

# CERTIFICATE OF ANALYSIS

## Coagulation Control A 5x1 ml



Attachment 04      DQ3P00.05  
3P42C00.04

Temp.: TF0316.07

REF      5021055-RUO  
LOT      3P42C00.04  
⌚      2026-02-28

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 HIV-Ak / HIV-Ab HCV-AK / HCV-Ab  The testing methods applied were FDA-approved or CE marked.	Negative Negative Negative	Negative Negative Negative	OK
Recovery of controls	<b>Siron LS</b>	37.5 - 50.7 sec	40.2 sec	OK

Prepared by

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02. OKT. 2024

\_\_\_\_\_ Date

Approved by

*Lucas HOJNICKI*  
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02. OKT. 2024

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