

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: 150615A



Expiration: 2019-06

CONSERVER A
2-8°C

ANALYSIS CERTIFICATE / CERTIFICAT D'ANALYSE

ANALYTICAL DATA / RESULTATS D'ANALYSE		SPECIFICATIONS										
1. Protein Content / Teneur protéique (Lowry method / Méthode Lowry)												
	1.39 mg/vial (mg/flacon)	≥1.35 mg/mL										
2. SDS-PAGE (4-12% acrylamide)												
	1 major band of about/ 1 bande principale d'environ: 58000 daltons	1 major band of about: 58,000 daltons										
3. Anti-Xa activity/ Activité anti-Xa (chromogenic assay in presence of heparin/ test chromogénique en présence d'héparine)												
	AT concentration/ Activité AT : 13 IU/vial (IU/flacon) (i.e. 9.4 IU/mg)	> 6 IU/mg										
4. Absence of heparin / Absence d'héparine (Blue Toluidine assay)												
	Absence	Absence										
5. Batch homogeneity / Homogénéité de lot:												
	N = 15 CV : 0.8 %	N≥5 CV ≤ 2%										
6. Stability after reconstitution/ stabilité après reconstitution (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>9.21</td> <td>9.50</td> <td>9.28</td> <td>9.93</td> </tr> </table>		Fresh	7 days / 2-8°C	7 days /RT	7 days /-20°C	IU/mg	9.21	9.50	9.28	9.93	> 6 IU/mg
	Fresh	7 days / 2-8°C	7 days /RT	7 days /-20°C								
IU/mg	9.21	9.50	9.28	9.93								

CONCLUSIONS

DATE : 17/07/2015

Passed/Conforme

Refused/Non-conforme

Quality Control Manager
Responsable contrôle qualité

S. LECOURT