

CERTIFICATE OF ANALYSIS

Coagulation Reference



Attachment 04 DQ1R00.03

1R45C00.04

Temp.: TFD326.07

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