

**ANALYSIS CERTIFICATE**

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

**Lot : FD01211A**

**QC Release : ... 05 MARS 2024**

**Expiration date : 2026-07-13**

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : ATIII(h)	2 vials	30	FD01211A	2026-07-13
R2 : FXa (b)	2 vials	30	FD01211A	2026-07-27
R3 : Substrate	2 vials	30	FD01211A	2026-07-14

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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) : 2.154            CV : 1.2 %</p> <p>b. AT content per vial (anti-Xa activity chromogenic assay)</p> <p style="margin-left: 40px;">5.3 IU</p> <p>c. Indicative AT content per vial (A280/Lowry on raw material)</p> <p style="margin-left: 40px;">636 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) : 2.167            CV : 0.7 %</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;">75 µg/vial</p> <p>d. Chromogenic activity on Xa substrate (10µg/ml) (raw material)</p> <p style="margin-left: 40px;">A405 with RVV : 1.936            A405 without RVV : 1.913</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) : 0.075</p> <p>b. Lot Homogeneity (A405 for 0 IU/mL heparin)</p> <p style="margin-left: 40px;">N : 20            Mean (A405) : 2.159            CV : 1.0 %</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;">98 %</p> <p>e. Experimental molecular weight (raw material)</p> <p style="margin-left: 40px;">641.4 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>

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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 <sup>2</sup>	
Purified milieu	UFH	1.140	0.926	0.713	0.405	0.234	0.140	0.998	
	LMWH	0.835	0.589	0.480	0.256	0.138	0.099	0.990	

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

7. <u>Stability of reconstituted reagents (purified milieu, CS-series)</u>									
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)	$R^2 \geq 0.98$ $\Delta A405(0-0.067) \geq 0.5$ $\Delta A405(0IU/mL) \leq 10\%$ between fresh and stored $A405(\text{Free pNA}) \leq 0.30$
Freshly restored	1.288	1.100	0.863	0.547	0.342	0.216	1.000	0.075	
15 days at 2-8°C	1.276	1.095	0.858	0.535	0.335	0.213	1.000	0.075	
7 days at RT (18-25°C)	1.324	1.149	0.921	0.580	0.365	0.229	0.998	0.075	
Frozen ≤ -20°C	1.299	1.118	0.875	0.541	0.334	0.207	0.998	0.077	

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

QC Manager : .....

**Quality Control Approval**

**05 MARS 2024**

**S. LECOURT**

