

ANALYSIS CERTIFICATE

BIOPHEN PLASMA CALIBRATOR - #222101

Lot : F1700283
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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ANALYSIS CERTIFICATE

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: 8h at 18-25°C
24h / 2-8°C	15,0	0,2	33,4	0,6	PT: 24h at 2-8°C
8h / 18-25°C	14,8	0	32,4	0,4	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

Normal Human Plasma for the calibration of some coagulation factors / *Plasma humain normal pour l'étalonnage de certains tests de coagulation*

REF 222101

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

LOT F1700283

2019-08-31

Parameters / Paramètres	Reagents / Réactifs	[C] % or Ratio
Factor VII+X (%) / <i>Facteur VII+X (%)</i>	HEMOCLOT VII+X #CK051K / CK051L	96
AT III (Activity or Antigen) (%) / <i>AT III (Activité ou Antigène) (%)</i>	BIOPHEN Antithrombin 2.5 / BIOPHEN Antithrombin 5 / BIOPHEN ^e AT anti-(h)-Xa LRT / LIAPHEN AT #221102 / 221105 / 221123 / 221127 / 120002	95 (chromogenic) 92 (antigenic)
α 2 – Antiplasmin (%) / <i>α2 – Antiplasmine (%)</i>	BIOPHEN ^e α 2-Antiplasmin (LRT) #220502	97
Protein C (Chromogenic) (%) / <i>Protéine C (Chromogène) (%)</i>	BIOPHEN Protein C2.5 / BIOPHEN Protein C 5 / BIOPHEN Protein C (LRT) #221205 / 221205 / 221211	94
Protein C (Clotting) (%) / <i>Protéine C (Coagulante) (%)</i>	HEMOCLOT Protein C #CK031K	87
Protein S (Clotting) (%) / <i>Protéine S (Coagulante) (%)</i>	HEMOCLOT Protein S #CK041K	101
Free Protein S (Elisa) (%) / <i>Protéine S libre (Elisa) (%)</i>	ZYMUTEST FREE PROTEIN S #RK015A	121
Prothrombin (Clotting or Chromogenic) (%) / <i>Prothrombine (Coagulante ou Chromogène) (%)</i>	BIOPHEN Prothrombin / Prothrombin Deficient Plasma #221605 / DP010A - DP010K	94
Factor V (Clotting) (%) / <i>Facteur V (Coagulante) (%)</i>	Factor V Deficient Plasma / HEMOCLOT Factor V reagent #DP020A - DP020K / CK071K	98
Factor VII (Clotting or Chromogenic) (%) / <i>Facteur VII (Coagulante ou Chromogène) (%)</i>	BIOPHEN VII / Factor VII Deficient Plasma / HEMOCLOT Factor VII reagent #221304 / DP030A - DP030K / CK081K	98
Factor VIII:C (Clotting or Chromogenic) (%) / <i>Facteur VIII:C (Coagulante ou Chromogène) (%)</i>	BIOPHEN VIII:C / BIOPHEN VIII:C (6) / Factor VIII:C Deficient Plasma #221402 / 221406 / DP040A - DP040K	97
Factor IX (Clotting or Chromogenic) (%) / <i>Facteur IX (Coagulante ou Chromogène) (%)</i>	BOPHEN Factor IX / BOPHEN Factor IX (6) / Factor IX Deficient Plasma #221802 / 221806 / DP050A - DP050K	89
Factor X (Clotting or Chromogenic) (%) / <i>Facteur X (Coagulante ou Chromogène) (%)</i>	BIOPHEN Fator X / Factor X Deficient Plasma #221705 / DP060A - DP060K	91
Factor XI (Clotting) (%) / <i>Facteur XI (Coagulante) (%)</i>	Factor XI Deficient Plasma #DP070A - DP070K	99
Factor XII (Clotting) (%) / <i>Facteur XII (Coagulante) (%)</i>	Factor XII Deficient Plasma #DP080A - DP080K	126
Plasminogen (Chromogenic) (%) / <i>Plasminogène (Chromogène) (%)</i>	BIOPHEN ^e Plasminogen / BIOPHEN Plasminogen (LRT) #221502 / 221511	97
Fibrinogen (Activity or Antigen) (g/L) / <i>Fibrinogène (Activité ou Antigène) (g/L)</i>	Fibriphen 1 / Fibriphen 2 / Fibriphen 5 / LIAPHEN Fibrinogen #CK571 / CK572 / CK575 / 120102	2.74
von Willebrand Factor (Antigen) (%) / <i>Facteur von Willebrand (Antigène) (%)</i>	LIAPHEN vWF #120206	115
(DVVtest / DVVconfirm) / <i>(DVVtest / DVVconfirm)</i>	DVVC / DVWT	≤ 1,20

Date of Approval / *Date d'Approbation* : 2017-06-06

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