

## ANALYSIS CERTIFICATE

**BIOPHEN DABIGATRAN® PLASMA CALIBRATOR LOW - #222901**

**Lot : F1701167  
F1701168**

**QC release: 2017-11-24**

**Expiration date : 2020-03-28**

<b>Components</b>	<b>Volume</b>	<b>Exp. (months)</b>	<b>Lot #</b>	<b>Exp. date</b>
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



## ANALYSIS CERTIFICATE

**BIOPHEN DABIGATRAN® PLASMA CALIBRATOR LOW - #222901** Lot : F1701167 F1701168

**QC release: 2017-11-24**

**Expiration date : 2020-03-28**

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

<b>2. <u>Concentration [C] and Standard Deviation (SD)</u></b>													
<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											

<b>3. <u>Aspect</u></b>	
<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

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

205

## ANALYSIS CERTIFICATE

**BIOPHEN DABIGATRAN® PLASMA CALIBRATOR LOW - #222901 Lot : F1701167 F1701168**

**2017-11-24**

**Expiration date : 2020-03-28**

Analytical data	Specifications												
<p><b>5. Calibration curve</b></p> <p style="text-align: center;"> <input type="checkbox"/> Manual Method          <input checked="" type="checkbox"/> STAR                 </p> <p><i>Thrombin Inhibitor</i> <b>CK002</b></p> <p style="text-align: right;">Lot F1700786</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse; text-align: center;"> <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											

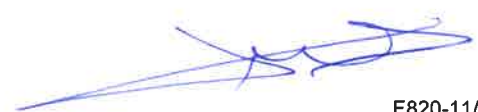
<p><b>6. Linearity</b></p> <p style="text-align: center;"><math>R^2</math>                      0,998</p>	<p><math>R^2 \geq 0.98</math></p>
---	-----------------------------------

<p><b>7. Accuracy</b></p> <p style="text-align: center;"> <input type="checkbox"/> Manual method          <input checked="" type="checkbox"/> STAR                 </p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse; text-align: center;"> <thead> <tr> <th colspan="3">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 style="text-align: center; margin-top: 5px;">                     *TV: Target Value          *MV: Measured Value                 </p>	CONTROLS			TV*	MV*	C1	Lot	F1701197	25	27	C2	Lot	F1701197	77	82	<p>MV* within the acceptance range</p> <p style="text-align: center; margin-top: 20px;">                         [ 15 - 35 ]                          [ 62 - 92 ]                     </p>
CONTROLS			TV*	MV*												
C1	Lot	F1701197	25	27												
C2	Lot	F1701197	77	82												

<p>Comments :</p>	<input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b>
-------------------	---

**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

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

Standardization / Standardisation : N/A

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

Quality Control Manager / Responsable Contrôle Qualité : S.LECOURT