



1. Intended use

Nordic High D-dimer Control should be used as quality control plasma for Nordic Blue D-dimer (Ref K5001) and Nordic Red D-dimer (Ref K5002).

2. Summary and 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 hemostatic 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.

Nordic High D-dimer Control consists of pooled, normal human plasma that has been enriched with D-dimer. The D-dimer value is specifically assigned for each new lot manufactured, and is in the mid range of the D-dimer assays.

It is recommended that the High D-dimer Control is assayed at regular intervals in order to ensure consistent assay results. If the control plasma result deviates from the recommended range, a new standard curve should be constructed.

3. Composition

High D-dimer Control: 10 x 1 mL lyophilized human plasma enriched with D-dimer. Refer to the label on the vial for the lot-specific D-dimer range.

4. Warnings and precautions

For *in vitro* diagnostic use. Handling by trained laboratory personnel only.

The control contains material of human origin. Each donor has been tested by approved methods and found negative for the presence of HBsAg and anti-HIV I & II and anti-HCV. However, as no method can offer complete assurance that infectious agents are absent, this material should be handled as any potentially infectious material.

5. Reagent preparation, storage and stability

High D-dimer Control: Add 1.00 mL of high quality distilled water (Type II water, CLSI Approved Guideline C03-A4). Re-close the vial and let it stand still for approximately 15 minutes. Then gently mix by swirling or inverting several times until the contents are completely reconstituted. After reconstitution, stable for 12 hours at 4 - 25 °C.

6. Material required but not provided

Pipettes and high quality de-ionized water. Nordic Low D-dimer Control (Part # K5003).

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 diagnostic 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-crosslinked and plasmin-modified complexes partially containing fibrinopeptide A. *Thromb Haemostas*, 78: 1069-1078, 1997.
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. *Scand J Lab Invest*, 58: 307-316, 1998.



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