

ANALYSIS CERTIFICATE

BIOPHEN LMWH CONTROL PLASMA - #223001

Lot : F1700054

QC release : 2017-01-06

Expiration date : 2019-05-04

Components	Volume	Exp. (months)	Lot #	Exp. date
C3 : Control 3	6 vials	30	F161301138	2019-05-04
C4 : Control 4	6 vials	30	F161301139	2019-05-04

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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= 20</td> <td style="width: 10%;">C3:</td> <td style="width: 20%;">0,377</td> <td style="width: 10%;">CV:</td> <td style="width: 20%;">0,9 %</td> <td style="width: 20%;"></td> </tr> <tr> <td>N= 20</td> <td>C4:</td> <td>0,269</td> <td>CV:</td> <td>1,3 %</td> <td></td> </tr> </table>	N= 20	C3:	0,377	CV:	0,9 %		N= 20	C4:	0,269	CV:	1,3 %		CV(OD) ≤ 2% CV(OD) ≤ 2%
N= 20	C3:	0,377	CV:	0,9 %									
N= 20	C4:	0,269	CV:	1,3 %									

2. <u>Concentration and acceptance range</u> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th style="width: 10%;">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: 20%;">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;">0,80</td> <td style="text-align: center;">0,036</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;">10</td> <td style="text-align: center;">1,21</td> <td style="text-align: center;">0,042</td> <td style="text-align: center;">1,03-1,39</td> </tr> </tbody> </table>	Controls	N series	[C] UI/mL	SD	Acceptance range (UI/mL)	C3	10	0,80	0,036	0,68-0,92	C4	10	1,21	0,042	1,03-1,39	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	0,80	0,036	0,68-0,92												
C4	10	1,21	0,042	1,03-1,39												

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;">0,84</td> <td style="text-align: center;">NA</td> <td style="text-align: center;">1,22</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;">0,82</td> <td style="text-align: center;">2,4</td> <td style="text-align: center;">1,21</td> <td style="text-align: center;">0,8</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;">0,82</td> <td style="text-align: center;">2,4</td> <td style="text-align: center;">1,21</td> <td style="text-align: center;">0,8</td> </tr> </tbody> </table>		Temp.	C3		C4		IU/mL	Δ[C]%	IU/mL	Δ[C]%	Fresh	/	0,84	NA	1,22	NA	48h	RT	0,82	2,4	1,21	0,8	7 days	2-8°C	0,82	2,4	1,21	0,8	<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]%																								
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Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2017-01-06

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 F1700054  2019-05-04

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

Control / Contrôle C3	LOT : F161301138
Target value / <i>Valeur cible</i> :	0.80 IU/mL / UI/mL
Acceptance range / <i>Intervalle d'acceptation</i> :	[0.68-0.92] IU/mL / UI/mL

Control / Contrôle C4	LOT : F161301139
Target value / <i>Valeur cible</i> :	1.21 IU/mL / UI/mL
Acceptance range / <i>Intervalle d'acceptation</i> :	[1.03-1.39] IU/mL / UI/mL

Standardization / *Standardisation* : Controls are calibrated against internal standard qualified against 3rd international standard for LMWH from NIBSC 11/176

Approved Date / *Date d'Approbation* : 2017/01/06

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