

**BIOPHEN
FIXa CONTROL SET
Ref 224601**

Two levels of FIXa controls for the quality control of FIXa measurements with chromogenic FIXa assay (Biophen FIXa)

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

Last revision: 23/06/2014

ENGLISH**INTENDED USE:**

Biophen FIXa Control Set is a set of controls intended for the quality control of activated Factor IX (FIXa) activity measurements, using Biophen FIXa colorimetric assay. This kit is optimised using BIOPHEN FIXa assay.

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

REAGENTS SUPPLIED:**C1 : Control 1**

Lyophilized preparation, with stabilizers, supplemented with FIXa (level 1 at about 10 mIU/mL) (each vial to be restored with **1 mL** distilled water).
6 vials of 1 mL

C2 : Control 2:

Lyophilized preparation, with stabilizers, supplemented with FIXa (level 2 at about 20 mIU/mL) (each vial to be restored with **1 mL** distilled water).
6 vials of 1 mL

The FIXa concentrations 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 min**, 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:

BIOPHEN FIXa Controls are 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 each control may present variations from lot to lot, but it is exactly determined for each lot.

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

The following example shows the FIXa concentrations indicated for one lot of BIOPHEN FIXa Controls (obtained on STAR):

BIOPHEN FIXa Control	FIXa (mIU/ml)	Acceptance range (mIU/ml)	Intra assay		Inter assay	
			N	SD	N	SD
Level 1	12.0	9.6 – 14.4	6	0.34	9	0.67
Level 2	19.9	16.9 – 22.9	6	0.71	9	0.72

The control **C1** has usually a concentration of 10 ± 5 mIU/mL.

The control **C2** has usually a concentration of 20 ± 5 mIU/mL.

QUALITY CONTROL:

BIOPHEN FIXa Controls (level 1 and 2) are proposed for the quality control of FIXa measurements, in FIX concentrates or in purified milieus, using **BIOPHEN FIXa kit (#221812)**.

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.

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.