

ANALYSIS CERTIFICATE

HEMOCLOT TT - #CK011K

Lot : F1600945

QC release: 2016-10-17

Expiration date : 2019-03-10

Components	Volume (2mL)	Exp. (months)	Internal Lot #	Lot #	Exp. date
Bovine Thrombin	6 vials	30	F161100945	F161100945	2019-03-10

gds

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Analytical data	Specifications									
<p>1. <u>Batch reproducibility for Thrombin (various vials tested)</u></p> <p style="text-align: right; margin-right: 100px;">N : 15</p> <p style="text-align: right; margin-right: 100px;">Mean CT : 21,7 Sec.</p> <p style="text-align: right; margin-right: 100px;">CV : 2,2 %</p>	<p>N ≥ 10</p> <p>≤ 3 %</p>									
<p>2. <u>Thrombin Time on normal citrated human plasmas</u></p> <p style="text-align: right; margin-right: 100px;">Instrument: STAR</p> <p style="text-align: right; margin-right: 100px;">N: 15</p> <p style="text-align: right; margin-right: 100px;">Mean CT : 17,9 Sec.</p> <p style="text-align: right; margin-right: 100px;">SD: 0,7 Sec.</p> <p style="text-align: right; margin-right: 100px;">Range: 16,6 - 19,1 Sec.</p>	<p>N ≥ 10</p> <p>15 to 25 Sec.</p> <p>≤ 3 Sec.</p>									
<p>3. <u>Stability</u></p> <p><i>Clotting time of restored reagents compared to freshly reconstituted, on normal citrated human plasma</i></p> <p style="text-align: right; margin-right: 100px;">Instrument: MC10 (manual)</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="width: 15%;"></th> <th style="width: 20%;">Fresh (2-8°C)</th> <th style="width: 20%;">Stored</th> </tr> </thead> <tbody> <tr> <td style="text-align: left;">48 hours at RT</td> <td>21,2 Sec</td> <td>21,4 Sec</td> </tr> <tr> <td style="text-align: left;">1 week at 2-8°C</td> <td>20,9 Sec</td> <td>20,4 Sec</td> </tr> </tbody> </table>		Fresh (2-8°C)	Stored	48 hours at RT	21,2 Sec	21,4 Sec	1 week at 2-8°C	20,9 Sec	20,4 Sec	<p>ΔCT stored/Fresh</p> <p>≤ 2 Sec.</p>
	Fresh (2-8°C)	Stored								
48 hours at RT	21,2 Sec	21,4 Sec								
1 week at 2-8°C	20,9 Sec	20,4 Sec								

Comments :



PASSED IN COMPLIANCE

Date : 2016-10-17

QC Manager :

S. LECOURT