

ANALYSIS CERTIFICATE

ARGATROBAN® CONTROL PLASMA - #SC035K

Lot : F1701356

QC release: 2017-12-08

Expiration date : 2020-05-02

Components	Volume	Exp. (months)	Lot #	Exp. date
C1 : Control 1	6 vials	30	F171201356	2020-05-02
C2 : Control 2	6 vials	30	F171201356	2020-05-02



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Analytical data	Specifications
1. <u>Within lot reproducibility</u>	
Mean CT	
N= 10 C1: 55,5 sec CV: 2,0 %	CT : CV ≤ 3%
N= 10 C2: 72,7 sec CV: 2,4 %	CT : CV ≤ 3%

2. <u>Concentration and acceptance range</u>					Target value: C1: 0.55 to 0.80 µg/mL C2: 1.10 to 1.40 µg/mL
Controls	N series	[C] µg/mL	SD	Acceptance range (µg/mL)	
C1	9	0,73	0,02	0,58 - 0,88	
C2	9	1,35	0,04	1,15 - 1,55	

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>				48h at RT 7 days at 2-8°C In acceptance range
	Temp.	C1	C2	
		µg/mL	µg/mL	
Fresh	/	0,73	1,38	
48h	RT	0,76	1,41	
7 days	2-8°C	0,74	1,39	

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2017-12-08

QC Manager : S.LECOURT





ARGATROBAN® CONTROL PLASMA

Human plasmas at two levels of Argatroban® for the quality control of Argatroban® measurements with anti-IIa methods/
Plasmas humains à deux niveaux d' Argatroban® pour le contrôle de qualité des dosages d' Argatroban® par méthode anti-IIa

REF SC035K-RUO

For in vitro use only. For research use only. / *Pour utilisation in vitro exclusive. Uniquement à usage de recherche.*

LOT F1701356  2020-05-02

Argatroban® Concentration in the controls / *Concentration en Argatroban® dans les contrôles*

Control / Contrôle C1	LOT : F171201356
Target value / <i>Valeur cible</i> :	0.73 µg/mL / µg/mL
Acceptance range / <i>Intervalle d'acceptation</i> :	[0.58 - 0.88] µg/mL / µg/mL

Control / Contrôle C2	LOT : F171201356
Target value / <i>Valeur cible</i> :	1.35 µg/mL / µg/mL
Acceptance range / <i>Intervalle d'acceptation</i> :	[1.15 - 1.55] µg/mL / µg/mL

Standardization / *Standardisation* : NIA

Approved Date / *Date d'Approbation* : 2017-12-08

Quality Control Manager / *Responsable Contrôle Qualité* : S.LECOURT