

BIOPHEN™ Apixaban Calibrator Low

REF 226101

CALI CALII CALIII 4 vials x 1 mL

IVD

BIOPHEN™ Apixaban Calibrator

REF 226201

CAL1 CAL2 CAL3 4 vials x 1 mL

English, revision: 11-2023

INTENDED USE:

For calibration of Apixaban assays, using a quantitative automated method. This device of *in vitro* diagnostic use is intended for professional use in the laboratory.

SUMMARY AND EXPLANATION:

Technical:

These calibrators are used to establish the calibration curve for anti-Xa chromogenic assays of Apixaban in plasma (BIOPHEN™ DiXal and BIOPHEN™ Heparin LRT, low range / standard range).

Clinical:

Measurement of Apixaban is performed in specific clinical situations to monitor the anticoagulant status. Particularly prior to emergency surgery, for patients presenting a risk factor associated with an hemorrhagic accident, for patients presenting thrombotic or hemorrhagic episodes, or in the event of suspected overdose.

REAGENTS:

- CALI** Lyophilized human plasma without Apixaban.
- CALII** Lyophilized human plasma containing approximately 50 ng/mL of Apixaban.
- CALIII** Lyophilized human plasma containing approximately 100 ng/mL of Apixaban.
- CAL1** Lyophilized human plasma without Apixaban.
- CAL2** Lyophilized human plasma containing approximately 300 ng/mL of Apixaban.
- CAL3** Lyophilized human plasma containing approximately 500 ng/mL of Apixaban.

Calibrator plasmas contain stabilizing agents.

The calibrator 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.

The product is classified as non-hazardous and is not subject to labeling according to EC Regulation No. 1272/2008 [CLP].

WARNINGS AND PRECAUTIONS:

- Some reagents provided in these kits contain materials of human 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.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.
- Summary of Safety and Performance (SSP) is available in the European database on medical devices (see Eudamed public website: <https://ec.europa.eu/tools/eudamed> or on request to HYPHEN BioMed).

REAGENT PREPARATION:

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.

CALI **CALII** **CALIII** **CAL1** **CAL2** **CAL3** 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.

This plasmatic reagent can be more or less turbid after reconstitution. This turbidity is mainly due to plasma lipids that, after freeze-drying, become "less" soluble and may form a slight deposit. If necessary, let each vial stabilize 10 minutes at room temperature and shake 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.

CALI **CALII** **CALIII** **CAL1** **CAL2** **CAL3** Reagent stability after reconstitution, free from any contamination or evaporation, and stored closed, is of:

- 7 days at 2-8°C.
- 60 days frozen at -20°C or less*
- Stability on board of the analyzer: see the specific Application Guide.

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

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED:

- Laboratory material.

TRACEABILITY:

Lot to lot variability measured on 3 lots is: %CV ≤ 10%.
 Calibrators are traceable to US Pharmacopoeia (USP) Reference Standard for Apixaban.
 Certificate of traceability and uncertainty is available on the HYPHEN BioMed website:

Uncertainty			
CALI	± 0.0 ng/mL	CAL1	± 0.0 ng/mL
CALII	± 2.4 ng/mL	CAL2	± 25 ng/mL
CALIII	± 5.8 ng/mL	CAL3	± 33 ng/mL

QUALITY CONTROL:

For calibration of Apixaban assays by anti-Xa methods (low range or standard range), with BIOPHEN™ DiXal (221030) and BIOPHEN™ Heparin LRT (221011 / 221013 / 221015) kits.

The target values are determined from multi-reagent and multi-instrument 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 established, 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 acceptance range for the method.

LIMITATIONS:

- 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.
- Any reagent presenting no limpid appearance or showing signs of contamination must be rejected.

REFERENCES:













1. Becker RC. *et al.*, Chromogenic laboratory assays to measure the factor Xa-Inhibiting properties of Apixaban-an oral, direct and selective factor Xa inhibitor. *J Thromb Thrombolysis*. 2011.
2. Douxfils J. *et al.*, Impact of Apixaban on routine and specific coagulation assays: a practical laboratory guide. *Thromb Haemost*. 2013.
3. Samama MM, Guinet C. Laboratory assessment of new anticoagulants. *Clin. Chem. Lab. Med.* 2011.

e-IFU (other languages) are available on www.hyphen-biomed.com.

For customer support or Application Guides, please contact your local provider or distributor (see www.hyphen-biomed.com).

Changes compared to the previous version.

The following symbols may appear on the product labeling:

.REF.	Catalogue number	.LOT.	Batch code	.IVD.	In-vitro diagnostic medical device
.Rx.	Numerical <x> identification of reagent		See instructions for use	.WHO STD.	WHO standard code
	Temperature limitation		Manufacturer		Use by YYYY-MM-DD
	CE marking of conformity with notified body ID number.		Reconstitution volume	.CONTENTS.	Contents
.Cx.	Numerical <x> identification of control	i-MA	See instructions in Method Application guide	.CONTAINS.	Contains
.EXP.	Expiration date		Contains sufficient for <n> tests	.UNIT.	Measurement unit
.TARGET VALUE.	Target Value		Keep away from sunlight and heat	.CALx.	Numerical <x> identification of calibrator
UDI	Unique Device Identifier		Contains biological material of animal origin		Contains human blood or plasma derivatives
.DANGER.	Danger	.WARNING.	Warning		UKCA marking of conformity
	Biological risks	ACCEPTANCE RANGE.	Acceptance range		