

Coagulation Reference 5x1 ml



Attachment 04 DQ1R00.02

Temp.: TP026.04

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 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	Control N LOT 1P31C01	2.7 - 4.0 g/l	3.5 g/l	OK
Fibrinogen	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 MASUFI

27. AUG. 2024
Date