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

CERTIFICATE OF ANALYSIS	
Product Description :	BIOPHEN FIXa
Product Code :	221812
Lot No. :	F1800844
Expiration date :	2020-11-09

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	F184900844	2020-11-09
R2 : Activation Reagent	2 vials	F184900844	2020-12-14
R3 : Substrate	2 vials	F184900844	2020-11-14
R4: Buffer	2 vials	F184900844	2020-11-21
Cal : FIXa Calibrator	2 vials	F181600844	2021-01-25

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	2.580 0.727 0.988
Detection Threshold	\leq 0.2 mIU/ml	< 0.1 mIU/ml

Calibration Curve for information

Conc.	1.1	1.2	4.4	11	22
OD STAR	0.074	0.160	0.323	0.709	1.104
OD WB	0.268	0.519	1.143	1.853	2.580

	Acceptance Range	MV
CI	[7.4 - 11.0]	9.0
CII	[14.9 - 20.1]	18.8

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 : 2018-08-30

Quality Control Manager : **M. PEYRAFITTE**

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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 F1800844

 2020-11-09

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

Factor IXa Calibrator / Calibrateur Facteur IXa	LOT : F181600844
[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* : 2018-08-30

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