



**5-CONTROL Factor IXa
positive control for NAPTT,
20 mIU**

6 x 1 mL

REF 5D-44206B

Store at 2-8°C

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

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5-CONTROL Factor IXa positive control for NAPTT, 20 mIU

REF	5D-44206B
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FIXa control for the quality control of Non-Activated Partial Thromboplastin Time (NAPTT) with 5-CLOT NaPTT reagent

**For Research Use Only.
Not for Use in Diagnostic Procedures.**

**Store at 2-8°C
6 x 1 mL**

English, last revision: 12-2018

INTENDED USE:

5-CONTROL Factor IXa positive control for NaPTT, 20 mIU is intended for the quality control of Non-Activated Partial Thromboplastin Time (NAPTT). This control is optimised using 5-CLOT NaPTT reagent (5D-51426).

This kit is for research use only and should not be used for patient diagnosis or treatment.

REAGENT SUPPLIED:

NAPTT Control (6 vials of 1 mL)
Lyophilized preparation, with stabilizers, supplemented with FIXa (at about 20 mIU/mL) (each vial to be restored with 1 mL distilled water).

The FIXa concentration and the acceptance ranges are indicated for each lot on the flyer provided within the kit.

Note:

- An antibiotic is added as preservative.
- The reagent contains Bovine Serum Albumin (BSA), prepared from bovine plasma, which was tested for the absence of infectious agents, and collected from animals free from BSE. However, no assay may warrant the total absence of infectious agents. Any product of biological origin must then be handled with all the required cautions, as being potentially infectious.

STORAGE CONDITIONS

Unopened reagents must be stored at 2-8°C. Kept in their original packaging they are then stable until the expiration date printed on the kit.

Note:

The stability studies for 3 weeks at 30°C show that the reagents can be shipped at room temperature for a short period without damage.

PREPARATION AND STABILITY OF REAGENTS:

Preparation:

- Reconstitute each vial with exactly **1 mL** of distilled water.
- Shake thoroughly until complete dissolution of the content (vortex).
- Incubate at room temperature (18-25°C) for **15 minutes**, while shaking the vial from time to time.
- Homogenise the content before each use.

Stability after reconstitution, in their original vial, and provided any contamination or evaporation is avoided:

- 24 hours at 2-8°C.
- 8 hours at room temperature (18-25°C).
- Do not freeze.

Cautions:

- In order to improve stability, reagents must be closed with their original screw caps following each use.
- Reagents must be handled with care, in order to avoid any contamination during use.
- It is recommended to homogenize each vial before use, in order to have a good reproducibility, all the time.

TRACEABILITY ON CONTROL MATERIALS:

NAPTT Control is calibrated against an Internal Reference Standard, initially validated by reference to the 1st International Standard for activated Factor IX (FIXa), human (NIBSC) (code 97/562).

CONCENTRATION

The exact concentration of this control may present variations from lot to lot, but it is exactly determined for each lot.

The FIXa concentration and the acceptance range are indicated for each lot on the flyer provided within the kit.

The following example shows the FIXa concentration indicated for one lot of 5-CONTROL Factor IXa positive control for NaPTT (obtained on STAR):

5-CONTROL Factor IXa positive control	FIXa (mIU/ml)	Acceptance range (mIU/ml)	Intra assay		Inter assay	
			N	SD	N	SD
NAPTT Control	19.9	16.9 – 22.9	6	0.71	9	0.72

NAPTT Control usually has a concentration of 20 ± 5 mIU/mL.

QUALITY CONTROL:

NAPTT Control is proposed for the quality control of Non-Activated Partial Thromboplastin Time (NAPTT) measurements, using 5-CLOT NAPTT reagent (5D-51426).

If controls are out of the acceptance range, the test series should be invalidated, and the assay should be rerun. Check all the components of the test system, before rerunning the assay.








CAUTIONS:

- Let each vial stabilize for 15 minutes at room temperature and shake gently before each use in order to homogenize the contents.
- Reagents must be handled with care, in order to avoid any contamination during use. Any reagent presenting an unusual aspect or a contamination sign must be rejected.

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

SYMBOLS:

Symbols used and signs listed in the ISO 15223-1 standard, see Symbol definitions below.

	Catalog number
	Batch code
	Expiration date
	Reconstitution volume
	YYYY-MM-DD Use by
	See instruction for use
	Temperature limitation