

ANALYSIS CERTIFICATE

BIOPHEN LMWH CONTROL PLASMA - #223001

Lot : F1700814 / F1700815

QC release : 26/07/2017

Expiration date : 2019-12-07

Components	Volume	Exp. (months)	Lot #	Exp. date
C3 : Control 3	6 vials	30	F171400691 / F171100692	2019-12-16
C4 : Control 4	6 vials	30	F171400686 / F171100687	2019-12-07

3/25

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Lot : F1700814 / F1700815

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Analytical data	Specifications										
1. <u>Within lot reproducibility</u> <div style="text-align: center;"><u>Mean OD</u></div> <table style="width: 100%; border: none;"> <tr> <td style="width: 20%;">N= 110</td> <td style="width: 20%;">C3:</td> <td style="width: 20%; text-align: center;">0,354</td> <td style="width: 20%;">CV:</td> <td style="width: 20%; text-align: center;">0,8 %</td> </tr> <tr> <td>N= 30</td> <td>C4:</td> <td style="text-align: center;">0,253</td> <td>CV:</td> <td style="text-align: center;">0,9 %</td> </tr> </table>	N= 110	C3:	0,354	CV:	0,8 %	N= 30	C4:	0,253	CV:	0,9 %	CV(OD) ≤ 2% CV(OD) ≤ 2%
N= 110	C3:	0,354	CV:	0,8 %							
N= 30	C4:	0,253	CV:	0,9 %							

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: 25%;">[C] UI/mL</th> <th style="width: 15%;">SD</th> <th style="width: 35%;">Acceptance range (UI/mL)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C3</td> <td style="text-align: center;">10</td> <td style="text-align: center;">0,78</td> <td style="text-align: center;">0,025</td> <td style="text-align: center;">[0,66 - 0,90]</td> </tr> <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;">0,033</td> <td style="text-align: center;">[0,97 - 1,31]</td> </tr> </tbody> </table>	Controls	N series	[C] UI/mL	SD	Acceptance range (UI/mL)	C3	10	0,78	0,025	[0,66 - 0,90]	C4	10	1,14	0,033	[0,97 - 1,31]	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	10	0,78	0,025	[0,66 - 0,90]												
C4	10	1,14	0,033	[0,97 - 1,31]												

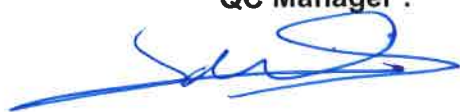
3. <u>Aspect</u> <input checked="" type="checkbox"/> Slightly opalescent to clear <input checked="" type="checkbox"/> No coagulum <input checked="" type="checkbox"/> Stable solution	Slightly opalescent to clear No coagulum Stable solution
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4. <u>Stability of reconstituted reagents</u> <table border="1" style="width: 100%; border-collapse: collapse; margin-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[C]%</th> <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;">0,78</td> <td style="text-align: center;">NA</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;">0,77</td> <td style="text-align: center;">1,3</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;">0,79</td> <td style="text-align: center;">1,3</td> <td style="text-align: center;">1,13</td> <td style="text-align: center;">0,9</td> </tr> </tbody> </table>		Temp.	C3		C4		IU/mL	Δ[C]%	IU/mL	Δ[C]%	Fresh	/	0,78	NA	1,14	NA	48h	RT	0,77	1,3	1,13	0,9	7 days	2-8°C	0,79	1,3	1,13	0,9	<u>48h at RT (18-25°C) and 7 days at 2-8°C</u> Δ [C] ≤ 10%
			Temp.	C3		C4																							
	IU/mL	Δ[C]%		IU/mL	Δ[C]%																								
Fresh	/	0,78	NA	1,14	NA																								
48h	RT	0,77	1,3	1,13	0,9																								
7 days	2-8°C	0,79	1,3	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 PLASMA

Human plasmas at two levels of Low Molecular Weight Heparin (LMWH) for the quality control of Heparin measurements with anti-Xa methods/
Plasmas humains à deux niveaux d'Héparine de Bas Poids Moléculaire (HBPM) pour le contrôle de qualité des dosages d'héparine par méthode anti-Xa

REF 223001

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

LOT

F1700814



2019-12-07

Low Molecular Weight Heparin Concentration [C] in the controls /
Concentration [C] en Héparine de Bas Poids Moléculaire dans les contrôles

Control / <i>Contrôle</i> C3	LOT : F171400691
Target value / <i>Valeur cible</i> :	0,78 IU/mL / UI/mL
Acceptance range / <i>Intervalle d'acceptation</i> :	[0,66 – 0,90] IU/mL / UI/mL

Control / <i>Contrôle</i> C4	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* : Controls are qualified against internal standard related to NIBSC standard 11/176

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

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