

ANALYSIS CERTIFICATE

BIOPHEN UFH CONTROL PLASMA - #223101

Lot : F1700670

QC Release : 2017-06-09

Expiration date : 2019-09-07

Components	Volume	Exp. (months)	Lot #	Exp. date
C1 : Control 1	6 vials	30	F171300314	2019-09-09
C2 : Control 2	6 vials	30	F171300315	2019-09-07



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Analytical data	Specifications
1. <u>Within lot reproducibility</u>	
Mean OD	
N= 75 C1: 0,614 CV: 0,4 %	CV(OD) ≤ 2%
N= 70 C2: 0,477 CV: 0,7 %	CV(OD) ≤ 2%

2. <u>Concentration and acceptance range</u>					
Controls	N series	[C] IU/mL	SD	Acceptance range (IU/mL)	
C1	11	0,24	0,015	0,14 - 0,34	C1: 0.10 to 0.30 IU/mL
C2	11	0,50	0,025	0,35 - 0,65	C2: 0.40 to 0.60 IU/mL

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

4. <u>Stability of reconstituted reagents</u>						
	Temp.	C1		C2		
		IU/mL	Δ [C]	IU/mL	Δ [C]	
Fresh	/	0,26	NA	0,55	NA	<u>48h at RT (18-25°C) and 7 days at 2-8°C</u> Δ [C] ≤ 0.05 IU/ml
48h	RT	0,26	0	0,56	0,01	
7 days	2-8°C	0,27	0,01	0,57	0,02	

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2017-06-09

QC Manager : S. LECOURT



BIOPHEN UFH CONTROL PLASMA

Human plasmas at two levels of Unfractionated Heparin (UFH) for the quality control of Heparin measurements with anti-Xa methods/
Plasmas humains à deux niveaux d'Héparine Non Fractionnée (HNF) pour le contrôle de qualité des dosages d'héparine par méthode anti-Xa

REF 223101

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

LOT F1700670

2019-09-07

Unfractionated Heparin Concentration [C] in the controls /
Concentration [C] en Héparine Non Fractionnée dans les contrôles

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

Control / Contrôle C2	LOT : F171300315
Target value / <i>Valeur cible</i> :	0.50 IU/mL / UI/mL
Acceptance range / <i>Intervalle d'acceptation</i> :	[0.35 - 0.65] IU/mL / UI/mL

Standardization / *Standardisation* :

Controls are calibrated against internal standard qualified against 3rd International standard for UFH from NIBSC 07/328

Approved Date / *Date d'Approbation* : 2017-06-09

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