


CERTIFICATE OF ANALYSIS
Coagulation Reference



Attachment 04 DQ1R00.03

Temp.: FR0326.07

1R45C00.04

REF 5220110-RUO
LOT 1R45C00.04
 2026-08-31

Analytical Procedures		Requirement	Result	
visual inspection	Cap color	green	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
	Batch table	present	confirmed	OK
	Appearance before reconstitution	buff colored plug of lyophilized material	confirmed	OK
Appearance after reconstitution	clear 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 Fibrinogen	Control N LOT 1P31C01	2.67 - 4.01 g/l	3.62 g/l	OK
	Control A LOT 3P42C00	0.93 - 1.39 g/l	1.26 g/l	OK

Prepared by Stefan BRUCKBERGER

18. FEB. 2025
Date

Approved by Michael KAFKA

18. FEB. 2025
Date