BIOPHEN™ Bivalirudin Control

CE

IVD

REF 225701

C1 C2 3 x 1 mL

Human plasmas for the quality control of Bivalirudin measurements by anti-IIa clotting and chromogenic methods.

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INTENDED USE:

The BIOPHEN™ Bivalirudin Control kit consists of lyophilized human plasmas, spiked with Bivalirudin at various concentrations, for the quality control of Bivalirudin assays.
They are titrated and optimized for the assay of Bivalirudin by anti-IIa clotting and chromogenic techniques.

SUMMARY AND EXPLANATION:

Technical:
These controls are proposed for the quality control of anti-IIa clotting and chromogenic assays of Bivalirudin in plasma (HEMOCLOT™ Thrombin Inhibitors and BIOPHEN™ DTI).
Clinical:
Bivalirudin can be used as an anticoagulant for curative indications, mainly in emergency situations. Measuring the Bivalirudin concentration in patients' plasma can be used for monitoring the therapy and adjusting drug dosage.

REAGENTS:

C1 **Control 1:** Lyophilized human plasma containing a titrated quantity of Bivalirudin of approximately 1.50 µg/mL.
C2 **Control 2:** Lyophilized human plasma containing a titrated quantity of Bivalirudin of approximately 4.00 µg/mL.

The control plasmas contain stabilizing agents.

The control 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.

C1 C2 **3 vials of 1 mL.**

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.
- Aging studies show that the reagents can be shipped at room temperature without degradation.
- This device of *in vitro* diagnostic 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.

C1 C2 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.
For manual method, allow to stabilize for 10 minutes at room temperature (18-25°C), homogenize before use.

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 stabilize each vial 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.

C1 C2 Reagent stability after reconstitution, free from any contamination or evaporation, and stored closed, is of:

- **7 days** at 2-8°C.
- **48 hours** at room temperature (18-25°C).
- **2 months** frozen at -20°C or less*
- **Stability on board of the analyzer: see the specific application.**

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

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED:

Reagents:
- Distilled water.

Materials:
- Calibrated pipettes.

TRACEABILITY:

The value assignment of controls is related to the corresponding Internal standard for Bivalirudin, initially standardized against a reference preparation of Bivalirudin.

QUALITY CONTROL:

The BIOPHEN™ Bivalirudin Control kit is used for the quality control of Bivalirudin assays in plasma by anti-IIa clotting and chromogenic methods, such as those provided by HEMOCLOT™ Thrombin Inhibitors (CK002K/CK002L) and BIOPHEN™ DTI (220202) kits.
The control target values are determined from multi-reagent (HEMOCLOT™ Thrombin Inhibitors, BIOPHEN™ DTI) 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 acceptance 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. Meddahi Samama. Les inhibiteurs directs de la thrombine, l'hirudine, la bivalirudine, l'argatroban, et le dabigatran etexilate. Journal des Maladies Vasculaires, 2011.

SYMBOLS:

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