

CERTIFICATE OF ANALYSIS

Coagulation Control N 5x1 mL



Attachment 04 DQ1P00.03

Temp.: TF026.07

1P31C01.03

REF	5020040-RUO
LOT	1P31C01.03
⌚	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 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	Siron LS	20.1 - 27.3 sec	22.3 sec	OK

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02. OKT. 2024

Date

Approved by

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02. OKT. 2024

Date