



A Company of Sysmex Group



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN PROTHROMBIN
Product Code : 221605
Lot No. : F2000319
Expiration date : 2024-02-17

Components	Quantity	Lot	Expiration Date
R1 : Ecarin	4 vials	F201200319	2024-05-06
R2 : Substrate	4 vials	F201200319	2024-02-20
R3: Buffer	4 vials	F201200319	2024-02-17

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	A405 (1:25) \geq 1.50 Delta A405 (1:25 ; 1:50) \geq 0.50 R ² \geq 0.98 Measured values for controls in acceptance ranges	2.18 1.04 0.99 Controls is acceptance ranges
Detection Threshold	\leq 5%	< 1 %

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

Date of Approval : 2020-06-11

Quality Control Manager : S.LECOURT