

ANALYSIS CERTIFICATE

BIOPHEN NORMAL CONTROL PLASMA - #223201

Lot : F1600705

QC Release : 09/09/2016

Expiration date : 2018-12-22

Components	Volume	Exp. (months)	Lot #	Exp. date
Normal Control Plasma	12 vials	30	F161200705	2018-12-22

Handwritten signature/initials

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BIOPHEN NORMAL CONTROL PLASMA - #223201

Lot : F1600705

QC Release : 09/09/2016

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Analytical data	Specifications
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<p>4. Stability of reconstituted reagents</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</th> <th>CT(sec)</th> <th>Δ CT</th> </tr> </thead> <tbody> <tr> <td>Fresh</td> <td>14,9</td> <td>NA</td> <td>31,8</td> <td>NA</td> </tr> <tr> <td>24h / 2-8°C</td> <td>15,0</td> <td>0,1</td> <td>32,2</td> <td>0,4</td> </tr> <tr> <td>8h / RT</td> <td>15,0</td> <td>0,1</td> <td>31,3</td> <td>0,5</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>110 *</td> <td>112**</td> <td>NA</td> <td>NA</td> </tr> <tr> <td>8h / 2-8°C</td> <td>102</td> <td>7,3</td> <td>97</td> <td>2,0</td> </tr> <tr> <td>4h / RT</td> <td>107</td> <td>4,5</td> <td>97</td> <td>2,0</td> </tr> </tbody> </table>		PT		APTT		CT(sec)	Δ CT	CT(sec)	Δ CT	Fresh	14,9	NA	31,8	NA	24h / 2-8°C	15,0	0,1	32,2	0,4	8h / RT	15,0	0,1	31,3	0,5		FVIII:C (%)		FV (%)		%	Δ[C]%	%	Δ[C]%	Fresh	110 *	112**	NA	NA	8h / 2-8°C	102	7,3	97	2,0	4h / RT	107	4,5	97	2,0	<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> <p style="margin-left: 40px;">*Fresh for 8h at 2-8°C ** Fresh for 4h at RT</p> <p style="text-align: center; margin-top: 10px;">Updated CoA regarding availability of new parameter : vWF: Ag</p>	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 20/04/2017

QC Manager :


 Marie PEYRAFITTE
 Resp. Validation

**BIOPHEN NORMAL CONTROL PLASMA**

Normal control plasma for coagulation assay quality control / Plasma humain normal pour contrôle de qualité des tests de coagulation

REF 223201

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

LOT

F1600705



2018-12-22

Parameters / Paramètres	Reagents / Réactifs	Acceptance Range / Intervalle d'acceptation	
Factor VII+X (%) / Facteur VII+X (%)	HEMOCLOT VII+X	74 -100	
AT III (Activity or Antigen) (%) / AT III (Activité ou Antigène) (%)	BIOPHEN Antithrombin 2.5 / BIOPHEN Antithrombin 5 / BIOPHEN® AT anti-(h)-Xa LRT LIAPHEN AT	75-101	
α2 – Antiplasmin (%) / α2 – Antiplasmine (%)	BIOPHEN® α2-Antiplasmin (LRT)	79-107	
Protein C (Chromogenic) (%) / Protéine C (Chromogène) (%)	BIOPHEN Protein C 2.5 / BIOPHEN Protein C 5 / BIOPHEN Protein C (LRT)	76-102	
Protein C (Clotting) (%) / Protéine C (Coagulante) (%)	HEMOCLOT Protein C	65-87	
Protein S (Clotting) (%) / Protéine S (Coagulante) (%)	HEMOCLOT Protein S	74-100	
Free Protein S (Elisa) (%) / Protéine S libre (Elisa) (%)	ZYMUTEST FREE PROTEIN S	81-109	
Prothrombin (Clotting or Chromogenic) (%) / Prothrombine (Coagulante ou Chromogène) (%)	BIOPHEN Prothrombin / Prothrombin Deficient Plasma	76-102	
Factor V (Clotting) (%) / Facteur V (Coagulante) (%)	Factor V Deficient Plasma / HEMOCLOT Factor V REAGENT	76-104	
Factor VII (Clotting or Chromogenic) (%) / Facteur VII (Coagulante ou Chromogène) (%)	BIOPHEN VII / Factor VII Deficient Plasma / HEMOCLOT Factor VII REAGENT	76-104	
Factor VIII:C (Clotting or Chromogenic) (%) / Facteur VIII:C (Coagulante ou Chromogène) (%)	BIOPHEN FVIII:C / BIOPHEN FVIII:C (6) Factor VIII:C Deficient Plasma	87-117	
Factor IX (Clotting or Chromogenic) (%) / Facteur IX (Coagulante ou Chromogène) (%)	BIOPHEN Factor IX / BIOPHEN Factor IX (6) Factor IX Deficient Plasma	71-95	
Factor X (Clotting or Chromogenic) (%) / Facteur X (Coagulante ou Chromogène) (%)	BIOPHEN Factor XI / Factor X Deficient Plasma	71-97	
Factor XI (Clotting) (%) / Facteur XI (Coagulante) (%)	Factor XI Deficient Plasma	71-107	
Factor XII (Clotting) (%) / Facteur XII (Coagulante) (%)	Factor XII Deficient Plasma	78-116	
Plasminogen (Chromogenic) (%) / Plasminogène (Chromogène) (%)	BIOPHEN® Plasminogen / BIOPHEN Plasminogen (LRT)	80-108	
Fibrinogen (Activity or Antigen) (g/L) / Fibrinogène (Activité ou Antigène) (g/L)	Fibrigen 1 / Fibrigen 2 / Fibrigen 5 / LIAPHEN Fibrinogen	2,31-3,13	
von Willebrand Factor (Antigen) (%) / Facteur von Willebrand (Antigène) (%)	LIAPHEN vWF:Ag	69 - 93	
(DVVtest / DVVconfirm) / (DVVtest / DVVconfirm)	DVWT / DVVC (ADI)	≤ 1,2	
Act. PC-r (Qualitative) / Act PC-r (Qualitatif)	HEMOCLOT Factor V-L	≥ 2,00	
Act. PC-r (% FVL) (Quantitative) / Act PC-r (% FVL) (Quantitatif)	HEMOCLOT Quant. V-L	<10	
PT (Sec) / TP (Sec)	(Meth/Supplier) / (Méth./Fournisseur.) : STAR / STAGO	Neoplastin CI Plus	13,3-17,3
INR (PT) / INR (TP)			1,03-1,23
PT (%) / TP (%)			61-83
aPTT LR (Sec) / TCA LR (Sec)	(Meth/Supplier) / (Méth./Fournisseur.) : STAR / HBM	CEPHEN 1 / CEPHEN 2.5 / CEPHEN 5 LR	27,1-37,1
aPTT LS (indicative) (Sec) / TCA LS (indicatif) (Sec)		CEPHEN 1 LS / CEPHEN 2.5 LS	27,2-37,2
Thrombin Time (Ratio) / Temps de Thrombine (Ratio)	(Meth/Supplier) / (Méth./Fournisseur.) : STAR / HBM	HEMOCLOT Thrombin Time (T.T.)	≤ 1,20
Thrombin Time (indicative) (Sec) / Temps de Thrombine (Indicatif) (Sec)			17,4-23,4

Date of Approval / Date d'Approbation : 20/04/2017

Quality Control Manager / Responsable Contrôle Qualité :

Marie PEYRAFITTE
Resp. Validation