CERTIFICATE OF ANALYSIS Technofluor ADAMTS13:Act 0 Cal



Attachment 07

DQFA00.02

FAC42C0.04

REF

5800102-RUO

LOT

FAC42C0.04

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2026-09-30

Analytical Procedures		Requirement				Result		
	Cap color	grey			conf	irmed	ОК	
visual inspection	Vial type		clear glass vial			conf	irmed	ОК
	Vial label	accord	according to packaging SOP			conf	irmed	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 buff colored plug of lyophilized material				confirmed		ОК
	Appearance before reconstitution					confirmed		ОК
	Appearance after reconstitution	amber colored liquid				confirmed		ОК
	HBsAg / HBsAg	Negative				Negative		-
Virology	HIV-Ak / HIV-Ab	Negative Negative				Negative Negative		
	HCV-AK / HCV-Ab							ок
The testing methods a	pplied were FDA-approved or CE marked.		-			3		
Recovery of controls	Control N							
	LOT 1P31C01	0.65	18	1.08	IU/mL	0.89	IU/mL	ОК
	Control A			AND WALLS	4 IU/mL			
	LOT 3P42C00	0.32	-	0.54		0.43	IU/mL	ОК

Prepared by

Michael KAFKA

2 4. JUNI 2025

Date

Approved by

Lukas GRUBELNIG & Cin

2 4. JUNI 2025

Date