

ANALYSIS CERTIFICATE

BIOPHEN LMWH CONTROL C4 - #224201

Lot : 52605-2

QC release : 11/08/2015

Expiration date : 2017-12

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



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Analytical data	Specifications
1. <u>Within lot reproducibility (N ≥ 10)</u> N= 40 C4 (OD) : 0,250 CV: 1,0 %	OD : CV ≤ 2%

2. <u>Concentration and acceptance range</u> <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px auto;"> <thead> <tr> <th style="width: 15%;">Controls</th> <th style="width: 15%;">N series</th> <th style="width: 25%;">[C] IU/mL</th> <th style="width: 15%;">SD</th> <th style="width: 30%;">Acceptance range (IU/mL)</th> </tr> </thead> <tbody> <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] IU/mL	SD	Acceptance range (IU/mL)	C4	12	1,18	0,034	1,00-1,36	C4: 1.05 to 1.35 IU/mL
Controls	N series	[C] IU/mL	SD	Acceptance range (IU/mL)							
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: 10px auto;"> <thead> <tr> <th rowspan="2"></th> <th rowspan="2">Temp.</th> <th colspan="2">C4</th> </tr> <tr> <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;">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;">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;">1,20</td> <td style="text-align: center;">2,6</td> </tr> </tbody> </table>		Temp.	C4		IU/mL	Δ %	Fresh	/	1,17	NA	48h	RT	1,22	4,3	7 days	2-8°C	1,20	2,6	<u>48h at RT</u> Δ [C] ≤ 10% <u>7 days at 2-8°C</u> Δ [C] ≤ 10%
			Temp.	C4															
	IU/mL	Δ %																	
Fresh	/	1,17	NA																
48h	RT	1,22	4,3																
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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 C4
Référence 224201

Pour diagnostic *in vitro* exclusivement

FRANÇAIS

Lot : 52605-2 - Exp. : 2017-12

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

BIOPHEN LMWH CONTROL C4
224201

For *in vitro* diagnostic use only

ENGLISH

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Approuvé
[Signature]

S. LECOURT
14 AOÛT 2015

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