

CERTIFICATE OF ANALYSIS
Factor VIII immunads.



Attachment 03 DQ480D.03

Temp.: TP036.07

4845C0D.02

REF	5154002-RUO
LOT	4845C0D.02
⌚	2026-12-31

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 VIII	Control N LOT 1P31C01	77.3 - 128.8 %	113.3 %	OK
	Control A LOT 3P42C00	25.5 - 42.5 %	32.1 %	OK

Prepared by Lucas HOLOWICZ

27. FEB. 2025
Date

Approved by Maylis RAUSCHER

27. FEB. 2025
Date