

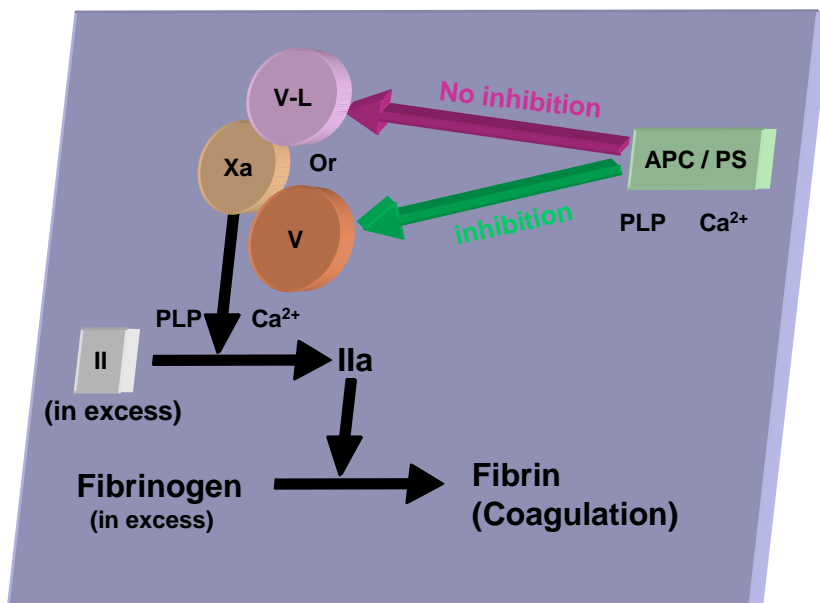


Measuring the APC Resistance associated with Factor V-L, quantitatively

HEMOCLOT Quanti. V-L (ACK065L) kit is a clotting method proposed for measuring Factor V-L (Factor V Leiden) concentration in citrated plasma, by its resistance to the action of Activated Protein C (APC). The assay is performed in the presence of Activated Protein C. In presence of APC and Protein S (in excess), the prolongation of clotting time is directly related to the concentration of Normal Factor V, and inversely related to the amount of Factor V-Leiden (mutation R506Q).

Clinical background

The Factor V-L is insensitive to the action of Activated Protein C. Its presence induces a prolonged coagulant activity in blood (due to a prolonged survival of Factor Va activity), following activation of coagulation. Patients with Factor V-L (mutation R506Q), are exposed to an increased thrombotic risk. This risk, already present in heterozygous patients, where the Normal Factor V and Factor V-L are both present, is strongly enhanced in homozygous patients, who only have Factor V-L.



Assay characteristics

- Quantitative reagent for measuring Factor V-L.
- No interference of plasma factor deficiencies (Other than that of Factor V).
- Excellent discrimination between Heterozygous, Homozygous and Normals.
- Single test method performed with only a Clotting Time (CT).

Adaptations on instruments available upon request

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Form AH11
04-2007

HEMOCLLOT Quanti. V-L

(Ref. ACK065K)

Kit composition

Reagent 1: R1

Clotting mixture:

Fibrinogen/Prothrombin/PS/APC/Polybren

Reagent 2: R2

Xa/Phospholipids

Assay principle

The **HEMOCLLOT Quanti V-L** Kit is a clotting method, triggered by purified Factor Xa, containing Phospholipids and Calcium, and is performed on the diluted tested plasma, in presence of Activated Protein C and Protein S. In the first step, the diluted plasma is mixed with purified clotting Factors (clotting mixture containing Prothrombin, Fibrinogen, Protein S and Activated Protein C (APC)), in a constant and optimised concentration. Then, the purified Factor Xa in presence of Phospholipids (PLP) is added. Clotting is initiated by the addition of Calcium (Ca²⁺). The clotting time is then recorded. Clotting time measured is inversely proportional to the concentration of factor V-L. There is an inverse linear relationship, on a bilogarithmic graph paper, between the factor V-L concentration and the corresponding clotting time.

HEMOCLLOT Quanti. V-L is now CE Marked and 510(k) approved

Calibration

The calibration curve can be established with the **Factor V-L Calibrator** kit (#ASC065K):

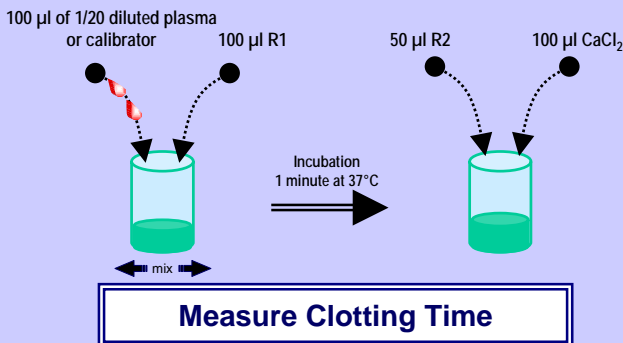
Factor V-L Calibrator is now CE Marked and 510(k) approved

Heterozygous Factor V-L Plasma Pool
(50% of Factor V \Rightarrow V-L)

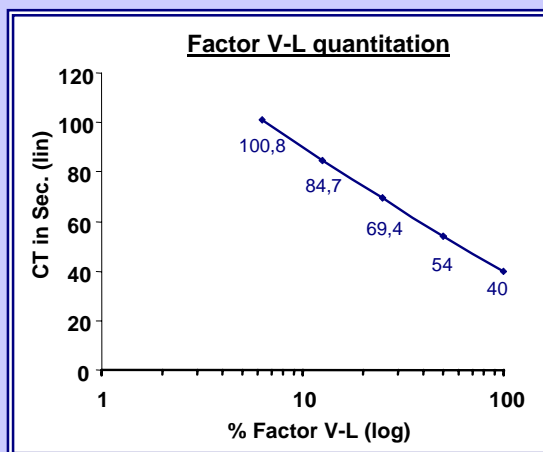
1/20 \Rightarrow 50% V-L

1/10 \Rightarrow 100% V-L

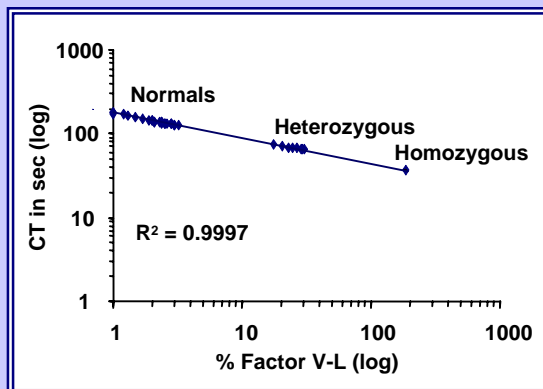
Protocole



Calibration curve



Assay of Factor V-L



NORMALS: V-L \leq 5%
HETEROZYGOUS: V-L 25 - 60 %
HOMOZYGOUS: V-L \geq 70 %

If necessary, measure Factor V

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