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

ANALYSIS CERTIFICATE

BIOPHEN FVIII:C- #221402 **Lot : F1500002**

QC Release : 20/01/2016 **Expiration date : 2018-05-19**

Components	Volume	Exp. (months)	Int. Ref.	Lot #	Exp. date
R1 : Human Factor X	2 vials	30	NA	F151100002	2018-05-21
R2 : Activation Reagent	2 vials	30	NA	F151100002	2018-05-27
R3 : SXa-11 substrate	2 vials	30	NA	F151100002	2018-05-21
R4+ : Tris-BSA buffer	4 vials	30	NA	F151100002	2018-05-19

305

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

ANALYSIS CERTIFICATE

BIOPHEN FVIII:C- #221402 **Lot : F1500002**

QC Release : 20/01/2016 **Expiration date : 2018-05-19**

Analytical data			Specifications
1. Human Factor X			
a. Reproducibility (water bath)(100 % VIII:C)			
N = **20**	Mean (A405):	**1,278**	N ≥ 10
	CV:	**1,47 %**	≤ 2 %
b. Factor X concentration (water bath)		**81 %**	≥ 50 %
2. Activation Reagent (IXa - Thrombin - PLPs - calcium)			
a. Reproducibility (water bath)(100 % VIII:C)			
N = **20**	Mean (A405):	**1,257**	N ≥ 10
	CV:	**1,36 %**	≤ 2 %
3. SXa-11 substrate (tested at 3 mg/ml for a,b)			
a. Blank value (N=10)	Mean (A405):	**0,229**	A405 ≤ 0.30
b. Stability of substrate blank (A405)			
Fresh: **0,221** / **7 days R.T**: **0,232**			A405 ≤ 0.30
c. Reproducibility (water bath)			
N = **20**	Mean (A405):	**1,180**	N ≥ 10
	CV:	**1,54 %**	≤ 2 %

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

ANALYSIS CERTIFICATE

BIOPHEN FVIII:C- #221402 **Lot : F1500002**

QC Release : 20/01/2016 **Expiration date : 2018-05-19**

Analytical data	Specifications

1. Calibration curve

High Range:

VIII:C (%)		A405 W. Bath	A405 STAR
0	0/0	0,015	0
C/4	25/20	0,246	0,209
C/2	50/50	0,584	0,442
C	100/100	1,272	0,682
2C	200/190	2,323	0,759
Linearity:	**r2 =**	0,9961	0,9950

Water Bath:
A405(200%) ≥ 1,60
ΔA405(100%-200%) ≥ 0.60

r2 ≥ 0.98

Low Range:

VIII:C (%)		A405 W. Bath	A405 STAR
0	0/0,93	0,011	0,041
C/4	6,25/6,25	0,294	0,324
C/2	12,5/12,5	0,628	0,664
C	25/25	1,234	1,195
Linearity:	**r2 =**	0,9990	0,9960

Water Bath:
A405(25%) ≥ 0.80
ΔA405(12.5%-25%) ≥ 0.30

r2 ≥ 0.98

2. Accuracy: W.BATH

Control	TV* % VIII :C	MV* % VIII :C
Normal Control	94	101
Abnormal Control	37	35

* TV= Target Value - MV= Measured Value

[84 - 104]
[31 - 43]

3. Detection threshold

Method : CS

High range: **< 0,5 %** — **≤ 10%**
Low range: **<0,8 %** — **≤ 2%**

4. Performances

Method : CS for normal plasma and w.bath for FVIII Deficient plasma

Normal plasmas:
N= **15** — **N ≥ 10**
Mean= **84 %** — **≥ 50 %**
Range: **55 to 126 %** — **About 50-150%**

FVIII Deficient Plasma:
2,8 % VIII:C (high range) — **< 10 %**
1,2 % VIII:C (low range) — **< 2 %**

5. Stability of restored reagents

Method : WATER BATH

VIII:C (%)		A405 Fresh	A405 24H RT	A405 72H 2-8°C
C/8	13	0,102	0,115	0,110
C/4	26	0,229	0,258	0,246
C/2	52	0,540	0,592	0,571
C	104	1,177	1,307	1,251
2C	208	2,189	2,399	2,393
Linearity:	**r2 =**	0,9968	0,9969	0,9979

Δ A405 point C ≤ 15%
Δ A405 point 2C ≤ 15%
between fresh and 24h RT or 72H at 2-8°C

Control	MV* % VIII :C	MV* % VIII :C	MV* % VIII :C
Normal Control	99	101	102
Abnormal Control	37	37	37

* MV= Measured Value

[84 - 104]
[31 - 43]

Comments :

☑ **PASSED IN COMPLIANCE**

Date : 20/01/2016 **QC Manager :** S.LECOURT