

CERTIFICATE OF ANALYSIS
Technofluor ADAMTS13:Act 0 Cal



Attachment 07 DQFA00.02

Temp.: TP0336.07

FAC42C0.03

REF	5800102-RUO
LOT	FAC42C0.03
⌚	2026-09-30

Analytical Procedures		Requirement	Result	
visual inspection	Cap color	grey	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
	Appearance before reconstitution	buff colored plug of lyophilized material	confirmed	OK
	Appearance after reconstitution	amber colored 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	0.65 - 1.08 IU/mL	0.89 IU/mL	OK
	Control A LOT 3P42C00	0.32 - 0.54 IU/mL	0.43 IU/mL	OK

Prepared by Stefan BRUCKBERGER

27. MRZ. 2025
Date

Approved by Smilja DURANOVIC

28. MRZ. 2025
Date