BIOPHEN™ V-L Control Plasma

CE

IVD

REF 223405

C 12 x 0.5 mL

Pathological human plasma for the quality control of Factor V-Leiden assays by clotting method.

HYPHEN BioMed
155 rue d'Eragny, 95000 Neuville-sur-Oise, France
Tél : +33 (0)1 34 40 65 10
Fax : +33 (0)1 34 48 72 36
www.hyphen-biomed.com
info@hyphen-biomed.com

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INTENDED USE:

The BIOPHEN™ V-L Control Plasma kit consists of undiluted lyophilized human plasma, titrated at one concentration of Factor V-Leiden (FV-L), for the quality control of FV-L assay.
It is titrated and optimized for the quantitative assay of FV-L by clotting method.

SUMMARY AND EXPLANATION:

Technical:
Activated Protein C plays a role of regulator in the coagulation process by specifically inactivating activated Factors V (Va) and VIII (VIIIa), in the presence of co-factors. The resistance phenomenon to activated Protein C (APC) is due in more than 90% of cases to the R506Q mutation of Factor V called "Factor V Leiden". This mutation in Factor V exon 10 (1691 G → A) substitutes arginine at position 506 by glutamine, prevents this site cleavage by APC.
This control is proposed for the quality control of clotting assay of FV-L in plasma (HEMOCLOT™ Quanti. VL).
Clinical:
FV-L mutation is the most common hereditary thrombophilia risk factor. Its prevalence is about 5% in Caucasian populations. Patients carrying FV-L mutation have an increased risk of venous thrombosis, 3 to 7 fold in heterozygotes and up to 80 fold in homozygotes.
This genetic anomaly can be evidenced by clotting assay in the presence or absence of APC.

REAGENTS:

C **Control :** Undiluted lyophilized human plasma, containing a titrated quantity of FV-L of approximately 40% (plasma presenting APC resistance).
12 vials of 0.5 mL.

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.

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.

C Reconstitute the contents of each vial with exactly **0.5 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 30 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 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.

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

- **24 hours** at 2-8°C.
- **8 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 FV-L control plasma is qualified relative to an Internal Standard (presenting activated Protein C resistance at various levels).

QUALITY CONTROL:

The BIOPHEN™ V-L Control Plasma kit is used for the quality control of FV-L assays by clotting method, such as that provided by the HEMOCLOT™ Quanti. VL kit (CK065K).
The control target values are determined from 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. Bertina RM. *et al.* Mutation in blood coagulation factor V associated with Resistance to Activated protein C. Nature. 1994.
2. Segers K. *et al.* Coagulation factor V and thrombophilia: Background and mechanisms. Thromb Haemost. 2007.
3. Kadauke S. *et al.* Activated protein C resistance testing for factor V Leiden. American Journal of Hematology. 2014.
4. Freyburger G. and Labrouche S. Facteur V Leiden (VL) et résistance à la protéine C activée (PCA), facteur II Leiden (G20210 G>A), aspects physiopathologiques et stratégies diagnostiques. Spectra Biologie. 2007.

SYMBOLS:

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

Changes compared to the previous version.