

ANALYSIS CERTIFICATE

BIOPHEN PLASMA CALIBRATOR - #222101 **F1700283**
Lot : **F1700288**

QC Release : **2017-06-06** **Expiration date :** **2019-08-31**

Components	Volume	Exp. (months)	Lot #	Exp. date
Plasma Calibrator	12 vials	30	F171200283 F171100288	2019-08-31

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BIOPHEN PLASMA CALIBRATOR - #222101

F1700283

Lot : F1700288

QC Release : 2017-06-06

Expiration date : 2019-08-31

Analytical data	Specifications
1. Within lot reproducibility N= 40 PT = 14,4 Sec CV: 0,7 % N= 40 APTT = 32,2 Sec CV: 0,9 %	CV ≤ 2% CV ≤ 2%

2. Value Assignment				[C] / Ratio
Parameters	N series	[C] / Ratio	SD	
Factor VII+X (%)	6	96	4,93	> 85%
Antithrombin (%) chromogenic/antigenic	11 / 6	95 / 92	7,22 / 1,94	> 85%
α2-Antiplasmin (%)	6	97	2,19	> 85%
Protein C chromogenic (%)	6	94	2,94	> 85%
Protein C clotting (%)	6	87	1,93	> 70%
Protein S clotting (%)	6	101	4,52	> 50%
Protein S free (Elisa) (%)	6	121	7,69	> 70%
Factor VIII:C (%)	9	97	4,62	> 60%
Prothrombin (%)	9	94	2,32	> 80%
Factor V (%)	6	98	4,80	> 80%
Factor VII (%)	11	98	4,31	> 80%
Factor IX (%)	8	89	1,92	> 60%
Factor X (%)	10	91	2,19	> 80%
Factor XI (%)	11	99	2,88	> 70%
Factor XII (%)	18	126	10,0	> 70%
Plasminogen (%)	11	97	3,58	> 80%
Fibrinogen (g/L)	8	2,74	0,04	> 2 g/L
vWF:Ag (%)	6	115	1,17	> 60%
DVVtest/confirm ratio	3	1,07	0,03	≤ 1.20

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

4. Stability of reconstituted reagents					
	PT		APTT		
	CT (sec)	Δ CT	CT (sec)	Δ CT	
Fresh	14,8	NA	32,8	NA	PT
24h / 2-8°C	15,0	0,2	33,4	0,6	8h at 18-25°C
8h / 18-25°C	14,8	0	32,4	0,4	24h at 2-8°C
					Δ CT ≤ 1sec
					Δ CT ≤ 3sec
					VIII:C or V: 4h at 18-25°C 8h at 2-8°C Δ[C] ≤ 10%

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

QC Manager : S. LECOURT



BIOPHEN PLASMA CALIBRATOR
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For in vitro diagnostic use only

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Controls	[C]
AT III	95 %
Protein C	94 %
DVVtest/DVVconfirm ratio	1.07

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Quality Control Approval

12 JUN 2017

S. Lecourt

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