

Anti-Thrombin (AT) Anti-Thrombine (AT)

Vial of 1.5 mg (PP004B) / Flacon de 1.5 mg (PP004B)
Set of 10 x 1.5 mg (PP004L)/ Coffret de 10 x 1.5 mg (PP004L)

Ref. PP004B / PP004L

STORE AT
2-8°C

Lot: F1700099



Expiration: 2021-01-02

CONSERVER A
2-8°C

ANALYSIS CERTIFICATE / CERTIFICAT D'ANALYSE

ANALYTICAL DATA / RESULTATS D'ANALYSE		SPECIFICATIONS										
1. <u>Protein Content / Teneur protéique</u> (Lowry method / Méthode Lowry)												
	1.62 mg/vial (mg/flacon)	≥1.35 mg/mL										
2. <u>SDS-PAGE (4-12% acrylamide)</u>												
	1 major band of about/ 1 bande principale d'environ: 58 000 daltons	1 major band of about: 58,000 daltons										
3. <u>Anti-Xa activity/ Activité anti-Xa</u> (chromogenic assay in presence of heparin/ test chromogénique en présence d'héparine)												
	AT concentration/ Activité AT : 16.8 IU/vial (UI/flacon) (i.e.10.4 IU/mg)	> 6 IU/mg										
4. <u>Absence of heparin / Absence d'héparine</u> (Blue Toluidine assay)												
	Absence	Absence										
5. <u>Batch homogeneity / Homogénéité de lot:</u>												
	N = 20 CV :1.52 %	N≥5 CV ≤ 2%										
6. <u>Stability after reconstitution/ stabilité après reconstitution</u> (chromogenic assay in presence of heparin/ test chromogénique en présence d'héparine)												
	<table border="1"> <tr> <td></td> <td>Fresh</td> <td>7 days / 2-8 °C</td> <td>7 days /RT</td> <td>7 days /-20 °C</td> </tr> <tr> <td>IU/mg</td> <td>9.9</td> <td>9.3</td> <td>8.7</td> <td>9.4</td> </tr> </table>		Fresh	7 days / 2-8 °C	7 days /RT	7 days /-20 °C	IU/mg	9.9	9.3	8.7	9.4	> 6 IU/mg
	Fresh	7 days / 2-8 °C	7 days /RT	7 days /-20 °C								
IU/mg	9.9	9.3	8.7	9.4								

CONCLUSIONS

DATE : 2017-02-09

Passed/Conforme Refused/Non-conforme

Quality Control Manager
Responsable contrôle qualité

NAME S.LECOURT