

CERTIFICATE OF ANALYSIS
TECHNOZYM ADAMTS13 INH CAL Set



Attachment 18 DQRP00.03

Temp.: TFB327.07

6PT61C0.02

REF	5450461-RUO
LOT	6PT61C0.02
	2028-02-29

Content	volume	Reagent	LOT	
1x	0.5 mL	ADAMTS13 INH Calibrator 1	1PT61C0	2028-02-29
1x	0.5 mL	ADAMTS13 INH Calibrator 2	2PT61C0	2028-02-29
1x	0.5 mL	ADAMTS13 INH Calibrator 3	3PT61C0	2028-02-29
1x	0.5 mL	ADAMTS13 INH Calibrator 4	4PT61C0	2028-02-29
1x	0.5 mL	ADAMTS13 INH Calibrator 5	5PT61C0	2028-02-29

Analytical Procedures		Requirement	Result	
visual inspection	Content	according to packaging SOP	confirmed	OK
	Vial label	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
	Slope Δ OD (Cal 1 - Cal 5)		\geq 0.7	1.5
Recovery of controls	ADAMTS13 INH High Control LOT RPY61C0	35.97 - 59.95 U/mL	54.30 U/mL	OK
	ADAMTS13 INH Low Control LOT RPZ61C0	8.21 - 19.15 U/mL	13.92 U/mL	OK

Prepared by Lucas HOLOVICZ

23. MRZ. 2026
Date

Approved by Fikret NASUFI

24. MRZ. 2026
Date