



# BIOPHEN

## V-L CAL (Undiluted)

### Ref 222401

For in vitro diagnostic use only

Last revision: 22/04/2011

#### **ENGLISH**

#### **INTENDED USE:**

Lyophilised, undiluted human plasmas, at defined Factor V-Leiden (FV-L) concentrations, for the calibration of Factor V-L activity quantitative clotting assay on human citrated plasma, using the HEMOCLOT Quanti. V-L kit (ref CK065K).

#### **REAGENTS:**

9 vials (3 sets of 3 vials) of 0.5ml of undiluted human plasma at different concentrations of FV-L, to cover the assay range, from about 10% to 100%. (3 vials for each concentration, 4 points for the calibration curve).

**CAL 1: Calibrator 1:** 0.5mL 3 vials.  
Undiluted human plasma, freeze-dried, containing FV-L (level 1 at about 10%) (to be restored with **0.5 mL distilled water**).

**CAL 2: Calibrator 2:** 0.5mL 3 vials.  
Undiluted human plasma, freeze-dried, containing FV-L (level 2 at about 25%) (to be restored with **0.5 mL distilled water**).

**CAL 3: Calibrator 3:** 0.5mL 3 vials.  
Undiluted human plasma, freeze-dried, containing FV-L (level 3 at about 50%) (to be restored with **0.5 mL distilled water**).

**Note:** The 1:10 dilution of calibrator 3 in Owren Koller buffer allows obtaining the first point of the calibration curve, at about 100% FVL (the exact concentration is twice the concentration indicated on the corresponding flyer).

**Note:** The exact concentration of FV-L may present variations from lot to lot, but it is exactly indicated for each lot, on the flyer provided in the kit.

The calibration curve covers the range from about 10% to 100% FV-L.

#### **Note:**

- Calibrator plasmas contain an antibiotic as preservative (ciprofloxacin).
- Each donor unit used for the preparation of plasmas is a human plasma, which has been tested with registered methods for the presence of Hepatitis B Surface Antigen, Hepatitis C Antibodies (HVC) and antibodies to HIV 1 and 2 and was found negative. However, no test can completely exclude the presence of infectious agents. Any product of human origin, and more especially plasma, must be considered as being potentially infectious and must be handled with all the required cautions for this kind of material.

#### **STORAGE CONDITIONS:**

Unopened reagents, must be stored at 2–8 °C, in their original packaging box. They are then stable until the expiration date printed on the kit.

**Note:** The stability studies at 30°C show that the reagents can be shipped at room temperature for a short period without damage.

#### **PREPARATION AND STABILITY OF REAGENTS:**

##### **1. Preparation :**

Reconstitute each vial with exactly **0.5 mL** of distilled water. Shake thoroughly until complete dissolution of the content (vortex). Incubate at room temperature (18-25°C) for 30 min, while shaking the vial from time to time.

Homogenise the content before each use.

**Note:** The indicated "C" concentration of FVL is obtained with a **1:20** dilution of each calibrator in **Owren Koller** type buffer, to establish the calibration curve of Hemoclot Quanti VL kit. The "**2C**" concentration (of about 100%) is obtained with a **1:10** dilution of calibrator 3 (CAL 3). Homogenise before each use.

##### **2. Stability of reconstituted reagents:**

When stored in the original vial, the stability of the reconstituted reagents is of:

- 24 hours at 2-8°C.
- 8 hours at room temperature (18-25°C).
- Do not freeze.

#### **Cautions:**

- The vials are closed under vacuum. Remove carefully the stopper, in order to avoid any lost of powder when opening the vials
- In order to improve stability, reagents must be closed with their original screw caps following each use.
- Reagents must be handled with care, in order to avoid any contamination during use.
- It is recommended to homogenize each vial before use, in order to have a good reproducibility, all the time.

#### **APPLICATION AND PERFORMANCE CHARACTERISTICS:**

BIOPHEN V-L calibration plasmas allow establishing the calibration curve for the quantitative measurement of Factor V Leiden in human citrated plasma, using the Hemoclot Quanti. V-L kit (ref. CK065K).

The exact concentration of FV-L may present variations from lot to lot, but it is exactly indicated for each lot, on the flyer provided in the kit

The BIOPHEN quality control plasmas (BIOPHEN Normal Control Plasma (ref 223201), and BIOPHEN Act PCR Control Plasma (ref 223405) can be used in order to obtain an homogeneous quality control system. The calibration curve is acceptable when the concentrations measured for the Control Plasmas are within the acceptance range. Each laboratory has to verify its own target value and acceptance range, according to the method used.

#### **CAUTIONS:**

- Like all lyophilised plasmas, the plasmas from the BIOPHEN V-L CAL (Undiluted) kit are more or less cloudy after reconstitution. This is due essentially to the lipids that, after lyophilisation, become less soluble and can form a light deposit.
- If necessary, let each vial stand 10 minutes at room temperature and shake gently before use in order to homogenise the content.
- Reagents must be handled with care, in order to avoid any contamination or activation during use. Any plasma containing a coagulum or contamination must be rejected.