



A Company of Sysmex Group



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

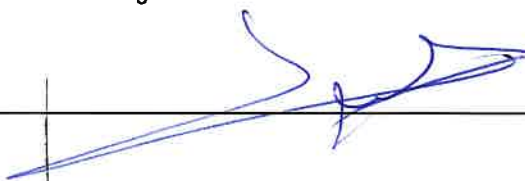
CERTIFICATE OF ANALYSIS	
Product Description :	BIOPHEN V-L CAL (Undiluted)
Product Code :	222401
Lot No. :	F2000117
Expiration date :	2022-07-16

Components	Quantity	Lot	Expiration Date
CAL 1	3 vials	F201400117	2022-07-16
CAL 2	3 vials	F201400117	2022-07-16
CAL 3	3 vials	F201400117	2022-07-16

Analytical Data	Specification	Result
Concentration	CAL 1 : 5-15% CAL 2 : 20-30% CAL 3 : 40-60%	9 26 52
Linearity and accuracy of calibration with values assigned	$R^2 \geq 0.98$ Measured values for controls in acceptance ranges	0.99 Controls are in acceptance ranges

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

Date of Approval : 2020-02-28 Quality Control Manager : **S.LECOURT**





BIOPHEN V-L CAL (Undiluted)

REF 222401

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

LOT F2000117  2022-07-16

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

<u>Calibrator / Calibrateur 1</u>	LOT : F201400117
[C] :	9 %
<u>Calibrator / Calibrateur 2</u>	LOT : F201400117
[C] :	26 %
<u>Calibrator / Calibrateur 3</u>	LOT : F201400117
[C] :	52 %

Standardization / Standardisation : NA

Approved Date / Date d'Approbation : 2020-02-28

Quality Control Manager / Responsable Contrôle Qualité : S.LECOURT

