

ANALYSIS CERTIFICATE

BIOPHEN FIXa - #221812

Lot : F1600269

QC Release : 29/04/2016

Expiration date : 2018-04-30

Components	Volume	Exp. (months)	Int. Ref.	Lot #	Exp. date
R1 : Human Factor X -FVIII:C	2 vials	30	151029A	54205-1	2018-04
R2 : "Activation" Reagent	2 vials	30	151110A	54205-2	2018-05
R3 : Sxa-11 substrate	2 vials	30	151020C	54205-3	2018-04
R4 : Tris-BSA buffer	2 vials	30	151013D	54205-4	2018-04
Cal : FIXa Calibrator	2 vials	30	F161400270	F161400270	2018-08-20

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Analytical data	Specifications									
1. <u>Human Factor X-VIII:C</u>										
a. Reproducibility: <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="text-align: left;"> <p>N = 15</p> </div> <div style="text-align: right;"> <p>Mean (A405): 2,403</p> <p>CV: 1,7 %</p> </div> </div>	<p>N ≥ 10</p> <p>≤ 2 %</p>									
b. Factor X concentration (water bath)	<p>86 %</p> <p>≥ 50 %</p>									
2. <u>"Activation" Reagent (Thrombin - PLPs - calcium)</u>										
a. Reproducibility (FIXa, C/2) <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="text-align: left;"> <p>N = 15</p> </div> <div style="text-align: right;"> <p>Mean (A405): 2,406</p> <p>CV: 0,7 %</p> </div> </div>	<p>N ≥ 10</p> <p>≤ 2 %</p>									
3. <u>SXa-11 substrate</u> (tested at 2.5 mg/ml for a,b)										
a. Blank value (N=10)	<p>Mean (A405): 0,179</p> <p>A405 ≤ 0.30</p>									
b. Stability of substrate blank (A405)	<p>A405</p> <p>7 days ≤ 0.30</p>									
<table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th style="width: 20%;">Time</th> <th style="width: 40%;">Fresh</th> <th style="width: 40%;">7 days</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">2-8°C</td> <td style="text-align: center;">0,140</td> <td style="text-align: center;">0,172</td> </tr> <tr> <td style="text-align: center;">R.T.</td> <td style="background-color: black;"></td> <td style="text-align: center;">0,186</td> </tr> </tbody> </table>	Time	Fresh	7 days	2-8°C	0,140	0,172	R.T.		0,186	
Time	Fresh	7 days								
2-8°C	0,140	0,172								
R.T.		0,186								
c. Reproducibility <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="text-align: left;"> <p>N = 15</p> </div> <div style="text-align: right;"> <p>Mean (A405): 2,366</p> <p>CV: 1,2 %</p> </div> </div>	<p>N ≥ 10</p> <p>≤ 2 %</p>									
4. <u>FIXa calibrator</u>										
<div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="text-align: left;"> <p>N =</p> <p>FIXa conc. =</p> <p>CV:</p> </div> <div style="text-align: right;"> <p>30</p> <p>25 mIU/ml</p> <p>6,9 %</p> </div> </div>	<p>N ≥ 9</p> <p>25 ± 5 mIU/ml</p> <p>≤ 10 %</p>									

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Analytical data			Specifications
1. <u>Calibration curve</u>			<p>Water Bath: A405(C/2) ≥ 1.5</p> <p>A405 (0) < 0.100</p> <p>ΔA405(C/2-C/4) ≥ 0.30</p> <p>r2 ≥ 0.98</p>
FIXa (mIU/ml)	A405	Δ A405	
	W. Bath	STAR	
0	0,006	0	
C/40	0,252	0,050	
C/20	0,499	0,115	
C/8 or C/10	1,085	0,230	
C/4	1,816	0,558	
C/2	2,628	0,963	
Linearity: r2 =	0,990	0,994	

2. <u>Detection threshold</u>	
$< 0,1 \text{ mIU/ml}$	$\leq 0.2 \text{ mIU/ml}$

3. <u>Stability of restored reagents (for the C/2 FIXa concentration)</u>									
<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">Fresh</th> <th style="text-align: center;">8hrs RT</th> <th style="text-align: center;">24 hrs 2-8°C</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">A405</td> <td style="text-align: center;">0,901</td> <td style="text-align: center;">0,803</td> <td style="text-align: center;">0,785</td> </tr> </tbody> </table>		Fresh	8hrs RT	24 hrs 2-8°C	A405	0,901	0,803	0,785	$\Delta \text{A405} \leq 0.20$
	Fresh	8hrs RT	24 hrs 2-8°C						
A405	0,901	0,803	0,785						

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 29/04/2016

QC Manager :

S. LECOURT



BIOPHEN Factor IXa (ACT. FIX)
Référence 221812

Pour recherche *in vitro* exclusivement

FRANÇAIS

Lot : F1600269 - Exp. : 2018-04-30

Calibrateur Facteur IXa

Lot : F161400270

C= 25 mUI/ml*

(* 1 mUI/ml est proche de 1 ng/ml)

BIOPHEN Factor IXa (ACT. FIX)
221812

For *in vitro* research use only

ENGLISH

Lot : F1600269 - Exp. : 2018-04-30

Factor IXa Calibrator

Lot : F161400270

C= 25 mIU/ml*

(* 1 mIU/ml is close to 1 ng/ml)

BIOPHEN Factor IXa (ACT. FIX)
Référence 221812

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Calibrateur Facteur IXa

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