

## ANALYSIS CERTIFICATE

**BIOPHEN HEPARIN 6 - # 221006**

**F1700344**  
**Lot : F1700346**

**QC Release:**

**2017-05-02**

**Expiration date : 2019-09-20**

<b>Components</b>	<b>Volume</b>	<b>Exp. (months)</b>	<b>Lot #</b>	<b>Exp. date</b>
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

*905*

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

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

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<p><b>3. <u>Assay method</u></b></p> <p><b><u>a. 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Analytical data			Specifications
<b>4. Stability of reconstituted reagents</b>			
	Fresh	7 days RT (18-25°C)	
<i>Substrate blank</i>			
A405	0,133	0,190	A405 ≤ 0.30
<i>A405 (LMWH calibration curve)</i>			
CAL1	0,690	0,718	
CAL2	0,482	0,500	
CAL3	0,344	0,344	
CAL4	0,237	0,250	
CAL5	0,187	0,192	
<i>Measured values for controls (IU/ml)</i>			
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 ]
<b>5. Detection threshold</b>			
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

