

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%

2. Concentration of tested parameters				C% / CT sec / Ratio
Parameters	Target Value	Acceptance range		
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%
DVVtest/DVVconfirm 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)	14,8	12,8-16,8		<16 sec
INR (PT)	(Meth./Supplier) : STAR/STAGO	1,14	1,04-1,24	< 1.3
PT (%)	Neoplastine CI Plus	74%	63-85	> 60%
aPTT Low sensitivity to Lupus (sec) (Meth./Supplier): STAR / HBM Cephon LR	32,4	27,4-37,4		37+/-5 sec
aPTT Good sensitivity to Lupus (sec) (Meth./Supplier) : STAR / HBM Cephon 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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Analytical data	Specifications
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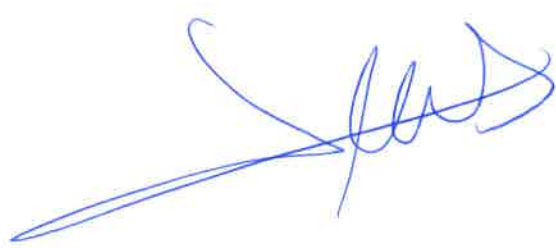
<p>4. Stability of reconstituted reagents</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th rowspan="2"></th> <th colspan="2">PT</th> <th colspan="2">APTT</th> </tr> <tr> <th>CT(sec)</th> <th>Δ CT</th> <th>CT(sec)</th> <th>Δ CT</th> </tr> </thead> <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;"> <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 style="text-align: center; margin-top: 20px;"> 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>Comments :</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 (%) / <i>Facteur VII+X (%)</i>		HEMOCLOT VII+X	75 - 101
AT III (Activity or Antigen) (%) / <i>AT III (Activité ou Antigène) (%)</i>		BIOPHEN Antithrombin 2.5 / BIOPHEN Antithrombin 5 / BIOPHEN* AT anti-(h)-Xa LRT / LIAPHEN LRT	78 - 106 (activity) 77 - 104 (antigen)
α2 - Antiplasmin (%) / <i>α2 - Antiplasmine (%)</i>		BIOPHEN* α 2-Antiplasmin (LRT)	86 - 116
Protein C (Chromogenic) (%) / <i>Protéine C (Chromogène) (%)</i>		BIOPHEN Protein C 2.5 / BIOPHEN Protein C 5 / BIOPHEN Protein C LRT	80 - 108
Protein C (Clotting) (%) / <i>Protéine C (Coagulante) (%)</i>		HEMOCLOT Protein C	77 - 104
Protein S (Clotting) (%) / <i>Protéine S (Coagulante) (%)</i>		HEMOCLOT Protein S	62 - 84
Free Protein S (Elisa) (%) / <i>Protéine S libre (Elisa) (%)</i>		ZYMUTEST FREE PROTEIN S	95 - 129
Prothrombin (Clotting or Chromogenic) (%) / <i>Prothrombine (Coagulante ou Chromogène) (%)</i>		BIOPHEN Prothrombin Prothrombin Deficient Plasma	75 - 101
Factor V (Clotting) (%) / <i>Facteur V (Coagulante) (%)</i>		Factor V Deficient Plasma HEMOCLOT Factor V Reagent	72 - 98
Factor VII (Clotting or Chromogenic) (%) / <i>Facteur VII (Coagulante ou Chromogène) (%)</i>		BIOPHEN VII Factor VII Deficient Plasma HEMOCLOT Factor VII reagent	77 - 105
Factor VIII:C (Clotting or Chromogenic) (%) / <i>Facteur VIII:C (Coagulante ou Chromogène) (%)</i>		BIOPHEN FVIII:C BIOPHEN FVIII:C (6) Factor VIII:C Deficient Plasma	86 - 116
Factor IX (Clotting or Chromogenic) (%) / <i>Facteur IX (Coagulante ou Chromogène) (%)</i>		BIOPHEN Factor IX BIOPHEN Factor IX (6) Factor IX Deficient Plasma	75 - 101
Factor X (Clotting or Chromogenic) (%) / <i>Facteur X (Coagulante ou Chromogène) (%)</i>		BIOPHEN Factor X Factor X Deficient Plasma	75 - 101
Factor XI (Clotting) (%) / <i>Facteur XI (Coagulante) (%)</i>		Factor XI Deficient Plasma	78 - 116
Factor XII (Clotting) (%) / <i>Facteur XII (Coagulante) (%)</i>		Factor XII Deficient Plasma	96 - 144
Plasminogen (Chromogenic) (%) / <i>Plasminogène (Chromogène) (%)</i>		BIOPHEN® Plasminogen BIOPHEN Plasminogen (LRT)	93 - 125
Fibrinogen (Activity or Antigen) (g/L) / <i>Fibrinogène (Activité ou Antigène) (g/L)</i>		Fibriphen 1 / Fibriphen 2 / Fibriphen 5 / LIAPHEN Fibrinogen	2.49 - 3.37
von Willebrand Factor (Antigen) (%) / <i>Facteur von Willebrand (Antigène) (%)</i>		Liaphen vWF (Ag)	85 - 115
(DVVtest / DVVconfirm) / <i>(DVVtest / DVVconfirm)</i>		DVV test / DVV confirm	≤ 1,2
Act. PC-r (Qualitative) / <i>Act PC-r (Qualitatif)</i>		Coatest APC IL	≥ 2,00
Act. PC-r (% FVL) (Quantitative) / <i>Act PC-r (% FVL) (Quantitatif)</i>		HEMOCLOT Quanti V-L	< 10%
PT (Sec) / <i>TP (Sec)</i>	(Meth/Supplier) / <i>(Méth./Fournisseur.)</i> : STAR / STAGO/NEOPLASTIN	Neoplastin CI Plus ISI 128	12.8 - 16.8
INR (PT) / <i>INR (TP)</i>			1.04 - 1.24
PT (%) / <i>TP (%)</i>			63 - 85
aPTT LR (Sec) / <i>TCA LR (Sec)</i>	(Meth/Supplier) / <i>(Méth./Fournisseur.)</i> :	CEPHEN 1 / CEPHEN 2.5 / CEPHEN 5	27.4 - 37.4
aPTT LS (indicative) (Sec) / <i>TCA LS (indicatif) (Sec)</i>	STAR / HBM/CEPHEN	CEPHEN 1 LS / CEPHEN 2.5 LS	29.4 - 39.4
Thrombin Time (Ratio) / <i>Temps de Thrombine (Ratio)</i>	(Meth/Supplier) / <i>(Méth./Fournisseur.)</i> :	HEMOCLOT Thrombin Inhibitors (TT)	≤ 1,20
Thrombin Time (indicative) (Sec) / <i>Temps de Thrombine (Indicatif) (Sec)</i>	STAR / HBM / TT	HEMOCLOT Thrombin Inhibitors (TT)	17.8 - 23.8

Date of Approval / *Date d'Approbation* : 2017-07-03Quality Control Manager / *Responsable Contrôle Qualité* : S. LECOURT