Red D-Dimer

CE | IVD | REF | D2010-012

In-Vitro-Diagnostic reagent for professional use

Intended Use

Immunoturbidimetric reagent for the quantitative determination of D-Dimer concentration in human plasma on optical Coagulometer at 600-800nm.

Fibrin fragments containing D-dimer antigen is always present in plasma as a result of plasmin degradation of cross-linked fibrin. After an injury, or when suffering from conditions associated with increased haemostatic activity, there is an increase in plasma D-dimer concentration. D-dimer determination has become a common aid in the diagnosis of thrombosis. Elevated levels of D-dimer are found in clinical conditions such as deep vein thrombosis (DVT), pulmonary embolism (PE) and disseminated intravascular coagulation (DIC) [1-4]. A negative D-dimer test result from a patient with a suspected thrombotic disorder has a high negative predictive value

Contents & Determinations

Product	Red D-Dimer (Kit)
REF.	D2010-012
Latex	3 x 4mL , containing BoviPolystyrene particles, coated with monoclonal antibodies, suspended in buffer with stabilisers and preservatives
Reaction Buffer	3 x 7 mL, containing buffer, Heterophilic Blocking Reagent (HBR), and preservatives.
Determinations	120 Det (on Coatron-X ECO)

Recommended additional material (not included in package)

Calibration	P8200-005 TECal DD, 5 x 1mL or plasma with known high level of D-Dimer. Dilution buffer to prepare calibrator levels like: A0593-035 Dilution Buffer, 5 x 7mL or A0590-125 IBS Buffer, 1 x 125mL or Normal saline (NaCl 0.9%) or Phosphate buffered saline (PBS)
Quality Control	P6001-010 TEControl N, 10 x 1mL P6101-010 TEControl A, 10 x 1mL

Preparation

Latex: liquid, ready to use. Swirl gently before use.
Reaction Buffer: liquid, ready to use.

Storage & Stability

Unopened reagents are stable until the expiration date shown on the label stored at 2°-8°C. Do not freeze. Opened reagent stored in original vial

Latex & Buffer	2-8 °C	20-25 °C	37°C
in closed condition	8 weeks	4 weeks	4 weeks
on-board - open condition	7 days	1 day	8 hours

Precautions

Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material. All components are checked for HIV, HBV, HCV. However, material should be considered as potentially infectious.

Specimen collection and storage[4]

1. Obtain venous blood by clean vein puncture.
2. Immediately mix 9 parts blood with 1 part sodium citrate (3.2% or 3.8%) and mix well
3. Centrifuge the specimen at 1500g for 15 min. (platelet < 10000/µL)
4. Separate plasma after centrifugation and store in plastic or siliconized glass tube.
5. Use plasma within 8 hours, otherwise store frozen and thaw just prior to use.

Procedure

A. Coatron A Method

See application book of device

B. Coatron X ECO Method

The performing is demonstrated on a video, which you can download on our website.

Pipette to empty cuvette	**25µL plasma**
Add	**100µL Reaction Buffer**
Incubate at 37°C	**1-2min**
Add	**100µL prewarmed Latex and mix well.**
	The device measures the rate of the Ag+Ab reaction between 15 –90s.

Laboratory techniques and requirements

1. Mix up & down at least 10x with pipette directly after adding latex reagent to obtain accurate results. Avoid air bubbles during mixing. Stop mixing latest 10sec after start. Dispose yellow tip after mixing.
2. Do not touch cuvette during measurement.
3. Very bright external UV light sources like sunlight will interfere result

Calibration Coatron X

A minimum of 3 calibration points is required. Prepare the concentrations according to table below, run in duplicates on device and transfer manually the results to its calibration curve.

	Concentration	Calibrator	Dilution Buffer
Cal. 1	~ 3200 ng/mL	200 µL TECal DD	-
Cal. 2	~ 1600 ng/mL	200 µL TECal DD	200 µL
Cal. 3	1 ng/mL	This point is not measured, but just entered as 1ng=0.001E	

A recalibration is suggested at least when control plasmas are not within the acceptable range and each time a new batch of reagent is used.

Expected Results

D-Dimer results can be reported in D-dimer units (DDU) or Fibrinogen Equivalent Units (FEU). 1 FEU is equal to 2.50 DDU. Teco is using DDU in certificates. Results below 200 ng/mL DDU can be regarded as D-dimer negative and are typical for normal healthy normal subjects[4-6]. Elevated levels are observed in causes of PE, DVT (deep venous thrombosis), DIC, trauma[7], pregnancy and with age[8-9].

As there is no internationally established standard for D- dimer, the concentration of D-dimer in any given specimen may differ when determined using D-dimer assays from different manufacturers. Thus, each laboratory should establish its own reference intervals or cut-off levels or control ranges.

Quality Control

TEControl N & or other commercial DD control plasma should be used for reliable quality control of performance at a frequency in accordance with good laboratory practice (GLP).

Limitations

Interfering substances	Tolerance Sysmex CS Series
Bilirubin	Up to 50 mg/dL
Haemoglobin	Up to 100 mg/dL
Triglycerides	Up to 160 mg/dL
Heparin (UFH):	Up to 3 U/mL

Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain anti-mouse antibodies (HAMA), which may cause over-estimation of D-dimer values. The presence of rheumatoid factor may also result in falsely elevated D-dimer values.

Performance Characteristics

(Sysmex CS Series)

Reportable range: 125 -3500 ng/mL DDU
Results below should be considered as "<125".
Results above should be re-assayed 1:4 diluted with Saline Solution.

Precision: 400 ng/mL DDU CV. = 3.5% (within run)
1000 ng/ml DDU CV. = 2.6% (within run)

Hook effect: 100000 ng/mL DDU.
Samples with above DD levels may be reported as false negatives.

Diagnostic performance:

CUT-OFF	Sensitivity	Specificity	NPV	PPV
DDU=200ng/mL FEU=500ng/mL	95%	64%	98%	44%

Warranty

This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

References

1. HEIT, John A., et al. Determinants of plasma fibrin D-dimer sensitivity for acute pulmonary embolism as defined by pulmonary angiography. Archives of Pathology and Laboratory Medicine, 1999, 123.3:235-240.
2. BOUNAMEAUX, Henri, et al. Plasma measurement of D-dimer as diagnostic aid in suspected venous thromboembolism: an overview. Thrombosis and haemostasis, 1994, 71.01: 001-006.
3. PFITZNER, Susanne A., et al. Fibrin Detected in Plasma of Patients with Disseminated intravascular Coagulation by Fibrin-specific Antibodies Consists Primarily of High Molecular Weight Factor XIIIa-crosslinked and Plasmin- modified Complexes Partially Containing Fibrinopeptide A. Thrombosis and haemostasis, 1997, 78.09: 1069-1078.
4. LINDAHL, T. L., et al. Clinical evaluation of a diagnostic strategy for deep venous thrombosis with exclusion by low plasma levels of fibrin degradation product D-dimer. Scandinavian journal of clinical and laboratory investigation, 1998, 58.4: 307-316.
5. CLSI. Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline – Fifth Edition. CLSI document H21-A5. Wayne, PA: Clinical and Laboratory Standards Institute; 2008.
6. GARDINER, Chris, et al. An evaluation of rapid D- dimer assays for the exclusion of deep vein thrombosis. British journal of haematology, 2005, 128.6: 842-848.
7. MEISSNER, Mark H.; CHANDLER, Wayne L.; ELLIOTT, Jennifer S. Venous thromboembolism in trauma: a local manifestation of systemic hypercoagulability?. Journal of Trauma and Acute Care Surgery, 2003, 54.2: 224-231.
8. BALLEGEER, V., et al. Fibrinolytic response to venous occlusion and fibrin fragment D-dimer levels in normal and complicated pregnancy. Thrombosis and haemostasis, 1987, 58.08: 1030-1032.
9. KARIO, Kazuomi; MATSUO, Takefumi; KOBAYASHI, Hiroko. Which factors affect high D- dimer levels in the elderly?. Thrombosis research, 1991, 62.5: 501-508.

	Expiry date	IVD	In Vitro Diagnostica		Biological hazard	REF	Catalogue Number		Consult accompanying documents
	Store at 2-8°C	CE	EU conformity		Manufacturer	LOT	Lot. Number	EC REP	Authorized Representative