

BIOPHEN™ ANTI-Xa (2 Stages Heparin assay) - #221005

Lot : FD22111B

QC Release : 13 DEC. 2024

Expiration date : 2027-04-27

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : ATIII(h)	2 vials	30	FD22111B	2027-05-03
R2 : FXa (b)	2 vials	30	FD22111B	2027-05-10
R3 : Substrate	2 vials	30	FD22111B	2027-04-27

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Analytical data	Specifications
1. AT III(h) a. Lot Homogeneity (A405 for 0 IU/mL heparin) N : 25 Mean (A405) : 2.051 CV : 2.15 % b. AT content per vial (anti-Xa activity chromogenic assay) 5.85 IU c. Indicative AT content per vial (A280/Lowry on raw material) 422 µg d. SDS PAGE (on raw material) 1 major band of about 58 000 Da e. Absence of heparin (on raw material) Absence	≤ 5 % ≥ 4.75 IU 1 major band of about 58,000 Da Absence
2. FXa(b) a. Lot Homogeneity (A405 for 0 IU/mL heparin) N : 25 Mean (A405) : 2.064 CV : 1.59 % b. SDS PAGE (4-12% acrylamide) (FX zymogen for raw material) 1 major band of about 55 000 Da c. Indicative FXa content per vial (Lowry, from zymogen raw material) 86.3 µg/vial d. Chromogenic activity on Xa substrate (10µg/ml) (raw material) A405 with RVV : 1.593 A405 without RVV : 1.569	≤ 5 % 1 major band of about 55,000 Da ΔA405 <10%
3. Substrate a. Blank value (free pNA) Mean (A405) : 0.073 b. Lot Homogeneity (A405 for 0 IU/mL heparin) N : 25 Mean (A405) : 2.052 CV : 3.42 % c. Indicative content per vial (raw material) 5 mg (about 7.8 µmol) d. HPLC analysis purity grade (raw material) 97.5 % e. Experimental molecular weight (raw material) 641.4 Da	A405 ≤ 0.30 ≤ 5 % ≥ 95% 641.7 ± 5 Da

TC



ANALYSIS CERTIFICATE

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5. <u>(in the tested dilution, CS-series)</u>									$R^2 \geq 0.98$ $\Delta A405(0-0.067) \geq 0.5$
A405	IU/mL (in the tested dilution)	0.0	0.006	0.017	0.033	0.050	0.067	R^2	
Purified milieu	UFH	1.303	1.147	0.940	0.665	0.434	0.259	0.992	
	LMWH	0.962	0.843	0.659	0.437	0.295	0.160	0.992	
6. <u>entrainment in the tested dilution, CS-series)</u>									
In Purified solution		≤ 0.005 IU/mL							≤ 0.005 IU/mL
7. <u>aged reagents (purified milieu, CS-series)</u>									$R^2 \geq 0.98$ $\Delta A405(0-0.067) \geq 0.5$ $\Delta A405(0IU/mL) \leq 10\%$ between fresh and stored $A405(\text{Free pNA}) \leq 0.30$
Reagents tested after 15 days at 2-8°C, or 7 days at RT (18-25°C) or Frozen $\leq -20^\circ\text{C}$									
A405 values for UFH									
	0.0	0.006	0.017	0.033	0.050	0.067	R^2	A405 (Free pNA)	
Freshly restored	1.303	1.147	0.940	0.665	0.434	0.259	0.992	0.073	
15 days at 2-8°C	1.298	1.126	0.932	0.642	0.433	0.289	0.998	0.073	
7 days at RT (18-25°C)	1.308	1.141	0.945	0.643	0.428	0.288	0.998	0.069	
Frozen $\leq -20^\circ\text{C}$	1.298	1.122	0.908	0.619	0.411	0.266	0.998	0.082	
Comments :									☒ PASSED IN COMPLIANCE

Date : 13 DEC. 2024

QC Manager :
Isabelle CORNUEJOLS
Resp. Labo CQ

Sophie LECOURT
Deputy Director Quality Control