

## ANALYSIS CERTIFICATE

**PLASMA ARGATROBAN® CALIBRATOR - #SC030K**

**Lot : F1600889**

**QC release: 2016-11-21**

**Expiration date : 2019-04-02**

Components	Volume	Exp. (months)	Lot #	Exp. date
CAL1 : Calibrator 1	4 vials	30	F161100889	2019-04-02
CAL2 : Calibrator 2	4 vials	30	F161100889	2019-04-02
CAL3 : Calibrator 3	4 vials	30	F161100889	2019-04-02
CAL4 : Calibrator 4	4 vials	30	F161100889	2019-04-02
CAL5 : Calibrator 5	4 vials	30	F161100889	2019-04-02

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Analytical data				Specifications
<b>1. <u>Within lot reproducibility</u></b>				
<b>Mean CT</b>				
N= 15	CAL1: 32,8	sec	CV: 2,1 %	CV (CT) ≤ 3%
N= 15	CAL2: 48,2	sec	CV: 1,6 %	CV (CT) ≤ 3%
N= 15	CAL3: 61,7	sec	CV: 1,1 %	CV (CT) ≤ 3%
N= 15	CAL4: 74,7	sec	CV: 1,7 %	CV (CT) ≤ 3%
N= 15	CAL5: 87,5	sec	CV: 2,5 %	CV (CT) ≤ 3%

<b>2. <u>Concentration [C] and Standard Deviation (SD)</u></b>				
<b>Controls</b>	<b>N series</b>	<b>[C] µg/mL</b>	<b>SD</b>	
<b>CAL1</b>	<b>10</b>	<b>0</b>	<b>0</b>	
<b>CAL2</b>	<b>10</b>	<b>0,53</b>	<b>0,021</b>	
<b>CAL3</b>	<b>10</b>	<b>1,01</b>	<b>0,037</b>	
<b>CAL4</b>	<b>10</b>	<b>1,53</b>	<b>0,090</b>	
<b>CAL5</b>	<b>10</b>	<b>2,05</b>	<b>0,136</b>	
				CAL1: ≤ 0.05 µg/ml CAL2: 0.35-0.65 µg/mL CAL3: 0.85-1.15 µg/mL CAL4: 1.30-1.65 µg/mL CAL5: 1.80-2.10 µg/mL

<b>3. <u>Aspect</u></b>		
a) :	<b>Slightly opalescent to clear</b>	a) Slightly opalescent to clear
b):	<b>No coagulum</b>	b) No coagulum
c):	<b>Stable solution</b>	c) Stable solution

<b>4. <u>Stability of reconstituted reagents</u></b>					
		<b>Fresh</b>	<b>48h</b>	<b>7 days</b>	
		/	18-25°C	2-8°C	
<b>CAL1</b>	µg/mL	<b>0</b>	<b>0</b>	<b>0</b>	<b>48 hours at 18-25°C:</b> <b>7 days at 2-8°C:</b>  Δ [C]% ≤ 10%
	Δ[C] %	NA	<b>0</b>	<b>0</b>	
<b>CAL2</b>	µg/mL	<b>0,54</b>	<b>0,57</b>	<b>0,58</b>	
	Δ[C] %	NA	<b>5,6</b>	<b>7,4</b>	
<b>CAL3</b>	µg/mL	<b>1,05</b>	<b>1,08</b>	<b>1,08</b>	
	Δ[C] %	NA	<b>2,9</b>	<b>2,9</b>	
<b>CAL4</b>	µg/mL	<b>1,58</b>	<b>1,55</b>	<b>1,59</b>	
	Δ[C] %	NA	<b>1,9</b>	<b>0,6</b>	
<b>CAL5</b>	µg/mL	<b>2,08</b>	<b>2,04</b>	<b>2,08</b>	
	Δ[C] %	NA	<b>1,9</b>	<b>0</b>	



ARGATROBAN® PLASMA CALIBRATOR  
Référence SC030K

Pour diagnostic *in vitro* exclusivement

FRANÇAIS

Lot : F1600889 - Exp. : 2019-04-02

Concentration [C] en ARGATROBAN® dans les calibrateurs

<u>Cal 1</u>	Lot : F161100889 [C] : 0 µg/mL
<u>Cal 2</u>	Lot : F161100889 [C] : 0.53 µg/mL
<u>Cal 3</u>	Lot : F161100889 [C] : 1.01 µg/mL
<u>Cal 4</u>	Lot : F161100889 [C] : 1.53 µg/mL
<u>Cal 5</u>	Lot : F161100889 [C] : 2.05 µg/mL

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Quality Control Approval

23 NOV. 2016

S. Lecourt

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