

CERTIFICATE OF ANALYSIS
Factor XI native



Attachment 03 DQ4E00.05

Temp.: TQ326.07

4E41C00.06

REF	5184004-RUO
LOT	4E41C00.06
	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 The testing methods applied were FDA-approved or CE marked.	Negative Negative Positive	Negative Negative Positive	OK
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 Stefan BRUCKBERGER

27. MRZ. 2025

Date

Approved by Fikret NASUFI *Fikret Nasufi*

27. MRZ. 2025

Date