



HYPHEN BioMed  
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France

## ANALYSIS CERTIFICATE



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

Lot :

FE2817

QC Release : 1.4 AOUT 2025

Expiration date :

2027-12-03

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : ATIII(h)	2 vials	30	FE2817	2027-12-03
R2 : FXa (b)	2 vials	30	FE2817	2028-01-07
R3 : Substrate	2 vials	30	FE2817	2027-12-07

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**Lot : FE2817**

**QC Release : 1.4 AOUT 2025**

**Expiration date : 2027-12-03**

Analytical data	Specifications
<p><b>1. AT III(h)</b></p> <p>a. Lot Homogeneity (A405 for 0 IU/mL heparin)</p> <p style="margin-left: 40px;">N : 20            Mean (A405) : 2.034            CV : 1.3 %</p> <p>b. AT content per vial (anti-Xa activity chromogenic assay)</p> <p style="margin-left: 40px;">5.93 IU</p> <p>c. Indicative AT content per vial (A280/Lowry on raw material)</p> <p style="margin-left: 40px;">766 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;"><b>Absence</b></p>	<p style="text-align: center;">≤ 5 %</p> <p style="text-align: center;">≥ 4.75 IU</p> <p style="text-align: center;">1 major band of about 58,000 Da</p> <p style="text-align: center;">Absence</p>
<p><b>2. FXa(b)</b></p> <p>a. Lot Homogeneity (A405 for 0 IU/mL heparin)</p> <p style="margin-left: 40px;">N : 20            Mean (A405) : 2.002            CV : 1.0 %</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;">96 µg/vial</p> <p>d. Chromogenic activity on Xa substrate (10µg/ml) (raw material)</p> <p style="margin-left: 40px;">A405 with RVV : 2.383            A405 without RVV : 2.376</p>	<p style="text-align: center;">≤ 5 %</p> <p style="text-align: center;">1 major band of about 55,000 Da</p> <p style="text-align: center;">ΔA405 &lt;10%</p>
<p><b>3. Substrate</b></p> <p>a. Blank value (free pNA)</p> <p style="margin-left: 40px;">Mean (A405) : 0.072</p> <p>b. Lot Homogeneity (A405 for 0 IU/mL heparin)</p> <p style="margin-left: 40px;">N : 20            Mean (A405) : 1.993            CV : 1.7 %</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;">95.8 %</p> <p>e. Experimental molecular weight (raw material)</p> <p style="margin-left: 40px;">641.3 Da</p>	<p style="text-align: center;">A405 ≤ 0.30</p> <p style="text-align: center;">≤ 5 %</p> <p style="text-align: center;">≥ 95%</p> <p style="text-align: center;">641.7 ± 5 Da</p>

*Jlo*

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

Lot : FE2817

QC Release : 14. AOUT 2025

Expiration date : 2027-12-03

Analytical data									Specifications
<b>5. Assay reactivity (in the tested dilution, CS-series)</b>									$R^2 \geq 0.98$ $\Delta A405(0-0.067) \geq 0.5$
A405	IU/mL (in the tested dilution)	0.0	0.006	0.017	0.033	0.050	0.067	R <sup>2</sup>	
Purified milieu	UFH	1.157	1.029	0.800	0.514	0.322	0.207	0.998	
	LMWH	0.835	0.735	0.555	0.344	0.204	0.130	0.998	

<b>6. Detection threshold (concentration in the tested dilution, CS-series)</b>									≤ 0.005 IU/mL
In Purified solution	0.003	IU/mL							

<b>7. Stability of reconstituted reagents (purified milieu, CS-series)</b>									$R^2 \geq 0.98$ $\Delta A405(0-0.067) \geq 0.5$ $\Delta A405(0IU/mL) \leq 10\%$ 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 ≤ -20°C									
A405 values for UFH									
	0.0	0.006	0.017	0.033	0.050	0.067	R <sup>2</sup>	A405 (Free pNA)	
Freshly restored	1.152	0.988	0.700	0.386	0.213	0.127	1.000	0.071	
15 days at 2-8°C	1.153	0.977	0.683	0.368	0.196	0.115	0.998	0.072	
7 days at RT (18-25°C)	1.121	0.958	0.685	0.371	0.203	0.117	0.998	0.089	
Frozen ≤ -20°C	1.138	1.003	0.762	0.457	0.270	0.157	0.998	0.075	

Comments :	<input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b>
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Date : 14. AOUT 2025

QC Manager : Isabelle CORNUEJOLS  
 Resp: Labo CC...  
