

CERTIFICATE OF ANALYSIS

Factor XI native



Attachment 03 DQ4E00.05

4E41C00.08

Temp.: TFG326.07

REF 5184004-RUO
 LOT 4E41C00.08
 2026-03-31

Analytical Procedures			Requirement		Result				
visual inspection	Cap color		blue		confirmed	OK			
	Vial type		clear glass vial		confirmed	OK			
	Vial label		according to packaging SOP		confirmed	OK			
	Vial barcode		according to packaging SOP		confirmed	OK			
	Box label		according to packaging SOP		confirmed	OK			
	Box barcode		according to packaging SOP		confirmed	OK			
	Package insert		present		confirmed	OK			
	Appearance before reconstitution		buff colored plug of lyophilized material		confirmed	OK			
Appearance after reconstitution		amber colored liquid		confirmed	OK				
Virology			HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab		Negative Negative Positive		OK		
The testing methods applied were FDA-approved or CE marked.									
Recovery of controls F XI	Control N								
	LOT	1P31C01	74.3	-	123.8	%	106.5	%	OK
	Control A								
	LOT	3P42C00	27.0	-	45.0	%	38.8	%	OK

Prepared by

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21. MAI 2025

Date

Approved by

Maylis RAUSCHER

21. MAI 2025

Date