

ANALYSIS CERTIFICATE

BIOPHEN DiXal - #221030

Lot : 53202

QC Release : 06/11/2015

Expiration date : 2018-02

Components	Qty	Exp. (months)	Int. Ref.	Lot #	Exp. date
R1 : Human FXa	3 vials	30	150821A	53202-1	2018-02
R2 : FXa substrate	3 vials	30	150807A	53202-2	2018-02
R3 : Buffer	4 vials	30	150810F	53202-3	2018-02

SDS

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Analytical data	Specifications
1. <u>Human FXa (R1)</u>	
a. Reproducibility (0 ng/ml) : N = 20 Mean (A405) : 1,942 CV : 1,45 %	N ≥ 10 ≤ 2 %
2. <u>FXa substrate (R2)</u> (tested at 2 mg/ml for a,b)	
a. Blank value (N=10) Mean (A405): 0,164	A405 ≤ 0.30
b. Reproducibility (0ng/ml) N = 20 Mean (A405): 1,970 CV: 1,75 %	N ≥ 10 ≤ 2 %
3. <u>Reaction buffer (R3)</u>	
Volume : > 25 ml pH 7,93	≥ 25 ml 7.85 ± 0.20 (indicative)
Aspect : <input checked="" type="checkbox"/> Clear <input checked="" type="checkbox"/> Transparent	Clear - Transparent

SAS

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Analytical data				Specifications	
4. Calibration curve					
Method : STAR					
ng/ml Rivaroxaban		ΔA405			
High Range	Low range	High Range	Low range		
0	0	2,540	2,157		
157	29	1,948	1,642		
321	66	1,481	1,172		
462	99	1,014	0,814		
525	128	0,863	0,648		
Linearity : R ² =		0,996	0,998	STAR : DA405(0-C) ≥ 1.0 in High Range R ² ≥ 0.98	

5. Detection threshold					
Method : STAR					
High Range		<1 ng/ml		≤ 50 ng/ml	
Low Range		<1 ng/ml		≤ 10 ng/ml	

6. Accuracy:					
Method : STAR					
Rivaroxaban Controls		TV* (ng/ml)	MV* (ng/ml)		
C1 Lot :	51404-1	107	122	[75 -139] ng/ml	
C2 Lot :	51404-2	297	320	[250 - 345] ng/ml	
CI Lot :	42203-1	24	26	[14 - 34] ng/ml	
CII Lot :	42203-2	87	87	[70 - 104] ng/ml	
* TV= Target Value - MV= Measured Value					

7. Performances					
Method : STAR					
Normal plasmas in High range		N =	5	N ≥ 3	
		Mean =	1 ng/ml	≤ 50 ng/ml In High Range of Rivaroxaban	
Normal plasmas in Low range		N =	5	N ≥ 3	
		Mean =	1,7 ng/ml	≤ 10 ng/ml In Low Range of Rivaroxaban	
		MV* (ng/ml) in High Range		High Range	
UFH	1,93 IU/ml	0		≤ 50 ng/ml	
LMWH	1,78 IU/ml	11		≤ 50 ng/ml	
Fondaparinux	1,76 µg/ml	2		≤ 50 ng/ml	
* MV= Measured Value					

8. Stability of restored reagents:					
Method : STAR					
		OD Fresh	OD 7 days RT	OD 7 days 2-8°C	OD Frozen = -20°C
Rate	0	2,541	2,497	2,533	2,571
	300	1,519	1,477	1,528	1,530
	525	0,756	0,737	0,755	0,772
R ²		1,000	1,000	1,000	1,000
Rate	c1	131	126	126	127
	c2	316	324	314	316
Δ A405 ≤ 0.10					
R ² ≥ 0.98					
[75 - 139] ng/ml					
[250 - 345] ng/ml					

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 06/11/2015

QC Manager : S.LECOURT

