**INTENDED USE:**
The BIOPHEN™ Apixaban Control kits consist of lyophilized human plasmas, spiked with Apixaban at various concentrations, for the quality control of Apixaban assays. They are titrated and optimized for the assay of Apixaban by anti-Xa chromogenic technique. This kit is for research use only and must not be used for patient diagnosis or treatment.

**SUMMARY AND EXPLANATION:**
These controls are proposed for the quality control of anti-Xa chromogenic assays of Apixaban in plasma (BIOPHEN™ DiXal and BIOPHEN™ Heparin LRT, low range / standard range).

**REAGENTS:**
**C1** Control 1: Lyophilized human plasma containing a titrated quantity of Apixaban of approximately 25 ng/mL.
**CII** Control II: Lyophilized human plasma containing a titrated quantity of Apixaban of approximately 75 ng/mL.
**C1** Control 1: Lyophilized human plasma containing a titrated quantity of Apixaban of approximately 200 ng/mL.
**C2** Control 2: Lyophilized human plasma containing a titrated quantity of Apixaban of approximately 400 ng/mL.

The control plasmas contain stabilizing agents.

**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.
- Use only the reagents from the same batch of kits.
- The device of in vitro use is intended for professional use in the laboratory.

**REAGENT PREPARATION:**
Gently remove the freeze-drying stopper, to avoid any product loss when opening the vial.

**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.

**REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED:**
- Distilled water.
- Calibrated pipettes.

**QUALITY CONTROL:**
The BIOPHEN™ Apixaban Control kits are used for the quality control of Apixaban assays by anti-Xa methods (low range or standard range), such as those provided by the BIOPHEN™ DiXal (221030-RUO) and BIOPHEN™ Heparin LRT (221011-RUO/221013-RUO/221015-RUO) kits. The control target values are determined from multi-reagent (BIOPHEN™ DiXal, BIOPHEN™ Heparin LRT) and multi-instrument (Sysmex CS-series or equivalent tests).

**STABILITY:**
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:**
- 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.
- Any reagent presenting an unusual 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.

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

**Changes compared to the previous version.**