CERTIFICATE OF ANALYSIS
Coagulation Control N 5x1 mL

Attachment 04 DQ1P00.03

Temp.: TF0326.07

1P31C01.02

REF 5020040-RUO

LOT 1P31C01.02

2026-06-30

Analytical Procedures		Requirement	Result	
visual inspection	Cap color	red	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	amber colored liquid	confirmed	OK
Virology	HBsAg / HBsAg	Negative	Negative	OK
	HIV-Ak / HIV-Ab	Negative	Negative	
	HCV-AK / HCV-Ab	Negative	Negative	
The testing methods applied were FDA-approved or CE marked.				
Recovery of controls	**Siron LS**	20.1 - 27.3 sec	24.1 sec	OK

Prepared by Stefan BRÜCKBERGER — 26. JUNI 2024 Date

Approved by Maylis RAUSCHER — 27. JUNI 2024 Date