

CERTIFICATE OF ANALYSIS
TECHNOZYM ADAMTS13 Activity ELISA Kit



Attachment 03 DQRU00.11
RU57C00.02

Temp.: TF0327.07

REF 5450701-US
LOT RU57C00.02
⌚ 2026-11-30

Content	volume	Reagent	LOT	⌚
2x	6mL	ADAMTS-13 Activity vWF73 Substrate	520	2026-11-30
1x	30mL	ADAMTS-13 Activity Reaction Buffer	520	2026-11-30
1x	12mL	ADAMTS-13 Activity HRP Conj Antibody	520	2026-11-30
1x	12mL	ADAMTS-13 Activity Color Reagent	520	2026-11-30
1x	53mL	ADAMTS-13 Activity Wash Buffer Conc	520	2026-11-30
1x	12mL	ADAMTS-13 Activity Stop Solution	520	2026-11-30
1x	n.a.	ADAMTS-13 Activity Plate 96T.	520	2026-11-30
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 1	1UT51C0	2027-03-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 2	2UT51C0	2027-03-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 3	3UT51C0	2027-03-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 4	4UT51C0	2027-03-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 6	6UT51C0	2027-03-31
1x	0.5mL	UY ADAMTS-13 Activity High Control	RUY51C0	2027-03-31
1x	0.5mL	UZ ADAMTS-13 Activity Low Control	RUZ51C0	2027-03-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 5	5UT51C0	2027-03-31

Analytical Procedures		Requirement		Result	
visual inspection	Content	according to packaging SOP		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
	Batch table	present		confirmed	OK
Verwendbarkeit Usability	deltaOD Cal1-Cal6	≥ 0.7		1.5	OK
Recovery of controls	ADAMTS-13 Activity High Control LOT RUY51C0	0.70	- 1.16 IU/mL	0.96 IU/mL	OK
	ADAMTS-13 Activity Low Control LOT RUZ51C0	0.15	- 0.35 IU/mL	0.24 IU/mL	OK

Prepared by Lucas HOLWICZ

25. JUNI 2025
Date

Approved by Fikret NASUFI Fikret Nasufi

25. JUNI 2025
Date