



HYPHEN BioMed
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 France



A Company of Sysmex Group

ANALYSIS CERTIFICATE

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. <u>Assay reactivity (in the tested dilution, CS-series)</u>								$R^2 \geq 0.98$ $\Delta A405 (0-0.04) \geq 0.65$
IU/mL	0.0	0.005	0.01	0.02	0.03	0.04	R ²	
A405 UFH purified	1.642	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	

6. <u>UFH Detection threshold (concentration in the tested dilution, CS-series)</u>								≤ 0.005 IU/mL
In Purified solution	0.0004		IU/mL					

7. <u>Stability of reconstituted reagents (purified milieu, CS-series)</u>								$R^2 \geq 0.98$ $\Delta A405 (0-0.04) \geq 0.65$ $\Delta A405 (0 \text{ IU/mL}) \leq 10\%$ between fresh and stored A405 (Free pNA) ≤ 0.30	
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	

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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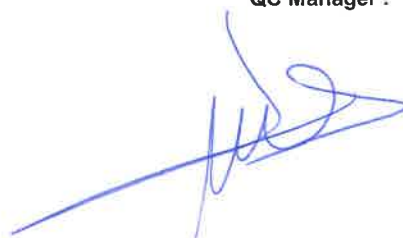
Date :

QC Manager :

Quality Control Approval

07 MARS 2024

S. LECOURT





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

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