

ANALYSIS CERTIFICATE

HEMOCLOT THROMBIN INHIBITORS #CK002L

**F1700786
Lot : F1700787**

QC Release: 2017-08-30

Expiration date : 2019-12-30

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : Normal pooled plasma	3 vials	30	F171300786 F171200787	2019-12-30
R2 : Human calcium thrombin	3 vials	30	F171300786 F171200787	2020-02-10

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Lot : F1700787

QC Release: 2017-08-30

Expiration date : 2019-12-30

Analytical data	Specifications			
3. Calibration curve				
Automated Method: STAR				
Standard Range				
Dabigatran Conc.-ng/mL	0	235	447	Δ CT (50 - 500 ng/mL) 65 ± 25 Sec (STAR) $R^2 \geq 0.98$
CT (Sec.)	31,5	59,8	85,3	
Δ CT (50-500 ng/ml)			54	
			$R^2 = 0,999$	
Low Range				$R^2 \geq 0.98$
Dabigatran Conc.-ng/mL	0	36	95	
CT (Sec.)	30,5	47,1	75,9	
			$R^2 = 0,998$	

4. Normal Plasmas: Method : STAR	
N : 12 Dabigatran Conc. : 0 ng/mL	$N \geq 10$ < 10 ng/mL

5. Accuracy: Method: STAR										
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Control (Standard range)</th> <th>TV* (ng/ml)</th> <th>MV* (ng/ml)</th> </tr> </thead> <tbody> <tr> <td>C1</td> <td style="text-align: center;">127</td> <td style="text-align: center;">128</td> </tr> <tr> <td>C2</td> <td style="text-align: center;">335</td> <td style="text-align: center;">333</td> </tr> </tbody> </table>	Control (Standard range)	TV* (ng/ml)	MV* (ng/ml)	C1	127	128	C2	335	333	$[102 - 152]$ ng/ml $[285 - 385]$ ng/ml
Control (Standard range)	TV* (ng/ml)	MV* (ng/ml)								
C1	127	128								
C2	335	333								
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Control (Low range)</th> <th>TV* (ng/ml)</th> <th>MV* (ng/ml)</th> </tr> </thead> <tbody> <tr> <td>C1</td> <td style="text-align: center;">23</td> <td style="text-align: center;">27</td> </tr> <tr> <td>C2</td> <td style="text-align: center;">68</td> <td style="text-align: center;">76</td> </tr> </tbody> </table>	Control (Low range)	TV* (ng/ml)	MV* (ng/ml)	C1	23	27	C2	68	76	$[13 - 33]$ ng/ml $[54 - 82]$ ng/ml
Control (Low range)	TV* (ng/ml)	MV* (ng/ml)								
C1	23	27								
C2	68	76								
* TV= Target Value - MV= Measured Value										

6. Stability of restored reagents (CT in sec)																										
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Dabigatran ng/mL</th> <th>Fresh</th> <th>8 hrs RT (18-25°C)</th> <th>24 hrs 2-8°C</th> <th>frozen $\leq -20^\circ\text{C}$</th> </tr> </thead> <tbody> <tr> <td>43</td> <td style="text-align: center;">37,2</td> <td style="text-align: center;">38,2</td> <td style="text-align: center;">38,1</td> <td style="text-align: center;">36,6</td> </tr> <tr> <td>257</td> <td style="text-align: center;">63,3</td> <td style="text-align: center;">63,5</td> <td style="text-align: center;">64,8</td> <td style="text-align: center;">60,4</td> </tr> <tr> <td>489</td> <td style="text-align: center;">88,5</td> <td style="text-align: center;">89,1</td> <td style="text-align: center;">90,6</td> <td style="text-align: center;">86,3</td> </tr> <tr> <td>R^2</td> <td style="text-align: center;">0,998</td> <td style="text-align: center;">0,998</td> <td style="text-align: center;">0,998</td> <td style="text-align: center;">1,00</td> </tr> </tbody> </table>	Dabigatran ng/mL	Fresh	8 hrs RT (18-25°C)	24 hrs 2-8°C	frozen $\leq -20^\circ\text{C}$	43	37,2	38,2	38,1	36,6	257	63,3	63,5	64,8	60,4	489	88,5	89,1	90,6	86,3	R^2	0,998	0,998	0,998	1,00	Δ CT ≤ 2 sec Δ CT ≤ 5 sec $R^2 \geq 0.98$
Dabigatran ng/mL	Fresh	8 hrs RT (18-25°C)	24 hrs 2-8°C	frozen $\leq -20^\circ\text{C}$																						
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Comments : PASSED IN COMPLIANCE

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