Coagulation Reference 5x1 ml

technoclone

Attachment 04 DQ1R00.02

Temp.: TF0326.06

1R45C00.02

REF 5220110-RUO

LOT 1R45C00.02

2026-08-31

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	Negative	Negative	OK
	HIV-Ak / HIV-Ab	Negative	Negative	
	HCV-AK / HCV-Ab	Negative	Negative	
The testing methods applied were FDA-approved or CE marked.				
Recovery of controls Fibrinogen	**Control N** LOT 1P31C01	2.7 - 4.0 g/l	3.5 g/l	OK
	Control A LOT 3P42C00	0.9 - 1.4 g/l	1.2 g/l	OK

Prepared by Maylis RAUSCHER 27. AUG. 2024 Date

Approved by Fikret NASUFI 27. AUG. 2024 Date