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

HYPHEN BioMed
A Company of Sysmex Group

ANALYSIS CERTIFICATE

BIOPHEN™ Anti-IIa (2 stages Heparin assay) - #220005 **Lot : FD22051B**

QC Release : 18 DEC. 2024 **Expiration date : 2027-04-24**

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : ATIII(h)	2 vials	30	FD22051B	2027-05-03
R2 : Thrombin	2 vials	30	FD22051B	2027-05-10
R3 : Substrate	2 vials	30	FD22051B	2027-04-24

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Analytical data	Specifications
1. ATIII (h)	
a. Lot homogeneity (A405 for 0 IU/ml heparin)	
N= 30 Mean (A405) : **2.810**	
CV : **3.07** %	≤ 5 %
b. AT content per vial (anti-Xa activity chromogenic assay on raw material)	
1.46 IU	≥ 1.2 IU
c. Indicative AT content per vial (A280nm/Lowry on raw material)	
105.4 µg	
d. SDS PAGE (on raw material)	1 major band of about 58,000 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)	
N= 30 Mean (A405) : **2.877**	
CV : **2.07** %	≤ 5 %
b. SDS PAGE (5% acrylamide) (on raw material)	1 major band of about 35,000 Da
1 major band of about **35,000** Da	
c. Indicative IIa content per vial (Lowry on raw material)	
39.8 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))	
5.25 nkats/µg	
3. Thrombin substrate	
a. Blank value	N≥5
N= 5 Mean (A405) : **0.108**	A405 ≤ 0.30
b. Lot homogeneity (A405 for 0 IU/ml heparin)	
N= 30 Mean (A405) : **2.886**	
CV : **2.45** %	≤ 5 %
c. Indicative content per vial (raw material)	
6.25 mg (about 11.25 µmol)	
d. HPLC analysis purity grade (raw material)	
98.4 %	≥ 95%
e. Experimental molecular weight (raw material)	
552.4 Da	553 ± 5 Da

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Analytical data	Specifications
5. Assay reactivity (in the tested dilution, CS-series)	$R^2 \geq 0.98$ $\Delta A405\ (0\text{-}0.04) \geq 0.65$

IU/mL	0.0	0.005	0.01	0.02	0.03	0.04	R^2
A405 UFH purified	1.545	1.276	1.078	0.754	0.592	0.450	0.996
A405LMWH purified	1.443	1.243	1.010	0.669	0.409	0.278	0.996

6. UFH Detection threshold (concentration in the tested dilution, CS-series)		
In Purified solution	**< 0.005** 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)	Specifications
Freshly restored	1.545	1.276	1.078	0.754	0.592	0.415	0.996	0.108	$R^2 \geq 0.98$
15 days at 2-8°C	1.576	1.325	1.137	0.805	0.629	0.470	0.996	0.109	$\Delta A405\ (0\text{-}0.04) \geq 0.65$
4 days at RT	1.543	1.301	1.122	0.828	0.637	0.503	0.996	0.108	Δ A405 (0 IU/mL) ≤ 10% between fresh and stored
Frozen ≤ -20°C	1.589	1.327	1.146	0.834	0.525	0.423	0.992	0.110	A405 (Free pNA) ≤ 0.30

Comments :

☒ **PASSED IN COMPLIANCE**

Date : 18 DEC. 2024

QC Manager : p.o.

Isabelle CORNUEJOLS
Resp. Labo CQ

Sophie LECOURT
Deputy Director Quality Control