

ANALYSIS CERTIFICATE

DABIGATRAN CONTROL PLASMA (#224701)

**Lot : F1700397
F1700398**

QC release : 2017-05-11

Expiration date : 2019-10-08

| Components | Volume | Exp. (months) | Lot # | Exp. date |
|-------------------|---------------|--------------------------|--------------------------|----------------------|
| C1 : Control 1 | 6 vials | 30 | F171400397 F171100398 | 2019-10-08 |
| C2 : Control 2 | 6 vials | 30 | F171400397 F171100398 | 2019-10-08 |

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DABIGATRAN CONTROL PLASMA (#224701)

F1700397
Lot : F1700398

QC release : 2017-05-11

Expiration date : 2019-10-08

| Analytical data | Specifications |
|--|----------------|
| 1. <u>Within lot reproducibility</u> | |
| <u>Mean CT (sec)</u> | |
| N= 35 C1: 53,0 CV: 0,6 % | CV (CT) ≤ 3% |
| N= 35 C2: 75,3 CV: 1,4 % | CV(CT) ≤ 3% |

| 2. <u>Concentration and acceptance range</u> | | | | | Target value for [C]: C1: 50 to 200 ng/mL C2: 200 to 400 ng/mL |
|---|----------|------------------------|--------------------------|-----|---|
| Controls | N series | Target value [C] ng/mL | Acceptance range (ng/mL) | SD | |
| C1 | 11 | 101 | 81 - 121 | 5,4 | |
| C2 | 11 | 300 | 255 - 345 | 9,7 | |

| | | |
|-------------------------------------|------------------------------|---------------------------------|
| 3. <u>Aspect</u> | | |
| <input checked="" type="checkbox"/> | Slightly opalescent to clear | a) Slightly opalescent to clear |
| <input checked="" type="checkbox"/> | No coagulum | b) No coagulum |
| <input checked="" type="checkbox"/> | Stable solution | c) Stable solution |

| 4. <u>Stability of reconstituted reagents</u> | | | | <u>48h at RT</u> Measured Values within the acceptance ranges <u>7 days at 2-8°C</u> Measured Values within the acceptance ranges |
|--|-------|-------|-------|--|
| | Temp. | C1 | C2 | |
| | | ng/mL | ng/mL | |
| Fresh | / | 107 | 313 | |
| 48h | RT | 105 | 311 | |
| 7 days | 2-8°C | 107 | 308 | |

| | |
|-------------------|---|
| Comments : | <input checked="" type="checkbox"/> PASSED IN COMPLIANCE |
|-------------------|---|

Date : 2017-05-11

QC Manager : **S.LECOURT**





DABIGATRAN CONTROL PLASMA

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

REF 224701

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

LOT F1700397



2019-10-08

Dabigatran Concentration in the controls / *Concentration en Dabigatran dans les contrôles*

| | |
|--|-----------------------------------|
| Control / Contrôle C1 | LOT : F171400397 |
| Target value / <i>Valeur cible</i> : | 101 ng/mL / ng/mL |
| Acceptance range / <i>Intervalle d'acceptation</i> : | [81 – 121] ng/mL / ng/mL |

| | |
|--|------------------------------------|
| Control / Contrôle C2 | LOT : F171400397 |
| Target value / <i>Valeur cible</i> : | 300 ng/mL / ng/mL |
| Acceptance range / <i>Intervalle d'acceptation</i> : | [255 – 345] ng/mL / ng/mL |

Standardization / *Standardisation* : NA

Approved Date / *Date d'Approbation* : 2017-05-11

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