

## ANALYSIS CERTIFICATE

**BIOPHEN ORGARAN CALIBRATOR - #222201**

**F1700986-  
Lot : F1700987**

**QC release : 2017-10-10**

**Expiration date : 2020-02-29**

Components	Volume	Exp. (months)	Lot #	Exp. date
CAL1 : Calibrator 1	4 vials	30	F171200986- F171100987	2020-02-29
CAL2 : Calibrator 2	4 vials	30	F171200986- F171100987	2020-02-29
CAL3 : Calibrator 3	4 vials	30	F171200986- F171100987	2020-02-29
CAL4 : Calibrator 4	4 vials	30	F171200986- F171100987	2020-02-29
CAL5 : Calibrator 5	4 vials	30	F171200986- F171100987	2020-02-29

SOS

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Analytical data				Specifications
<b>1. <u>Within lot reproducibility</u></b>				
		Mean OD		
N= 15	CAL1:	0,742	CV: 0,3 %	CV (OD) ≤ 2%
N= 15	CAL2:	0,456	CV: 1,0 %	CV (OD) ≤ 2%
N= 15	CAL3:	0,296	CV: 1,5 %	CV (OD) ≤ 2%
N= 15	CAL4:	0,200	CV: 1,1 %	CV (OD) ≤ 2%
N= 15	CAL5:	0,143	CV: 1,2 %	CV (OD) ≤ 2%
<b>2. <u>Concentration [C] and Standard Deviation (SD)</u></b>				
	<b>Controls</b>	<b>[C] U/mL</b>	<b>SD</b>	
	CAL1	0	0,02	CAL1: ≤ 0.05 U/ml
	CAL2	0,43	0,02	CAL2: 0.30-0.50 U/mL
	CAL3	0,85	0,03	CAL3: 0.70-0.90 U/mL
	CAL4	1,25	0,04	CAL4: 1.10-1.30 U/mL
	CAL5	1,64	0,05	CAL5: 1.45-1.75 U/mL
<b>3. <u>Aspect</u></b>				
	Slightly opalescent to clear			a) Slightly opalescent to clear
	No coagulum			b) No coagulum
	Stable solution			c) Stable solution
<b>4. <u>Stability of reconstituted reagents</u></b>				
		Fresh	48h	7 days
		/	RT	2-8°C
CAL1	U/mL	0	0	0
	Δ C	NA	0	0
CAL2	U/mL	0,45	0,46	0,46
	Δ C	NA	0,01	0,01
CAL3	U/mL	0,89	0,88	0,88
	Δ %	NA	1,1	1,1
CAL4	U/mL	1,28	1,29	1,27
	Δ %	NA	0,8	0,8
CAL5	U/mL	1,62	1,61	1,62
	Δ %	NA	0,6	0
<b>48 hours at RT and 7 days at 2-8°C:</b> Δ [C] ≤ 0,05U/ml to cal1 and cal2 Δ [C] ≤ 10% to cal3, cal4 and cal5				

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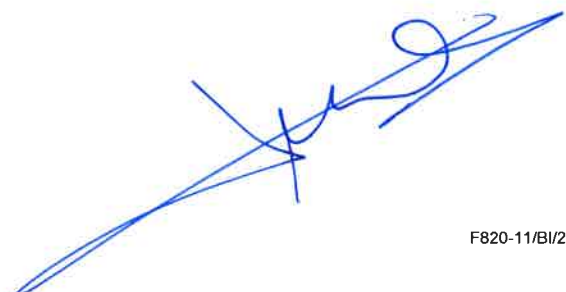
**QC release : 2017-10-10**

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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 F1700493</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;"></th> <th style="width: 15%;">U/ml</th> <th style="width: 15%;">A<sub>405</sub></th> </tr> </thead> <tbody> <tr> <td>Cal 1</td> <td style="text-align: center;">0,00</td> <td style="text-align: center;">1,840</td> </tr> <tr> <td>Cal 2</td> <td style="text-align: center;">0,43</td> <td style="text-align: center;">1,224</td> </tr> <tr> <td>Cal 3</td> <td style="text-align: center;">0,85</td> <td style="text-align: center;">0,851</td> </tr> <tr> <td>Cal 4</td> <td style="text-align: center;">1,25</td> <td style="text-align: center;">0,576</td> </tr> <tr> <td>Cal 5</td> <td style="text-align: center;">1,64</td> <td style="text-align: center;">0,396</td> </tr> </tbody> </table>		U/ml	A <sub>405</sub>	Cal 1	0,00	1,840	Cal 2	0,43	1,224	Cal 3	0,85	0,851	Cal 4	1,25	0,576	Cal 5	1,64	0,396	
	U/ml	A <sub>405</sub>																	
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<p>6. <u>Linearity</u></p> <p style="text-align: center;">R<sup>2</sup>      0,998</p>	<p>R<sup>2</sup> ≥ 0,98</p>																		
<p>7. <u>Accuracy</u>      Method : STAR</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%;">CONTROLS</th> <th style="width: 10%;">TV*</th> <th style="width: 20%;">acceptance range</th> <th style="width: 10%;">MV*</th> </tr> </thead> <tbody> <tr> <td>C1</td> <td style="text-align: center;">Lot F1700708</td> <td style="text-align: center;">0,54</td> <td style="text-align: center;">0,44 - 0,64</td> <td style="text-align: center;">0,55</td> </tr> <tr> <td>C2</td> <td style="text-align: center;">Lot F1700708</td> <td style="text-align: center;">1,05</td> <td style="text-align: center;">0,89 - 1,21</td> <td style="text-align: center;">1,01</td> </tr> </tbody> </table> <p style="text-align: center; font-size: small;">*TV: Target Value      *MV: Measured Value</p>		CONTROLS	TV*	acceptance range	MV*	C1	Lot F1700708	0,54	0,44 - 0,64	0,55	C2	Lot F1700708	1,05	0,89 - 1,21	1,01	<p>[ 0,44 - 0,64 ] U/ml</p> <p>[ 0,89 - 1,21 ] U/ml</p>			
	CONTROLS	TV*	acceptance range	MV*															
C1	Lot F1700708	0,54	0,44 - 0,64	0,55															
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<p><u>Comments :</u></p>	<p><input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b></p>																		

**Date : 2017-10-10**

**QC Manager : S.LECOURT**





## BIOPHEN ORGARAN® CALIBRATOR

Calibration plasmas for the assay of Sodium Danaparoid (Orgaran®) with anti-Xa methods /  
Gamme de plasmas humains, à titre défini en Danaparoïde de Sodium (Orgaran®) pour l'étalonnage des dosages par méthode anti-Xa

**REF** 222201

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

**LOT**

F1700986



2020-02-29

### Sodium Danaparoid (Orgaran®) Concentration [C] in the calibrators / Concentration [C] en Danaparoïde de Sodium (Orgaran®) dans les calibrateurs

<u>Calibrator / Calibrateur 1</u>	LOT : F171200986
[C] :	0 U/mL
<u>Calibrator / Calibrateur 2</u>	LOT : F171200986
[C] :	0,43 U/mL
<u>Calibrator / Calibrateur 3</u>	LOT : F171200986
[C] :	0,85 U/mL
<u>Calibrator / Calibrateur 4</u>	LOT : F171200986
[C] :	1,25 U/mL
<u>Calibrator / Calibrateur 5</u>	LOT : F171200986
[C] :	1,64 U/mL

Standardization / Standardisation : N/A

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

Quality Control Manager / Responsable Contrôle Qualité : S.LECOURT