

**CERTIFICATE OF ANALYSIS
TECHNOZYM ADAMTS13 INH ELISA 48 T.**



Temp.: TP0327.07

Attachment 17 DQRP00.03

RP64C0S.02

REF 5450451-RUO
 LOT RP64C0S.02
 2027-07-31

Content	volume	Reagent	LOT	
1x	-	ADAMTS13 INH plate 48 T.	RPS58CS	2027-11-30
1x	0.3 mL	ADAMTS13 INH POX	RPV53C0	2027-11-30
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
1x	0.5 mL	ADAMTS13 INH High Control	RPY61C0	2028-02-29
1x	0.5 mL	ADAMTS13 INH Low Control	RPZ61C0	2028-02-29
1x	12 mL	Stop Solution	RKK52C0	2027-07-31
1x	12 mL	TMB Substrate	RKN53C0	2027-12-31
1x	80 mL	Wash buffer concentrate	RNA52C0	2027-11-30
1x	90 mL	Incubation buffer	RNB52C0	2027-11-30

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
Recovery of controls	Slope Δ OD (Cal 1 - Cal 5)	≥ 0.7	1.5	OK
	ADAMTS13 INH High Control LOT RPY61C0	35.97 - 59.95 U/mL	54.26 U/mL	OK
	ADAMTS13 INH Low Control LOT RPZ61C0	8.21 - 19.15 U/mL	15.08 U/mL	OK

Prepared by

Lucas HOLOVICZ

22. MARZ. 2026
 Date

Approved by

Filaret NASUFI

24. MRZ. 2026
 Date