

ANALYSIS CERTIFICATE

BIOPHEN LMWH CONTROL PLASMA - #223001

Lot : 52605

QC release : 11/08/2015

Expiration date : 2017-12

Components	Volume	Exp. (months)	Int. Ref.	Lot #	Exp. date
C3 : Control 3	6 vials	30	150623C	52605-1	2017-12
C4 : Control 4	6 vials	30	150626A	52605-2	2017-12

SAS

ANALYSIS CERTIFICATE

BIOPHEN LMWH CONTROL PLASMA - #223001

Lot : 52605

QC release : 11/08/2015

Expiration date : 2017-12

Analytical data	Specifications												
1. <u>Within lot reproducibility</u> (N ≥ 10) <table style="width: 100%; border: none;"> <tr> <td style="width: 20%; text-align: center;">N= 70</td> <td style="width: 10%; text-align: center;">C3:</td> <td style="width: 20%; text-align: center;"><u>Mean OD</u> 0,340</td> <td style="width: 10%; text-align: center;">CV:</td> <td style="width: 20%; text-align: center;">0,8 %</td> <td style="width: 10%;"></td> </tr> <tr> <td style="text-align: center;">N= 40</td> <td style="text-align: center;">C4:</td> <td style="text-align: center;">0,250</td> <td style="text-align: center;">CV:</td> <td style="text-align: center;">1,0 %</td> <td></td> </tr> </table>	N= 70	C3:	<u>Mean OD</u> 0,340	CV:	0,8 %		N= 40	C4:	0,250	CV:	1,0 %		OD : CV ≤ 2% OD : CV ≤ 2%
N= 70	C3:	<u>Mean OD</u> 0,340	CV:	0,8 %									
N= 40	C4:	0,250	CV:	1,0 %									

2. <u>Concentration and acceptance range</u> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th style="width: 15%;">Controls</th> <th style="width: 10%;">N series</th> <th style="width: 20%;">[C] UI/mL</th> <th style="width: 10%;">SD</th> <th style="width: 25%;">Acceptance range (UI/mL)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C3</td> <td style="text-align: center;">12</td> <td style="text-align: center;">0,80</td> <td style="text-align: center;">0,024</td> <td style="text-align: center;">[0,68-0,92]</td> </tr> <tr> <td style="text-align: center;">C4</td> <td style="text-align: center;">12</td> <td style="text-align: center;">1,18</td> <td style="text-align: center;">0,034</td> <td style="text-align: center;">[1,00-1,36]</td> </tr> </tbody> </table>	Controls	N series	[C] UI/mL	SD	Acceptance range (UI/mL)	C3	12	0,80	0,024	[0,68-0,92]	C4	12	1,18	0,034	[1,00-1,36]	C3: 0.70 to 0.90 IU/mL C4: 1.05 to 1.35 IU/mL
Controls	N series	[C] UI/mL	SD	Acceptance range (UI/mL)												
C3	12	0,80	0,024	[0,68-0,92]												
C4	12	1,18	0,034	[1,00-1,36]												

3. <u>Aspect</u> <input checked="" type="checkbox"/> Slightly opalescent to clear <input checked="" type="checkbox"/> No coagulum <input checked="" type="checkbox"/> Stable solution	a) Slightly opalescent to clear b) No coagulum c) Stable solution
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4. <u>Stability of reconstituted reagents</u> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th rowspan="2"></th> <th rowspan="2">Temp.</th> <th colspan="2">C3</th> <th colspan="2">C4</th> </tr> <tr> <th>IU/mL</th> <th>Δ %</th> <th>IU/mL</th> <th>Δ %</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Fresh</td> <td style="text-align: center;">/</td> <td style="text-align: center;">0,78</td> <td style="text-align: center;">NA</td> <td style="text-align: center;">1,17</td> <td style="text-align: center;">NA</td> </tr> <tr> <td style="text-align: center;">48h</td> <td style="text-align: center;">RT</td> <td style="text-align: center;">0,78</td> <td style="text-align: center;">0</td> <td style="text-align: center;">1,22</td> <td style="text-align: center;">4,3</td> </tr> <tr> <td style="text-align: center;">7 days</td> <td style="text-align: center;">2-8°C</td> <td style="text-align: center;">0,80</td> <td style="text-align: center;">2,6</td> <td style="text-align: center;">1,20</td> <td style="text-align: center;">2,6</td> </tr> </tbody> </table>		Temp.	C3		C4		IU/mL	Δ %	IU/mL	Δ %	Fresh	/	0,78	NA	1,17	NA	48h	RT	0,78	0	1,22	4,3	7 days	2-8°C	0,80	2,6	1,20	2,6	48h at RT Δ [C] ≤ 10% 7 days at 2-8°C Δ [C] ≤ 10%
			Temp.	C3		C4																							
	IU/mL	Δ %		IU/mL	Δ %																								
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Comments : 	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 11/08/2015

QC Manager : S.LECOURT



BIOPHEN LMWH CONTROL PLASMA
Référence 223001

Pour diagnostic *in vitro* exclusivement

FRANÇAIS

Lot : 52605 - Exp. : 2017-12

C3 (Contrôle 3) Lot : 52605-1
[C] : 0.80 UI/mL
Intervalle de confiance : 0.68-0.92 UI/mL

C4 (Contrôle 4) Lot : 52605-2
[C] : 1.18 UI/mL
Intervalle de confiance : 1.00-1.36 UI/mL

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223001

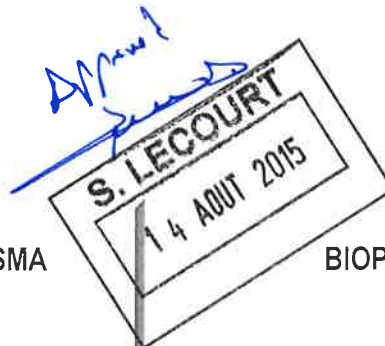
For *in vitro* diagnostic use only

ENGLISH

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