

ANALYSIS CERTIFICATE

PLASMA HIRUDIN STANDARD HIGH - #SC020L

Lot : F1700202/F1700226

QC release:

2017-03-23

Expiration date : 2019-08-13

Components	Volume	Exp. (months)	Lot #	Exp. date
Std 0 : Normal pl: about 0 µg/ml of Hir.	3 vials	30	F171100202 F171100226	2019-08-13
Std 5 : Normal pl: about 5 µg/ml of Hir.	3 vials	30	F171100202 F171100226	2019-08-13

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Analytical data				Specifications
1. <u>Within lot reproducibility</u>				
Std 0:	N= 5	CT (sec)= 31,2	CV: 0,4 %	CV (CT) ≤ 3%
Std 5:	N= 5	CT (sec)= 78,8	CV: 0,7 %	CV (CT) ≤ 3%
2. <u>Hirudin Concentration [C] and Standard Deviation (SD)</u>				
	N series	[C] µg/mL	SD	
Std 0	7	0	0,06	[C] <0.1 µg/ml
Std 5	7	4,67	0,27	[C] = 5.0 ± 0.4 µg/mL
3. <u>Aspect</u>				
a) :	Slightly opalescent to clear			a) Slightly opalescent to clear
b):	No coagulum			b) No coagulum
c):	Stable solution			c) Stable solution
4. <u>Stability of reconstituted reagents</u>				
		Fresh	24h	48h
		/	RT	2-8°C
Std 0	CT (sec)	33,9	34,2	34,0
	Δ sec	NA	0,3	0,1
Std 5	CT (sec)	108,4	108,1	107,6
	[C] µg/mL	4,98	4,97	4,88
	Δ([C])%	NA	0,2	2,0
24 hours at RT: 48 hours at 2-8°C: Δ [CT] ≤ 2sec Δ [C] ≤ 10%				

305

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Analytical data	Specifications																		
<p>5. <u>Calibration curve (High range using the 1:20 dilution)</u></p> <p style="text-align: center;">Method : STAR</p> <p style="text-align: center;">Hemoclot Thrombin Inhibitors Lot: F1600598</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th colspan="2">µg/ml</th> <th>CT (sec)</th> </tr> </thead> <tbody> <tr> <td>Std 0</td> <td>0</td> <td>33,3</td> </tr> <tr> <td>C:4</td> <td>1,17</td> <td>46,4</td> </tr> <tr> <td>C:2</td> <td>2,34</td> <td>65,3</td> </tr> <tr> <td>C:1.33</td> <td>3,51</td> <td>86,2</td> </tr> <tr> <td>Std5 "C"</td> <td>4,67</td> <td>106,6</td> </tr> </tbody> </table>	µg/ml		CT (sec)	Std 0	0	33,3	C:4	1,17	46,4	C:2	2,34	65,3	C:1.33	3,51	86,2	Std5 "C"	4,67	106,6	
µg/ml		CT (sec)																	
Std 0	0	33,3																	
C:4	1,17	46,4																	
C:2	2,34	65,3																	
C:1.33	3,51	86,2																	
Std5 "C"	4,67	106,6																	

<p>6. <u>Linearity</u></p> <p style="text-align: center;">R² 0,99</p>	R ² ≥ 0.98
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<p>7. <u>Accuracy</u></p> <p style="text-align: center;">Method : STAR</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th colspan="3">CONTROLS</th> <th>TV*</th> <th>MV*</th> </tr> </thead> <tbody> <tr> <td>C2</td> <td>Lot</td> <td>F1700206</td> <td>1,89</td> <td>1,90</td> </tr> </tbody> </table> <p style="text-align: center;">*TV: Target Value *MV: Measured Value</p>	CONTROLS			TV*	MV*	C2	Lot	F1700206	1,89	1,90	<p>MV* within the acceptance range</p> <p style="text-align: center;">[1,64 - 2,14]</p>
CONTROLS			TV*	MV*							
C2	Lot	F1700206	1,89	1,90							

<p>Comments :</p>	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2017-03-23

QC Manager : S.LECOURT





PLASMA HIRUDIN STANDARD HIGH

Calibration plasmas for Hirudin clotting assay (Hemoclot Thrombin Inhibitors) /
Plasma de calibration pour dosage coagulométrique d'Hirudine (Hemoclot Thrombin Inhibitors)

REF SC020L

For in vitro diagnostic use only / Pour diagnostic in vitro exclusivement

LOT F1700202



2019-08-13

Hirudin Concentration [C] in the standard /
Concentration [C] en Hirudin dans les standards

<u>Standard / Standard 0</u>	LOT : F171100202
[C] :	0 µg/mL / µg/mL
<u>Standard / Standard 5</u>	LOT : F171100202
[C] :	4.67 µg/mL / µg/mL

Standardization / Standardisation : NA

Approved Date / Date d'Approbation : 2017-03-23

Quality Control Manager / Responsable Contrôle Qualité : S.LECOURT