

A Company of Sysmex Group



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

## **CERTIFICATE OF ANALYSIS**

Product Description:

**HEMOCLOT QUANTI. V-L** 

**Product Code:** 

CK065K

Lot No.:

FB15851C

Expiration date :

2025-03-23

Components	Quantity	Lot	Expiration Date
R1: coagulation factors	3 vials	FB1585FS1C	2025-03-23
R2 : Purified Factor Xa-PLPs	3 vials	FB1585FT1C	2025-03-30

Analytical Data Specification		Result
	Delta CT (100-10%) ≥ 35 sec	77 sec
	CT (100%) = 32 +/- 5 sec	32 sec
Calibration curve (manual method)	$R^2 \ge 0.98$	
	Controls measured in acceptance ranges	PASS
	Normal Plasma ≤ 10%	PASS

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

Date of Approval: 2022-10-25

Quality Control Manager:

**S.LECOURT**