

CERTIFICATE OF ANALYSIS

TECHNOZYM ADAMTS13 Activity ELISA Kit



Attachment 03 DQRU00.11

RU53C00.02

Temp.: TF0327.07

REF 5450701-US
 LOT RU53C00.02
 2026-07-31

Content	volume	Reagent	LOT	
2x	6mL	ADAMTS-13 Activity vWF73 Substrate	500	2026-07-31
1x	30mL	ADAMTS-13 Activity Reaction Buffer	500	2026-07-31
1x	12mL	ADAMTS-13 Activity HRP Conj Antibody	500	2026-07-31
1x	12mL	ADAMTS-13 Activity Color Reagent	500	2026-07-31
1x	53mL	ADAMTS-13 Activity Wash Buffer Conc	500	2026-07-31
1x	12mL	ADAMTS-13 Activity Stop Solution	500	2026-07-31
1x	n.a.	ADAMTS-13 Activity Plate 96T.	500	2026-07-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 1	1UT42C0	2026-08-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 2	2UT42C0	2026-08-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 3	3UT42C0	2026-07-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 4	4UT42C0	2026-08-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 6	6UT42C0	2026-08-31
1x	0.5mL	UY ADAMTS-13 Activity High Control	RUY42C0	2026-08-31
1x	0.5mL	UZ ADAMTS-13 Activity Low Control	RUZ42C0	2026-08-31
1x	0.5mL	UT ADAMTS-13 Activity Calibrator 5	5UT42C0	2026-08-31

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		2.0	OK
Recovery of controls	ADAMTS-13 Activity High Control LOT RUY42C0	0.71	- 1.19 IU/mL	0.96 IU/mL	OK
	ADAMTS-13 Activity Low Control LOT RUZ42C0	0.17	- 0.39 IU/mL	0.27 IU/mL	OK

Prepared by

Lucas Holmberg

20. MRZ. 2025

Date

Approved by

Fikret Nasufi

20. MRZ. 2025

Date