BIOPHEN™ Calibrator Factor VIIa

CE
IVD

REF 226301
CAL 6 x 2 mL

Calibrator for FVIIa measurements with clotting assay.

HYPHEN BioMed
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INTENDED USE:

The BIOPHEN™ Calibrator Factor VIIa kit is a calibrator for activated Factor VII (FVIIa) activity measurements titrated and optimized 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:

CAL **Factor VIIa Calibrator** (established against highly purified human FVIIa), containing a titrated quantity of FVIIa of approximately 400 mIU/mL. Purified human Factor VIIa, lyophilised. Contains BSA.
6 vials of 2mL.

The calibrator 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:

- Calibrator contains 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 calibrators 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.

CAL 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.

CAL **Factor VIIa Calibrator**
Reconstitute the contents of each vial with exactly **2 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 calibrator is related to the International Standard for Factor VIIa.

PROPERTIES:

The BIOPHEN™ Calibrator Factor VIIa is used to establish a calibration curve to measure Factor VIIa levels by clotting method, such as that provided by HEMOCLOT™ Factor VIIa (CK092K) kit.
The calibrator 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.
A new calibration curve should be defined, preferably for each test series, and at least for each new reagent batch, or after analyzer maintenance, or when the measured quality control values fall outside the acceptable range for the method.

LIMITATIONS:

- Any calibrator showing signs of bacterial or fungal contamination must be rejected.
- If the calibrators 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 calibrators 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.