CERTIFICATE OF ANALYSIS FP: Fibrinogen Reagent 5 x 2 mL



Attachment 11

DQ6E0A.03

Temp.: TF0326.07

6E36CA0.03

REF

5138085-RUO

LOT

6E36CA0.03

23

2025-12-31

Analytical Procedures		Requirement	Result	
visual inspection	Cap color	grey	confirmed	ОК
	Vial type	clear glass vial	confirmed	ОК
	Vial label	according to packaging SOP	confirmed	ОК
	Vial barcode	according to packaging SOP	confirmed	ОК
	Box label	according to packaging SOP	confirmed	ОК
	Box barcode	according to packaging SOP	confirmed	ОК
	Package insert	present	confirmed	ОК
	Batch table	present	confirmed	ОК
	Appearance before reconstitution	white colored plug of lyophilized material	confirmed	ОК
	Appearance after reconstitution	clear liquid	confirmed	ОК
Recovery of controls	Control N	2.67 - 4.01 g/L	3.68 g/L	ок
	LOT 1P31C01	2.07 - 4.01 g/L		OK
Fibrinogen	Control A	0.03 1.30 0/1	1.25 0/1	OK
	LOT 3P42C00	0.93 - 1.39 g/L	1.25 g/L	ОК

Prepared by

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1 5. JAN. 2025

Date

Stefan BRUCKBERGER

Approved by

16. JAN. 2025

Date