

Coagulation Reference 50x1 ml



Attachment 05      DQ1R00.02

1R45C00.02

Temp.: TP0316.06

REF      5220120-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

28. AUG. 2024  
Date

Approved by      Stefan BRUCKBERGER

28. AUG. 2024  
Date