

ANALYSIS CERTIFICATE

HEMOCLOT THROMBIN INHIBITORS #CK002L

Lot : 52803

QC Release: 13/08/2015

Expiration date : 2018-01

Components	Qty	Exp. (months)	Int. Ref.	Lot #	Exp. date
R1 : Normal pooled plasma	3 vials	30	150710C	52803-1	2018-01
R2 : Human calcium thrombin	3 vials	30	150717A	52803-2	2018-01

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Analytical data	Specifications
1. <u>R1 reproducibility on basic clotting time:</u>	
Method: KC10	N ≥ 10
N : 35	
CV: 1,4 %	≤ 3 %
2. <u>R2 reproducibility on basic clotting time:</u>	
Method: KC10	N ≥ 10
N : 35	
CV: 1,6 %	≤ 3 %

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Analytical data	Specifications																
<p>3. Calibration curve</p> <p style="text-align: center;">Automated Method: STAR</p> <p style="text-align: center;">High Range</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <tr> <td style="width: 30%;">Dabigatran Conc.-ng/mL</td> <td style="width: 10%; text-align: center;">0</td> <td style="width: 10%; text-align: center;">253</td> <td style="width: 10%; text-align: center;">447</td> </tr> <tr> <td>CT (Sec.)</td> <td style="text-align: center;">31,4</td> <td style="text-align: center;">54,3</td> <td style="text-align: center;">76,2</td> </tr> </table> <p style="text-align: center;">Δ CT (50-500 ng/ml) 46 r² = 0,9969</p> <p style="text-align: center;">Low Range</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <tr> <td style="width: 30%;">Dabigatran Conc.-ng/mL</td> <td style="width: 10%; text-align: center;">0</td> <td style="width: 10%; text-align: center;">69</td> <td style="width: 10%; text-align: center;">95</td> </tr> <tr> <td>CT (Sec.)</td> <td style="text-align: center;">30,3</td> <td style="text-align: center;">56,4</td> <td style="text-align: center;">67,3</td> </tr> </table> <p style="text-align: center;">r² = 0,9996</p>	Dabigatran Conc.-ng/mL	0	253	447	CT (Sec.)	31,4	54,3	76,2	Dabigatran Conc.-ng/mL	0	69	95	CT (Sec.)	30,3	56,4	67,3	<p>Δ CT (50 - 500 ng/mL) 65 ± 25 Sec (STAR) r² ≥ 0.98</p> <p style="text-align: right; margin-top: 20px;">r² ≥ 0.98</p>
Dabigatran Conc.-ng/mL	0	253	447														
CT (Sec.)	31,4	54,3	76,2														
Dabigatran Conc.-ng/mL	0	69	95														
CT (Sec.)	30,3	56,4	67,3														

<p>4. Normal Plasmas: Method : STAR</p> <p style="text-align: right;">N : 10</p> <p style="text-align: right;">Dabigatran Conc. : <1 ng/mL</p>	<p style="text-align: center;">N ≥ 10 < 10 ng/mL</p>
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<p>5. Accuracy: Method: STAR</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <tr> <td style="width: 30%;">Control (High range)</td> <td style="width: 10%;">TV* (ng/ml)</td> <td style="width: 10%;">MV* (ng/ml)</td> </tr> <tr> <td>C1</td> <td style="text-align: center;">111</td> <td style="text-align: center;">117</td> </tr> <tr> <td>C2</td> <td style="text-align: center;">292</td> <td style="text-align: center;">304</td> </tr> </table> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <tr> <td style="width: 30%;">Control (Low range)</td> <td style="width: 10%;">TV* (ng/ml)</td> <td style="width: 10%;">MV* (ng/ml)</td> </tr> <tr> <td>C1</td> <td style="text-align: center;">30</td> <td style="text-align: center;">29</td> </tr> <tr> <td>C2</td> <td style="text-align: center;">81</td> <td style="text-align: center;">84</td> </tr> </table> <p><small>* TV= Target Value - MV= Measured Value</small></p>	Control (High range)	TV* (ng/ml)	MV* (ng/ml)	C1	111	117	C2	292	304	Control (Low range)	TV* (ng/ml)	MV* (ng/ml)	C1	30	29	C2	81	84	<p style="text-align: center;">[91 - 131 ng/ml] [262 - 322 ng/ml]</p> <p style="text-align: center; margin-top: 20px;">[20 - 40 ng/ml] [65 -97 ng/ml]</p>
Control (High range)	TV* (ng/ml)	MV* (ng/ml)																	
C1	111	117																	
C2	292	304																	
Control (Low range)	TV* (ng/ml)	MV* (ng/ml)																	
C1	30	29																	
C2	81	84																	

<p>6. Stability of restored reagents (CT in sec)</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <tr> <td style="width: 15%;">Dabigatran ng/mL</td> <td style="width: 15%;">Fresh</td> <td style="width: 15%;">8 hrs RT</td> <td style="width: 15%;">24 hrs 2-8°C</td> <td style="width: 15%;">frozen</td> </tr> <tr> <td>30</td> <td style="text-align: center;">34,7</td> <td style="text-align: center;">35,7</td> <td style="text-align: center;">34,7</td> <td style="text-align: center;">34,7</td> </tr> <tr> <td>255</td> <td style="text-align: center;">58,7</td> <td style="text-align: center;">60,0</td> <td style="text-align: center;">58,3</td> <td style="text-align: center;">59,1</td> </tr> <tr> <td>468</td> <td style="text-align: center;">81,9</td> <td style="text-align: center;">84,2</td> <td style="text-align: center;">80,4</td> <td style="text-align: center;">83,0</td> </tr> <tr> <td>r2</td> <td style="text-align: center;">1,00</td> <td style="text-align: center;">1,00</td> <td style="text-align: center;">1,00</td> <td style="text-align: center;">0,99</td> </tr> </table>	Dabigatran ng/mL	Fresh	8 hrs RT	24 hrs 2-8°C	frozen	30	34,7	35,7	34,7	34,7	255	58,7	60,0	58,3	59,1	468	81,9	84,2	80,4	83,0	r2	1,00	1,00	1,00	0,99	<p style="text-align: center;">Δ CT ≤ 2sec</p> <p style="text-align: center;">Δ CT ≤ 5sec r2 ≥ 0.98</p>
Dabigatran ng/mL	Fresh	8 hrs RT	24 hrs 2-8°C	frozen																						
30	34,7	35,7	34,7	34,7																						
255	58,7	60,0	58,3	59,1																						
468	81,9	84,2	80,4	83,0																						
r2	1,00	1,00	1,00	0,99																						

Comments : PASSED IN COMPLIANCE

Date : 13/08/2015 QC Manager : S.LECOURT

po MPE