

ANALYSIS CERTIFICATE

BIOPHEN HEPARIN CALIBRATOR - #222001

Lot : F1600445

QC release : 13/06/2016

Expiration date : 2018-10-27

Components	Volume	Exp. (months)	Lot #	Exp. date
CAL1 : Calibrator 1	4 vials	30	F161100445	2018-10-27
CAL2 : Calibrator 2	4 vials	30	F161100445	2018-10-27
CAL3 : Calibrator 3	4 vials	30	F161100445	2018-10-27
CAL4 : Calibrator 4	4 vials	30	F161100445	2018-10-27
CAL5 : Calibrator 5	4 vials	30	F161100445	2018-10-27



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Analytical data			Specifications
1. <u>Within lot reproducibility</u>			
mean OD			
N= 25	CAL1: 0,688	CV: 0,5 %	CV (OD) ≤ 2%
N= 25	CAL2: 0,453	CV: 0,5 %	CV (OD) ≤ 2%
N= 25	CAL3: 0,308	CV: 0,8 %	CV (OD) ≤ 2%
N= 25	CAL4: 0,217	CV: 1,1 %	CV (OD) ≤ 2%
N= 20	CAL5: 0,162	CV: 0,8 %	CV (OD) ≤ 2%

2. <u>Concentration [C] and Standard Deviation (SD)</u>				
Controls	N series	[C] IU/mL	SD	
CAL1	11	0	0,01	CAL1: ≤ 0.05 IU/ml
CAL2	11	0,40	0,01	CAL2: 0.30-0.50 IU/mL
CAL3	11	0,80	0,03	CAL3: 0.70-0.90 IU/mL
CAL4	11	1,18	0,03	CAL4: 1.10-1.30 IU/mL
CAL5	11	1,50	0,04	CAL5: 1.45-1.75 IU/mL

3. <u>Aspect</u>		
<input checked="" type="checkbox"/>	Slightly opalescent to clear	a) Slightly opalescent to clear
<input checked="" type="checkbox"/>	No coagulum	b) No coagulum
<input checked="" type="checkbox"/>	Stable solution	c) Stable solution

4. <u>Stability of reconstituted reagents</u>					
		Fresh	48h	7 days	
		/	RT	2-8°C	
CAL1	IU/mL	0	0	0	48 hours at RT and 7 days at 2-8°C: $\Delta [C] \leq 0.05 \text{ IU/ml}$ for cal1 and cal2 $\Delta [C] \leq 10\%$ for cal3, cal4 and cal5
	ΔC	NA	0	0	
CAL2	IU/mL	0,39	0,40	0,41	
	ΔC	NA	0,01	0,02	
CAL3	IU/mL	0,80	0,82	0,82	
	$\Delta \%$	NA	2,5	2,5	
CAL4	IU/mL	1,16	1,20	1,21	
	$\Delta \%$	NA	3,4	4,3	
CAL5	IU/mL	1,48	1,52	1,52	
	$\Delta \%$	NA	2,7	2,7	

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Analytical data	Specifications																		
<p>5. <u>Calibration curve</u></p> <p style="text-align: center;">Method : STAR</p> <p style="text-align: center;">BIOPHEN Heparin Lot 53003</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;"></th> <th style="width: 20%;">IU/ml</th> <th style="width: 20%;">A₄₀₅</th> </tr> </thead> <tbody> <tr> <td>Cal 1</td> <td style="text-align: center;">0</td> <td style="text-align: center;">1,530</td> </tr> <tr> <td>Cal 2</td> <td style="text-align: center;">0,40</td> <td style="text-align: center;">1,104</td> </tr> <tr> <td>Cal 3</td> <td style="text-align: center;">0,80</td> <td style="text-align: center;">0,788</td> </tr> <tr> <td>Cal 4</td> <td style="text-align: center;">1,18</td> <td style="text-align: center;">0,586</td> </tr> <tr> <td>Cal 5</td> <td style="text-align: center;">1,50</td> <td style="text-align: center;">0,471</td> </tr> </tbody> </table>		IU/ml	A ₄₀₅	Cal 1	0	1,530	Cal 2	0,40	1,104	Cal 3	0,80	0,788	Cal 4	1,18	0,586	Cal 5	1,50	0,471	
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<p>6. <u>Linearity</u></p> <p style="text-align: center;">R² 0,998</p>	<p>R² ≥ 0.98</p>
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<p>7. <u>Accuracy</u> Method : STAR</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th colspan="3" style="text-align: center;">CONTROLS</th> <th style="text-align: center;">TV*</th> <th style="text-align: center;">MV*</th> </tr> </thead> <tbody> <tr> <td>C1</td> <td>Lot</td> <td>53903-1</td> <td style="text-align: center;">0,24</td> <td style="text-align: center;">0,28</td> </tr> <tr> <td>C2</td> <td>Lot</td> <td>53903-2</td> <td style="text-align: center;">0,49</td> <td style="text-align: center;">0,53</td> </tr> <tr> <td>C3</td> <td>Lot</td> <td>52605-1</td> <td style="text-align: center;">0,80</td> <td style="text-align: center;">0,84</td> </tr> <tr> <td>C4</td> <td>Lot</td> <td>52605-2</td> <td style="text-align: center;">1,18</td> <td style="text-align: center;">1,21</td> </tr> <tr> <td>CI</td> <td>Lot</td> <td>53602-1</td> <td style="text-align: center;">0,28</td> <td style="text-align: center;">0,30</td> </tr> <tr> <td>CII</td> <td>Lot</td> <td>53803-2</td> <td style="text-align: center;">0,50</td> <td style="text-align: center;">0,54</td> </tr> </tbody> </table> <p style="text-align: center; font-size: small;">*TV: Target Value *MV: Measured Value</p>	CONTROLS			TV*	MV*	C1	Lot	53903-1	0,24	0,28	C2	Lot	53903-2	0,49	0,53	C3	Lot	52605-1	0,80	0,84	C4	Lot	52605-2	1,18	1,21	CI	Lot	53602-1	0,28	0,30	CII	Lot	53803-2	0,50	0,54	<p style="text-align: center;">[0,14 - 0,34] IU/ml [0,34 - 0,64] IU/ml [0,68 - 0,92] IU/ml [1,00 - 1,36] IU/ml [0,20 - 0,36] IU/ml [0,38 - 0,62] IU/ml</p>
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<p><u>Comments :</u></p>	<p><input checked="" type="checkbox"/> PASSED IN COMPLIANCE</p>
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Date : 13/06/2016

QC Manager :

S. LECOURT





BIOPHEN HEPARIN CALIBRATOR

Calibration plasmas for the assay of Heparins with anti-Xa methods /

Gamme de plasmas humains, à titre défini en Héparine de Bas Poids Moléculaire pour l'étalonnage des dosages d'héparine par méthode anti-Xa

REF 222001

For in vitro diagnostic use only / *Pour diagnostic in vitro exclusivement*

LOT F1600445

2018-10-27

Low Molecular Weight Heparin Concentration [C] in the calibrators /
Concentration [C] en Héparine de Bas Poids Moléculaire dans les calibrateurs

<u>Calibrator / Calibrateur 1</u>	LOT : F161100445
[C] :	0 IU/mL / UI/mL
<u>Calibrator / Calibrateur 2</u>	LOT : F161100445
[C] :	0,40 IU/mL / UI/mL
<u>Calibrator / Calibrateur 3</u>	LOT : F161100445
[C] :	0,80 IU/mL / UI/mL
<u>Calibrator / Calibrateur 4</u>	LOT : F161100445
[C] :	1,18 IU/mL / UI/mL
<u>Calibrator / Calibrateur 5</u>	LOT : F161100445
[C] :	1.50 IU/mL / UI/mL

Standardization / *Standardisation* : Calibrator is calibrated against internal standard qualified against international Standard from NIBSC (lot11/176)

Approved Date / *Date d'Approbation* : 13/06/2016

Quality Control Manager / *Responsable Contrôle Qualité* : S. LECOURT