

ANALYSIS CERTIFICATE

BIOPHEN™ DiXal - #221030

**Lot : F1700574
F1700575**

QC Release : 2017-07-11

Expiration date : 2019-11-25

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : Human FXa	3 vials	30	F171500574 F171100575	2019-12-08
R2 : FXa substrate	3 vials	30	F171500574 F171100575	2019-11-25
R3 : Buffer	4 vials	30	F171500574 F171100575	2019-11-29

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Analytical data	Specifications
<p>1. <u>Human FXa (R1)</u></p> <p>a. Reproducibility (0 ng/ml) :</p> <p style="margin-left: 40px;">N = 35</p> <p style="margin-left: 80px;">Mean (A405) : 1,913</p> <p style="margin-left: 80px;">CV : 1,9 %</p>	<p>≤ 2 %</p>
<p>2. <u>FXa substrate (R2)</u> (tested at 2 mg/ml for a,b)</p> <p>a. Blank value (N=10) Mean (A405): 0,161</p> <p>b. Reproducibility (0 ng/ml)</p> <p style="margin-left: 40px;">N = 35</p> <p style="margin-left: 80px;">Mean (A405): 1,926</p> <p style="margin-left: 80px;">CV: 1,8 %</p>	<p>A405 ≤ 0.30</p> <p>≤ 2 %</p>
<p>3. <u>Reaction buffer (R3)</u></p> <p style="margin-left: 80px;">Volume : >20 ml</p> <p style="margin-left: 80px;">pH 7,97</p> <p style="margin-left: 40px;">Aspect : <input checked="" type="checkbox"/> Clear <input checked="" type="checkbox"/> Transparent</p>	<p>≥ 20 ml</p> <p>Indicative</p> <p>Clear - Transparent</p>

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Analytical data					Specifications
4. <u>Calibration curve</u>					STAR : $\Delta A405(Cal1-Cal5) \geq 1.0$ (Standard Range) $R^2 \geq 0.98$
Method : CS5100					
ng/ml Rivaroxaban		AA405			
Standard Range	Low range	Standard Range	Low range		
CAL 1	0	0	1,9496	1,2654	
CAL 2	157	29	1,6082	1,0385	
CAL 3	321	66	1,2850	0,8407	
CAL 4	462	99	1,0059	0,6926	
CAL 5	525	128	0,8507	0,5667	
Linearity :		R ² =	1,000	0,998	

5. <u>Detection threshold</u>			
Method : CS			
Standard Range	<1 ng/ml		≤ 50 ng/ml
Low Range	<1 ng/ml		≤ 10 ng/ml

6. <u>Accuracy</u>			
Method : CS			
Rivaroxaban Controls	TV* (ng/ml)	MV* (ng/ml)	
C1 Lot : F1600888	104	118	[73 - 135] ng/ml
C2 Lot : F1600888	316	324	[265 - 367] ng/ml
C1 Lot : F1601248	24	26	[14 - 34] ng/ml
C11 Lot : F1601248	84	83	[67 - 101] ng/ml

* TV= Target Value - MV= Measured Value

7. <u>Performances</u>			
Method : CS5100			
Normal plasmas in Standard range	N =	3	N ≥ 3
	Mean =	16,6 ng/ml	≤ 50 ng/ml in Standard Range of Rivaroxaban
Normal plasmas in Low range	N =	3	N ≥ 3
	Mean =	7,5 ng/ml	≤ 10 ng/ml in Low Range of Rivaroxaban
		MV* (ng/ml) in Standard Range	
UFH	IU/ml	6,6	Standard Range
LMWH	IU/ml	12	≤ 50 ng/ml
Fondaparinux	µg/ml	13	≤ 50 ng/ml

* MV= Measured Value

8. <u>Stability of restored reagents</u>						
Method : CS5100						
ng/ml Rivaroxaban	OD Fresh	OD 7 days RT	OD 7 days 2-8°C	OD Frozen -20°C		$\Delta A405 (Cal1) \leq 0.10$ $R^2 \geq 0.98$ [73 - 135] ng/ml [265 - 367] ng/ml
CAL 1	0	1,9574	1,9053	1,9125	1,9267	
CAL 2	266	1,4809	1,3606	1,3836	1,3857	
CAL 3	490	1,0929	0,9219	0,9378	0,9327	
R ²	1,000	1,000	1,000	1,000		
	Rate Fresh	Rate 7 days RT	Rate 7 days 2-8°C	Rate Frozen -20°C		
C1 Lot : F1600888	116	106	111	111		
C2 Lot : F1600888	318	321	318	317		

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2017-07-11

QC Manager : S. LECOURT

