

# CERTIFICATE OF ANALYSIS

## Coagulation Reference



Attachment 04 DQ1R00.03

1R45C00.04

Temp.: TF0336.07

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	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

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18. FEB. 2025

Date

Approved by

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18. FEB. 2025

Date