



HYPHEN BioMed
155 rue d'Eragny
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France



A Company of Sysmex Group

ANALYSIS CERTIFICATE

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

Lot : F1801568

QC Release : 2019-04-05

Expiration date : 2021-05-18

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : ATIII(h)	2 vials	30	F181301568	2021-05-23
R2 : Thrombin	2 vials	30	F181301568	2021-08-22
R3 : Substrate	2 vials	30	F181301568	2021-05-18

SP3



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Analytical data	Specifications
<p>1. ATIII (h)</p> <p>a. Lot homogeneity (A405 for 0 IU/ml heparin) N= 20 Mean (A405) : 2.686 CV : 0.8 %</p> <p>b. AT content per vial (anti-Xa activity chromogenic assay on raw material) 1.68 IU</p> <p>c. Indicative AT content per vial (A280nm/Lowry on raw material) 190 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) N= 20 Mean (A405) : 2.771 CV : 1.5 %</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) 27 µg</p> <p>d. Indicative clotting activity per vial (clotting assay on raw material) (respectively to the WHO/NIBSC standard for h(IIa)) 112 NIH (or IU)</p> <p>e. Indicative specific chromogenic activity (on raw material) (chromogenic assay using CS-01(38)) 4.94 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) : 0.119</p> <p>b. Lot homogeneity (A405 for 0 IU/ml heparin) N= 20 Mean (A405) : 2.641 CV : 2.0 %</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) 98.7 %</p> <p>e. Experimental molecular weight (raw material) 552 Da</p>	<p>N≥5 A405 ≤ 0.30</p> <p>≤ 5 %</p> <p>≥ 95%</p> <p>553 ± 5 Da</p>

5.95

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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	1.388	1.129	0.906	0.567	0.364	0.244	0.998	
A405LMWH purified	1.462	1.169	0.869	0.439	0.225	0.133	0.996	

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)								$R^2 \geq 0.98$ $\Delta A405 (0-0.04) \geq 0.65$ $\Delta A405 (0 \text{ IU/mL}) \leq 10\%$ between fresh and stored $A405 (\text{Free pNA}) \leq 0.30$	
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	1.409	1.129	0.931	0.522	0.292	0.175	0.998		0.114
15 days at 2-8°C	1.309	1.051	0.879	0.578	0.392	0.189	0.984	0.059	
4 days at RT	1.398	1.137	0.906	0.654	0.328	0.224	0.990	0.106	
Frozen ≤ -20°C	1.398	1.156	0.892	0.626	0.339	0.176	0.988	0.112	

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2019-04-05

QC Manager : S.LECOURT

