

ANALYSIS CERTIFICATE

HEMOCLOT THROMBIN INHIBITORS #CK002K

Lot : F1701300 / F1701299

QC Release: 01-12-2017

Expiration date : 2020-04-18

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : Normal pooled plasma	3 vials	30	F171301299 F171201300	2020-04-18
R2 : Human calcium thrombin	3 vials	30	F171301299 F171201300	2020-04-27

SOS

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HEMOCLOT THROMBIN INHIBITORS #CK002K

Lot : F1701300 / F1701299

QC Release: 01-12-2017

Expiration date : 2020-04-18

Analytical data	Specifications			
3. Calibration curve				
<p style="text-align: center;">Automated method: STA-R</p>				
<p style="text-align: center;">Standard Range</p>				
Dabigatran Conc.-ng/mL	0	351	535	Δ CT (50 - 500 ng/mL) 65 ± 25 Sec (STAR) $R^2 \geq 0.98$
CT (Sec.)	32,1	75,3	99,3	
Δ CT (50-500 ng/ml)		56 sec		
$R^2 =$		1		
<p style="text-align: center;">Low Range</p>				$R^2 \geq 0.98$
Dabigatran Conc.-ng/mL	0	69	132	
CT (Sec.)	30,3	63,7	87,9	
$R^2 =$		0,999		

4. Normal Plasmas: Method : STA-R N : 10 Dabigatran Conc. : <1 ng/mL	$N \geq 10$ < 10 ng/mL
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5. Accuracy: Method: STA-R													
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2">Control (Standard Range)</th> <th>TV* (ng/ml)</th> <th>MV* (ng/ml)</th> </tr> </thead> <tbody> <tr> <td>C1</td> <td>F1600526</td> <td style="text-align: center;">112</td> <td style="text-align: center;">113</td> </tr> <tr> <td>C2</td> <td>F1600526</td> <td style="text-align: center;">302</td> <td style="text-align: center;">304</td> </tr> </tbody> </table>	Control (Standard Range)		TV* (ng/ml)	MV* (ng/ml)	C1	F1600526	112	113	C2	F1600526	302	304	[90- 134] ng/ml [257- 347] ng/ml
Control (Standard Range)		TV* (ng/ml)	MV* (ng/ml)										
C1	F1600526	112	113										
C2	F1600526	302	304										
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2">Control (Low Range)</th> <th>TV* (ng/ml)</th> <th>MV* (ng/ml)</th> </tr> </thead> <tbody> <tr> <td>C1</td> <td>F1601249</td> <td style="text-align: center;">23</td> <td style="text-align: center;">28</td> </tr> <tr> <td>C2</td> <td>F1601249</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	F1601249	23	28	C2	F1601249	68	76	[13- 33] ng/ml [54- 82] ng/ml
Control (Low Range)		TV* (ng/ml)	MV* (ng/ml)										
C1	F1601249	23	28										
C2	F1601249	68	76										
<small>* TV= Target Value - MV= Measured Value</small>													

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 ≤ -20°C</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">0</td> <td style="text-align: center;">30,6</td> <td style="text-align: center;">31,4</td> <td style="text-align: center;">31,5</td> <td style="text-align: center;">29,8</td> </tr> <tr> <td style="text-align: center;">53</td> <td style="text-align: center;">57,4</td> <td style="text-align: center;">60,2</td> <td style="text-align: center;">58,7</td> <td style="text-align: center;">56,8</td> </tr> <tr> <td style="text-align: center;">106</td> <td style="text-align: center;">80,7</td> <td style="text-align: center;">85,1</td> <td style="text-align: center;">83,3</td> <td style="text-align: center;">80,3</td> </tr> <tr> <td style="text-align: center;">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;">0,998</td> </tr> </tbody> </table>	Dabigatran ng/mL	Fresh	8 hrs RT (18-25°C)	24 hrs 2-8°C	frozen ≤ -20°C	0	30,6	31,4	31,5	29,8	53	57,4	60,2	58,7	56,8	106	80,7	85,1	83,3	80,3	R^2	0,998	0,998	0,998	0,998	Δ CT ≤ 2sec Δ CT ≤ 5sec $R^2 \geq 0.98$
Dabigatran ng/mL	Fresh	8 hrs RT (18-25°C)	24 hrs 2-8°C	frozen ≤ -20°C																						
0	30,6	31,4	31,5	29,8																						
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106	80,7	85,1	83,3	80,3																						
R^2	0,998	0,998	0,998	0,998																						

Comments : **PASSED IN COMPLIANCE**

Date : 01/12/2017 QC Manager : S. LECOURT