BIOPHEN™ FVIIa Control Set

REF 224901

C1 3 x 1 mL, C2 3 x 1 mL

IVD

Controls at 2 levels of FVIIa for the quality control of FVIIa assay by clotting assay.

HYPHEN BioMed

Sales and Support:
CoaChrom Diagnostica GmbH
www.coachrom.com | info@coachrom.com
Tel: +43-1-236 222 1 | Fax: +43-1-236 222 111
Toll-free contact for Germany:
Tel: 0800-24 66 33-0 | Fax: 0800-24 66 33-3

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INTENDED USE:

BIOPHEN™ FVIIa Control Set kit is a set of controls intended for the quality control of activated Factor VII (FVIIa) activity measurements, using a clotting assay with the HEMOCLOT™ Factor VIIa (CK092K) kit.

SUMMARY AND EXPLANATION:

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 preparation of FVIIa with stabilizers,** level 1, of approximately 75 mIU/mL. Contains BSA.
3 vials of 1mL.

C2 **Control 2: Lyophilized preparation of FVIIa with stabilizers,** level 2, of approximately 250 mIU/mL. Contains BSA.
3 vials of 1mL.

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

WARNINGS AND PRECAUTIONS:

- Controls contain stabilizing agents.
- Biological products must be handled with all necessary precautions and considered as being potentially infectious.
- Waste should be disposed of in accordance with applicable local regulations.
- Handle the reagents with care to avoid contamination during use. If possible, avoid reagent evaporation during use by limiting the liquid-air exchange surface. Evaporation reduces the reagent's stability in the analyzer.
- To ensure reagent stability, seal the vials after use with their respective caps, or close the plastic micro-containers into which the controls may have been transferred, depending on the protocol used.
- Aging studies, conducted over a 3-weeks period at 30°C, show that the reagents can be shipped at room temperature over a short period of time, without degradation.
- The bovine plasma used to prepare the BSA has been tested by recorded methods and is certified free of infectious agents, in particular the causative agent of bovine spongiform encephalitis.
- For *in vitro* diagnostic use.

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

REAGENT PREPARATION AND STABILITY:

The reagents are lyophilized under a vacuum in their vials. To avoid any product loss when opening the vial of lyophilized reagents, gently remove the freeze-drying stopper.

C1 C2 **Controls 1 and 2**:
Reconstitute the contents of each vial with exactly **1 mL distilled water**, shake vigorously until fully dissolved.
Allow to stabilize for 30 min. at room temperature (18-25°C), shaking occasionally.
Homogenize prior to use.
Reagent stability after reconstitution, free from any contamination or evaporation, and stored in the original vial, is of:

- **24 hours** at 2-8°C.
- **12 hours** at room temperature (18-25°C).
- **1 month** at -20°C or less*

*Thaw only once, as rapidly as possible at 37°C, adapting the incubation period to the volume of reagent. The stability of the thawed reagent should be checked under laboratory work conditions.

STORAGE CONDITIONS:

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.

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 Factor VIIa.

PROPERTIES:

The BIOPHEN™ FVIIa Control Set (level 1 and 2) is used for the quality control of FVIIa assays, using the HEMOCLOT™ Factor VIIa (CK092K) kit.
The control target values are determined with the HEMOCLOT™ Factor VIIa (CK092K) kit 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 acceptable range, the series of assays must be invalidated and the analyses repeated. Check all system parameters before repeating the series.

LIMITATIONS:

- Any control showing signs of bacterial or fungal contamination must be rejected.
- 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.

REFERENCES:

1. Kempton CL and Meeks SL. Toward optimal therapy for inhibitors in hemophilia. Blood. 124(23):3365-72, 2014.
2. Mannucci M. and Franchini M. Recombinant factor VIIa as haemostatic therapy in advanced liver disease. Blood Transfus. 11: 487-90, 2013.

SYMBOLS:

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