

ANALYSIS CERTIFICATE

BIOPHEN™ ANTI-Xa (2 Stages Heparin assay) - #221005

Lot : FA197317

QC Release : 2021-11-23

Expiration date : 2024-04-08

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : ATIII(h)	2 vials	30	FA197317	2024-04-08
R2 : FXa (b)	2 vials	30	FA197317	2024-04-15
R3 : Substrate	2 vials	30	FA197317	2024-04-13

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Analytical data	Specifications
<p>1. AT III(h)</p> <p>a. Lot Homogeneity (A405 for 0 IU/mL heparin)</p> <p style="margin-left: 40px;">N : 20 Mean (A405) : 2.014 CV : 0.72 %</p> <p>b. AT content per vial (anti-Xa activity chromogenic assay)</p> <p style="margin-left: 40px;">6.34 IU</p> <p>c. Indicative AT content per vial (A280/Lowry on raw material)</p> <p style="margin-left: 40px;">≈ 750 µg</p> <p>d. SDS PAGE (on raw material)</p> <p style="margin-left: 40px;">1 major band of about 58,000 Da</p> <p>e. Absence of heparin (on raw material)</p> <p style="margin-left: 40px;">Absence</p>	<p>≤ 5 %</p> <p>≥ 4.75 IU</p> <p>1 major band of about 58,000 Da</p> <p>Absence</p>
<p>2. FXa(b)</p> <p>a. Lot Homogeneity (A405 for 0 IU/mL heparin)</p> <p style="margin-left: 40px;">N : 20 Mean (A405) : 2.023 CV : 0.93 %</p> <p>b. SDS PAGE (4-12% acrylamide) (FX zymogen for raw material)</p> <p style="margin-left: 40px;">1 major band of about 55,000 Da</p> <p>c. Indicative FXa content per vial (Lowry, from zymogen raw material)</p> <p style="margin-left: 40px;">≈ 87.3 µg/vial</p> <p>d. Chromogenic activity on Xa substrate (10µg/ml) (raw material)</p> <p style="margin-left: 40px;">A405 with RVV : 2.202 A405 without RVV : 2.15</p> <p>e. Indicative chromogenic activity on Xa substrate (CS-11(22)) (raw material)</p> <p style="margin-left: 40px;">≈ 1.21 nkats / vial</p>	<p>≤ 5 %</p> <p>1 major band of about 55,000 Da</p> <p>ΔA405 <10%</p>
<p>3. Substrate</p> <p>a. Blank value (free pNA)</p> <p style="margin-left: 40px;">Mean (A405) : 0.201</p> <p>b. Lot Homogeneity (A405 for 0 IU/mL heparin)</p> <p style="margin-left: 40px;">N : 20 Mean (A405) : 2.047 CV : 0.93 %</p> <p>c. Indicative content per vial (raw material)</p> <p style="margin-left: 40px;">≈ 5 mg (about 7.8 µmol)</p> <p>d. HPLC analysis purity grade (raw material)</p> <p style="margin-left: 40px;">96.3 %</p> <p>e. Experimental molecular weight (raw material)</p> <p style="margin-left: 40px;">641.3 Da</p>	<p>A405 ≤ 0.30</p> <p>≤ 5 %</p> <p>≥ 95%</p> <p>641.7 ± 5 Da</p>

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Analytical data									Specifications
5. <u>Assay reactivity (in the tested dilution, CS-series)</u>									$R^2 \geq 0.98$ $\Delta A405(0-0.067) \geq 0.5$
A405	IU/mL (in the tested dilution)	0.0	0.006	0.017	0.033	0.050	0.067	R ²	
Purified milieu	UFH	1.169	1.019	0.785	0.494	0.303	0.184	0.998	
	LMWH	0.909	0.761	0.529	0.291	0.162	0.092	1	
6. <u>Detection threshold (concentration in the tested dilution, CS-series)</u>									≤ 0.005 IU/mL
In Purified solution		0.002 IU/mL							
7. <u>Stability of reconstituted reagents (purified milieu, CS-series)</u>									$R^2 \geq 0.98$ $\Delta A405(0-0.067) \geq 0.5$ $\Delta A405(0IU/mL) \leq 10\%$ between fresh and stored $A405(\text{Free pNA}) \leq 0.30$
Reagents tested after 15 days at 2-8°C, or 7 days at RT (18-25°C) or Frozen $\leq -20^\circ\text{C}$									
A405 values for UFH									
	0.0	0.006	0.017	0.033	0.050	0.067	R ²	A405 (Free pNA)	
Freshly restored	1.179	1.062	0.833	0.552	0.365	0.241	0.998	0.071	
15 days at 2-8°C	1.194	1.070	0.830	0.545	0.354	0.231	1	0.070	
7 days at RT (18-25°C)	1.188	1.072	0.847	0.554	0.361	0.237	0.998	0.071	
Frozen $\leq -20^\circ\text{C}$	1.180	1.059	0.834	0.547	0.354	0.288	0.998	0.071	

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2021-11-23

QC Manager : S.LECOURT

