

ANALYSIS CERTIFICATE

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

Lot : F1700232

QC Release : 2017-06-26

Expiration date : 2019-08-19

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : ATIII(h)	2 vials	30	F171100232	2019-08-19
R2 : FXa (b)	2 vials	30	F171100232	2019-08-26
R3 : Substrate	2 vials	30	F171100232	2019-08-24

ANALYSIS CERTIFICATE

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

Lot : F1700232

QC Release : 2017-06-26

Expiration date : 2019-08-19

Analytical data	Specifications
<p>1. <u>AT III(h)</u></p> <p>a. Lot Homogeneity (A405 for 0 IU/mL heparin)</p> <p style="margin-left: 40px;">N : 25 Mean (A405) : 2,000 CV : 1,3 %</p> <p>b. AT content per vial (anti-Xa activity chromogenic assay)</p> <p style="margin-left: 40px;">6,95 IU</p> <p>c. Indicative AT content per vial (A280/Lowry on raw material)</p> <p style="margin-left: 40px;">695 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 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>2. <u>FXa(b)</u></p> <p>a. Lot Homogeneity (A405 for 0 IU/mL heparin)</p> <p style="margin-left: 40px;">N : 20 Mean (A405) : 1,999 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;">58 µg/vial</p> <p>d. Chromogenic activity on Xa substrate (10µg/ml) (raw material)</p> <p style="margin-left: 40px;">A405 with RVV : 1,145 A405 without RVV : 1,135</p> <p>e. Indicative chromogenic activity on Xa substrate (CS-11(22)) (raw material)</p> <p style="margin-left: 40px;">162,4 nkats / vial</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 <10%</p>
<p>3. <u>Substrate</u></p> <p>a. Blank value (free pNA)</p> <p style="margin-left: 40px;">Mean (A405) : 0,077</p> <p>b. Lot Homogeneity (A405 for 0 IU/mL heparin)</p> <p style="margin-left: 40px;">N : 25 Mean (A405) : 1,996 CV : 1,1 %</p> <p>c. Indicative content per vial (raw material)</p> <p style="margin-left: 40px;">5 mg (about 7,83 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;">641,5 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>

ANALYSIS CERTIFICATE

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

Lot : F1700232

QC Release : 2017-06-26

Expiration date : 2019-08-19

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	1,163	1,152	0,803	0,515	0,329	0,210	0,996	
	LMWH	0,883	0,827	0,552	0,324	0,165	0,102	0,996	

6. Detection threshold (concentration in the tested dilution, CS-series)									
In Purified solution		0,003 IU/mL (UFH & LMWH)						≤ 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 $A405(\text{Free pNA}) \leq 0.30$
Freshly restored	1,136	1,002	0,785	0,511	0,335	0,214	1,000	0,074	
15 days at 2-8°C	1,142	0,999	0,780	0,503	0,327	0,207	1,000	0,075	
7 days at RT (18-25°C)	1,162	1,016	0,796	0,522	0,338	0,220	1,000	0,079	
Frozen $\leq -20^\circ\text{C}$	1,122	0,985	0,774	0,504	0,326	0,210	1,000	0,076	

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
------------	-----------------------------------------------------------------

Date : 2017-06-26

QC Manager :

S. LECOURT

