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™ Rivaroxaban Calibrator Low - #226001 **Lot : F1601010**

QC release: 2016-11-22 **Expiration date : 2019-04-02**

Components	Volume	Exp. (months)	Lot #	Exp. date
CAL I : Calibrator 1	4 vials	30	F161101010	2019-04-02
CAL II : Calibrator 2	4 vials	30	F161101010	2019-04-02
CAL III : Calibrator 3	4 vials	30	F161101010	2019-04-02

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Analytical data			Specifications
1. Within lot reproducibility			
N= 10	CV:	0,5 %	CV (OD) ≤ 2%
N= 10	CV:	0,4 %	CV (OD) ≤ 2%
N= 10	CV:	0,8 %	CV (OD) ≤ 2%

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

Controls	[C] ng/mL	SD	
CAL I	0	1,74	CAL1: < 20 ng/ml
CAL II	51	2,94	CAL2: 40-60 ng/mL
CAL III	109	4,39	CAL3: 80-120 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
CAL I	ng/mL	0	0	0
	Δ [C]	NA	0	0
CAL II	ng/mL	51	51	52
	Δ [C]	NA	0	1
CAL III	ng/mL	111	111	110
	Δ [C]	NA	0	1

48 hours at RT:

Δ [C] ≤ 15 ng/ml

7 days at 2-8°C:

Δ [C] ≤ 15 ng/ml

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Analytical data	Specifications
5. Calibration curve ☐ Manual method ☑ STAR **BIOPHEN DiXal** **Lot F1600443**	

	ng/ml	A_{405}
CAL I	0	2,313
CAL II	51	1,436
CAL III	109	0,753

6. Linearity R^2 0,998	$R^2 \geq 0.98$

7. Accuracy ☐ Manual method ☑ STAR	MV* within the acceptance range

CONTROLS			TV*	MV*	
C I	Lot	50502-1	25	24	[15 - 35]
C II	Lot	50502-2	76	70	[61 - 91]

*TV: Target Value *MV: Measured Value

Comments :

☑ **PASSED IN COMPLIANCE**

Date : 2016-11-22 **QC Manager : S.LECOURT**

BIOPHEN® RIVAROXABAN CALIBRATOR LOW
Reference 226001

Pour diagnostic *in vitro* exclusivement.

FRANÇAIS

Lot : F1601010 - Exp. : 2019-04-02

Concentration [C] en Rivaroxaban dans les calibrateurs

Cal 1	Lot :	**F161101010**	
	[C] :	**0**	ng/mL
Cal 2	Lot :	**F161101010**	
	[C] :	**51**	ng/mL
Cal 3	Lot :	**F161101010**	
	[C] :	**109**	ng/mL

BIOPHEN® RIVAROXABAN CALIBRATOR LOW
Reference 226001

For *in vitro* diagnostic use only

ENGLISH

Lot : F1601010 - Exp. : 2019-04-02

Rivaroxaban concentration [C] in the calibrators

Cal 1	Lot :	**F161101010**	
	[C] :	**0**	ng/mL
Cal 2	Lot :	**F161101010**	
	[C] :	**51**	ng/mL
Cal 3	Lot :	**F161101010**	
	[C] :	**109**	ng/mL

Quality Control Approval
23 NOV. 2016
S. Lecourt

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	[C] :	**109**	ng/mL

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ENGLISH

Lot : F1601010 - Exp. : 2019-04-02

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	[C] :	**51**	ng/mL
Cal 3	Lot :	**F161101010**	
	[C] :	**109**	ng/mL