



A Company of Sysmex Group



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

CERTIFICATE OF ANALYSIS	
Product Description:	BIOPHEN Factor XIII
Product Code:	227005
Lot No.:	F2000453
Expiration date:	2022-09-16

Components	Quantity	Lot	Expiration Date
R1 : Thrombin	3 vials	F201700453	2022-09-16
R2 : Detection Reagent	3 vials	F201700453	2022-09-16

Analytical Data	Specification	Result
Calibration curve : reactivity, slope, linearity and accuracy on CS	OD/min(100%) > 0.016 Delta OD/min (100-50%) ≥ 0.006 R ² ≥ 0.98 Measured values for controls in acceptance ranges	0.0236 0.0103 R ² = 0.99 Measured values for controls in acceptance ranges
Detection Threshold	≤ 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: 2020-04-30 Quality Control Manager: S. LECOURT