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D-Dimer for DIAcheck & Coalyser

Diagnostic Reagent for the quantitative in vitro determination of D-Dimer in human plasma on DIACheck devices and Coalyser.

REF	Cont.	
T099702	**1 x 5 mL**	**D-Dimer Latex Reagent**
	1 x 7 mL	**D-Dimer Reaction Buffer**
	1 x 7 mL	**Diluent**
	1 x 1 mL	**D-Dimer Calibrator (lyo.)**
	1 x 1 mL	**D-Dimer Control Low (lyo.)**
	1 x 1 mL	**D-Dimer Control High (lyo.)**
T099703	**2 x 5 mL**	**D-Dimer Latex Reagent**
	2 x 7 mL	**D-Dimer Reaction Buffer**
	1 x 7 mL	**Diluent**
	1 x 1 mL	**D-Dimer Calibrator (lyo.)**
	1 x 1 mL	**D-Dimer Control Low (lyo.)**
	1 x 1 mL	**D-Dimer Control High (lyo.)**

For professional in vitro diagnostic use only.

GENERAL INFORMATION

Method: Immunoturbidimetric Assay
Wavelength: 400-600 nm
Temperature: 37°C
Sample: Sodium Citrate Plasma

Number of Tests
T099702 62 Tests on DIAcheck
T099703 125 Tests on DIAcheck

DIAGNOSTIC IMMPLICATION AND TEST PRINCIPLE

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. The determination of D-Dimer has become a prevalent 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. Dialab D-Dimer for DIACheck & Coalyser consists of sub-micron sizes polystyrene particles coupled to monoclonal antibodies specific for D-Dimer. When the reagent is exposed to a D-Dimer containing plasma sample, the particles will agglutinate, giving rise to increased light-scattering. When exposed to the appropriate wavelength of light, the increase in measured turbidity, or light-scattering, is proportional to the amount of D-Dimer in the sample.

REAGENT COMPOSITION AND PREPARATION

D-Dimer Latex Reagent: liquid, ready to use, polystyrene particles, coated with monoclonal antibodies, suspended in buffer with stabilisers and sodium azide (<0.1%) as a preservative. As the micro-particles will settle during storage, swirl the vial gently a few times each day before it is used, to ensure a homogenous suspension. Do not shake.
D-Dimer Reaction Buffer: liquid, ready to use, containing buffer and sodium azide (<0.1%) as preservative.
Diluent: 0.9% Saline solution with sodium azide (<0.1%), ready to use
D-Dimer Calibrator, D-Dimer Control Low/High: contain lyophilized citrated plasma of human origin enriched with D-Dimer. Reconstitute with 1mL distilled water. Keep the reconstituted calibrator/control at 15-25°C for 15-30 minutes and verify that the lyophilised cake is completely dissolved before use.

REAGENT STABILITY AND STORAGE

Conditions: protect from light
Storage: at 2 - 8°C
Stability: up to the expiration date shown on label

Opened/reconstituted reagents:

Storage:	at 2 - 8°C	8 – 25°C
Stability of Latex & Buffer	4 weeks	2 weeks
Stability of Calibrator	10 hours	10 hours
Stability of Controls	54 hours	54 hours

SAMPLE COLLECTION AND STORAGE

Venous blood is collected in 0.11 or 0.13 M trisodium citrate at a ratio of 9 parts blood to 1 part anticoagulant (1:10 ratio). The ratio is critical. If using commercial vacuum tubes, a full draw must be assured. Trauma or stasis during blood sampling should be avoided. The presence of a clot in a specimen is a cause for rejection.
Refer to CLSI guideline H21-A5 for further instructions on specimen collection, handling and storage 9.
Plasma samples can be stored at room temperature (18-25°C) for up to 4 hours; refrigerated (2-8°C) for up to 4 hours; frozen at -20°C for up to 2 weeks or at -70°C for up to 6 months. Frozen samples should be thawed rapidly and tested immediately. If testing cannot be performed immediately, the sample may be kept refrigerated (2-8°C) for maximally 2 hours prior to testing. No contact with glass should occur.

TEST PROCEDURE

	DIAcheck C1, C2, C4	Coalyser
Pipette into an empty cuvette	20 µL plasma	60 µL Plasma
Pipette into cuvette	40 µL Buffer	40 µL Buffer
Incubate at 37°C	2 minutes, activate channel	2 minutes
Pipette into cuvette	80 µL pre-warmed Latex Reagent and mix at least 5 x with pipette. Reading will begin automatically and mOD values will be displayed. Results are displayed in dOD (E)/min.	120 µL pre-warmed Latex

CALIBRATION

For the calibration curve prepare a dilution series of the calibrator with Diluent (saline solution, 0.9%). Use at least 3 calibration points. A new calibration curve must be run for each new lot of reagent and if the control values are outside the assigned range.

EXPECTED RESULTS

The D-Dimer results should be used together with other clinical and diagnostic information for forming a diagnosis. The normal level of D-Dimer in the population is typically below 200 ng/mL[4,5]. However, 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 range and cut-off values. Elevated levels of D-Dimer are found in patients with deep venous thrombosis (DVT), pulmonary embolism, disseminated intravascular coagulation and trauma[6]. D-Dimer levels increase during pregnancy[7] and with age[8]. D-Dimer results can be reported in units of D-Dimer (ng/mL) or in Fibrinogen Equivalent Units (FEU). 1 ng/mL D-Dimer is approximately 2 FEU, although a stoichiometric calibration would suggest a different theoretical conversion factor.

QUALITY CONTROL

D-Dimer Control Low and D-Dimer Control High or other commercially DD control plasma should be used for reliable quality control of performance at a frequency in accordance with good laboratory practice (GLP).

LIMITATIONS AND INTERFERENCE

D-Dimer for DIACheck & Coalyser is not affected by UF and LMW Heparin up to 100 U/mL, by Bilirubin up to 0,1 g/L, by Triglycerides up to 2,5 g/L and by Haemoglobin up to 4 g/L.
Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain anti-mouse antibodies (HAMA). Such antibodies may cause over-estimation of D-Dimer levels. The presence of rheumatoid arthritis factor may result in falsely elevated D-Dimer values. Turbid or opalescent plasma may cause erratic results and should be interpreted with caution; dilute the sample and re-assay.
The monoclonal antibody in D-Dimer for DIACheck & Coalyser has been screened for its specificity against cross-linked fibrin degradation products. D-Dimer for DIACheck & Coalyser has more than 100-fold specificity for D-Dimer (Fibrin or purified D-Dimer), over Fibrinogen, Fibrinogen D or Fragment E.

WARNINGS AND PRECAUTIONS

- Calibrator and controls contain material of human origin.
- The plasma used in the production is tested free of antibodies to HIV I and II, Hepatitis B and Hepatitis C. No test can however completely exclude the presence of infected material and the product should be treated as potentially infectious.
- Waste is disposed of according to local regulations.
- Wear appropriate clothing.
- Avoid contact with skin and eyes.

PERFORMANCE CHARACTERISTICS

Precision:
Within run precision was assessed over multiple runs using specific lots of reagents and control.
The coefficient of variation obtained in this study was ≤ 3%.

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

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5. 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
6. Meissner, M.H., Venous thromboembolism in trauma: a local manifestation os systemic hypercoagulability? J. Trauma, 54(2):224-231,2003.
7. Ballegeer, V. et al. Fibrinolytic response to venous occlusion and fibrin fragment D-dimer levels in normal and complicated pregnancy. Thromb Hamestasis 58: 1030-1032, 1987
8. Kario, K.et al Which factors affect high D-dimer levels in the elderly? Thromb Res, 65(5):501- 508, 1991
9. CLSI. Collection, Transport and Processing of Blood Specimens for testing Plasma-Based Coagulation Assays,5th Ed, CLSI document H21-A5, Vol. 28 No. 5

LOT-SPECIFIC DATA

	Lot	Unit	Value (DDU)
D-Dimer Calibrator	17388	ng/mL	2972
D-Dimer Control Low	16021	ng/mL	300
D-Dimer Control High	16004	ng/mL	830