

# CERTIFICATE OF ANALYSIS

## Coagulation Control A



Temp.: TPO26.07

Attachment 04 DQ3P00.06

3P54C00.02

REF 5021055-RUO  
 LOT 3P54C00.02  
 2027-11-30

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	31.8 - 43.0 sec	40.8 sec	OK

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**03. DEZ. 2025**

Date

Approved by

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**03. DEZ. 2025**

Date