

CERTIFICATE OF ANALYSIS

Coagulation Control N



Attachment 04 DQ1P00.04

Temp.: TP0326.07

1P42C00.02

REF 5020040-RUO
 LOT 1P42C00.02
 2026-09-30

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	OK
		HIV-Ak / HIV-Ab	Negative	
		HCV-AK / HCV-Ab	Negative	
The testing methods applied were FDA-approved or CE marked.				
Recovery of controls	Siron LS	19.6 - 26.5 sec	24.3 sec	OK

Prepared by

Lukas GRUBELNIG *Dr. Grubelnig*

27. MAI 2025

Date

Approved by

Fikret NASUFI *Fikret Nasufi*

28. MAI 2025

Date