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

ANALYSIS CERTIFICATE

HYPHEN BioMed
A Company of Sysmex Group

BIOPHEN™ Anti-IIa (2 stages Heparin assay) - #220005 **Lot : FD00861A**

QC Release : 07 MARS 2024 **Expiration date : 2026-07-05**

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : ATIII(h)	2 vials	30	FD00861A	2026-07-05
R2 : Thrombin	2 vials	30	FD00861A	2026-07-24
R3 : Substrate	2 vials	30	FD00861A	2026-07-06

SQS

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Analytical data	Specifications
5. Assay reactivity (in the tested dilution, CS-series)	

IU/mL	0.0	0.005	0.01	0.02	0.03	0.04	R^2
A405 UFH purified	1.642	1.348	1.122	0.777	0.550	0.402	0.998
A405LMWH purified	1.378	1.129	0.907	0.522	0.316	0.212	0.996

$R^2 \geq 0.98$

ΔA405 (0-0.04) ≥ 0.65

6. UFH Detection threshold (concentration in the tested dilution, CS-series)

In Purified solution **0.0004** IU/mL

≤ 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 ≤ -20°C

A405 values for UFH

UFH IU/mL	0.0	0.005	0.01	0.02	0.03	0.04	R^2	A405 (Free pNA)
Freshly restored	1.470	1.196	1.004	0.695	0.494	0.371	0.998	0.108
15 days at 2-8°C	1.442	1.186	1.000	0.707	0.507	0.379	0.998	0.093
4 days at RT	1.426	1.205	1.033	0.760	0.562	0.423	1.000	0.093
Frozen ≤ -20°C	1.410	1.140	0.942	0.636	0.434	0.309	0.999	0.098

$R^2 \geq 0.98$

ΔA405 (0-0.04) ≥ 0.65

Δ A405 (0 IU/mL) ≤ 10% between fresh and stored

A405 (Free pNA) ≤ 0.30

Comments :

☑ **PASSED IN COMPLIANCE**

Date : ..... **QC Manager : .....**

Quality Control Approval

07 MARS 2024

S. LECOURT

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Analytical data	Specifications
1. ATIII (h)	
a. Lot homogeneity (A405 for 0 IU/ml heparin) **N=** 25 Mean (A405) : **2.908** CV : **0.80** %	≤ 5 %
b. AT content per vial (anti-Xa activity chromogenic assay on raw material) **1.3** IU	≥ 1.2 IU
c. Indicative AT content per vial (A280nm/Lowry on raw material) **130** µg	
d. SDS PAGE (on raw material) 1 major band of about **58000** Da	1 major band of about 58,000 Da
e. Absence of heparin **Absence**	Absence
2. Thrombin (h)	
a. Lot homogeneity (A405 for 0 IU/ml heparin) **25** Mean (A405) : **2.937** CV : **0.95** %	≤ 5 %
b. SDS PAGE (5% acrylamide) (on raw material) 1 major band of about **35000** Da	1 major band of about 35,000 Da
c. Indicative IIa content per vial (Lowry on raw material) **39.86** µg	
d. Indicative clotting activity per vial (clotting assay on raw material) (respectively to the WHO/NIBSC standard for h(IIa) **85** NIH (or IU)	
e. Indicative specific chromogenic activity (on raw material) (chromogenic assay using CS-01(38)) **5.41** nkats/µg	
3. Thrombin substrate	
a. Blank value **N=** 5 Mean (A405) : **0.107**	N≥5 A405 ≤ 0.30
b. Lot homogeneity (A405 for 0 IU/ml heparin) **N=** 25 Mean (A405) : **2.882** CV : **1.11** %	≤ 5 %
c. Indicative content per vial (raw material) **6.25** mg (about 11.25 µmol)	
d. HPLC analysis purity grade (raw material) **99** %	≥ 95%
e. Experimental molecular weight (raw material) **553** Da	553 ± 5 Da