

ANALYSIS CERTIFICATE

BIOPHEN NORMAL CONTROL PLASMA - #223201

**Lot : F1700449
F1700456**

QC Release : 2017-07-03

Expiration date : 2019-10-14

Components	Volume	Exp. (months)	Lot #	Exp. date
Normal Control Plasma	12 vials	30	F171400449 F171100456	2019-10-14



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Analytical data				Specifications
1. Within lot reproducibility				
N= 80	PT =	12,5 Sec	CV:	1,1 %
N= 80	APTT =	27,9 Sec	CV:	0,4 %
				CV ≤ 2%
				CV ≤ 2%

Parameters			Target Value	Acceptance range	C% / CT sec / Ratio
Factor VII+X (%)			88%	75-101	>75 %
α2-Antiplasmin (%)			101%	86-116	≥ 80%
ATIII (%) Activity Antigen			92% 90%	78-106 77-104	> 80%
Protein C (chromogenic) (%)			94%	80-108	> 80%
Protein C (Clotting) (%)			90%	77-104	> 60%
Protein S (clotting) (%)			73%	62-84	> 50%
Free Protein S (ELISA) (%)			112%	95-129	> 60%
Prothrombin (%)			88%	75-101	> 75%
Factor V (%)			85%	72-98	> 75%
Factor VII (%)			91%	77-105	> 75%
Factor VIII:C (%)			101%	86-116	> 60%
Factor IX (%)			88%	75-101	> 60%
Factor X (%)			88%	75-101	> 75%
Factor XI (%)			97%	78-116	> 70%
Factor XII (%)			120%	96-144	> 70%
Plasminogen (%)			109%	93-125	> 75%
Fibrinogen (g/L)			2,93	2,49-3,37	> 2.0 g/L
vWF:Ag (%)			100%	85-115	> 60%
DVTtest/DVconfirm ratio			1,13	≤ 1.2	≤ 1.2
Act. PC-r (qualitative)			2,39	≥ 2.00	≥ 2.00
Act. PC-r (% FVL) (quantitative)			<1%	0-10	< 10%
PT (sec)	(Meth./Supplier) : STAR/STAGO Neoplastine CI Plus		14,8	12,8-16,8	<16 sec
INR (PT)			1,14	1,04-1,24	< 1.3
PT (%)			74%	63-85	> 60%
aPTT Low sensitivity to Lupus (sec) (Meth./Supplier): STAR / HBM Cephén LR			32,4	27,4-37,4	37+/-5 sec
aPTT Good sensitivity to Lupus (sec) (Meth./Supplier) : STAR / HBM Cephén LS			34,4	29,4-39,4	Indicative Value
TT Ratio (Meth./Supplier) : STAR / HBM Hemoclot TT			1,04	≤ 1.20	≤ 1.20
TT (sec) (Meth./Supplier) : STAR / HBM Hemoclot TT			20,8 sec	17,8-23,8	Indicative Value

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

SAS

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Expiration date : 2019-10-14

Analytical data	Specifications
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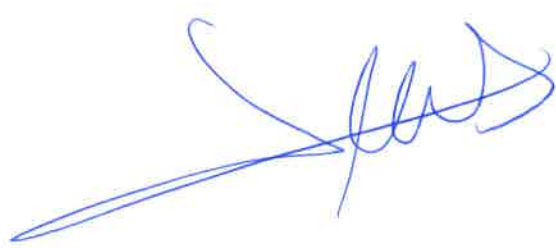
<p>4. Stability of reconstituted reagents</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th rowspan="2"></th> <th colspan="2">PT</th> <th colspan="2">APTT</th> </tr> <tr> <th>CT(sec)</th> <th>Δ CT</th> <th>CT(sec)</th> <th>Δ CT</th> </tr> </thead> <tbody> <tr> <td>Fresh</td> <td>14,7</td> <td>NA</td> <td>32,5</td> <td>NA</td> </tr> <tr> <td>24h / 2-8°C</td> <td>15,2</td> <td>0,5</td> <td>34,0</td> <td>1,5</td> </tr> <tr> <td>8h / RT</td> <td>14,7</td> <td>0</td> <td>32,9</td> <td>0,4</td> </tr> </tbody> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2"></th> <th colspan="2">FVIII:C (%)</th> <th colspan="2">FV (%)</th> </tr> <tr> <th>%</th> <th>Δ[C]%</th> <th>%</th> <th>Δ[C]%</th> </tr> </thead> <tbody> <tr> <td>Fresh</td> <td>102</td> <td>NA</td> <td>87</td> <td>NA</td> </tr> <tr> <td>8h / 2-8°C</td> <td>95</td> <td>7</td> <td>85</td> <td>2</td> </tr> <tr> <td>4h / RT</td> <td>102</td> <td>0</td> <td>89</td> <td>2</td> </tr> </tbody> </table>		PT		APTT		CT(sec)	Δ CT	CT(sec)	Δ CT	Fresh	14,7	NA	32,5	NA	24h / 2-8°C	15,2	0,5	34,0	1,5	8h / RT	14,7	0	32,9	0,4		FVIII:C (%)		FV (%)		%	Δ[C]%	%	Δ[C]%	Fresh	102	NA	87	NA	8h / 2-8°C	95	7	85	2	4h / RT	102	0	89	2	<table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th>PT</th> <th>APTT</th> </tr> </thead> <tbody> <tr> <td>8h at RT</td> <td>8h at RT</td> </tr> <tr> <td>24h at 2-8°C</td> <td>24h at 2-8°C</td> </tr> <tr> <td>Δ CT ≤ 1sec</td> <td>Δ CT ≤ 3sec</td> </tr> </tbody> </table> <p>VIII:C or V: 4h at RT 8h at 2-8°C Δ[C] ≤ 10%</p>	PT	APTT	8h at RT	8h at RT	24h at 2-8°C	24h at 2-8°C	Δ CT ≤ 1sec	Δ CT ≤ 3sec
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<p><u>Comments :</u></p>	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2017-07-03

QC Manager :

S. LECOURT



**BIOPHEN NORMAL CONTROL PLASMA**Normal control plasma for coagulation assay quality control / *Plasma humain normal pour contrôle de qualité des tests de coagulation***REF** 223201For in vitro diagnostic use only / *Pour diagnostic in vitro exclusivement***LOT** F1700449

2019-10-14

Parameters / Paramètres		Reagents / Réactifs	Acceptance Range / Intervalle d'acceptation
Factor VII+X (%) / Facteur VII+X (%)		HEMOCLOT VII+X	75 - 101
AT III (Activity or Antigen) (%) / AT III (Activité ou Antigène) (%)		BIOPHEN Antithrombin 2.5 / BIOPHEN Antithrombin 5 / BIOPHEN* AT anti-(h)-Xa LRT / LIAPHEN LRT	78 - 106 (activity) 77 - 104 (antigen)
α2 - Antiplasmin (%) / α2 - Antiplasmine (%)		BIOPHEN* α 2-Antiplasmin (LRT)	86 - 116
Protein C (Chromogenic) (%) / Protéine C (Chromogène) (%)		BIOPHEN Protein C 2.5 / BIOPHEN Protein C 5 / BIOPHEN Protein C LRT	80 - 108
Protein C (Clotting) (%) / Protéine C (Coagulante) (%)		HEMOCLOT Protein C	77 - 104
Protein S (Clotting) (%) / Protéine S (Coagulante) (%)		HEMOCLOT Protein S	62 - 84
Free Protein S (Elisa) (%) / Protéine S libre (Elisa) (%)		ZYMUTEST FREE PROTEIN S	95 - 129
Prothrombin (Clotting or Chromogenic) (%) / Prothrombine (Coagulante ou Chromogène) (%)		BIOPHEN Prothrombin Prothrombin Deficient Plasma	75 - 101
Factor V (Clotting) (%) / Facteur V (Coagulante) (%)		Factor V Deficient Plasma HEMOCLOT Factor V Reagent	72 - 98
Factor VII (Clotting or Chromogenic) (%) / Facteur VII (Coagulante ou Chromogène) (%)		BIOPHEN VII Factor VII Deficient Plasma HEMOCLOT Factor VII reagent	77 - 105
Factor VIII:C (Clotting or Chromogenic) (%) / Facteur VIII:C (Coagulante ou Chromogène) (%)		BIOPHEN FVIII:C BIOPHEN FVIII:C (6) Factor VIII:C Deficient Plasma	86 - 116
Factor IX (Clotting or Chromogenic) (%) / Facteur IX (Coagulante ou Chromogène) (%)		BIOPHEN Factor IX BIOPHEN Factor IX (6) Factor IX Deficient Plasma	75 - 101
Factor X (Clotting or Chromogenic) (%) / Facteur X (Coagulante ou Chromogène) (%)		BIOPHEN Factor X Factor X Deficient Plasma	75 - 101
Factor XI (Clotting) (%) / Facteur XI (Coagulante) (%)		Factor XI Deficient Plasma	78 - 116
Factor XII (Clotting) (%) / Facteur XII (Coagulante) (%)		Factor XII Deficient Plasma	96 - 144
Plasminogen (Chromogenic) (%) / Plasminogène (Chromogène) (%)		BIOPHEN® Plasminogen BIOPHEN Plasminogen (LRT)	93 - 125
Fibrinogen (Activity or Antigen) (g/L) / Fibrinogène (Activité ou Antigène) (g/L)		Fibriphen 1 / Fibriphen 2 / Fibriphen 5 / LIAPHEN Fibrinogen	2.49 - 3.37
von Willebrand Factor (Antigen) (%) / Facteur von Willebrand (Antigène) (%)		Liaphen vWF (Ag)	85 - 115
(DVVtest / DVVconfirm) / (DVVtest / DVVconfirm)		DVV test / DVV confirm	≤ 1,2
Act. PC-r (Qualitative) / Act PC-r (Qualitatif)		Coatest APC IL	≥ 2,00
Act. PC-r (% FVL) (Quantitative) / Act PC-r (% FVL) (Quantitatif)		HEMOCLOT Quanti V-L	< 10%
PT (Sec) / TP (Sec)	(Meth/Supplier) / (Méth./Fournisseur.) : STAR / STAGO/NEOPLASTIN	Neoplastin CI Plus ISI 128	12.8 - 16.8
INR (PT) / INR (TP)			1.04 - 1.24
PT (%) / TP (%)			63 - 85
aPTT LR (Sec) / TCA LR (Sec)	(Meth/Supplier) / (Méth./Fournisseur.) :	CEPHEN 1 / CEPHEN 2.5 / CEPHEN 5	27.4 - 37.4
aPTT LS (indicative) (Sec) / TCA LS (indicatif) (Sec)	STAR / HBM/CEPHEN	CEPHEN 1 LS / CEPHEN 2.5 LS	29.4 - 39.4
Thrombin Time (Ratio) / Temps de Thrombine (Ratio)	(Meth/Supplier) / (Méth./Fournisseur.) :	HEMOCLOT Thrombin Inhibitors (TT)	≤ 1,20
Thrombin Time (indicative) (Sec) / Temps de Thrombine (Indicatif) (Sec)	STAR / HBM / TT	HEMOCLOT Thrombin Inhibitors (TT)	17.8 - 23.8

Date of Approval / Date d'Approbation : 2017-07-03

Quality Control Manager / Responsable Contrôle Qualité : S. LECOURT