

BIOPHEN™ V-L Plasma Calibrator

REF 222401

CAL1 CAL2 CAL3 3 x 0.5 mL

Human Plasmas for the calibration of Factor V-Leiden assays
by clotting method.

English, last revision: 01-2021

INTENDED USE:

The BIOPHEN™ V-L Plasma Calibrator kit consists of undiluted lyophilized human plasmas, titrated at various concentrations of Factor V-Leiden (FV-L), for the calibration of FV-L assay.

It is titrated and optimized for the 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.

These calibrators are used to establish the calibration curve for 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:

CAL1 Calibrator 1: Undiluted lyophilized human plasma, containing a titrated quantity of FV-L of approximately 10% (plasma presenting APC resistance) (level 1).

CAL2 Calibrator 2: Undiluted lyophilized human plasma, containing a titrated quantity of FV-L of approximately 25% (plasma presenting APC resistance) (level 2).

CAL3 Calibrator 3: Undiluted lyophilized human plasma, containing a titrated quantity of FV-L of approximately 50% (plasma presenting APC resistance) (level 3).

Calibrator plasmas contain stabilizing agents.

The calibrator 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.

CAL1 CAL2 CAL3 3 vials of 0.5 mL

Note: The 1:10 dilution of CAL3 in Imidazole buffer allows obtaining the first point of the calibration curve, at about 100% of FV-L (the exact concentration is twice the concentration "C" indicated on the corresponding flyer).

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.

CAL1 CAL2 CAL3 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.

CAL1 CAL2 CAL3 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).
- Stability on board of the analyzer: see the specific application.

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED:**Reagents:**

- Distilled water.
- Imidazole buffer (AR021B/AR021K/AR021L/AR021M/AR021N).

Materials:

- Calibrated pipettes.

TRACEABILITY:

The FV-L calibration plasmas are qualified relative to an Internal Standard (presenting activated Protein C resistance, at various levels).

QUALITY CONTROL:

The BIOPHEN™ V-L Plasma Calibrator is used to establish a calibration curve to measure FV-L levels in plasma by clotting method, such as that provided by HEMOCLOT™ Quanti. VL (CK065K) kit.

The calibrators 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.

A new calibration curve should be established, 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 acceptance range for the method.

LIMITATIONS:

- 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.
- Any reagent presenting an unusual appearance or showing signs of contamination must be rejected.

REFERENCES:

- Bertina R.M. *et al.* Mutation in blood coagulation factor V associated with Resistance to Activated protein C. Nature. 1994.
- Segers K. *et al.* Coagulation factor V and thrombophilia: Background and mechanisms. Thromb Haemost. 2007.
- Kadauke S. *et al.* Activated protein C resistance testing for factor V Leiden. American Journal of Hematology. 2014.
- Freyburger G. and Labrousse 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.