BIOPHEN™ FXIa Control Set

REF 224801

C1 C2 3 x 1 mL

FXIa controls for the quality control of FXIa assay by chromogenic method.

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

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INTENDED USE:

BIOPHEN™ FXIa Control Set kits consist of lyophilized activated Factor XI (FXIa) at various concentrations, for the quality control of FXIa activity measurements.
They are titrated and optimized for the assay of FXIa by chromogenic technique.
This kit is for research use only and must not be used for patient diagnosis or treatment.

SUMMARY AND EXPLANATION:

Technical:
These controls are proposed for the quality control of chromogenic assays of FXIa in purified medium (BIOPHEN™ FXIa).

REAGENTS:

C1 **Control 1:** Lyophilized purified human FXIa containing a titrated quantity of FXIa of approximately 10 mIU/mL. Contains BSA.
C2 **Control 2:** Lyophilized purified human FXIa containing a titrated quantity of FXIa of approximately 30 mIU/mL. Contains BSA.

Controls contain stabilizing agents.

The control concentrations may vary slightly from one batch to another. For the assay, see the exact values indicated on the flyer provided with the kit used.

C1 C2 **3 vials of 1 mL**

WARNINGS AND PRECAUTIONS:

- Some reagents provided in these kits contain materials of human and animal origin. Whenever human plasma is required for the preparation of these reagents, approved methods are used to test the plasma for the antibodies to HIV 1, HIV 2 and HCV, and for hepatitis B surface antigen, and results are found to be negative. However, no test method can offer complete assurance that infectious agents are absent. Therefore, users of reagents of these types must exercise extreme care in full compliance with safety precautions in the manipulation of these biological materials as if they were infectious.
- Waste should be disposed of in accordance with applicable local regulations.
- Use only the reagents from the same batch of kits.
- Aging studies show that the reagents can be shipped at room temperature without degradation.
- This device of *in vitro* use is intended for professional use in the laboratory.

REAGENT PREPARATION:

Gently remove the freeze-drying stopper, to avoid any product loss when opening the vial.

C1 C2 Reconstitute the contents of each vial with exactly **1 mL of distilled water.**
Shake vigorously until complete dissolution while avoiding formation of foam and load it directly on the analyzer following application guide instruction.
For manual method, allow to stabilize for 15 minutes at room temperature (18-25°C), homogenize before use.

STORAGE AND STABILITY:

Unopened reagents should be stored at 2-8°C in their original packaging. Under these conditions, they can be used until the expiry date printed on the kit.

C1 C2 Reagent stability after reconstitution, free from any contamination or evaporation, and stored closed, is of:

- **24 hours** at 2-8°C.
- **8 hours** at room temperature (18-25°C).
- **Stability on board of the analyzer: see the specific application.**

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED:

Reagents:
- Distilled water.

Materials:
- Calibrated pipettes.

TRACEABILITY:

The FXIa concentration of the BIOPHEN™ FXIa Control Set provided in the kit is defined against the International Standard of reference for activated Factor XI (FXIa), human (NIBSC).

QUALITY CONTROL:

The BIOPHEN™ FXIa Control Set kit is used for the quality control of FXIa assays by chromogenic methods, such as those provided by BIOPHEN™ FXIa (220412) kit.
The use of quality controls serves to validate method compliance, along with between-series assay homogeneity for a given batch of reagents.
Include the quality controls with each series, as per good laboratory practice, in order to validate the test.
If the controls fall outside of the acceptance range, the series of assays must be invalidated and the analyses repeated. Check all system parameters before repeating the series.

LIMITATIONS:

- If the controls are used under measurement conditions other than those validated by HYPHEN BioMed, the test results may vary. The laboratory is responsible for validating the use of these controls in its own analytical system.
- Any reagent presenting an unusual appearance or showing signs of contamination must be rejected.

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

SYMBOLS:

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