

ANALYSIS CERTIFICATE

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

Lot: FB105418

QC Release: 23/08/2022

Expiration date: 2024-12-13

Components	Qty	Exp. (months)	Lot #	Exp. date
R1: ATIII(h)	2 vials	30	FB105418	2024-12-13
R2: FXa (b)	2 vials	30	FB105418	2025-01-17
R3: Substrate	2 vials	30	FB105418	2024-12-13

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Analytical data									Specifications
5. Assay reactivity (in the tested dilution, CS-series)									$R^2 \geq 0.98$ $\Delta A405(0-0.067) \geq 0.5$
A405	IU/mL (in the tested dilution)	0.0	0.006	0.017	0.033	0.050	0.067	R ²	
Purified milieu	UFH	1.239	1.100	0.851	0.527	0.336	0.218	0.99	
	LMWH	1.072	0.890	0.616	0.341	0.198	0.125	0.99	

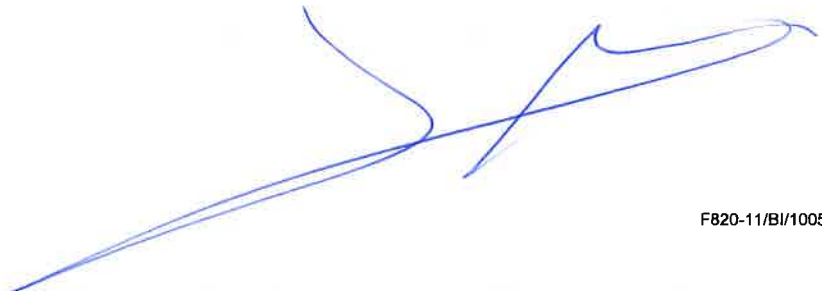
6. Detection threshold (concentration in the tested dilution, CS-series)									
In Purified solution		< 0.002 IU/mL							≤ 0.005 IU/mL

7. Stability of reconstituted reagents (purified milieu, CS-series)									
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)	$R^2 \geq 0.98$ $\Delta A405(0-0.067) \geq 0.5$ $\Delta A405(0IU/mL) \leq 10\%$ between fresh and stored A405(Free pNA) ≤ 0.30
Freshly restored	1.134	1.014	0.744	0.486	0.294	0.170	0.996	0.078	
15 days at 2-8°C	1.137	1.017	0.740	0.485	0.295	0.166	0.996	0.089	
7 days at RT (18-25°C)	1.171	1.052	0.761	0.503	0.300	0.171	0.996	0.082	
Frozen $\leq -20^\circ\text{C}$	1.137	1.020	0.734	0.476	0.285	0.162	0.998	0.094	

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date: 2022-08-23

QC Manager: S. LECOURT



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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: 25 Mean (A405): 2.010 CV: 1.63 %</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;">676 µg</p> <p>d. SDS PAGE (on raw material)</p> <p style="margin-left: 40px;">1 major band of about 58000 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: 25 Mean (A405): 2.024 CV: 1.78 %</p> <p>b. SDS PAGE (4-12% acrylamide) (FX zymogen for raw material)</p> <p style="margin-left: 40px;">1 major band of about 55000 Da</p> <p>c. Indicative FXa content per vial (Lowry, from zymogen raw material)</p> <p style="margin-left: 40px;">72 µg/vial</p> <p>d. Chromogenic activity on Xa substrate (10µg/ml) (raw material)</p> <p style="margin-left: 40px;">A405 with RVV: 1.897 A405 without RVV: 1.838</p> <p>e. Indicative chromogenic activity on Xa substrate (CS-11(22)) (raw material)</p> <p style="margin-left: 40px;">/ 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): 0.078</p> <p>b. Lot Homogeneity (A405 for 0 IU/mL heparin)</p> <p style="margin-left: 40px;">N: 25 Mean (A405): 2.025 CV: 1.87 %</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;">642 Da</p>	<p>A405 ≤ 0.30</p> <p>≤ 5 %</p> <p>≥ 95%</p> <p>641.7 ± 5 Da</p>