



HYPHEN BioMed
155 rue d'Eragny
95000 Neuville-sur-Oise
France

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN V-L CAL (Undiluted)
Product Code : 222401
Lot No. : F1801111
Expiration date : 2021-01-09

Components	Quantity	Lot	Expiration Date
CAL 1	3 vials	F181301111	2021-01-09
CAL 2	3 vials	F181301111	2021-01-09
CAL 3	3 vials	F181301111	2021-01-09

Analytical Data	Specification	Result
Concentration	CAL 1 : 5-15% CAL 2 : 20-30% CAL 3 : 40-60%	7% 21% 50%
Linearity and accuracy of calibration with values assigned	$R^2 \geq 0.98$ Measured values for controls in acceptance ranges	0,998 controls in acceptance range

This is to certify that above product has been produced and passed the inspection according to specifications of HYPHEN BioMed.

Date of Approval : 13/08/2018

Quality Control Manager :

M. PEYRAFITTE



BIOPHEN V-L CAL (Undiluted)

REF 222401

For in vitro diagnostic use only / *Pour diagnostic in vitro exclusivement*

LOT

F1801111



2021-01-09

Factor V-L Concentration [C] in calibrator / *Concentration [C] en Facteur V-L dans les calibrateurs*

<u>Calibrator / Calibrateur 1</u>	LOT : F181301111
[C] :	7 %
<u>Calibrator / Calibrateur 2</u>	LOT : F181301111
[C] :	21 %
<u>Calibrator / Calibrateur 3</u>	LOT : F181301111
[C] :	50 %

Standardization / *Standardisation* : **NA**

Approved Date / *Date d'Approbation* : 13/08/2018

Quality Control Manager / *Responsable Contrôle Qualité* : M. PEYRAFITTE

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