BIOPHEN™ Apixaban Calibrator

REF 226201

CAL1 CAL2 CAL3 4 x 1 mL

IVD

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Human plasmas for the calibration of Apixaban assays by the anti-Xa method.

Not for Sale in the US

English, last revision: 03-2018

INTENDED USE:

The BIOPHEN™ Apixaban Calibrator kit consists of lyophilized human plasmas, overloaded with Apixaban at various concentrations, for the calibration of Apixaban assays.
It is titrated and optimized for the assay of Apixaban by the anti-Xa chromogenic technique and, more specifically, for the BIOPHEN™ DiXal (221030) and BIOPHEN™ Heparin LRT (221011/221013/221015).

SUMMARY AND EXPLANATION:

Apixaban is an oral anticoagulant used for both curative and preventive purposes. Though monitoring is not needed in treated patients, measurement in human plasma may be of use in certain cases, particularly in the event of suspected overdosage (bleeding risk). These calibrators are used to establish the calibration curve of anti-Xa chromogenic assays of Apixaban in plasma.

REAGENTS:

CAL1 **Calibrator 1:**
Lyophilized human plasma containing no Apixaban (titrated quantity less than 50 ng/mL).
4 x 1 mL vials.
CAL2 **Calibrator 2:**
Lyophilized human plasma containing a titrated quantity of Apixaban of approximately 300 ng/mL.
4 x 1 mL vials.
CAL3 **Calibrator 3:**
Lyophilized human plasma containing a titrated quantity of Apixaban of approximately 600 ng/mL.
4 x 1 mL vials.

The calibrator Apixaban 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 plasmas contain stabilizing agents.
- Each pouch of human plasma used for kit preparation was obtained from healthy donors. Each plasma used was screened for the presence of the HBs antigen, of anti-HIV1, anti-HIV2 and anti-HCV antibodies, using approved methods, and found to be negative. Nevertheless, no tests can totally exclude the presence of infectious agents. For this reason, every precaution required for the use of potentially infectious products should be take when handling and disposing of plasma.
- 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 plasmas may have been transferred, depending on the protocol used.
- Aging studies, conducted over a 3-week period at 30°C, show that the reagents can be shipped at room temperature over a short period of time, without degradation.
- For *in vitro* diagnostic use.

REAGENT PREPARATION AND STABILITY:

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

CAL1 CAL2 CAL3
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:

- **7 days** at 2-8°C.
- **48 hours** at room temperature (18-25°C).
- **At least 2 months** frozen 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 Apixaban calibration plasmas are titrated relative to an Reference Internal Standard, whose qualification is linked to the reference method by LC-MS/MS.

PROPERTIES:

The BIOPHEN™ Apixaban Calibrator kit is used to establish a calibration curve to measure Apixaban levels by anti-Xa methods, such as those provided by BIOPHEN™ DiXal (221030) and BIOPHEN™ Heparin (LRT) kits (221011/221013/221015).
The calibrator target values are determined based on multi-reagent (BIOPHEN™ DiXal, BIOPHEN™ Heparin (LRT)) 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:

- Like all lyophilized plasmas, calibration plasmas are more or less turbid once resuspended. This turbidity is mainly due to plasma lipids that, after freeze-drying, become "less" soluble and may form a slight deposit.
- Any plasma displaying a coagulum or 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. 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.
2. Douxfils J. *et al*., Impact of Apixaban on routine and specific coagulation assays: a practical laboratory guide. Thromb Haemost. 2013 June; 110.2; 1-12.
3. Samama MM, Guinet C. Laboratory assessment of new anticoagulants. Clin. Chem. Lab. Med. 2011; 49(5), 761-772.

SYMBOLS:

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

Changes compared to the previous version.