NAPTT Control-1

5-DIAGNOSTICS
Research and Diagnostic Solutions. Delivered.

Ref. 5D-44206A

For Research Only. Not for Use in Diagnostic Procedures.
For *in vitro* use only

Intended Use:

NAPTT Control-1 is a lyophilized preparation supplemented with activated Factor IX for use in NAPTT and other assays where a Factor IXa control is needed.

Contents:

NAPTT Control-1, 1 mL **6 vials**
Lyophilized preparation with Factor IXa, stabilizers and preservatives. Factor IXa concentration about 10 mIU/mL (exact value according to the attached CoA).

Reconstitution:

Reconstitute each vial with **1.0 mL** of distilled water and incubate at room temperature for 15 minutes while shaking the vial from time to time.

Storage:

Unopened reagents must be stored at **2-8°C** in original packaging box. They are then stable until the expiration date printed on the box. Do not freeze.

Stability after reconstitution:

- 8 hours at room temperature
- 24 hours at 2-8°C

Applications:

NAPTT Control-1 can be used as a control for NAPTT (ref.no. 5D-51426) or Factor IXa assays.

Each lot must be qualified for its compliance with the method used.

The results obtained should be for research use only and not for patient diagnosis or treatment.

Specification:

NAPTT Control-1 is calibrated against an internal standard which was calibrated against the 1st International Standard for Factor IXa (NIBSC 97/562).

Cautions:

Each donor unit used for the preparation of this control was tested and found negative by FDA accepted methods for Anti-HIV 1/2, Anti-HTLV I & II, HBsAg, Anti-HCV, Syphilis, HBC Ab, HIV-1 p24 Ag or HIV-1 RNA, HCV RNA and HBV RNA. However, no test can completely exclude the presence of infectious agents therefore any product of human origin must be considered as being potentially infectious and must be handled with all required cautions.

References:

1. European Pharmacopeia 8.0: 2.6.22. Activated Coagulation Factors.
2. Langdell RD, Wagner RH, Brinkhouse KM. J Lab Clin Med. 1953; 41; 637-647.

5D-44206A 2018-01-15 IFU.2.0

5-Diagnostics AG Heuberg 7 CH-4051 Basel, Switzerland
ordering@5-diagnostics.com | www.5-diagnostics.com
Tel: +41-61-588 0784 | Fax: +41-61-588 0786