Coagulation Reference 5x1 ml

technoclone

Attachment 04 DQ1R00.02

Temp.: TF0326.06

1R04C02.02

REF 5220110-RUO

LOT 1R04C02.02

2025-08-31

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 The testing methods applied were FDA-approved or CE marked.	HBsAg / HBsAg HIV-Ak / HIV-Ab HCV-AK / HCV-Ab	Negative Negative Negative	Negative Negative Negative	OK
Recovery of controls FVII clotting	**Control N** LOT 1P31C00	71.3 - 118.8 %	95.3 %	OK
	Control A LOT 3P41C00	33.0 - 55.0 %	42.6 %	OK

Prepared by Lukas HOLOWICZ 28. FEB. 2024 Date

Approved by Maylis RAUSCHER 29. FEB. 2024 Date