



Manufactured By: HYPHEN BioMed

HYPHEN BioMed SAS

New Quantitative Assay for Factor V-Leiden

**Measuring APC Resistance Associated
With Factor V-Leiden,
Quantitatively**

A Simple and Calibrated Assay for measuring the Factor V-Leiden Concentration, using a Single Clotting Test.



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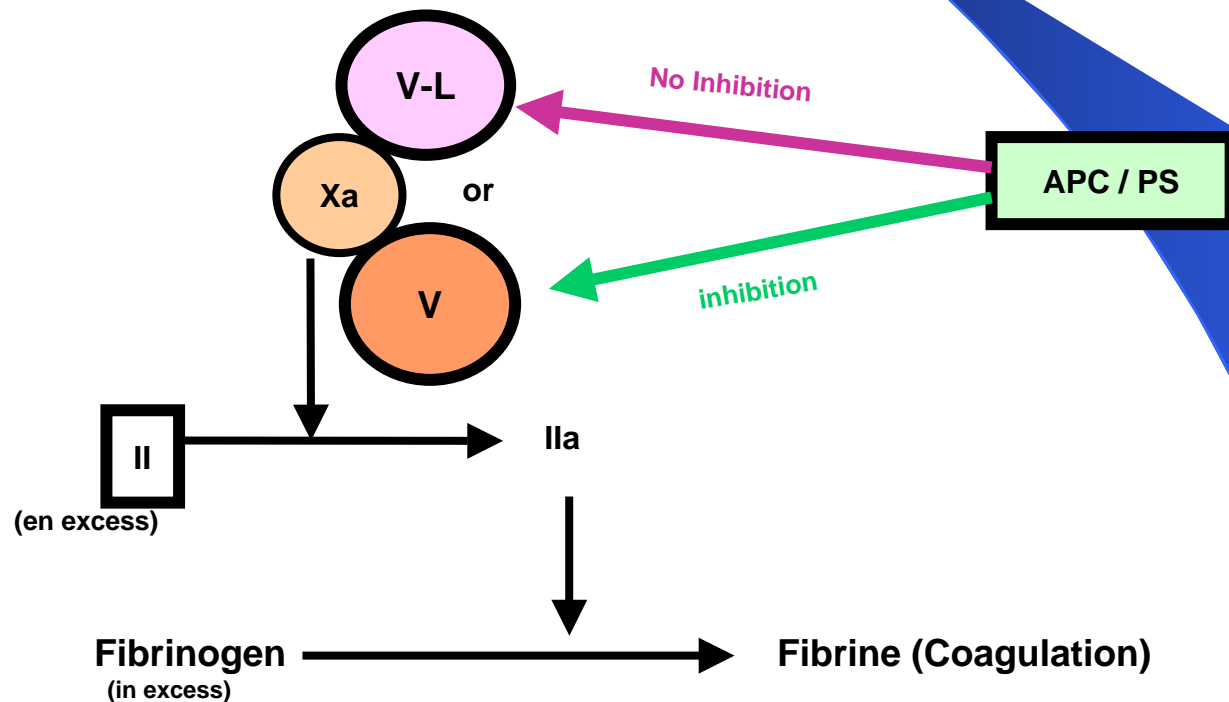
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Form AH14
4-2007

Quantitative Evaluation of FACTOR V-LEIDEN



RESULTS with the usual assay

CT1 without APC
CT2 with APC

$CT2/CT1 < 1.80$ \Rightarrow V-L

$1.80 < CT2/CT1 < 2.00$ \Rightarrow ??

$CT2/CT1 > 2.00$ \Rightarrow V-N

REAGENTS (QUANTITATIVE V-L)

- R1
(Fibrinogen/Prothrombin/PS/APC/Polybren)
- R2
(Xa/Phospholipids/Ca⁺⁺)

1/20 Diluted Plasma

⇒ C.T.

CALIBRATION

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

PROTOCOL

At 37°C :

100 µL R1

50 µL Plasma diluted 1/20

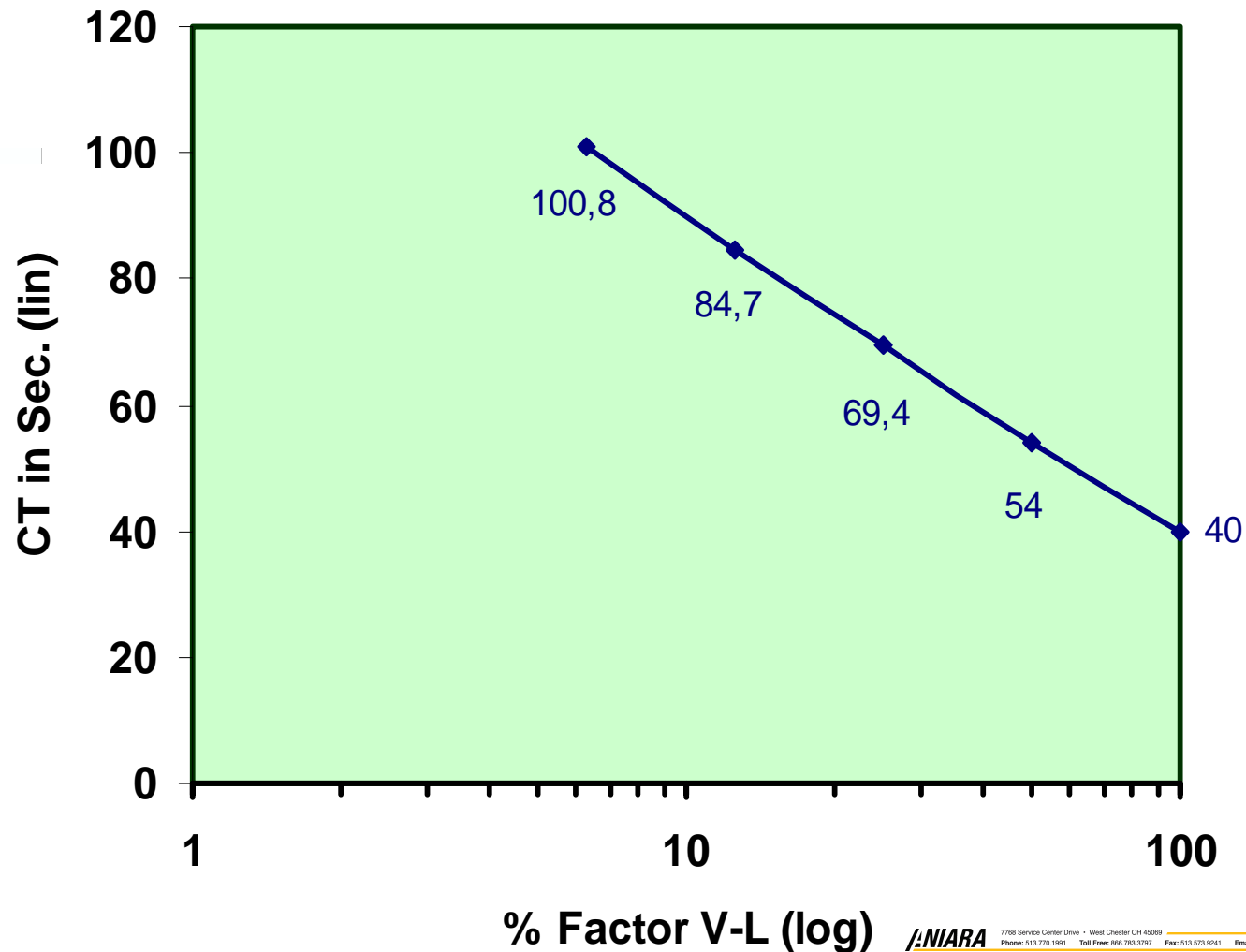
Incubation 1 minute at 37°C

100 µL R2

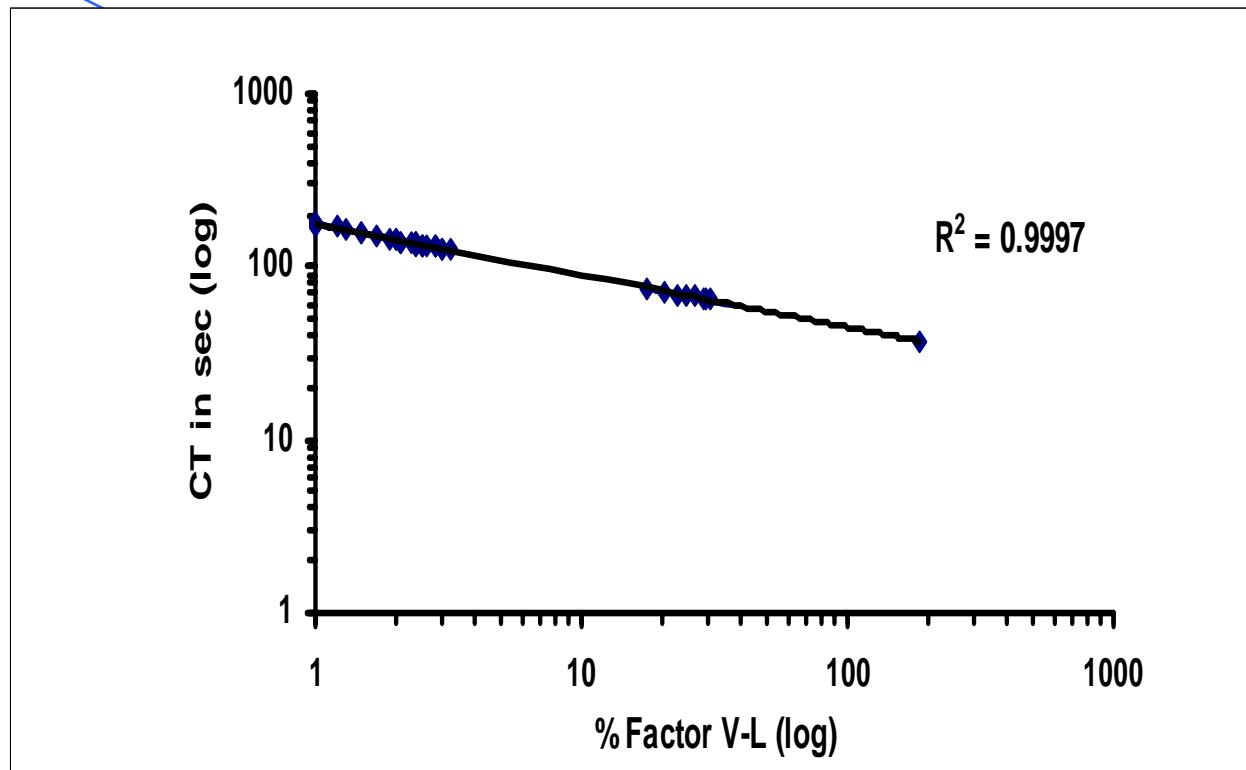
Measure Clotting Time (CT)

CALIBRATION CURVE

Factor V-L quantitation



QUANTITATIVE ASSAY OF FACTOR V-L



RESULTS with the New Assay

NORMALS : $V-L \leq 5\%$

HETEROZYGOUS : $V-L$ de 25 - 60 %

HOMOZYGOUS : $V-L \geq 70\%$

If necessary : Measure factor V

CONCLUSIONS

- Quantitative Reagent for Measuring Factor V-Leiden
- No Interference of Plasma Factor Deficiencies (Other than that of Factor V).
- Excellent Discrimination Between Heterozygous/Homozygous and Normals.
- Only a Clotting Time (CT).