

ANALYSIS CERTIFICATE

BIOPHEN UFH CONTROL C1 - #224101

Lot : 53903-1

QC Release : 19/10/2015

Expiration date : 2018-03

Components	Volume	Exp. (months)	Int. Ref.	Lot #	Exp. date
C1 : Control 1	12 vials	30	150924A	53903-1	2018-03

pas

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Analytical data	Specifications
1. <u>Within lot reproducibility (N ≥ 10)</u> N= 55 C1 (OD): 0,532 CV: 0,6 %	CV (OD) ≤ 2%

2. <u>Concentration and acceptance range</u>											
<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">Controls</th> <th style="width: 15%;">N series</th> <th style="width: 25%;">[C] IU/mL</th> <th style="width: 15%;">SD</th> <th style="width: 30%;">Acceptance range (IU/mL)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C1</td> <td style="text-align: center;">10</td> <td style="text-align: center;">0,24</td> <td style="text-align: center;">0,019</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)	C1	10	0,24	0,019	0,14-0,34	C1: 0.10 to 0.30 IU/mL
Controls	N series	[C] IU/mL	SD	Acceptance range (IU/mL)							
C1	10	0,24	0,019	0,14-0,34							

3. <u>Aspect</u>	
<input checked="" type="checkbox"/> Slightly opalescent to clear <input checked="" type="checkbox"/> No coagulum <input checked="" type="checkbox"/> Stable solution	a) Slightly opalescent to clear b) No coagulum c) Stable solution

4. <u>Stability of reconstituted reagents</u>																			
<table border="1" style="margin: auto; border-collapse: collapse;"> <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	48h at RT Δ [C] ≤ 0.05 IU/ml 7 days at 2-8°C 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																

Comments : 	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 19/10/2015

 **QC Manager :**

S.LECOURT

BIOPHEN UFH CONTROL C1
Référence 224101

Pour diagnostic *in vitro* exclusivement

FRANÇAIS

Lot : 53903-1 - Exp. : 2018-03

BIOPHEN UFH CONTROL C1
224101

For *in vitro* diagnostic use only

ENGLISH

Lot : 53903-1 - Exp. : 2018-03

C1 (Contrôle 1) Lot : 53903-1
[C] : 0.24 UI/mL
Intervalle de confiance : 0.14 – 0.34 UI/mL

C1 (Control 1) Lot : 53903-1
[C] : 0.24 IU/mL
Acceptance range: 0.14 – 0.34 IU/mL

*Paul
Scherer
19.6.15*

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