

## ANALYSIS CERTIFICATE

**BIOPHEN UFH CONTROL C1 - #224101**

**Lot : F1700314**

**QC Release : 2017-04-24**

**Expiration date : 2019-09-09**

<b>Components</b>	<b>Volume</b>	<b>Exp. (months)</b>	<b>Lot #</b>	<b>Exp. date</b>
C1 : Control 1	12 vials	30	F171300314	2019-09-09

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Analytical data	Specifications
<b>1. <u>Within lot reproducibility</u></b>  N= 75      C1 (OD): 0,614      CV: 0,4 %	CV (OD) ≤ 2%

<b>2. <u>Concentration and acceptance range</u></b>  <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px auto;"> <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>C1</b></td> <td style="text-align: center;">11</td> <td style="text-align: center;">0,24</td> <td style="text-align: center;">0,015</td> <td style="text-align: center;">0,14-0,34</td> </tr> </tbody> </table>	Controls	N series	[C] IU/mL	SD	Acceptance range (IU/mL)	<b>C1</b>	11	0,24	0,015	0,14-0,34	C1: 0.10 to 0.30 IU/mL
Controls	N series	[C] IU/mL	SD	Acceptance range (IU/mL)							
<b>C1</b>	11	0,24	0,015	0,14-0,34							

<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: 10px auto;"> <thead> <tr> <th rowspan="2"></th> <th rowspan="2">Temp.</th> <th colspan="2">C1</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;">0,26</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;">0,26</td> <td style="text-align: center;">0</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;">0,27</td> <td style="text-align: center;">0,01</td> </tr> </tbody> </table>		Temp.	C1		IU/mL	Δ [C]	Fresh	/	0,26	NA	48h	RT	0,26	0	7 days	2-8°C	0,27	0,01	<b><u>48h at RT (18-25°C) and 7 days at 2-8°C</u></b>  Δ [C] ≤ 0.05 IU/ml
			Temp.	C1															
	IU/mL	Δ [C]																	
Fresh	/	0,26	NA																
48h	RT	0,26	0																
7 days	2-8°C	0,27	0,01																

<b>Comments :</b>	<input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b>
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**Date : 2017-04-24**

**QC Manager :**

**S.LECOURT**





## BIOPHEN UFH CONTROL C1

Human plasma at one level of Unfractionated Heparin (UFH) for the quality control of Heparin measurements with anti-Xa methods/  
*Plasma humain à un niveau d'Héparine Non Fractionnée (HNF) pour le contrôle de qualité des dosages d'héparine par méthode anti-Xa*

**REF** 224101

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

**LOT**

F1700314



2019-09-09

Unfractionated Heparin Concentration [C] in the control /  
*Concentration [C] en Héparine Non Fractionnée dans le contrôle*

Control / <i>Contrôle C1</i>	LOT : F171300314
Target value / <i>Valeur cible</i> :	0.24 IU/mL / <i>UI/mL</i>
Acceptance range / <i>Intervalle d'acceptation</i> :	[0.14 – 0.34] IU/mL / <i>UI/mL</i>

Standardization / *Standardisation* : Control is calibrated against internal qualified against 3<sup>rd</sup> international standard for UFH from NIBSC 071328

Approved Date / *Date d'Approbation* : 2017-04-24

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