

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: 140220B



Expiration: 2018-02

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)												
	1.74 mg/vial (mg/flacon)	≥1.35 mg/mL										
2. SDS-PAGE (4-12% acrylamide)												
	1 major band of about/ 1 bande principale d'environ: 58 000 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 : 14.6 IU/vial (UI/flacon) (i.e. 8.4 IU/mg)	> 6 IU/mg										
4. Absence of heparin / Absence d'héparine (Blue Toluidine assay)												
	Absence	Absence										
5. Batch homogeneity / Homogénéité de lot:												
	N = 10 CV : 2 %	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"> <thead> <tr> <th></th> <th>Fresh</th> <th>7 days / 2-8°C</th> <th>7 days /RT</th> <th>7 days /-20°C</th> </tr> </thead> <tbody> <tr> <td>IU/mg</td> <td>9.3</td> <td>9.7</td> <td>9.5</td> <td>9.6</td> </tr> </tbody> </table>		Fresh	7 days / 2-8°C	7 days /RT	7 days /-20°C	IU/mg	9.3	9.7	9.5	9.6	> 6 IU/mg
	Fresh	7 days / 2-8°C	7 days /RT	7 days /-20°C								
IU/mg	9.3	9.7	9.5	9.6								

CONCLUSIONS

DATE : 11/03/2014

Passed/Conforme

Refused/Non-conforme

Quality Control Manager
Responsable contrôle qualité

NAME : S. LECOURT