

ANALYSIS CERTIFICATE

BIOPHEN UFH CALIBRATOR - #222301

**Lot : F1700632
F1700633**

QC release : 2017-07-11

Expiration date : 2019-11-26

Components	Volume	Exp. (months)	Lot #	Exp. date
CAL1 : Calibrator 1	4 vials	30	F171600632 F171100633	2019-11-26
CAL2 : Calibrator 2	4 vials	30	F171600632 F171100633	2019-11-26
CAL3 : Calibrator 3	4 vials	30	F171600632 F171100633	2019-11-26
CAL4 : Calibrator 4	4 vials	30	F171600632 F171100633	2019-11-26
CAL5 : Calibrator 5	4 vials	30	F171600632 F171100633	2019-11-26

305

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Analytical data				Specifications
1. Within lot reproducibility				
	Mean OD			
N= 15	CAL1:	0,728	CV:	0,5 %
N= 15	CAL2:	0,549	CV:	0,4 %
N= 15	CAL3:	0,407	CV:	0,6 %
N= 15	CAL4:	0,304	CV:	1,1 %
N= 15	CAL5:	0,227	CV:	1,0 %
				CV (OD) ≤ 2%
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2. Concentration [C] and Standard Deviation (SD)				
	Controls	N series	[C] IU/mL	SD
	CAL1	12	0	0,022
	CAL2	12	0,34	0,018
	CAL3	12	0,65	0,021
	CAL4	12	0,96	0,038
	CAL5	12	1,30	0,030
				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. Aspect				
<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. Stability of reconstituted reagents				
		Fresh	48h	7 days
		/	RT	2-8°C
CAL1	IU/mL	0	0	0
	Δ C	NA	0	0
CAL2	IU/mL	0,35	0,35	0,35
	Δ C	NA	0	0
CAL3	IU/mL	0,69	0,70	0,68
	Δ %	NA	1,4	1,4
CAL4	IU/mL	0,99	1,04	1,00
	Δ %	NA	5,1	1,0
CAL5	IU/mL	1,34	1,36	1,32
	Δ %	NA	1,5	1,5
				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

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Analytical data	Specifications																		
<p>5. <u>Calibration curve</u></p> <p style="text-align: center;">Method : CS</p> <p style="text-align: center;">BIOPHEN Heparin Lot F1600547</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;">0,709</td> </tr> <tr> <td>Cal 2</td> <td style="text-align: center;">0,34</td> <td style="text-align: center;">0,483</td> </tr> <tr> <td>Cal 3</td> <td style="text-align: center;">0,65</td> <td style="text-align: center;">0,355</td> </tr> <tr> <td>Cal 4</td> <td style="text-align: center;">0,96</td> <td style="text-align: center;">0,263</td> </tr> <tr> <td>Cal 5</td> <td style="text-align: center;">1,30</td> <td style="text-align: center;">0,194</td> </tr> </tbody> </table>		IU/ml	A ₄₀₅	Cal 1	0	0,709	Cal 2	0,34	0,483	Cal 3	0,65	0,355	Cal 4	0,96	0,263	Cal 5	1,30	0,194	
	IU/ml	A ₄₀₅																	
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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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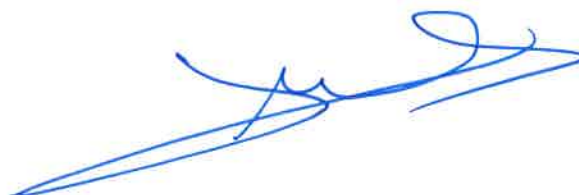
<p>7. <u>Accuracy</u> Method : CS</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th colspan="3" style="text-align: center;">CONTROLS</th> <th style="text-align: center;">TV*</th> <th style="text-align: center;">MV*</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C1</td> <td style="text-align: center;">Lot</td> <td style="text-align: center;">53903-1</td> <td style="text-align: center;">0,24</td> <td style="text-align: center;">0,24</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">Lot</td> <td style="text-align: center;">53903-2</td> <td style="text-align: center;">0,49</td> <td style="text-align: center;">0,50</td> </tr> <tr> <td style="text-align: center;">C3</td> <td style="text-align: center;">Lot</td> <td style="text-align: center;">F1601129</td> <td style="text-align: center;">0,24</td> <td style="text-align: center;">0,24</td> </tr> <tr> <td style="text-align: center;">C4</td> <td style="text-align: center;">Lot</td> <td style="text-align: center;">F1601128</td> <td style="text-align: center;">0,47</td> <td style="text-align: center;">0,48</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	0,24	C2	Lot	53903-2	0,49	0,50	C3	Lot	F1601129	0,24	0,24	C4	Lot	F1601128	0,47	0,48	<p style="text-align: center;">[0,14 - 0,34] IU/ml</p> <p style="text-align: center;">[0,34 - 0,64] IU/ml</p> <p style="text-align: center;">[0,14 - 0,34] IU/ml</p> <p style="text-align: center;">[0,32 - 0,62] IU/ml</p>
CONTROLS			TV*	MV*																						
C1	Lot	53903-1	0,24	0,24																						
C2	Lot	53903-2	0,49	0,50																						
C3	Lot	F1601129	0,24	0,24																						
C4	Lot	F1601128	0,47	0,48																						

<p>Comments :</p>	<p><input checked="" type="checkbox"/> PASSED IN COMPLIANCE</p>
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Date : 2017-07-11

QC Manager :

S. LECOURT





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
Web site: www.hyphen-biomed.com

ENGLISH / FRANÇAIS



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 F1700632

2019-11-26

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

<u>Calibrator / Calibreur 1</u>	LOT : F171600632
[C] :	0 IU/mL / UI/mL
<u>Calibrator / Calibreur 2</u>	LOT : F171600632
[C] :	0.34 IU/mL / UI/mL
<u>Calibrator / Calibreur 3</u>	LOT : F171600632
[C] :	0.65 IU/mL / UI/mL
<u>Calibrator / Calibreur 4</u>	LOT : F171600632
[C] :	0.96 IU/mL / UI/mL
<u>Calibrator / Calibreur 5</u>	LOT : F171600632
[C] :	1.30 IU/mL / UI/mL

Standardization / Standardisation :

Calibrator is qualified against internal standard qualified against International standard from NIBSC 07/328

Approved Date / Date d'Approbation : 2017-07-11

Quality Control Manager / Responsable Contrôle Qualité : S. LECOURT