BIOPHEN™ FVIIa Control Set

REF 224901

C1 C2 3 x 1 mL

IVD

FVIIa controls for the quality control of FVIIa assay by clotting method.

HYPHEN BioMed

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INTENDED USE:

BIOPHEN™ FVIIa Control Set kit consists of lyophilized activated Factor VII (FVIIa) at various concentration, for the quality control of FVIIa activity measurements.
They are titrated and optimized for the assay of FVIIa by clotting technique.

SUMMARY AND EXPLANATION:

Technical:
These controls are proposed for the quality control of clotting assays of FVIIa (HEMOCLOT™ Factor VIIa).
Clinical:
Recombinant activated Factor VII (rFVIIa) may be used for treatment of patients with haemophilia and inhibitors, or in various contexts of haemorrhage[1,2].

REAGENTS:

C1 **Control 1:** Lyophilized purified human FVIIa containing a titrated quantity of FVIIa of approximately 75 mIU/mL. Contains BSA.
C2 **Control 2:** Lyophilized purified human FVIIa containing a titrated quantity of FVIIa of approximately 250 mIU/mL. Contains BSA.

C1 C2 **3 vials of 1mL.**

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.

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* diagnostic 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 30 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.
- **12 hours** at room temperature (18-25°C).
- **2 months** frozen at -20°C or less*
- **Stability on board of the analyzer: see the specific application.**

*Thaw only once, as rapidly as possible at 37°C and use immediately.

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED:

Reagents:
- Distilled water.

Materials:
- Calibrated pipettes.

TRACEABILITY:

The determination of assigned value for controls is related to the International Standard for FVIIa.

QUALITY CONTROL:

The BIOPHEN™ FVIIa Control Set kit is used for the quality control of FVIIa assays by clotting methods, such as those provided by the HEMOCLOT™ Factor VIIa (CK092K) kit.
The control target values are determined with the HEMOCLOT™ Factor VIIa and multi-instrument (Sysmex CS-series or equivalent) tests.
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.

REFERENCES:

1. Kempton C.L. and Meeks S.L. Toward optimal therapy for inhibitors in hemophilia. Blood. 2014.
2. Mannucci M. and Franchini M. Recombinant factor VIIa as haemostatic therapy in advanced liver disease. Blood Transfus. 2013.

SYMBOLS:

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

C1 C2 H412: Harmful to aquatic life with long lasting effects.

Changes compared to the previous version.