

ANALYSIS CERTIFICATE

BIOPHEN DABIGATRAN® PLASMA CALIBRATOR LOW - #222901

**Lot : F1701167
F1701168**

QC release: 2017-11-24

Expiration date : 2020-03-28

Components	Volume	Exp. (months)	Lot #	Exp. date
CAL1 : Calibrator 1	4 vials	30	F171201167 F171101168	2020-03-28
CAL2 : Calibrator 2	4 vials	30	F171201167 F171101168	2020-03-28
CAL3 : Calibrator 3	4 vials	30	F171201167 F171101168	2020-03-28



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Analytical data	Specifications
1. <u>Within lot reproducibility</u>	
N= 10 CV: 1,2 %	CV (CT) ≤ 3%
N= 10 CV: 1,0 %	CV (CT) ≤ 3%
N= 10 CV: 0,8 %	CV (CT) ≤ 3%

2. <u>Concentration [C] and Standard Deviation (SD)</u>													
<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">Controls</th> <th style="width: 40%;">[C] ng/mL</th> <th style="width: 40%;">SD</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">CAL1</td> <td style="text-align: center;">0</td> <td style="text-align: center;">1,1</td> </tr> <tr> <td style="text-align: center;">CAL2</td> <td style="text-align: center;">53</td> <td style="text-align: center;">2,0</td> </tr> <tr> <td style="text-align: center;">CAL3</td> <td style="text-align: center;">106</td> <td style="text-align: center;">5,1</td> </tr> </tbody> </table>	Controls	[C] ng/mL	SD	CAL1	0	1,1	CAL2	53	2,0	CAL3	106	5,1	CAL1: < 20 ng/ml CAL2: 40-60 ng/mL CAL3: 80-120 ng/mL
Controls	[C] ng/mL	SD											
CAL1	0	1,1											
CAL2	53	2,0											
CAL3	106	5,1											

3. <u>Aspect</u>	
<input checked="" type="checkbox"/> Slightly opalescent to clear <input checked="" type="checkbox"/> No coagulum <input checked="" type="checkbox"/> Stable solution	a) Slightly opalescent to clear b) No coagulum c) Stable solution

4. <u>Stability of reconstituted reagents</u>					
		Fresh	48h	7 days	
		/	RT	2-8°C	
CAL1	ng/mL	0	0	0	48 hours at RT: $\Delta [C] \leq 15 \text{ ng/ml}$ 7 days at 2-8°C: $\Delta [C] \leq 15 \text{ ng/ml}$
	$\Delta [C]$	NA	0	0	
CAL2	ng/mL	56	57	57	
	$\Delta [C]$	NA	1	1	
CAL3	ng/mL	105	108	105	
	$\Delta [C]$	NA	3	0	

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Analytical data	Specifications												
<p>5. <u>Calibration curve</u> <input type="checkbox"/> Manual Method <input checked="" type="checkbox"/> STAR</p> <p><i>Thrombin Inhibitor</i> CK002 Lot F1700786</p> <table border="1"><thead><tr><th></th><th>ng/ml</th><th>CT (sec)</th></tr></thead><tbody><tr><td>Cal 1</td><td>0</td><td>30,3</td></tr><tr><td>Cal 2</td><td>53</td><td>55,3</td></tr><tr><td>Cal 3</td><td>106</td><td>77,5</td></tr></tbody></table>		ng/ml	CT (sec)	Cal 1	0	30,3	Cal 2	53	55,3	Cal 3	106	77,5	
	ng/ml	CT (sec)											
Cal 1	0	30,3											
Cal 2	53	55,3											
Cal 3	106	77,5											

6. <u>Linearity</u> R^2 0,998	$R^2 \geq 0.98$
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7. <u>Accuracy</u> <input type="checkbox"/> Manual method <input checked="" type="checkbox"/> STAR	MV* within the acceptance range															
<table border="1"><thead><tr><th></th><th colspan="2">CONTROLS</th><th>TV*</th><th>MV*</th></tr></thead><tbody><tr><td>C1</td><td>Lot</td><td>F1701197</td><td>25</td><td>27</td></tr><tr><td>C2</td><td>Lot</td><td>F1701197</td><td>77</td><td>82</td></tr></tbody></table> <p>*TV: Target Value *MV: Measured Value</p>		CONTROLS		TV*	MV*	C1	Lot	F1701197	25	27	C2	Lot	F1701197	77	82	[15 - 35] [62 - 92]
	CONTROLS		TV*	MV*												
C1	Lot	F1701197	25	27												
C2	Lot	F1701197	77	82												

Comments :

PASSED
IN COMPLIANCE

Date : 2017-11-24

QC Manager : S.LECOURT




BIOPHEN® DABIGATRAN CALIBRATOR LOW

Set of human plasma assigned for Dabigatran intended to the calibration of the Dabigatran assays using anti-lia method /
Gamme de plasmas humains à titre défini en Dabigatran pour l'étalonnage des dosages de Dabigatran par méthode anti-lia

REF 222901

For in vitro diagnostic use only / Pour diagnostic in vitro exclusivement

LOT F1701167  2020-03-28

Dabigatran Concentration [C] in the calibrators /
Concentration [C] en Dabigatran dans les calibrateurs

<u>Calibrator / Calibrateur 1</u>	LOT : F171201167
[C] :	0 ng/mL / ng/mL
<u>Calibrator / Calibrateur 2</u>	LOT : F171201167
[C] :	53 ng/mL / ng/mL
<u>Calibrator / Calibrateur 3</u>	LOT : F171201167
[C] :	106 ng/mL / ng/mL

Standardization / Standardisation : N/A

Approved Date / Date d'Approbation : 2017-11-24

Quality Control Manager / Responsable Contrôle Qualité : S.LECOURT