

ANALYSIS CERTIFICATE

HEMOCLOT THROMBIN INHIBITORS #CK002K

Lot : F1600826

QC Release: 12/09/2016

Expiration date : 2019-02-05

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : Normal pooled plasma	3 vials	30	F161100826	2019-02-05
R2 : Human calcium thrombin	3 vials	30	F161100826	2019-02-08

Res.

ANALYSIS CERTIFICATE

HEMOCLOT THROMBIN INHIBITORS #CK002K

Lot : F1600826

QC Release: 12/09/2016

Expiration date : 2019-02-05

Analytical data	Specifications																
<p>3. Calibration curve</p> <p>Automated method: STA-R</p> <p>High 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>32,5</td> <td>58,2</td> <td>79,9</td> </tr> </table> <p>Δ CT (50-500 ng/ml) 48 $R^2 = 0,9993$</p> <p>Low Range</p> <table border="1"> <tr> <td>Dabigatran Conc.-ng/mL</td> <td>0</td> <td>69</td> <td>95</td> </tr> <tr> <td>CT (Sec.)</td> <td>31,5</td> <td>60,6</td> <td>69,9</td> </tr> </table> <p>$R^2 = 0,9994$</p>	Dabigatran Conc.-ng/mL	0	235	447	CT (Sec.)	32,5	58,2	79,9	Dabigatran Conc.-ng/mL	0	69	95	CT (Sec.)	31,5	60,6	69,9	<p>Δ CT (50 - 500 ng/mL) 65 ± 25 Sec (STAR)</p> <p>$R^2 \geq 0.98$</p> <p>$R^2 \geq 0.98$</p>
Dabigatran Conc.-ng/mL	0	235	447														
CT (Sec.)	32,5	58,2	79,9														
Dabigatran Conc.-ng/mL	0	69	95														
CT (Sec.)	31,5	60,6	69,9														

<p>4. Normal Plasmas: Method : STA-R</p> <p>N : 13</p> <p>Dabigatran Conc. : <1 ng/mL</p>	<p>N \geq 10</p> <p>< 10 ng/mL</p>
---	--

<p>5. Accuracy: Method: STA-R</p> <table border="1"> <tr> <td colspan="2">Control (High Range)</td> <td>TV* (ng/ml)</td> <td>MV* (ng/ml)</td> </tr> <tr> <td>C1</td> <td>F1600526</td> <td>112</td> <td>119</td> </tr> <tr> <td>C2</td> <td>F1600526</td> <td>302</td> <td>315</td> </tr> </table> <table border="1"> <tr> <td colspan="2">Control (Low Range)</td> <td>TV* (ng/ml)</td> <td>MV* (ng/ml)</td> </tr> <tr> <td>C1</td> <td>44505-1</td> <td>28</td> <td>27</td> </tr> <tr> <td>C2</td> <td>44505-2</td> <td>82</td> <td>80</td> </tr> </table> <p>* TV= Target Value - MV= Measured Value</p>	Control (High Range)		TV* (ng/ml)	MV* (ng/ml)	C1	F1600526	112	119	C2	F1600526	302	315	Control (Low Range)		TV* (ng/ml)	MV* (ng/ml)	C1	44505-1	28	27	C2	44505-2	82	80	<p>[90- 134] ng/ml</p> <p>[257- 347] ng/ml</p> <p>[18- 38] ng/ml</p> <p>[66- 98] ng/ml</p>
Control (High Range)		TV* (ng/ml)	MV* (ng/ml)																						
C1	F1600526	112	119																						
C2	F1600526	302	315																						
Control (Low Range)		TV* (ng/ml)	MV* (ng/ml)																						
C1	44505-1	28	27																						
C2	44505-2	82	80																						

<p>6. Stability of restored reagents (CT in sec)</p> <table border="1"> <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°C</th> </tr> <tr> <td>43</td> <td>37,5</td> <td>37,7</td> <td>38,6</td> <td>37,1</td> </tr> <tr> <td>297</td> <td>65,9</td> <td>66,8</td> <td>66,2</td> <td>65,9</td> </tr> <tr> <td>553</td> <td>90,5</td> <td>95,0</td> <td>91,2</td> <td>93,6</td> </tr> <tr> <td>R^2</td> <td>0,998</td> <td>1,000</td> <td>0,998</td> <td>1,000</td> </tr> </table>	Dabigatran ng/mL	Fresh	8 hrs RT (18-25°C)	24 hrs 2-8°C	frozen \leq -20°C	43	37,5	37,7	38,6	37,1	297	65,9	66,8	66,2	65,9	553	90,5	95,0	91,2	93,6	R^2	0,998	1,000	0,998	1,000	<p>Δ CT \leq 2sec</p> <p>Δ CT \leq 5sec</p> <p>$R^2 \geq 0.98$</p>
Dabigatran ng/mL	Fresh	8 hrs RT (18-25°C)	24 hrs 2-8°C	frozen \leq -20°C																						
43	37,5	37,7	38,6	37,1																						
297	65,9	66,8	66,2	65,9																						
553	90,5	95,0	91,2	93,6																						
R^2	0,998	1,000	0,998	1,000																						

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

Date :	12.09.2016	QC Manager :	S. LECOURT
--------	------------	--------------	------------