HYPHEN BioMed
ZAC Neuville Université - 155 rue d'Eragny
95000 Neuville sur Oise (France)
Tel: 33.1.34.40.65.10 - Fax: 33.1.34.48.72.36

ANALYSIS CERTIFICATE

BIOPHEN HEPARIN 6 - # 221006

F1700344
Lot : F1700346

QC Release: **2017-05-02**

Expiration date : 2019-09-20

Components	Volume	Exp. (months)	Lot #	Exp. date
R1 : SXa-11 substrate	4 vials of 15 mg	30	F171200344 F171100346	2019-09-20
R2 : Bovine FXa	4 vials of 15 µg	30	F171200344 F171100346	2019-09-28

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ANALYSIS CERTIFICATE

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F1700346

QC Release: **2017-05-02** **Expiration date :** **2019-09-20**

Analytical data				Specifications
1. SXa-11 substrate				
a. Blank value (N=10)	Mean (A405):	**0,185**		A405 ≤ 0.30
b. Reproducibility (water bath)				
N= **20**	Mean (A405):	**1,978**		
	CV(DO):	**0,4**	%	≤ 2 %

2. Bovine Factor Xa				
a. Reproducibility (water bath)				
N= **20**	Mean (A405):	**1,973**		
	CV(DO):	**0,9**	%	≤ 2 %
b. Factor Xa reactivity (water bath)				
	A405 :	**2,069**		≥ 1.50

SAS

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Analytical data	Specifications

3. Assay method

a. STAR method

Calibration curves

	UFH IU/ml	A405	LMWH IU/ml	A405
CAL1	0	1,679	0	1,674
CAL2	0,46	1,133	0,47	1,108
CAL3	0,88	0,738	0,94	0,730
CAL4	1,33	0,483	1,47	0,422
CAL5	1,76	0,310	1,93	0,293

For a same A405 (UFH/LMWH)
MV = TV ±0.05 IU/ml for rate ≤ 0.50 IU/ml
MV = TV ±0.10 IU/ml for rate > 0.50 IU/ml

Controls

	Lot	TV*	MV**	
C1/UFH	53903-1	0,24	0,22	MV = TV ± 0.05 IU/ml
C2/UFH	53903-2	0,49	0,47	MV = TV ± 0.05 IU/ml
C3/LMWH	44202-1	0,79	0,75	MV = TV ± 0.10 IU/ml
C4/LMWH	F1600910	1,16	1,12	MV = TV ± 0.10 IU/ml

*TV: Target Value **MV: Measured value

b. CS Method

Calibration curves

	UFH IU/ml	A405	LMWH IU/ml	A405
CAL1	0	0,735	0	0,730
CAL2	0,46	0,491	0,47	0,462
CAL3	0,88	0,326	0,94	0,306
CAL4	1,33	0,214	1,47	0,193
CAL5	1,76	0,138	1,93	0,134

For a same A405 (UFH/LMWH)
MV = TV ±0.05 IU/ml for rate ≤ 0.50 IU/ml
MV = TV ±0.10 IU/ml for rate > 0.50 IU/ml

Controls

	Lot	TV*	MV**	
C1/UFH	53903-1	0,24	0,19	MV = TV ± 0.05 IU/ml
C2/UFH	53903-2	0,49	0,45	MV = TV ± 0.05 IU/ml
C3/LMWH	44202-1	0,79	0,77	MV = TV ± 0.10 IU/ml
C4/LMWH	F1600910	1,16	1,16	MV = TV ± 0.10 IU/ml

*TV: Target Value **MV: Measured value

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QC Release: 2017-05-02 **Expiration date : 2019-09-20**

Analytical data			Specifications
4. Stability of reconstituted reagents			
	Fresh	**7 days RT (18-25°C)**	
	Substrate blank		
A405	**0,133**	**0,190**	A405 ≤ 0.30
	A405 (LMWH calibration curve)		
CAL1	**0,690**	**0,718**	Δ A405 ≤ 0.10
CAL2	**0,482**	**0,500**	7 days at RT (18-25°C)
CAL3	**0,344**	**0,344**	
CAL4	**0,237**	**0,250**	
CAL5	**0,187**	**0,192**	
	Measured values for controls (IU/ml)		
C1/UFH	**0,17**	**0,21**	[0,14 - 0,34]
C2/UFH	**0,43**	**0,48**	[**0,34 - 0,64**]
C3/LMWH	**0,73**	**0,79**	[0,68 - 0,92]
C4/LMWH	**1,12**	**1,17**	[**1,00 - 1,36**]
5. Detection threshold			
A405 (0 IU/ml) - 3SD =		**0,795**	
Detection threshold:		**<0,01** IU/ml	≤ 0.05 IU/ml

Comments :

☒ **PASSED**
IN COMPLIANCE

Date : 2017-05-02 **QC Manager :** **S.LECOURT**