BIOPHEN™ Apixaban Control

REF 225301-RUO

C1 C2 6 x 1 mL

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Human plasmas for the quality control of Apixaban assays by the anti-Xa method.
FOR RESEARCH USE ONLY.
DO NOT USE IN DIAGNOSTIC PROCEDURES.

English, last revision: 04-2017

INTENDED USE:

The BIOPHEN™ Apixaban Control kit consists of lyophilized human plasmas, overloaded with Apixaban at two concentrations, for the quality control 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-RUO) and BIOPHEN™ Heparin LRT (221011-RUO/221013-RUO/221015-RUO).
This kit should be used for research use only and must not be used for patient diagnosis or treatment.

REAGENTS:

C1 Control 1:
Lyophilized human plasma containing a titrated quantity of Apixaban of approximately 200 ng/mL.
6 x 1 mL vials.
C2 Control 2:
Lyophilized human plasma containing a titrated quantity of Apixaban of approximately 400 ng/mL.
6 x 1 mL vials.

The control 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:

- Control 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* 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.

C1 C2
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 control plasmas are titrated relative to a Reference Internal Standard, whose qualification is linked to the reference method by LC-MS/MS.

PROPERTIES:

The BIOPHEN™ Apixaban Control kit is used for the quality control of Apixaban assays by anti-Xa methods, such as those provided by the BIOPHEN™ DiXal (221030-RUO) and BIOPHEN™ Heparin (LRT) kits (221011-RUO/221013-RUO/221015-RUO).
The control target values are determined from 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.
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:

- Like all lyophilized plasmas, control 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 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.

The results obtained should be used for research use only and must not be used for patient diagnosis or treatment.

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.

SYMBOLS:

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

Changes compared to the previous version.