intercept: 0.06

Prozone Effect: No prozone effect has been observed up to 450 mg/L value which is tested for CRP.

Precision[9]**:**

Repeatability

Mean Concentration (ug FEU/mL)	SD	CV	n
0.53	0.01	1.31%	20
2.94	0.03	1.02%	20

Reproducibility

Mean Concentration (ug FEU/mL)	SD	CV	n
0.76	0.02	2.32%	40
2.83	0.06	2.09%	40

Precision Studies data have been verified by using CLSI EP05-A3 protocol.

Linearity: The method is linear up to 10 ug FEU/mL.
For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.

Linearity may considerably vary depending on the instrument used.

INTERFERING SUBSTANCES [3, 4, 5, 12]
No significant interference was observed for hemoglobin, conjugated bilirubin, lipemia up to the interferent concentration given below.

Bilirubin: up to 15 mg/dL
Triglycerides: up to 700 mg/dL
Hemoglobin: up to 350 mg/dL

The acceptable interference limit is set 10% below the highest interference concentration within + 10% recovery of the target.

Interferences may affect the results due to medication or endogenous substances.

These performance characteristics have been obtained by using an analyzer. Results may vary if a different instrument or a manual procedure is used.

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