

ANALYSIS CERTIFICATE

BIOPHEN ABNORMAL CONTROL PLASMA - #223301

**Lot : F1700450
F1700457**

QC Release : 2017-07-03

Expiration date : 2019-10-11

Components	Volume	Exp. (months)	Lot #	Exp. date
Abnormal Control Plasma	12 vials	30	F171100450 F171100457	2019-10-11

805

ANALYSIS CERTIFICATE

BIOPHEN ABNORMAL CONTROL PLASMA - #223301

Lot : F1700450
 F1700457

QC Release : 2017-07-03

Expiration date : 2019-10-11

Analytical data				Specifications
1. <u>Within lot reproducibility</u>				
N= 70	PT =	23,4 Sec	CV: 1,5 %	CV ≤ 2%
N= 70	APTT =	73,0 Sec	CV: 1,1 %	CV ≤ 2%

2. <u>Concentration of tested parameters</u>				C% / CT sec / Ratio
Parameters	Target Value	Acceptance range		
Factor VII+X (%)	29%	23-35		20-50 %
α2-Antiplasmin (%)	37%	30-44		20-50 %
ATIII (%) Activity	35%	28-42		20-50 %
ATIII (%) Antigen	37%	30-44		20-50 %
Protein C (%) (chromogenic)	35%	28-42		20-50 %
Protein C (%) (clotting)	31%	25-37		20-50 %
Protein S (%) (clotting)	31%	25-37		20-50 %
Free Protein S (%)	33%	26-40		20-50 %
Prothrombin (%)	35%	28-42		20-50 %
Factor V (%)	30%	24-36		20-50 %
Factor VII (%)	29%	23-35		20-50 %
Factor VIII:C (%)	29%	23-35		20-50 %
Factor IX (%)	28%	22-34		20-50 %
Factor X (%)	32%	26-38		20-50 %
Factor XI (%)	28%	20-36		20-50 %
Factor XII (%)	38%	28-48		20-50 %
Plasminogen (%)	41%	33-49		20-50 %
Fibrinogen (g/L)	1,53 g/L	1,22-1,84		> 1g/L
vWF:Ag (%)	46%	37-55		20-50 %
DVVtest/DVVconfirm ratio	1,01	≤ 1.2		≤ 1.2
PT (sec)	(Meth./Supplier) : Neoplastin STAR / STAGO Cl plus	28,1 sec	25,1-31,1	> 14 sec
INR (PT)		2,55	2,35-2,75	> 1.3
PT (%)		29%	23-35	20-50 %
aPTT Low sensitivity to Lupus (sec) (Meth./Supplier) : STAR/HBM/Cephen LR	67,8	59,8-75,8		> 45 sec
aPTT Good sensitivity to Lupus (sec) (Meth./Supplier) : STAR/HBM/Cephen LS	59,3	51,3-67,3		<i>Indicative Value</i>

3. <u>Aspect</u>		
<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

PO5

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Analytical data	Specifications
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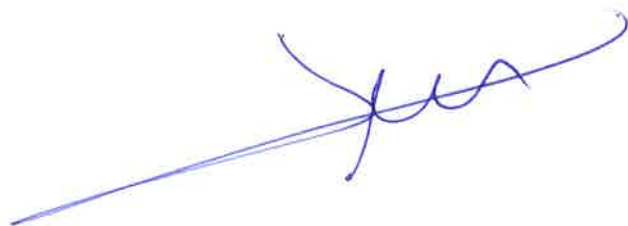
<p>4. <u>Stability of reconstituted reagents</u></p> <table border="1" style="margin-bottom: 10px; width: 100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2"></th> <th colspan="2">PT</th> <th colspan="2">APTT</th> </tr> <tr> <th>CT(sec)</th> <th>Δ CT(sec)</th> <th>CT (sec)</th> <th>Δ CT(sec)</th> </tr> </thead> <tbody> <tr> <td>Fresh</td> <td>27,6</td> <td>NA</td> <td>67,2</td> <td>NA</td> </tr> <tr> <td>24h / 2-8°C</td> <td>28,0</td> <td>0,4</td> <td>67,1</td> <td>0,1</td> </tr> <tr> <td>8h / RT</td> <td>27,0</td> <td>0,6</td> <td>69,2</td> <td>2,0</td> </tr> </tbody> </table> <table border="1" style="margin-bottom: 10px; 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>26</td> <td>NA</td> <td>29</td> <td>NA</td> </tr> <tr> <td>8h / 2-8°C</td> <td>25</td> <td>1</td> <td>27</td> <td>2</td> </tr> <tr> <td>4h /RT</td> <td>28</td> <td>2</td> <td>30</td> <td>1</td> </tr> </tbody> </table>		PT		APTT		CT(sec)	Δ CT(sec)	CT (sec)	Δ CT(sec)	Fresh	27,6	NA	67,2	NA	24h / 2-8°C	28,0	0,4	67,1	0,1	8h / RT	27,0	0,6	69,2	2,0		FVIII:C (%)		FV (%)		%	Δ[C]%	%	Δ[C]%	Fresh	26	NA	29	NA	8h / 2-8°C	25	1	27	2	4h /RT	28	2	30	1	<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><u>Comments</u> :</p>	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2017-07-03

QC Manager :

S. LECOURT



**BIOPHEN ABNORMAL CONTROL PLASMA**Abnormal control plasma for coagulation assay quality control / *Plasma humain anormal pour contrôle de qualité des tests de coagulation***REF** 223301For in vitro diagnostic use only / *Pour diagnostic in vitro exclusivement***LOT** F1700450

2019-10-11

Parameters / Paramètres	Reagents / Réactifs	Acceptance Range / Intervalle d'acceptation	
Factor VII+X (%) / <i>Facteur VII+X (%)</i>	HEMOCLOT VII+X	23 - 35	
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 AT	28 - 42 (activity) 30 - 44 (antigen)	
α2 - Antiplasmin (%) / <i>α2 - Antiplasmine (%)</i>	BIOPHEN® α2-Antiplasmin LRT	30 - 44	
Protein C (Chromogenic) (%) / <i>Protéine C (Chromogène) (%)</i>	BIOPHEN Protein C 2.5 BIOPHEN Protein C 5 BIOPHEN Protein C LRT	28 - 42	
Protein C (Clotting) (%) / <i>Protéine C (Coagulante) (%)</i>	HEMOCLOT Protein C	25 - 37	
Protein S (Clotting) (%) / <i>Protéine S (Coagulante) (%)</i>	HEMOCLOT Protein S	25 - 37	
Free Protein S (Elisa) (%) / <i>Protéine S libre (Elisa) (%)</i>	ZYMUTEST FREE PROTEIN S	26 - 40	
Prothrombin (Clotting or Chromogenic) (%) / <i>Prothrombine (Coagulante ou Chromogène) (%)</i>	BIOPHEN Prothrombin Prothrombin Deficient Plasma	28 - 42	
Factor V (Clotting) (%) / <i>Facteur V (Coagulante) (%)</i>	Factor V Deficient Plasma HEMOCLOT Factor V Reagent	24 - 36	
Factor VII (Clotting or Chromogenic) (%) / <i>Facteur VII (Coagulante ou Chromogène) (%)</i>	BIOPHEN VII Factor VII Deficient Plasma HEMOCLOT Factor VII reagent	23 - 35	
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	23 - 35	
Factor IX (Clotting or Chromogenic) (%) / <i>Facteur IX (Coagulante ou Chromogène) (%)</i>	BIOPHEN Factor IX BIOPHEN Factor IX (6) Factor IX Deficient Plasma	22 - 34	
Factor X (Clotting or Chromogenic) (%) / <i>Facteur X (Coagulante ou Chromogène) (%)</i>	BIOPHEN Factor X Factor X Deficient Plasma	26 - 38	
Factor XI (Clotting) (%) / <i>Facteur XI (Coagulante) (%)</i>	Factor XI Deficient Plasma	20 - 36	
Factor XII (Clotting) (%) / <i>Facteur XII (Coagulante) (%)</i>	Factor XII Deficient Plasma	28 - 48	
Plasminogen (Chromogenic) (%) / <i>Plasminogène (Chromogène) (%)</i>	BIOPHEN® Plasminogen BIOPHEN Plasminogen (LRT)	33 - 49	
Fibrinogen (Activity or Antigen) (g/L) / <i>Fibrinogène (Activité ou Antigène) (g/L)</i>	Fibriphen 1 / Fibriphen 2 / Fibriphen 5 / LIAPHEN Fibrinogen	1.22 - 1.84	
von Willebrand Factor (Antigen) (%) / <i>Facteur von Willebrand (Antigène) (%)</i>	Liaphen vWF (Ag)	37 - 55	
(DVVtest / DVVconfirm) / <i>(DVVtest / DVVconfirm)</i>	DVV test / DVV confirm	≤ 1,2	
PT (Sec) / <i>TP (Sec)</i>	(Meth/Supplier) / (Méth./Fournisseur.) : STAR / STAGO/NEOPLASTIN	25.1 - 31.1	
INR (PT) / <i>INR (TP)</i>		Neoplastin CI Plus ISI 1.28	2.35 - 2.75
PT (%) / <i>TP (%)</i>		23 - 35	
aPTT LR (Sec) / <i>TCA LR (Sec)</i>	(Meth/Supplier) / (Méth./Fournisseur.) :	CEPHEN 1 / CEPHEN 2.5 / CEPHEN 5	59.8 - 75.8
aPTT LS (indicative) (Sec) / <i>TCA LS (indicatif) (Sec)</i>	STAR / HBM/CEPHEN	CEPHEN 1 LS / CEPHEN 2.5 LS	51.3 - 67.3

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