

ANALYSIS CERTIFICATE

BIOPHEN™ Anti-IIa (2 stages Heparin assay) - #220005

Lot: FC129419

QC Release: 2023-07-05

Expiration date: 2025-11-02

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : ATIII(h)	2 vials	30	FC129419	2025-11-07
R2 : Thrombin	2 vials	30	FC129419	2025-11-17
R3 : Substrate	2 vials	30	FC129419	2025-11-02

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Analytical data	Specifications
1. ATIII (h) a. Lot homogeneity (A405 for 0 IU/ml heparin) N= 25 Mean (A405): 2.86 CV: 1.4 % b. AT content per vial (anti-Xa activity chromogenic assay on raw material) 1.65 IU c. Indicative AT content per vial (A280nm/Lowry on raw material) 190 µg d. SDS PAGE (on raw material) 1 major band of about 58 000 Da e. Absence of heparin Absence	≤ 5 % ≥ 1.2 IU 1 major band of about 58,000 Da Absence
2. Thrombin (h) a. Lot homogeneity (A405 for 0 IU/ml heparin) N= 25 Mean (A405): 2.88 CV: 1.7 % b. SDS PAGE (5% acrylamide) (on raw material) 1 major band of about 35 000 Da c. Indicative IIa content per vial (Lowry on raw material) ~39 µg d. Indicative clotting activity per vial (clotting assay on raw material) (respectively to the WHO/NIBSC standard for h(IIa)) ~ 75 NIH (or IU) e. Indicative specific chromogenic activity (on raw material) (chromogenic assay using CS-01(38)) ~ 4.45 nkats/µg	≤ 5 % 1 major band of about 35,000 Da
3. Thrombin substrate a. Blank value N= 5 Mean (A405): 0.106 b. Lot homogeneity (A405 for 0 IU/ml heparin) N= 25 Mean (A405): 2.53 CV: 4.3 % c. Indicative content per vial (raw material) 6.25 mg (about 11.3 µmol) d. HPLC analysis purity grade (raw material) 98 % e. Experimental molecular weight (raw material) 553 Da	N≥5 A405 ≤ 0.30 ≤ 5 % ≥ 95% 553 ± 5 Da

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Analytical data								Specifications	
5. Assay reactivity (in the tested dilution, CS-series)								$R^2 \geq 0.98$ $\Delta A405 (0-0.04) \geq 0.65$	
IU/mL	0.0	0.005	0.01	0.02	0.03	0.04	R^2		
A405 UFH purified	1.451	1.116	0.878	0.522	0.323	0.211	0.99		
A405LMWH purified	1.324	0.831	0.565	0.228	0.113	0.071	0.98		
6. UFH Detection threshold (concentration in the tested dilution, CS-series)								≤ 0.005 IU/mL	
In Purified solution < 0.005 IU/mL									
7. Stability of reconstituted reagents (purified milieu, CS-series) Reagents tested after 15 days at 2-8°C, or 4 days at RT (18-25°C) or Frozen $\leq -20^\circ\text{C}$ A405 values for UFH								$R^2 \geq 0.98$ $\Delta A405 (0-0.04) \geq 0.65$ $\Delta A405 (0 \text{ IU/mL}) \leq 10\%$ between fresh and stored $A405 (\text{Free pNA}) \leq 0.30$	
UFH IU/mL	0.0	0.005	0.01	0.02	0.03	0.04	R^2		A405 (Free pNA)
Freshly restored	1.672	1.298	1.043	0.644	0.405	0.271	0.99		0.124
15 days at 2-8°C	1.663	1.279	1.018	0.634	0.407	0.273	0.99		0.108
4 days at RT	1.645	1.259	0.997	0.616	0.385	0.251	1.00		0.107
Frozen $\leq -20^\circ\text{C}$	1.633	1.230	0.957	0.566	0.337	0.214	1.00		0.111
Comments :								☒ PASSED IN COMPLIANCE	

Date: 2023-07-05

QC Manager: S. LECOURT

