


CERTIFICATE OF ANALYSIS
Factor IX immunads.



Attachment 03 DQ490D.04

Temp.: TP0326.07

4943C0D.01

REF 5164004-RUO
LOT 4943C0D.01
 2026-10-31

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	Control N LOT 1P31C01	87.8 - 146.3 %	106.2 %	OK
	Control A LOT 3P42C00	16.5 - 27.5 %	20.0 %	OK

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 Date

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05. NOV. 2024
 Date