CE
In Vitro Diagnostic

Behnk Elektronik

BE DDimer Turbidimetric Immunoassay

Reagent for quantitative determination of D-Dimer (DD) in the human plasma

REF 771500:
BU (3 x7 mL) AC (3 x 4 mL), CAL (2 x 1 mL) DIL (2x 7 mL)

PRINCIPLE

BE DDimer reagent consists in sub-micron sized polystyrene particles coupled to monoclonal antibodies specific for D-Dimer. When plasma specimen containing D-Dimer is exposed to the reagent, the particles will agglutinate, giving rise to increased light-scattering. This phenomenon leads to an increase of absorbance measured at 400-800 nm which is proportional to the concentration of D-Dimer in the specimen.

CLINICAL SIGNIFICANCE [1] [2] [3] [4]

Fibrin fragments containing D-Dimer antigen is always present in plasma as a result of plasmin degradation. After an injury or in case of conditions associated with increased haemostatic activity, the D-Dimer concentration increases in plasma. The determination of D-Dimer concentration helps in the diagnosis of thrombosis. Deep vein thrombosis (DVT), pulmonary embolism (PE) and disseminated intravascular coagulation (DIC) are associated with elevated level of D-Dimer. A negative D-Dimer test result has a high negative predictive value for patient with a suspected thrombotic disorder.

REAGENTS

BU **DD BU** Reaction Buffer
Buffer
Preservatives < 0.1%

AC **DD AC** Latex Reagent
Polystyrene particles coated with monoclonal antibodies
Buffer
Preservatives < 0.1%

CAL **DD CAL** D-Dimer Calibrator
Lyophilised plasma enriched with D-Dimer
The concentration of this standard is batch-specific
(See **Assigned value on the label of the vial**)

Human Origin

DIL **DD DIL** Dilution Buffer
For dilution of D-Dimer Calibrator and to dilute plasma of patients.
According to 1272/2008 regulation, these reagents are not classified as dangerous.

SAFETY CAUTIONS

Behnk reagent kits are designated for professional in vitro diagnostic use.
Good Laboratory Practices must be applied during use of reagents, reference or control plasmas, and human samples and should be handled as potentially infectious.
For further information, Material Safety datasheet is available upon request.
Dispose of waste in accordance with the local regulations.

PREPARATION OF REAGENTS

CAL: Add 1ml of demineralised water. Close the vial and let stand for 15min at room temperature. Mix gently by swirling before use.
Other reagents are ready to use.

STABILITY AND STORAGE

Unopened vials stored at 2-8 °C are stable until the expiry date stated on the label.

- Once opened, when free from contamination, reagents BU, AC and DIL are stable for 2 weeks at 20-25°C and 4 weeks at 2-8° C.
- CAL: transfer the necessary quantity, well recapped and stored in the original vial. Once reconstituted and without contamination, standard (CAL) is stable for 12 hours at 20-25 °C, 1 week at 2-8 °C and 6 months at -20 °C.

SAMPLES COLLECTION AND HANDLING [5]

Plasma from careful venipuncture with anticoagulant ratio of 1/10 (trisodium citrate solution 0.109 M). Mix immediately the blood with anticoagulant.
Avoid drawing with a syringe that could result in the formation of micro-clots.
Centrifuge 10 minutes at 2500 g.

LIMITS [8]

This test should be used with other clinical and diagnostic information in order to diagnose and manage patients.
Patients who have received mouse monoclonal antibodies for diagnosis or therapy may have plasmas containing anti-mouse antibodies (HAMA). Such antibodies may lead to false enhance D-Dimer concentration. The same may occur with Rheumatoid Factor.
For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment
2. Coagulation analyzer useful with turbidimetric detection (400-800 nm wavelength)
3. Demineralised water

EXPECTED VALUES [6] [7]

- Plasma: < 200 ng/mL (DDU)

D-Dimer concentrations increase during pregnancy and with age.
Each laboratory should establish its own normal ranges for the population that it serves.

CALIBRATION

REF 771500: **DD CAL** D-Dimer Calibrator

This Standard is traceable to an In-House Reference Preparation which underwent a one-time value assignment to align with another commercially available assay which reports results in ng/mL (DDU).

Follow the D-Dimer calibration procedure of the analyzer.

QUALITY CONTROL

REF 773200 BE DDTrol 1 and REF 773201 BE DDTrol 2
Controls are required for checking the accuracy and reproducibility of the results.
The control intervals should be adapted to each laboratory's individual requirements.
Values obtained should fall within the defined limits.
Follow the applicable government regulations and local guidelines for quality control.

PROCEDURE

Automated method on Behnk Thrombolyzer series
Refer to the full detailed application specific to the automated system
Note:

- Performances and stability data have been validated on Thrombolyzer Compact X (available on request).
- Procedure on other automated coagulation analyzer, performances and stability data must be validated by user.

CALCULATION [6]

Results are expressed in DDU directly given by the analyser.
To convert results in Fibrinogen eq. units (FEU), multiply the result (DDU) by 2.5.

PERFORMANCES

The within run and between run studies were performed with two levels (middle and high) of plasma on Thrombolyzer Compact X:

Within Run N=40	Level 1	Level 2
Mean (ng/mL)	595	1203
S.D.:	11,2	33,3
C.V. % :	1,9	2,8

Run to run N=40	Level 1	Level 2
Mean (ng/mL)	595	1203
S.D.:	6,4	25,9
C.V. % :	1,1	2,2

Detection limit: approx. 98 ng/mL
Prozone effect: tested up to 97468 ng/mL, no effect found within the measuring range (approx. up to 6363 ng/mL)
Measuring range: between 100 (QL) and 3200 ng/mL
Cut off: 150 ng/mL
Comparison with a commercially available reagent (same method) on Thrombolyzer Compact X and Sysmex CA-1500: using 50 specimens between 114 and 3095 ng/mL:
y = 0.95 x r = 0.9742
Interferences:

Lipids	No interference up to 200 mg/dL
Bilirubin	No interference up to 855 µmol/L
Low molecular weight Heparin	No interference up to 100 U/mL
Non-fractioned Heparin	No interference up to 100 U/mL

Other substances may interfere with the results (see § Limits)
Calibration Stability:
Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

REFERENCES

(1) Heit, J.A. et al. Determinants of plasma fibrin D-Dimer sensitivity for acute pulmonary embolism as defined by pulmonary angiography. Arch Pathol Lab Med, 123:235-239,1999
(2) Bounameaux, H., et al. Plasma measurement of D-Dimer as diagnosis aid in suspected venous thromboembolism: an overview. Thromb Haemostas, 71:1-6,1994
(3) Pfitzner S.A. et al. Fibrin detected in plasma of patients with disseminated intravascular coagulation by fibrin-specific antibodies consists primarily of high molecular weight factor XIII-cross linked and plasmin-modified complexes partially containing fibrinopeptide A. Thromb Haemostas, 78: 1069-1078, 1997
(4) Lindhal T. et al. Clinical evaluation of a diagnosis strategy for deep venous thrombosis with exclusion by low plasma levels of fibrin degradation product D-Dimer. Scan J Lab Invest, 58: 307-316, 1998
(5) CLSI Approved Guideline H21-A5
(6) Edlund and Nilsson, A proposed stochiometrical calibration procedure to achieve transferability of D-DIMER measurements and characterize the performance of different methods. Clin Biochem, 39:137-142, 2006.
(7) Gardiner, C. Et al. An evaluation of rapid D-Dimer assays for the exclusion of deep vein thrombosis. British Journal of Haematology, 128:842-848, 2005
(8) YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p 3 216 to 3-216

Manufacturer	Use by	In Vitro Diagnostic	Temperature limitation	Catalogue number	See insert	Batch number	Store away from light	Sufficient for	Dilute with	Demineralized water	Biological hazard
		IVD		REF		LOT			→	H2O	

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