

BIOPHEN®
FXIa CONTROL SET
Ref 224801



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Two levels of FXIa controls for the quality control of FXIa measurements with chromogenic FXIa assay (BIOPHEN® FXIa)

FOR RESEARCH USE ONLY.
NOT FOR USE IN DIAGNOSTIC PROCEDURES.

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ENGLISH:

INTENDED USE:

BIOPHEN® FXIa Control Set is a set of controls intended for the quality control of activated Factor XI (FXIa) activity measurements, using BIOPHEN® FXIa colorimetric assay. This kit is optimized using BIOPHEN® FXIa assay.

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

REAGENTS:

C1: Control 1

Lyophilized preparation, with stabilizers, supplemented with FXIa (level 1 at about 10mIU/mL) – 3 vials of 1 mL.

C2: Control 2:

Lyophilized preparation, with stabilizers, supplemented with FXIa (level 2 at about 40mIU/mL) – 3 vials of 1 mL.

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

CAUTIONS AND WARNINGS:

- Any product of biological origin must then be handled with all the required cautions, as being potentially infectious.
- 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.
- The disposal of waste materials must be carried out according to current local regulations
- 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. Take care to limit as much as possible any evaporation of the reagents during use, by limiting the liquid-air surface exchange. Evaporation reduces reagent stability on instrument board.
- 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:

Control plasma

Reconstitute each vial with exactly 1mL of distilled water, shake thoroughly for complete homogenization.

Let the reagent stabilize for 15 min at room temperature (18-25°C); while shaking the vial from time to time. Homogenize before each use.

Stability of reagent, provided that any contamination or evaporation is avoided, kept in its original vial or in a closed plastic microcentrifuge tube:

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

STORAGE CONDITIONS:

Reagents must be stored at 2-8°C, in their original packaging box. They are then usable until the expiration date printed on the box.

TRACEABILITY:

BIOPHEN® FXIa Controls set are calibrated against internal reference standard qualified against the NIBSC standard in force.

CONCENTRATION:

The following example shows the FXIa concentrations indicated for one lot of BIOPHEN FXIa Controls (obtained on STA-R®):

BIOPHEN® FXIa Control	FXIa mIU/mL	Intra assay		Inter assay	
		N	SD	N	SD
Level 1	10 mIU/mL	15	0.32	5	0.9
Level 2	40 mIU/mL	15	0.99	5	2.65

The control **C1** has usually a concentration of 10 mIU/mL.

The control **C2** has usually a concentration of 40 mIU/mL.

QUALITY CONTROL:

BIOPHEN® FXIa Controls (level 1 and 2) are proposed for the quality control of FXIa measurements, in FXI concentrates or in purified milieus, using **BIOPHEN® FXIa kit (#220412)**

They allow validating these calibration curves. They are especially useful for controlling the stability of the calibration curves, from run to run, when using a same lot of reagents.

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.

LIMITATION:

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

SYMBOLS:

Used symbols and signs listed in the ISO standard 15223-1.