

Dia-CONT Ddi



D-Dimer Control

Cat. No.: 09102 Dia-CONT Ddi N 2 x 1 ml

Cat. No.: 09202 Dia-CONT Ddi P 2 x 1 ml

Intended use

D-dimer containing moieties are formed by plasmin degradation of Factor XIII a 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) 1,2. D-dimer levels rise during pregnancy and high levels are associated with complications³. The negative predictive value of D-dimer for thrombosis is high⁴, although a negative D-dimer does not completely rule out thrombosis. The Dia-CONT Ddi N/P kit contains plasmas with low and high levels of D-dimer. The control plasmas are for use to control the laboratory systems functioning.



Warnings

The reagents contained in this kit are for *in vitro* diagnostic use only under professional's leadership.



Precaution

Potentially dangerous material – **DO NOT INGEST!** Wear gloves when handling all kit components. Plasma products have been screened and found negative (unless otherwise stated on the kit box or vial) for the presence of Hepatitis B Antigen (HbsAg) HIV 1 and 2 antibody and HCV antibody; however they

should be handled with the same precautions as a human plasma sample. All immunodepleted plasmas are HCV negative

Waste Material Treatment

Refer to the product safety data sheets for risk and safety phrases and disposal.

Materials provided

Component	Content	Description	Preparation
D-Dimer Control - N	2 x 1 ml	Each vial contains lyophilised D-dimer enriched human plasma.	Reconstitute each vial with 1 mL of saline solution. Allow to stand for 5 minutes and mix well before use. Do not shake.
D-Dimer Control - P	2 x 1 mL	Each vial contains lyophilised D-dimer enriched human plasma.	Reconstitute each vial with 1 mL of saline solution. Allow to stand for 5 minutes and mix well before use. Do not shake.
Each kit contains instructions for use.			
Each kit contains lot specific reference values insert.			

Materials required but not provided

Cat. No.: 07912 Dia-D-DIMER B

Cat. No.: 32075 Dia-D-DIMER

Cat. No.: 32120 Dia-D-DIMER



Storage and stability

Unopened vials are stable until the given expiry date when stored under conditions indicated on the vial or kit label. Reconstituted vials are stable for 5 days at +2 –+8°C, or 3 months at -20°C. Do not freeze / thaw more than once.



Procedure

Each control should be treated in the same manner as the unknown specimen in accordance with the instructions outlined in each particular test protocol.

Interpretation of results

Lot specific expected values are provided with each pack of controls. If the control results are outside the quoted ranges do not start the measurement of patients specimens.

Limitations

The values listed are for use with Diagon Ltd. D-dimer procedures only. The use of other D-dimer procedures and products may lead to erroneous results.

Quality control

Each laboratory should establish a quality control program. Normal and abnormal control plasmas should be tested prior to each batch of patient samples, to ensure satisfactory instrument and operator performance. If controls do not perform as expected, patient specimen measurements should not be started.

Reference values

Reference values can vary between laboratories depending on the techniques and systems in use. For this reason each laboratory should establish its own reference ranges.

Performance characteristics

The following performance characteristics have been determined by Diagon Ltd. using an opto-mechanical coagulation instrument. Each laboratory should establish its own performance data.

Reproducibility

		Intra-assay precision	Inter-assay precision
Sample	n	CV (%)	CV (%)
D-DimerControl - N	35	3,3	2,5
D-DimerControl - P	35	6,4	0,9

References

1. Elms MJ *et al* (1986) Rapid Detection of Cross-Linked Fibrin Degradation Products in Plasma Using Monoclonal Antibody-Coated Latex Particles, *J. Clin. Pathol*, **85**: 360-64.
2. Declerck PV *et al* (1987) Fibrinolytic Response and Fibrin Fragment D-dimer in Patients With Deep Vein Thrombosis, *Thromb. Haemost*, **58**: 1025-9.
3. Ballegeer V *et al* (1987) Fibrinolytic Response to Venous Occlusion and Fibrin Fragment D-dimer Levels in Normal and Complicated Pregnancy, *Thromb. Haemost*, **58**: 1030-2.

4. Hansson PO *et al* (1994) Can Laboratory Testing Improve Screening Strategies for Deep Vein Thrombosis at an Emergency Unit?, *J. Intern. Med*, 235: 143-51. HL-2-1188P 2012/07 (9) Dia-ContDdiControl N & P

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Symbols			
	In vitro diagnostics devices		Check in user manual
	Biohazard		Temperature range
	Manufacturer		Expiry date
	LOT number		CE conformity sign
	Catalogue number		