HYPHEN BioMed
ZAC Neuville Université - 155 rue d'Eragny
95000 Neuville sur Oise (France)
Tel: 33.1.34.40.65.10 - Fax: 33.1.34.48.72.36

CERTIFICATE of ANALYSIS

HEMOCLOT® Factor VIIa (#CK092K) **Lot : F1600385**

QC Release: 04/05/2016 **Expiration date : 2018-09-22**

Reagents	Qty	Exp. (months)	Int. Ref.	Lot #	Exp. date
R1 : FVII Deficient Plasma	3 vials	31	F161500385	F161500385	2018-09-22
R2 : rTTF and Phospholipids	3 vials	31	F161500385	F161500385	2018-10-01
R3 : Hepes-BSA Buffer	3 vials	31	F161500385	F161500385	2018-09-23

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Analytical data				Specifications
1. FVII Deficient Plasma (R1)				
a. Aspect				
☒ Slightly opalescent to clear, no coagulum, stable				Slightly opalescent to clear, no coagulum, stable
b. Lot homogeneity (reactivity on point C/2)				
	Method:	**MC10**		
	N :	**20**		N ≥ 10
	Mean (CT sec):	**36,9**		
	CV:	**1,2**	%	≤ 3 %
c. PT and APTT characterization:				
	PT (sec)	**58,3**	(Neoplastin STAGO)	> 40 sec
	APTT (sec)	**38,1**	(Cephen HBM)	< 40 sec
d. FVII deficiency:				
	FVII conc:	0,2%		<1%

Analytical data				Specifications
2. rTTF and Phospholipids (R2)				
a. Aspect				
☒ Clear, transparent, no white coloration				Clear, transparent, no white coloration
b. Lot homogeneity (reactivity on point C/2)				
	Method:	**MC10**		
	N :	**20**		N ≥ 10
	Mean (CT sec):	**37,7**		
	CV:	**1,3**	%	≤ 3 %

Analytical data				Specifications
3. Hepes BSA buffer (R3)				
a. Aspect				
☒ Clear, transparent, no sign of contamination				Clear, transparent, no sign of contamination
b. pH				
		7,42		7.40 ± 0.10
C. Volume				
	N :	**3**		N ≥ 3
	Volume:	**> 20 mL**		V ≥ 20mL

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Analytical data			Specifications
1. Calibration curve (CS)			
Instrument: CS 5100			
mIU/mL FVIIa		**CT (sec)**	**On CS:** **ΔCT(C - C:100) ≥ 90 sec** **CT (C:2) = 40 ± 7 sec**
C	450	32,6	
C:2	225	40,6	
C:5	90	54,5	
C:10	45,0	69,2	
C:20	22,5	89,0	
C:100	4,5	152,0	
Linearity:	**r2 =**	0,999	**r2 ≥ 0.98**
2. Specificity (CS)			
Instrument: CS 5100			
FVII Def. Plasma: < 3 mIU/mL			**≤ 3 mIU/mL**
3. Accuracy:			
Instrument: CS 5100			
Control		**TV* (mIU/mL FVIIa)**	**MV* (mIU/mL FVIIa)**
C1 (in house preparation)		80	88
C2 (in house preparation)		250	265
*** TV= Target Value - MV= Measured Value**			Measured value in compliance [55 - 105] mIU/mL [200 - 300] mIU/mL

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Analytical data	Specifications

5. Stability of reagents (CT sec, on CS)

Instrument: CS 5100

mIU/mL FVIIa		Fresh 24 h RT	Fresh 72 h 2-8°	24 h RT	72 h 2-8°C	Frozen	Specifications
C	450	31,4	33,5	31,9	33,2	33,4	On CS: ΔCT(C - C:100) ≥ 90 sec CT (C:2) = 40 ± 7 sec ΔCT(fresh/stored "C") ≤ 10%
C:2	225	38,6	41,9	39,7	41,1	41,7	
C:5	90	51,8	56,4	53,1	54,9	56,4	
C:10	45	65,5	72,1	67,0	69,0	71,4	
C:20	22,5	83,5	94,0	84,5	85,5	92,3	
C:100	4,5	145,1	162,6	139,6	140,2	160,0	
r2		1,00	1,00	0,99	0,99	1,00	r2 ≥ 0.98
C1 (in mIU/mL) (in house preparation)		86	89	86	83	88	[55 - 105] mIU/mL
C2 (in mIU/mL) (in house preparation)		263	271	272	274	275	[200 - 300] mIU/mL

Comments : ☒ **PASSED IN COMPLIANCE**

Date : 04/05/2016 **QC Manager : S. LECOURT**