



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FIXa

Product Code : 221812

Lot No. : F1900206

Expiration date : 2021-08-09

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	F194A00206	2021-08-27
R2 : Activation Reagent	2 vials	F194A00206	2021-09-13
R3 : Substrate	2 vials	F194A00206	2021-08-21
R4: Buffer	2 vials	F194A00206	2021-08-27
Cal : FIXa Calibrator	2 vials	F194A00206	2021-08-09

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope	Water-Bath A405 (C/2) \geq 1.5 Delta A405 (C/2; C/4) \geq 0.30 R ² \geq 0.98	2.573 0.735 0.99
Detection Threshold	\leq 0.2 mIU/ml	< 0.1 mIU/ml

Calibration Curve for information

Conc.	22	11	4.4	2.2	1.1
OD STAR	1.176	0.773	0.383	0.197	0.097
Conc.	22	11	5.5	2.2	1.1
OD WB	2.573	1.838	1.170	0.563	0.297

	Acceptance Range	MV
CI	[5.4 - 8,2]	7.0
CII	[14.5 - 19.7]	17.2

MV = Measured value

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

Date of Approval : 2019-04-19

Quality Control Manager : **S.LECOURT**



BIOPHEN® Factor IXa (ACT.FIX)

Chromogenic assay for the quantitative determination of FIXa activity in purified milieu/
Dosage fonctionnel du Facteur IXa sur milieu purifié par méthode colorimétrique

REF 221812

For in vitro use only. For research use only. / *Pour utilisation in vitro exclusive. Uniquement à usage de recherche.*

LOT F1900206



2021-08-09

Factor IXa Concentration [C] in the calibrator /
Concentration [C] en Facteur IXa dans le calibrateur

Factor IXa Calibrator / Calibrateur Facteur IXa	LOT : F194A00206
[C] :	22 mIU/mL* / mUI/ML* <i>(*1 mIU/mL is close to 1 ng/mL / *1mUI/mL est proche de 1 ng/mL)</i>

Standardization / *Standardisation* : **Calibrator is qualified against international standard for FIXa (97/562)**

Approved Date / *Date d'Approbation* : 2019-04-12

Quality Control Manager / *Responsable Contrôle Qualité* : S.LECOURT.

