

ANALYSIS CERTIFICATE

BIOPHEN LMWH CONTROL LOW CII - #224401

Lot : F1601030

QC release : 2016-11-21

Expiration date : 2019-04-08

Components	Volume	Exp. (months)	Lot #	Exp. date
CII : Control II	12 vials	30	F161101030	2019-04-08

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Analytical data	Specifications
1. <u>Within lot reproducibility</u> N = 45 CII (OD) : 0,456 CV: 0,8 %	CV(OD) ≤ 2%

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: 15%;">N series</th> <th style="width: 20%;">[C] IU/mL</th> <th style="width: 15%;">SD</th> <th style="width: 35%;">Acceptance range (IU/mL)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">CII</td> <td style="text-align: center;">10</td> <td style="text-align: center;">0,51</td> <td style="text-align: center;">0,023</td> <td style="text-align: center;">0,39-0,63</td> </tr> </tbody> </table>	Controls	N series	[C] IU/mL	SD	Acceptance range (IU/mL)	CII	10	0,51	0,023	0,39-0,63	CI: 0.35 to 0.65 IU/mL
Controls	N series	[C] IU/mL	SD	Acceptance range (IU/mL)							
CII	10	0,51	0,023	0,39-0,63							

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">CI</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;">0,56</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;">0,55</td> <td style="text-align: center;">0,01</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;">0,57</td> <td style="text-align: center;">0,01</td> </tr> </tbody> </table>		Temp.	CI		IU/mL	Δ [C]	Fresh	/	0,56	NA	48h	RT	0,55	0,01	7 days	2-8°C	0,57	0,01	<u>48h at RT (18-25°C) and 7 days at 2-8°C</u> Δ [C] ≤ 0.05 IU/ml
			Temp.	CI															
	IU/mL	Δ [C]																	
Fresh	/	0,56	NA																
48h	RT	0,55	0,01																
7 days	2-8°C	0,57	0,01																

<u>Comments :</u>	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2016-11-21

QC Manager :

S.LECOURT





BIOPHEN LMWH CONTROL LOW CII

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 224401

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

LOT F1601030  2019-04-08

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

Control / <i>Contrôle CII</i>	LOT : F161101030
Target value / <i>Valeur cible</i> :	0.51 IU/mL / <i>UI/mL</i>
Acceptance range / <i>Intervalle d'acceptation</i> :	[0.39 – 0.63] IU/mL / <i>UI/mL</i>

Standardization / *Standardisation* : Control is calibrated against internal standard qualified against from NIBSC 11/176

Approved Date / *Date d'Approbation* : 2016-11-21

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