

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

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Expiration date : 2019-12-30

Analytical data	Specifications
1. <u>R1 reproducibility on basic clotting time:</u> Method: MC10 N : 30 CV: 1,0 %	 CV(TC) ≤ 3 %
2. <u>R2 reproducibility on basic clotting time:</u> Method: MC10 N : 30 CV: 1,5 %	 CV(TC) ≤ 3 %

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Analytical data	Specifications																
<p>3. Calibration curve</p> <p>Automated Method: STAR</p> <p>Standard Range</p> <table border="1"><tr><td>Dabigatran Conc.-ng/mL</td><td>0</td><td>235</td><td>447</td></tr><tr><td>CT (Sec.)</td><td>31,5</td><td>59,8</td><td>85,3</td></tr></table> <p>Δ CT (50-500 ng/ml) 54 R² = 0,999</p> <p>Low Range</p> <table border="1"><tr><td>Dabigatran Conc.-ng/mL</td><td>0</td><td>36</td><td>95</td></tr><tr><td>CT (Sec.)</td><td>30,5</td><td>47,1</td><td>75,9</td></tr></table> <p>R² = 0,998</p>	Dabigatran Conc.-ng/mL	0	235	447	CT (Sec.)	31,5	59,8	85,3	Dabigatran Conc.-ng/mL	0	36	95	CT (Sec.)	30,5	47,1	75,9	<p>Δ CT (50 - 500 ng/mL) 65 ± 25 Sec (STAR) R² ≥ 0.98</p> <p>R² ≥ 0.98</p>
Dabigatran Conc.-ng/mL	0	235	447														
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Dabigatran Conc.-ng/mL	0	36	95														
CT (Sec.)	30,5	47,1	75,9														

<p>4. Normal Plasmas: Method : STAR</p> <p>N : 12</p> <p>Dabigatran Conc. : 0 ng/mL</p>	<p>N ≥ 10 < 10 ng/mL</p>
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<p>5. Accuracy: Method: STAR</p> <table border="1"><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>127</td><td>128</td></tr><tr><td>C2</td><td>335</td><td>333</td></tr></tbody></table> <table border="1"><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>23</td><td>27</td></tr><tr><td>C2</td><td>68</td><td>76</td></tr></tbody></table> <p>* TV= Target Value - MV= Measured Value</p>	Control (Standard range)	TV* (ng/ml)	MV* (ng/ml)	C1	127	128	C2	335	333	Control (Low range)	TV* (ng/ml)	MV* (ng/ml)	C1	23	27	C2	68	76	<p>[102 - 152] ng/ml [285 - 385] ng/ml</p> <p>[13 - 33] ng/ml [54 - 82] ng/ml</p>
Control (Standard range)	TV* (ng/ml)	MV* (ng/ml)																	
C1	127	128																	
C2	335	333																	
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C2	68	76																	

<p>6. Stability of restored reagents (CT in sec)</p> <table border="1"><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>43</td><td>37,2</td><td>38,2</td><td>38,1</td><td>36,6</td></tr><tr><td>257</td><td>63,3</td><td>63,5</td><td>64,8</td><td>60,4</td></tr><tr><td>489</td><td>88,5</td><td>89,1</td><td>90,6</td><td>86,3</td></tr><tr><td>R²</td><td>0,998</td><td>0,998</td><td>0,998</td><td>1,00</td></tr></tbody></table>	Dabigatran ng/mL	Fresh	8 hrs RT (18-25°C)	24 hrs 2-8°C	frozen ≤ -20°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	<p>Δ CT ≤ 2sec Δ CT ≤ 5sec R² ≥ 0.98</p>
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Comments : PASSED IN COMPLIANCE

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