

**CERTIFICATE OF ANALYSIS**  
**Factor IX immunads.**



Temp.: TP0326.07

Attachment 03      DQ490D.04

4961C0D.01

**REF**                      5164004-RUO  
**LOT**                        4961C0D.01  
                      2028-03-31

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 Negative	Negative Negative Negative	OK
Recovery of controls F IX	<b>Control N</b> LOT 1P53C00	85.5   -   142.5   %	108.9   %	OK
	<b>Control A</b> LOT 3P54C00	18.0   -   30.0   %	24.4   %	OK

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16. APR. 2026  
 Date

Approved by Lukas GRUBELNIG  
*Lukas Grubelnig*

16. APR. 2026  
 Date