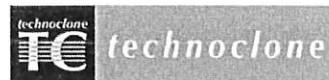


# CERTIFICATE OF ANALYSIS

## Factor IX immunads.



Attachment 03 DQ490D.04

4954C0D.01

Temp.: TP0226.07

REF 5164004-RUO  
 LOT 4954C0D.01  
 2027-07-31

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 Negative	Negative Negative Negative OK
The testing methods applied were FDA-approved or CE marked.				
Recovery of controls F IX	<b>Control N</b>			
	LOT 1P53C00	85.5 - 142.5 %	97.3 %	OK
	<b>Control A</b>			
	LOT 3P54C00	18.0 - 30.0 %	23.9 %	OK

Prepared by

Lukas GRUBELNIG

03. DEZ. 2025

Date

Approved by

Maylis FAUSCHER

03. DEZ. 2025

Date