HYPHEN BioMed
ZAC Neuville Université - 155 rue d'Eragny
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ANALYSIS CERTIFICATE

BIOPHEN™ Apixaban Calibrator - #226201

Lot : **F1700659**
F1700660

QC release: **2017-08-30**

Expiration date : **2019-12-27**

Components	Volume	Exp. (months)	Lot #	Exp. date
CAL1 : Calibrator 1	4 vials	30	F171200659 F171100660	2019-12-27
CAL2 : Calibrator 2	4 vials	30	F171200659 F171100660	2019-12-27
CAL3 : Calibrator 3	4 vials	30	F171200659 F171100660	2019-12-27

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BIOPHEN™ Apixaban Calibrator - #226201

Lot : F1700659
F1700660

QC release: 2017-08-30

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Analytical data			Specifications
1. Within lot reproducibility			
N= **15**	CV:	**0,9 %**	CV (OD) ≤ 2%
N= **15**	CV:	**0,8 %**	CV (OD) ≤ 2%
N= **15**	CV:	**1,3 %**	CV (OD) ≤ 2%

2. Concentration [C] and Standard Deviation (SD)

Controls	[C] ng/mL	SD
CAL1	**0**	**7,4**
CAL2	**290**	**18,5**
CAL3	**578**	**28,1**

CAL1: < 50 ng/ml

CAL2: 200-400 ng/mL

CAL3: 500-700 ng/mL

3. Aspect

- ☑ **Slightly opalescent to clear** — a) Slightly opalescent to clear
- ☑ **No coagulum** — b) No coagulum
- ☑ **Stable solution** — c) Stable solution

4. Stability of reconstituted reagents

		Fresh	48h	7 days
		/	RT	2-8°C
CAL1	**ng/mL**	**12**	**11**	**12**
	Δ [C]	NA	**1**	**0**
CAL2	**ng/mL**	**280**	**278**	**265**
	Δ [C]	NA	**2**	**15**
CAL3	**ng/mL**	**591**	**587**	**598**
	Δ [C]	NA	**4**	**7**

48 hours at RT:

Δ [C] ≤ 30 ng/ml

7 days at 2-8°C:

Δ [C] ≤ 30 ng/ml

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Analytical data	Specifications

5. Calibration curve

☐ Manual method ☑ STAR

BIOPHEN DiXal **Lot F1700574**

	ng/ml	A_{405}
Cal 1	0	2,529
Cal 2	290	1,799
Cal 3	578	1,116

6. Linearity

R^2 0,998 — $R^2 \geq 0.98$

7. Accuracy

☐ Manual method ☑ STAR

MV* within the acceptance range

CONTROLS			TV*	MV*	
C1	Lot	F1700656	178	191	[151 - 205]
C2	Lot	F1700656	384	405	[326 - 442]

*TV: Target Value *MV: Measured Value

Comments :

☑ **PASSED IN COMPLIANCE**

Date : 2017-08-30 **QC Manager : S. LECOURT**

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CE IVD

BIOPHEN™ Apixaban Calibrator

REF 226201

LOT F1700659 2019-12-27

	UNIT	TARGET VALUE	WHO STD
CAL 1 LOT F171200659	ng/mL	0	NA
CAL 2 LOT F171200659		290	
CAL 3 LOT F171200659		578	