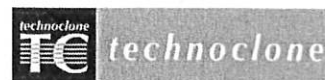


# CERTIFICATE OF ANALYSIS

## Coagulation Reference



Attachment 04 DQ1R00.03

1R59C00.02

Temp.: TP0326.07

REF 5220110-RUO  
 LOT 1R59C00.02  
 2027-08-31

Analytical Procedures		Requirement	Result	
visual inspection	Cap color	green	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	clear liquid	confirmed	OK
Virology		HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab	Negative Negative Negative	OK
The testing methods applied were FDA-approved or CE marked.				
Recovery of controls Fibrinogen	<b>Control N</b> LOT 1P53C00	2.53 - 3.79 g/l	3.52 g/l	OK
	<b>Control A</b> LOT 3P54C00	0.85 - 1.27 g/l	1.05 g/l	OK

Prepared by Lavdrim NASUFI

27. NOV. 2025

Date

Approved by Smilja DURANOVIC

28. NOV. 2025

Date