

ANALYSIS CERTIFICATE

BIOPHEN HEPARIN CALIBRATOR - #222001

F1701060

Lot : F1701061

QC release : 2017-10-23

Expiration date : 2020-03-07

Components	Volume	Exp. (months)	Lot #	Exp. date
CAL1 : Calibrator 1	4 vials	30	F171501060 F171101061	2020-03-07
CAL2 : Calibrator 2	4 vials	30	F171501060 F171101061	2020-03-07
CAL3 : Calibrator 3	4 vials	30	F171501060 F171101061	2020-03-07
CAL4 : Calibrator 4	4 vials	30	F171501060 F171101061	2020-03-07
CAL5 : Calibrator 5	4 vials	30	F171501060 F171101061	2020-03-07



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Analytical data				Specifications
1. <u>Within lot reproducibility</u>				
<u>mean OD</u>				
N= 15	CAL1:	0,737	CV: 0,4 %	CV (OD) ≤ 2%
N= 15	CAL2:	0,512	CV: 0,6 %	CV (OD) ≤ 2%
N= 15	CAL3:	0,358	CV: 0,9 %	CV (OD) ≤ 2%
N= 15	CAL4:	0,256	CV: 1,2 %	CV (OD) ≤ 2%
N= 15	CAL5:	0,185	CV: 1,0 %	CV (OD) ≤ 2%

2. <u>Concentration [C] and Standard Deviation (SD)</u>				
Controls	N series	[C] IU/mL	SD	
CAL1	10	0	0,007	CAL1: ≤ 0.05 IU/ml
CAL2	10	0,38	0,012	CAL2: 0.30-0.50 IU/mL
CAL3	10	0,77	0,019	CAL3: 0.70-0.90 IU/mL
CAL4	10	1,14	0,028	CAL4: 1.10-1.30 IU/mL
CAL5	10	1,51	0,028	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: Δ [C] ≤ 0.05IU/ml for cal1 and cal2 Δ [C] ≤ 10% for cal3, cal4 and cal5
	Δ C	NA	0	0	
CAL2	IU/mL	0,39	0,39	0,40	
	Δ C	NA	0	0,01	
CAL3	IU/mL	0,79	0,78	0,78	
	Δ %	NA	1,3	1,3	
CAL4	IU/mL	1,16	1,15	1,15	
	Δ %	NA	0,9	0,9	
CAL5	IU/mL	1,49	1,50	1,49	
	Δ %	NA	0,7	0	

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Analytical data	Specifications																		
<p>5. Calibration curve</p> <p style="text-align: center;">Method : CS5100</p> <p style="text-align: center;">BIOPHEN Heparin Lot F1700921</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: 10%;">A₄₀₅</th> </tr> </thead> <tbody> <tr> <td>Cal 1</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0,747</td> </tr> <tr> <td>Cal 2</td> <td style="text-align: center;">0,38</td> <td style="text-align: center;">0,521</td> </tr> <tr> <td>Cal 3</td> <td style="text-align: center;">0,77</td> <td style="text-align: center;">0,365</td> </tr> <tr> <td>Cal 4</td> <td style="text-align: center;">1,14</td> <td style="text-align: center;">0,259</td> </tr> <tr> <td>Cal 5</td> <td style="text-align: center;">1,51</td> <td style="text-align: center;">0,189</td> </tr> </tbody> </table>		IU/ml	A ₄₀₅	Cal 1	0	0,747	Cal 2	0,38	0,521	Cal 3	0,77	0,365	Cal 4	1,14	0,259	Cal 5	1,51	0,189	
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<p>6. Linearity</p> <p style="text-align: center;">R² 1,000</p>	<p>R² ≥ 0.98</p>
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<p>7. Accuracy Method : CS5100</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>F1601129</td> <td style="text-align: center;">0,24</td> <td style="text-align: center;">0,22</td> </tr> <tr> <td>C2</td> <td>Lot</td> <td>F1601128</td> <td style="text-align: center;">0,47</td> <td style="text-align: center;">0,47</td> </tr> <tr> <td>C3</td> <td>Lot</td> <td>F1600872</td> <td style="text-align: center;">0,79</td> <td style="text-align: center;">0,80</td> </tr> <tr> <td>C4</td> <td>Lot</td> <td>F1700686</td> <td style="text-align: center;">1,14</td> <td style="text-align: center;">1,15</td> </tr> <tr> <td>CI</td> <td>Lot</td> <td>F1601029</td> <td style="text-align: center;">0,26</td> <td style="text-align: center;">0,27</td> </tr> <tr> <td>CII</td> <td>Lot</td> <td>F1601030</td> <td style="text-align: center;">0,51</td> <td style="text-align: center;">0,53</td> </tr> </tbody> </table> <p style="text-align: center; font-size: small;">*TV: Target Value *MV: Measured Value</p>	CONTROLS			TV*	MV*	C1	Lot	F1601129	0,24	0,22	C2	Lot	F1601128	0,47	0,47	C3	Lot	F1600872	0,79	0,80	C4	Lot	F1700686	1,14	1,15	CI	Lot	F1601029	0,26	0,27	CII	Lot	F1601030	0,51	0,53	<p>[0,14 - 0,34] IU/ml</p> <p>[0,32 - 0,62] IU/ml</p> <p>[0,69 - 0,89] IU/ml</p> <p>[0,97 - 1,31] IU/ml</p> <p>[0,18 - 0,34] IU/ml</p> <p>[0,41 - 0,61] IU/ml</p>
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<p>Comments :</p>	<p><input checked="" type="checkbox"/> PASSED IN COMPLIANCE</p>
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Date : 2017-10-23

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 F1701060



2020-03-07

**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 : F171501060
[C] :	0 IU/mL / UI/mL
<u>Calibrator / Calibrateur 2</u>	LOT : F171501060
[C] :	0.38 IU/mL / UI/mL
<u>Calibrator / Calibrateur 3</u>	LOT : F171501060
[C] :	0.77 IU/mL / UI/mL
<u>Calibrator / Calibrateur 4</u>	LOT : F171501060
[C] :	1.14 IU/mL / UI/mL
<u>Calibrator / Calibrateur 5</u>	LOT : F171501060
[C] :	1.51 IU/mL / UI/mL

Standardization / *Standardisation* : Calibrator is calibrated against internal standard qualified against international standard from NIBSC lot 11/176

Approved Date / *Date d'Approbation* : 2017-10-23

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