



HYPHEN BioMed
155 rue d'Eragny
95000 Neuville-sur-Oise
France

CERTIFICATE OF ANALYSIS

Product Description : HEMOCLOT PROTEIN C
Product Code : CK032K
Lot No. : FB1697BH
Expiration date : 2025-04-04

Components	Quantity	Lot	Expiration Date
R1: Protein C Deficient Plasma	3 vials	FB1697FMBH	2025-04-14
R2: Protein C Activator	3 vials	FB1697FNBH	2025-04-04

Analytical Data	Specification	Result
Calibration curve on STAR	Delta CT (1/10-1/160) > 20 sec	22.1 sec
	CT (1/10) > 50 sec	61.9 sec
	CT(1/50) = 30 - 46sec	42.6 sec
	R ² ≥ 0.98	0.993
	Controls measured in acceptance ranges	PASS
Calibration curve on CS	Delta CT (3/2-1/9) > 30 sec	40.0 sec
	CT(1/4) = 35 - 55 sec	47.0 sec
	CT (3/2) > 70 sec	82.2 sec
	R ² ≥ 0.98	0.990
	Controls measured in acceptance ranges	PASS
Normal Plasma > 70% - Plasma Deficient ≤ 15%		PASS

Calibration Curve for information

STAR	
1/10	61.9
1/15	53.3
1/30	46.0
1/160	39.8
1/50	42.6
R ²	0.993

CS	
3/2	82.2
1/1	70.8
3/5	58.3
1/9	42.2
1/4	47.0
R ²	0.990

	TV	MV
Normal Ctrl	[84 - 113]	100
Abnormal Ctrl	[30 - 45]	39

TV= Target Value - MV= Measured Value

This is to certify that above product has been produced and passed the inspection according to specifications of HYPHEN BioMed.

Date of Approval : 2022-11-16

Quality Control Manager : S. LECOURT

