

ANALYSIS CERTIFICATE

BIOPHEN LMWH CONTROL C4 - #224201

Lot : F1700686 / F1700687

QC release : 26/07/2017

Expiration date : 2019-12-07

Components	Volume	Exp. (months)	Lot #	Exp. date
C4 : Control 4	12 vials	30	F171400686 / F171100687	2019-12-07

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Lot : F1700686 / F1700687

QC Release : 26/07/2017

Expiration date : 2019-12-07

Analytical data	Specifications
1. <u>Within lot reproducibility</u> N= 30 C4 (OD) : 0,253 CV: 0,9 %	CV(OD) ≤ 2%

2. <u>Concentration and acceptance range</u> <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px 0;"> <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;">10</td> <td style="text-align: center;">1,14</td> <td style="text-align: center;">0,03</td> <td style="text-align: center;">0,97 - 1,31</td> </tr> </tbody> </table>	Controls	N series	[C] IU/mL	SD	Acceptance range (IU/mL)	C4	10	1,14	0,03	0,97 - 1,31	C4: 1.05 to 1.35 IU/mL
Controls	N series	[C] IU/mL	SD	Acceptance range (IU/mL)							
C4	10	1,14	0,03	0,97 - 1,31							

3. <u>Aspect</u> <input checked="" type="checkbox"/> Slightly opalescent to clear <input checked="" type="checkbox"/> No coagulum <input checked="" type="checkbox"/> Stable solution	Slightly opalescent to clear No coagulum Stable solution
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4. <u>Stability of reconstituted reagents</u> <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px 0;"> <thead> <tr> <th rowspan="2"></th> <th rowspan="2">Temp.</th> <th colspan="2">C4</th> </tr> <tr> <th>IU/mL</th> <th>Δ[C]%</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Fresh</td> <td style="text-align: center;">/</td> <td style="text-align: center;">1,14</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;">1,13</td> <td style="text-align: center;">0,9%</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;">1,13</td> <td style="text-align: center;">0,9%</td> </tr> </tbody> </table>		Temp.	C4		IU/mL	Δ[C]%	Fresh	/	1,14	NA	48h	RT	1,13	0,9%	7 days	2-8°C	1,13	0,9%	<u>48h at RT (18-25°C) and 7 days at 2-8°C</u> Δ [C]% ≤ 10%
			Temp.	C4															
	IU/mL	Δ[C]%																	
Fresh	/	1,14	NA																
48h	RT	1,13	0,9%																
7 days	2-8°C	1,13	0,9%																

Comments : 	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 26/07/2017

QC Manager : S. LECOURT



BIOPHEN LMWH CONTROL C4

Human plasma at one level of Low Molecular Weight Heparin (LMWH) for the quality control of Heparin measurements with anti-Xa methods/
Plasma humain à un niveau d'Héparine de Bas Poids Moléculaire (HBPM) pour le contrôle de qualité des dosages d'héparine par méthode anti-Xa

REF 224201

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

LOT

F1700686



2019-12-07

Low Molecular Weight Heparin Concentration [C] in the control /
Concentration [C] en Héparine de Bas Poids Moléculaire dans le contrôle

Control / <i>Contrôle C4</i>	LOT : F171400686
Target value / <i>Valeur cible</i> :	1,14 IU/mL / UI/mL
Acceptance range / <i>Intervalle d'acceptation</i> :	[0,97 – 1,31] IU/mL / UI/mL

Standardization / *Standardisation* : **Control is qualified against internal standard related to IS NIBSC standard 11/176**

Approved Date / *Date d'Approbation* : 26/07/2017

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