

ANALYSIS CERTIFICATE

BIOPHEN UFH CALIBRATOR - #222301

Lot : F1600591

QC release : 25.07.2016

Expiration date : 2018-11-27

Components	Volume	Exp. (months)	Lot #	Exp. date
CAL1 : Calibrator 1	4 vials	30	F161200591	2018-11-27
CAL2 : Calibrator 2	4 vials	30	F161200591	2018-11-27
CAL3 : Calibrator 3	4 vials	30	F161200591	2018-11-27
CAL4 : Calibrator 4	4 vials	30	F161200591	2018-11-27
CAL5 : Calibrator 5	4 vials	30	F161200591	2018-11-27

SAS

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Analytical data				Specifications
1. <u>Within lot reproducibility</u>				
	Mean OD			
N= 10	CAL1:	0,677	CV: 0,6 %	CV (OD) ≤ 2%
N= 10	CAL2:	0,519	CV: 0,5 %	CV (OD) ≤ 2%
N= 10	CAL3:	0,395	CV: 0,8 %	CV (OD) ≤ 2%
N= 10	CAL4:	0,303	CV: 1,0 %	CV (OD) ≤ 2%
N= 10	CAL5:	0,235	CV: 1,0 %	CV (OD) ≤ 2%

2. <u>Concentration [C] and Standard Deviation (SD)</u>				
	Controls	N series	[C] IU/mL	SD
	CAL1	9	0	0,018
	CAL2	9	0,35	0,021
	CAL3	9	0,64	0,021
	CAL4	9	1,00	0,031
	CAL5	9	1,31	0,043
				CAL1: ≤ 0.05 IU/ml
				CAL2: 0.20-0.45 IU/mL
				CAL3: 0.50-0.80 IU/mL
				CAL4: 0.80-1.15 IU/mL
				CAL5: 1.15-1.50 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	
		I	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	0,35	0,35	0,34	
	Δ C	NA	0	0,01	
CAL3	IU/mL	0,67	0,67	0,66	
	Δ %	NA	0	1,5	
CAL4	IU/mL	0,96	0,98	0,96	
	Δ %	NA	2,1	0	
CAL5	IU/mL	1,27	1,30	1,29	
	Δ %	NA	2,4	1,6	

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Analytical data		Specifications																		
<p>5. Calibration curve</p> <p style="text-align: center;">Method : CS5100</p> <p>BIOPHEN Heparin Lot F1600093</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th></th> <th>IU/ml</th> <th>A₄₀₅</th> </tr> </thead> <tbody> <tr> <td>Cal 1</td> <td>0</td> <td>0,733</td> </tr> <tr> <td>Cal 2</td> <td>0,35</td> <td>0,527</td> </tr> <tr> <td>Cal 3</td> <td>0,64</td> <td>0,397</td> </tr> <tr> <td>Cal 4</td> <td>1,00</td> <td>0,299</td> </tr> <tr> <td>Cal 5</td> <td>1,31</td> <td>0,225</td> </tr> </tbody> </table>				IU/ml	A ₄₀₅	Cal 1	0	0,733	Cal 2	0,35	0,527	Cal 3	0,64	0,397	Cal 4	1,00	0,299	Cal 5	1,31	0,225
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6. Linearity	R ² 0,9980	R ² ≥ 0.98
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7. Accuracy		Method : CS5100																						
	<table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th colspan="2">CONTROLS</th> <th>TV*</th> <th>MV*</th> </tr> </thead> <tbody> <tr> <td>C1</td> <td>Lot 53903-1</td> <td>0,24</td> <td>0,25</td> </tr> <tr> <td>C2</td> <td>Lot 53903-2</td> <td>0,49</td> <td>0,51</td> </tr> <tr> <td>C3</td> <td>Lot 52605-1</td> <td>0,80</td> <td>0,83</td> </tr> <tr> <td>C4</td> <td>Lot 44202-2</td> <td>1,19</td> <td>1,25</td> </tr> </tbody> </table>		CONTROLS		TV*	MV*	C1	Lot 53903-1	0,24	0,25	C2	Lot 53903-2	0,49	0,51	C3	Lot 52605-1	0,80	0,83	C4	Lot 44202-2	1,19	1,25		
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C4	Lot 44202-2	1,19	1,25																					
				[0,14 - 0,34] IU/ml																				
				[0,34 - 0,64] IU/ml																				
				[0,68 - 0,92] IU/ml																				
				[1,01 - 1,37] IU/ml																				
		*TV: Target Value	*MV: Measured Value																					

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 25.07.2016

QC Manager :

S. LECOURT





BIOPHEN UFH CALIBRATOR

Calibration plasmas for the assay of UFH with anti-Xa method /

Gamme de plasmas humains, à titre défini en Héparine Non Fractionnée (HNF) pour l'étalonnage des dosages d'héparine par méthode anti-Xa

REF 222301

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

LOT F1600591  2018-11-27

Unfractionated Heparin (UFH) Concentration [C] in the calibrators /
Concentration [C] en Héparine Non Fractionnée (HNF) dans les calibrateurs

<u>Calibrator / Calibrateur 1</u>	LOT : F161200591
[C] :	0 IU/mL / UI/mL
<u>Calibrator / Calibrateur 2</u>	LOT : F161200591
[C] :	0.35 IU/mL / UI/mL
<u>Calibrator / Calibrateur 3</u>	LOT : F161200591
[C] :	0.64 IU/mL / UI/mL
<u>Calibrator / Calibrateur 4</u>	LOT : F161200591
[C] :	1.00 IU/mL / UI/mL
<u>Calibrator / Calibrateur 5</u>	LOT : F161200591
[C] :	1.31 IU/mL / UI/mL

Standardization / *Standardisation* : Calibrators are qualified against internal standard related to International Standard 07/328 (NIBSC)

Approved Date / *Date d'Approbation* : 25.07.2016

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