



A Company of Sysmex Group



HYPHEN BioMed  
155 rue d'Eragny  
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France

### CERTIFICATE OF ANALYSIS

**Product Description:** HEMOCLOT PROTEIN S  
**Product Code:** CK041K  
**Lot No.:** FB0751A3  
**Expiration date:** 2024-10-19

Components	Quantity	Lot	Expiration Date
R1: Protein S Deficient Plasma	3 vials	FB0751i3A3	2024-10-19
R2 : Protein S Activator	3 vials	FB0751i4A3	2024-10-25

Analytical Data	Specification	Result
Calibration curve on STAR	Delta CT (0%-100%) ≥ 40 sec	41 sec
	CT(0%) = 40-60 sec	46 sec
	CT(100%) ≤ 120 sec	87 sec
	R <sup>2</sup> ≥ 0.98	0.99
	Controls measured in acceptance ranges	PASS
	Normal Plasma > 60%	PASS
	Plasma Deficient ≤ 10%	< 1%

#### Calibration Curve for information

Manual Method	
0	45.9
25	58.3
50	67.9
67	78.5
100	88.0
R <sup>2</sup>	0.998

STAR	
0	46.0
25	55.5
50	64.5
67	69.3
100	86.9
R <sup>2</sup>	0.992

	TV	MV
Normal Ctrl	[ 88 - 120 ]	104
Abnormal Ctrl	[ 26 - 39 ]	37

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: 2022-05-31

Quality Control Manager: S. LECOURT