

## ANALYSIS CERTIFICATE

**BIOPHEN LMWH CONTROL LOW CII - #224401**

**Lot : F1700803**

**QC release : 2017-08-30**

**Expiration date : 2020-01-06**

<b>Components</b>	<b>Volume</b>	<b>Exp. (months)</b>	<b>Lot #</b>	<b>Exp. date</b>
CII : Control II	12 vials	30	F171400803	2020-01-06

g/b

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Analytical data	Specifications
<b>1. <u>Within lot reproducibility</u></b>  N = 45      CII (OD) : 0,436                      CV: 0,6 %	CV(OD) ≤ 2%

<b>2. <u>Concentration and acceptance range</u></b>  <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;"><b>CII</b></td> <td style="text-align: center;">11</td> <td style="text-align: center;">0,50</td> <td style="text-align: center;">0,020</td> <td style="text-align: center;">0,38 - ,62</td> </tr> </tbody> </table>	Controls	N series	[C] IU/mL	SD	Acceptance range (IU/mL)	<b>CII</b>	11	0,50	0,020	0,38 - ,62	CI: 0.35 to 0.65 IU/mL
Controls	N series	[C] IU/mL	SD	Acceptance range (IU/mL)							
<b>CII</b>	11	0,50	0,020	0,38 - ,62							

<b>3. <u>Aspect</u></b>  <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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<b>4. <u>Stability of reconstituted reagents</u></b>  <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;">0,54</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;">0,52</td> <td style="text-align: center;">0,02</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;">0,52</td> <td style="text-align: center;">0,02</td> </tr> </tbody> </table>		Temp.	CI		IU/mL	Δ [C]	Fresh	/	0,54	NA	48h	RT	0,52	0,02	7 days	2-8°C	0,52	0,02	<b><u>48h at RT (18-25°C) and 7 days at 2-8°C</u></b>  Δ [C] ≤ 0.05 IU/ml
			Temp.	CI															
	IU/mL	Δ [C]																	
Fresh	/	0,54	NA																
48h	RT	0,52	0,02																
7 days	2-8°C	0,52	0,02																

<b><u>Comments :</u></b>	<input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b>
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Date : 2017-08-30

QC Manager :

S. LECOURT





## BIOPHEN LMWH CONTROL LOW CII

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** 224401

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

**LOT** F1700803  2020-01-06

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 : F171400803
Target value / <i>Valeur cible</i> :	0.50 IU/mL / <i>UI/mL</i>
Acceptance range / <i>Intervalle d'acceptation</i> :	[0.38 – 0.62] IU/mL / <i>UI/mL</i>

Standardization / *Standardisation* :

Control is qualified against internal standard qualified against 3<sup>rd</sup> international standard from NIBSC 11/176

Approved Date / *Date d'Approbation* : 2017-08-30

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